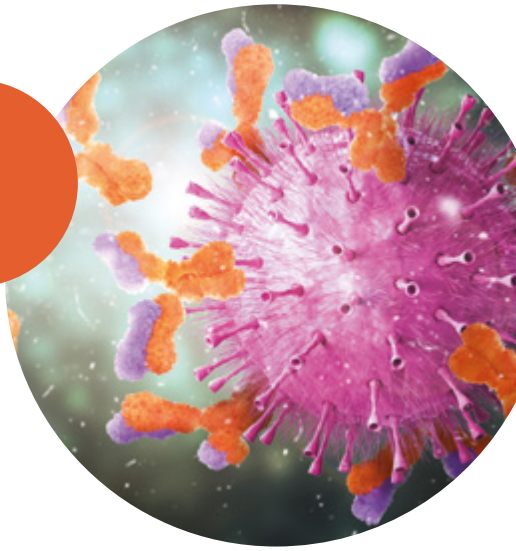
HSA

An tÚdarás Sláinte agus Sábháilteachta
Health and Safety Authority



Managing Exposure to Biological Agents in Laboratories

Managing Exposure to Biological Agents in Laboratories

Contents

Reference to chapters within this guidance is to this document unless otherwise specified.

Version 1, November 2023

Glossary and abbreviations

The definitions and abbreviations given here are in the context of the Biological Agents Regulations, and this guidance only.

Airlock: a chamber isolated from the laboratory. Where required, entry to the laboratory must be through an airlock with the clean side of the airlock separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

Animal by-products: entire animal bodies, parts of animals, products of animal origin or other products obtained from animals that are not fit or intended for human consumption.

Animal room: a room for laboratory animals that have been deliberately infected with a group 2, 3 or 4 biological agent or are suspected or known to be carriers of such an agent.

Antibiotics: drugs that are used to treat bacterial and other infectious diseases but do not affect viruses.

Aseptic technique: a technique aimed at preventing contamination of items such as cultures, samples, cells and media from micro-organisms in the environment.

Autoclave: an apparatus designed to sterilise reusable materials, equipment or waste by exposure to steam, either injected directly or indirectly at a pressure above atmospheric pressure. For example, autoclaves are used for sterilisation of liquid and solid wastes and for the preparation of sterile media and materials.

Biobank: a facility that collects, processes and stores biological material. It may also be referred to as a biorepository or a biological resource centre.

Biocidal products (biocides): substances or preparations intended to destroy, deter or render harmless pest organisms such as fungi, bacteria, viruses, rodents and insects (that is, they are antimicrobial or pesticidal).

Biosafety: the containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and toxins or their accidental release.

Biosecurity: the principles, technologies and practices used for the protection, control and accountability of biological materials or equipment, skills and data, with the aim of preventing unauthorised access to or loss, theft, misuse, diversion or release of pathogenic biological agents.

Cleaning: the removal of visible soil (organic and inorganic material) from objects and surfaces. Cleaning can be carried out manually or by mechanical means using water and soap, detergents or enzymatic products.

Contamination: contact with a biological agent.

Containment level: refers to the four biosafety levels, ranging from basic containment level 1 (CL1) to maximum containment level 4 (CL4). Containment levels may also be referred to as biosafety levels (BSL-1 to BSL-4).

Containment measures: the design features, construction, containment facilities, equipment, practices and operational procedures required for working with biological agents from the various risk groups.

Culturing: the process by which biological agents are intentionally propagated.

Dangerous goods: substances and articles that are classified as hazardous for transport and present a risk to people, property and the environment.

Decontamination: a general term that refers to a process or a combination of processes that reduce a biological agent's concentration to a degree that does not present a health risk. Such processes can range from physical cleaning to sterilisation.

Diagnostic sample: any human or animal material, including but not limited to excreta, secreta, blood and its components, tissue and tissue fluids submitted for purposes of diagnosis.

Diagnostic service: the provision of services in relation to diagnostic work.

Diagnostic work: any activity undertaken in a diagnostic laboratory with the sole intention of analysing specimens or samples from a human patient or animal in which a biological agent may be, is or is suspected of being present for purposes relating to the assessment of the clinical progress, or assistance in the clinical management, of that patient or animal.

Disease: a condition in which the body's normal structures or functions are impaired.

Disinfection: a decontamination process that involves the targeted treatment of materials, objects or surfaces with physical or chemical processes. As the presence of dirt or organic matter can reduce the efficacy of disinfection and sterilisation, pre-cleaning of items may be required before disinfection or sterilisation.

Double-door autoclave: an autoclave with a door at each end of the chamber. It may also be referred to as a pass-through or double-ended autoclave.

Endemic: regularly found among particular people in a certain area.

Higher containment level: containment level 3 and level 4.

Host: an organism in which a pathogen lives, multiplies and causes disease.

Import: the transfer of materials from outside the European Union (EU) into the EU, from countries often referred to as third countries.

Inactivation: the irreversible destruction of the reproductive and infectious ability of a biological agent.

Incineration: the total destruction by burning of all living and organic matter by dry heat at not less than 800 °C.

Incubation period: the time that elapses before a disease becomes apparent following exposure to a biological agent.

Infection: the entry, establishment and multiplication of a pathogen within a host.

Infectious dose: the amount of pathogen required to establish an infection in a susceptible host.

Infectivity: the likelihood that a biological agent will infect a host, given that the host is exposed to the agent.

Intentional work: where there is a specific intent to work with or use a biological agent, such as an employee working directly with a biological agent in a research laboratory.

Laboratory-acquired or laboratory-associated infection: refers to all direct or indirect human infections, with or without the onset of symptoms, following exposure to pathogenic organisms in a laboratory.

Lower containment level: containment level 1 and level 2.

Make safe: the process to reduce the microbial content of contaminated material so that it can be handled or disposed of without causing an infection hazard.

Micro-organism: a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material.

Opportunistic biological agent: a biological agent that only causes an illness when the person's ability to defend themselves is impaired, for example by immunosuppression.

Parasite: an organism that lives in or on an organism of another species and derives nutrients from it.

Pathogen: a biological agent that causes disease or illness.

Permit to work: a document issued by an authorised person to permit work to be carried out safely in a defined area under specified conditions.

Pesticide control service number: the number assigned to a biocidal product by the Pesticide Registration and Control Divisions of the Department of Agriculture, Food and the Marine.

Polymerase chain reaction: a laboratory technique used to make many copies of a specific segment of DNA (deoxyribonucleic acid).

Prion: a small proteinaceous infectious particle generally considered responsible for causing a group of neurodegenerative diseases known as transmissible spongiform encephalopathies.

Propagation: the action of intentionally increasing or multiplying the number of biological agents.

Prophylaxis: treatment or measures taken to prevent a disease from occurring and includes vaccination.

Reprotoxic: refers to biological agents that may impair fertility in men and women or cause adverse effects during pregnancy.

Sharps: items, whether intact or broken that may cause cuts or puncture wounds. Examples include items with sharp points or cutting edges capable of cutting or piercing human skin such as syringe needles, scissors, tweezers, scalpels, slides, cover slips, blades, pipettes, capillary tubes and broken glass or plastic.

Shower out: shower before leaving the contained area.

Sterilisation: a decontamination process that renders an object free from all viable micro-organisms, including bacterial spores (unlike disinfection). Sterilisation can be carried out using chemicals (known as chemical sterilants) such as aldehydes, hydrogen peroxides or ozone – some chemical disinfectants will kill spores with prolonged exposure times – or by physical processes such as the use of dry heat in an oven, steam under pressure as in autoclaving or radiation.

Toxin: a poisonous substance that is a natural product of the metabolic activity of certain micro-organisms such as bacteria.

Transmission: the transfer of a biological agent from an object to living things or between living things, either directly or indirectly via aerosols, droplets, body fluids, vectors, food, water or contaminated objects.

Unintentional work: where there is no plan to work specifically with a biological agent but exposure to an agent may occur because of the work. For example, working with diagnostic samples or biological materials, which may contain biological agents (including adventitious agents).

Vaccination: the administration of a vaccine to stimulate the production of an immune response (production of antibodies) and is a form of active immunisation.

Vaccine: any preparation intended to produce immunity to a disease by stimulating the production of antibodies.

Vector: an organism that carries and transmits a pathogen from a host to another host. For example, certain species of mosquitoes are vectors that transmit the biological agent responsible for malaria.

Virulence: the relative ability of a biological agent to produce disease.

Abbreviations

ABP	animal by-product
ADN	Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	Agreement Concerning the International Carriage of Dangerous Goods by Road
AQL	acceptable quality level
BIBO	bag-in bag-out
BSA	bovine serum albumin
BSO	biological safety officer
CCTV	closed-circuit television
CE	conformité européenne
CL1	containment level 1, may also be referred as biosafety level 1 (BSL1)
CL2	containment level 2, may also be referred as biosafety level 2 (BSL2)
CL3	containment level 3, may also be referred as biosafety level 2 (BSL3)
CL4	containment level 4, may also be referred as biosafety level 4 (BSL4)
DAFM	Department of Agriculture, Food and the Marine
DGR	Dangerous Goods Regulations
DGSA	Dangerous Goods Safety Adviser
EPA	Environmental Protection Agency
EU	European Union
FBS	foetal bovine serum
GMM	genetically modified micro-organism
GDPR	General Data Protection Regulation
GMMO	genetically modified micro-organism (acronym used in the ADR)
GMPP	good microbiological practice and procedure
GMO	genetically modified organism
HEPA	high-efficiency particulate air
HSA	Health and Safety Authority
IAA	Irish Aviation Authority
IATA	International Air Transport Association
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
LAI	laboratory-acquired or laboratory-associated infection
LEV	local exhaust ventilation
MSC	microbiological safety cabinet, also known as a biological safety cabinet or a safety cabinet
N.O.S	not otherwise specified
NTFSO	National Transfrontier Shipment Office
NWCPO	National Waste Collection Permit Office
OELV	occupational exposure limit value
PAPR	powered air-purifying respirator
PCR	pesticide chain reaction
PCS	pesticide control service
PPC	personal protective clothing
PPE	personal protective equipment
PSN	proper shipping name
RID	Regulation Concerning the International Carriage of Dangerous Goods by Rail
RPE	respiratory protective equipment
SOP	standard operating procedure
TDG	Transport of Dangerous Goods
UPS	uninterruptable power supply
UV-C	ultraviolet-C, shortwave ultraviolet
UVGI	ultraviolet germicidal irradiation

Acknowledgements
The Health and Safety Authority gratefully acknowledges the contributions of the Department of Enterprise, Trade and Employment; the Department of Agriculture, Food and the Marine; the Environmental Protection Agency; numerous biological safety officers; equipment suppliers and all who participated in the development of this guidance.

Chapter 1. Introduction

Aim of the guidance

The aim of this guidance is to promote good occupational health and safety within Irish laboratories that work with biological agents or where exposure to biological agents may occur. The guidance will assist in complying with the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020) – commonly known as the Biological Agents Regulations. The guidance is not intended as a legal interpretation of the Biological Agents Regulations or any other health and safety legislation.

Scope of the guidance

The guidance focuses on the Biological Agents Regulations and laboratories where exposure to biological agents, or materials that may contain biological agents, could occur. It targets laboratory designers, employers and employees – specifically laboratory managers and workers. The emphasis is primarily on the hazards, risks and control measures for biological agents. When managing safety in the laboratory, consider other hazards and risks such as chemicals (including gases), radiation, electricity, fire, and hot and cold work.

The guidance does not cover animal rooms in which laboratory animals are or suspected to be carriers of pathogens or are deliberately infected with pathogens. Nor does the guidance specifically address biobanks, although some of the information will be of relevance. As the guidance focuses on occupational risk, it does not address risks to animal or plant health or effects on the environment, which may also need to be considered.

What is a laboratory?

A laboratory is a place of work where activities such as teaching, testing, scientific research or development, clinical or diagnostic evaluation, investigation and experimentation are conducted under controlled conditions.

The laboratory may be a room, a suite of rooms or a facility specifically built, purposed, adapted, refurbished, reconfigured or equipped to function as a laboratory. It may be a stand-alone entity or part of a larger place of work such as a hospital or academic institution.

There are many types of laboratories. The terminology used for the laboratory often reflects the main purpose. For example, laboratories may be referred to as biomedical, biological, clinical, diagnostic, medical, research, healthcare, forensic, pathology, veterinary, teaching, public health, environmental, production or quality control. The laboratory may be State run or privately operated.

Many of these laboratories use biological agents or handle materials that contain or could contain biological agents. In some laboratories, work will be carried out with biological agents directly, for example by culturing or amplifying them. In other cases, work will be carried out with material that is likely to contain biological agents, although the agent is not actually being grown, such as in a blood typing laboratory.

Chapter 2. Legal requirements

The main occupational health and safety legislation applicable to biological agents is the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020 (S.I. No. 572 of 2013 as amended by S.I. No. 539 of 2020) – the Biological Agents Regulations.

Definition of biological agents

Biological agents are defined under these Regulations as 'micro-organisms', including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity, classified into 4 risk groups according to their level of risk of infection, as follows:

(a) a "group 1 biological agent" means one that is unlikely to cause human disease to employees;

(b) a "group 2 biological agent" means one that can cause human disease and might be a hazard to employees, although it is unlikely to spread to the community and in respect of which there is usually effective prophylaxis or treatment available;

(c) a "group 3 biological agent" means one that can cause severe human disease and presents a serious hazard to employees and that may present a risk of spreading to the community, though there is usually effective prophylaxis or treatment available;

(d) a "group 4 biological agent" means one that causes severe human disease and is a serious hazard to employees and that may present a high risk of spreading to the community and in respect of which there is usually no effective prophylaxis or treatment available'.

"A micro-organism is further defined under these Regulations as "a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material".

Application of the Biological Agents Regulations

The aim of the Biological Agents Regulations is to protect employees from actual or potential exposure to biological agents because of work activities. The focus of the Regulations is on employees' health and they do not take account of animal or plant health or effects on the environment. The Regulations set down the minimum requirements for the control of exposure to biological agents. They apply to all workplaces where exposure to biological agents occurs or may occur and they cover the principal areas of biosafety – risk assessment, risk management, risk communication and risk monitoring.

Enforcement of the Biological Agents Regulations

The Biological Agents Regulations are made under the Safety, Health and Welfare at Work Act 2005 and enforced by the Health and Safety Authority (HSA). Most of the Authority's inspections are unannounced.

A person found guilty of an offence under the Biological Agents Regulations is liable on:

- summary conviction to a fine not exceeding €5,000 or imprisonment for a term not exceeding 12 months or both, or
- conviction on indictment to a fine not exceeding €3 million or imprisonment for a term not exceeding 2 years or both.

The Biological Agents Code of Practice

The Biological Agents Regulations are accompanied by a Code of Practice – the *2020 Code of Practice for the Safety, Health and Welfare at Work (Biological Agents) Regulations 2013 and 2020* (commonly known as the 2020 Biological Agents Code of Practice). Take account of this Code of Practice when reading this guidance.

Schedule 1 of this Code of Practice lists biological agents known to cause disease in healthy workers and classifies them into risk groups 2-4. The Schedule identifies specific fungi and parasites known to produce allergic effects and bacteria

known to produce exotoxins. It also indicates bacteria and viruses for which effective vaccines, registered within the European Union (EU), are available. Such agents are denoted with an A, T or V, respectively in the 'notes' column in the Code of Practice. Group 3 biological agents marked with a double asterisk (**) are eligible for a degree of dispensation from level 3 containment measures, due to that specific biological agent not normally being infectious via the airborne route. For agents with D in the 'notes' column, keep occupational exposure lists for more than 10 years after the end of the last known exposure (see Chapter 16).

Schedules 2 and 4 of this Code of Practice specifically apply to laboratories. Schedule 2 of the Code outlines the minimum containment measures for containment levels 2, 3 and 4. Schedule 4 provides dispensations for certain biological agents from specific minimum containment measures. Take account of these Schedules when conducting a biological agents risk assessment.

Status of the Code of Practice

Codes of Practice such as the 2020 Biological Agents Code of Practice have a different status to legislation. If there is a prosecution for a breach of health and safety legislation and it is proved that the requirements of the Code of Practice were not followed, you will need to show that you complied in some alternative way.

Other legislation applicable to laboratories

Other health and safety legislation enforced by the HSA and applicable to laboratories includes:

- The Safety, Health and Welfare at Work Act 2005 (No. 10 of 2005) – commonly known as the 2005 Act.
    - This legislation sets down the framework for the safe management of work. Among other things, it requires employers to have a safety statement; conduct risk assessments; consult with employees on matters of health and safety; provide instruction, information and training so that employees can carry out work safely; and have emergency plans. The legislation also sets out the duties of employees to co-operate with the employer in health and safety matters. Note that any references to a substance within this legislation include micro-organisms.
- The Safety, Health and Welfare at Work (General Application) Regulations 2007 to 2023 (S.I. No. 299 of 2007 as amended) – commonly known as the General Application Regulations.
    - This is a composite set of Regulations. They set down requirements in relation to topics such as the workplace, use of work equipment, personal protective equipment (PPE), manual handling, display screen equipment, electricity, work at height, noise, vibration, sensitive risk groups such as pregnant workers or young persons, night and shift work, safety signs, first aid, explosive atmospheres, artificial optical radiation, pressure systems (which include autoclaves) and the reporting of accidents and incidents.
    - Chapter 1 of Part 6 of the General Application Regulations requires an employer to conduct a specific risk assessment prior to employing a child (person aged under 16 years) or a young person (person who is 16 but not yet 18 years). The aim of this assessment is to identify anything that may be a risk to the safety, health or development of such persons. In conducting the assessment, account must be taken of any work activity likely to involve a risk of harmful exposure to a group 2, group 3 or group 4 biological agent. You must not employ the child or young person where the risk assessment reveals harmful exposure to any agents that are toxic, are carcinogenic, cause heritable genetic damage or harm to an unborn child or in any way chronically affect human health.
    - Chapter 2 of Part 6 of the General Application Regulations requires a specific risk assessment to be conducted for pregnant, post-natal and breastfeeding employees. These Regulations come into play once the employee informs their employer that they are pregnant. You must assess the risk to their health and safety and any possible effect on the pregnancy or breastfeeding. This includes any activity likely to involve a risk of exposure to a group 2, group 3 or group 4 biological

agent where it is known that the biological agent or the therapeutic measures required by such agents endanger the health of pregnant employees and the unborn child. Specifically, a pregnant worker must not work with toxoplasma parasites or rubella viruses unless shown to be immune to these agents.

- The Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 to 2021 (S.I. No. 619 of 2001 as amended) – commonly known as the Chemical Agents Regulations.
    - These Regulations require you to determine and assess the risk of exposure to hazardous chemical agents such as reagents and disinfectants and to prevent or control exposure.
- The Safety, Health and Welfare at Work (Carcinogens) Regulations 2001 to 2019 (S.I. No. 78 of 2001 as amended) – commonly known as the Carcinogens Regulations.
    - Under these Regulations, you must carry out an assessment of the risks associated with the use of carcinogens or mutagens in the workplace and take steps to control the risk by eliminating or minimising the exposure. Certain disinfectants are classified as carcinogenic.
- European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 as amended (S.I. No. 349 of 2011 as amended) – referred to in this guidance as the ADR Regulations.
    - These Regulations give effect to an international agreement – the Agreement Concerning the International Carriage of Dangerous Goods by Road, commonly known as the ADR. For further information, see Chapter 11.
- European Union (Prevention of Sharps Injuries in the Healthcare Sector) Regulations 2014 (S.I. No. 135 of 2014) – commonly known as the Sharps Regulations.
    - Take account of these Regulations if you are a healthcare provider or if you provide services to a healthcare employer and provision of the services is under the authority of the healthcare employer, or in a healthcare premises. For example, laboratory services within a hospital where sharps are used will fall under this legislation. Other sectors where sharps are used should consider the Regulations' requirements as best practice in eliminating or reducing the risk from sharps injuries.

Guidance on relevant occupational health and safety legislation is available on the HSA's website at www.hsa.ie.

Relevant legislation enforced by other Government Departments and agencies

This guidance is written in the context of occupational health and safety legislation, which is enforced by the HSA. However, other Government Departments and agencies also have a role in enforcing legislation in connection with biological agents or infectious materials. Examples of such legislation are the:

- Genetically Modified Organisms (Contained Use) Regulations 2001 to 2010 (S.I. No. 73 of 2001 as amended) – commonly known as the Contained Use Regulations.
    - The Environmental Protection Agency (EPA) enforces this legislation, designed to protect human health and the environment. The legislation applies to contained use facilities such as laboratories. It requires a risk assessment to be conducted and a record of the assessment to be kept. This risk assessment is process based and requires consideration of the harmful effects of the genetic modification activities. In conducting the risk assessment, identify any harmful effects with the donor micro-organism, the inserted genetic material, the vector, the recipient micro-organism and the resulting genetically modified micro-organism (GMM), and assess whether it is a hazard to human health or to the environment. Consider whether the GMM has more hazardous properties than the parental micro-organism.
      For example, increased antibiotic resistance or host range, sequences that could code for toxins or other hazardous gene products, whether it could revert to virulence, whether it could transmit genetic information to other micro-

organisms, whether the sensitivity to effective treatment or prophylaxis has been altered and whether the GMM can survive outside the workplace. Based on the risk assessment, assign a class of activity (Class 1-Class 4) depending on the level of risk the activity poses to human health or the environment. Apply the containment and other protective measures that correspond to the contained use classification. Notification to, and consent from, the EPA is required for the first-time use of a premises for all classes. Consent is also required for subsequent Class 2 activities where a user requests a consent and for every subsequent Class 3 and Class 4 activity.

- European Union (Animal By-Products) Regulations 2014 (S.I. No. 187 of 2014).
    - Authorised officers on behalf of the Minister for Agriculture, Food and the Marine enforce this legislation. The Regulations cover the import, use and disposal of animal by-products (ABPs) which includes cells, tissues or laboratory reagents derived from animals, such as bovine serum albumin (BSA) or foetal bovine serum (FBS). A VET 15 import licence is required for import of products of animal origin for research and diagnostic purposes.
- The Importation of Pathogenic Agents Order, 1997 (S.I. No. 373 of 1997).
    - This legislation is enforced by authorised officers on behalf of the Minister for Agriculture, Food and the Marine. The legislation covers the import of animal pathogenic agents into Ireland, which are only permitted under a VET 40 import licence.
- Biological Weapons Act 2011 (S.I. No. 13 of 2011).
    - This legislation prohibits the development, production, stockpiling, or use of a microbial or other biological agent, or toxin for hostile purposes. An Garda Síochána enforces this legislation on behalf of the Minister for Foreign Affairs.
- The Control of Exports Act (No. 1 of 2008), Control of Exports (Brokering Activities, Goods and Technology) Regulations 2021 (S.I. No. 207 of 2021) and Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items (recast).
    - The Department of Enterprise, Trade and Employment and the Revenue Commissioners enforce this legislation, which covers dual use and military export licences and may apply to certain biological agents and toxins.

As legislation is always under review, check its status at www.irishstatutebook.ie.

Standards

Numerous European and international standards and agreements relate to laboratories. Standards are voluntary and good practice and do not have legal status unless specifically referred to in legislation, in which case a laboratory must comply with them. Standards can assist in complying with legislation. For example, the standard *ISO 35001: Biorisk management for laboratories and other related organisations* outlines a management framework for laboratories to protect workers, the community and the environment from biorisk (which encompasses biosafety and biosecurity). This standard may be of assistance when a laboratory is setting up its safety management system as required under the 2005 Act.

Standards can differ from the law in their requirements and protective measures for laboratories. Irrespective of any standard or agreement, legally you must meet the minimum health and safety requirements under the 2005 Act and associated Regulations.

As standards are also under regular review and revision, check their status on the NSAI (National Standards Authority of Ireland) website.

Chapter 3. Exposure to biological agents in the laboratory

Workers may encounter biological agents in the laboratory either because they:

- knowingly work with or use them – intentional work such as in a research laboratory, or
- work with materials that may contain them – unintentional work such as working with diagnostic samples or biological materials, which may contain biological agents (including adventitious agents).

In some areas of work – such as medical diagnostics or microbiological research – a transition can arise from unintentionally working with biological agents to intentionally working with them; for example, where an unknown biological agent is identified in the initial diagnosis and then propagated as a known biological agent.

Some of these biological agents may have potential to cause adverse health effects such as illness, disease, toxic effects or allergies if workers are exposed to them during the course of their work activities or because of an accident or incident. A biological agent that causes disease or illness is known as a pathogen.

Route of exposure

Within the laboratory, the main routes of exposure to biological agents are via:

- ingestion – for example, through mouth pipetting of cultures or hand-to-mouth contamination;
- inhalation – for example, inhaling aerosols generated by a spilt culture tube;
- inoculation – for example, via a puncture, cut or needle stick injury; and
- absorption – for example, infectious splashes or droplets entering the mucous membranes such as the nose or eye or making dermal contact.

Appropriate training of employees, adherence to good microbiological practice and procedure and safe systems of work (see Chapter 8), and appropriate use of PPE (see Chapter 14) can generally prevent ingestion, inoculation and absorption of biological agents. Prevention of aerosol inhalation can be more difficult, as aerosols are often hard to detect and thus to control. The principle of containment plays a key role in the control of aerosols (see Chapter 5).

Aerosol generation

Aerosols generated in the laboratory can be a serious hazard. The small size of micro-organisms allows easy spread by aerosol, resulting in contamination of laboratory work surfaces and potential worker exposure through inhalation.

Procedures that impart energy to a microbial suspension will produce aerosols. For example, pipetting, vigorous shaking, using uncontained or malfunctioning high-energy equipment (blenders, non-self-contained centrifuges, sonicators, homogenisers and vortex mixers) and equipment failure can all produce aerosols (see Figure 1 for other examples). These procedures and equipment generate respirable-size particles that remain airborne for protracted periods, creating a hazard for the person performing the operation, co-workers in the laboratory and, potentially, persons occupying adjacent spaces open to airflow from the laboratory.

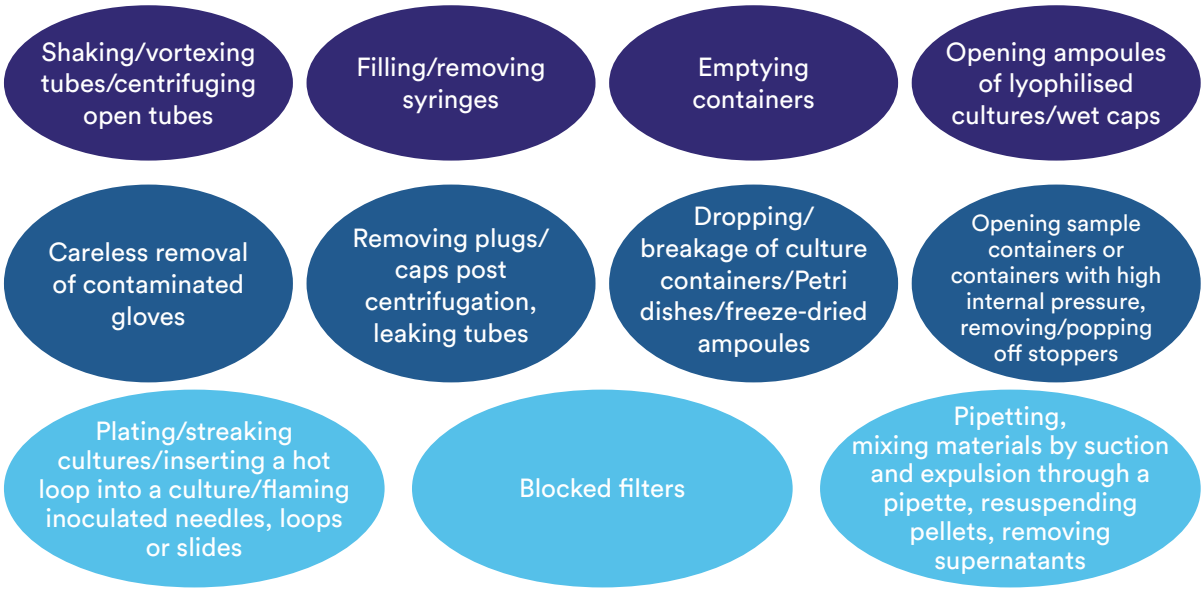


Figure 1: Examples of activities with elevated risk of exposure to aerosols

Laboratory incidents and accidents

Laboratory incidents and accidents may result in potential or actual exposure to a biological agent or release of a biological agent. Such an exposure may have potential to infect and cause disease in not only laboratory staff but also members of the community and the natural environment.

Depending on the biological agent involved and the nature of the incident or accident, it may result in asymptomatic carriage; illness; environmental, animal or product contamination; or spread of disease to the neighbouring community. Asymptomatic carriers, depending on the biological agent, may have potential to infect other persons such as family members. Besides consequences to health, laboratory incidents and accidents may have economic, reputational and legal consequences.

An incident is an occurrence that involves the risk of exposure of an employee at the place of work to a biological agent.

An accident may arise out of or in the course of employment and, in the case of a person carrying out work, may result in personal injury such as a disease, disability, occupational illness or death.

Laboratory-acquired infections (LAIs)

The term 'laboratory-acquired infection' or 'laboratory-associated infection' (LAI) refers to all direct or indirect human infections, with or without the onset of symptoms, following exposure to pathogenic organisms in a laboratory.

There are three types of infection:

- Primary infection – the laboratory worker becomes infected.
- Secondary infection – the infected laboratory worker infects other people: for example, fellow workers or family members.
- Tertiary infection – the secondarily infected people infect other people.

LAIs have occurred and do occur in Ireland. In some cases, it may not be possible to link the LAI to a specific incident, especially where aerosols are involved. Identifying LAIs as such can be difficult, as workers are often unaware that exposure has occurred and that they might be infected. Also, incubation periods can vary among biological agents and between infected people. LAIs may occur asymptomatically or with mild symptoms or symptoms similar to endemic diseases. As a result, they may not be linked back to the work or may even be diagnosed incorrectly.

In many cases, poor working practices are a contributory factor. Internationally, some common causes of LAIs are:

- puncture, cutting or sharps injuries;
- inhalation of aerosols, for example from spillages or from leakages during centrifugation or from dropped Petri dishes or ampoules;
- mouth pipetting or swallowing;
- splashes;
- failure to use correct containment;
- technical failures in equipment or infrastructure;
- poor hygiene;
- improper use of equipment or suboptimal laboratory technique;
- improper or inadequate decontamination;
- poor waste management/mishandling or improper disposal of contaminated waste; and
- human factors such as human error, carelessness, stress, absent-mindedness, distraction or inappropriate behaviour.

The repetitive nature of certain laboratory manipulations and excessive workload may also be contributory factors.

Good laboratory design and containment, management, organisational and work practices; the correct use of appropriate equipment; the provision of instruction, information and training; and proactive safety supervision can all help prevent LAIs.

Chapter 4. Health and safety management in the laboratory

The 2005 Act, the General Application Regulations and the Biological Agents Regulations set out the duties to manage health and safety in the workplace.

For any undertaking, the key elements of a health and safety management system, outlined in Figure 2, are:

- policy and commitment,
- planning,
- implementation and operation,
- measuring performance, and
- auditing and reviewing performance.

