

LABORATORY BIOSAFETY MANUAL
FOURTH EDITION
AND
ASSOCIATED MONOGRAPHS

PERSONAL PROTECTIVE EQUIPMENT



World Health
Organization

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Personal protective equipment

(Laboratory biosafety manual, fourth edition and associated monographs)

ISBN 978-92-4-001141-0 (electronic version)

ISBN 978-92-4-001142-7 (print version)

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Design and layout by Paul Bloxham

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Financial support

Development and publication of this document have been made possible with financial support from the Global Partnership Program, Global Affairs Canada, the Biosecurity Engagement Program, United States Department of State and the Defense Threat Reduction Agency, US Department of Defense.

Glossary of terms

Aerosol: Liquid or solid particles suspended in air and of a size that may allow inhalation into the lower respiratory tract (usually less than 10 micrometres in diameter).

Aerosol/airborne transmission: The spread of infection caused by the inhalation of aerosols.

Aerosol-generating procedure: Any procedure that intentionally or inadvertently results in the creation of liquid or solid particles, which become suspended in the air (aerosols).

Biological agent: A microorganism, virus, biological toxin, particle or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity or otherwise create a hazard to humans, animals or plants.

Biological safety cabinet (BSC): An enclosed, ventilated working space designed to provide protection to the operator, the laboratory environment and/or the work materials for activities where there is an aerosol hazard. Containment is achieved by segregation of the work from the main area of the laboratory and/or through the use of controlled, directional airflow mechanisms. Exhaust air is passed through a high-efficiency particulate air (HEPA) filter before recirculating into the laboratory or into the building's heating, ventilation and air conditioning system. There are different classes (I, II and III) of BSCs that provide different levels of containment.

Biosafety: Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release.

Calibration: Establishment of the relationship between the measurement provided by the instrument and the corresponding values of a known standard, allowing correction to improve accuracy. For example, laboratory equipment such as pipetting devices may need calibration periodically to ensure proper performance.

Consequence (of a laboratory incident): The outcome of an incident (exposure to and/or release of a biological agent) of varying severity of harm, occurring in the course of laboratory operations. Consequences may include a laboratory-associated infection, other illness or physical injury, environmental contamination, or asymptomatic carriage of a biological agent.

Containment: The combination of physical design parameters and operational practices that protect personnel, the immediate work environment and the community from exposure to biological agents. The term "biocontainment" is also used in this context.

Core requirements: A set of minimum requirements defined in the fourth edition of the World Health Organization (WHO) *Laboratory biosafety manual* to describe a combination of risk control measures that are both the foundation for, and an integral part of, laboratory biosafety. These measures reflect international standards and best practice in biosafety that are necessary to work safely with biological agents, even where the associated risks are minimal.

Cross contamination: The process by which biological agents are unintentionally transferred from one substance or object to another, with potentially harmful effect.

Decontamination: Reduction of viable biological agents or other hazardous materials on a surface or object(s) to a pre-defined level by chemical and/or physical means.

Disinfectant: Agents capable of eliminating viable biological agents on surfaces or in liquid waste. These will have varying effectiveness depending on the properties of the chemical, its concentration, shelf life and contact time with the agent.

Disinfection: A process to eliminate viable biological agents from items or surfaces for further safe handling or use.

Engineering controls: Risk control measures that are built into the design of a laboratory or laboratory equipment to contain the hazards. Biological safety cabinets (BSCs) and isolators are forms of engineering control in order to minimize the risk of exposure to and/or unintended release of biological agents.

Exposure: An event during which an individual comes in contact with, or is in close proximity to, biological agents with the potential for infection or harm to occur. Routes of exposure can include inhalation, ingestion, percutaneous injury and absorption and are usually dependent upon the characteristics of the biological agent. However, some infection routes are specific to the laboratory environment and are not commonly seen in the general community.

Good microbiological practice and procedure (GMPP): A basic laboratory code of practice applicable to all types of laboratory activities with biological agents, including general behaviours and aseptic techniques that should always be observed in the laboratory. This code serves to protect laboratory personnel and the community from infection, prevent contamination of the environment, and provide protection for the work materials in use.

Hazard: An object or situation that has the potential to cause adverse effects when an organism, system or (sub)population is exposed to it. In the case of laboratory biosafety, the hazard is defined as biological agents which have the potential to cause adverse effects to personnel and/or humans, animals, and the wider community and environment. A hazard does not become a risk until the likelihood and consequences of that hazard causing harm are taken into account.

Heightened control measures: A set of risk control measures as described in the WHO *Laboratory biosafety manual* that may need to be applied in a laboratory facility because the outcome of a risk assessment indicates that the biological agents being handled and/or the activities to be performed with them are associated with a risk that cannot be brought below the risk tolerance level with the core requirements only.

Incident: An occurrence that has the potential to, or results in, the exposure of laboratory personnel to biological agents and/or their release into the environment that may or may not lead to actual harm.

Infectious dose: The amount of biological agent required to cause an infection in the host, measured in number of organisms. Often defined as the ID_{50} , the dose that will cause infection in 50% of those exposed.

Initial risk: Risk associated with laboratory activities or procedures that are conducted in the absence of risk control measures.

Laboratory-associated infection: Any infection acquired or reasonably assumed as a result of exposure to a biological agent in the course of laboratory-related activities. A person-to-person transmission following the incident may result in linked secondary cases. Laboratory-associated infections are also known as laboratory-acquired infections.

Likelihood (of a laboratory incident): The probability of an incident (that is exposure to and/or a release of a biological agent) occurring in the course of laboratory work.

Maximum containment measures: A set of highly detailed and stringent risk control measures described in the fourth edition of the WHO *Laboratory biosafety manual* that are considered necessary during laboratory work where a risk assessment indicates that the activities to be performed pose very high risks to laboratory personnel, the wider community and/or the environment, and therefore an extremely high level of protection must be provided. These are especially needed for certain types of work with biological agents that may have catastrophic consequences if an exposure or release were to occur.

Personal protective equipment (PPE): Equipment and/or clothing worn by personnel to provide a barrier against biological agents, thereby minimizing the likelihood of exposure. PPE includes, but is not limited to, laboratory coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, masks and respirators.

Primary containment device: A contained workspace designed to provide protection to its operator, the laboratory environment and/or the work materials for activities where there is an aerosol hazard. Protection is achieved by segregation of the work from the main area of the laboratory and/or through the use of controlled, directional airflow mechanisms. Primary containment devices include biological safety cabinets (BSCs), isolators, local exhaust ventilators and ventilated working spaces.

Qualitative fit test: A pass/fail test method that relies on the sensory response of a person wearing a facepiece to detect a challenge chemical in order to assess the adequacy of the fit of the facepiece.

Quantitative fit factor: The numeric value of the fit of a particular tight-fitting facepiece to a specific individual.

Quantitative fit test: A test method that uses an instrument to assess (quantify) the amount of leakage of unfiltered external air into a facepiece through the face seal in order to assess the adequacy of its fit.

Risk: A combination of the likelihood of an incident occurring and the severity of the consequences (harm) if that incident were to occur.

Risk assessment: A systematic process of gathering information and evaluating the likelihood and consequences of exposure to or release of workplace hazard(s) and determining the appropriate risk control measures to reduce the risk to an acceptable risk.

Risk control measure: Use of a combination of tools, which include communication, assessment, training, and physical and operational controls, to reduce the risk of an incident/event to an acceptable risk. The risk assessment cycle will determine the strategy that should be used to control the risks and the specific types of risk control measures required to achieve this.

Safety culture: A set of values, beliefs and patterns of behaviour instilled and facilitated in an open and trusting atmosphere by individuals and organizations working together to support or enhance best practice for laboratory biosafety, irrespective of whether it is stipulated in applicable codes of practice and/or regulations.

Sharps: Any device or object that is a puncture or wound hazard because of its pointed ends or edges. In the laboratory, sharps can include needles, syringes with attached needles, blades, scalpels or broken glass.

Soap: A water soluble cleaning compound used for cleaning skin and other materials. Note, soap does not necessarily inactivate biological agents.

Standard operating procedures (SOPs): A set of well-documented and validated stepwise instructions outlining how to perform laboratory practices and procedures in a safe, timely and reliable manner, in line with institutional policies, best practice and applicable national or international regulations.

Tight-fitting respiratory facepiece: A respiratory facepiece that forms a protective barrier between the wearer's respiratory tract and the ambient atmosphere by forming a seal with the wearer's skin.

Transmission: The transfer of biological agent(s) from objects to living things, or between living things, either directly or indirectly, for example, via aerosols, droplets, body fluids, vectors, food/water or other contaminated objects.

Validation: Systematic and documented confirmation that the specified requirements are adequate to ensure the intended outcome or results. For example, in order to prove a material is decontaminated, laboratory personnel must validate the robustness of the decontamination method by measurement of the remaining biological agents against the detection limit.

Executive summary

Laboratory biosafety is essential for the protection of laboratory personnel and the wider community against exposure to and inadvertent release of biological agents. Personal protective equipment (PPE) is often used to protect laboratory personnel from exposure to biological and other hazards such as chemicals that may be present in the laboratory. The types of PPE worn in laboratories where biological agents are being handled are designed to protect the body, eyes and face, feet, hands and the respiratory system and hearing. The type(s) of PPE required and specifics on when this equipment should be used are determined as part of the risk assessment for the work being carried out in the laboratory. This monograph provides information on the types, selection and use of PPE for personnel carrying out risk assessments, such as biosafety officers or laboratory managers, and laboratory personnel or scientists who use PPE for laboratory activities.

The information in this monograph on PPE is designed to accompany and support the fourth edition of the WHO *Laboratory biosafety manual* (core document) and the other associated monographs. The manual and the monographs adopt a risk- and evidence-based approach to biosafety, rather than a prescriptive approach, in order to ensure that laboratory facilities, safety equipment and work practices are locally relevant, proportionate to needs and sustainable.

Emphasis is placed on the importance of a “safety culture” that incorporates risk assessment, good microbiological practice and procedure and standard operating procedures, relevant introductory, refresher and mentoring training of personnel, and prompt reporting of incidents and accidents followed by appropriate investigation and corrective actions. This new approach aims to facilitate laboratory design and ways of operating that ensure greater sustainability of laboratory work while maintaining adequate and appropriate control of biosafety.

The associated monographs provide detailed information and help implement systems and strategies on the following specialized topics: risk assessment, laboratory design and maintenance, biological safety cabinets and other primary containment devices, decontamination and waste management, biosafety programme management, and outbreak preparedness and resilience.

This monograph covers the factors to be considered when selecting PPE, including a risk assessment of the work being done and regulations. The different types of PPE available are described, which include, but are not limited to, laboratory coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, face shields, masks and respirators. In addition, the correct way to put on and remove and test certain PPE is explained, and the PPE needed for implementation of core requirements, heightened control and maximum containment measures is described. Hand hygiene methods, and cleaning, maintenance, storage and disposal of PPE are also discussed, as well as national and international standards and regulations on PPE.

INTRODUCTION TO PPE

Laboratory biosafety is fundamental to protecting the laboratory workforce, and the wider community, against exposures or releases of pathogenic biological agents. Reviews of recent laboratory-associated infections show that most were caused by human factors, which included a failure to use or improper use of PPE (1–4). PPE and other dedicated laboratory clothing act as a barrier to minimize the likelihood of laboratory personnel being exposed to aerosols, splashes or inadvertent inoculation. However, it is important to note that the use of PPE does not remove the hazard, that is the biological agent.

PPE is any equipment (for example, gloves) worn by a person to protect that individual from exposure to one or more hazards.

The PPE required depends on the following factors:

- characteristics of the biological agent being handled,
- volumes and concentrations of the biological agent,
- presence of additional hazards (for example, extreme temperatures, chemical or radiological hazards),
- type of work being carried out,
- other risk control measures being used, such as a biological safety cabinet (BSC),
- other PPE being worn,
- individual needs of the laboratory personnel, and
- availability of national regulations and organizational requirements.

A thorough risk assessment will determine the necessity for and type of PPE required. More information on risk assessment can be found in the fourth edition of the WHO *Laboratory biosafety manual* (5) and *Monograph: risk assessment* (6).

1.1 Intended scope

As with the fourth edition of the *Laboratory biosafety manual* (5) (core document), this monograph adopts a risk- and evidence-based approach to biosafety rather than a prescriptive approach to ensure that selection and use of laboratory PPE are locally relevant, proportionate to the risks identified and sustainable. Selection and use of PPE should form part of the safety culture that incorporates risk assessment, good microbiological practice and procedure (GMPP), training and reporting of incidents to reduce the risks associated with working with biological agents.

The associated monographs provide detailed information and help implement systems and strategies on the following specialized topics: risk assessment (6), laboratory design and maintenance (7), biological safety cabinets and other primary containment devices (8), decontamination and waste management (9), biosafety programme management (10), and outbreak preparedness and resilience (11).

This monograph provides an overview of the types of PPE that might be required as part of core laboratory requirements. It also offers options for PPE when heightened control measures have been identified as necessary and covers the types of PPE that should be used when high-risk operations need to be performed within maximum containment measures.

The monograph covers the following areas:

- selection of PPE based on risk assessment,
- PPE options for core requirements, heightened control measures and maximum containment measures,
- types of PPE, and how to safely put on, use and remove PPE items,
- hand hygiene,
- cleaning, maintenance, storage and disposal of PPE, and
- standards and regulations on PPE.