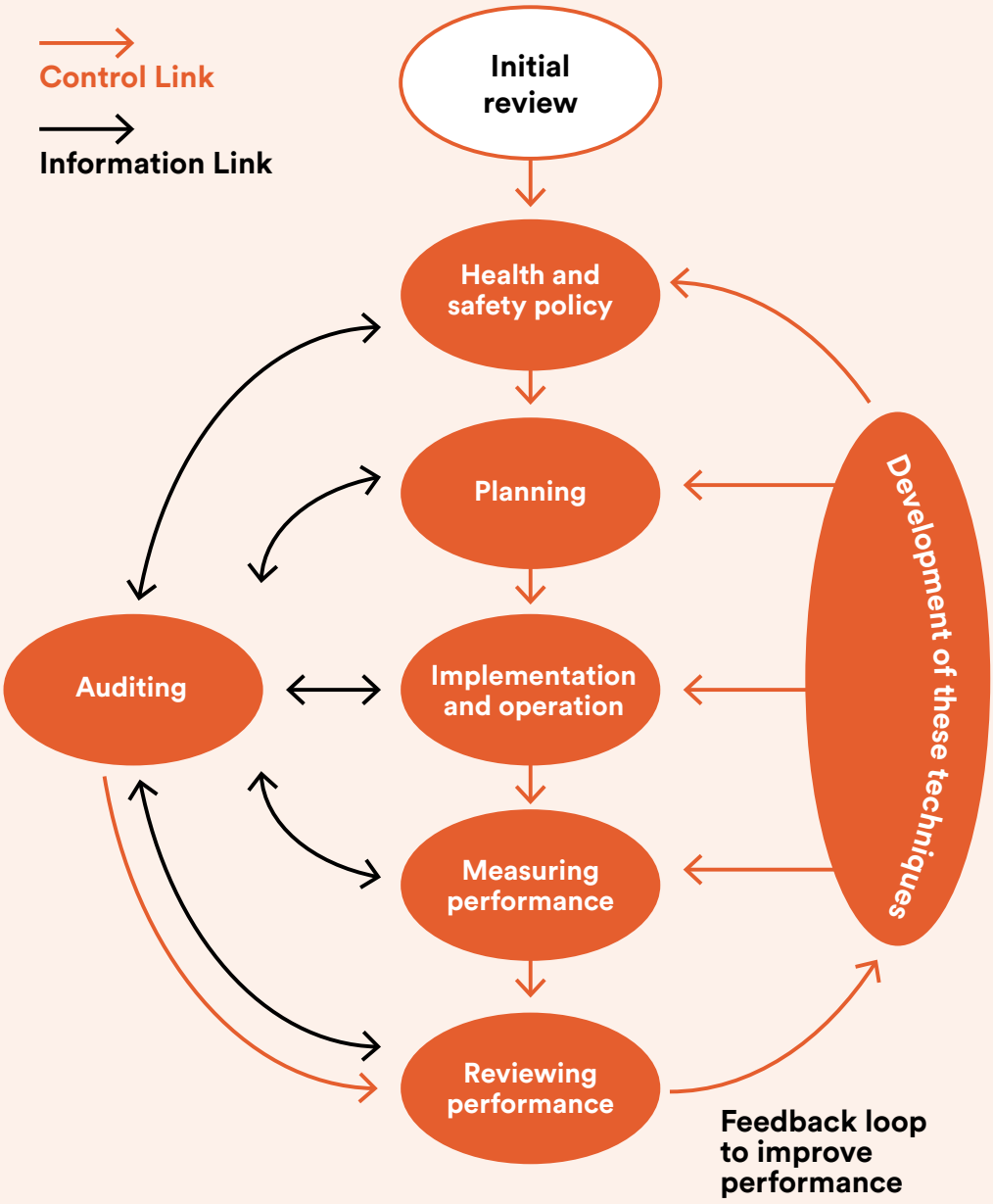


Figure 2: Key elements of health and safety management

The HSA publication *Workplace Safety and Health Management* gives guidance on general health and safety management.

A good health and safety management system in laboratories will encompass:

- management responsibilities (see Chapter 4),
- risk assessment (see Chapter 7),
- staff selection, qualification, training and supervision (see Chapter 4),
- local safety policies, standard operating procedures (SOPs) and documented safe systems of work (Chapter 8),
- emergency procedures and plans (Chapter 12),
- accident and incident reporting (Chapter 12),
- health surveillance (Chapter 16), and
- record-keeping.

Roles and responsibilities

The employer is ultimately responsible for managing health and safety in the workplace. However, in the laboratory, the day-to-day responsibility for health and safety may be delegated to senior laboratory managers. These managers have an important role in developing, fostering and maintaining good health and safety in the laboratory.

Put in place an appropriate structure, with distinct lines of responsibility and accountability, to manage health and safety within the laboratory. Clearly define, communicate and document roles and responsibilities and ensure they are understood. It should be evident who has the authority to carry out defined work or procedures.

Biological safety officers and committees

The Biological Agents Regulations do not have a specific requirement for a biological safety officer (BSO) or a biological safety committee. However, the Contained Use Regulations (see Chapter 2) refer to the establishment of biological safety committees or subcommittees where required.

Whether a BSO or biological safety committee is required will depend on the work environment and the nature and extent of the work. A biological safety committee can have an important role in the bioethical and scientific analysis of research projects before they are authorised. In addition, such committees provide good oversight and integration where several laboratories are located on a single site.

BSO is an advisory position, as the management of biosafety will rest with the employer and those conducting and managing the work. Where appointed, a BSO must be competent and the appointment made in writing. Ensure the BSO reports directly to senior management and is in a position to stop work if it is unsafe.

Resources

Sufficient staff, time, space and equipment must be available to carry out work safely. In addition, ensure there are adequate support services, staff and budget to safely operate and maintain the containment facilities. Put in place appropriate continuity and succession plans to ensure sharing of critical safety knowledge and maintenance of control measures in the event of personnel absence, unavailability or departure.

Competence

The requirement for competence is enshrined in health and safety legislation. The 2005 Act refers to a person being deemed competent:

> "where having regard to the task he or she is required to perform and taking account of the size or hazards (or both of them) of the undertaking or establishment in which he or she undertakes work, the person possesses sufficient training, experience and knowledge appropriate to the nature of the work to be undertaken."

Qualifications or position does not mean that a person is competent. Even the most well qualified or senior person may require supervision until deemed competent to work safely. You must ensure that new employees – even those who may have previously worked at a similar containment level – are competent to work in your laboratory. Familiarisation and supervision will be required as laboratory operations and set-ups can vary. Ensure laboratory workers have demonstrated competence in working at lower containment levels before they are authorised to work at a higher containment level. As competence may decline if skills are not used, maintain it by providing refresher training, as required.

Employee communication and consultation

Health and safety management is more effective when people collaborate. Consult with employees, safety representatives or both with regard to health and safety measures. Put in place a means for workers to report health and safety concerns, without fear of reprisal. Ensure workers are informed and aware of the risks associated with the work. Safety signage can assist in communicating some hazards and control measures.

Employees' duties

Employees have legal duties under general health and safety legislation. They must:

- comply with relevant laws and protect their own safety and health, as well as the safety and health of anyone who may be affected by their acts or omissions at work;
- ensure that they are not under the influence of any intoxicant to the extent that they could be a danger to themselves or others while at work;
- co-operate with their employer and other persons with regard to safety, health and welfare at work;
- not engage in any improper conduct or other behaviour that could endanger their own safety or health or that of anyone else;
- participate in and implement any health and safety training offered by the employer;
- not interfere with, misuse or damage anything provided for securing safety, health and welfare;
- report to their employer or other relevant person any unsafe work, any defect or any breach of legislation they are aware of that may endanger a person's safety, health and welfare;
- not misrepresent themselves with regard to their level of training; and
- report immediately to their employer, or the person responsible for health and safety at the workplace, any accident or incident that they are aware of involving exposure to, risk of exposure to or release of a biological agent that could endanger an employee's health or safety.

Instruction, information and training

Instruct, inform and train laboratory workers so that they can work safely and carry out their work tasks competently and to an appropriate standard. For new entrants, provide induction training that covers laboratory safety measures – an introduction to the laboratory layout, the safety statement and the relevant risk assessments, local rules, any legal requirements and the emergency plans and procedures.

Workers must have adequate safety training in line with the biological agents they may be exposed to and the level of containment they will be working at. Provide such training before they commence the work. A training needs analysis will assist in identifying any training needs.

The Biological Agents Regulations specifically require that where there is work with or contact with biological agents, employees, their safety representative or both receive sufficient and appropriate training on the basis of all available information, particularly information and instructions concerning:

- potential risks to health;
- precautions to be taken to prevent exposure;
- hygiene requirements;
- wearing and use of suitable work clothing, special protective clothing and PPE; and
- steps to be taken by employees to prevent incidents and in the case of incidents.

You must provide this information to any other employer whose employees, or any self-employed person who, may be exposed to a biological agent arising from the conduct of the undertaking.

This instruction, information and training should encompass, as relevant, the:

- biological agents the worker could be exposed to;
- risks created by that exposure;
- signs and symptoms of exposure to the agents;
- results of the risk assessment;
- safe working methods for specific biological agent risk groups;
- applicable prevention and containment measures;
- correct handwashing technique;
- safe use of PPE;
- safe inactivation and disposal of biological agents and contaminated equipment or materials;
- pros and cons of vaccinations;
- post-exposure prophylaxis procedures;
- emergency and first aid plans;
- reporting procedures for incidents and accidents, including exposure to biological agents; and
- correct use of equipment such as microbiological safety cabinets (MSCs), autoclaves and centrifuges.

In line with the 2005 Act, provide instruction, information and training in a manner, form and, as appropriate, language that is reasonably likely to be understood. For example, this may mean providing information in a different language where English is not the person's principal language. An information card may be useful in some cases.

Keep training records, detailing training content, who provided the training, who attended and the date and duration of the training. Confirm the records with the employee's signature. Make records available to inspectors of the HSA or other relevant enforcement agencies when requested. Carry out refresher training at regular intervals and as required, to maintain competency.

Safety supervision

Provide employees with any necessary supervision, as required by the 2005 Act, to ensure that they work safely. The level of supervision will depend on the risk associated with the work activity and the competence of the worker. In assigning work tasks, ensure that the task is within the capabilities of the worker with regard to safety, health and welfare. For example, supervision may be required for new, inexperienced or temporary workers until competence is established. Over time, workers may become complacent about working with or exposure to biological agents, and even the most knowledgeable, trained and experienced person may require occasional safety supervision to ensure adherence to safe systems of work. Visitors, contractors and lone workers may also require some form of supervision. Supervisors must be competent to carry out their duties effectively and may require appropriate training.

Management of contractors

Put in place appropriate contractor management procedures to ensure that any selected contractors are competent and to manage their safety and, where required, ensure laboratory security. Inform service providers such as cleaning, security, waste management and disposal, and equipment service providers, about any hazards and risks. Provide adequate instruction and information to ensure they do not endanger themselves or others. Where external service providers or contractors are used, ensure that they have appropriate safety management systems in place.

Look for an up-to-date safety statement, site-specific risk assessments and documented safe systems of work for the planned work.

For higher containment level laboratories, have documented contractor access policies in place. Where cleaning, repair or servicing is required, ensure that workers, including contractors, are not exposed to biological hazards. Have appropriate procedures and consultation in place so that contractors do not enter areas where there is a risk to their health from biological agents. Use warning and prohibition safety signage, such as the 'biohazard' sign and the 'no access for unauthorised' persons sign, to inform of hazards and control measures.

Students

The Biological Agents Regulations do not directly apply to third-level students, as they are not employees under health and safety legislation. Third-level institutions still have a duty of care to people who are not their employees, and their safety management system and safe systems of work should address the health and safety of students in relation to biological agents.

Visitors

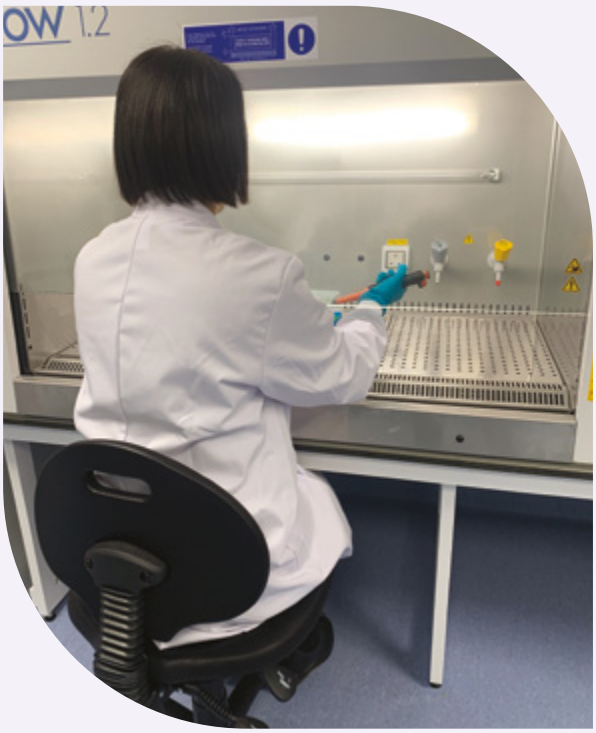
Make visitors aware of any relevant hazards, risks and control measures. Bring local laboratory rules to their attention and accompany visitors at all times. In certain circumstances, a 'no visitors' policy may be required, especially at higher containment levels.

Co-operation and co-ordination

Some workplaces may be shared by more than one employer; for example, a laboratory in a university may have a campus business operating in it, or employees from several employers may collaborate on a project. The 2005 Act requires co-operation and co-ordination to ensure compliance with health and safety legislation. Inform everyone in the workplace sufficiently about all the risks that may affect them. If there is no controlling employer in charge, make an agreement to meet the requirements of the law and clearly identify who is responsible for what. Ensure adequate communication between all the parties on matters of health and safety, especially with regard to biological agent hazards and risks.

Chapter 5. Containment, containment measures and containment levels

The Biological Agents Regulations set out special measures for laboratories based on the principle of containment. Where work involves the handling of a risk group 2, 3 or 4 biological agent, you must assess the risk with the planned work activities (see Chapter 7). In doing so, you must take account of the minimum containment levels outlined below, and determine the appropriate containment level and containment measures for the work.



Containment

Containment is one of the most important principles in preventing release of biological agents. It refers to the way in which biological agents are managed to prevent or control exposure. It involves measures to isolate or separate the potentially hazardous biological agent in order to eliminate or reduce exposure of workers, other people and the outside environment to the agent.

Containment can be viewed as:

- primary, or
- secondary.

In certain circumstances, a third level of containment – tertiary containment – may be required.

Primary containment

Primary containment protects the workers and the immediate laboratory environment from exposure to biological agents. With primary containment, controls isolate the hazard at the source. Such controls include good microbiological practice and procedure (see Chapter 8), containment devices or safety equipment such as MSCs (see Chapter 15), isolators, sealed tubes or flasks and sealed centrifuge rotors, which contain the biological agents.

Secondary containment

Secondary containment protects the laboratory's external environment (other workers, the community, other people and the natural environment) from exposure to biological agents. A combination of laboratory design and operating procedures, such as restricted access, air handling, 'shower out' in some laboratories and safe disposal of waste, achieve this.

Note that in a laboratory, the MSC is primary containment and the room is secondary containment.

Tertiary containment

Tertiary containment deals with the overall building and its physical operation. This containment is relevant to biosecurity, where issues such as walls, fences, security and animal exclusion zones may need consideration. See Chapter 7 for further information on biosecurity and biosecurity risk assessment.

Containment levels

Containment is defined in levels that increase in complexity as the risk increases. There are four containment levels for laboratories – containment levels 1-4 (CL1-CL4). Containment level 1 is a basic containment level whereas containment level 4 is the maximum containment level (see Figure 3). As the containment level of the laboratory increases, the safety requirements increase.

Reference in this document to 'lower containment levels' is to containment levels 1 and 2, whereas 'higher containment levels' refers to containment levels 3 and 4. The key differences between lower and higher containment level laboratories are in their management, the degree of safety supervision required, their operation and the specific physical containment requirements.

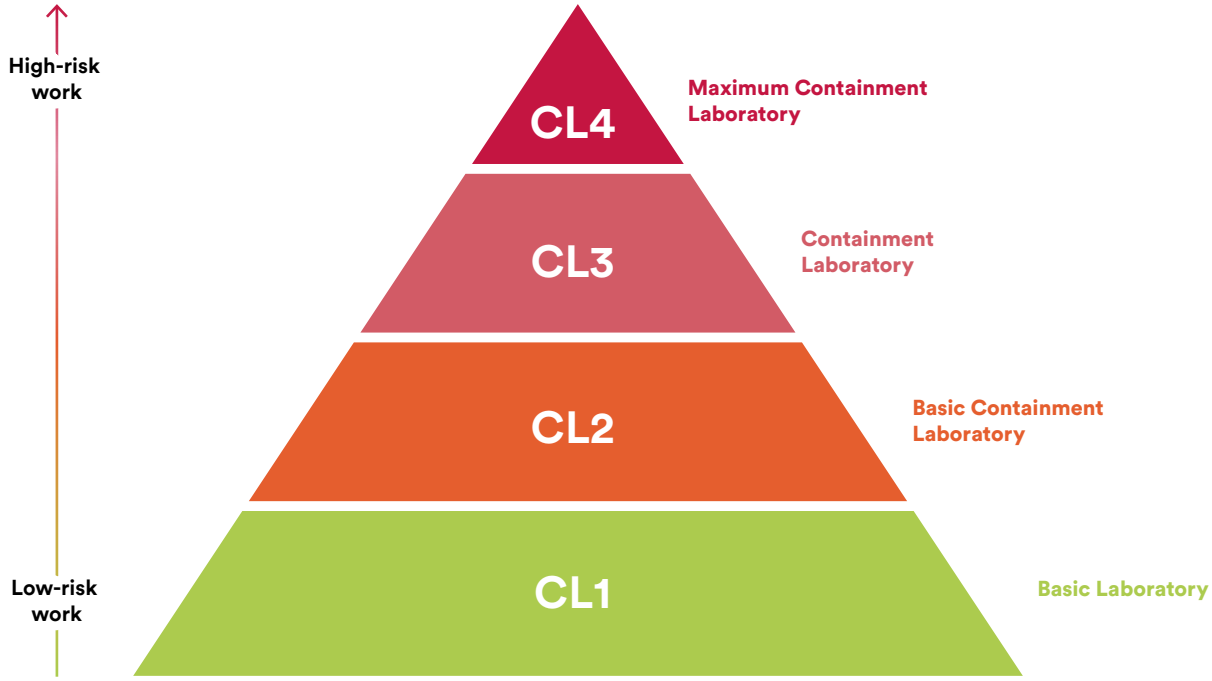


Figure 3: Summary of containment levels

Containment measures

Schedule 2 of the 2020 Biological Agents Code of Practice details minimum containment measures for each containment level. Containment measures are a combination of primary and secondary containment aimed at preventing release of a biological agent, and typically cover three elements:

- facility design and layout;
- safety equipment; and
- work practices, including the management of waste.

Each containment level builds on the containment measures of the level preceding it – CL3 builds on CL2 and CL4 builds on the requirements of CL3. For example, the requirement for a laboratory to contain its own equipment increases with the level of containment – not required at CL2, recommended at CL3 and required at CL4.

All laboratories, regardless of their containment level, must follow good microbiological practice and procedure (see Chapter 8). As the laboratory containment level increases, the level of training and supervision required also increases.

Containment level 1 (CL1)

This is the most basic level of containment and is generally for work with biological agents or biological materials with no identified adverse health effects in healthy employees – that is, there is no potential to cause disease, allergy or toxicity. No special design features beyond those suitable for a well-designed and functional laboratory are required. No special safety equipment is required and work can be carried out on an open bench top.

MSCs (see Chapter 15) are not generally required at CL1, but may be present for the purpose of product protection. Achievement of containment is by the use of practices such as good occupational safety and hygiene and good microbiological practice and procedure. Dedicated handwashing facilities must be available within the laboratory. This containment level is usually encountered in student and undergraduate teaching laboratories and some basic research laboratories.

Containment level 2 (CL2)

Subject to risk assessment and the minimum containment levels outlined below, this level may be used for biological agents that, although capable of causing disease, present only a low to moderate risk to employees. Work at CL2 can be carried out on an open bench provided that the potential for producing splashes and aerosols is low. Where there is a risk of splashes or aerosols, an MSC must be used. This containment level may be encountered in clinical, diagnostic, industrial, teaching and basic research laboratories.

Containment level 3 (CL3)

This containment level is usually used for work with infectious materials and biological agents where there is a serious hazard and risk to employees; for example, work with biological agents transmitted by the airborne route that cause serious or life-threatening disease.
The intent of containment measures at this level is to prevent any escape of biological agents and any employee exposure.
Work is performed in an MSC or other closed equipment (primary containment). Secondary containment includes controlled access to the area and ventilation systems that minimise the release of infectious aerosols from the laboratory. Specialised advice is required for construction of such containment facilities.

This level is currently the highest containment level dealing with human pathogens in Ireland. It is generally found in clinical, diagnostic, research and some industrial laboratories.

Containment level 4 (CL4)

This is the maximum containment level and is for extremely high-risk work such as work with dangerous or exotic biological agents of a life-threatening nature. The containment measures at this level intend to consistently prevent the escape of biological agents due to the serious hazard to employees and the community.

These laboratories have complex, advanced requirements. The facility is either a separate building or in a separated, controlled area within a building, which is sealed and verified by room pressure decay testing. Specialised ventilation and waste management systems are in place to decontaminate air and other effluents produced in the facility, preventing release of viable agents to the environment. All work activities are carried out in Class III MSCs (cabinet laboratory) or Class I or II MSCs used with one-piece positive pressure personal suits ventilated by a life support system (suit laboratory).

Containment level 4 laboratories are extremely expensive to plan, design, build, operate and maintain. As no such facilities currently exist in Ireland for human pathogens, the remainder of the document does not deal with them in any detail.

Minimum containment levels

The 2020 Biological Agents Code of Practice specifically refers to three of the containment levels – CL2, CL3 and CL4. The three containment levels correlate but do not necessarily equate to the risk group classification (groups 2-4).

Risk group does not equal (≠) containment level
Assignment of a containment level for the work activity requires risk assessment

The containment level required for the work must be determined by risk assessment, taking account of the minimum acceptable containment levels.

The minimum containment levels are:

- containment level 2 (CL2) when handling a group 2 biological agent;
- containment level 3 (CL3) when handling a group 3 biological agent;
- containment level 4 (CL4) when handling a group 4 biological agent;
- containment level 2 for laboratories handling materials when it is uncertain whether pathogens are present and the laboratory does not plan to intentionally cultivate, concentrate or otherwise increase the risk of exposure to a biological agent; and
- containment level 3 (or 4 where appropriate) when it is known or strongly suspected that a group 3 (or 4) biological agent is present even if the laboratory has no plan to intentionally propagate, concentrate or otherwise increase the risk of exposure to the group 3 or group 4 biological agent.

Minimum containment levels and diagnostic laboratories

Diagnostic samples would normally be regarded as containing risk group 2 agents and be handled at containment level 2. However, if it is known or strongly suspected that a higher-risk biological agent is present, then the corresponding containment level (level 3 or level 4) must be used.

Diagnostic laboratories will from time to time isolate a group 3 pathogen when working at CL2. Once it is identified, conduct work on such isolates and on material known or suspected to contain group 3 biological agents in a CL3 laboratory. Based on the risk assessment, where the pathogen is subsequently inactivated, further work may then be carried out at a lower containment level.

Dispensations from full containment level 3

For group 3 biological agents indicated by a double asterisk (**) in Schedule 1 of the 2020 Biological Agents Code of Practice, specific containment measures normally required at CL3 may be dispensed with under certain circumstances, because of either the nature of the agent being handled or the type of work being undertaken. For example, the agent may present a limited risk of infection for employees because it is not normally infectious by the airborne route. Schedule 4 of the 2020 Biological Agents Code of Practice details the dispensations available. Most dispensations are for diagnostic work and not for intentional work such as research with the biological agent. Special dispensations are rare and catered for only in exceptional circumstances.

A dispensation does not mean the work can be carried out at CL2. It means that certain physical containment measures required at CL3 may be changed or dispensed with – subject to risk assessment. The dispensation does not relate to management measures. Staff training, record keeping, and access control must still be to CL3 standards. The use of a dispensation is subject to risk assessment.

Chapter 6. Laboratory design and maintenance

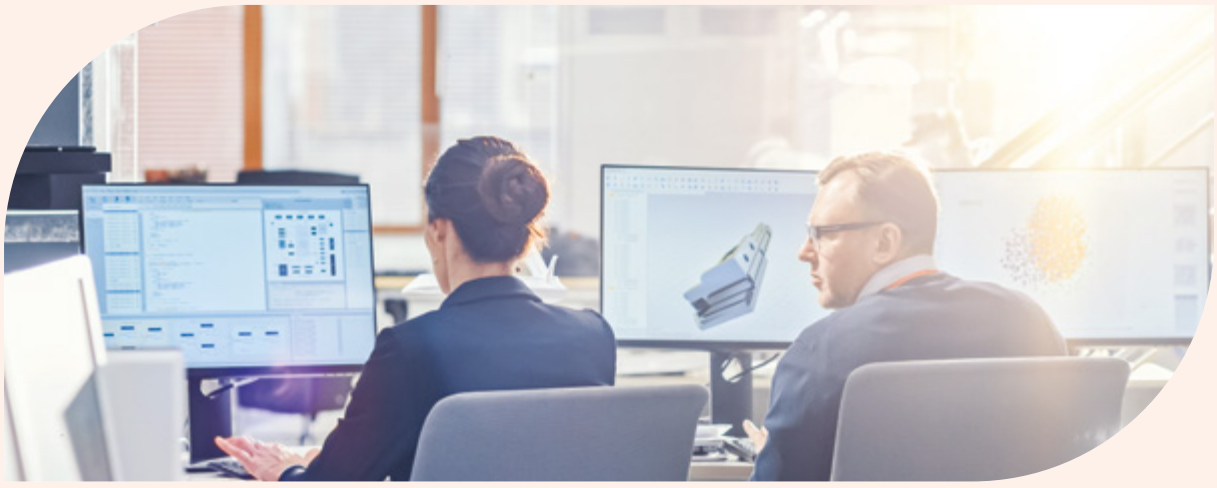
Good laboratory design and maintenance are critical factors in the containment of biological agents. Incorporate safety at the laboratory design stage. To inform the design, good planning and risk assessment are required whether one is constructing a new laboratory or refurbishing, reconfiguring or upgrading an existing laboratory.

This chapter covers, in tabulated form, some of the main containment measures as detailed in Schedule 2 of the 2020 Biological Agents Code of Practice. Consider these when planning, designing or upgrading a containment laboratory.[1] Good practices for safe operation of the laboratory are also included. However, as laboratories can vary significantly in their design, set-up, and construction, only general information is provided. The information provided addresses mainly containment level 2 and level 3 laboratories, with reference to containment level 4 for information purposes only.

Planning the laboratory

Assess the planned laboratory activities before designing, building or reconfiguring a laboratory. Considerations for the written risk assessment include the biological agents that will be or could be present, the properties of the specimens that will be or may be encountered, the equipment required, the workflow of the laboratory activities, the throughput of the laboratory and the number of employees that will use the laboratory. This will help determine the appropriate siting of the laboratory, the containment level and containment measures required and the appropriate laboratory design.

Schedule 2 of the 2020 Biological Agents Code of Practice outlines the containment measures required for each containment level. Most of these measures are relevant to the design stage. Include at this stage the control, storage and security of any biological agents and any possible expansion requirements. Take account of accessibility for maintenance, certification and validation requirements, such as high-efficiency particulate air (HEPA) filter integrity, in the laboratory design. Ensure the laboratory is easy to clean and not in an area of general circulation. Clearly define the laboratory containment boundary, including drains and location of HEPA filters and valves.



1 Depending on the laboratory, you may need to take account of other requirements, such as accreditation requirements or other legal requirements such as the Contained Use Regulations.

Recommended measures

Where a containment measure is 'Recommended' in the 2020 Biological Agents Code of Practice, implement it at the planning and design stage, unless the written risk assessment proves that the containment measure is not required. Keep a record of the reasoning for the decision not to include the measure, for the laboratory's lifetime. All relevant laboratory managers must be aware of this reasoning and be able to provide the written reasoning to the HSA on request.

Other health and safety requirements

Ensure the laboratory complies with the workplace requirements set out in Chapter 1 of Part 2 of the General Application Regulations (commonly known as the Workplace Regulations). When building or refurbishing a laboratory, take special account of the Safety, Health and Welfare at Work (Construction) Regulations 2013 to 2021 (commonly known as the Construction Regulations) – see also 'Safety File' below. Ensure all safety signage complies with Chapter 1 of Part 7 and Schedule 9 of the General Application Regulations (commonly known as the Safety Signs at Places of Work Regulations).

Competent persons

The higher the containment level, the more technical expertise is required to assist with facility design and construction, such as the services of a biocontainment design engineer, ventilation engineer and architect. In Ireland, this expertise may not be readily available and expertise from outside the jurisdiction may be required, especially if one is designing and constructing a CL3 or CL4 laboratory. Those engaged must be competent to do the work and familiar with Irish health and safety legislation. Note that clean room design, although it uses similar technologies, has different containment objectives to a containment laboratory for biological agents.

Siting and separation

Consider the physical siting of the laboratory for biosafety and biosecurity reasons. For example, potential for flooding or the effect of an accidental release of a biological agent on the neighbouring community or surrounding environment may make the location unsuitable.

In siting the laboratory, take account of risks to laboratory air pressures and air direction. Consider the position of air intakes and exhausts. Locate the laboratory away from areas that could affect unidirectional airflow or the maintenance of differential pressure. For example, exterior doors, lifts, the effect of high wind against the building and temperature fluctuations can all have an effect.

Table 1: Separation requirements for containment laboratories

Containment measure	Containment level		
	2	3	4
The workplace is to be separated from any other activities in the same building	No	Recommended	Yes

In order to reduce the risk of cross-contamination and exposure of others to biological agents, the need for separation from other work activities will be greater at higher containment levels (see Table 1). For example, where a CL3 laboratory is part of a larger facility, locate the laboratory away from public areas and corridors used by personnel who do not work in the laboratory and from areas that are open to unrestricted traffic flow. In general, a lobby (sometimes referred to as an anteroom) will be needed. At higher containment levels, consider biosecurity and provide suitable tertiary means of containment such as barriers, bollards and fences, as required.

Access control

Table 2: Access requirements for containment laboratories

Containment measure	Containment level		
	2	3	4
Access is to be restricted to nominated workers only	Recommended	Yes	Yes, via airlock

Access to CL3 and CL4 laboratories must be limited to authorised and competent workers and this is a recommendation for CL2 (see Table 2). It ensures that only people who are aware of the risks and have received appropriate training and authorisation can access the areas. Authorise in writing and keep the list available.

Put in place an access control system, for example swipe card access, keypads, biometric locks, non-reproducible keys or physical security. Change any entry codes regularly or as needed. Where a laboratory constitutes a whole floor, access control may be best sited on lifts and stairs. People should not hold doors open for others to enter without using the access control system. Keep entry logs at higher containment levels. Put in place mechanisms to prevent unrestricted access to high-risk pathogens or sensitive information. Ensure appropriate procedures are in place to remove authorised access, where necessary.

In granting access, consider entry by emergency responders. In certain cases, temporary access may be required; for example, maintenance personnel or contractors may have to access the area. In such cases, provide temporary authorisation and appropriate instruction and information so that they conduct their work safely within the area. Provide supervision by a competent person familiar with the operation of the laboratory as required. Post signage prohibiting access by unauthorised personnel, where required.

Airlocks

Where required at CL4, entry to the laboratory must be through the airlock, with the clean side of the airlock separated from the restricted side by changing or showering facilities and preferably by interlocked doors. Along with such facilities, allocated areas for personal clothing must be available within the airlock. Connect the airlock to the ventilation system to allow appropriate negative pressure and air changes within the airlock. Mark access doors to the airlock with the biohazard sign and the containment level. Ensure doors are airtight. Provide the outer airlock door with a means of indicating when work is in progress, for example by means of a traffic light system. The access method should allow only one person to enter at a time. Provide additional fumigatable and ventilated airlocks as required, for equipment that cannot enter via the double-door autoclave or personnel airlock.