The monograph focuses on the use of PPE to prevent exposure to biological agents; however, other hazards such as sharps and chemicals will also be considered. The monograph does not cover equipment that is designed or required for protection of specimens.

This monograph should complement any national regulation and oversight mechanisms that may be in place, and be used as a guide to help the local biosafety programme.

1.2 Principles of selection and use of PPE

Making the workplace safe includes providing instructions, procedures, training and supervision to encourage people to work safely and responsibly. Even where engineering controls and safe systems of work are in place, some hazards might remain. Such hazards may contribute to injuries, including:

- inhalation of contaminated air harming the lungs,
- falling materials harming the head or feet,
- splashes of infectious materials or hazardous chemicals harming the eyes,
- contact with corrosive materials harming the skin, and
- extreme heat or cold harming the body.

PPE is needed in these cases to reduce the risk of these events resulting in consequences to the personnel. When PPE is still required after implementing risk control measures (and there will be circumstances when it is, for example, head protection on most construction sites), employers must provide their personnel with this equipment free of charge.

The type(s) of equipment must be chosen carefully (see section 2 selection of PPE) and personnel must be trained in its proper use and know how to detect and report any faults.

SELECTION OF PPE

The need for PPE will be determined by the risk assessment for the work to be carried out and the biological agents and other hazards being handled.

2.1 Risk assessment

The control of biological risks should be based on a risk assessment. This stepwise process is described in the fourth edition of the *Laboratory biosafety manual* (5) and the *Monograph: risk assessment* (6). Risk assessment is used to determine whether risk control measures, including PPE, can be applied to reduce the risks to acceptable risks (the justifiable risk based on the benefits of the work).

2.2 Selection criteria for PPE

The following questions should be answered by laboratory management and the user before selection of any PPE.

- Who will be exposed and to what?
- How long will the PPE be worn?
- What type of biological material is protection needed against (for example, diagnostic specimens, cultures, large-scale production)?
- Are there any contraindications for the use of a certain type of PPE (for example, asthma, claustrophobia, dermatitis)?

The following factors must be considered when selecting and using PPE:

- size and shape,
- fit, comfort and mobility to ensure protection during and for the duration of activities,
- effect on dexterity,
- requirement for cleaning, disinfection and maintenance,

- disposable versus reusable equipment,
- compatibility with other equipment,
- robustness (resistance to abrasion, cutting, tearing and puncture),
- potential for heat stress,
- risk of entanglement in moving machinery, and
- appropriate training in use for high-risk work, particularly in relation to correctly putting on and removing when contaminated.

When more than one item of PPE is worn, the items will need to be checked to ensure that they are compatible with one another. For example, eye protection may interfere with the seal of a respirator and prevent it from providing the necessary protection to the wearer. Selected products will need to be checked before purchase as there may be national regulations with which they need to comply. Users of the PPE will need to be appropriately trained in its use and maintenance, and be able to identify and report any faults before using it for actual work.

Key principles for selecting and using PPE include the following.

- Choose products that are fit for purpose in accordance with local and national regulations or adopted international standards – suppliers can advise.
- Choose equipment that suits the user – consider the size, fit and weight of the PPE. If the users help choose the PPE, they will be more likely to use it.
- If more than one item of PPE is worn at the same time, make sure they can be used together; for example, wearing safety glasses may disturb the seal of a respirator, causing air leaks.
- Instruct and train personnel on how to use PPE, why it is needed, when to use it and what its limitations are.
- Never allow exemptions from wearing PPE for those jobs that “only take a few minutes”.
- Where possible, check with manufacturers on what PPE would be most appropriate. Explaining the type of work to be carried out can help manufacturers advise on the most suitable PPE to be used.
- If in doubt, seek further advice from a specialist adviser, such as a supplier or biosafety expert.

2.3 National regulations and organizational requirements

There may be national regulations with which PPE will need to be compliant. For example, PPE might need to have been assessed against a set of standard tests in order for it to be used legally in a particular country. Information on standards is given in section 14 standards and regulations. At the organizational level, specific operating procedures may require the use of certain PPE when working in the laboratory; for example, the wearing of eye protection may be required irrespective of the type of laboratory activity being carried out.

A policy on the use of assigned PPE should be put in place and consistently enforced. All personnel must be made aware of the rules on the use of PPE and the consequences of noncompliance (that is in addition to the potential for injury or illness).

2.4 Considerations concerning the biological agent(s)

The characteristics of the biological agent that should be considered when determining the type of PPE to be worn include:

- routes of transmission,
- infectious dose,
- environmental stability,
- consequences of exposure and/or release, and
- availability of vaccines or prophylaxis.

2.4.1 Routes of transmission

The routes of transmission of the biological agent(s) being handled are important to consider when assessing risks as they will inform the risk control measures needed, including PPE selection. For example, to prevent the airborne transmission of a biological agent during a laboratory activity where no BSC is available, the use of respiratory protective equipment, such as a respirator, would generally be required to prevent respiratory exposure of the personnel to the biological agent.

It is important to note that the natural transmission routes of a biological agent may differ in the laboratory depending on the concentrations used and the procedures being carried out.

2.4.2 Infectious dose

The infectious dose will not alter the likelihood of exposure of an individual to a biological agent being handled. However, the consequences and therefore overall risk will differ; the lower the infectious dose, the more likely infection would result if exposure were to occur. As such, the type(s) of risk control measures that need to be put in place to prevent exposure and release may differ. For example, when working with large volumes of a biological agent transmissible through the contact route that has a low infectious dose, the risk assessment may determine that the use of a second pair of gloves is necessary so that, should an exposure occur, the top pair of gloves can be removed while maintaining a barrier with the bottom layer of gloves.

2.4.3 Environmental stability

Certain biological agents may survive for a long time on laboratory surfaces. Personnel working in the laboratory may therefore be exposed for prolonged times when touching contaminated laboratory surfaces. Biological agents that are more stable in the environment may result in an increased likelihood of exposure for laboratory personnel if decontamination is not carried out properly and if appropriate PPE is not worn. Based on risk assessment, gloves may be required for activities carried out in certain areas of a laboratory if environmentally stable biological agents transmissible by contact were previously used in that area.

2.4.4 Consequences of exposure and/or release

The consequences of exposure and/or release, for example, the severity of harm a laboratory-associated infection can cause, should be considered when determining the PPE needed. For example, when handling biological agents that can cause a severe illness, different kinds of PPE will need to be selected among other risk control measures.

2.4.5 Availability of vaccines or prophylaxis

The availability of vaccines or prophylaxis can influence the selection of PPE. For example, for work with a biological agent transmitted through the air for which no vaccine or prophylaxis is available, the use of respiratory protective equipment should be considered.

2.5 Type of work being carried out

Whatever the biological agent being handled, the risk will change depending on the type of laboratory activity being carried out. This change may in turn have an effect on the level of control required to reduce the risk to an acceptable risk. This will therefore alter the type of PPE required. For example, molecular techniques may require the use of a laboratory coat, gloves and eye protection where splash is likely. However, undertaking an aerosol-generating procedure with the same biological agent may require the use of respiratory protection and a full visor, if handled outside of a BSC. Even where engineering controls and safe systems of work are in place, some risks might remain moderate. PPE is therefore needed in these cases to reduce the risk.

2.6 Other hazards

While the fourth edition of the *Laboratory biosafety manual (5)* and associated monographs focus on biological safety, it is important to consider protection against other hazards and irritants, such as:

- allergens,
- sharps,
- temperature,
- non-ionizing radiation (for example, ultraviolet light, laser)
- noise,
- chemical fumes (smell),
- electricity,
- chemicals,
- gas,
- radiation, and
- bites (animal or arthropod).

It is imperative that these are considered when selecting the type(s) of PPE to be worn as it may be required to protect against more than the biological hazard. For example, chemical breakthrough of gloves can occur quickly in the presence of certain chemicals, such as acetone. This breakthrough not only results in exposure of the skin to the chemical, but the chemical could also facilitate the carriage of biological agents through the glove material and the subsequent exposure of the skin to the biological agent. Another example is the removal of stocks from a liquid nitrogen store. While a laboratory coat and gloves would normally be worn to remove stocks from a standard $-20\text{ }^{\circ}\text{C}$ freezer, the very low temperature of liquid nitrogen and potential for splash would warrant the use of additional PPE such as a thermal apron, thermal gloves and a face shield.

2.7 Other risk control measures

The type of PPE required to perform a certain task or series of tasks is also dependent on other risk control measures that have been put in place based on the risk assessment. For example, where it has been stipulated that a BSC is to be used, less PPE will be required than if the same task was being performed without the use of a BSC (Table 2.1).

Table 2.1 Example PPE for a laboratory activity with and without risk control measures

TASK	RISK CONTROL MEASURE(S)	PPE
Liquid culture preparation of influenza A virus	None	Laboratory coat, gloves, respiratory protection, eye protection
	BSC	Laboratory coat, gloves

BSC = biological safety cabinet; PPE = personal protective equipment.

2.8 Combination of PPE

In some situations, several hazards may need to be considered, such as procedures where biological, chemical and thermal protection are required simultaneously. Therefore, clothing requirements may not be met with a single garment. Combinations of PPE with different properties can rapidly lead to problems with compatibility, mobility and heat stress. Therefore, this situation needs to be considered when conducting risk assessment, prior to purchasing the PPE and before starting work.

When combinations of PPE are worn together, they must complement one another and continue to fit properly. For example, the use of a face shield while wearing a solid-front gown would have no negative effect on the fit or functionality of either piece of equipment. On the other hand, the use of safety goggles with elasticized straps while wearing a respirator could create a situation where the tight-fitting nosepieces of each piece of equipment might interfere with the seal of the other. The proper fit and function of PPE when used in combination should be ensured for each user.

2.9 User requirements and feedback

It is important to note that there is not one size, shape, type and/or brand of PPE that is suitable for all personnel. Compliance with wearing PPE will generally be improved when users have an input on comfort and fit. Therefore, consultation with laboratory personnel and testing a variety of items is advisable to ensure the most appropriate items are acquired. Any PPE used in the laboratory must be correctly fitted for each individual. Personnel must also be given adequate training in order to ensure the PPE is functioning correctly, and is used properly and effectively. Incorrect use of PPE, for example, unfastened laboratory coats, will not give the protection they are designed to provide. Depending on the type of PPE, training may also include basic maintenance, decontamination and repair protocols to ensure that the item lasts and its protective features are sustained.

Feedback from the user should be sought regularly to gain information about the proper functioning of the PPE, the need to replace reusable PPE (for example, because of abrasion), potential difficulties users may have or any other issues that may adversely affect their ability to carry out the work effectively.

Providing statistics and descriptions of PPE failures as part of the biological risk-management system is useful to encourage regular implementation of improvements based on lessons learnt.

2.10 Availability of PPE

It is the responsibility of the employer or the institution to provide a sufficient selection of appropriate PPE for its personnel based on a risk assessment. The employer must provide a choice of different pieces of equipment so that all personnel receive the appropriate protective equipment (for example, the availability of different models of N95 respirators). In addition to the actual protection, the wearing comfort must also be taken into account.

2.11 Other considerations for selection of PPE

Making the workplace safe includes providing instructions, procedures, training and supervision to encourage people to work safely and responsibly.

Other factors may need to be considered when selecting the most appropriate PPE. These include:

- available space and conditions for storing reusable PPE,
- reliability of equipment over time,
- ease of maintenance; for example, some items may need to be sent off site periodically for calibration,
- disposal requirements; for example, equipment containing batteries may need to be disposed of through specialist contractors,
- record keeping of reusable items and stocks of disposable equipment,
- lead times for purchasing replacement equipment,
- cost of purchasing, maintaining and repairing equipment, and
- shelf life recommended by the manufacturer (for example, for a respirator with a chemical cartridge).

PPE FOR CORE REQUIREMENTS

Core requirements are a combination of risk control measures that are both the foundation for and an integral part of laboratory biosafety. These requirements are defined in the fourth edition of the *Laboratory biosafety manual (5)* and should be applied in all laboratory facilities. They reflect international standards and best practice in biosafety that are a set of minimum requirements and considerations for working safely with biological agents, even where the risks are considered minimal. The most important requirement of any laboratory facility is GMPP. This term covers a code of practice applicable to all types of activities with biological agents. It includes general behaviours, best working practices and technical procedures that should be observed in the laboratory. These should be carried out in a standardized way so that laboratory personnel and the community are protected from infection, the environment is protected from contamination and products are protected for work with biological agents.

The *Laboratory biosafety manual (5)* suggests the following as PPE core requirements:

- laboratory coats,
- footwear,
- gloves, and
- eye protection.

The use of respiratory protection is not generally required for protection against biological agents as a core requirement. Where a risk assessment indicates that respiratory protection is needed to protect against biological agents, this is considered a heightened control measure (see section 4 PPE for heightened control measures).

3.1 Laboratory coats

Laboratory coats are designed to prevent personal clothing from becoming splashed or contaminated by biological and/or chemical materials. There are various types of laboratory coat, but for the purposes of core requirements, laboratory coats must:

- fit correctly and be long enough to cover the knees, but not trail on the floor,
- have full length sleeves, preferably with fitted cuffs,
- not have the sleeves rolled up as this would expose the arms to potential contamination,
- be fastened,
- only be worn in designated areas, for example, not in the office,
- be removed and decontaminated when they are known to be contaminated, for example, from a spill, and
- be laundered regularly.

Where possible, laboratory coats should also be:

- high-necked and side-fastening with an overlap at the front to provide extra splash protection,
- made of a splash-resistant material, and
- made of flame-resistant material.

3.2 Footwear

Footwear must be worn in the laboratory. It must be of a design that minimizes slips and trips and can prevent injury from falling objects. Footwear should cover the top of the foot, and should be well fitting and comfortable to allow personnel to perform their tasks without their feet hurting.

3.3 Gloves

Appropriate gloves must be worn for all procedures that may involve planned or inadvertent contact with blood, body fluids and other potential or known infectious materials. Disposable gloves can be used but they should not be disinfected or reused as exposure to disinfectants and prolonged wear will reduce the integrity of the glove and decrease protection to the user. Gloves should always be inspected before use to check that they are intact.

Different types of glove may be needed for different work or with other occupational hazards, such as gloves that protect the user from heat, sharps or chemicals. Various sizes should be available to ensure that gloves properly fit the user to allow adequate movement and dexterity for the procedures being performed. Nitrile, vinyl and latex gloves are often used for protection against biological agents.

3.4 Eye protection

Safety glasses, safety goggles, face shields (visors) or other protective devices must be worn whenever it is necessary to protect the eyes and face from splashes, flying objects and artificial ultraviolet radiation. Reusable eye protection can be used but it must be regularly cleaned. If splashed, it must be cleaned and decontaminated with appropriate cleaning and disinfectant products.

Personal prescription glasses (spectacles) must not be used as a form of eye protection as they do not cover enough of the face around the eyes, particularly around the side of the head. Specialized prescription safety glasses must be purchased for personnel with such needs. Some goggles are available that have recesses that enable the user to wear glasses underneath them.

Where possible, goggles should be made of materials resistant to impact when being worn to protect against flying objects.

PPE FOR HEIGHTENED CONTROL MEASURES

Where determined by the risk assessment, additional PPE may be required as part of the risk control, over and above those defined as core requirements. These additional requirements are the heightened control measures and maximum containment measures proposed to address the higher initial risks associated with the performance of more specialized work and/or work with more hazardous biological agents.

Where national regulations exist, there may be compulsory, pre-defined lists of risk control measure(s) to be used. Beyond such requirements, the outcomes of the local risk assessment must be used to guide the selection of risk control measures, bearing in mind available resources, competency of personnel and practicality of implementation. Heightened control measures may include specialized PPE and/or specialized protocols with core requirement PPE that help further reduce identified risks.

4.1 Laboratory coats and additional body protection

Heightened control measures may require the following additions or alternatives to normal laboratory coats:

- laboratory coats that overlap at the front, which provide extra protection against splashes and spills;
- alternative protective clothing, such as gowns and coveralls with a zip flap for protection against splashes;
- an additional apron, fluid-resistant laboratory coat and/or disposable fluid-resistant sleeves, for example, for procedures where the possibility of large splashes cannot be discounted;
- scrubs or other dedicated laboratory protective clothing, for example, to prevent contamination of personal clothing; and
- appropriate decontamination of laboratory coats and other reusable items (for example, by autoclaving) before laundering.

More information on laboratory coats and additional body protection can be found in section 6 laboratory coats, gowns, aprons and coveralls.

4.1.1 Aprons

Additional hazard-specific splash protection may be required for certain procedures, such as, removing specimens from liquid nitrogen, when handling liquid chemicals, during autopsy, or where large volumes of liquid are being handled.

4.1.2 Gowns

Gowns offer a similar range of coverage as laboratory coats, although generally they are solid-front, back-closing garments with elasticized cuffs that can be worn on top of personal clothing or scrubs. Disposable gowns are generally intended as single-use items of PPE; however, they can on occasion be worn a few times before disposal, where the risk assessment specifies that the likelihood of contamination is low. Alternatively, wraparound reusable gowns may also be used, although they require regular decontamination and laundering.

4.1.3 Coveralls

Coveralls cover the whole body and are generally worn on top of scrubs or personal clothes. Depending on the quality, they may be disposable or reused if properly decontaminated. Care must be taken while removing coveralls to prevent any contamination of the person wearing them. Coveralls with a zip flap should be considered for protection against splashes.

4.2 Footwear

Footwear may need to be changed before entering the laboratory if: there is a requirement to prevent cross contamination (alternatively disposable overshoes may be worn); personal footwear is inappropriate for working in the laboratory (for example, open-toed footwear or high heels); or specific splash protection is required. More information can be found in section 7 footwear.

4.3 Gloves

Additional gloves (for example, double gloving, cut-resistant gloves) may be required for some activities. These activities may include: animal work; work with concentrated liquid waste material; where a two-step decontamination process is used; or removal of contaminated PPE.

An appropriate range of sizes must be available to ensure proper fitting of the multiple layers. It is important to note that wearing several layers of gloves can reduce dexterity and the ability to handle specimens correctly, thereby potentially increasing the likelihood of exposure. This must be considered during the risk assessment process and incorporated into training. More information can be found in section 8 gloves.

4.4 Eye protection

Eye protection is required in the same circumstances as outlined in the core requirements. However, these items need to be compatible with respiratory protection, if worn. More information can be found in section 9 eye and face protection.

4.5 Respiratory protection

Respiratory protective equipment is a form of PPE designed to protect the wearer from inhaling particles that contain biological agents that may be present in the air or generated during certain laboratory procedures. Respiratory protection can be used to protect personnel from aerosols as an alternative or in addition to carrying out work in a BSC. However, respiratory protection should only be used after careful consideration of the risks as this equipment only protects the wearer. Therefore, other measures may be required to ensure that any other laboratory personnel and/or the local environment at risk of exposure/contamination are also protected.

Respiratory protective equipment must be selected carefully based on the results of a risk assessment. It must only be used by trained personnel who know what the appropriate equipment for the work is and how to use it correctly. More information on respiratory protective equipment can be found in section 10 respiratory protection.

PPE FOR MAXIMUM CONTAINMENT MEASURES

Most laboratory work will be done using core requirements or with heightened control measures. However, in exceptional circumstances, the risk assessment may necessitate the use of a maximum containment facility to control risks to personnel and the wider community. Maximum containment facilities will only be required where biological agents of high consequence are used for work that presents an increased likelihood of exposure or release, or in accordance with national regulations.

Maximum containment laboratories are those that offer the highest level of protection to the laboratory personnel as well as the wider community and environment. There are a limited number of such laboratories in the world as they are very expensive to build, operate and maintain. Normally, such laboratories must comply with highly detailed national legislation and guidance, even before being given permission to operate, and they have annual regulatory inspections. This section gives only a basic introduction to such facilities. More detail can be found in the *Monograph: laboratory design and maintenance (7)*, and in relevant national guidance documents.

There are two designs of maximum containment facilities. The first is a cabinet line facility, where all work is carried out in a closed system of class III BSCs or isolators. The second is a facility where operators work in positive-pressure encapsulating suits in open-fronted BSCs – also in a negative-pressure laboratory. In a suit laboratory system, the suit must be designed to withstand contact with the equipment, chemicals, disinfectants and other materials used in the suit laboratory. The suit must also allow tasks and contact with any animal species to be carried out safely. Detailed SOPs should be developed on safe use of the suit, with personnel receiving practice and training on how to implement the SOPs correctly.

5.1 Cabinet line facilities

Class III BSCs or isolators provide an enhanced level of protection for the operator and the environment for high-risk activities (further details are given in *Monograph: biological safety cabinets and other primary containment devices (8)*). Depending on the risk assessment, a complete change of clothing may be required before entering the laboratory. All jewellery must be removed. Laboratory clothing may include undergarments, pants, shirts, scrub suits, jumpsuits, disposable coveralls or laboratory coats (tie-back or wrap-around gowns). Disposable gloves must be worn to protect the operator in case of a tear in the cabinet glove. Eye, face and respiratory protection may be needed in addition, if this is an effective means of protection according to the risk assessment.

Operators may have to take a personal body shower before leaving the laboratory area. Used laboratory clothing must be treated as contaminated materials and decontaminated before laundering. Prescription spectacles must be decontaminated before removal from the laboratory area.

5.2 Positive-pressure suits

Positive-pressure suits are fully encapsulating items of PPE that provide a total barrier between laboratory personnel and the surrounding laboratory environment. They consist of a full-body suit, made of hard-wearing material, with an integral visor and footwear, external air hose, internal air delivery system, and open cuffs where durable gloves are attached and changed on a regular basis. Unlike other forms of PPE that allow the wearer relative freedom of movement within a laboratory space, positive-pressure suits require that users maintain a nearly constant, direct connection with the air supply of the facility through an attached hose. This critical connection provides the user with breathing air that has passed through high-efficiency particulate air (HEPA) filters and maintains an internal environment at positive pressure compared with the surrounding laboratory space. Here, the suit's protective properties rely not only on operator use but also on proper performance of the facility's dedicated breathing air system.

Several makes and models of positive-pressure suits are available, each with particular features. Features of these suits that vary between manufacturers include: the material used to make the suit; visor size; field of vision provided; gloving system; boot type; airflow requirement; number and placement of air diffusers and exhaust valves; and overall bulkiness of the suit when inflated.

As positive-pressure suits are reusable, their integrity must be tested regularly through quantitative or qualitative means to ensure they function properly. The frequency of such testing should be determined through the risk assessment; however, visual checks of the entire suit surface must be carried out before each use. In addition, an effective maintenance system needs to be in place that covers cleaning, disinfection, examination, replacement, repair and testing of a suit.

Because of their inherent complexity, a rigorous training programme is required to ensure that all users have a full understanding of the function of positive-pressure suits and their proper use. The physical demands, restricted movements and altered spatial awareness that come with working in a positive-pressure suit require that all users have intensive practical training before starting any high-risk activities.

LABORATORY COATS, GOWNS, APRONS AND COVERALLS

Laboratory coats, gowns, aprons and coveralls/suits can all be used to protect personal clothing and the body from becoming contaminated through direct contact with contaminated surfaces and splashes. It is important that these items are:

- worn as recommended by the manufacturer,
- only worn in designated areas,
- compatible with other PPE, for example, gloves with longer cuffs might be required,
- checked before use,
- put on correctly to ensure that they provide the protection intended, and
- removed correctly to avoid contamination of personal clothing and skin if the PPE was contaminated during use.

6.1 General information

Given the nature of the work to be performed and the environment in which it takes place, protection may be required against multiple types of hazards. Markings on garments identify the intended fields of use. Table 6.1 gives the various types of protective coverall/suit according to the ISO classification system and the protection they provide the wearer, and examples of where they would be used. Other national or local classification systems have to be considered because they might differ from the ISO classification (as an example the US classification covers level A to D (12)). Consideration must also be given to the specific chemicals being used, the material the PPE suit is made of (its penetration, permeation and degradation) and the areas of the body to be protected and hence the type of PPE needed (for example, apron to full suit). No material gives indefinite chemical protection and therefore effective decontamination of the PPE after exposure may not be possible.

Table 6.1 Protection of coveralls/suits against substances used in the laboratory

ISO CLASSIFICATION ^a	PROTECTION	EXAMPLE OF USE
TYPE 1	Gas tight (used with breathing apparatus)	Maximum containment suit
TYPE 2	Non-gas tight (used with breathing apparatus)	Intense spraying/fogging
TYPE 3	Liquid tight, resistant to jets of liquid	With large volumes of liquids
TYPE 4	Liquid spray tight	Spray application in a controlled environment
TYPE 5	Dry particle protection	Dust/powder application
TYPE 6	Limited chemical/light spray protection	Where light splashes may occur
B	Protection against biological agents ^b	Decontamination of biologically contaminated environments

ISO = International Organization for Standardization.

^a As per ISO 16602:2007.

^b Any suit type offering demonstrated protection against biological agents will be denoted by a letter "B" (for example, type 4-B, type 5-B).

6.2 Pre-use checks

Before putting on laboratory coats and any additional or alternative body protection, they should be checked for integrity; for example, that there are no unintended holes, loose stitching, rips or tears. If a loss of integrity is identified, the PPE should either be discarded or mended before use.

6.3 Putting on body protection

When putting on laboratory coats and additional or alternative body protection, care should be taken to avoid damaging the material. This is especially important for single-use garments, because they are inherently less resistant than reusable items of a similar nature. When putting on reusable items, care should be taken to minimize contact with the outer/exposed side of the material in case of incomplete decontamination from the previous use.

6.4 Removing body protection

There are many different types and styles of laboratory coats and additional or alternative forms of body protection. The following subsections provide a general guide to removing protective clothing. Where gloves have been used, a risk assessment should have been carried out to determine the most appropriate steps before removing the laboratory coat, gown, apron or coverall. Gloves may either be 1) removed first followed by hand washing, 2) decontaminated, or 3) removed and replaced by clean gloves before removing the laboratory coat, gown, apron or coverall. If gloves become contaminated during the removal process, they may have to be decontaminated or replaced by clean gloves.

6.4.1 Laboratory coats

To remove a laboratory coat, open the front and hold the cuff of one arm with the fingers of the other hand and pull the arm out of the sleeve. Then do the same with the other sleeve. Hang the laboratory coat up or turn it inside out for disposal, decontamination or laundering.

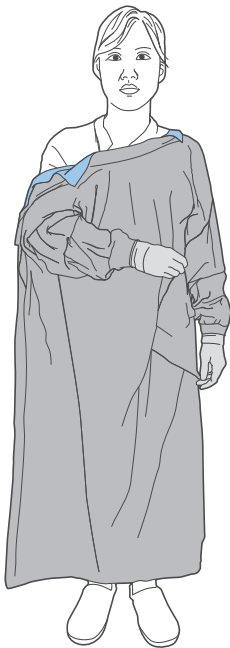


Figure 6.1 Removal of a laboratory gown

6.4.2 Gowns

To remove a gown, untie the fastening holding the gown together and pull the gown from back to front by rolling it from inside to outside (Figure 6.1).