Air handling, ventilation and HEPA filtration

Table 3: Negative pressure requirements for containment laboratories

Containment measure	Containment level		
	2	3	4
The workplace is to be maintained at an air pressure negative to atmosphere	No	Recommended	Yes

Negative pressure is a recommendation at CL3 (see Table 3). This means it must be in place unless the risk assessment proves it is not required or a dispensation from this containment measure exists under Schedule 4 of the 2020 Biological Agents Code of Practice. For example, where group 3 biological agents transmissible by air are encountered, negative pressure is required. Negative pressure is required at CL4. Provide and maintain negative pressure by differential cascade. The provision of such systems can be complex and requires specialist containment engineering input.

At the lower containment levels, ventilation may be provided solely for worker comfort reasons. At CL2, natural ventilation via windows may suffice, but only open windows when work is not taking place. Vector-proof screens may be required on such windows. When an MSC is in use, a supply of make-up or replacement air will be required to replace that extracted.

Where inward airflow is mechanically supplied, interlock supply and exhaust fans to prevent overly positive and overly negative air pressure in the laboratory, in the event of fan failure. Provide the ventilation system with a means of preventing reverse airflow, such as slam-shut mechanisms. Consider interlocks and air controls in design risk assessments and test failure scenarios at commissioning. Ensure air pressure meters, readable from both inside and outside the laboratory are available. Check and record readings prior to entry to the area.

Consider room and ceiling height and ducting size. Situate inlet air systems so that any exhausted air or other contaminants, such as neighbouring industrial or traffic pollution, do not contaminate them. Exhausted or discharged air should not be capable of re-entering the laboratory or other buildings (see also 'Siting and separation' above).

Table 4: HEPA filter requirements for input and extract air

Containment measure	Containment level		
	2	3	4
Input air and extract air to the workplace are to be filtered using HEPA filters or likewise	No	Yes, on extract air	Yes, on input and extract air

HEPA filtration is not required at CL2 (see Table 4). Pass extracted air through a HEPA filter or comparable device at CL3 and CL4. Consider double filtration where failure of a single filter could result in serious consequences at CL3 – double filtration is required at CL4. HEPA filter input air at CL4. HEPA filters should meet the performance criteria of Class H14 filters as defined in EN 1822-1.

It must be possible to change filters without releasing biological agents. Site HEPA filters so that they are accessible for testing and safely removable. Put in place appropriate decontamination procedures, such as in situ fumigation or bag-in/bag-out (BIBO) with subsequent decontamination where fumigation is not effective, for example with prions. Where it is planned to fumigate the filters in situ, ensure that the ductwork from the laboratory to the terminal HEPA filter is fumigatable. Common errors include spiral ductwork and long duct runs to the terminal HEPA filter.

Communication system

Put in place an appropriate means of communication between the laboratory and the external work environment at CL3 and CL4. Forms of communication can be windows, speech panels, intercoms, data links or telephones. The system selected should be compatible with the containment level requirements. Paperless systems are desirable at higher containment levels. Where it is unavoidable at CL3, keep paperwork in a designated area of the laboratory and do not remove from the laboratory unless it is capable of being decontaminated.

Doors

Separate laboratories from adjoining rooms by appropriately fire-rated doors. Self-closing doors are essential at higher containment levels and desirable at CL2. Size door openings to allow introduction or removal of equipment. Avoid recesses and hollows in doors and frames. Where multiple laboratories are in the containment area, fit the doors with a viewing window. Emergency exit doors must open outwards. Where possible, avoid emergency exit routes evacuating people through areas of high containment. Display the biohazard sign and indicate the laboratory containment level on the main laboratory door at CL2 to CL4. Where required, display the contact details for the responsible person in charge of the area.

Drains

Use robust material in drain line construction and weld sections. Avoid connection of laboratory drains to areas outside of the laboratory. Floor drains at higher containment levels are not desirable. Double contain drains and manholes outside the laboratory at CL3 and CL4. Sterilise effluent, including that from the shower, at CL4 by thermal or chemical means before release. Depending on the risk assessment, this may also be required for some CL3 laboratories. Place HEPA filters on CL3 and CL4 drain line vents. As required, install P-traps under sinks of sufficient depth to ensure maintenance of a liquid barrier when air pressures fluctuate. P-traps may require weekly filling to avoid drying out. Ensure drains and tanks are leak tested at commissioning stage.

Electricity and emergency power supply

Electrical systems must comply with Part 3 of the General Application Regulations (commonly known as the Electricity at Work Regulations), especially with regard to protection against electrical shock, identification, marking, testing and inspection.

Provide sufficient electrical sockets, situated away from sinks, wet areas or processes, with additional contingency, for all equipment, battery-charging stations and so on. Proper planning of equipment location and electrical needs will avoid a requirement for subsequent modifications and use of extension leads.

Position electrical outlets as far as possible from safety showers and valves for any flammable gases. Locate electrical panels, fuse boards, uninterruptible power supply (UPS) systems or battery banks outside the containment laboratory, for ease of maintenance and to reduce fire risk.

At higher containment levels, install an emergency/backup power supply for safety-critical containment measures or equipment that are still required during a power failure, such as negative pressure, emergency call devices, monitoring equipment or physical security systems.

Services, ceiling and wall voids

Consider ease of access to services for maintenance and the risk services might pose. Ensure access hatches are appropriately sized and located. Do not run drains and water services inside cavity walls or in ceiling voids. With overhead plant rooms, locate drains and water services to the periphery of the laboratory, with bunding and leak detection. Services that pass through walls and floors must have appropriate fire protection and prevent the entry of rodents or insects.

Equipment

Table 5: Requirements for a containment laboratories to have its own equipment

Containment measure	Containment level		
	2	3	4
A laboratory is to contain its own equipment	No	Recommended	Yes

The requirements that a laboratory contain its own equipment is recommended at CL3 and required at CL4 (see Table 5). The requirement covers all types of equipment, including autoclaves and MSCs. The main purpose is to contain contaminated items and equipment within the laboratory.

Consider the type of equipment that is required for use in the laboratory at the design stage, to ensure that there is sufficient space and height in the laboratory. Take account of door and corridor dimensions, changes in directions and any potential obstructions to ensure safe delivery and removal of equipment, as required. Any lifts used for equipment must be capable of taking the load and be of sufficient width. Design all equipment for safety and ease of replacement during operation and maintenance and at end of life.

In selecting equipment, take account of the prevention or minimisation of internal contamination and the ability to clean and decontaminate the equipment. For example, cleanable protective covers may be required for computer keyboards. Where disinfection or laboratory fumigation may be required, consider equipment compatibility with disinfectants and fumigants. Ensure equipment is CE (conformité européenne) marked and complies with any relevant European standards.

Locate and position equipment correctly to ensure safe use, stability and prevention of tipping. Where MSCs are required, consider the siting, as inappropriate positioning or the siting of other equipment will affect the performance of the cabinet and operator protection. Ensure the autoclave area has local exhaust ventilation for removal of heat, steam and odours and is large enough to enable materials to be loaded and unloaded safely, and for manoeuvring trolleys. Ensure the autoclave area is bunded at higher containment levels. A double-door autoclave on the containment boundary is preferable for a CL3 or CL4 laboratory.

Eyewash facilities

Provide emergency plumbed eyewash facilities, in line with EN 15154-2, in basic laboratories where any corrosive chemicals are in use or there is potential for eye infection. Unmaintained eyewash facilities can facilitate the growth of biological agents, for example *Legionella* or other bacteria, which may worsen or cause additional damage to the eye. Maintain and regularly flush such equipment in accordance with the *National Guidelines for the Control of Legionellosis in Ireland*, 2009 and the manufacturer's recommendations. Keep records of such maintenance.

Fire safety

Install fire-fighting equipment, fire detectors and an appropriate fire alarm and control system, which complies with relevant fire safety legislation. In designing the fire system, consider containment and any possible need for continuance of ventilation during an emergency.

Furniture

Provide ergonomically designed furniture such as stools, chairs and height-adjustable seating to ensure safe, healthy working at benches and MSCs. Ensure furniture is smooth and made of impervious non-fabric material to facilitate easy cleaning. Consider compatibility with disinfectants and fumigants, as required. The furniture must be capable of supporting

anticipated loading and uses. Secure fixed furniture items to the floor or supporting wall, in line with the manufacturer's recommendations. Where floor covering is to be coved to the furniture, install furniture first.

Illumination

Install appropriate lighting to ensure safe working. Select lighting fixtures to minimise the horizontal surface on which dust can settle and to minimise glare. For example, consider sealed or flush-mounted fittings, which can be maintained from above at higher containment levels. Ensure fixture compatibility with fumigation, where required. Allow for ease of changing of light bulbs. Fit sufficient emergency lighting to allow work to stop safely in the event of a power cut.

Observation windows and other windows

Table 6: Requirements for observation windows in containment laboratories

Containment measure	Containment level		
	2	3	4
An observation window, or alternative, is to be present so that occupants can be seen	Recommended	Recommended	Yes

An observation window allows viewing of workers, especially lone workers, and quick identification of any problems or issues that may arise, such as a spillage or a medical emergency (see Table 6). It also enables other workers to enter the laboratory at appropriate times on work completion.

At CL3 and CL4, install unopenable windows sealed to prevent escape or ingress of air. At CL4, windows must also be unbreakable; this may also be required at CL3 for biosecurity reasons. Where windows are not available or are undesirable or blind spots exist, consider alternatives such as closed-circuit television (CCTV) cameras or video surveillance. At CL4, set up external monitoring of the laboratory to assist immediate implementation of emergency procedures, when necessary.

Sealability

Table 7: Requirements for laboratory sealability for fumigation

Containment measure	Containment level		
	2	3	4
The workplace is to be sealable to permit fumigation	No	Recommended	Yes

Decide sealability requirements (see Table 7). CL1 and CL2 laboratories do not generally require fumigation (see Chapter 9) but where the risk assessment identifies that it is required, the laboratories must be sealable (made airtight). Proper sealing ensures retention of fumigant within the laboratory, effective fumigation and no escape of fumigant outside of the area. Sealability also assists in preventing accidental release of any biological agents and prevents entry of vectors. CL3 laboratories (unless the results of the risk assessment show that it is not required or a dispensation from this containment measure exists under Schedule 4 of the 2020 Biological Agents Code of Practice), CL4 laboratories and associated ventilation systems must be sealable in order to carry out fumigation.

In such cases, minimise penetrations. Make all necessary junctions, penetrations, ductwork, walls, floors and ceilings gas impermeable. Prevent gas entrapment, which may occur in ceiling voids, coving cavities, cavity doors and walls. Seal all doors, windows, junction boxes and hidden penetrations such as behind electrical sockets or switches.

Consider siting of controls for fumigation. For example, where required, locate controls for the laboratory ventilation system, externally ducted containment devices such as MSCs and power to the fumigation equipment externally to the sealed area in order to enable safe venting.

Showers

Table 8: Requirements for showers for containment laboratories

Containment measure	Containment level		
	2	3	4
Personnel should shower before leaving the contained area	No	Recommended	Recommended

The purpose and function of such a shower relates to containment of a biological agent within the contained area. This differs from emergency safety showers (often found in basic laboratories) designed to extinguish flames or flush the body following exposure, for example, to chemicals or heat.

Where required for containment purposes (see Table 8), the entry/exit shower must be pass-through in design so that traffic flows in one direction. To ensure air change, provide an extract vent or maintain the shower at negative pressure to the outside changing area. Where showering is required for containment purposes, collect wastewater and inactivate before disposal. Detail how long a person should shower to ensure containment.

The use of timed showers or monitoring of showering times is essential. Where installed showers are not in regular use, implement a regular flushing and cleaning regime to prevent the growth of bacteria such as *Legionella*. Dirty clothing and PPE must not be able to contaminate clean clothing, people or equipment.

Space

Provide adequate workspace for the worker to carry out their work safely and comfortably. In determining space requirements, take account of the number of workers, equipment (bench mounted or freestanding) and the nature of the work. For example, with MSCs, the inward airflow may be disturbed by people passing behind the user, turbulence of air around equipment within the cabinet or sudden changes in air pressure within the room such as doors opening. Therefore, provision of appropriate space is essential in order to ensure adequate worker protection. Automated technology can also take up significant space.

Provide separate areas as required for the preparation of media, sample collection and receipt, write-up, a holding area for materials awaiting sterilisation, autoclave/sterilisation area, storage of sterile materials and clerical or office work. Have a designated area or room for laboratories that receive large numbers of samples. All areas must be easy to clean. During the design stage, it is advisable and easier to take account of future requirements for additional capacity in the event of laboratory expansion or change or increase in sample numbers.

Storage

Table 9: Requirements for safe storage of biological agents

Containment measure	Containment level		
	2	3	4
Safe storage of a biological agent	Yes	Yes	Yes, secure storage

Keep stocks of biological agents to a minimum and store biological agents appropriately. The higher the agent's risk group, the more secure the storage must be (see Table 9). Storage must be in areas compatible with the biological agent's risk group classification or higher. Clearly mark the storage areas with the biohazard sign to indicate that the contents may present a risk. Put in place an inventory of stored or in-use cultures (and where relevant toxins) and allow only authorised users access. Ensure the inventory is accurate and up to date and that it enables items to be located and any missing items to be identified. At a minimum, the inventory should identify the biological agent, the responsible person for the agent (or toxin), their contact details, the quantity/volume/number of containers (as appropriate) and storage location. Information may need to be coded and secure for biosecurity reasons (see Chapter 7).

Keep a record of users and the time and date of access to the storage as required. Review the inventory on a regular basis and especially in advance of any departure of responsible people in order to ensure that there are no 'orphaned' biological agents (or toxins). Safely destroy and dispose of unaccountable or unlabelled stocks and containers. Ensure backup facilities also have an inventory and are secure. When transferring biological agents off site, keep appropriate records to show that the agents have safely arrived at their destination. Ensure that appropriate plans are in place in the event of missing high-risk biological agents.

Store all biological agents in appropriate containers that are clearly and correctly labelled and identifiable. As necessary (mandatory at CL4), lock refrigerators, freezers, cold rooms and storage containers holding biological agents and restrict access to authorised personnel. Where required, put in place appropriate security to prevent intruders, vandals or persons with malicious intent from accessing the biological agents.

In addition to biological agent's storage, provide adequate storage for PPE, waste and laboratory consumables so that benches, corridors and emergency escape routes do not become storage areas. Take account that clean and contaminated materials will need to be stored separately. Provide storage areas in higher containment laboratories for dedicated cleaning equipment. Provide appropriate storage facilities also for storing personal items and food outside of the laboratory.

Surfaces

Table 10: Requirements for surfaces in containment laboratories

Containment measure	Containment level		
	2	3	4
Surfaces impervious to water and easy to clean	Yes, for bench and floor	Yes, for bench, floor and other surfaces determined by risk assessment	Yes, for bench, walls, floor and ceiling
Surfaces resistant to acids, alkalis, solvents, disinfectants	Recommended	Yes	Yes

Rough, chipped, cracked or damaged surfaces will be difficult to clean and disinfect. Bench surfaces at all containment levels must be smooth, level, hardwearing and resistant to scratches, chipping, splitting, stains and general impact, easy to clean and impervious to water (see Table 10). In addition, surfaces must be resistant to acids, alkalis, solvents and disinfectants (recommended for CL2 and required at CL3 and CL4). This should also include common cleaning agents and common laboratory chemicals. Test new materials by mock-up before approval for installation.

Where work is carried out on benches, the bench tops must be able to withstand heat created by general laboratory work; for example, use of Bunsen burners, hot loops and media. Open spaces between and under benches, cabinets and equipment must be accessible for cleaning. Take account of ergonomics with respect to bench heights and reach. Provide adequate space to enable safe working. In order to facilitate cleaning, ensure that benches have seamless coved splashbacks and are not cluttered.

Floors at all containment levels must be impervious to water and easy to wash and clean – seamless and coved to the wall. Ensure coving is not hollow and rigidly adheres to the wall. This may require design detail to enable plasterboard walls to deal with flex.

Flooring should not have potential for slips, trips or falls, and floor finishes should be smooth and non-slip, whether wet or dry. Other factors to consider when selecting flooring for laboratories include the anticipated floor loading; surface drag; generation of static electricity; compatibility with disinfectants, including fumigants where required; and capacity to retain spillages. The floor should be capable of taking the weight of equipment without damage.

The risk assessment must determine whether walls and ceilings are required to be impervious to water and easy to clean at CL3 (required at CL4). In such cases, floor-to-wall, wall-to-ceiling and wall-to-wall junctions should enable easy cleaning. Maintain the continuity of floor-to-wall and wall-to-ceiling seals. Where fumigation is required, ensure that all relevant surfaces are impervious to the fumigant.

Vector control

Table 11: Requirements for vector control in containment laboratories

Containment measure	Containment level		
	2	3	4
Effective vector control; for example, rodents and insects	Recommended	Yes	Yes

Vectors can carry and disseminate some biological agents. As they are mobile, they can increase the range of the biological agent. Vector control is especially important when working with biological agents that are vector borne. The exact type of control required will depend on the nature of the vector. Put in place appropriate vector control at CL2 (unless the risk assessment proves that it is not required), CL3 and CL4 (see Table 11). Ensure that appropriate contractor management procedures are in place where provision and maintenance of vector control is by external contractors and keep records.

Washing facilities

Proper handwashing is one of the best practices to prevent infection. Install a wash-hand basin in the laboratory with hot and cold running water and locate it near the exit (CL2 and CL3). The wash-hand basin should be easy to clean and of adequate size to avoid splashing the floor and surroundings. Ensure that washable splashbacks are in place, all joints are completely sealed and water pressure prevents splashing. Have adequate space for the operation of taps, capable of operation without hand touching; for example, sensor, elbow, or knee operated.

Provide hand hygiene products (soap, hand antiseptic) and a means of drying hands. Where there is a risk of product contamination, use liquid hand hygiene products in disposable containers. Site them so that they do not become a source of contamination or hinder sink cleaning. Store the container closed and do not top up. Where reusable containers are used, wash and dry them thoroughly before refilling. Wastewater from wash-hand basins may require inactivation at CL3.

Provide hands-free waste bins in order to avoid hand recontamination. Ensure that they close quietly and empty them regularly. Instruct and inform employees on proper handwashing techniques. At a minimum, wash hands at the start and the end of the working day, after removing gloves, after working in an MSC, after handling biological agents or contaminated materials and when leaving the laboratory.

Welfare facilities

Provide separate facilities outside of the laboratory for workers to take breaks, eat and drink, so that that there is no risk of contamination. Where laboratories operate an on-call system, ensure that appropriate rest and shower facilities are available.

Commissioning

Commissioning is an all-inclusive process that should include all laboratory systems and be guided by client-agreed requirements and acceptance criteria, developed during the design and specification phase. Document and agree the commissioning plan.

Carry out commissioning prior to the laboratory becoming fully operational. This ensures that the laboratory, its components and its equipment are safe, and constructed and perform as intended. Where possible, use an independent third party. Keep design drawings, operational parameters and commissioning reports for the lifetime of the laboratory. Maintain all commissioning documents, drawings, specifications and information relating to the facility in the Safety File or similar.

Clearly label and tag all relevant controls, pipework, electrical controls and fuse boards. Identify and record all maintenance, calibration and testing requirements in line with any legal requirements and the manufacturer's recommendations. Create a register of relevant equipment along with the manufacturer's instruction manuals.

Consider the following non-exhaustive list as part of the commissioning plan:

- communication devices;
- door interlocks for airlocks and ante-rooms;
- access control and security devices;
- HEPA filter efficiency;
- fan interlocks;
- MSCs;
- autoclaves and disinfection systems;
- backflow preventers on water and air systems;
- emergency generators;
- effluent treatment systems;
- room integrity (CL3 and CL4);
- tightness of containment ductwork and HEPA housings (CL3 and CL4); and
- building management systems.

Verify room sealability using a pressure decay or flow test.

Safety File

The Safety File is as required under the Construction Regulations and is a record of information for the end user, which focuses on safety and health. It contains information on the completed structure and will alert those who are responsible for the structure and services in it of the significant safety and health risks that will need to be addressed during subsequent maintenance, repair, refurbishment, reconfiguration, extension, construction or demolition work.

Relevant information in the Safety File may include:

- construction/technical drawings, specifications and bills of quantities, used and produced throughout the construction process;
- the general design criteria adopted, and details of the equipment and maintenance facilities within the structure;
- maintenance procedures and requirements for the structure;
- manuals, and where appropriate certificates, produced by specialist contractors and suppliers that outline effective operating parameters, operating and maintenance procedures and schedules for plant and equipment installed as part of the structure (typically lifts, electrical and mechanical installations, pressure vessels, control and instrumentation systems, window cleaning facilities); and
- details of the location and nature of utilities and services, including emergency and fire-fighting, ventilation, drainage and effluent treatment systems.

Make the Safety File available, if necessary, for example, to subsequent designers or contractors engaged in renovation or maintenance of the laboratory, or pass it on to any new owner of the laboratory.

Change management

Put in place appropriate change management procedures. This ensures that any planned changes to the laboratory structure or operational specifications that may affect safety, health and welfare are brought to the attention of relevant persons and the potential impact is assessed beforehand. Update relevant documentation, including the Safety File, to record any approved changes.

Laboratory cleaning

Clean surfaces within the laboratory, such as walls, floors and benches, on a regular basis and disinfect as required, especially after any spillages (see Chapter 12). Remove dirt, organic matter and stains by washing with soap and water or detergent, vacuuming and wet mopping. Routinely clean external surfaces of frequently handled instruments and equipment such as telephones and computers, which may be contaminated, using detergent or disinfectant and in line with manufacturer's recommendations. For further information on disinfection, see Chapter 9.

Carry out laboratory cleaning outside of work hours or when work is not ongoing. Use trained personnel, confined to specific agreed areas. Do not dry sweep, and if vacuuming at higher containment levels, use a HEPA-filter vacuum cleaner with disposable bag. Ensure that only laboratory staff handle infectious materials.

Laboratory maintenance

Maintain the structure and integrity of the laboratory, including fixtures, fittings, finishes and seals. Lack of, improper or poor maintenance can contribute to laboratory accidents and incidents. For example, cracks in laboratory benches or flooring can hinder disinfection and contribute to slips, trips and falls or dropped items containing biological agents. The higher the containment level, the greater will be the requirement for preventive maintenance to ensure containment.

Ensure that laboratory sealability, where in place, is subject to preventive maintenance. Conduct regular visual inspections to detect any breaches that may give rise to leakage points; for example, look for evidence of dust trails indicating air drawn in from other areas. Routinely use smoke tubes, generators and other methods such as the soap bubble method or a combination of methods. Note that smoke is an irritant and smoke generators can leave a residue. Carry out sealability tests using room pressure decay testing annually or more frequently where identified in the risk assessment. Where repairs are required, verify their effectiveness.

Regularly inspect and maintain all drainage systems to ensure integrity at higher containment levels.

In line with the General Application Regulations, where a forced ventilation system is used, maintain it in working order, and ensure that a control system indicates any breakdown. Carry out periodic inspections and operate the system in such a way that it does not subject employees to uncomfortable draughts.

Periodically inspect and test electrical installations. Base the periodicity on risk assessment, taking account of factors such as the age, quality and environmental circumstances and manufacturer's recommendations. Suggested periods for laboratories are 1 year between visual checks and 5 years between inspection and testing.

Keep all inspection records for 5 years from the date of inspection and ensure that they are available to HSA inspectors.

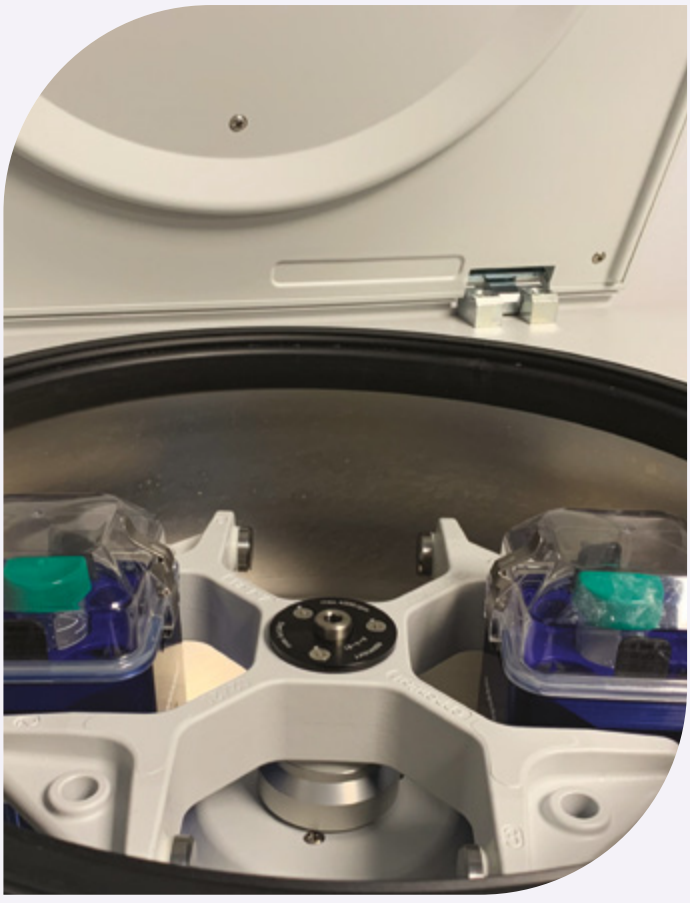
Decommissioning

Decommission all laboratories to ensure safety and the security of any biological agents during the process. Use clearance certificates and permits to work, as required, to identify requirements and conditions for entry to the decommissioned facility.

Chapter 7. Risk assessment of biological agents

Risk assessment is at the core of all health and safety legislation. The Biological Agents Regulations build on the general risk assessment requirements under the 2005 Act. The Regulations specifically require you to assess any existing or potential risk to the health and safety of employees resulting from any activity at the workplace likely to involve a risk of exposure to a biological agent.

As laboratory work activities vary greatly and different types of biological agents or materials containing biological agents may be encountered, detail cannot be given here on how to conduct specific risk assessments. In addition, different risk assessment methodologies also exist. Therefore, a general overview of the risk assessment process and a non-exhaustive list of considerations is provided.



Risk assessment involves the following:

1. Identify the hazards.
2. Assess the risks presented by the hazards.
3. Put control measures in place to reduce the risk of the hazards causing harm.

A **hazard** is anything (a source or a situation) with the potential to cause harm in terms of human injury or ill health, which in the case of biological agents and the Biological Agents Regulations means infections, diseases, allergies or toxic effects. Consider other harmful effects such as carcinogenic[2], mutagenic or reprotoxic effects. Identify how someone could be harmed (how they could be exposed to a hazardous biological agent and what the effects could be).

Risk is the likelihood that somebody will be harmed by the hazard and how serious the harm or ill health could be. When considering risk, take account of the number of people who could be at risk from the hazard.

Likelihood (or chance) is a measure of how likely it is that exposure to a biological agent will happen. When appropriate control measures are in place and people work safely, there is less chance that exposure will occur.

Control measures are the steps taken to remove the hazards, or at least reduce the risk of them causing harm to as low a level as possible. Containment measures are a specific type of control measure.

2 See the International Agency for Research on Cancer (IARC), Biological Agents: IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 100B.

Risk assessment requires careful judgement, as adverse consequences are more likely if risks are underestimated. The assessment should reflect the nature of the work activity – the more hazardous it is, the more in depth the assessment should be.

Purpose of a biological agents risk assessment

A risk assessment under the Biological Agents Regulations is a process used to identify:

- the work activities that may result in exposure to a biological agent;
- the hazardous characteristics of the known or potential biological agent;
- how the worker may be exposed to the agent;
- the likelihood that infection or other harm may occur; and
- the probable consequences of such harm.

This then forms the basis for determining:

- how exposure can be avoided or, if this is not possible, minimised;
- the safe work practices to be applied; and
- the measures to be taken to control unavoidable exposure.

The principal aim of the risk assessment is the protection of the laboratory worker's health and safety. Protecting the employee will also help to protect other people, the community and the environment.[3]

A general laboratory risk assessment, which considers matters such as the safety and condition of the laboratory, its layout and its equipment, will fall under the requirements for a written risk assessment under the 2005 Act.

Conducting the risk assessment

Carry out the biological agents risk assessment before the start of work activities or bringing or receiving any biological agents into the workplace. Where notification is required, conduct the risk assessment well in advance to accommodate the 30-day time frame (see Chapter 13).

A competent person or persons must conduct the risk assessment; if there is no such person, seek expert advice. The person(s) conducting the risk assessment must be familiar with the laboratory facilities and the equipment available. Consult employees or their safety representative (or both) in relation to the risk assessment.

What should be considered in the risk assessment

In order to conduct a good risk assessment, clearly describe what work activity is being assessed. This may be, for example, setting up a new laboratory, conducting a research project with a specific biological agent or conducting a specific diagnostic test where there is potential for exposure to biological agents. Detail the date(s) of the assessment, the person responsible for the work and the person(s) conducting the risk assessment.

When conducting the risk assessment, take account of the requirements of Regulation 7 of the Biological Agents Regulations. This requires that you conduct the risk assessment based on all available information, including:

- the classification of each biological agent that is or may be a hazard to human health (see Schedule 1 of the 2020 Biological Agents Code of Practice in relation to group classification);
- information on diseases that may be contracted as a result of the employee's work;
- potential allergenic or toxigenic effects as a result of the work of the employees;
- knowledge of a disease from which an employee is found to be suffering and that has a direct connection with their work; and
- any recommendations made by the HSA indicating that a particular biological agent should be controlled in order to protect employees' health.

3 The Biological Agents Regulations are principally concerned with workers' health. Risk assessments with extended focus on the potential harm to animals, plants and the environment may be required under other legal requirements such as the Contained Use Regulations or animal disease legislation.

Regulation 17(2) of the Biological Agents Regulations sets out the special measures for laboratories. It requires that where work is to be carried out that involves the handling of any group 2, 3 or 4 biological agent for research, development, teaching or diagnostic purposes, you determine the containment level and implement the containment measures specified in the 2020 Biological Agents Code of Practice. In doing so, take account of the minimum containment levels (see Chapter 5) when determining the final containment level.

The risk assessment process

1. Identify the hazard

Hazard identification means the process of recognising that a hazard exists and defining its characteristics – identifying the potential for harm and how it could occur. The hazards to employees will depend on the work activity – the type and quantity of biological material or agents encountered, the specific work task, the procedures and the competency of the person conducting the work.

(a) The biological agent(s)

In assessing the work activity, identify the source of the biological agent and consider the potential for harm to occur. Is it intentional or unintentional work with a biological agent? For example, is it work with a specific biological agent, work with biological material that may be infected, such as human blood or tissue samples, or work with cell cultures? What is the nature, history and origin of the material or biological agent involved in the work activity? Are specific biological agents commonly associated with the biological material? For work with biological materials or cells, determine the source and the range of biological agents expected or possibly present, such as adventitious biological agents.

Gather information on the biological agent(s) that are or may be present. Identify any properties or characteristics that give potential to cause harm. For example, establish the natural routes of infection, modes of transmission and environmental stability of the biological agent(s). Ascertain the effects of exposure to the biological agent(s), the signs and symptoms of ill health, communicability and the availability and effectiveness of medical treatments.

Remember that in some cases the microbial products rather than the micro-organism may be harmful. Where there is a known or suspected biological agent or agents, consult the 2020 Biological Agents Code of Practice to see if it has a risk group classification. Take account of any notations; for example, whether effective vaccines are available. Note that risk group classification is based on the effect of infection – you will need to consider whether other sensitising, toxic or health-damaging effects exist.

Risk group classification

The risk group classification gives an indication of the inherent hazards of the biological agent but does not consider many factors, which the risk assessment must address. For example, it does not consider:

- who may be affected – workers may be present who are more susceptible to infection. For example, immunosuppressed workers, personnel with pre-existing disease, those on medication, new or inexperienced workers;
- the route of exposure – how the biological agent may get into the body when workers are conducting work activities;
- the infectious dose – the amount of pathogen required to establish an infection in a susceptible host;
- the nature of the work – for example, propagation versus diagnostic work, in vitro versus in vivo work, small-scale versus larger-scale work or work that creates aerosols; or
- whether the biological agent is resistant to drugs, disinfectants or heat inactivation.

If the agent is not listed in Schedule 1 of the Code of Practice, do not assume that it is automatically a risk group 1 biological agent. You will need to determine the risk group classification based on the information gathered during the risk assessment process.

Classify the biological agent to one of the risk groups (groups 1-4) according to the level of risk of infection (referred to as the classification criteria – see page 18 of the 2020 Biological Agents Code of Practice). In doing so, take account of the latest scientific knowledge. If in doubt as to which of two groups (for example, group 2 or group 3) to assign the biological agent to, assign it to the higher group. If the biological agent subsequently appears in a later edition of the Code of Practice, this classification must take priority. In such cases, you will need to review the information used in your risk assessment and update the risk assessment, if required, to reflect the new classification.

For activities involving exposure to biological agents from two or more risk groups, assess the risk based on the danger presented by all the biological agents. Gather information on all the relevant biological agents. This may be the case, for example, if a contaminant is present – which may have a higher risk group classification than the original biological agent.

Based on the collated information, where the biological agent:

- is unclassified, classify it to a specific risk group, taking account of the classification criteria; or
- has a classification in accordance with the 2020 Biological Agents Code of Practice but has been altered in any way, verify that you are satisfied with the risk group classification. For example, if a biological agent has been newly attenuated, experimental data should support your judgement that the attenuated pathogen is less hazardous than the wild-type parent and that the strain will not revert to virulence before you make any reduction in the risk group classification.

Refer to the minimum containment levels for the various risk groups (see Chapter 5). This will give an initial indication of the minimum containment level and containment measures required for employee protection. Note that no account of the work and the people conducting the work has been taken yet. In addition, if there is a risk to animal health or the environment, a higher containment level than that required for employee protection may be required.

The assessor will need to ascertain at the end of the risk assessment process whether the minimum containment measures are adequate for the work being carried out. Use the information gathered to tailor the decontamination procedures for the biological agent(s), educate workers, and help decide whether health surveillance would be of benefit.

Genetically modified micro-organisms

Although there is specific legislation dealing with GMMs (see Chapter 2), they will also fall under the Biological Agents Regulations where there is a risk to workers' health due to a work activity involving a GMM. In conducting the biological agents risk assessment, consider whether the genetic modification has resulted in a decreased, increased or unchanged potential for the biological agent to cause harm. For example, has the GMM an altered susceptibility to antibiotics or effective medical treatments, and are additional precautions required?

Cell cultures

Cell cultures are not generally infectious and do not survive in the external environment. However, employees working with human or animal cells and tissues may deliberately infect them with pathogens. In addition, latent or adventitious pathogens may be present in the cells and tissues. During the culture process, there may be a risk of cells mutating into tumour cells or becoming infected with micro-organisms from biological material such as serum or trypsin solutions of animal origin or from the workers. They may also present a hazard if expressing allergenic, toxic or biological active substances or harmful gene products; for example, some human or animal cells or tissues may contain tumour cells. With genetically modified organism (GMO) cells or cell lines, a risk assessment under the Contained Use Regulations will also be required.

Information sources on biological agents

There are many sources of information that you can use to find out more about the hazardous properties of the biological agent. These include:

- guidance or information published by the HSA or other authoritative organisations;
- previous experience or the history of the biological agent or material;
- consultation with peers;
- technical reference sources (textbooks, scientific or technical papers);
- professional institutions, associations or specialist consultancy services;
- information available from culture collections, animal studies, reports of acquired infections or clinical reports;
- databases such as the GESTIS Biological Agents Database or the Government of Canada's Pathogen Safety Data Sheets (note that the risk group classifications in the 2020 Biological Agents Code of Practice take precedence over any risk group classifications in these databases); and
- reliable sources on the Internet.

(b) Who might be affected and how may they be harmed

Using the information gathered about the biological agent(s) and taking account of the nature of the work, the work activities, the manipulations, the equipment, the facilities and the handling of waste, consider how people may be exposed to the biological agent(s) and who may be exposed.

The work, work practices and the procedures

Examine the work, the work practices and the procedures. Establish whether the natural route of exposure is also the likely route of exposure in the laboratory. Can other routes of exposure occur because of the laboratory manipulations?[4] Have exposures or releases occurred before?

Consider whether the work increases the risk. For example:

- What is the scale of the work – the quantity, titre, potential volume of samples/biological agents, potential for infectious waste generation?
- Is the biological agent being enriched, concentrated or propagated?
- Is the work standard or non-standard, routine or infrequent, simple or complex, manual or automated?
- How often and for how long will the work activity/procedure be performed; for example, once off or several times a day?
- Is there potential for creation of aerosols, larger airborne particles (droplets) or splashes?
- Is time pressure associated with the work?
- Is there potential for accident or incident; for example, a spillage, needle stick injury, accidental transfer, or release of the biological agent or loss of containment?
- Is the biological agent or infectious material being stored or transported?

Consider all aspects of the work – routine work and non-routine work such as maintenance and emergency situations.

Who may be affected?

An adverse health outcome may occur when a pathogen interacts with a person. So in conducting the risk assessment, it is vital to consider those affected by the work – are there people at increased risk or workers who might not be able to do the work?

Individuals can differ in their susceptibility to infection and disease due to their health and immune status, and as a result may be more vulnerable or sensitive to infection or ill health. Opportunistic biological agents, which normally do not cause infections in healthy employees, may cause infection in a person if their immune status is weak. Consider the worker's health status, their individual susceptibility to infection and human factors such as fatigue.

4 It is important to remember that, in the laboratory, the route of exposure to the biological agent may differ from the biological agent's natural route. For instance, some micro-organisms may be infective by inhalation in the laboratory, whereas in their natural environment they are normally transmitted only by insect bite. The nature and severity of disease caused by a laboratory infection may also differ from that of the naturally acquired disease.

Pay particular attention to:

- workers with pre-existing medical conditions, allergies or disabilities;
- immunosuppressed or immunocompromised workers;
- people of childbearing age;[5]
- new or inexperienced workers;
- lone workers;
- older or more susceptible workers;
- workers with insufficient or inadequate information, training, instruction or supervision; or
- those with poor attitudes or behaviours.

For example, workers who use inhalers or immunosuppressive drugs or have cuts or skin conditions such as psoriasis or dermatitis may be more vulnerable to certain biological agents, if additional control measures are not in place.

Medical opinion may be required if certain pathogens are present or used. For example, some biological agents may pose a risk to male or female fertility. In such cases, inform workers of the risk before commencement of work activities that involve actual or potential exposure to such biological agents.

The principal people at risk of exposure are those conducting the work activity. However, other people may also be affected or exposed to a biological agent due to the work they do. For example, other workers within the laboratory, maintenance personnel, contractors, cleaners, students or visitors may not be fully aware of the work activities and the associated hazards and risks and may be exposed if adequate control measures are not in place or control measures fail. Consider them equally.

(c) The laboratory worker's competency

The risk assessment must also determine whether the person conducting the work is competent to do so. Lack of experience or understanding, failure to comply with documented safe systems of work, using equipment incorrectly or improperly and poor work techniques can lead to increased risk of exposure and work errors.

In relation to conducting the work activity safely, identify the proficiencies and training requirements and consider whether the employee has:

- sufficient training, qualifications, knowledge and experience;
- a good attitude to health and safety;
- the ability to follow appropriate procedures;
- the ability to work safely and react appropriately in an emergency situation; and
- any supervision requirements.

You must ensure that laboratory personnel have acquired technical proficiency in the use of microbiological practices and safety equipment required for safe handling of the biological agent(s) or the materials. This includes the ability to recognise hazards, handle emergencies and obtain assistance where necessary.

The individual's capabilities, attitude to health and safety, risk perception and tolerance, reliability and ability to follow safe systems of work and work under stress are especially important where there is potential for exposure to higher-risk biological agents. Address any potential deficiencies in the laboratory worker's practices before exposure to higher-risk biological agents.

2. Assess the risk

Having gathered all the information on the biological agent, the work and who may be affected, evaluate the likelihood of harm occurring (an exposure to or release of a biological agent) along with the severity of the consequences in the event of this happening.

Where the results of the risk assessment show that exposure or potential exposure is to a group 1 biological agent, including attenuated vaccines, which has no identifiable health effects on employees – that is, there are no sensitising, toxic or other health-damaging effects – most of the requirements and measures under the Biological Agents Regulations will not apply. However, the requirement to conduct the risk assessment and provide the HSA, when requested, with the information

5 Additional specific risk assessments are required for pregnant, breastfeeding and young workers under the General Application Regulations (see Chapter 2). The specific requirement for a pregnancy risk assessment only comes into force once an employee tells their employer they are pregnant. The biological agents risk assessment must consider harm from biological agents on people of childbearing age in advance of any pregnancy risk assessment.

used in conducting the risk assessment and the findings of the risk assessment will still apply. Observation of the principles of good occupational safety and hygiene is required in such cases.

On identification of a risk of exposure, determine the nature, degree and duration of the risk. Take account of the existing control measures in place and the minimum containment level and measures. Determine which risks are acceptable (work can proceed with the existing controls) and which are unacceptable (the work should not be carried out at all or work cannot proceed until additional controls are implemented to reduce the risk to an acceptable level). Consider whether vaccination and health surveillance should be made available.

> When assessing a new or novel biological agent for which little information is available, always take a preventive approach until further information becomes available.

3. Control the risk

You are required to prevent exposure of employees to a biological agent where the risk assessment reveals there is a risk to employees' health and safety. Similarly to the hierarchy of control in the 2005 Act, the Biological Agents Regulations require the avoidance and minimisation of risk.

Elimination and substitution

The Biological Agents Regulations require that where the use of a harmful biological agent has been identified, you must avoid its use if the nature of the work activity permits. Replace with a biological agent that under its conditions of use and in line with the present state of knowledge is not dangerous or is less dangerous to employees' health. This is known as a biological barrier, biological containment or a biological control measure and is a more reliable and safer control than one that, for example, depends on a person following their training. Achieve this for example by using:

- an attenuated, less pathogenic, less virulent or inactivated strain that can achieve the same experimental aim in preference to a wild-type strain;
- a non-toxigenic strain where possible; for example, when carrying out quality control tests or quality assurance or for teaching purposes; or
- substitute procedures that inactivate the biological agent, resulting in reduced replicability, infectivity, transmissibility and virulence.

For unintentional work, substitution is not usually an option.

Prevention and risk reduction measures

Based on the risk assessment findings, determine and apply the appropriate containment level and measures for the work activity. In some cases, this may mean working at a higher containment level, working at a higher containment level until inactivation of the biological agent, or working at the minimum containment level and putting in place additional or enhanced control measures.

Within the laboratory, usually a combination of control measures is required to minimise the risks to the lowest level. Select control measures, tailored to the specific biological agent(s), to reduce the level of exposure to the lowest level practicable to protect employee health.

Where it is not technically possible to prevent exposure, apply the prevention and risk reduction measures (specified in Schedule 2 of the Biological Agents Regulations and summarised in Table 12) in order to ensure that the exposure of employees is reduced to as low as level as necessary to protect the employees' health and safety.

Table 12: Summary of prevention and risk reduction measures based on Schedule 2 of the Biological Agents Regulations

Prevention and risk reduction measures	Potential example	Further information
Keep the number of employees exposed/likely to be exposed as low as possible.	• Restrict work to specific laboratories or work sites. • Introduce access control to the laboratory. • Limit the number of staff working in an area or on a task. • Segregate/isolate the work from others not involved with the work activity.	See Chapter 6.
Design work processes and engineering control measures to avoid or minimise the release of a biological agent into the workplace.	**Work processes** • Eliminate the work producing the hazard; for example, redesign the work or use inactivated materials. • Do not use a biological agent – use molecular or biochemical models instead of a pathogen; use nucleic acid-based assays instead of in vitro or in vivo propagation. • Reduce the quantity or culture volumes of biological agents used or stored or the frequency of use; use a lower titre or a less hazardous work process. Replace a high-exposure work activity with a lower exposure one. • Reduce or limit access to biological agents. Work with one agent at a time. • Reduce the number and locations of biological agents stored. • Use smaller or micro volumes of the agent. • Avoid the use of sharps or glass, especially at higher containment levels. • Document operating procedures and analytical methods.	See Chapters 6 and 15.

Prevention and risk reduction measures	Potential example	Further information
Design work processes and engineering control measures to avoid or minimise the release of a biological agent into the workplace.	**Engineering controls** • Isolate the agent from the worker – for example, use an MSC when work could create an infectious aerosol or splash and use enclosed centrifuge cups and sealed rotors. • Where possible, use work procedures that are performed in a largely automated way and in which: o only a few manual steps with the least possible volumes are necessary, o aerosol formation is minimised, o the material is inactivated quickly, and o the device used can be decontaminated. • Use appropriate ventilation – negative pressure ventilation or local exhaust ventilation (MSC). • Use automatic taps and dispensers. • Prohibit the use of needles where possible: use needleless systems or where required use needle-safe devices such as self-sheathing needles. • Use HEPA filtration.	See Chapters 6 and 15.
Use both collective protection measures and individual protection measures where exposure is not avoidable by other means.	• Use engineering controls and provide PPE, appropriate to the hazard, for workers and visitors. • Ensure equipment is compatible with the worker. • Provide face fit testing for tight-fitting respirators. • Train and instruct employees in the correct use of PPE – donning, doffing, safe disposal, decontamination, and storage where applicable. • Make vaccines readily available to anyone who may be exposed. • Provide health surveillance where identified.	See Chapters 14 and 16.

Prevention and risk reduction measures	Potential example	Further information
Use hygiene measures compatible with the aim of preventing or reducing the accidental transfer or release of a biological agent from the place of work.	• Select equipment that is easy to decontaminate. • Ensure appropriate handwashing facilities are in place. • Shower out where required to ensure containment. • Design and document suitable systems of work; for example, hand hygiene, disinfection, clothing and jewellery policies. • Provide training in correct handwashing techniques. • Ensure there is no eating or drinking in the laboratory.	See Chapters 6, 8 and 9.
Use the biohazard sign and other relevant warning signs.	• Display the biohazard sign and relevant containment level on the laboratory door. • Highlight areas where biohazards may be present; for example, refrigerators, storage areas, waste stores. • Use signage to warn people in the event of a spillage. • Use other appropriate signage; for example, no unauthorised entry or mandatory signage denoting PPE to be worn.	See Chapters 4, 6, 10 and 12.
Draw up plans to deal with accidents involving a biological agent.	• Ensure that an incident and accident reporting mechanism is in place. • Prepare documented emergency plans; for example, needle stick injury and spill control plans. • Display notices outlining the procedures in the event of a serious accident or incident. • Provide instruction, information and training to employees on how to handle an accident or incident.	See Chapter 12.
Test, where necessary and technically possible, for the presence of a biological agent used at work outside the primary physical confinement.	• Carry out monitoring, where required, to detect if there is a breach of containment; for example, use swabs, settle or contact plates, or air sampling within the laboratory.	See monitoring control measures below.

Prevention and risk reduction measures	Potential example	Further information
Use of means for the safe collection, storage and disposal of waste by employees, including the use of secure and identifiable containers after suitable treatment where appropriate.	• Segregate infectious waste appropriately. • Use appropriate waste containers – colour coded, as appropriate. • Ensure waste storage rooms are appropriately designed. • Ensure validated means of decontamination. • Inactivate material quickly by validated means. • Document the waste inactivation and disposal policy.	See Chapters 9, 10 and 15.
Arrange for the safe handling and transport of a biological agent within the workplace.	• Ensure that appropriate, easily decontaminated containers are available for internal transport purposes.	See Chapter 11.

Document the risk assessment

On completion, keep the risk assessment in written form, as required by law. In doing so, the risk assessment can refer to specific procedures contained in other documents or databases that workers know about and can easily access, such as:

- Safe systems of work
- Operating instructions
- Laboratory rules
- Manufacturers' instructions
- The company's safety and health policies or procedures

You must provide the HSA, if requested, with the information used for making the risk assessment.

Communication

Communicate the findings and the control measures to relevant persons, including employees and others affected by the work activities, such as students. Brief all relevant persons on the risks and the precautions taken to control them. Ensure they fully understand what is expected of them in order to work safely. Employees must be aware of the signs and symptoms of disease caused by the agents or materials in the laboratory.

Encourage them to communicate with the relevant manager or supervisor if at any stage they feel additional control measures are required.

Monitoring control measures

Check control measures regularly to ensure that they are still effective. As part of this process, testing may be required (where technically possible) for the presence of the biological agent being used outside of the primary physical confinement. For example, this may involve tracing for viable organisms outside the MSC or within incubators, centrifuges or walk-in refrigerators, or on surfaces. Methods may involve use of swabs, settle or contact plates, or air sampling.

Review of the risk assessment

The biological agents risk assessment is a living document. Review the risk assessment as often as necessary and if there is a change in conditions at the place of work that may affect an employee's exposure to a biological agent. This ensures that the identified risks are still valid and the control measures in use are working, still effective and appropriate.

For example, review the risk assessment if:

- a new biological agent is introduced or emerges;
- new information becomes available such as a biological agent being reclassified or previously unknown pathogenic properties being identified;
- accident report information or accident investigation findings indicate so;
- the procedure, processes, or technology change – for example, safer worker practices or new equipment or technologies are identified;
- the work changes – for example, scaling up from laboratory level or changing from in vitro to in vivo work;
- laboratory activities, facilities or personnel change;
- the health status of personnel changes;
- modifications are made to the laboratory;
- there is another reason to believe the risk assessment is no longer valid – for example, after a laboratory incident or exposure;
- the results of health surveillance indicate an issue; or
- there is a confirmed case of occupationally acquired disease.

In the review, consider any requirements for refresher training and, where vaccinations are relevant, the immunisation status of the worker. Following the review, amend the written risk assessment and any relevant systems of work as appropriate.

Biosecurity and biosecurity risk assessment

Although the Biological Agents Regulations do not specifically address biosecurity, aspects can relate to biosecurity; for example, the requirements to have safe storage of a biological agent (see Chapter 6). Provision of information here on biosecurity is for awareness-raising purposes.

Laboratories working with dangerous pathogens are potential targets for people who wish to acquire pathogenic material or training in their handling. Biosecurity relates to protection, control and accountability for high-risk biological agents (dangerous pathogens) and toxins and other valuable biological materials; that is, preventing their loss, unauthorised access, theft, misuse or incorrect use, diversion or intentional release. Laboratories may have additional reasons for ensuring biosecurity; for example, if there is information of medical, commercial or scientific value. Note that toxins on their own are considered chemical agents under health and safety legislation. However, in terms of biosecurity, biological agents and toxins are considered together.

Conduct a specific biosecurity risk assessment where biological agents, their toxins or sensitive information might be a risk to national or international security if they were stolen or misused. In conducting the risk assessment, review the fundamental properties of the biological agent or toxin. Consider both the product and the work:

- What is the potential for malicious or dual use?
- What are the potential consequences of malicious use?
- Will the planned laboratory activity change the risk?
- Could the work, or part of the work, be used to cause harm in unscrupulous hands?
- What precautions in relation to biosecurity are required?

As required, put in place measures to prevent unauthorised access to the facility and relevant information, for example, by means of physical structures, security, use of identification cards, means of restricting access and CCTV cameras. Regularly test and maintain any physical security systems to ensure they perform as required.

Hold sensitive information securely and provide graded access. Where required, put in place policies in relation to computers, tablets, media storage, cameras and telephones.

Have record and data control procedures that ensure secure disposal of sensitive information. Check and verify references of personnel with access to high-risk biological agents or toxins. Have control measures in place to ensure that any requests from individuals or facilities for biological agents and toxins are legitimate. Keep records of biological agents and toxins sent, received, removed or destroyed in line with the risk level. See Chapter 12 in relation to emergency and biosecurity plans

Chapter 8. Safe systems of work

No matter how well designed a laboratory is, worker protection cannot be guaranteed unless safe systems of work are in place and adhered to.

A system of work is a set of procedures according to which work must be carried out. Safe systems of work are required where hazards cannot be eliminated and some risk still exists. They can reduce or eliminate exposure to hazards and help prevent contamination of work and the spread of biological agents in the workplace, but only if they are strictly followed. Good microbiological practice and procedure (GMPP) sets down basic safe systems of work. Supplement these with specific documented systems of work as the level of risk increases. The development of specific safe systems of work will rely on knowledge of potential or actual biological agents and the risks associated with the work activities, which will have been gathered during your risk assessment. In order to ensure adherence to safe systems of work, adequate safety supervision must be in place.

Good microbiological practice and procedure

GMPP is a general term covering standard operating practices and procedures that apply to all work activities where biological agents may be present. GMPP addresses general behaviours, best working practices and technical procedures, including aseptic technique. It aims to prevent contamination of employees, the laboratory and the community from biological agents and protect the work from environmental contamination. The principles of GMPP are usually an integral part of third-level education training programmes and apply to all types of work involving micro-organisms, regardless of containment level.

Good microbiological practice and procedure: best working practice examples

- Do not store personal items such as coats or bags in the laboratory.
- Wear a fully buttoned-up laboratory coat in the laboratory and remove it before leaving the laboratory. Do not wear coats in the canteen, toilet, and so on. Wear suitable clothing – wear closed-toe shoes, do not wear loose clothing (see Chapter 14 on personal clothing) or unsuitable jewellery; for example, wrist and hand jewellery, other than plain wedding bands, may interfere with proper handwashing.
- Keep outdoor clothing separate from the working areas. On leaving the laboratory, remove protective clothing and leave it in the changing area. Take care to avoid transfer of infectious material from one area to another.
- Keep fingernails short and when in the laboratory do not wear nail varnish or false nails.
- Keep the laboratory door closed while work is in progress.
- Maintain an inward flow of air into the laboratory.
- Ensure the laboratory is tidy and clean and contains only work-related items. Leave bench tops clean and tidy.
- Ensure effective disinfectants are available.
- Decontaminate working surfaces, including MSCs, after completing work, after any spillages and at the end of the working day.
- Clearly identify and date cultures. Do not store cultures for long periods on a bench.
- Prevent release of fungal spores, which can be allergenic or cause cross-contamination, by sealing fungal Petri dishes with laboratory stretch film.

- Only carry what can be held safely and comfortably. Use secondary containers or trolleys for transporting items.
- Store used equipment awaiting sterilisation safely. Immerse pipettes totally in disinfectant.
- Wear appropriate protective eyewear where required; for example, where there is risk of splashes or impact, opening the autoclave or reheating laboratory media.
- Treat waste material before disposal – for example, render non-viable or incinerate. Transport waste in robust containers (durable, leak-proof, closed containers) without spillage.
- Reports spills, accidents and incidents.

Good technical procedures

Good technical procedures are working methods applied to eliminate or minimise exposure to biological agents. The methods aim to minimise the means of transmission, for example by aerosols, splashes or sharps, and prevent entry into the body (see Table 13).

Table 13: Examples of methods to protect routes of entry into the body

Route of exposure	Examples of methods to prevent exposure
Inhalation	• Do not sniff cultures. • Use disposal loops in preference to reusable loops to avoid spatter. • Minimise aerosol production and release into the workplace. • Use an MSC or other suitable equipment designed to contain aerosols where generation of infectious aerosols is likely; for example, when carrying out manipulations such as shaking, mixing and ultrasonic disruption. • Use correct and careful pipetting techniques. • Ensure equipment is designed to prevent aerosol release; for example, use closed containers for centrifuges. • Operate equipment to minimise aerosolisation. • Allow sufficient time before opening any containers post manipulation. • Have documented emergency plans in the event of equipment failure.

Route of exposure	Examples of methods to prevent exposure
Ingestion	• Avoid hand-to-mouth contact. Keep potentially contaminated items, for example pens or hands, away from the face. Do not eat, chew, drink, smoke, vape, bite nails, place materials in the mouth, use personal medications or apply cosmetics. Avoid licking labels and envelopes and sucking or chewing pens. • Do not store or bring food or drink for personal consumption into the laboratory. Only store them if they are submitted for work purposes such as scientific investigation, and label as such. • Restrict the use of personal electronic devices. • Do not mouth pipette – use pipetting devices. • Wear disposable gloves when handling actually or potentially infectious samples or agents. • Remove gloves correctly and with care to avoid contaminating skin (and aerosol formation). • Wash hands and fingernails and disinfect as appropriate; for example, before commencing work, after handling infectious material, before leaving the laboratory, after removal of protective clothing, if hands become contaminated or before handling writing materials or manuals. Dry hands thoroughly, using disposable towels or other suitable means.
Absorption	• Avoid hands touching the face, nose or eyes. • Wear laboratory coats or appropriate special or protective clothing. • Cover any cuts, grazes or broken or damaged skin with an appropriate waterproof dressing before entering the laboratory, and keep it dry. • Tie back hair to prevent contamination (it is a fire risk also). • Shield eyes, face and mouth from splashes. Contact lenses do not provide protection and are not advised while working in laboratories. • Conduct splash-producing procedures in an MSC.
Inoculation	• Where possible, do not use sharps such as needles or scalpels (see ‘Sharps in the laboratory’ below). • Where unavoidable: o Minimise the use of needles and sharps and use safety-engineered needles. o Pay due care and attention to the position of the hand not holding the sharp. o Do not re-sheath, re-cap, clip, bend, break or remove needles from disposable syringes. o Dispose of syringes safely and correctly – as a full unit into a puncture-proof, leak-proof sharps bin and treat as infectious waste (see Chapters 10 and 11). o Place bins as close to work as possible. o Do not overfill the sharps bin, and seal once full. Disinfect the outside and store safely until appropriately discarded.

Route of exposure	Examples of methods to prevent exposure
Inoculation (Continued)	• Use: o Plastic ware instead of glassware o Blunt or round-ended scissors in preference to ones with pointed ends o Ampoule cutters for opening ampoules • Where glassware is required, inspect it regularly for chips, cracks and weaknesses. Dispose of glassware in line with the broken glassware policy. Use forceps or other appropriate tools to pick up broken glassware.

Documented safe systems of work

The greater the health risk, the more comprehensive are the measures required to ensure worker health and safety. The requirement for documented safe systems of work and the detail required will increase as the containment levels increase. Put in place documented safe systems of work for activities such as:

- taking, handling and processing samples of human or animal origin;
- culture, purification and storage;
- centrifugation;
- use, control and disposal of needles and sharps (see below);
- correct and safe use of equipment – for example, vacuum pumps, centrifuges, pipettes, MSCs, sonicators and other mechanical forms of cell or tissue disruption;
- handling sample breakages or spills, for example in a centrifuge;
- use of disinfectants, including spill control and routine decontamination; and
- handwashing and showering.

Fatigue

Worker fatigue may not only contribute to poor results due to error, lack of concentration or judgement but also increase the risk of an accident or incident. A worker may work excessive hours due to an ongoing research project or a willingness to work extra hours and not realise they are fatigued. Similar to any other health and safety risk, manage fatigue risks.

Put in place a documented policy that outlines controls to reduce fatigue; for example, limits on project working hours or shift cover. Where night or shift work occurs, ensure compliance with Chapter 3 of Part 6 of the General Application Regulations (commonly known as the Night Work and Shift Work Regulations).

Lone working

Avoid lone working if the risk assessment determines that an employee is at significantly higher risk if working alone. Have lone working procedures in place, as appropriate. Ensure adherence to procedures and safe work practices by use of appropriate random supervision. Provide an emergency call device or similar device that can be activated from inside the laboratory.

Sharps in the laboratory

Sharps such as syringe needles have potential for accidental self-inoculation or aerosol generation and are a greater hazard when contaminated. Justify the use of sharps and document procedures for their safe use and disposal. Ensure a documented emergency plan is in place in the event of a sharps injury and is known to all. Where appropriate, take account of the Sharps Regulations (see Chapter 2).

Chapter 9. Decontamination, disinfection and sterilisation

Pathogens will require inactivation to render them harmless. Materials or equipment contaminated with pathogens must be decontaminated before reuse or final disposal in order to ensure the safety of workers, other people and the environment.

The 2020 Biological Agents Code of Practice requires specified disinfection procedures for CL2-CL4 laboratories. 'Specified' means a documented procedure tailored to the material or biological agent that requires inactivation.

Selecting the inactivation method

The most effective means of inactivation are physical means (see Figure 4). In laboratories, this usually means the application of heat in the form of steam, as in autoclaving (see Chapter 15). Chemical disinfection is generally used for surfaces or equipment that cannot be heat-treated or for cleaning up spills of infectious material (see below).

In deciding the inactivation method, consider what needs decontamination, along with the pros and cons of the method. Factors to consider include:

- the organism type;
- the material, item or surface – for example, what volume requires treatment, are any inhibitory substances such as proteins present that will hinder the process, is the equipment sensitive? Computers or laboratory equipment may be difficult to decontaminate;
- compatibility of the method with the material requiring decontamination – for example, some disinfectants are corrosive and may interact with stainless steel or rubber seals; some materials are not suitable for autoclaving; and
- the hazards posed to the worker – most disinfectants have associated health hazards, while autoclaves have pressure, steam and heat hazards.

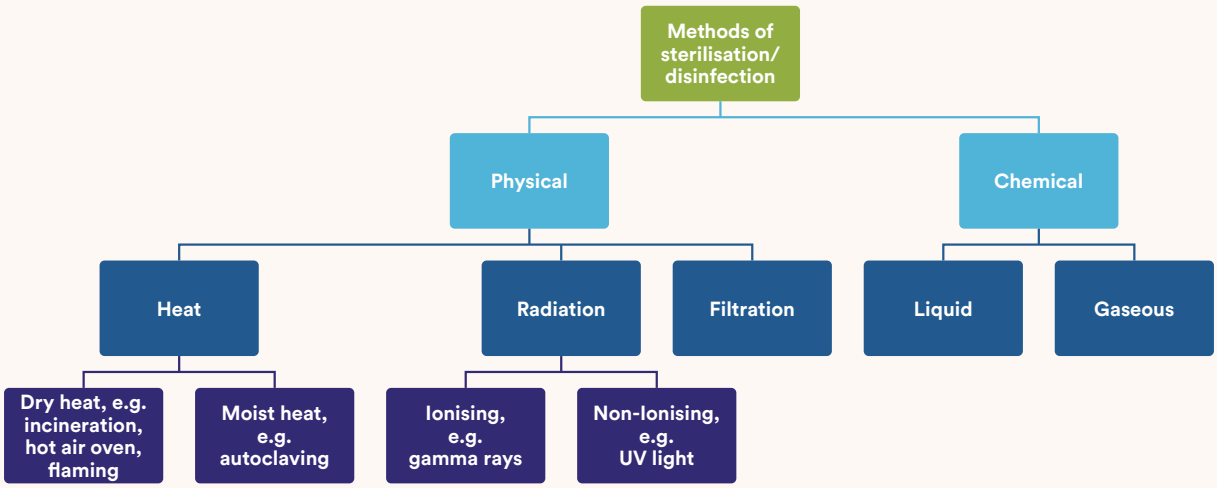


Figure 4: Methods of sterilisation and disinfection

Specify and document the selected decontamination method in a policy that addresses both routine and emergency decontamination. Use validated inactivation methods that are capable of inactivation under the specific conditions encountered at the place of work.