6.4.3 Aprons

To remove a disposable apron, untie or break (for example, if using a disposable plastic apron) the fastening at the neck and roll the apron down (Figure 6.2). This allows the potentially contaminated front of the apron to be contained as it is rolled. Then, untie or break the fastening at the back of the waist and roll the apron further without contaminating the hands.

To remove a reusable apron, first wipe the front of the apron with a suitable disinfectant. Then, untie the fastening at the back of the waist and slip the neck fastening over the head. Hang up the apron or send for laundering.



Figure 6.2 Procedure to remove a disposable apron

6.4.4 Coveralls

To remove disposable coveralls, open the front, slip the coverall over the shoulders, pull the arms from the sleeves (Figure 6.3). Then, roll the coverall down inside out (this step may require assistance from another person). Finally, remove the coverall and, if necessary and worn, remove the boots.

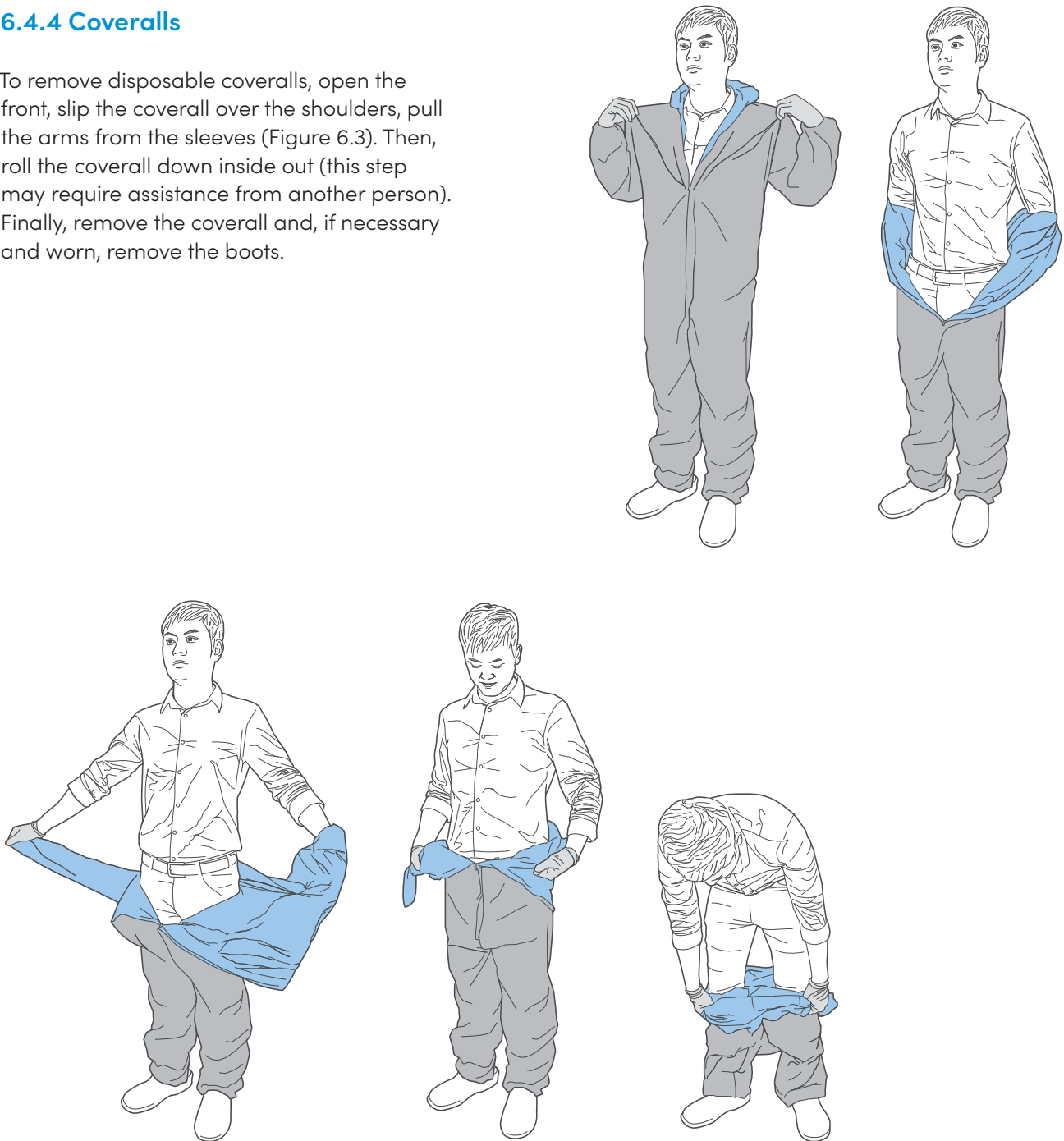


Figure 6.3 Procedure to remove a disposable laboratory coverall

FOOTWEAR

Suitable, well-fitting, closed-toe footwear is required in the laboratory to minimize the likelihood of slips and trips and to prevent injury from falling objects. Shoe covers are useful when entering a laboratory to clean up a spill or for visitors. Footwear might need to be changed before entering the laboratory to prevent contamination of personal footwear, or if additional foot protection is required against splashes, impact, chemicals or temperature extremes.

Footwear is available in a range of styles, for example, shoes, low ankle boots and high ankle boots. For each type, there are a range of mandatory and optional performance requirements.

The following factors must be considered when selecting and using footwear:

- size, form and comfort,
- material the footwear is made of (for example, polymer/synthetic material, leather or mixed materials) and ease of cleaning and disinfection,
- means of fastening/holding in place,
- properties of the sole, for example, resistance to penetration by sharp objects, electrical conduction, insulation or antistatic, heat resistance, oil resistance, heat/cold insulation, and
- other properties, for example, resistance to water penetration/absorption, protection of foot bones, resistance to cutting.

Where boots are required, it might be helpful to use one or two sizes larger than normal, not too big that they would increase the risk of a trip, but large enough that they can be removed easily without assistance.

7.1 Protective footwear against chemicals

The degree of resistance to a certain chemical is determined by standardized testing of chemical degradation and/or permeation in accordance with international standards. See section 14 standards and regulations.

7.2 Non-slip footwear

There is no such thing as “non-slip” footwear, but some types of sole (material and tread pattern) offer much better performance than others. Standard biomechanical machine tests are available to assess slip resistance, but they do not reproduce realistic foot/floor interactions, and may not provide meaningful results. Alternative, more realistic assessment techniques exist which give much better correlation with risks in use, although not all are based on a particular standard.

GLOVES

Most laboratory tasks require handling and manipulation of specimens. Because of this, hands are the part of the body most likely to become contaminated when doing laboratory work. Appropriate gloves must be worn for all procedures that may involve direct or accidental contact with blood, body fluids and other potentially infectious materials. Disposable, single-use, microbiologically approved latex, vinyl, neoprene or nitrile surgical-type gloves are widely used for general laboratory work. Reusable gloves may also be used but they must be correctly cleaned, disinfected and removed. It is important to note that gloves are only effective if they are selected, put on, used and removed correctly. Gloves must not be worn outside the laboratory areas.

People have different-sized hands and even an individual's hands can change in size over time; for example, if the wearer gains or loses weight, or where ambient temperature changes occur throughout the year. It is important that the correct size of gloves is used. If gloves are too tight, this will cause them to overstretch and increase the likelihood of material failure. Conversely, if they are too big, then they may fall off the wearer's hands, or the excess material may crease or may get caught on equipment, increasing the likelihood of tearing or contamination. A range of glove sizes must therefore be available for laboratory personnel to wear.

8.1 Glove types

Many different types of gloves are available, and the type selected and used must be appropriate for the task being performed. For example, gloves that protect against biological agents may not necessarily protect against chemicals such as disinfectants. It is therefore important to know what activities are going to be carried out, and the likely concentrations and volumes of hazardous materials that will be dealt with. An informed decision can then be made on the type of gloves that need to be worn based on the risk assessment.

Glove materials vary. The most commonly used material is nitrile but a number of other materials are also used, including latex. It is important to note that latex protein can cause allergy over time. Allergic reactions such as dermatitis and immediate hypersensitivity have been reported in laboratory and other personnel wearing latex gloves, particularly latex gloves with powder. Gloves that are powder-free and made of low latex protein are available which can reduce the likelihood of allergy. Alternatives to powdered latex gloves should be available in the laboratory and these must be used by individuals where latex allergy has been determined.

8.1.1 Protection factors

Glove manufacturers should provide detailed information on the levels of protection provided by the various gloves they offer. Manufacturers' product information will give specifications and useful details about the protection provided by their gloves. These specifications should be checked before use. More information on protection factors and standard tests can be found in section 14 standards and regulations.

8.1.2 Reusable gloves for other laboratory hazards

Certain laboratory activities require hand protection from more than biological and chemical hazards. Protection may be needed from temperature extremes, including exposure to sub-zero or cryogenic temperatures when retrieving specimens from freezers or liquid nitrogen tanks, or to very high temperatures when removing items from an autoclave, hot plate or microwave. Most often, gloves that offer protection from extreme temperatures are not rated for protection against biological agents because they are meant for activities where infectious material is either absent, inactivated, or preserved in a primary container in a state (frozen) that poses minimal likelihood of exposure.

Some types of gloves may be required to protect from mechanical hazards such as sharps, including scalpels, needles, scissors and bone cutters. Gloves designed for this purpose are assigned specific cut-resistant or puncture-resistant ratings in accordance with standardized testing procedures such as BS EN 388:2016+A1:2018 (see section 14 standards and regulations). As the nature of these gloves may result in limited dexterity for the wearer, their use should be based on risk assessment and users must be adequately trained in their use before handling infectious materials. In addition, as most of these gloves are meant to be reusable and do not necessarily offer protection from biological materials, disposable laboratory gloves designed for protection against biological agents may need to be worn underneath and/or over the top of the mechanical protective gloves to minimize cross contamination of reusable gloves.

8.2 Pre-use checks

Before putting on a pair of gloves, they should be checked to ensure they protect against the hazards being handled and that they have not expired.

It is important to note that with any batch of gloves, a small number will have been damaged or not correctly formed during the manufacturing process. Therefore, manufacturers test a number of gloves from each batch to calculate an acceptance quality level (AQL) for that batch. For example, if the glove packaging shows an acceptance quality level of 1.5, this means that 1.5% of the gloves in this box may be imperfect. Therefore, it is essential to check each glove before use.

To ensure a glove is safe to put on and use, look for any imperfections in the glove material, such as discolouration, obvious holes or tears, or where the glove material has become firmly stuck to itself. Holes in the glove may not be easily visible. A simple way to check is to slightly inflate the glove. Do not breathe air into the glove as moist breath will make the glove difficult to put on and hand-to-mouth contact within the laboratory should be avoided. Where possible, flap the glove a few times to capture room air and then gently push the captured air down the glove to inflate the palm and finger areas. If the glove remains inflated, it is safe to put on. If it deflates, it must be disposed of.

With thicker reusable gloves, visual checks for obvious signs of degradation should always be done before use.

8.3 Putting on gloves

When putting on a pair of gloves, it is important that the material is not overstretched as this can cause the gloves to tear and increases the likelihood of holes appearing in the material. Rings should be removed beforehand as they can damage the gloves. Talcum powder may be helpful when putting on disposable gloves. When gloves with longer cuffs are available for use, they should be pulled over top of laboratory coat cuffs.

With reusable gloves that protect against a particular chemical or mechanical hazard, it is best practice to put on a clean pair of disposable gloves underneath to protect the skin from any potential residual contamination of the glove material from a previous use.

8.4 Using gloves

Disposable gloves should not be disinfected, for example, with ethanol, before starting work and they should not be reused as exposure to disinfectants and prolonged wear will reduce the integrity of the glove material.

If disposable gloves become noticeably contaminated, they should be removed immediately and disposed of appropriately to prevent further contamination of other PPE, equipment and specimens. Reusable gloves (for example, gloves for use with disinfectant dunk tanks or those providing protection from sharps) should be appropriately cleaned and decontaminated before being removed and stored for next use. A rigorous cleaning and disinfection protocol is therefore required for the reuse of such specialized gloves to ensure removal of biological hazards and/or chemical residues that could compromise the integrity of the gloves. This cleaning must always be done according to the manufacturer's instructions.

If at any time during use disposable or reusable gloves show any noticeable loss of integrity (for example, chemical permeation, holes, abrasions or tears), they must be removed immediately and disposed of correctly. If gloves become contaminated and are not removed correctly, the hands and wrists of the wearer can become exposed to hazardous materials.

8.5 Removing gloves

To remove disposable gloves correctly, pinch the thumb and forefinger together on one hand. With the other hand, pinch the material just below the top of the cuff of the glove, and pull the glove down towards the closed thumb and forefinger, turning the glove inside out in the process. Stop on reaching the thumb and forefinger so that the glove is only partially removed. Repeat on the other hand. At this point the gloves are both partially removed with the clean undersides of the gloves now forming the outer surface. The gloves can now be removed by touching only the clean underside of the material (Figure 8.1).

Used disposable gloves should be discarded with contaminated laboratory waste. Once gloves are removed hands must be washed.