Chemical disinfection

Chemical disinfectants are usually the preferred method for decontaminating surfaces and equipment or reusable items that heat or steam may damage. They can be used for liquid wastes; however, their use is not as effective or as easily monitored for efficacy as steam sterilisation. They are generally used after a spill, where contamination is known or suspected to have occurred, after completion of work and periodically as part of the normal cleaning regime. Most chemical disinfectants are harmful or potentially harmful to humans and animals. Select, store, handle, use and dispose of them safely.

Chemical disinfectants and antiseptics

Chemical disinfectants are applied to non-living objects and materials, such as surfaces and instruments, whereas antiseptics (a type of disinfectant) are applied to living tissues. The term 'germicide' is often used for chemical disinfectants and antiseptics, while other terms such as 'virucide', 'fungicide', 'bactericide', 'sporicide' and 'tuberculocide' refer to the type of organism killed.

Legal requirements

The use of chemical disinfectants falls under the Chemical Agents Regulations (see Chapter 2). These Regulations require that a chemical risk assessment be conducted. The risk assessment must take account of the disinfectant 'from cradle to grave' – from the disinfectant arriving on the premises, through its storage and use, to its safe disposal. In conducting the risk assessment, consider any possible adverse interactions with other chemicals that may be present. Put in place appropriate control measures to ensure the safe and correct use of disinfectants.

The Carcinogen Regulations (see Chapter 2) will also apply where a disinfectant is known, or presumed, to have carcinogenic or mutagenic potential for humans. Under these Regulations, you must reduce the use of a carcinogen or mutagen, in particular by replacing it (in so far as is technically possible) with a substance, mixture or process that eliminates or reduces the risk to an employee's health or safety. Where this is not technically possible, a closed system must be used (in so far as is technically possible). If this is not possible, reduce the level of exposure of employees to as low a level as is technically possible.

The HSA enforces both the Chemical Agents and the Carcinogens Regulations.

Biocidal products (biocides)

As chemical disinfectants and antiseptics are also classed as biocidal products (biocides), the European Union (Biocidal Products) Regulations 2013 as amended (S.I. No. 427 of 2013 as amended) will also apply. These Regulations are enforced by the Department of Agriculture, Food and the Marine (DAFM).

Biocides can have a chemical or biological action and contain or generate an active substance (or substances) that is used to prevent or control harmful or unwanted organisms. In order to protect humans, non-target animals and the environment, biocidal products are regulated and are divided into 22 product types based on their intended use. The product types in turn are classed into four main groups, with Group 1 covering disinfectants (see Figure 5). Most disinfectants used within laboratories will fall into the product type 2 category.

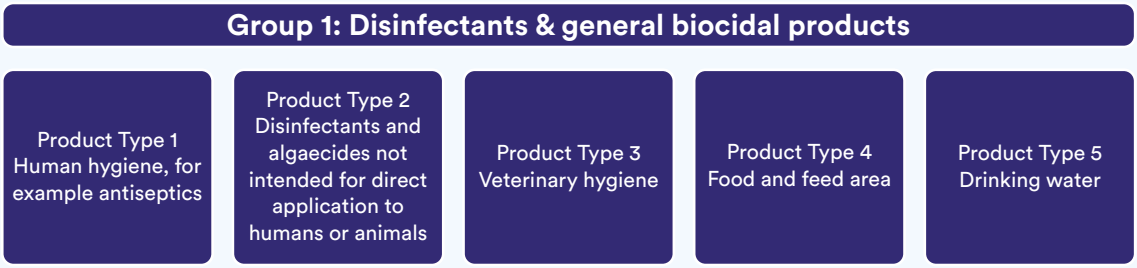


Figure 5: Disinfectant and biocide groups

Notified and authorised biocidal products

The active substance (what makes the product efficacious) is evaluated and approved at EU level. Notified products are products where the active substance is being evaluated at EU level and these will have a notification number (a pesticide control service (PCS) number).

Once the active substance has approval, the product is evaluated and authorised, usually at national level (or EU level). Every product containing that active substance must then be authorised for each specific formulation (for example, liquid or spray), intended use (for example, control of ticks or mosquitoes) and user category (for example, professional users or general public). The product will then have an authorisation number (either an IE/BPA No. or an EU No.). These numbers must appear on the label. Use authorised products only as described on the label.

Biocides, including chemical disinfectants and antiseptics, can only be distributed and used in Ireland if they have been notified to or authorised by the DAFM. You can view a list of notified and authorised biocidal products that are available on the Irish market on DAFM's biocide webpages. Check the list before purchasing or using a chemical disinfectant.

Selecting chemical disinfectants

Chemical disinfectants have different ranges of activity and various pros and cons. For example, a disinfectant that works against bacteria may not work against viruses, so it is important to select the correct disinfectant for the application. It is unlikely that any one product will suit all disinfectant requirements. The type of disinfectant selected will depend on the micro-organism, the circumstances under which the disinfectant will be used, the method of application and the nature of the material to be disinfected.

When selecting a disinfectant, factors to consider include:

- **Efficacy:** the disinfectant's active substance must work against the targeted micro-organisms, and the type and concentration of microbial contamination. Assess efficacy, using manufacturer's literature, peer-reviewed literature and in-house testing. If using disinfectants to treat cultures, nucleic acids and plasmids that may carry antibiotic resistance genes, note that these may not be destroyed. Release of these to the sewerage system may contribute to natural bacteria becoming resistant or even multi-resistant to commonly used antibiotics.
- **Form of the organism:** for example, vegetative bacteria or bacterial spores. This will determine the persistence of the organism. The method of disinfection must consider the most resistant form of the organism.
- **Health hazards:** most disinfectants are hazardous to human health. They may produce toxic or corrosive effects or induce an allergic sensitisation. Some are irritating to the eyes, skin and respiratory systems; some are carcinogenic or potentially carcinogenic; and some are physically hazardous – for example, flammable or explosive. Where possible, select the safest option. Obtain information from the supplier, including the safety data sheet, which will outline the hazards and incompatibilities, free of charge in advance of planning to use the disinfectant.
- **Compatibility:** disinfectants must be compatible with the item being disinfected – for example, stainless steel can be damaged by strong acid and hypochlorite, while plastics can be affected by disinfectants containing organic solvents. In addition, some disinfectants may react with incompatible chemicals and generate toxic gases – for example, if you mix hypochlorites with acids, gaseous chlorine results, or if you mix hypochlorites with formaldehyde, the lung carcinogen bis(chloromethyl) ether is produced. Ensure chemical compatibility where more than one disinfectant is required or where detergents or cleaning agents are used for pre-cleaning. Consider compatibility with autoclaving as required – for example,

chlorine-based disinfectants have potential to damage the autoclave.

- **Type of surface:** smooth surfaces are easier to disinfect than rough or porous materials.
- **Form of the disinfectant:** some disinfectants come in powder or tablet form and may need to be dissolved before use. This may result in a time delay if a person is dealing with a spillage.

Considerations when using disinfectants

For effective disinfection, use disinfectants correctly and in line with manufacturer's instructions. Incorrect use of disinfectants may contribute to increased resistance in micro-organisms.

Several factors affect the activity of disinfectants, such as:

- **Contact time:** apply chemical disinfectants to the item for sufficient time to enable the disinfection to work. Consider the disinfectant's volatility or rate of evaporation as this may result in inadequate contact time. The manufacturer's instructions will detail the required contact time.
- **Shelf life/stability:** disinfectants can deteriorate on dilution or over time, so adherence to the manufacturer's instructions regarding shelf life is essential. For example, high ambient temperatures and sunlight can reduce shelf life and some disinfectants may need to be freshly prepared before use. Label diluted disinfectants clearly, apply hazard pictograms as appropriate and a 'use by' or 'expiry' date in line with the manufacturer's instructions. Do not top up disinfectants. Out-of-date stock or inactivated product will not provide effective disinfection. Disinfectants may also lose their efficacy over time – a disinfectant that worked on a certain micro-organism may over time no longer work on it.
- **Concentration and dilution:** use the correct concentration and dilution of the disinfectant. Over-dilution will make the disinfectant ineffective, while under-dilution may damage surfaces.
- **Presence of other contaminants or organic load:** for example, proteins, organic matter, soaps, buffered culture media, detergents and liquid culture nutrient supplements can all reduce effectiveness. Oil and grease residues on surfaces may prevent effective contact with the disinfectant. Pre-cleaning of items is usually required for effective disinfection. Carry out any pre-cleaning with due care to avoid exposure to and spread of contamination.
- **pH, temperature and humidity:** for effective disinfection, observe the correct pH, temperature and humidity ranges. High temperatures may increase evaporation of some disinfectants and reduce the contact time or cause the disinfectant to degrade faster. Some disinfectants may not work sufficiently at cold temperatures – for example, if disinfecting a refrigerator. Humidity can also affect disinfectant performance.
- **Water hardness:** can reduce the rate of kill of certain disinfectants.

Safe use of disinfectants

- Carry out a chemical risk assessment of the disinfectant and implement appropriate control measures to ensure safe use. Bring the results of the risk assessment to the attention of the relevant users of the disinfectant. Address any chemical incompatibilities in the risk assessment.
- Ensure the safety data sheet for the disinfectant is up to date and readily accessible to the users.
- Follow the manufacturer's instructions to ensure correct use. Keep the minimum amount of disinfectant for use in the workplace. Wipe rather than spray disinfectant.
- Draw up a documented disinfection policy, taking account of the manufacturer's instructions and the results of the chemical risk assessment. The policy should cover at a minimum:
    - routine and emergency disinfection;
    - the specific type of disinfectant to use, its effective concentration, contact time and how long it will be stable for once made up;
    - the target micro-organisms for which the disinfectant is known to be effective (and ones for which it is not effective, if appropriate);
    - what is suitable for disinfection and what is not suitable;
    - any hazards and risks associated with the disinfectant and how to use it safely – for example, what PPE to wear; and
    - safe disposal of the disinfectant.
- Instruct and train employees on the correct and safe use and handling of disinfectants – when to use, what to use, how to use, how to protect themselves and safe disposal.
- Consider rotational use of disinfectants to prevent micro-organism resistance.
- Confirm the effectiveness of the disinfectant before use. For work with higher-risk biological agents, validation of the disinfectant under the conditions of use will be required. Numerous European Standards exist for specifying the test methods and requirements for establishing chemical disinfectant activity. For further information, see *EN 14885 Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics.*

Fumigation

Liquid disinfectants require direct contact for decontamination. This may not always be feasible in large areas or difficult-to-reach spaces. In such cases, a disinfectant in a gas or vapour state may be needed.

- Gaseous decontamination involves use of a chemical that is a stable gas at room temperature, for example use of true gases, such as chlorine dioxide or ozone.
- Vaporous decontamination involves use of a chemical that is stable as a liquid at room temperature and converted either to a gas or to microscopic droplets before its use, for example the use of vapour generated by heating source liquids such as formaldehyde or hydrogen peroxide.

The use of such gaseous or vaporous decontamination methods is commonly called fumigation.

Hazards of fumigation

Fumigation is a potentially hazardous process as it involves the release of toxic gases into the atmosphere. Several different types of fumigants are available and, similarly to liquid disinfectants, they all have advantages and disadvantages. All have occupational exposure limit values (OELVs)[6] and the concentration used for fumigation is generally higher than the OELV.

6 OELVs are listed in the most recent Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations and the Safety, Health and Welfare at Work (Carcinogens) Regulations, available at www.hsa.ie.

Formaldehyde, typically delivered by heating formalin (35%-40%) with an appropriate amount of water in a thermostatically controlled unit, has commonly been used in the past. However, formaldehyde is toxic if swallowed, inhaled or in contact with skin, causes severe skin burns and eye damage (it is corrosive), may cause cancer, is suspected of causing genetic defects and may cause an allergic skin reaction. As a result, its use is being phased out.

Hydrogen peroxide-based systems, which may be vapour or dry mist methods, and true gases such as ozone and chlorine dioxide are also available. Hydrogen peroxide can cause severe skin burns and eye damage, may cause fire or explosion (it is a strong oxidiser) and is harmful if swallowed or inhaled. Chlorine dioxide gas is fatal if inhaled, toxic if swallowed, causes skin irritation, severe skin burns and serious eye damage (it is corrosive) and may cause or intensify fire (it is an oxidiser) or mass explode in fire or if heated. Ozone is fatal if inhaled, may cause or intensify fire (it is an oxidiser) and causes serious eye irritation.

When is fumigation required?

Carry out a risk assessment to adequately identify and justify the circumstances under which fumigation is required, the risks associated with the fumigant and the process. For example, laboratories and MSCs may need to be decontaminated:

- if there is a large spillage;
- before maintenance work, especially where access to internal working parts or filter changes may be required;
- if there is a significant change in the nature of the work, such as work with a different pathogen; or
- if the laboratory is being decommissioned.

Selecting a fumigant

Before selecting and using a fumigant, carry out a chemical risk assessment in line with the requirements of the Chemical Agents Regulations. Select the most appropriate method for the application. Factors to consider when selecting a fumigant are the safety of the system, the reproducibility and reliability of the system performance, time (fumigation and room venting time) and ease of use.

Take account of equipment manufacturers', suppliers' or service providers' advice.

Validation of the initial fumigation process

Upon identification of the selected fumigant, validate the process for effectiveness before routine use. This ensures that the process performs consistently to the required standards and is reproducible. Perform a minimum of three decontamination processes for validation purposes. Draw up a validation plan detailing the room specification, the furniture and equipment layout, the type of indicators used to verify the process, the method for incubation of biological indicators and the defined method for reading the chemical and biological indicators. Identify on a map the most difficult areas to decontaminate, the best location for the fumigation equipment and the location points for the biological and chemical indicators. Carry out revalidation after any major renovations or changes to the laboratory.

Documented safe systems of work

Because of the potentially hazardous nature of the fumigation process, ensure that strict controls and procedures, including permit to work systems, are in place. Taking account of the risk assessment and suppliers' or manufacturers' instructions, document a safe system of work. Identify when and where fumigation is required, who is authorised to carry out the process, the precise details of how the process is to be conducted, the measures necessary to protect people, steps to ensure safe fumigation and, as appropriate, how the fumigant will be removed or neutralised. There must be appropriate consultation with others who work in the fumigation areas. Where external contractors carry out the fumigation, they must provide you with a site-specific risk assessment and documented safe system of work. Maintain and operate fumigation equipment in accordance with the documented safe systems of work. As highlighted in Chapter 6, where fumigation is carried out the laboratory must be sealable. Irrespective of this, an appropriate emergency plan must be in place detailing action to be taken in the event of a fumigant leak.

Prior to fumigation

Advise staff in the area in advance of fumigation and post appropriate temporary warning signs. Safely remove from the laboratory any incompatible materials that may react with the fumigant. Open incubators, refrigerators, drawers, cabinets and so on as needed in order to ensure effective fumigation. Lock off access to the area and do not allow unauthorised personnel to gain access until declaration that the area is safe. Control the fumigation process remotely from outside the laboratory. Ideally, carry out fumigation at off-peak, quiet times in order to minimise risk of exposure in the event of a leak.

During fumigation

During fumigation, restrict the amount of fumigant used to the minimum necessary to carry out the fumigation effectively and safely. Monitor the process and use the most relevant biological indicators to verify the effectiveness of the fumigation process.

Post fumigation

Neutralise or extract the fumigant, as required, at the end of the fumigation period. If venting to atmosphere, ensure that the fumigant cannot re-enter the building via windows or other ventilation systems or endanger other people. The fumigator must ensure that all areas are safe for reoccupation and only then remove barriers or warning signs. Keep records of fumigation.

Where removal of fumigation equipment from the area is required post fumigation, ventilate, and inspect it for residues while wearing appropriate PPE, before storing or loading onto transport.

Instruction, information and training

Personnel carrying out fumigation must be authorised in writing, be competent and have appropriate instruction, information and training to ensure they carry out the process safely and do not endanger themselves or others. Ensure they are trained in the hazards of the fumigants, the use of the equipment, storage and transport of the fumigant, the signs and symptoms of fumigant poisoning, the procedures to follow, what precautions to take, procedures for deeming the area safe for reoccupation, and emergency procedures. In addition, ensure they have received training in the use of the respirator and have undergone fit testing, as appropriate.

Ultraviolet germicidal irradiation (UVGI)

UVGI is the use of shortwave ultraviolet (UV-C) light to kill or inactivate micro-organisms. Most germicidal ultraviolet lamps generate predominantly 254 nanometres radiant energy (see Figure 6). Within laboratories, UV-C lamps may be used for disinfection purposes in MSCs and airlocks. They may also be found if one is working with cell cultures, polymerase chain reaction (PCR) or other genetic materials, where

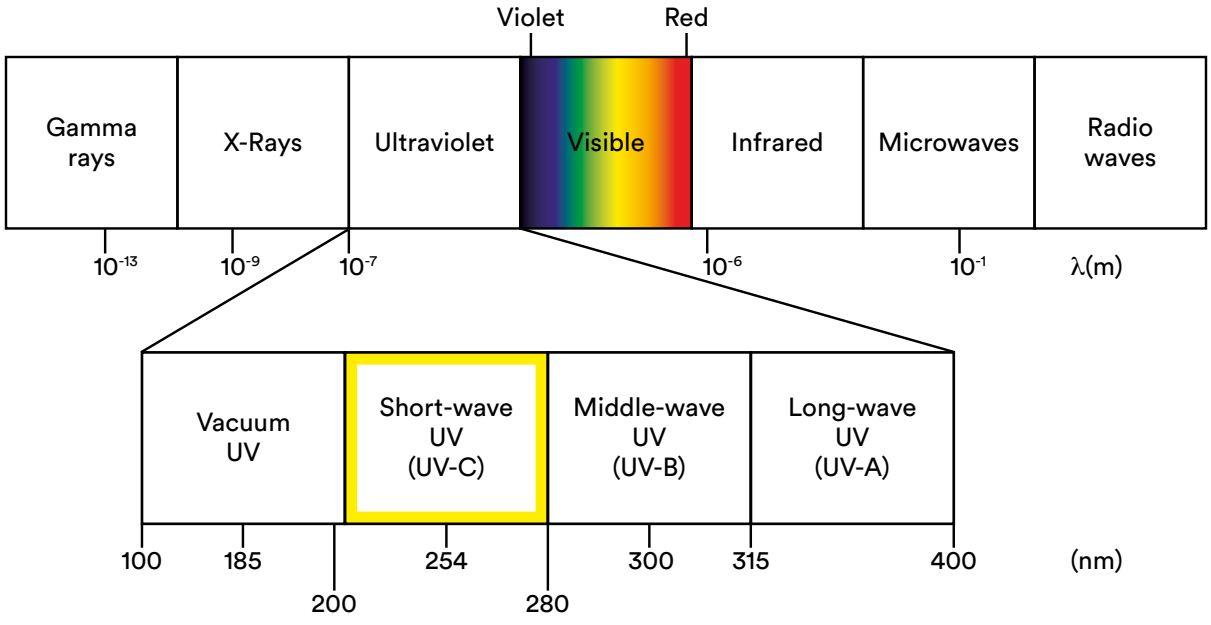


Figure 6: UV-C on the electromagnetic spectrum

the main purpose is prevention of product contamination and destruction of nucleic acids.

The benefits of UV-C disinfection are that it does not leave a residue and the disinfection activity stops on deactivation of the lamp. Due to its lack of penetrating power, it is mainly limited to surface disinfection. If a biological agent is embedded in a porous surface, covered by dust or soiling or on the underside of a surface, it will not be inactivated, as it is not directly exposed. The level of UV exposure required will also vary from pathogen to pathogen. As a result, regard UV-C irradiation only as a supplement to other disinfection methods. As the light may affect some materials, such as plastics and rubber-based materials, check material compatibility before use.

If inappropriately used, UV-C radiation can cause erythema (a reddening of the skin similar to sunburn) and eye injuries such as photokeratitis (inflammation of the cornea). Avoid direct skin exposure and looking directly at lamps.

As UV-C is a form of artificial optical radiation, Part 9 of the General Application Regulations (S.I. No. 299 of 2007 as specifically amended by S.I. No. 176 of 2010 – commonly known as the Control of Artificial Optical Radiation at Work Regulations) apply. Under these Regulations, you must ensure no exposure of workers to artificial optical radiation in excess of exposure limit values. Consider UV sterilisation as generating hazardous levels of light and perform a risk assessment. Take account of manufacturer's safety guidance to ensure that exposure limit values are not exceeded.

Where UV-C is used, ensure interlock systems are in place to prevent the operation of the cabinet or entry to the airlock when the lamp is on. Place appropriate safety signage to indicate the presence of UV light. As UV lamp intensity decreases with time, maintain and clean lamps and regularly replace bulbs in order to maintain efficiency. As bulbs may contain mercury, have appropriate procedures in place in the event of a bulb breakage. Ensure workers have access to the manufacturer's instruction manuals and appropriate instruction, information and training in the safe use of the equipment, symptoms of exposure and, where required, use of PPE.

Chapter 10. Waste management and disposal

Laboratories can generate many types of waste, including waste contaminated with biological agents or materials that may contain biological agents. Waste is a complex area and different Government Departments, agencies and authorities may be involved in the regulation of waste. Who the relevant regulator is will depend on the waste type, where the waste is located, where the waste is within the disposal chain, and whether it has been decontaminated.

The term 'biological agent' does not feature in waste legislation. Instead, waste legislation is based on the infectivity of the waste (infectious waste) and potential harm to humans, animals, plants and the environment.

Regulation of waste

The Department of the Environment, Climate and Communications is responsible for waste policy in Ireland. The Waste Management Acts 1996-2001 regulate waste and the EPA and local authorities enforce this legislation. The legal duty is on those generating and disposing of waste to ensure safe and correct disposal.

Producers of waste must categorise it into hazardous and non-hazardous waste. Infectious waste is a category of hazardous waste and is defined as "waste containing viable micro-organisms or their toxins which are known or reliably believed to cause disease in humans or other living organisms".[7]

The DAFM and other relevant agencies enforce legislation with respect to animal by-products (ABPs). Strict controls cover the use and disposal of ABPs in order to protect both public and animal health. Take account of this legislation with respect to cell cultures of animal origin or animal-derived laboratory reagents.

The HSA also has an enforcement role with regard to infectious waste under occupational health and safety legislation – specifically the Biological Agents Regulations and the ADR Regulations, which give effect to the ADR (see Chapter 2). The Biological Agent Regulations require "the use of means for the safe collection, storage and disposal of waste by employees, including the use of secure and identifiable containers, after suitable treatment where appropriate". Under the Regulations, it is important that all infectious waste is contained and controlled to prevent the spread of contamination within and from the workplace.

The ADR covers the carriage of dangerous goods by road. It aims to protect the health and safety of anyone who may encounter dangerous substances during transport by road. The ADR does not refer to biological agents but instead refers to infectious substances (see Chapter 11).

Infectious laboratory waste

Infectious waste in the laboratory may be in the form of solid, liquid, slurry or sharps. Some waste may also be of mixed form: for example, both infectious and radioactive. Waste may include microbiological cultures, biological materials, sharps, Petri dishes, waste contaminated with blood and other bodily fluids, commercial identification kits, contaminated PPE and wastewater from showers and sinks. Base your waste management procedures on the types of waste generated, as all will require validated safe disposal.

Documented waste policy

Put in place a documented policy in relation to the safe handling and disposal of biological agents and infectious waste. Ensure the policy covers the identification of the different types of infectious waste and its segregation, handling, storage, treatment and disposal.

7 European Union (Properties of Waste which Render it Hazardous) Regulations 2015 (S.I. No. 233 of 2015).

Cover the following:

- the responsibilities of various personnel and the extent of their responsibility;
- the specification for waste containers and enclosures;
- the means of safe, transport, storage and handling on site before disposal;
- the training required;
- what to do in the case of an accident or incident such as a spillage;
- what PPE to wear; and
- how the waste is safely disposed of.

Waste segregation and handling

Segregate laboratory waste, for example into non-infectious waste, sharps and infectious waste, and clearly identify it, for example via colour coding. Identify and stream all potential sources of contamination correctly to ensure effective decontamination of mixed waste. Do not allow waste to accumulate in the laboratory. Contain the waste within a secondary container in order to collect any seepage; for example, place autoclave bags into suitable containers to contain any spillages. Place disposable equipment in a container with an appropriate lid, close to the workstation, before treatment. Do not overfill, drop, crush or throw autoclave bags or containers. Do not compact or reduce the volume of untreated waste.

Containers and bins

Containers for waste, commonly referred to as bins, come in many formats such as sharps, autoclave and wheeled bins. Select bins for infectious waste based on the nature of the waste and the handling, transport and treatment methods. Use the selected bins only for such waste and ensure they are spill and puncture proof. Ensure that reusable bins can be effectively and safely decontaminated. Keep adequate supplies of bins available and segregate clean and dirty bins. Mark bins with the biohazard sign, unless used only for containment level 1 waste. Ensure autoclave bins are such that steam can penetrate the load. Where bins are for off-site transport via the public road, they are considered as packagings and must comply with the ADR requirements, as appropriate (see Chapter 11).

Manual handling aids

Ensure designated manual handling aids such as transport trolleys or wheeled bins are available for handling waste. Select appropriate aids that are ergonomically designed; are easy to use, clean and disinfect; and contain any leakages. The aids must also enable safe loading and unloading and not cause damage to the waste: for example, have no sharp edges.

On-site treatment

How the waste is treated depends on the characteristics of the waste (whether solid, liquid or mixed) and the associated risk of the biological agent. Chemical means, for example disinfectants or physical means such as autoclaving or incineration, can be used. However, autoclaving of biological waste (covered in Chapter 15) is usually preferred over the use of chemical disinfectants, especially where higher-risk group pathogens are involved. This is because chemical disinfectants, as outlined in Chapter 9, have a range of properties, most are hazardous to health, and no single disinfectant is effective in all situations. In addition, on-site treatment is preferable to off-site treatment.

Where treatment of infectious waste occurs on site, specify the decontamination method, along with the means of verification of correct operation of any decontamination equipment and decontamination performance. Dispose of deactivated liquid waste directly to a municipal drain or through a waste stream with a registered waste provider.

Packaging of infectious waste

Place contaminated items intended to be autoclaved or incinerated off site into leak-proof packaging with closed fitted lids. Place items or material for decontamination and reuse in sealed autoclave packagings. Clearly mark packagings for incineration so that their source is identifiable.

Waste storage

Deal with infectious waste as promptly as possible and do not allow accumulation. However, in certain circumstances, infectious waste may need to be stored on site, for example if waste from a CL2 laboratory is awaiting transport off site for treatment. Store CL3 laboratory waste only in exceptional circumstances, for example if an autoclave is inaccessible, in the event of equipment breakdown or while awaiting confirmation of effective decontamination. As required, ensure facilities are large enough to store the waste safely. Store all waste for the minimum length of time.

The storage area for waste must be a secure, dry, designated area. Post the biohazard sign and ensure the area is accessible only to authorised personnel. Site the store away from general storage areas, food preparation or eating areas, public areas and incoming goods. Ensure it is well lit and ventilated, and where self-closing doors are in place provide a means of opening the door from the inside. Put vector control procedures in place and ensure washing facilities and spill kits are readily accessible. Provide separate facilities for treated waste and waste awaiting decontamination. Where the storage area is located outside (CL2 waste only), the area must be totally enclosed and sited on a secure, well-drained, impervious, hard-standing area with wash down facilities. Storage bins must be lockable.

Refrigerated storage may be required for certain types of waste or if, for some reason, untreated waste has to be stored for a prolonged period. Where generation of only small quantities of waste occurs, designate an area of the laboratory, refrigerator or freezer for this. Store such waste in heavy-duty rigid bins, identified with the biohazard sign.

Waste collection

Laboratory waste that has been autoclaved correctly by a validated process and is no longer infectious will not be subject to the ADR unless it falls into another class of dangerous goods – for example, it is a chemical hazard. Where un-autoclaved waste is moved off site by public road, the ADR applies and appropriate records must be available (see Chapter 11).

Hand over waste for transport off site to an authorised waste collector only. Such collectors must have an in-date collection permit issued by the National Waste Collection Permit Office (NWCPO), based in Offaly County Council. For infectious waste and other hazardous waste, a waste transfer form, along with the documentation that is required under the ADR, is also needed. The National Transfrontier Shipment Office (NTFSO) Office in Dublin City Council handles these forms. The producer of the waste, known as the consignor under the ADR, must retain copies of the completed transfer form in order to show that the waste has been correctly disposed of. The forms must be available for inspection by the HSA or other relevant enforcement agencies.

Chapter 11. Movement and transport of biological agents and infectious material

Transport refers to movement of goods from one location to another using a means of transport. Movement may be internal within the workplace, nationally, within Europe or internationally and encompasses correct transport and ensuring that appropriate documentation such as permits or licences[8] are in place. Transport and movement are complex areas, so this chapter provides only a general overview.

Movement within the workplace

Within a workplace, the movement of biological agents or materials that contain or might contain biological agents falls under the Biological Agents Regulations. When moving infectious material or agents outside the main containment area, appropriate procedures must be in place to prevent accidental spills or splashes. Carry infectious agents or materials in closed, rigid, break-proof and liquid-tight containers. The containers must be capable of disinfection, marked with a biohazard sign and labelled in a permanent fashion. It must not be possible for external influences to open these accidentally. Appropriate packaging must be in place to ensure that items such as request forms are not contaminated. Where possible, transit should avoid communal or public areas.

Transporting biological agents

The transport of infectious biological agents or materials outside of the workplace does not fall under the Biological Agents Regulations but instead falls under the Transport of Dangerous Goods (TDG) legislation (see 'Transport modes' below). Dangerous goods are substances and articles that are classified as hazardous for transport and present a risk to people, property and the environment.

TDG legislation does not specifically refer to biological agents but uses the term 'infectious substances'. For the purposes of transport, an infectious substance is "a substance, which is known or reasonably expected to contain pathogens, which can cause disease in humans or animals". Note that plant pathogens are not included in TDG legislation as they are provided for in Phytosanitary Regulations.[9]

Within a laboratory, cultures, diagnostic samples, consumables, waste or equipment containing or contaminated by biological agents that can cause disease in humans or animals would be considered infectious substances for the purposes of transport outside of the workplace.

Purpose of TDG legislation

If infectious biological agents and materials are not handled, packaged and transported correctly, there is a risk of release of the agent or material and contamination of people or the environment. For example, if a package leaks there is potential for contamination of those involved in the transport chain (such as packers, loaders, unloaders, carriers, customs officials and postal workers), laboratory staff and the public. Having rules and regulations for national and international transport ensures that packages are handled properly, goods are not delayed, lost or returned, and any incidents are dealt with appropriately.

8 Permits and licences are not under the remit of the Health and Safety Authority.

9 European Union (Plant Health) Regulations 2020 (S.I. No. 459 of 2020) and European Union (Plant Health Controls) Regulations 2021 (S.I. No. 310 of 2021).

Transport modes

If transporting biological agents or infectious substances from a place of work, decide on the means of transport and refer to the United Nations Model Regulations, which provide the minimum requirements for the regulation of all modes of transport – air, sea, road, inland waterways and rail. For each mode of transport there are international rules and national regulations, which set out requirements for how dangerous goods should be packaged, labelled and marked, as well as provisions concerning the individual modes of transport, transport equipment and operations.

The international rules governing the modes of transport are as follows:

- Air: International Civil Aviation Organization (ICAO) technical instructions (note that airlines that are members of the International Air Transport Association (IATA) refer to the manual of the IATA Dangerous Goods Regulations (IATA DGR).
- Sea: International Maritime Dangerous Goods (IMDG) Code.
- Road: Agreement concerning the International Carriage of Dangerous Goods by Road (ADR).
- Rail: Regulation concerning the International Carriage of Dangerous Goods by Rail (RID).
- Inland waterways: Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN).

Transport requirements can vary according to the transport mode; requirements for air are generally the most stringent (for certain dangerous goods). Specific quantity limits may exist for air transport, which determine whether the package requires transport by passenger or cargo plane. If transporting dangerous goods using several different modes of transport – for example, road and air – seek advice from a competent Dangerous Goods Safety Adviser (DGSA) specialising in multimodal transport.

Nationally, the HSA enforces the regulations on carriage of dangerous goods by road. The Irish Aviation Authority (IAA) enforces the regulations on the transport of dangerous goods by air, and the Department of Transport and its relevant agencies enforce the regulations on the transport of dangerous goods by sea and rail. Currently, dangerous goods are not transported by inland waterways in Ireland.

In addition to the international rules and TDG legislation, An Post prohibits and restricts certain dangerous goods. For example, infectious substances are prohibited from international mail services, and certain conditions must be met for national services. Commercial enterprises such as airlines or couriers may have additional safety requirements. Certain goods can also be prohibited or restricted at import and export and are listed on the Revenue's website.

Transport by road

The remainder of this chapter provides a brief overview of the legislation for the carriage by road of infectious substances, enforced by the HSA. The ADR[10] provisions are very complex: seek the advice of a competent DGSA where required in relation to the packaging of infectious substances and infectious waste, package marking, labelling and the preparation of appropriate documentation.

Four steps are involved in the safe transport of dangerous goods by road:

1. Classification.
2. Packaging.
3. Labelling.
4. Requirements for carriage (such as driver training, vehicle safety equipment and documentation).

The correct classification of consignments of dangerous goods such as infectious substances, and the preparation of a transport document, for every transport operation, assists participants in the transport chain and public services. For example, in the event of a road traffic collision, the emergency services will know what is being transported and will be able to respond appropriately.

10 See the United Nations Economic Commission for Europe (UNECE) website for the latest edition of the ADR.

Classification

Under the ADR, there are nine specific hazard classes, with some classes having subdivisions, for example Class 6 as indicated in Figure 7. Infectious substances fall under Class 6.2.

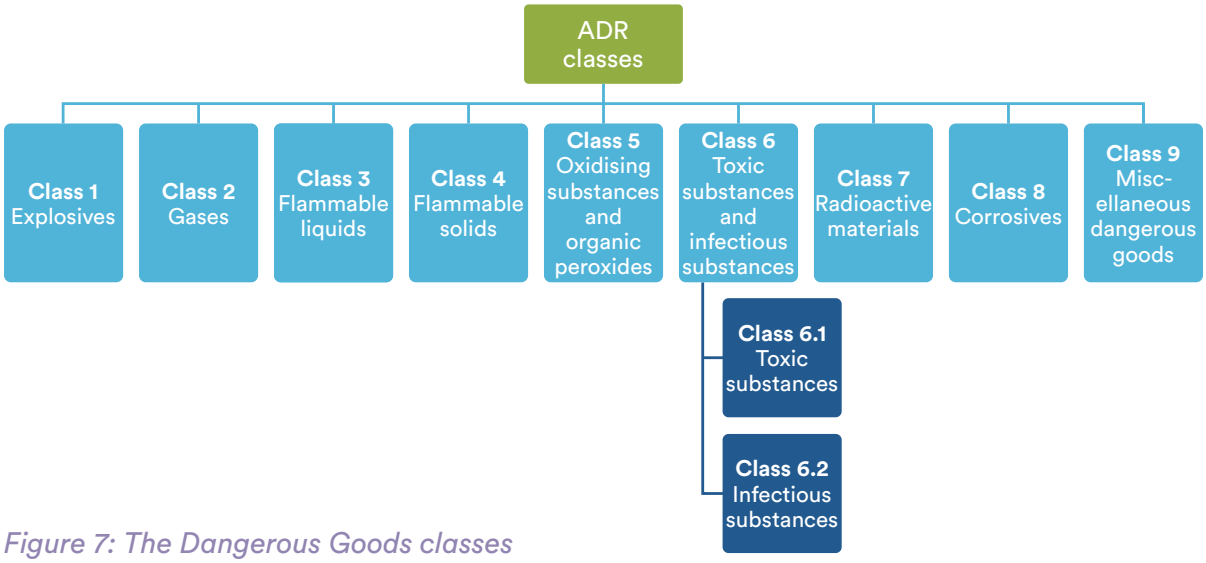


Figure 7: The Dangerous Goods classes

Infectious substances are defined in the ADR as "substances which are known or are reasonably expected to carry pathogens". Pathogens in turn are defined under the ADR as "micro-organisms (including bacteria, viruses, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals". Note that the ADR is broader in scope than the Biological Agents Regulations as the criteria for classification cover micro-organisms that cause disease in animals as well as humans.

The process of classifying a hazardous substance or an article, and assignment to a UN number and proper shipping name (PSN), is the responsibility of the consignor of the dangerous goods. The UN number is a four-digit number that identifies the hazardous substances and articles. The PSN is the most accurate way of describing the dangerous goods assigned to the UN number, and is shown in capital letters in the ADR (see Table 14). The consignor is the organisation, for example the laboratory that produces (consigns) the dangerous goods for transport.

The classification scheme for infectious substances (Class 6.2) reflects the risks associated with the pathogen or infectious substance during transport. Note that the classification criteria under the provisions of the ADR differ from the biological agent's risk group classification under the 2020 Biological Agents Code of Practice.

Depending on the outcome of the classification process, infectious substances are assigned to one of five UN numbers (2814, 2900, 3373, 3291 or 3549 as appropriate) with the appropriate PSN (see Table 14). Each of the UN numbers has specific packing instructions and labelling requirements.

Substances that do not contain infectious substances are not subject to the ADR unless they meet the criteria for inclusion in another class: for example, Class 3, flammable liquids or Class 6.1, toxic substances (see Figure 7).

Categories A and B

An infectious substance (Class 6.2) will fall into one of two categories (Category A or B) based on how pathogenic it is and its form, for example whether it is a concentrated culture or a patient sample.

A Category A substance is an infectious substance that is carried in a form that, when exposure to it occurs (when it is released outside of the protective packaging, resulting in physical contact with humans or animals), it is capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals. The ADR provides an indicative and non-exhaustive list of infectious substances assigned to Category A.

Note that although there is no direct relationship with the risk groups under the Biological Agents Regulations, Category A substances consist mainly of group 3 and group 4 biological agents. Examples include Ebolavirus and Lassamammarena virus.

Depending on whether the substance affects humans and animals or animals only, a Category A infectious substance will be assigned one of the following UN numbers and PSNs:

- UN 2814, INFECTIOUS SUBSTANCE AFFECTING HUMANS.
- UN 2900, INFECTIOUS SUBSTANCE AFFECTING ANIMALS only.

A Category B substance is an infectious substance that does not meet the criteria for inclusion in Category A, meaning that the substance would not cause permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals. Such substances are assigned the following UN numbers and PSNs (with separate entries for human material and animal material):

- UN 3373 BIOLOGICAL SUBSTANCE, CATEGORY B.
- UN 3373, BIOLOGICAL SUBSTANCE, CATEGORY B (animal material only).

Substances from humans or animals suspected of containing infectious substances will be assigned to Category A or B based on professional judgement, medical history of the patient or animal, and endemic local conditions.

Medical or clinical waste

Regulated medical, biomedical or clinical wastes constitute waste derived from the medical treatment of an animal or human and require classification as Category A or B waste.

Medical or clinical wastes containing Category A infectious substances are assigned to UN 2814 or UN 2900. Solid medical waste containing Category A infectious waste generated from medical treatment of humans or veterinary treatment of animals may be assigned to UN 3549 (this does not include Category A liquid waste or waste from bio-research, which is assigned to UN 2814 or UN 2900).

Medical or clinical waste containing Category B substances is assigned to UN 3291. There are three PSNs for UN 3291:

- UN 3291, (BIO)MEDICAL WASTE, N.O.S.[11]
- UN 3291, CLINICAL WASTE, UNSPECIFIED, N.O.S.
- UN 3291, REGULATED MEDICAL WASTE, N.O.S.

Transport of genetically modified micro-organisms (GMMs – referred to as GMMOs under the ADR) and genetically modified organisms (GMOs)

GMMs and GMOs are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. If they cause disease in humans or animals they may be classified as infectious substances (Class 6.2, UN 2814, 2900 or 3373). They are assigned to Class 9, Miscellaneous Dangerous Goods, with the UN number 3245, if they do not meet the definition of toxic substances or of infectious substances, but are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction.

- UN 3245, GENETICALLY MODIFIED MICROORGANISMS or GENETICALLY MODIFIED ORGANISMS.
- UN 3245, GENETICALLY MODIFIED MICROORGANISMS or GENETICALLY MODIFIED ORGANISMS in refrigerated liquid nitrogen.

Non-infectious GMMs and GMOs that do not meet the definition of toxic substances and are not capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction are not subject to the provisions of the ADR.

11 N.O.S. = not otherwise specified

Exemptions

The ADR includes a list of exemptions for substances that have a minimal likelihood that pathogens are present and as a result are exempt from the provisions of the ADR. Examples of exempt substances listed in the ADR are dried blood spots and faecal occult blood screening samples. If unsure as to whether or not a substance is exempt from the provisions of the ADR, seek the advice of a DGSA.

Some animal and human specimens for which there is minimal likelihood that pathogens are present are not subject to ADR if the specimen is carried in a packaging that will prevent any leakage and is marked with the words "exempt human specimen" or "exempt animal specimen". An example of an exempt human specimen would be non-infected human or animal tissues for biopsy. Where the sample has been collected directly from the human or animal and the medical history is known and indicates that the sample is non-infectious, it is exempt from ADR provided the packaging meets certain conditions.

Table 14: Examples of UN numbers and proper shipping names for Class 6.2 and Class 9

Class	Name	Proper shipping name	UN number
Class 6.2	Infectious substance – Category A	INFECTIOUS SUBSTANCE, AFFECTING HUMANS	UN 2814
		INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only	UN 2900
	Infectious substance – Category B	BIOLOGICAL SUBSTANCE, CATEGORY B	UN 3373
	Medical/Clinical waste – Category A	INFECTIOUS SUBSTANCE, AFFECTING HUMANS	UN 2814
		INFECTIOUS SUBSTANCE, AFFECTING ANIMALS only	UN 2900
		MEDICAL WASTE, CATEGORY A, AFFECTING HUMANS, solid	UN 3549
		MEDICAL WASTE, CATEGORY A, AFFECTING ANIMALS ONLY, solid	UN 3549
	Medical/Clinical waste – Category B	(BIO)MEDICAL WASTE, N.O.S.	UN 3291
		CLINICAL WASTE, UNSPECIFIED N.O.S.	UN 3291
		REGULATED MEDICAL WASTE	UN 3291
	Patient or animal specimen (non-infectious)	Exempt human specimen	-
		Exempt animal specimen	-
Class 9	Genetically modified micro-organism (non-infectious but dangerous to environment)	GENETICALLY MODIFIED MICROORGANISM	UN 3245
	Dry ice	Dry ice solid	UN 1845*

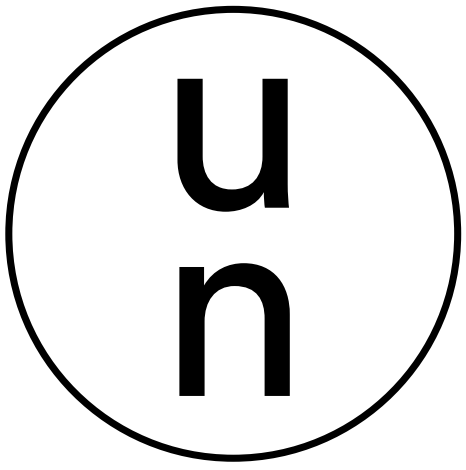
*Dry ice/solid carbon dioxide (UN 1845), used as a refrigerant for shipment of some biological materials, is an asphyxiant in enclosed spaces and has the potential to explode if placed in a sealed container. It is subject to special provisions of ADR applicable to dry ice and to packages, vehicles and containers containing substances presenting a risk of asphyxiation when used for cooling or conditioning purposes. Note that UN 2814, UN 2900, UN 3291 and UN 3245 have an alternative PSN if carried in refrigerated liquid nitrogen.

Packaging

Packaging of infectious substances must be designed to minimise the potential for damage, leaks or spills during transport and to ensure the integrity of the materials being transported. It must meet specified testing requirements to ensure it withstands the stresses it may encounter during transport and must be used as designed.

Each UN number has particular specifications for packaging type, packing procedures, labelling and transport, which are set out in the ADR (Table A of the ADR). There are very specific packing instructions in the ADR for infectious substances, depending on the UN number (UN 2814, 2900, 3373, 3291 or 3549), all of which are listed in Table A of the ADR Chapter 3.2.

All infectious substances (UN 2814, 2900 and 3373) require triple packaging[12] and for Category A infectious substances, the outer packaging must be UN type-approved. UN-approved packaging is identifiable by the symbol:



Labelling and documentation

Packages containing infectious substances must be appropriately marked and labelled in accordance with the provisions of the ADR. Package orientation labels may be required, depending on the volume. The documentation required for each transport operation must be in compliance with the provisions of the ADR.

Biosecurity implications

Take precautions to ensure that packages are not available to the public, and only hand over to known or identifiable persons or companies that have the appropriate training for the dangerous goods being handled and the mode of transport being used.

Receipt of dangerous goods

The person receiving the dangerous goods (the consignee) should check packages both externally and internally for damage or leaks, and that the itemised list matches the contents. The consignee should have a documented emergency plan to deal with any damaged or leaking packages. Open packages containing infectious substances in line with the minimum containment measures for the risk group classification.

12 See the latest version of the World Health Organization Guidance on Regulations for the transport of infectious substances (updated every 2 years).

Chapter 12. Emergency procedures and plans

The Biological Agents Regulations require that for any activity where there is a risk to the health and safety of employees due to work with a biological agent, you must establish and maintain safety precautions, emergency procedures and plans appropriate to the hazards in the place of work.

The specific requirement for emergency plans for biological agents supplements the requirement for general emergency plans for the laboratory under the 2005 Act. For example, general emergency plans may cover a fire, bomb threat, gas leak, sudden release of large amounts of steam from an autoclave or the failure of a carbon dioxide tank.

Specific biological agents emergency plans

Put in place emergency plans for hazardous biological agents. Document the actions required in the event of an incident, accident or emergency involving biological agents. Plans may encompass emergency procedures, including safe shutdown of equipment, first aid arrangements, use of safety equipment and PPE, cleaning and decontamination, and safe waste disposal. Consider specifically the prevention of contamination spread by emergency responders and spread to the environment. Keep emergency plans up to date and review, amend and revise as appropriate.

Where the risk assessment (Chapter 7) reveals a risk to an employee's health and safety, you must provide the HSA, when requested, with appropriate information relating to the emergency plan for employee protection from exposure to a biological agent that might result from a loss of physical containment.

Planning

The level and extent of the planning will depend on the risk group of the agents encountered, used or stored and the containment level of the laboratory – the higher the containment level, the more extensive and detailed the plan will be. In preparing the plan, take account of the findings of the risk assessment. This will have identified where the potential for accidents and incidents is and have provided information on the biological agent(s) and their effect if containment is lost: for example, whether the agent could be transported further by wind, survive in the environment, affect the community, and affect animals or plants.

Consult with external emergency services as required, especially at higher containment levels. Such services will need to be aware of their role and any potential risk of exposure. For example, under what conditions can they enter a containment laboratory, and what protective measures are required to protect themselves and prevent the spread of contamination? They need to be aware that their actions will not increase the risk: for example, by uncontrolled release of contaminated fire water. What precautions will the emergency services need to take when leaving the laboratory? Consult and provide adequate information as necessary with hospitals or paramedics who may have to handle infected patients. Consider liaison with the public and media. Liaise with relevant Government Departments, agencies and authorities pertaining to any biosecurity issues as required.

In developing the emergency plan, consider and detail:

- roles and responsibilities;
- what to do with the biological agents – will alternative safe transport and storage for high-risk biological agents be required?
- what fire-extinguishing agent is suitable – for example, will the use of water spread the contamination?
- will fire water need to be contained and decontaminated?
- the safe shutdown of a containment laboratory following or during an emergency;
- out-of-hours response (for example, how to contact responsible people and implement an emergency response when the full complement of staff may not be on site);

- effects on equipment, systems and control measures; and
- exposed personnel and contaminated clothing and equipment – this may include core workers, contractors, emergency service personnel and their equipment. For example, some equipment such as firefighter or ambulance equipment may need to be held on site until it is effectively decontaminated. Ensure spare clothing is available.

At higher containment levels, include details and schematics or technical drawings of the laboratory, sewage/effluent, drainage, ventilation and air handling systems. This information will be contained in the Safety File (see Chapter 2) but may require duplication in the emergency plan for ease of use. Hold the emergency plan securely and ensure it is readily available in an emergency.

Check all relevant emergency and safety equipment regularly. Test emergency plans, especially at higher containment levels, by means of drills and exercises (activities that test and evaluate the response to the emergency).

Contingency plans

Put in place contingency plans to ensure resumption of normal operations as soon as possible in order to minimise losses and ensure that operations are safe and secure. Consider the need for adequate redundancy, availability of alternative facilities or personnel, alternative means of decontaminating materials and the provision of backup systems such as power supplies.

Types of incidents and accidents

Examples of incidents and accidents that require consideration and planning include:

- exposure to biological agents via:
  - human blood or body fluids exposure;
  - sharps injury; or
  - aerosolisation of infectious organisms.
- release of a biological agent via:
  - spillage of infectious materials or pathogens outside of the MSC, within the MSC, within a centrifuge, within the laboratory – for example, if an egg injected with virus were to fall and break – or on protective clothing;
  - an infected person;
  - leakage of infectious material; or
  - inadequately decontaminated biological agents, material or waste.
- failure of:
  - PPE, such as a tear in a glove or failure of a powered air-purifying respirator (PAPR);
  - chemical disinfection or autoclaving
  - utilities, for example power, water, or steam failure; or
  - equipment such as ventilation, the autoclave or the MSC.
- receipt of:
  - a leaking package containing pathogens in the receiving area;
  - a suspicious package or an unsolicited, mislabelled or unlabelled sample or culture; or
  - an unexpected high-risk biological agent, for example, a group 4 biological agent in a containment level 3 laboratory.
- breach or loss of containment – consider the mode and scale of release, the effects of weather and other environmental influences in such cases:
  - release of a live pathogen into a sewer;
  - breakage of a container during transport;
  - fire or a broken window in a high-containment facility;
  - release of uncontaminated waste;
  - natural risks for example, floods or other events that could affect containment;
- unexpected virulence (unknown biological agents or biological agents expected to be avirulent);
- collapse of a person in the laboratory, especially in a high-containment facility; or
- direct evacuation while laboratory personnel are working in a high-containment facility.

Biosecurity plans

Depending on the containment level and the type of agents held within the laboratory, develop procedures and emergency plans for biosecurity issues such as:

- a break-in in the laboratory;
- sabotage, vandalism, or tampering;
- an unauthorised individual in containment;
- loss, theft, misuse, diversion or intentional unauthorised release of an agent or sensitive data, information or equipment;
- potential violence or aggression;
- bomb threat or some other threat to the laboratory;
- explosion in containment that results in access to the pathogen storage area; and
- breach in electronic information systems in relation to high-risk biological agents.

Information, instruction and training

You must provide employees, their safety representative or both with information, instruction and training in relation to actions in the case of incidents: for example, how to shut off relevant services safely in an emergency so that additional hazards are not created, or how to use spill kits and dispose of them safely. Provide refresher training to ensure that people remain competent to deal with incidents such as spillages.

The Biological Agents Regulations specifically require employers to provide written instructions at the place of work and, if appropriate, to display notices that at a minimum include the procedures to follow in the case of a serious accident or incident involving the handling of a biological agent and the handling of a group 4 biological agent.

Dealing with spillages

Improper handling of a spillage or breakage may lead to increased spread of the contamination and increased risk of infection. Dealing with spillages will depend on several factors such as:

- the nature of the spill – is it a liquid or solid?
- the biological agent or type of material involved – is it pathogenic?
- is it an environmental hazard?
- are there associated hazards?
- size or volume of the spill – the quantity, low or high titres or concentrations;
- location of the spill – for example, is it within an MSC, in or outside of the laboratory, in a centrifuge or in a public area?

The creation of aerosols is a major risk when there is a spill or breakage of infectious material. If glassware is involved, take care as broken pieces may pierce the skin. Air currents generated by ventilation may move infectious aerosols around. Employees in the area or those responding to the spillage may recirculate settled infectious materials. This may result in a larger contaminated area. So, prompt action is required to handle spillages to prevent escalation of harm and spread of contamination.

Draw up specific spill plans: for example, for spills in the laboratory, in the MSC, in a centrifuge and for specific biological agents. Handle leaking containers in an MSC and disinfect the exterior. PPE must be appropriate for the risk involved and detailed within the plan; for example, full-face respirators may be required in certain circumstances (see Chapter 14). Spare clothing may be required in the event of serious spillages. Provide specific training for dealing with spillages covering risk recognition, communication, reporting and decontamination.

Spill kits

Ensure spill kits are readily available and contents are based on the anticipated types of spills. Purchase kits or prepare in-house kits. Kits will usually contain, at a minimum, absorbent material sufficient for the quantity of the spill, disinfectant compatible with the biological agent and material, PPE, disposable (or autoclavable) tools such as forceps and a scoop and simple instructions for use. As there is potential for exposure to aerosols after a spill, ensure appropriate respiratory protective equipment (RPE) is available.

Include waste containers, barriers or tape and warning signage to prevent persons from entering the contaminated area, and signage for writing contact details and the earliest time of permitted re-entry to the laboratory, as required. Ensure the spill kit location is signposted and check contents on a regular basis. The assigned person must ensure that the contents remain in date and suitable for the application.

Handling spillages

Deal with all spillages promptly to prevent further contamination. Contain spillages where possible and safe to do so. Outlined below are procedures that you should tailor to individual circumstances.

Small or low-risk spillages

Deal with small spillages, where the material or biological agent involved is low risk and there is no significant aerosol risk or generation, promptly by covering the affected area with absorbent material and an appropriate disinfectant for the biological agent concerned.

- Define and isolate the contaminated area.
- Notify colleagues of the spillage.
- Wearing appropriate PPE, remove any sharp items or lumps using sturdy forceps.
- Apply absorbent material to the spill, remove bulk and reapply.
- Pour rather than spray disinfectant to prevent aerosol dispersion over the contaminated area. Prevent further spread of the spillage by gently pouring the disinfectant from a low height, spiralling inwards. Adhere to the disinfectant's contact time and use it in line with the laboratory's emergency plan.
- Clean the area and dispose of all waste as infectious waste.

If in doubt about the severity of an incident, treat it as a major spillage and notify the relevant people in charge.

Major or high-risk spillages

In the event of a major spillage (or spillages) involving high-risk biological agents, airborne/respiratory pathogens or aerosol formation, evacuate people from the area, if safe to do so. Take care to avoid spreading contamination. Where possible, confine the contamination and notify relevant people. Any exposed persons should seek medical assistance or support. In such cases, other personnel may be required to manage the spillage. Remove contaminated clothing in order to prevent further contamination. Ensure availability of appropriate spare clothing.

Allow adequate time for any aerosols to settle. Depending on the biological agent, this may take several hours. Post 'no entry' signage during this time, along with contact details and the earliest time of permitted re-entry to the laboratory. If the area needs to be re-entered during this time – for example, to remove an injured person – or after this time, wear suitable PPE, including clothing (see Chapter 14).

After the appropriate time, clean and decontaminate the area. Identify the spill area – at a minimum this will be the spillage and the surrounding zone to at least twice the area of the visible spillage. Cover with disposable absorbing material soaked in appropriate disinfectant for the biological agent involved. Adhere to the appropriate contact time for the disinfectant and treat all waste as infectious waste.

Depending on the biological agent involved, fumigation may be required, for example if a spore-forming agent or a higher-risk agent is involved (see Chapter 9). Appropriately decontaminate all equipment and material used in handling the spillage by a validated means. Keep records of spillages where there is potential for infection. Notify the HSA and other relevant agencies as per legal requirements (see below).

First aid

Provide and maintain first aid provisions in line with the requirements of Chapter 2 of Part 7 of the General Application Regulations – commonly known as the First-Aid Regulations. Clearly mark first aid equipment and ensure that it is easily accessible and sufficient for the number of workers. Document the details of the arrangements made for the provision of first aid in relation to the specific biological agents encountered, the names of any occupational first-aiders and location of equipment and facilities. Check and maintain all first aid equipment regularly.

Accident and incident informing and reporting

The Biological Agent Regulations set down specific requirements in relation to informing people about accidents and incidents and the reporting of them.

Employees must report immediately to their employer, or the person responsible for safety and health at the place of work, any accident or incident of which they are aware that involves exposure or a risk of exposure to or the release of a biological agent involving or likely to involve a risk to the health and safety of employees. Immediate reporting is vital with biological agents. This enables quick action to prevent harm such as employee infection and potential disease, the further spread of the biological agent and possible infection of co-workers or others.

Reporting also allows follow-up of accidents and incidents to prevent a similar or repeat occurrence in the future. Put in place appropriate reporting procedures that clearly identify what requires reporting, to whom to report and the responsible people to ensure that follow-up occurs to identify the roots cause(s) and prevent repeat occurrences.

Bring any cases of unexplained illness to the attention of the laboratory supervisor or manager. This enables establishment of whether the symptoms are work related and whether other workers could similarly be exposed. Monitor employee absenteeism to ensure no linkage to a laboratory-acquired infection (LAI).

You must immediately inform employees, the safety representative or both of any accident or incident that may have resulted in the release of a biological agent that could cause severe human infection or illness (or both). Inform them as quickly as possible of the causes and the measures taken or to be taken to rectify the situation.

Notify the HSA immediately of any accident or incident that may have resulted in the release of a biological agent that could cause severe human infection or illness (or both). This mainly applies to group 3 and group 4 biological agents. The quickest means is usually by telephoning the HSA Contact Centre on 0818 289 389 (or +3531 614 7000) or by emailing contactus@hsa.ie. Information to notify includes full and detailed information on:

- the employer name/legal entity and registered address,
- the location of the accident or incident,
- the circumstances of the accident or incident,
- the biological agent involved,
- the quantities involved,
- possible effects of the accident or incident on workers' or other persons' health, and
- the measures taken/being taken to mitigate the effects of the accident or incident – including whether the relevant emergency services and Government Departments, agencies and authorities have been notified.

Where a GMM is involved, there is also a requirement to notify the EPA of any significant and unintended releases that could cause an immediate or delayed hazard to human health or the environment.

Chapter 13. Notification

Under the Biological Agents Regulations, there is a legal requirement for you to notify the HSA if planning to use or carry out diagnostic services in relation to certain biological agent risk groups for the first time (see Figure 8).

The purpose of notification

The purpose of notification is to enable the HSA to know who is working with the various risk groups (the legal entity) and where the work is carried out or the agent is being stored. Notification is not a licensing or authorisation system – the HSA does not license, approve or authorise laboratories to work with biological agents. The responsibility for ensuring that appropriate risk assessments and preventive controls measures are in place when working with a biological agent lies fully with the employer.

Required notifications

Notification is required 30 days before commencement of work with respect to:

- first-time use of group 2 biological agents – the subsequent use of further/new group 2 biological agents does not need to be notified;
- first-time use of group 3 biological agents – the subsequent use of new group 3 biological agents does not need to be notified, except where the employer provisionally classifies that biological agent (self-classifies); and
- first-time use of group 4 biological agents – notify all subsequent use of any further/new group 4 biological agents.

The notification for first-time use of group 2 and group 3 biological agents is usually a once-off notification (except when self-classifying a new group 3 biological agent). In certain circumstances, the HSA may request that the use of specific biological agents is also notified.

Complex places of work such as universities or employers with laboratories at multiple locations will need to notify for the building or the location. Where different legal entities are sharing a place of work and working with the same notifiable risk group, both entities will be required to notify.

Use of a biological agent

'Use' implies the intentional use of a known biological agent risk group. If biological agents of risk groups 2-4 are being stored in a culture collection, notification is required as the collection will need to be maintained and this will involve viability checks of the agent and deliberate propagation.

In certain areas of work such as medical diagnostics or microbiological research, there may be a transition from 'non-use' of a biological agent to use of a biological agent; for example, if the biological agent identified in the initial diagnosis is propagated for the purpose of further characterisation such as subtyping or resistance testing. In such cases, notification will be required. Notification of the use of cell cultures is not required unless deliberate infection work is being carried out.

Diagnostic laboratories

Diagnostic laboratories may handle samples that are likely to contain biological agents. There is no requirement to notify where the laboratory is providing a purely diagnostic service in relation to group 2 or group 3 biological agents. However, if a laboratory plans to provide a diagnostic service in relation to a group 4 biological agent, notify the initial intention to do so 30 days in advance of carrying out this work for the first time. If, subsequently, a diagnostic service is planned by the same laboratory for a different group 4 biological agent, notify this also 30 days in advance of this work. Where defined control strains are used in diagnostic detection work, this would be considered intentional use of a known biological agent and notification requirements must be met.

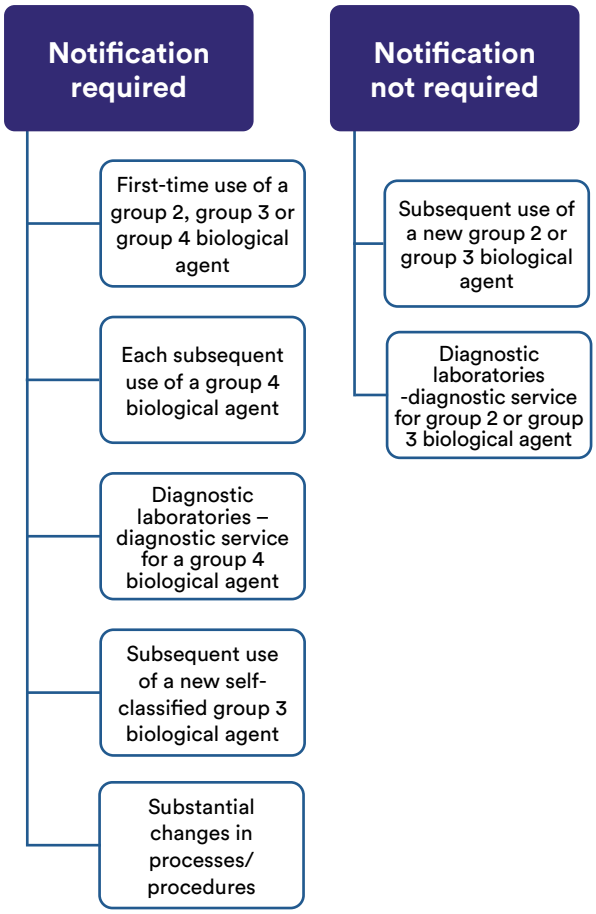


Figure 8: The notification process

How to notify

Notification may be made using the biological agents notification form (available to download under topics/business licensing and notification requirements at www.hsa.ie) or by other suitable methods. If using an alternative method, provide the following legally required information:

- The name and address of the employer and, where different, the place of work. This must be the legal entity, and must include the company's registration number where applicable (see the Companies Registration Office Ireland or contact your company's finance department for this number). Include the Eircode of the place of work, where available, in the address.
- The name and competencies of the person responsible for safety and health at work. Include details of the local area management personnel who have day-to-day responsibility for health and safety within the laboratory, area or department. Provide information that demonstrates whether the person has the competencies to manage or supervise work activities with the notified risk group – for example, previous experience working at the containment level or with the biological agent.
- The results of the risk assessment.
- The species of the biological agent.
- The protection and preventive and risk reduction measures that are envisaged.

Provide sufficient information about the risk assessment and preventive measures in order to demonstrate that you have identified the hazards and risks associated with the agents in conjunction with the planned work. Include information such as the route of exposure, how workers may be exposed during the course of their work, what the potential outcome of exposure may be, and what control measures are in place to prevent the exposure. It is not sufficient just to identify the biological agents risk group and list the containment level used.