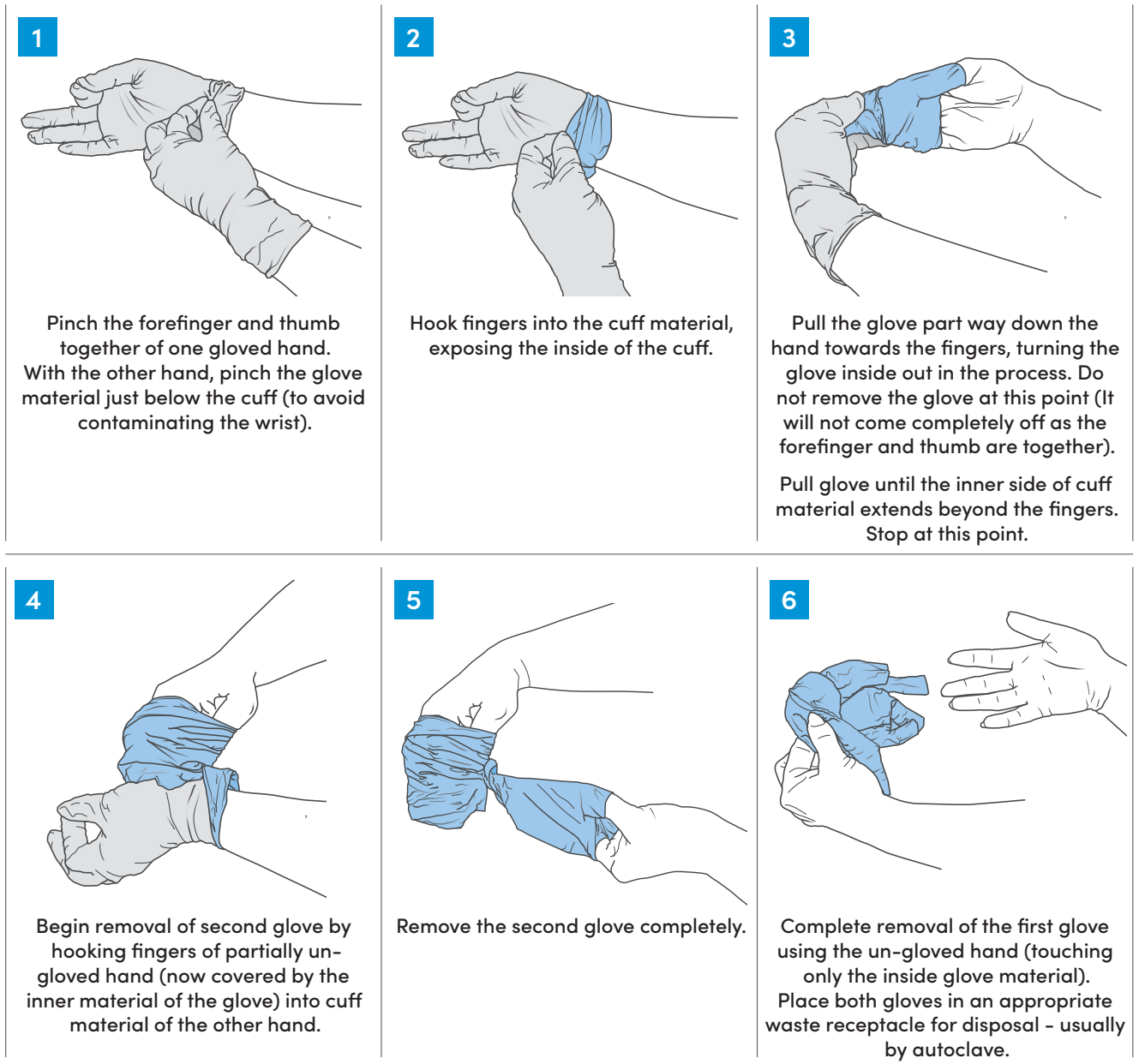


Figure 8.1 Removing disposable gloves

EYE AND FACE PROTECTION

Eye protection is designed to protect the wearer from anything that might impact the eye such as particles and splashes. It may also protect against ultraviolet light.

A number of different types of eye protection are available including safety glasses, safety goggles and face shields or visors. It is important to note that prescription spectacles are not classified as eye protection. Therefore, they must not be used as protection because they do not cover enough of the eye, particularly around the side of the face, and are not necessarily designed to protect against ultraviolet light or flying objects. Where prescription lenses are required, either prescription safety glasses or specialized goggles that have been designed to be worn over the top of prescription spectacles should be purchased. As eye protection is generally reusable, it must be regularly cleaned and decontaminated with an appropriate disinfectant.

9.1 Putting on and using eye protection

Eye protection should be worn in the laboratory where there is a likelihood of splash, or exposure to other hazards such as ultraviolet light. It should be put on with clean hands (for example, not after handling microorganisms) to avoid contamination of the face and the eye protection itself. Any straps must be positioned according to the manufacturer's instructions.

Eye protection must fit correctly and be comfortable to wear. Examples of an incorrect fit include goggles being too tight and safety glasses falling down the bridge of the nose. Badly fitting eye protection does not offer the wearer an adequate level of protection. In fact, it increases the likelihood of exposure to hazardous materials because of constant readjustment of the eye protection with potentially contaminated hands.

If eye protection becomes visibly contaminated during use, it should be removed, cleaned and decontaminated before reuse.

9.2 Removing eye protection

Eye protection should be removed with clean hands to avoid contamination of the head. There are several ways to remove eye protection, which will depend on the type being used (for example, goggles versus safety spectacles), the number of additional PPE items being worn, the order in which the PPE items are removed and the level of contamination. However, a common method of removing goggles and visors is to pull the strap at the back of the head forward (Figure 9.1). This must be done with clean hands or clean gloved hands. Care must be taken to avoid the front of the goggles flipping up. Alternative methods of removal may be appropriate where combinations of PPE are worn.

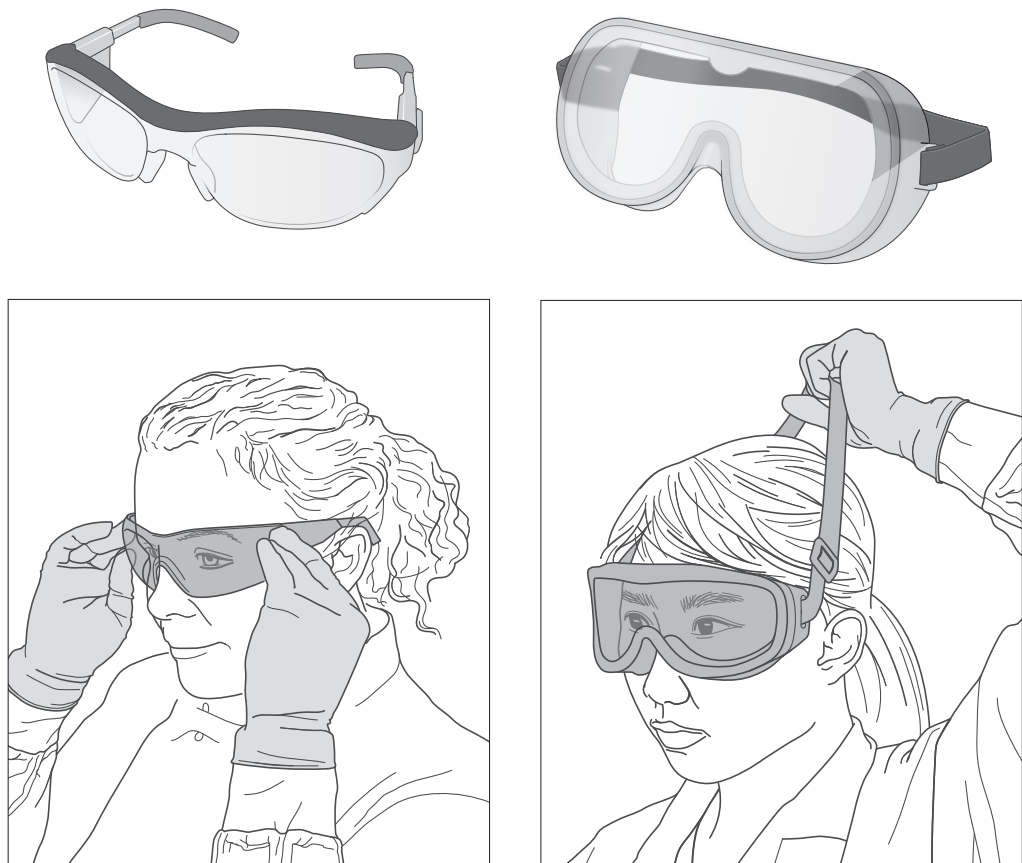


Figure 9.1 Types of eye protection and correct removal of eye protection

SECTION 10 RESPIRATORY PROTECTION

Respiratory protective equipment is a category of PPE designed to protect the wearer from inhaling hazardous particles and gases including chemical and biological agents that may be present in the air. When working with biological agents, respiratory protection may be used when carrying out high-risk or aerosol-generating procedures, for example, cleaning up a large spill of infectious material.

The choice of respiratory protective equipment will depend on the type of hazard(s) present, the work environment and the laboratory personnel who may have to wear this equipment as determined by the risk assessment.

When respiratory protective equipment is required, the following conditions must be met.

- The level of protection provided by the respiratory protective equipment is appropriate for the risks identified and its use reduces exposure (for example, by filtering infectious particles) to the level required to protect the wearer's health.
- The wearer can work freely while wearing the respiratory protective equipment and without additional risks (for example, impaired lung function, claustrophobia).
- It is worn correctly, as specified in the manufacturer's instructions only.
- It fits the person wearing it. This may require procuring different types and brands of respiratory protective equipment for different laboratory personnel and/or procedures.
- Where reusable respiratory protective equipment is used, it is appropriately cleaned and decontaminated after use, and properly stored and maintained.
- It complements any other PPE being worn. This is especially important in the use of eye protection.

Two main types of respiratory protective equipment are available: respirators (filtering devices) and breathing apparatus, which require a supply of air of breathing quality from an independent source, such as an air cylinder or air compressor. In this monograph, information is provided on respirators. The requirement for breathing apparatus in the context of laboratory biosafety is limited to maximum containment measures (positive-pressure suits) and therefore will not be covered here.

10.1 Surgical masks

The main intended use of surgical masks is to protect patients and the clinical area from infectious agents from the nose and mouth of the person wearing the mask. As such, they are not classified as respiratory protective equipment. However, in certain situations and if worn properly, a surgical mask and additional eye protection can protect the wearer against droplets and splashes of potentially contaminated liquids. The use of respiratory protective equipment should be considered if the risk assessment so dictates, or the work should be done in a primary containment device. It is important to note that not all surgical masks offer splash protection.

10.2 Respirators

Respirators are a type of respiratory protective equipment that use filters to remove contaminants from the air being breathed in. Respirators are available with interchangeable filters for protection against gases, vapours and particulates, including biological agents. The filter fitted to the respirator must be appropriate for the type of contaminant against which protection is required. That is to say, a respirator offering protection against aerosolized biological agents and/or particles does not protect the wearer against gases or noxious vapours. Conversely, respirators equipped with gas filters do not necessarily protect against biological agents. Respirators can be powered or non-powered.

- Non-powered respirators – rely on the wearer's breathing to draw air through the filter.
- Powered respirators – use a motor to pass air through the filter to give a supply of clean air.

Filtering facepiece respirators (Figure 10.1)

- Half masks are designed for particle filtration.
- Masks consist entirely or mostly (if a valve is present) of filter material.
- They cover the nose, mouth and chin.
- They are fitted in place with adjustable straps.
- Air breathed in passes directly through the filter material.
- Air breathed out passes directly through the filter material or exhalation valve (if built in).
- Exhalation valves increase wearer comfort.
- They are normally intended for single use.



Figure 10.1 Filtering facepiece respirator

Half mask respirators (Figure 10.2)

- Half masks are designed to hold filters protecting against either particles and/or gases/vapours.
- They cover the nose, mouth and chin.
- They are fitted in place with adjustable straps.
- Air is breathed in through filters.
- Air is breathed out through an exhalation valve.
- They are usually designed to permit cleaning, disinfection and reuse.

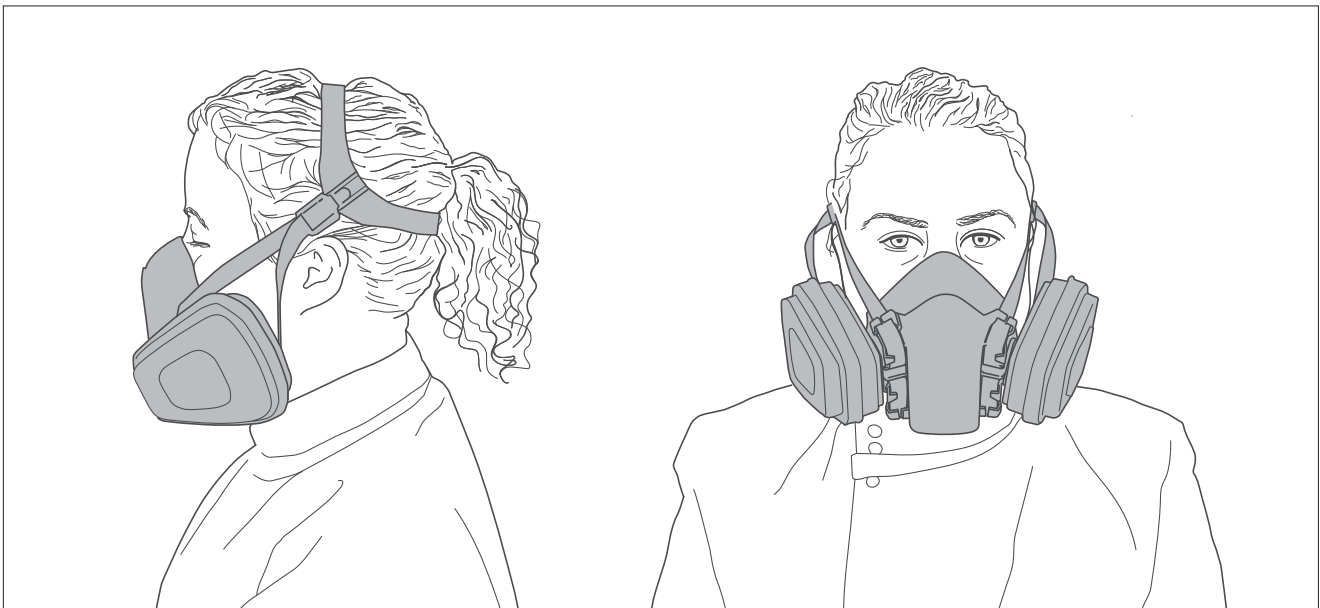


Figure 10.2 Half mask respirator

Full face mask respirators (Figure 10.3)

- Full face masks cover the eyes, nose, mouth and chin.
- They are sealed against the face of the wearer and held in place with adjustable straps.
- They can have particle filters and/or gas/vapour filters.
- Air is breathed in through filters.
- Air is breathed out through an exhalation valve.
- Most full face masks have an inner mask to reduce inhalation of exhaled carbon dioxide, reduce misting and increase comfort.
- Some have a speech diaphragm to help communication.
- Some are designed for use with spectacles.
- A built-in visor protects against splash.
- They are usually designed to permit cleaning, disinfection and reuse.



Figure 10.3 Full face mask respirator

Powered respirators (Figure 10.4)

- They are powered filtering devices, also known as powered air-purifying respirators.
- They have multiple components including battery-operated power for a fan unit, filter(s) and facepiece: either tight-fitting such as a full or half face mask, or loose-fitting such as a visor, helmet, hood or full suit.
- They have particle filters, gas/vapour filters or combined filters.
- A fan unit actively draws room air through a filter cartridge and blows filtered air into the hood, protecting the wearer by creating a positive air pressure. Usually, different levels of airflow are available.
- A connecting hose supplies air from the blower fan to the hood.
- They are usually designed to permit cleaning, disinfection and reuse.
- Models with loose-fitting hoods are appropriate for individuals with facial hair and do not need fit testing.
- They do not offer any protection if the battery/fan air supply fails or the connecting hose is not connected properly; therefore correct maintenance is essential for these types of respiratory protective equipment.

The airflow of the device must be checked before each use.

10.3 Types of filter

Filters are devices designed to provide a barrier between users and potential hazards by trapping the hazardous substance in a matrix of fibres and allowing only filtered ambient air to pass through. Filters are classified according to the form of the hazardous substance(s) they can be used against – particles, gases/vapours, multiple gases or combined (particles and gases/vapours). When selected appropriately, filters provide suitable protection from various types of workplace hazard; however, they do not protect wearers against oxygen-deficient atmospheres.

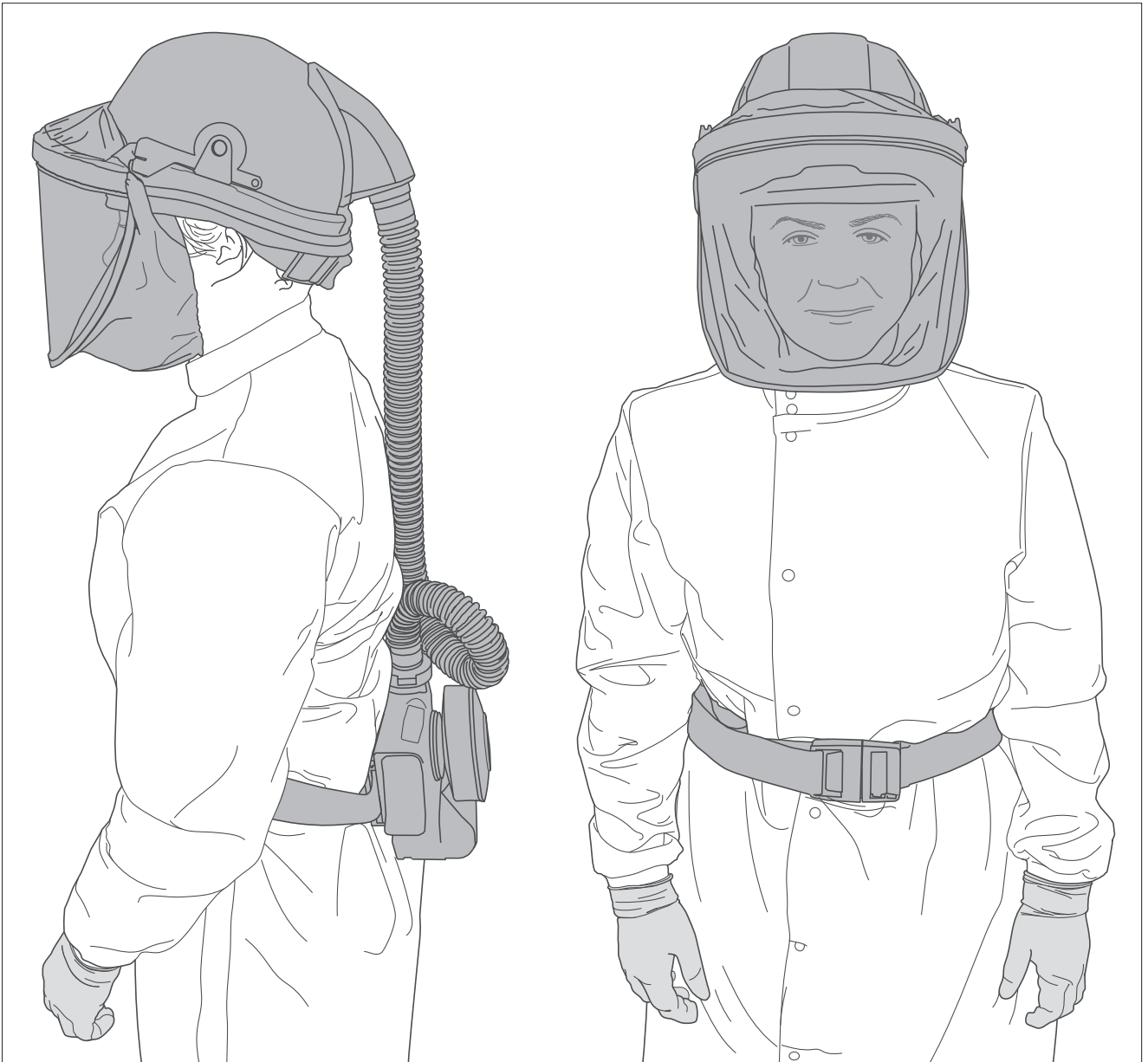


Figure 10.4 Powered respirator

Table 10.1 European Union and United States classification of filter descriptors

FILTER DESCRIPTOR	EUROPEAN UNION CLASSIFICATION ^a	MINIMUM FILTRATION EFFICIENCY (%)	UNITED STATES CLASSIFICATION ^b	MINIMUM FILTRATION EFFICIENCY (%)
Low efficiency	P1 (for example, FFP1)	80	N95, P95, R95	95
Medium efficiency	P2 (for example, FFP2)	94	N99, P99, R99	99
Very high efficiency	P3 (for example, FFP3)	99	N100, P100, R100	99.97

FFP = filtering facepiece (tested against both dry and oil particulates).

^a Comité Européen de Normalisation [European Committee for Standardization] classification.

^b National Institute for Occupational Safety and Health classifications (N means not resistant to oil, R means resistant to oil and P means oil proof).

10.3.1 Particle filters

Particle filters trap and hold particles (dust, mist, fumes, smoke, microorganisms) from the air flowing through them. Large particles are easier to trap than small ones. These filters can be used against both solid particles and liquid particles (mists, fine sprays and aerosols).

Particle filters are classified according to their efficiency. Different classification systems exist (based on various national and international standards). Table 10.1 shows the different nomenclature used between current classification systems in Europe and the United States of America.

The various classifications of respiratory protective equipment are easily confused. This situation was highlighted in the 2002–2004 outbreak of severe acute respiratory syndrome where N95 masks were being recommended by health authorities, which led to a global shortage of N95 masks even though the equivalent FFP2 masks were available. New ISO standards: ISO 16900 (parts 1–14); ISO 16972; ISO 16973; and 16974 are currently being revised to standardize the classification of respirators to reduce confusion and allow a faster response to outbreaks. A classification for an equivalent N95/FFP2 mask could be classed, for example, as PC3W1bTF2 RPD. More details are given in section 14 standards and regulations.

As a filter is used, it becomes loaded with the contaminant(s) and eventually becomes blocked. This makes it difficult for the air to flow through the filter and indicates that it should be replaced. Sometimes, the blockage might impair the efficiency of the filtration media by decreasing its global electric charge or even reversing it. As a result, pores might form in the media that could allow the passage of hazardous particles. To avoid this possibility, masks can be tested by the dolomite clogging test. This test checks whether the mask still has a good level of breathing resistance after being subjected to high levels of dolomite dust. If a mask passes the dolomite test (often indicated by the “D” symbol), then it can be worn over a long period even at high levels of dust concentration.

10.3.2 Gas/vapour filters

Gas/vapour filters are available for use against groups of contaminants such as organic vapours or specific contaminants. Typically, these filters are used to protect against vapours or gases from certain disinfectants such as formaldehyde, for example, when re-entering the laboratory after fumigation, when residual fumigant may be present. Gas/vapour filters have different lengths of time they can be used in a certain situation. They are classified according to this length of time and the type of substance they can be used to protect against.

As a gas filter is used, it becomes saturated with the gaseous contaminant and will eventually no longer be able to remove the contaminant. This is referred to as “breakthrough” and indicates that the filter should no longer be used. It is important that the gas filter is changed before breakthrough occurs; otherwise, the wearer will be exposed to the contaminant. Manufacturers’ specifications provide further information on the service life of gas filters and must be strictly followed.

It is important to note that gas/vapour filters do not provide protection against biological agents. Where protection is required against a gas or vapour and a biological agent, the gas/vapour filter must be combined with a particle filter.

10.4 Fit testing of respiratory protective equipment

Many respirators whose protection factors rely on an effective seal between the facepiece and the wearer’s face must be fit tested. The purpose of fit testing respiratory protective equipment is to verify that the selected make, model and size of a tight-fitting respiratory protective equipment adequately fits the wearer. Fit testing also serves as a validation that the wearer knows how to correctly inspect, put on and remove the respiratory protective equipment and check the fit of the face seal.

Tight-fitting respiratory protective equipment will only provide effective protection if the wearer is clean-shaven and free of jewellery in the area of the face seal. Wearers should also be clean-shaven and free of jewellery when fit tested. Periodic retesting is also warranted as physical changes following pregnancy, weight loss or gain, or any other major physical intervention may affect the fit of certain types of tight-fitting facepieces and result in insufficient protection.

Loose-fitting respiratory protective equipment, such as hoods, do not rely on a tight facial fit and therefore do not require a fit test.

Respiratory protective equipment is available in different sizes to allow for the facial differences of personnel. Gender, ethnicity, build and many other factors mean that one size and type of respiratory protective equipment is unlikely to be suitable for everyone.

There are two fit testing methods: quantitative and qualitative (Figure 10.5). They are equally effective for identifying whether a tight-fitting facepiece fits correctly.

10.4.1 Quantitative fit testing

Quantitative fit testing provides a numerical indicator of fit called a fit factor. This type of testing can be used to fit test filtering facepieces, half masks and full face masks. The most common method uses an ambient aerosol condensation nuclei-counting instrument.

Fit testing instruments that use condensation nuclei-counting measure the concentration (c) of particles in the ambient air surrounding the wearer outside the respirator (known as c_{out}) and the particle concentration in the breathing zone inside the respirator (known as c_{in}). The concentrations of particles are measured while the respirator wearer being fit tested performs a series of exercises designed to stress the face seal in ways that approximately mimic the anticipated workplace movements. The quantitative fit factor is calculated from the ratio of the two measures to make sure the respirator will protect the wearer sufficiently during the intended workplace activities.

Condensation nuclei-counting instruments for fit testing usually use the particles in the ambient air as the challenge aerosol. This eliminates the need for aerosol generators and fit test chambers; however, aerosol generators can be used to increase aerosol concentration when needed (in clean environments such as hospitals).

10.4.2 Qualitative fit testing

Qualitative fit testing methods use test agents with distinctive tastes or smells for detecting leakage through the face seal. Three test agents are commonly used as aerosol (particles) challenges for a qualitative fit test: a sweet-tasting aerosol (sodium saccharin), a bitter-tasting aerosol (denatonium benzoate) and a sweet-smelling vapour (banana, isoamyl acetate). Fit testing need only be done using one of the substances.