The Biological Agents Regulations require submission of notifications to the HSA at least 30 days before commencing the work. Take account of this regulatory period when planning the work, as the Regulations do not facilitate derogations.

Submit notifications:

- by email to bioagents_notif@hsa.ie, or
- by post to Biological Agents Notifications, the Health and Safety Authority, The Metropolitan Building, James Joyce Street, Dublin 1, D01 K0Y8.

Retain a copy of the notification for your own records. For large places of work – for example universities – we recommend that a central co-ordinator submit notifications.

Receipt of the notification

Upon receipt of the notification, if insufficient information is provided or the notification is incomplete and a timely response to requests for further information is not received, the 30-day period will not commence until the appropriate information has been received. Where an HSA inspector requests further information, this is a bona fide request from an inspector. Failure to comply with a bona fide request is an offence under the 2005 Act.

Under Regulation 4 of the Biological Agents Regulations, the HSA can prohibit the use of the biological agent(s) referred to in the notification or require the application of additional controls to safeguard the safety, health and welfare of employees from exposure to the notified biological agent(s).

Re-notification

Re-notification is required for all groups if there are substantial changes, of importance to safety and health at work, to either (or both) processes or procedures that result in the original notification being invalid or out of date. Examples of this include where:

- new information comes to light that affects the results of the notified risk assessment findings;
- the protective and preventive measures identified in the original notification change – for example, the work activity is scaled up from laboratory scale to production scale and different protective and preventive measures are required;
- the legal entity ceases to work with the notified group or ceases business; or
- the company or establishment changes its legal name.

Notification to the EPA

The EPA also has specific notification requirements in relation to the contained use of GMMs.

Chapter 14. Individual protection – work clothing, special protective clothing and PPE

Where a risk to health or safety is caused by working with a biological agent, the Biological Agents Regulations require that you provide all employees at risk with suitable work clothing, special protective clothing and PPE.

Laboratory clothing and PPE

Within the laboratory, various types of clothing can be used – laboratory coats, gowns, aprons, head covers, sleeve protectors/oversleeves, coveralls, full body suits, boot/shoe covers and footwear. The clothing may be designed and used for different reasons – as PPE to prevent employee harm, to prevent transfer of contamination outside the workplace or to prevent product contamination, or soiling of own clothes.

PPE is usually regarded as the last resort in the hierarchy of control measures under the 2005 Act. This is because it does not remove the hazard. PPE only protects the worker, it can fail and it relies on correct fitting, maintenance and use of the equipment. In addition, achievement of theoretical levels of protection is rare, the use of PPE can restrict the wearer and, in some cases, the wearer can feel more protected than they actually are. However, the Biological Agents Regulations recognise that where it is not technically possible to prevent exposure to a biological agent, the use of both collective protective measures and individual protection measures such as PPE will be required.

What is PPE?

PPE is defined in the General Application Regulations and is any equipment designed to be worn or held by an employee to protect them against one or more hazards likely to endanger their safety and health at work. The term 'PPE' includes personal protective clothing (PPC), RPE and any interchangeable components for the equipment that are essential for providing the protective function of the equipment, such as filters for respiratory equipment. It does not include working clothes and uniforms unless specifically designed to protect the employee's health and safety.

There are many types of PPE. The aim of PPE is to protect the routes of entry into the body from any residual risks to health and safety (see Table 15) or to provide protection when engineering controls are not feasible, for example during laboratory maintenance.

Whether PPE is required and the choice of PPE will depend on the biological agents risk assessment, other hazards that may be present and the containment and control measures that are in place. Chapter 3 of Part 2 of the General Application Regulations (S.I. No. 299 of 2007 as specifically amended by S.I. No. 610 of 2021 – commonly known as the PPE Regulations) requires you to assess PPE before use to ensure it is fit for purpose. The Regulations also set down requirements for PPE use, maintenance, replacement and provision of instruction, information and training. Wear all PPE as identified through the risk assessment.

Table 15: Routes of exposure and PPE potentially required

Route of exposure	PPE potentially required
Inhalation	Respiratory protective equipment (RPE)
Absorption	Skin/body protection – face, eye, hand, leg, arm, head, foot
Inoculation	Hand protection – cut-proof gloves
Ingestion	Hand protection – gloves; splash protection – visor

Personal or street clothing

Personal clothing or street clothing (the employee's own clothing) is not PPE; however, it offers a degree of protection when the employee is working in the basic laboratory. For example, where safety footwear is not deemed necessary, wear sensible, closed-toe shoes rather than open-toe shoes. Some clothing may be hazardous when worn in the laboratory: for example, loose clothing may catch on equipment or knock over items. Clothing must also be capable of being worn under a laboratory coat.

Put in place a clothing and jewellery policy for personnel working in laboratories, identifying what is suitable attire. The wearing of jewellery in laboratories, especially hand and arm jewellery other than a plain wedding band, is not generally recommended.

Working clothes, special protective clothing, laboratory coats and gowns

In the context of the Biological Agents Regulations, working clothes are clothing worn at work and not worn home due to the risk of contamination. Special protective clothing is other special clothing, not specifically designed as PPE but that still may have some protective function, such as oversleeves or shoe covers. Special clothing, where required, is supplied by the employer. It may be worn to indicate job status or designated work area and to protect street clothing against limited splashes and spills when working with non-hazardous materials.

Depending on the material and the manufacturing, some laboratory coats may be classified as special clothing while others are classified as PPE. For example, standard laboratory coats – that is, front-opening white coats, made of loose-weave cotton or a cotton blend with open necks, wide cuffs and gaps between the sleeve and glove – are not considered as PPE but as special clothing, as they are not liquid resistant. Such coats will not offer specific protection if one is working with infectious materials. Other laboratory coats may be manufactured to electrostatic control standards (EN 61340-5-1) or as protective clothing against liquid chemical standards (EN 13034). As a result, one type of laboratory coat may not work for all laboratory operations.

A recommendation is colour coding of coats that have different properties. Provide workers with several sets of special or protective clothing so that they can change in the event of contamination.

Where used, laboratory coats must be appropriate for the hazard encountered, fit correctly, not restrict movement, have full-length sleeves and not create additional hazards. Generally, at CL1 and CL2, the wrap-over-style coat (Howie-style coat) may be used. These coats have snap closures, to ensure easy removal in the event of contamination, and tight-fitted cuffs (elastic or knitted), over which gloves fit; no skin should be exposed between gloves and the sleeve. The coats fasten close to the collar to provide optimal protection and must only be worn in designated work areas and worn fully closed with sleeves rolled down.

Maintain coats in good repair with no holes, rips or tears that could allow hazardous substances to enter. Where coats are reusable, clean them regularly. Remove coats contaminated with hazardous biological agents immediately and decontaminate (via autoclaving) before washing or disposal. Control and organise laundering and, ideally, carry it out on site. Do not take laboratory coats home to launder.

Provide separate well-defined storage areas for protective clothing and street clothing. When they are not in use, hang laboratory coats on a designated peg either in a lobby before entry to the laboratory or at the entrance to it. Store laboratory coats separately from street clothing and, in order to prevent cross-contamination, do not hang them over other laboratory coats.

Generally, solid-front, back-closing laboratory gowns or coats, with close-fitting cuffs and quick-release studs or fastenings, or coveralls are used at CL3. These provide better protection and must be autoclaved prior to laundering or disposal. Depending on the pathogen, disposable head covers and dedicated sterilisable footwear may be worn. Depending on the risk assessment, showering may be required.

At CL4, a complete change of clothing, including undergarments, is required. Remove clothing after work, in the dirty side of the changing area, and place in a container for autoclaving. One-piece, positive pressure-ventilated impervious

suits are worn in suit laboratories. Showering is required before leaving the area.

Types and categories of PPE

There are three categories of PPE:

- Category I – simple design PPE – some laboratory coats may fall into this category;
- Category II – PPE which is neither simple nor complex; and
- Category III – Complex design PPE.

PPE specifically designed for protection against micro-organisms will fall under PPE of complex design Category III (protects against risks with very severe consequences). Category III PPE must be CE marked, type tested and marked with the number of the notified body.

Considerations for selecting PPE

Improperly selected or used, or unmaintained, PPE will not provide the appropriate protection and may give the worker a false sense of security. As PPE can be a complex area, seek advice and information from suppliers and manufacturers, qualified occupational hygienists or appropriate health and safety professionals. Identify employees who are required to wear PPE and supply appropriate, correct-fitting equipment and clothing.

In selecting PPE, take account of the nature of the work, including the length of time PPE is worn, the individual's needs and the fact that some PPE can impair dexterity or visibility. Ensure the PPE selected is compatible with any other PPE that may need to be or is required to be worn. Consider combination effects: for example, in the laboratory, protection may also be required against chemical exposure or exposure to sharps. Provide PPE free of charge to employees and do not use past any expiry date. Consider PPE for visitors and contractors and for normal working and emergencies.

Remove contaminated PPE correctly on leaving the working area in order to avoid spread of contamination. Keep it apart from uncontaminated clothing and equipment. Safely discard any disposable PPE. Clean and decontaminate reusable PPE and keep it in good working order and hygienic condition. Ensure mechanisms are in place for provision of replacement and spare PPE, routine checks and maintenance. Store reusable PPE where it cannot be contaminated by biological agents and contaminate outdoor clothing.

Instruction, information and training in use of PPE

The incorrect use of PPE can result in contamination of the worker, the environment and other people; for example, if the worker touches their face or surfaces with contaminated gloves. Employees required to wear PPE must receive appropriate instruction, information and training with regard to its use. This should cover as appropriate, when PPE is required, what it protects against, what it does not protect against, its limitations, how to wear it correctly (putting it on (donning) and taking it off (doffing)), the lifespan, and how to check, clean, decontaminate, maintain, store and discard of it safely. A documented procedure can assist here. In providing such training, take account of the manufacturer's instructions and keep records of the training. Mirrors, buddy systems, and posters denoting correct procedures can help employees wear PPE correctly. In addition, ensure adequate safety supervision is in place.

Employee duties with respect to PPE

Employees have a duty to use required PPE properly and report any defects in or damage to the PPE immediately. They must participate in any training or instruction provided on PPE and inform their employer of any health/medical conditions they have that might be affected by the use of the PPE provided to them.

Personal protective clothing (PPC)

PPC may cover or replace personal clothing. With respect to biological agents, PPC is a garment designed and intended to afford protection to the skin against exposure to or contact with infective agents. Where such protection is required, the clothing material must be certified to EN 14126, the standard for protective clothing performance against infective agents. This standard is not a stand-alone standard; it refers to the material only and does not, for example, consider seam or zip penetration. Account of the relevant chemical protective clothing standard for design and construction of the garment will also be required (see below).

Standard EN 14126

Standard EN 14126 Protective clothing – Performance requirements and tests methods for protective clothing against infective agents references four tests to assess a fabric's ability to resist penetration of bacteria or viruses via different routes of contamination, such as in a pressurised liquid (like a body fluid) or on a contaminated surface (see Table 16). Depending on test performance, a class is assigned, either 1-6 or 1-3 depending on the test.

The higher the number, the better the material's resistance under the test conditions. Note that all four tests do not need to be performed for a garment to be certified to EN 14126. Therefore, when selecting protective clothing against infective agents, it is important to check what tests have been performed and the assigned class, to ensure that the clothing material is suitable for the biological agent and the expected transmission method.

Table 16: Tests referenced under EN 14126

Test method	Description	Class
ISO 16604*	Resistance to penetration by contaminated liquids under hydrostatic pressure	1-6
EN ISO 22610	Resistance to penetration by infective agents due to mechanical contact with substances containing contaminated liquids	1-6
ISO 22611	Resistance to penetration by contaminated liquid aerosols	1-3
ISO 22612	Resistance to penetration by contaminated solid particles	1-3

*ISO 16603 is a precursor test to ISO 16604.

Chemical protective clothing standards

PPC against infective agents must also meet the appropriate chemical protective clothing standard (see Table 17). There are currently five types of chemical protective clothing, based on the chemical state (liquid – light aerosol, liquid or jet spray, dust, or gas). Type 1 provides the highest protection as it is sealed. Type 3 and Type 4 garments usually have sealed seams (welded or stitched and taped seams and a sealable front fastening), whereas a Type 5 or Type 6 garment will normally have standard stitched seams and a single zipper with a simple cover. Type 1 and Type 5 are full body types, whereas Type 3, Type 4 and Type 6 include partial body (PB) garments – covering only a part of the body – such as aprons, gowns or jackets.

Table 17: Chemical clothing protection standards

Type	Level of protection	Chemical protective clothing product standard
Type 1	Gas-tight suits Type 1a: gas-tight suit with breathing apparatus worn under the suit Type 1b: gas-tight suit with breathing apparatus worn outside the suit Type 1c: gas-tight suit with internal overpressure (ventilated suit)	EN 943-1 EN 943-2 (for emergency teams)
Type 3	Protection against a jet of liquid	EN 14605
Type 4	Protection against a liquid spray	EN 14605
Type 5	Protection against dust and solid particles	EN ISO 13982-1
Type 6	Protection against small splashes (low-level protection)	EN 13034

Protective clothing against infective agents will be CE marked, reference the type and carry the suffix B (for example, Type 5-B) and the protection against biological hazard pictogram (see shield symbol – Figure 9). Certain clothing may also be dual purpose – certified as PPE and as a medical device. Read and follow the manufacturer's instructions for use and take account of any limitations of the clothing.

Hand protection – gloves

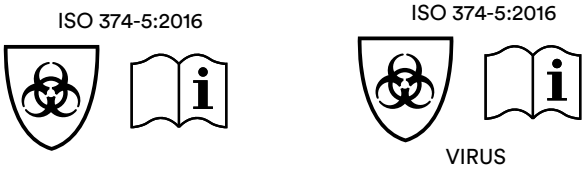
Gloves may be worn for different purposes within the laboratory, for example to protect the individual against hazards such as biological or chemical agents, hot or cold items or cuts from sharp instruments, or in some cases to protect the work from contamination. Where it is worn, it is important that the employee understands what the glove is protecting against.

Many different types of gloves are available. As there is no one-type-fits-all glove that protects the employee from all hazards, proper selection is important to ensure that the most appropriate type of glove is selected for the work and any associated hazards and risks. Gloves are effective only if selected and used properly. Ensure they do not create an additional hazard, for example if working with a Bunsen burner.

Factors to consider when selecting gloves are the type of work activity, length of use, grip, glove length, dexterity, comfort and insulation. Select gloves that do not cause allergic reactions such as dermatitis. Synthetic materials such as nitrile have a lower skin allergy risk than latex. If using latex, use powder free in preference to powdered.

Gloves specifically for protection against biological agents

Appropriate gloves can form a protective barrier where contact with potentially contaminated surfaces, samples or equipment can occur. Gloves designed to provide worker protection against micro-organisms must meet the performance requirements of European Standard EN ISO 374-2, and the manufacturer's box containing the gloves should be marked with the protection against biological hazard pictogram. Gloves specifically designed for protection against viruses, as well as bacteria and fungi, must meet the requirements of EN ISO 374-5 and have the word 'virus' written underneath the shield (see Figure 9). Gloves that comply with EN 455 only are medical devices and designed for patient protection and not worker protection.



Marking of gloves protecting against bacteria and fungi

Marking of gloves protecting against viruses, bacteria and fungi

Figure 9: Markings for gloves providing protection against micro-organisms

Employees should know how to interpret the information provided on glove packaging. As gloves will deteriorate over time, check expiry dates to verify that they are still in date. The AQL is the acceptable quality level and is the highest number of defective gloves per 100 gloves (percentage defective gloves in a batch – see Table 18). Disposable gloves/single-use gloves are indicated by a 2 with a diagonal through it, meaning they should not be used a second time.

Table 18: Acceptable quality level for gloves

AQL	Penetration	Minimal for
<4.00	Level 1	
<1.50	Level 2	Risk group 2 bacteria and fungi
<0.65	Level 3	Risk group 3 and risk group 4 bacteria and fungi

In some cases, hand protection, such as in the form of liquid-tight gloves that provide protection against mechanical and biological risks, will be required: for example, gloves meeting EN ISO 21420 (the basic glove standard), EN 388 (standard for mechanical risks), EN ISO 374-2 and an AQL ≤ 1.5.

To ensure that gloves fit the worker correctly, provide different sizes of gloves. If double gloving, use different-coloured gloves so that any breakages will be more visible. Check gloves for defects before donning (pre-use checks). At higher containment levels, pull gloves over the wrists of the gown rather than wearing them inside the gown. Spraying disinfectant on gloves

may damage the glove integrity and reduce the protection provided. Store gloves in a dry place away from direct sunlight to avoid ultraviolet degradation. Change gloves when they are damaged, they become contaminated or their integrity is compromised, or when changing experiments. This will help to prevent personal contamination and prevent cross-contamination of other items or equipment. Wash hands after glove removal and autoclave contaminated gloves before disposal.

Eye and face protection

Eye and face protection may be selected and worn for different purposes within the laboratory: for example, for impact protection, protection against splashes or droplets from biological or chemical agents such as disinfectants, or protection against ultraviolet radiation. Eye protection is available in different forms – safety glasses, goggles, face shields and visors. It is important to select the correct protection and that workers understand when, where and why such protection is required. The main standard for eye and face protection for occupational use is EN ISO 16321-1, while EN ISO 19734 provides guidance on the selection, use and maintenance of eye and face protection.

Conduct work with infectious biological agents that has potential to create splashes or aerosols in an MSC. In general, wear safety glasses to protect against moderate eye impact and minor splashes; wear safety goggles against chemical splashes, impact and dust. Face shields will protect the face against dust, splashes or sprays but will not provide impact protection. Wear these in conjunction with safety glasses or goggles as appropriate. Examples of where eye protection or face protection will be required are when dealing with chemicals, when opening containers with potential for projection of infectious droplets, where there is potential for splashes of biological agents, when heating up agar on hot plates, when removing stocks from liquid nitrogen or when opening an autoclave.

Prescription glasses or contact lenses will not protect the eye. Provide, as appropriate, prescription safety glasses or goggles. Put on eye protection with clean hands to prevent contamination. Ensure it fits correctly in order to prevent the worker having to adjust the protection, possibly using contaminated hands.

Remove contaminated eyewear immediately using clean hands, in order to avoid head contamination. Clean, disinfect where required, and store eye protection in accordance with the manufacturer's instructions, and keep it away from ultraviolet light. Clean and safely decontaminate eye and face protection before disposal.

Foot protection

Wear suitable, well-fitting closed-toe shoes to prevent slips, trips and falls or exposure to hazard materials. Ensure footwear is easy to decontaminate, as appropriate. Overshoes may be required to prevent shoe contamination or transfer of contamination outside the contained area. For higher-risk work activities, easily decontaminated safety shoes or boots with puncture-proof soles and toecaps to EN ISO 20345 may be required.

Respiratory protective equipment (PPE)

Where the risk assessment identifies that respiratory protective equipment is required for protection against biological agents, there are two main categories of protection:

- Respirators – these purify the ambient air breathed in by passing it through a medium, which removes the contaminants; in other words, they filter the contaminated air. They may be in the form of disposable half face, reusable half face, full face or power assisted respirators (powered air-purifying respirators (PAPRs)). PAPRs use an electric blower to push ambient air through a filter and can have a mask or hood/helmet – hoods/helmets will not require fit testing (see below). No respirator will prevent the inhalation of all particles.
- Breathing apparatus – these supply uncontaminated air or breathable gas from an uncontaminated source, for example from a line from an air compressor or from a self-contained unit/ high-pressure cylinder worn by the user. Such equipment may be used in CL4 laboratories, in a situation where there is a high risk of an emergency or exposure to a risk group 4 agent or where oxygen is deficient. Standard EN 12021 outlines the minimum quality standards for breathable compressed air.

Filters

Filters are classified as particle, gas/vapour, multi-gas or combined (particle and gas/vapour). Airborne micro-organisms can be considered as particles. Particle filters are classified and tested according to their efficiency – P1 (low efficiency), P2 (medium efficiency) and P3 (high efficiency) (see Table 19). Use the highest efficiency for protection against risk group 3 pathogens where required.

Table 19: Filter efficiencies and European Standards

Disposable half-mask respirator (EN 149)	Filter efficiency	Reusable half mask (EN 140)/full-face mask (EN 136) and particle filter (EN 143)	Filter efficiency
FFP1	≥80%	P1	≥80%
FFP2	≥94%	P2	≥94%
FFP3	≥99%	P3	≥99.95%

Disposable filtering facepieces are marked with the manufacturer's name or logo, model number, EN 149, CE mark, the notified body number, and NR (non-reusable – designed for a single work shift of no more than 8 hours) or R (reusable).

Filters used in reusable half- or full-face masks will be similarly marked but state EN 143 for the particle filter. Filters for power-assisted hood devices will have, in addition, EN 12941 and TH1, TH2 or TH3 (TH meaning turbo hood) marked. Filters for power-assisted mask devices will have EN 12942 and TM1, TM2 or TM3 (TM meaning turbo mask) markings. Where product sterility is important, check that exhaled air is filtered; for example, air exhaled via FFP3 exhalation valves (shrouded or not) and PAPRs is not filtered.

In selecting RPE, consider combined risks – for example, biological agents and disinfectants. In such cases, combined filtration may be required whereby particle protection may require supplementation with a relevant gas filter (EN 14387) or breathing apparatus may be required.

Discard disposable filtering facepieces and particle filters used for protection against micro-organisms after first use, as organisms may grow and pass through the material. Consider all used filters as potentially contaminated and dispose of appropriately. Ensure safe filter changing procedures are in place, to avoid hand contamination, for any PAPRs with high-efficiency filters.

Clean, decontaminate, store (do not hang RPE on hooks as it may cause deformation of the equipment) and maintain respirators with non-disposable components and breathing apparatus in accordance with manufacturer's instructions and in a manner that minimises the contamination of the user or other persons.

Fit testing

Provide face fit testing for tight-fitting respirators before initial use. This ensures that the protection is adequate for the worker. Repeat fit testing if a different make of RPE is used, if the worker's body weight or face changes (for example, if there are dental changes or if scarring occurs around the seal area of the RPE), or if the worker complains of discomfort. Use loose-fitting hoods where workers have beards or workers are unable to achieve an adequate fit with a disposable, half- or full-face respirator. Take care that any other PPE worn does not interfere with the RPE, conduct RPE fit testing while wearing all the required PPE. Keep records of fit testing. In addition, before commencing any work, the operator must conduct a face fit check when wearing tight-fitting respirators in order to ensure a good face seal.

Chapter 15. Equipment

Equipment failure or incorrect use of equipment can result in loss of containment and potential exposure of workers and others to pathogens. This chapter concentrates on two important pieces of equipment used to contain biological agents – the autoclave and the microbiological safety cabinet. Other equipment and items are briefly covered.

Equipment used at work must comply with the requirements of Chapter 2 of Part 2 of the General Application Regulations – commonly known as the Use of Work Equipment Regulations. In addition, under the 2005 Act, you must consult with employees or their safety representatives in advance and in good time regarding the planning and introduction of new technologies, particularly in relation to the consequences of the choice of equipment, working conditions and the working environment for the safety, health and welfare of employees.

Autoclaves

Autoclaves are classified as pressure equipment and fall under Part 10 of the General Application Regulations (specifically S.I. No. 445 of 2012 – commonly known as the Pressure Systems Regulations). They use time, pressure and temperature to sterilise, which can vary depending on what is being sterilised. Appropriate commissioning and validation must be carried out. Certificates of thorough examination, maintenance plans and documented safe systems of work must be in place.

Hazards associated with autoclaves

Autoclaves involve close interaction with the user, so user awareness of the hazards and risks is important. Insufficient inactivation or improper selection and use of the autoclave can lead to release of biological agents, for example, on opening the autoclave, via exhaust gases, condensate or leaks. The handling or the disposal of improperly inactivated materials or waste may also affect other people outside of the laboratory.

The main physical hazards are due to heat or steam – burns or scalds from steam, hot materials, fluids and liquids or the autoclave itself. As autoclaves are pressure vessels there is potential for explosion and ejection of parts, contents or steam; for example, if the pressure relief valve fails or corrosion or cracks weaken the vessel. Ergonomic (including manual handling) injuries may occur during loading and unloading.

Types of autoclave

Two types of autoclave are common in laboratories, which rely on generation of steam either by:

- an electrical heater (indirect), or
- an external system (direct).

The presence of moisture or air and heat and steam penetration affect steam sterilisation. Air removal, generally by downward displacement or use of a vacuum pump, is important as air pockets will stop the penetration of steam into the required areas. Sterilisation only commences on removal of all air from the autoclave and attainment of the operating temperature.

Safe design and construction

The relevant standard covering the use of autoclaves in laboratories is *EN 12347 Biotechnology – Performance Criteria for Steam Sterilizers and Autoclaves*. When purchasing an autoclave or arranging maintenance work, confirm that the autoclave complies with the standard and is CE marked. It should not be possible to open autoclaves prematurely. Door safety devices must securely fasten the door shut while it is subject to internal pressure, preventing the door being violently blown open. The safety device must ensure that the vessel cannot be pressurised until the door is securely closed.

It should not be possible to open the door until the internal pressure has been fully vented to atmospheric pressure. The door must be restrained for the first part of its travel until the seal has been broken. The autoclave must be suitable for the intended use, the quantity and

the load. For example, autoclaving is not suitable for heat-sensitive equipment.

Installation

Install the autoclave so that it fails to safety, for example in the event of system failure, loss of pressure or power, over-pressure or over-temperature, interlock or sensor failures or on emergency stop activation. There must be adequate space around the autoclave for operational and maintenance purposes. Insulate all pipework with burn potential. Additional measures may be required for some biological agents to prevent their release from the autoclave before or after sterilisation. Exhaust gases and condensate at higher containment levels may require treatment to prevent loss of containment, such as filters for exhaust air and discharge of condensate to a treatment vessel. This will be determined through risk assessment at CL3 and required at CL4. See also Chapter 6 in relation to other considerations when installing an autoclave.

Installation validation and verification

As effective autoclaving of materials and waste relies on the correct time, temperature and steam penetration, validation must be carried out by a competent person on autoclave installation. This is done using calibrated platinum resistance thermometers (PT100) or thermocouples placed throughout the autoclave. This ensures the correct attainment and maintenance of the temperature and the accuracy and calibration of measuring devices. This process should be repeated annually at lower containment levels and every 6 months at higher containment levels. If the autoclave undergoes maintenance, repair, or relocation, repeat accuracy and calibration checks.

Taking account of the manufacturer's instructions and recommendations, especially with regard to standard loads, conduct load and 'make safe' performance tests. Do not overload the autoclave, as this may impede air removal and sterilisation. Do not stack items unless baskets or shelving are available to allow space between them. Ensure that the form and container material enables air removal. Use representative loads and test organisms with a resistance pattern representative of the organisms likely to be encountered. Use thermocouples or probes, especially at the centre of the load. Repeat at least three times to ensure reproducibility for make safe loads. Establish effective operating parameters and develop and document a loading plan detailing the type of loads, how they should be loaded, the temperature and time settings for the various loads and the maximum number or volume of items allowed for a successful autoclave cycle.

Autoclave operation

Operate the autoclave in accordance with the manufacturer's instructions and recommendations. Ensure these are readily available to the user and that the user is trained (see below). Prepare a documented safe system of work for the autoclave. Detail:

- what can be autoclaved;
- what cannot be autoclaved;
- the containers to be used;
- the correct procedure for loading (referencing loading plans) and unloading;
- the checks to be carried out to ensure appropriate sterilisation;
- the planned maintenance and thorough examination requirements; and
- what to do in the event of an equipment malfunction or sterilisation failure.

Ensure contingency plans are in place in the event of the autoclave being out of service, for example during a breakdown. Consider how the waste will be stored or handled until the autoclave is back on line (see Chapter 10).

Material must be suitable for autoclaving: for example, substances or solvents that can emit vapours and cracked glassware must not be autoclaved. Note that certain commonly used disinfectants if autoclaved will damage and even destroy the autoclave. Do not mix loads such as general waste and bottled fluids or clean and contaminated material. Loosen caps on full or empty bottles to equalise pressure. Transport materials to the autoclave in robust containers and trolleys without spillage. Fasten autoclave bags for transport to the autoclave but unfasten as appropriate for autoclaving to allow steam penetration. Affix autoclave tape and indicate the date on it. Such tape and indicators on autoclave bags are Type 1 external chemical indicators. They only show

that the item has undergone an autoclave cycle and help differentiate between processed and unprocessed loads. They will change colour on reaching the temperature, but this does not indicate that the cycle was successful and that the holding time and correct pressure were achieved and maintained.

Monitor the autoclave cycle to ensure the correct temperature and holding times (see below). Take care with goods after sterilisation as bottles may explode or shatter if weakened, damaged or fully sealed, if incorrect lids are used or if they are exposed to sudden temperature changes. Media may also boil out of bottles, causing scalds. Allow items to cool before unloading. Wear appropriate PPE when loading and unloading the autoclave such as heat-resistant gloves that cover the hand and forearm, safety glasses and visor, closed-toe shoes and laboratory coat.

Routine monitoring and verification of autoclave performance

There are three ways of monitoring autoclave make safe performance – physical, chemical and biological. Use a combination to ensure correct autoclave performance.

Physical monitoring involves checking the autoclave parameters – thermometers, pressure gauges and timing mechanisms. The placement of a thermocouple or probe within the drain and the centre of the load ensures correct temperature attainment and maintenance. Check computer displays and printouts, which record the relevant parameters, after each make safe run and keep on file.

Chemical monitoring uses chemical indicators that undergo a visual physical or chemical change when exposed to parameters such as high temperature or combinations of time and temperature. They can help indicate if there are autoclave problems. Six types of indicators exist (Type 1-Type 6). External chemical indicators such as autoclave tape (a Type 1 indicator) will indicate that a load has been exposed to the autoclave process but not that the process was successful. Internal chemical indicators placed within the load will indicate whether there was successful steam or temperature penetration. Use an air removal test, for example Bowie and Dick type test (a Type 2 chemical indicator), every day before a make safe run, to monitor the effectiveness of mechanical air removal from vacuum autoclaves. Do not rely on chemical monitoring alone for make safe load release.

Biological indicators or spore tests assess the sterilisation process by killing known resistant micro-organisms. With biological indicators, store autoclaved waste for the time required to allow growth of the spores.

When using biological and chemical indicators, check they are in date and use only as specified by the manufacturer. Keep records of the cycle indicating what was autoclaved, the temperature and time, operator's name and results of monitoring checks.

Once waste has been successfully autoclaved, establish that it is safe to dispose of and does not pose a risk to persons or the environment, and dispose of by the appropriate waste stream. When disposing of autoclaved bags, the biohazard sign should be defaced and bags labelled as autoclaved waste.

Instruction, information and training

Under the 2005 Act, employees must receive instruction, information and training so that they can carry out their work safely. This will also ensure that the work is carried out correctly. The Pressure System Regulations have additional requirements. Under these Regulations, employees must have at their disposal adequate information and, where appropriate, written instructions concerning:

- conditions of use;
- safe operation;
- foreseeable abnormal conditions;
- action to be taken in the event of an emergency; and
- conclusions to be drawn from experience in using such equipment, where appropriate.

Thorough examination

The Pressure System Regulations require among other things that:

- a competent person examine autoclaves within a period of 26 months, or 14 months in the case of self-generating autoclaves. Note that examination is not the same as maintenance, and this examination

is commonly known as a thorough examination; and
- reports of examination are kept at the place of work where the pressure vessel is permanently located. Ensure they are available for inspection by the HSA or other relevant agencies. The laboratory manager must see the report.

A thorough examination is a systematic and detailed examination of the autoclave and its safety-critical parts, which if they failed could result in serious or even fatal injury. A written report (commonly known as a 'Report of Thorough Examination') issued following the inspection will detail any defects that require addressing. Where serious defects are identified, you must be notified immediately and a copy of the report sent to the HSA.

Any defects identified during the thorough examination will require rectification, usually by the person or company who carries out the servicing and maintenance.

Servicing and maintenance

Servicing and maintenance differ from thorough examination. They keep the autoclave in good, safe working condition, reduce downtime and extend the life of the autoclave. Carry out all routine servicing and maintenance in accordance with the manufacturer's recommendations. Plan servicing and maintenance as part of your preventive maintenance programme, based on usage. Keep a record of all maintenance and service. As required, use a permit to work system, especially where autoclaves require entry.

Microbiological safety cabinets (MSCs)

MSCs, often referred to as biological safety cabinets, biosafety cabinets or safety cabinets, are a form of local exhaust ventilation (LEV). They are vital primary containment devices in laboratories handling biological agents or infectious materials. Improper use and lack of understanding of the operation of the MSC can result in contaminated work and worker exposure to pathogens.

Failure of the MSC or inappropriate use or siting may also result in employee exposure. Depending on the type of MSC, they can provide three major types of protection: personal, environmental and product.

Purpose of MSCs

The main purpose of an MSC is to contain potential aerosols where there is a risk of respiratory exposure and protect the user from infectious aerosols or splashes. As a minimum, use the MSC whenever there is a potential for aerosol or splash creation, when high concentrations or large volumes of infectious agents or materials are present, when the agent is suspected to be highly infectious, especially via inhalation, or the agent can cause severe or fatal infections.

Standard EN 12469

The effectiveness of the MSC and the provision of operator protection depends on good design, suitable installation, ongoing maintenance, and correct use. Minimum performance criteria are set out in the European Standard EN 12469 Biotechnology – Performance criteria for microbiological safety cabinets. This standard specifies test procedures for protection of operators and the environment, product protection and prevention of cross-contamination. MSCs manufactured to this standard are not designed to protect the user from other hazards that may be encountered in the laboratory, such as chemical or radiation hazards.

Types of microbiological safety cabinets

Three types of MSC are recognised in the European Standard – Class I, Class II and Class III (note that the class of MSC does not correlate with the biological agents risk group). The class of cabinet used must be suitable for the work and the biological agent used or encountered. Carry out a risk assessment to ensure the correct type of cabinet for the work being carried out.

Outside of Europe, different standards apply for MSCs. For example, in the United States of America (USA), five types of Class II cabinets are recognised – Type A1 and A2, Type B1 and B2 and Type C. The Class II MSC commonly used in Ireland is generally equivalent to a Class II, Type A2 MSC. The main difference between the subtypes of cabinets is in the percentage of air exhausted to that of air recirculated and the means of exhaust – some cabinets exhaust air directly back to the laboratory while others exhaust it through dedicated ductwork to the outside. The preferred option for venting is to duct the MSC exhaust air to the exterior of the building. Depending on the design, some of the cabinets may provide protection against exposure to radionuclides and volatile toxic chemicals where used in connection with a microbiological process.

When purchasing an MSC, employers should discuss their needs with the supplier and ensure that the MSC provides adequate protection for the planned work, taking note that exhaust high-efficiency particulate air (HEPA) filtration removes only airborne aerosols and not chemical vapours.

Class I cabinet

A Class I cabinet is an open-fronted cabinet designed to protect the operator by continuously drawing air into the front of the cabinet. It works by drawing air into the cabinet away from the employee and expels it at the top of the cabinet via a HEPA filter, which removes any contamination. Class I cabinets can be used with risk group 2 and risk group 3 biological agents when performing procedures likely to cause an aerosol. The Class I cabinet protects the user and the environment from exposure to the agents but it does not prevent the work being carried out in the cabinet from coming into contact with airborne contaminants that may be in the room air.

Class II cabinet

A Class II cabinet is also an open-fronted cabinet but protects both the operator from exposure and the work from external contamination. The inward air, which prevents any aerosol generated during the work activity escaping through the front opening, flows through a front inlet grille. As the unfiltered inflow air does not enter the work zone of the cabinet, the work inside is protected from external contamination. The inward air is directed downwards into a plenum below the work surface and is HEPA filtered before being redirected into the work area as a laminar downflow of clean air. The inflow air direction in combination with the downflow curtain of filtered air protects the employee. Class II cabinets can be used with risk group 2 and risk group 3 biological agents when performing a procedure likely to cause an aerosol and when the experimental work must also be protected from contamination.

Class III cabinet

A Class III cabinet is a totally enclosed cabinet in which operations are conducted via gloves attached to glove ports. Air enters the cabinet through a HEPA filter at the side or rear of the cabinet and is exhausted in a similar way to a Class I cabinet. Class III cabinets are designed to completely contain the hazardous agent and are used mainly for work with group 4 biological agents or work with group 3 biological agents deemed to be of high risk, for example where highly concentrated samples are being handled. They offer the greatest protection to the employee and the workplace.

Requirements for safe working with MSCs

Four major components contribute to ensuring safe working with MSCs:

- the design, construction and function of the cabinet itself;
- good laboratory design (specifically with respect to cabinet location, installation and room ventilation);
- correct use – systems of work that incorporate good operational technique; and
- regular appropriate testing and maintenance.

Siting and positioning

Before purchase, check the manufacturer's minimum requirements for height clearance. Site the MSC to minimise disturbance of the airflow at the front of the cabinet. Locate it away from doors, windows, air conditioning diffusers, supply/make-up air outlets, room exhaust grilles, and traffic routes for personnel. Provide adequate clearance to enable exhaust filter testing.

The key requirements are that:

- the cabinet has sufficient clearance from walls, corners, ceilings and doorways;
- no obstacles are placed where they may interfere with the airflow; and
- sufficient room is provided for the operator, to avoid interference with other employees.

Proper use of MSCs

The MSC provides a primary barrier to protect the laboratory employee against the risk of hazardous aerosols, but only if used with good microbiological practice and procedure (see Chapter 8). An MSC will not protect against contact contamination, so wear gloves as necessary and change them regularly. Use slow, controlled movements within the cabinet to reduce the disruption of airflow. Use of double gloves and arm protection or oversleeves may be appropriate in some cases. Put in place documented disinfection procedures that take account of the manufacturer's instructions. Consider any incompatibilities: for example, disinfectants that contain chlorides or halogens can damage stainless steel surfaces and where used may need to be rinsed with sterile water or wiped down with a similar compatible non-corrosive antimicrobial agent.

Preparation for work

- Wear appropriate protective clothing according to the level of containment and the risk assessment for the work.
- Switch the cabinet on and run for sufficient time to allow removal of standing air, introduction of clean air and airflow stability before starting the work. Do not use unless the airflow indicator is registering in the 'safe' zone.
- Ensure the inside of the cabinet is clean and free of clutter.
- Adjust the chair so the face is above the opening and underarms are near the bottom of the glass screen.
- Prepare thoroughly for the work: for example, number or code tubes, flasks and dishes; organise media and solutions. A checklist may be useful, or referral to documented procedures, safe systems of work or codes.
- Ensure active solutions of appropriate disinfectants and granules or powders, as required, are available according to the risk assessment, disinfection policy and procedures.
- Keep the laboratory door closed.
- Ensure any equipment required for the work is available and ready for use.

Use of cabinets

- Wipe the surface of the MSC with the appropriate disinfectant before and after use.
- Place work items in the cabinet. Keep clean and dirty materials separate and work from clean to dirty. Keep clean materials distant from aerosol-generating activities. Ensure that contaminated material never crosses over clean material.
- Obstructions will adversely affect performance and, in particular, operator protection. Minimise the quantity of items in the cabinet to lessen disruption of airflow. Do not use large equipment (for example, centrifuges, especially air-cooled models) within open-fronted cabinets unless tests show maintenance of containment performance (operator protection). Avoid equipment that can create air turbulence in the cabinet (for example, Bunsen burners).

- For open-fronted cabinets, always work as near to the centre of the work area as possible, but at least 15 cm from the front of the cabinet. Maintain the airflow by minimising movements in and out and around the cabinet. Avoid abrupt movements; move arms in and out of the cabinet slowly.
- Where required, use horizontal pipette discard trays containing the appropriate disinfectant.
- For Class II cabinets, never obstruct the air inflow grille or any exhaust grilles.
- Dispose of contaminated equipment and material appropriately after use: for example, into containers or disinfectants.
- Never use a cabinet if its operational safety is in doubt. If the airflow alarm sounds, stop work immediately, make the work area secure, for open-fronted cabinets place the front on the cabinet/fully close the sash, and inform the appropriate people according to local protocols and procedures.

Clearing the cabinet after use

- Check the performance of the cabinet.
- Surface decontaminate any potentially contaminated items before removing them from the cabinet.
- Ensure that all containers for autoclaving and incineration are marked correctly and secured. Only remove contaminated materials from the cabinet as directed by local protocols and procedures. Normally, this will mean direct removal of material to the autoclave, although exceptionally it may be permitted to place containers in a holding area within the containment area.
- Wipe all surfaces with disinfectant. A second wiping with sterile water may be required where a corrosive disinfectant such as bleach is used.
- Where local arrangements require that cabinets cannot be left running, leave fan(s) on for 5-10 minutes to purge the atmosphere inside the cabinet. Turn off the MSC and replace the front of open-fronted cabinets/fully close the sash or inward filter cover (Class III).
- Adopt precautions for cleaning the interior of MSCs used for work with dangerous pathogens. Wipe down the interior of the MSC with appropriate disinfectant after use or fumigate if required (see below).
- Avoid removing the working surface grilles where possible. If it is absolutely necessary, take the following precautions:
    - Wear heavy-duty PVC or rubber gloves that can be disinfected after use over disposable gloves, to provide adequate protection for hands and wrists.
    - Wipe the appropriate disinfectant (at the prescribed dilution for the pathogens in use) onto all exposed surfaces and allow sufficient contact time before proceeding.
    - Do not attempt to lift the grilles, which may have sharp edges, by placing the fingers through the holes or slots. If no handles are available, use an implement to hook or lever the grilles up from their housing, in order to grasp edges safely.
    - Use a thick wad of material for cleaning to protect gloved hands from sharp edges
    - Disinfect the outer gloves before removal.
    - Autoclave the cleaning material before disposal.
    - Do not store materials in the MSC.

Training and competence

Allow only trained, competent employees to work with an MSC. Provide training and full instruction in the following as a minimum:

- the class of cabinet and its airflow patterns;
- mode of operation and function of all controls and indicators;
- how to work at the cabinet safely;
- appropriate and inappropriate use of cabinets;
- limitations of performance;
- how to decontaminate after use;

- principles of airflow and operator protection tests; and
- what to do if the cabinet alarm sounds.

Inspection, maintenance and testing

Inspect and test the MSC upon installation. To ensure its continued safe performance and satisfy legislative requirements for risk-control equipment, regularly inspect, service, maintain and test it – taking account of the manufacturer's instructions and local circumstances. Table 20 sets out the minimum recommended frequency for maintenance and testing. In low-risk areas such as containment level 1 or equivalent, an annual frequency for all operations may be acceptable subject to regular risk assessment review. To inform users, display evidence of current inspection and testing on the exterior of the MSC. Before maintenance or service work, disinfect or fumigate the MSC and the working area, equipment and facilities as appropriate to ensure they are safe. Reinspect and retest on moving or relocating an MSC.

Table 20: Summary of minimum recommended checks for MSCs

Operation	Frequency
Alarms/indicators	Daily
Airflow	Monthly (user check) 6 monthly (external check)
Filter integrity	6 monthly
Mechanical and electrical function	6 monthly
Mechanical integrity (including visible ductwork)	Annually
Operator protection (KI discus test)	CL2 – annually CL3 – 6 monthly

MSC Fumigation

Fumigation is the final part of the decontamination process (see Chapter 9). It may be carried out for several reasons, such as to protect:

- workers and the laboratory environment from highly infectious agents, for example, if there is a spillage of a high-risk agent in the MSC. Where safe to do so, treat spills with appropriate disinfectant and clean up before fumigation;
- maintenance and service personnel who may need to access contaminated areas, for example during removal of HEPA filters or replacing parts. Fumigate MSCs before relocation in order to protect the movers and prevent any risk of infection during the removal process; or
- product being processed in the MSC from contamination, for example, during a project or process changeover.

Develop a documented safe system of work for MSC fumigation that covers all aspects of the activity from start to finish. Document and record all fumigations.

Other types of cabinets

Do not confuse laminar flow hoods (often used when preparing culture media or sterile solutions), anaerobic workstations, clean benches and positive pressure cabinets with MSCs. These protect the product from contamination and, unlike an MSC, have no safety function, and do not protect the user. Fume hoods or cupboards are designed to provide protection against chemical agents, not biological agents. Do not use any of this equipment for work with infectious biological agents. Tissue culture cabinets, used for tissue culture work, provide some operator protection along with product protection. However, as they are not designed to meet the relevant EN standard for MSCs, do not use then for work with infectious agents.

Other equipment

Post the biohazard sign as required on incubators, refrigerators, freezers and storage dewars used for biological agents, especially at lower containment levels if they are located outside the immediate work area. Display other safety signage as required.

Centrifuges

Several hazards are associated with the use of centrifuges: for example, rotating parts, sample imbalance causing machine movement and the potential for sample leaks and release of infectious aerosols. Document procedures in relation to the operation of the centrifuge and cover actions in the event of a breakage or leak involving infectious material.

Take account of the manufacturer's instructions. Use sealed buckets or rotors for infectious material. Before use, check lids, rotors, seals, tubes, buckets and O-rings for any damage or defects and remove from use if damaged or defective. Do not overfill tubes and ensure the material is compatible with the tubes and seals. Never overload the centrifuge and balance the rotor properly at all times before operating. In the event of a leak, use disinfectants suitable for the biological agent and compatible with the centrifuge parts. Filter exhaust air from high-speed centrifuge vacuum lines when used for infectious materials. Centrifuges must be operated only by trained personnel.

Freeze driers and freeze drying

Operate freeze driers in accordance with manufacturer's instructions, using the appropriate containment level for the biological agent. Reconstitute freeze-dried ampoules in an MSC. Use a proprietary ampoule cutter and safe working procedures to prevent aerosol generation and cuts.

Refrigerators and freezers

Refrigerators and freezers containing hazardous biological agents must be well organised, clearly marked with the biohazard sign and as appropriate, secure. Restrict access when the refrigerator or freezer is located in the laboratory (CL3) or if high-risk biological agents are present. When it is located external to the laboratory, ensure locked and controlled access. Where high-risk biological agents are stored, bolt the equipment to the floor or wall to prevent unwanted removal. Do not store food or drink for consumption within laboratory refrigerators and freezers. Clearly mark food or drink in food laboratories as 'only for research purposes' or equivalent. Ensure stored items are clearly identifiable. Keep an inventory of refrigerators and freezers. Do not overfill, review contents and clean and decontaminate regularly. Ensure that documented spill control procedures are in place.

When defrosting refrigerators and freezers, store contents safely and securely. If discarding biological agents, defrost fully before autoclaving. Monitor temperatures as necessary. Backup power supplies or an alarm may be required in the event of a power failure. Service and maintain all refrigerators and freezers in line with the manufacturer's recommendations. Do not store flammable materials in such equipment unless it is 'spark proof'. It is recommended to display employee's contact details on the front of the refrigerator when it is used by several employees.

Incubators and water baths

When working with biological agents, ensure that the contents of incubators and water baths are secure, and that there is no spillage or leakage. In certain cases, locks may be required on incubators. Taking account of the manufacturer's instructions, clean and decontaminate incubators and water baths regularly. This is usually done by means of thermal or chemical disinfection.

Liquid nitrogen

Liquid nitrogen may be used for storing and transporting biological agents, samples or cells. Due to its low temperature (-196 °C), it has potential to cause severe cold burns or cause tissues to stick to metals that are cooled by it. Rapid expansion can result in increased concentrations of the gas and has potential to cause asphyxiation by the gas displacing oxygen. Do not store or use liquid nitrogen in confined areas, walk-in freezers or areas with little or no ventilation. Ensure oxygen monitors are in place in liquid nitrogen storage and dispensing areas.

Document safe systems of work for loading and unloading items stored in liquid nitrogen or for transport of liquid nitrogen within the workplace. If transporting liquid nitrogen between floors in a building using a lift, do not permit people in the lift. Lock out the lift so that it only opens at the destination floor. Wear cryogenic gloves or gauntlets (to standard EN 511) and face protection such as a face shield (see Chapter 14) when handling liquid nitrogen. Take care when dispensing liquid nitrogen, avoid trousers with turn-ups, and ensure that splashes do not enter shoes. An impervious apron can prevent this. Ensure documented plans are in place in the event of storage vessel contamination from leaking or ruptured vials or improper external disinfection of vials. Note that ampoules and cryotubes have potential to explode when removed from liquid nitrogen, creating aerosols and droplets.

Cryogenic tanks used for liquid nitrogen can be fixed, mobile or transportable. Store and transport liquid nitrogen in appropriate cryogenic containers such as non-pressurised open-neck dewar flasks. Pressurised liquid nitrogen dewars/static pressurised storage tanks fall under the Pressure Systems Regulations and will require inspection and certification. The safe working pressure must be clearly marked on such vessels.

A safety data sheet for the liquid nitrogen must be available to users. In the event of an emergency or accident, workers must know what to do.

Microscopes

Regularly clean and disinfect shared equipment, such as microscopes and eyepieces, to protect staff. Appropriately decontaminate microscope slides before safe discard. Where wet slide preparations are used, disinfect the microscope stage in line with the manufacturer's recommendations. Consider ergonomics when purchasing and setting up microscopes.

Proper use of equipment

Safety equipment such as MSCs, centrifuge safety cups and sealed rotors provide a high degree of protection to the worker against aerosols and droplets. Safety equipment that is not working properly is hazardous, especially when the worker is unaware of the malfunction. Use equipment in accordance with documented safe systems of work and as per manufacturer's instructions. Provide instruction, information and training in the correct use of equipment, proper work procedures and potential malfunctions. Routine inspections and periodic recertification of equipment, where required, are essential. Ensure systems are in place for reporting defective equipment and its removal from use. Take defective equipment out of service immediately and clearly label it. Do not modify equipment unless such modification is approved by the manufacturer.

Maintenance and servicing equipment

The General Application Regulations require that equipment is fit for purpose and maintained. Regularly check, service and maintain equipment such as MSCs, centrifuges, autoclaves and air-handling units to ensure its condition, integrity and fitness for purpose. Draw up a preventive maintenance plan and procedures, taking account of any manufacturer's recommendations.

Procedures for servicing equipment should specify:

- which control measures need servicing;
- the work to be carried out on each of them;
- when the work should be done;
- who is to do the work and who is responsible for it;
- how to put right any defects found; and
- how to ensure equipment is decontaminated before handover to a service agent for service or repair, or before disposal. Where decontamination is not possible, notify the service agent in advance to enable preparation of appropriate safe systems of work. Any maintenance tools and equipment used may require decontamination before removal from the laboratory.

Chapter 16. Health surveillance, vaccination and occupational exposure lists

Where the risk assessment identifies that there is a risk to the worker's health due to exposure to biological agents, the Biological Agents Regulations require that you make provision for appropriate health surveillance. Health surveillance is not an alternative to the proper control of exposure.

What is health surveillance?

Health surveillance is a system of ongoing health checks that allow for early identification of work-related ill health in employees exposed to certain risks, such as biological agents. This helps identify any corrective actions that may be required.

Health surveillance is appropriate if:

- an identifiable disease or adverse health effect is linked with exposure;
- there is a reasonable likelihood that the disease or effect may occur due to the work activity; and
- there are valid, low-risk techniques for detecting indications of the disease or effect.

Health surveillance must be safe, easy to perform, acceptable and of benefit to the employee. Health surveillance for biological risks may not always be appropriate. An example of where it may be useful is if the biological agent causes serious disease that has an insidious onset, and effective treatment is available. If a biological agent or its products cause respiratory sensitisation, health surveillance may also be appropriate.

Health surveillance hierarchy

When considering the provision of health surveillance, take account of the health surveillance hierarchy, namely:

- Self-reporting of symptoms – in such cases, the symptoms are normally evident to the individual. The employee must have the appropriate instruction, information and training to know what to look out for, what to report and to whom.
- Inspection by a responsible person – a responsible person (non-medical, for example a laboratory supervisor) carries out checks on employees, for example an employee who develops a visible rash or somebody working with a sensitiser who develops a cough or wheeze at work. The responsible person will require training and appropriate support.
- Questionnaire – an occupational health nurse or doctor periodically asks a series of questions related to the health effects associated with the work activity. Medical personnel then follow up on positive responses.
- Application of special tests – these are administered by medical personnel where there is a justifiable valid reason for conducting tests, such as spirometry or blood tests.
- Examination by a doctor or nurse.

The Biological Agents Regulations require that a responsible medical practitioner undertake health surveillance. A responsible medical practitioner is a registered medical practitioner employed or engaged by the employer to provide health surveillance. The medical practitioner must be familiar with the exposure conditions or circumstances of each employee and carry out the health surveillance in line with the principles and practices of occupational medicine.

Where the risk assessment identifies the requirement for health surveillance, make it available before exposure to the biological agent, in order to form a baseline. Then carry out surveillance at regular intervals in order to detect any ill effects before they occur. Employees must receive appropriate information on the risks associated with potential exposure to the biological agents in the workplace and expected symptoms. The employee must understand the reason for the health surveillance and is within their rights to refuse to partake in any surveillance. The employer must provide information and advice to the employee about any health surveillance that they may need to undergo following the end of exposure. An employee can request a review of the results of their health surveillance.

Where an employee is suffering from an infection or illness suspected to be due to exposure to a biological agent at the workplace, put other employees who may have been similarly exposed under surveillance. Do not wait until requested by a responsible medical practitioner or by the HSA. In such cases, review the risk assessment, update, and amend as appropriate.

Where the continued employment of a worker in a particular job is contraindicated for health reasons due to exposure to biological agents, the responsible medical practitioner should collaborate in finding alternative employment for that worker in the undertaking, or another appropriate solution.

Health record

Where an employee receives health surveillance, the employer must create an individual health record (see Table 21 for a basic example). These records must not contain any medically confidential information.

Such records will be subject to General Data Protection Regulation (GDPR) requirements. The employee is entitled to have access to the results of their health surveillance or to any review of their health surveillance.

Table 21: Example of a simple health record

Health record					
Name					
Gender		Personal public service number (PPSN)			
Home address					
Date when present employment started					
Historical record of jobs in this employment involving exposure to biological agents requiring health surveillance (job title and description)					
Results of health surveillance					
Date carried out	Reason for health surveillance	Who undertook health surveillance	Outcome (fit/not fit/ fit with restrictions)	Additional comments	Health surveillance review date

Medical records

Medical records differ from health records in that the responsible medical practitioner creates them. These are secure medically confidential records. The information contained in a medical record depends on the nature of the medical examination carried out. Such records must not be disclosed to others without the employee's consent. The Biological Agents Regulations permit the responsible medical practitioner carrying out health surveillance to allow an occupational medical adviser access to an individual employee's confidential medical record, but the employee must still provide consent in such cases.

Retention of records

Most group 3 and group 4 biological agents cause disease shortly after exposure, but some agents may cause disease many years after exposure, such as Hepacivirus C, or can cause long-term chronic ill health effects, so records must be kept for longer. The employer and responsible medical practitioner must keep the relevant records for at least 10 years after the end of exposure of the employee to the biological agent. Keep the health and medical records for an appropriate longer period, not exceeding 40 years, after the last known exposure where the risk assessment identifies that the exposure may result in infection:

- with a biological agent known to be capable of establishing persistent or latent infections;
- that is currently not diagnosable until illness develops many years later;
- that has particularly long incubation periods before illness develops;
- that results in illness that reoccurs at times over a long period despite treatment; or
- that results in illness that may have serious long-term sequelae.

Transfer of medical records

In the event of the employer's undertaking ceasing activity or the responsible medical practitioner ceasing to practice as a registered medical practitioner, the employee medical records must be made available to the HSA or such person as directed by the HSA. The directed person or the HSA must retain the records for the remaining relevant time.

Reporting disease or death

An employer, registered medical practitioner or responsible medical practitioner who becomes aware of or diagnoses a case of disease or death of an employee due to occupational exposure to a biological agent must notify the HSA. The Biological Agents Reporting Form (BAR form) may be used for this purpose.

Health screening

Health surveillance differs from health screening. Health screening may be carried out before conducting work to identify any individuals who may be at particular risk of infection or to check immunity status, before working with or exposure to biological agents. This will enable appropriate precautions to be put in place prior to the work commencing.

Vaccination

Schedule 1 of the 2020 Biological Agents Code of Practice indicates specific bacteria and viruses for which an effective vaccine that has been registered within the EU, is available. Where the risk assessment shows that there is a risk to the health and safety of employees due to working with or exposure to a biological agent for which an effective vaccine is available, the employer must offer vaccination free of charge to employees – unless they are already immune to the biological agent. Offer vaccination prior to the employee commencing the work. Carry out vaccination by or under the supervision of a responsible medical practitioner who will know when vaccination is not advisable. For example, pregnant women must not receive certain vaccines. In offering vaccination, advise employees of the benefits and drawbacks of both vaccination and non-vaccination. Vaccination must be in accordance with the *Immunisation Guidelines for Ireland*, available on the Royal College of Physicians in Ireland website. A review of immunisation status may be required for certain vaccines.

Vaccination can reduce the consequences of exposure, but do not rely on it to provide total protection. View it as a supplement to control measures. Consider in the risk assessment employees with a low titre or response to the vaccine, and those who are unable to receive the vaccine or do not wish to take up the offer of vaccination.

Additional control measures may be required in such cases. There may be instances, based on the risk assessment, when an unvaccinated employee would not be regarded as safe to perform certain work tasks despite additional protective measures being in place. In such cases, the employer may have no option but to redeploy the worker to another work task. A recommendation is that the employer and the responsible medical practitioner agree any such decision, in consultation with the employee.

The person administering the vaccine may draw up a vaccination certificate (paper or electronic). This forms a useful record for an employee, especially if they travel for work. Make the certificate available to the employee concerned and when requested by the HSA. Information to include in the certificate would be the date of vaccination and the expected duration of cover of the vaccine (this may require a blood test, as in the case of hepatitis B). Do not include any personal health information on the certificate.

Occupational exposure lists

The Biological Agents Regulations require the employer to keep an occupational exposure list where there is a risk to the health or safety of employees due to work with certain biological agents. Keep the list for employees exposed to group 3 and group 4 biological agents and any of following group 2 biological agents:

- Human gammaherpesvirus 8,
- *Papillomaviridae*,
- Human polyomavirus 1 (BK virus),
- Human polyomavirus 2 (JC virus), and
- Hepatitis delta virus.

Indicate on the list the type of work to be done or being done by each employee and, where possible, the biological agents to which they have been or may be exposed. Include records of exposures, accidents and incidents as appropriate.

Keep the exposure list for the same periods as the health and medical records – 10 years or more (up to 40 years) following the last known exposure of the employee concerned. The annotation 'D' in Schedule 1 of the 2020 Biological Agents Code of Practice indicates biological agents where you must keep the list for more than 10 years.

Employees are entitled to access information on the list that relates to them, whereas employees, the safety representative or both are entitled to access collective information from the list provided that it does not identify any individual employees. Make the list available on request to the responsible medical practitioner, an occupational medical adviser or the HSA.

Appendix 1. List of standards

The following is a list of standards referenced within this guidance.

As standards are always under regular review and revision, check their status on the National Standards Authority of Ireland website. Note that an I.S. EN standard is a European (EN) standard adopted as a national Irish standard (I.S). An ISO standard is an international standard adopted by the International Organization for Standardization. When an ISO standard is adopted by the European Union, it becomes an EN ISO.

EN 136: Respiratory protective devices – Full-face masks – Requirements, testing, marking

EN 140: Respiratory protective devices – Half-masks and quarter-masks – Requirements, testing, marking

EN 143: Respiratory protective devices – Particle filters – Requirements, testing, marking

EN 149: Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking

EN 388: Protective gloves against mechanical risks

EN 455-1: Medical gloves for single use – Part 1: Requirements and testing for freedom from holes

EN 455-2: Medical gloves for single use – Part 2: Requirements and testing for physical properties

EN 455-3: Medical gloves for single use – Part 3: Requirements and testing for biological evaluation

EN 455-4: Medical gloves for single use – Part 4: Requirements and testing for shelf life determination

EN 511: Protective gloves against cold

EN 943-1: Protective clothing against dangerous solid, liquid and gaseous chemicals, including liquid and solid aerosols – Part 1: Performance requirements for Type 1 (gas-tight) chemical protective suits

EN 943-2: Protective clothing against dangerous solid, liquid and gaseous chemicals, including liquid and solid aerosols – Part 2: Performance requirements for Type 1 (gas-tight) chemical protective suits for emergency teams (ET)

EN 1822-1: High efficiency air filters (EPA, HEPA and ULPA) – Part 1: Classification, performance testing, marking

EN 12021: Respiratory equipment – compressed gases for breathing apparatus

EN 12347: Biotechnology – Performance criteria for steam sterilizers and autoclaves

EN 12469: Biotechnology – Performance criteria for microbiological safety cabinets

EN 12941: Respiratory protective devices – Powered filtering devices incorporating a helmet or a hood – Requirements, testing, marking

EN 12942: Respiratory protective devices – Power assisted filtering devices incorporating full face masks, half masks or quarter masks – Requirements, testing, marking

EN 13034: Protective clothing against liquid chemicals – Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)

EN 14126: Protective clothing – Performance requirements and tests methods for protective clothing against infective agents

EN 14387: Respiratory protective devices – Gas filter(s) and combined filter(s) – Requirements, testing, marking

EN 14605: Protective clothing against liquid chemicals – Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

EN 14885: Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics

EN 15154-2: Emergency safety showers – Part 2: Plumbed-in eye wash units

EN 61340-5-1: Electrostatics – Part 5-1: Protection of electronic devices from electrostatic phenomena – General requirements

EN ISO 374-2: Protective gloves against dangerous chemicals and micro-organisms Part 2: Determination of resistance to penetration

EN ISO 374-5: Protective gloves against dangerous chemicals and micro-organisms – Part 5: Terminology and performance requirements for micro-organisms risks

EN ISO 13982-1: Protective clothing for use against solid particulates – Part 1: Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (Type 5 clothing)

EN ISO 16321-1: Eye and face protection for occupational use – Part 1: General requirements

EN ISO 19734: Eye and face protection – Guidance on selection, use and maintenance

EN ISO 20345: Personal protective equipment – Safety footwear

EN ISO 21420: Protective gloves – General requirements and test methods

EN ISO 22610: Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment – Test method to determine the resistance to wet bacterial penetration

ISO 16603: Clothing for protection against contact with blood and body fluids – Determination of the resistance of protective clothing materials to penetration by blood and body fluids – Test method using synthetic blood

ISO 16604: Clothing for protection against contact with blood and body fluids – Determination of resistance of protective clothing materials to penetration by blood-borne pathogens – Test method using Phi-X 174 bacteriophage

ISO 22611: Clothing for protection against infectious agents – Test method for resistance to penetration by biologically contaminated aerosols

ISO 22612: Clothing for protection against infectious agents – Test method for resistance to dry microbial penetration

ISO 35001: Biorisk management for laboratories and other related organisations

Managing Exposure to Biological Agents in Laboratories

HSA

An tÚdarás Sláinte agus Sábháilteachta
Health and Safety Authority

Our Vision:

Healthy, safe and productive lives and enterprises

Health and Safety Authority
Tel: 0818 289 389

www.hsa.ie

ISBN: 978-1-84496-296-9

HSA0521