The fit tests use a wearer's ability to taste or smell small amounts of the fit test aerosol to determine the effectiveness of the face seal. However, a small proportion of individuals cannot taste or smell the test agents and so this needs to be checked before the fit testing procedure. To test the individual's ability to taste/smell low concentrations of the fit test agent, a weak solution of the selected substance is sprayed into a fit test hood placed over the wearer's head while not wearing the facepiece. If the individual cannot taste or smell the agent, then an alternative agent should be checked and used, or the quantitative fit testing method used instead.

Where it has been determined that the individual can taste/smell the selected agent, then the qualitative fit testing can be done. While the wearer is wearing a facepiece, the fit test hood is placed over the head and a stronger solution (compared with the initial taste/smell check) is sprayed into the fit test hood at measured intervals, while the wearer conducts a fit test exercise (for example, moving, talking). If the wearer being fit tested does not detect the taste of the test solution, the fit test is considered a pass.

Qualitative fit testing can be used to fit test filtering facepieces and half masks but not full face masks.

10.5 Pre-use checks

Every time either new or reusable respiratory protective equipment is to be worn, it is essential to check that it is safe to wear before putting it on. All respiratory protective equipment should be checked for all the following before putting on.

- Size and class of respiratory protective equipment are correct.
- Correct filters are being used.
- There are no obvious signs of damage, for example, broken straps or tears in filter material; if damage is identified, the respiratory protective equipment should not be worn.

For certain types of respiratory protective equipment, the following should also be checked before putting on.

- Inhalation valve is positioned correctly in front of housing filters.
- Exhalation valve is positioned correctly.
- Visor is intact and free of scratches.
- Body of the facepiece and the seals have no splits.
- Screw threads for positioning filters are intact.
- Head harness is intact.
- Battery is fully charged if a powered air-purifying respirator is used.

10.6 Putting on respiratory protective equipment

The respiratory protective equipment must be put on as instructed in the manufacturer's instructions. As a general guide the following principles should be followed when putting on respiratory protective equipment.

- The wearer must be clean-shaven, have long hair tied back and have removed any jewellery in the area of the face seal.
- The chin should sit comfortably within the lower edge of the facemask.
- The top of the face seal should sit comfortably on the forehead below the hairline for full face masks.
- The head harness should be centred on the back of the head for full face masks.

- Straps must be placed at the angle defined by the manufacturer, and not at any other angle as this can lead to reduced protection.
- Straps should be in the same line of direction to the mask as the anchorage points (Figure 10.5).

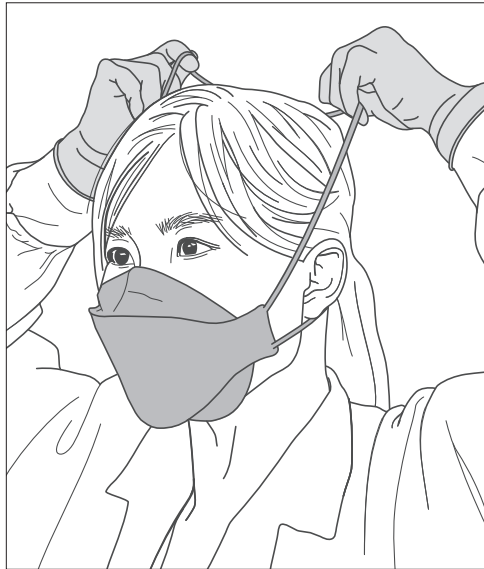


Figure 10.5 Putting on respiratory protective equipment

- Straps must not be twisted.
- Straps should be tightened together in pairs (lowest straps first).
- Straps should be tightened by applying equal pull to each side to keep the facepiece centred on the face.
- Straps should be tightened sufficiently to secure firmly on the face, but not overtightened.
- Hair should be checked to ensure it is not trapped in the face seal.

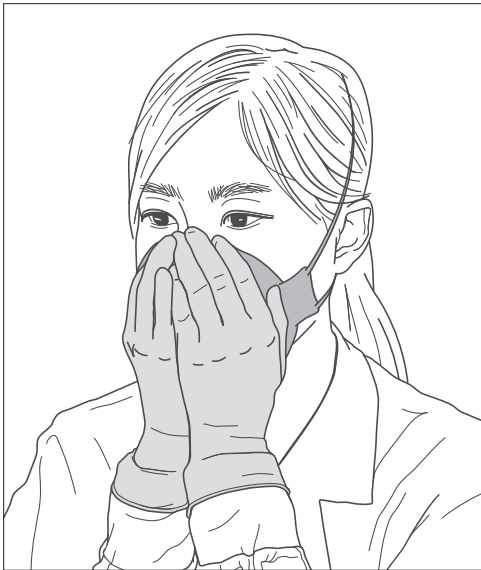


Figure 10.6 Face seal fit check of a filtering facepiece

10.7 Fit checking

The respiratory protective equipment should be checked before use to ensure it is fitting correctly. To do this, the following should be carried out:

- check the fit around the nose if half masks are being used,
- check the fit around the chin,
- check the positioning of the straps, and
- perform a face seal fit check.

To perform a fit check of the face seal of a filtering facepiece respirator, cover as much of the filter material as possible, inhale sharply and hold for 10 seconds (Figure 10.6). The facepiece should collapse in towards the face. Next, with hands still covering the filter material, exhale gently and steadily. This should result in the facepiece enlarging slightly but air should not leak between the face and the face seal of the mask.

If there is any indication that air is leaking between the facemask and the skin, a proper face seal has not formed. The mask should be readjusted and the test performed again; however, if this does not work, then the mask should not be used as it does not fit correctly. Where safety spectacles or goggles are being worn in addition to a mask, it might be necessary to recheck the fit of the mask once the eye protection is in place.

Where a half or full face mask is being worn, a fit check can be performed in a similar way by covering the filter openings, inhaling sharply and holding for 10 seconds (Figure 10.7 A). The facepiece should collapse in towards the face and stay.

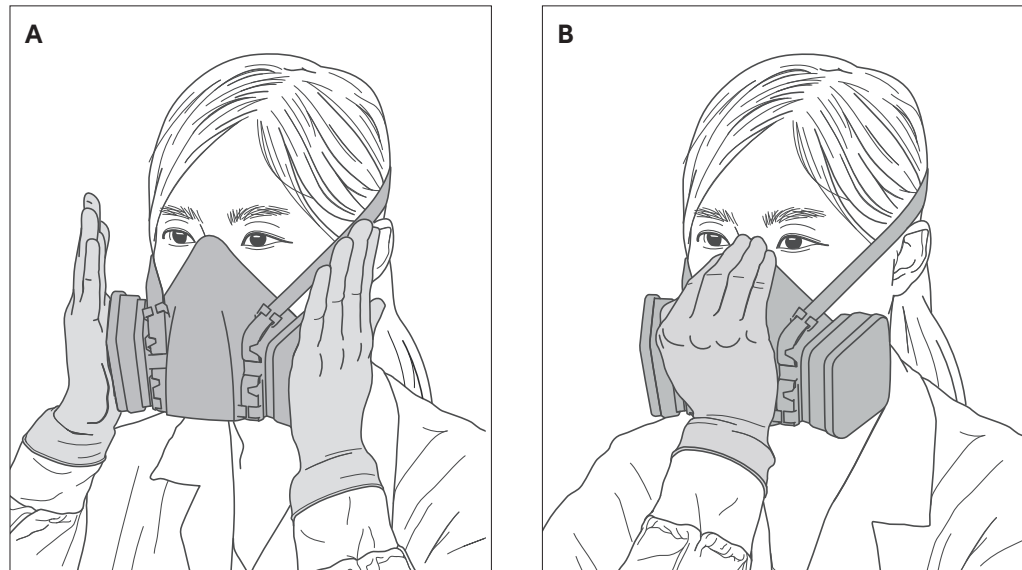


Figure 10.7 Inhalation (A) and exhalation (B) fit checks for use with half and full face masks. In A, the facepiece should collapse in towards the face and stay. In B, the facepiece should enlarge slightly and air should not leak between the face and face seal.

For the exhalation phase, the exhalation valve should be covered before exhaling steadily (Figure 10.7 B). The facepiece should enlarge slightly and air should not leak between the face and face seal. Again, if this does not happen, it is likely that air is leaking in between the facemask and the skin and a proper face seal is not formed. Again, the mask may be readjusted and the fit retested; however, if this test also does not work, then the mask should not be used. The test should be repeated after eye protection is put on, if this is being used.

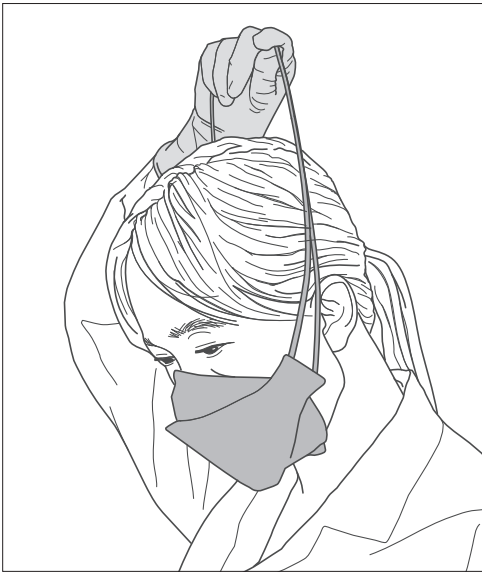


Figure 10.8 Removing respiratory protective equipment

10.8 Removing respiratory protective equipment

Removing an item of respiratory protective equipment should be carried out according to the manufacturer's instructions. Respiratory protective equipment can be removed in different ways, which often depends on the type of respiratory protective equipment being used. The goal is to ensure that the wearer is not exposed to potential contamination on the outside surface of the respiratory protective equipment and other potential sources of contamination during the removal process. If gloves have been used, a risk assessment should have been carried out to determine the most appropriate steps before removing the mask. Before removing the mask, gloves may be:

- removed first followed by hand washing, or
- decontaminated, or
- removed and replaced by clean gloves or removed to the clean gloves underneath if double gloves have been worn.

If eye protection has been worn, this should be removed before removing the respiratory protective equipment. To remove the mask itself, take the bottom strap at the back of the head and move it up to collect the top strap. Lean forward slightly and remove the straps from behind the head so that the mask hangs down. Then dispose of it safely (Figure 10.8). Wash hands before removing any other PPE, for example, laboratory coat. There are other procedures for removing masks that may be appropriate.

HEAD AND HEARING PROTECTION

11.1 Head protection

For certain activities, additional safety equipment such as hair nets and head covers are used to protect the hair from contamination. The need for and selection of head protection should be based on a risk assessment. Head protection in laboratories can also be used in combination with a respiratory protective device such as a powered air-purifying respirator.

Hair that is long enough to be tied back should be tied back before entering the laboratory. This is to prevent/reduce hand to head contact while in the laboratory, for example, to push hair behind the ears. In some cases, it may be appropriate to wear hair nets for product quality control purposes, for example, in pharmaceutical laboratories.

If head coverings are worn, these need to be pushed under the collar of the laboratory coat to prevent them from becoming contaminated in the event of a splash.

11.2 Hearing protection

Certain laboratory procedures, such as sonication or blending, may produce an uncomfortable level of noise for laboratory personnel. This noise level may be potentially damaging to an individual's hearing if conducted on a regular basis for extended periods. With positive-pressure suits, the airflow in the suit itself creates a high noise microenvironment for the wearer. The use of hearing protection, such as reusable earmuffs or single-use disposable earplugs, should be determined following risk assessment for tasks and processes associated with high noise levels.

HAND HYGIENE

No matter how well a PPE item is used and removed, there is always potential for hands to become contaminated with hazardous materials. It is therefore essential that hand hygiene (preferably hand washing) is carried out before leaving the laboratory area.

Where possible, elbow or foot operated taps should be used to avoid recontaminating hands after washing. If this is not possible, a clean paper towel should be used to turn on the tap and, once hands have been washed, another clean paper towel should be used to turn off the tap. If taps/faucets need to be turned on and off by hand, a clean paper towel should be used to turn them off.

Hand-washing techniques can vary slightly, but generally a soap/cleanser should be applied to one hand and the other hand should be used to turn on the tap and then held under the tap to wet it. Hands should then be rubbed together to form a lather. All areas of the hands and wrists should be rubbed and covered with soap. Commonly missed areas include between the fingers, back of the thumb, fingernails, creases in the palms and the wrists. Therefore, attention should be paid to these areas. Hands should then be rinsed, preferably with warm water, until all soap is removed before drying hands completely (Figure 12.1).

It is important to note that soap can be an irritant to skin. Thoroughly rinsing and drying hands after washing (particularly under rings) can reduce the likelihood of skin irritation and dermatitis. Using a hand cream/moisturiser after hand washing can also reduce the likelihood of skin irritation.



Figure 12.1 Hand hygiene – recommended procedure

CLEANING, MAINTENANCE, STORAGE AND DISPOSAL OF PPE

PPE must be stored and maintained correctly. This will require enough storage room, which should be separate from personal lockers. For some items, such as boots and multiple boxes of gloves, this may require a considerable amount of space.

13.1 Cleaning and disinfection

Contaminated reusable PPE should be cleaned before disinfection. After disinfection, it should be flushed with water to remove disinfectant residues before storage or disposal. The exception to this general rule is laboratory coats, aprons and gowns that should be autoclaved or disinfected before being laundered. Any cleaning and disinfection procedure should be carried out according to the manufacturer's instructions. The cleaning agents and disinfectants must be compatible with the PPE materials and effective against the biological agents being handled in the laboratory. In some cases, the disinfectants required to inactivate a given biological agent may damage the PPE and therefore reusable PPE should be replaced by disposable alternatives.

It is also important to note that repeated disinfection can shorten the shelf life of PPE and cause degradation over time so that the PPE can become ineffective. Therefore, reusable PPE must be checked after cleaning and disinfection, and before reuse.

13.2 Maintenance and storage

All forms of reusable PPE require regular checks to ensure they are still visibly intact and offer the required protection. This is true for items used frequently and also for those used infrequently. Checks of the shelf life, particularly for items that are worn infrequently, must also be carried out as part of a regular maintenance programme. For multicomponent PPE, all individual components (respirator filters, cartridges and masks) must be checked, associated monitors should be calibrated regularly, and any problems must be reported immediately.

PPE must be properly looked after and stored when not in use, for example, in a clean, dry cupboard. If it is reusable, it must be cleaned and kept in good condition.

Consideration should be given to the following elements.

- Replacement parts which match the original (for example, respirator filters) are available and in stock.
- An adequate number of replacement PPE is in stock.
- Responsibilities for maintenance and how it is to be done are defined.
- A stock of additional PPE, and clear instructions for its use, is available for visitors or personnel who are present only for limited time, for example, disposable laboratory coats/gowns and shoe covers in different sizes.
- A stock of disposable PPE for emergency situations is available.
- A record is kept of the use of reusable PPE, for example, date of first use, each use thereafter, shelf life, person using the PPE.
- When charging a battery, the battery unit is not left in the charger unattended.

Personnel must make proper use of PPE and report its loss or destruction or any fault in it.

13.3 Laboratory coats

Laboratory coats must be stored, cleaned and disposed of appropriately.

When not in use, laboratory coats should be hung on a peg either in an anteroom for putting on before entering the laboratory or on a peg near the entrance within the laboratory. They should not be hung up on top of other laboratory coats or in lockers next to personal clothes or belongings as this would increase the likelihood of cross contamination. Where laboratory coats are stored within a laboratory, they should be stored close to the entrance to avoid walking through the laboratory to get them.

Reusable laboratory coats should be laundered at regular intervals, ideally onsite. Following known or suspected splashes or soiling by a biological agent, they should be autoclaved before laundering. Where these facilities are not available, laboratory coats should be soaked in an appropriate disinfectant for the time recommended by the manufacturer of the disinfectant, wrung out and then rinsed in clean water (preferably two times) to remove the disinfectant. If considered necessary, laboratory coats can then be sent for laundering, if there is a washing service close by. Laboratory coats should not be taken home to be laundered.

Laboratory coats should be autoclaved or disinfected before disposal.

13.4 Reusable gloves

Reusable gloves, for example, for use to protect against chemicals, can only be reused for a set period of time depending on the breakthrough time identified by the manufacturer. Most chemicals are only tested for up to a maximum of eight hours. Gloves must be cleaned before storage to remove any chemical contamination and prevent prolonged action of the chemical on the glove material, which could lead to breakthrough. Cleaning reusable gloves must be carried out according to the manufacturer's instructions.

New gloves and those saved for reuse must be stored in a dry place away from direct sunlight as ultraviolet light can cause degradation of glove materials. Disposable gloves, even when stored in unopened boxes, must also be protected from humidity and kept at temperatures between 4 °C and 35 °C to maintain their shelf life.

Reusable gloves should be appropriately decontaminated (by autoclaving or chemical means) before disposal.

13.5 Eye protection

Eye protection is normally reusable. It must be cleaned and decontaminated before storage to remove any potential contamination. It must be stored in a clean, dry place away from direct sunlight as ultraviolet light can cause degradation of the lenses and elastic strap material over time.

Eye protection should be decontaminated before disposal.

13.6 Respiratory protective equipment

Reusable respiratory protective equipment, such as full face or half masks or powered respirators, must be cleaned and decontaminated after each use in accordance with the manufacturer's instructions to preserve the integrity of the material.

13.6.1 Full and half mask respirators

Before cleaning, reusable respiratory protective equipment should be separated into its individual components, such as cartridges, filters and any other accessories. Use of the selected disinfectant and cleaning agents must follow the PPE manufacturer's guidelines to minimize potential damage to plastics or other materials, which could result in reduced performance and hence protection.

The general cleaning procedure for full and half mask respirators is as follows.

- Clean mask in warm water with a mild cleaning agent using a sponge.
- Decontaminate using a disinfectant recommended by the manufacturer of the respirator for an appropriate contact time.
- Rinse thoroughly with warm water.
- Air dry.
- Reassemble.

Once dry, respirators must be stored in clean areas away from dust and potential contamination. Designated storage bags or containers are recommended to protect respirators and keep them clean between use.

13.6.2 Powered air-purifying respirators

Powered air-purifying respirators require decontamination after each use and before storage. Headgear, breathing tube and blower units should be detached from the battery pack. Because of the presence of electrical components, extra care must be taken to prevent water entering battery packs and motor units during the cleaning process.

The general cleaning procedure is as follows.

- Clean reusable components by wiping with a cloth dampened with warm water and a mild detergent.
- Decontaminate by wiping with a clean cloth dampened with a 5000 ppm chlorine solution or other disinfectant recommended by the manufacturer of the respirator for an appropriate contact time.
- Rinse all cleaned and disinfected components by wiping with a clean soft cloth dampened with clean warm water.
- Air dry.
- Reassemble.

Sufficient storage capacity must be provided for the individual units, for example, hooks on which the individual respirators, hoods and waist belts can be suspended. Powered air-purifying respirators also require a battery charging station. A sufficient number of sockets is therefore required so that all batteries in use can be charged at the same time.

13.6.3 Disposal of respiratory protective equipment

All respirators, whether full face masks, half masks or powered-air purifying respirators, should be decontaminated by autoclaving or by another approved method before disposal.

STANDARDS AND REGULATIONS

Standards refer to a set of principles, examples and/or measures that are used for comparison. For example, standard tests can be used to assess materials by determining and comparing their resistance to biological agents, chemicals or water, or their mechanical (for example, puncture) protective qualities. The purpose of using standards and norms for PPE is to ensure a minimum protection level is met and that the PPE is selected and used correctly.

14.1 National standards

Standards are formulated by teams of industry experts, consumers, research organizations, government departments and others. Standards have different structures: some are very detailed, others give more general information and some simply define terms. Countries often have their own standards, for example, BSEN are British/European standards, ANSI are American standards and DIN standards are German. The specific procedures and tests within standards can differ between countries. Which standards are applicable in a given country or situation should be noted. Examples of similar standards for gloves from different countries are shown in Table 14.1.

14.2 International standards

To facilitate coordination and unification of industrial standards, the ISO provides international standards (also known as ISO standards) for international use. These standards offer a global benchmark against which PPE items can be compared, which helps the international trade of such products. Examples of useful ISO standards related to PPE are given in Table 14.2.

Table 14.1 Examples of standards from different regions to test glove resistance to chemicals and biological agents

COUNTRY/ REGION	STANDARDS FOR GLOVE RESISTANCE TO CHEMICALS AND MICROORGANISMS
Europe/ international	EN 374: 2016 Protective gloves against dangerous chemicals and micro-organisms (there are five parts to this standard with separate tests: part 5 = virus challenge test)
United States of America	ANSI/ISEA 105-2016 American National Standard for hand protection classification. Permeation testing is done in accordance with ASTM F739-12e1 and penetration testing in accordance with ASTM F903-18
Australia/ New Zealand	AS/NZS 2161.10.3: 2005 (R2016) Occupational protective gloves. Protective gloves against chemicals and micro-organisms – Determination of resistance to permeation by chemicals
Asia	EN 374: 2003 Many countries across the Asia Pacific region have adopted the EN standards for their own use
China	GB 28881-2012 Hand protection. Protective gloves against chemicals and micro-organisms
Africa/South Africa	EN 374-1:2003 SANS 416:122012 PVC gloves type 1. Protective gloves against chemicals (South Africa)

PVC = polyvinyl chloride.

14.3 Protection levels of PPE

Where standards have been used to assess and benchmark an item of PPE, the level of protection and the standard or standards used to test it will be denoted in one or more of the following forms:

- information sheet provided with the PPE,
- on the PPE packaging,
- printed directly on the PPE, and/or
- manufacturer's instructions, for example, on a website.

This information is often accompanied by symbols, codes and the associated standard. Useful examples of symbols indicating types of protection are shown in Table 14.3.

Table 14.2 Examples of useful ISO standards for various types of personal protective equipment





ISO STANDARD	TYPES OF PERSONAL PROTECTIVE EQUIPMENT
	Clothing
ISO 16602:2007	Protective clothing for protection against chemicals – Classification, labelling and performance requirements
ISO 16603:2004	Resistance to penetration by blood and body fluids using synthetic blood
ISO 16604:2004-04 BS ISO 16604:2004-09-08	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 22612:2005-05	Clothing for protection against infectious agents – Test method for resistance to dry microbial penetration
	Gloves
ISO 374-1:2016	Protective gloves against dangerous chemicals and micro-organisms – Part 1: Terminology and performance requirements for chemical risks
ISO 374-2:2018	Protective gloves against dangerous chemicals and micro-organisms – Part 2: Determination of resistance to penetration
ISO 374-4:2019	Protective gloves against dangerous chemicals and micro-organisms – Part 4: Determination of resistance to degradation by chemicals
ISO 374-5:2016	Protective gloves against dangerous chemicals and micro-organisms – Part 5: Terminology and performance requirements for micro-organisms risks
	Footwear
ISO 20346: 2014	Personal protective equipment – Protective footwear
ISO 20345: 2011	Personal protective equipment – Safety footwear
ISO 20347: 2012	Personal protective equipment – Occupational footwear
ISO/TR 18690: 2012	Guidance for the selection, use and maintenance of safety and occupational footwear and other personal protective equipment offering foot and leg protection
	Respiratory protective equipment
ISO 16972:2010	Respiratory protective devices – Terms, definitions, graphical symbols and units of measurement
ISO 16900-7:2015	Respiratory protective devices – Methods of test and test equipment – Part 7: Practical performance test methods

Table 14.2 Examples of useful ISO standards for various types of personal protective equipment (continued)

ISO STANDARD	TYPES OF PERSONAL PROTECTIVE EQUIPMENT
	Eye and face
ISO 12311:2013	Personal protective equipment – Test methods for sunglasses and related eyewear
ISO 4007:2012	Personal protective equipment – Eye and face protection




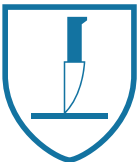

ISO = International Organization for Standardization.

Table 14.3 Examples of common symbols on PPE and referenced ISO standard

SYMBOL	MEANING	EXAMPLE ISO OR OTHER STANDARDS
	Operator's manual; operating instructions (reference number 1641). Usually provides information on the level of protection offered by the PPE	ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms – Part 1: Terminology and performance requirements for chemical risks
	Use by date (reference number 2607). Use by date is indicated alongside this symbol. Any PPE used after this time may not offer the required protection	ISO 7000: Graphical symbols for use on equipment
	Offers protection against bacteria and fungi. May also provide protection against viruses, but has not been explicitly tested	ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms – Part 5: Terminology and performance requirements for micro-organisms risks
	Offers protection against viruses, bacteria and fungi (refer to subsection 14.3.1 for more information on biological protection)	ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms – Part 5: Terminology and performance requirements for micro-organisms risks

ISO = International Organization for Standardization, PPE = personal protective equipment.

Table 14.3 Examples of common symbols on PPE and referenced ISO standards (continued)

SYMBOL	MEANING	EXAMPLE ISO OR OTHER STANDARDS
	<p>Offers some protection against chemicals. Manufacturer's instructions should be read to find the type and level of protection offered for various chemicals (refer to subsection 14.3.2 for more information on chemical protection)</p>	<p>ISO 374-1:2016+A1:2018 Protective gloves against dangerous chemicals and micro-organisms – Part 1: Terminology and performance requirements for chemical risks</p>
	<p>Protection against heat and flame (reference number 2417). Requirement examples: gloves when handling molten agarose and autoclaved items that are still hot</p>	<p>BS EN 407:2017 (Draft) Protective gloves against thermal risks (heat and/or fire)</p>
	<p>Protection against cold (reference number 2412). Requirement example: PPE for handling liquid nitrogen</p>	<p>BS EN 511:2006 Protective gloves against cold</p>
	<p>Protection against cuts and stabs (reference number 2483). Requirement example: possibly for gloves when using scalpels and needles</p>	<p>ISO 13999-1:1999. Protective clothing. Gloves and arm guards protecting against cuts and stabs by hand knives – Part 1: Chain-mail gloves and arm guards ISO 13999-3:2002. Protective clothing. Gloves and arm guards protecting against cuts and stabs by hand knives – Part 3: Impact cut test for fabric, leather and other materials</p>
	<p>Protection against mechanical hazards (reference number 2490). Requirement example: some PPE for use in necropsy</p>	<p>BS EN 388:2016+A1:2018 Protective gloves against mechanical risks. The standard describes how to manufacture, test and supply gloves that are used to protect wearers from mechanical injuries</p>

ISO = International Organization for Standardization, PPE = personal protective equipment.

14.3.1 Biological protection

Testing materials for protection against bacteria and fungi rely solely on ISO 374-2:2018: Protective gloves against dangerous chemicals and microorganisms – Part 2: Determination of resistance to penetration. Penetration protection is determined by one of two methods: either filling a number of gloves within a batch with water and checking for leaks, or inflating the gloves with air, immersing in water and checking for bubbles. This is thought to be sufficient to ensure bacterial and fungal protection. Because viruses are smaller, a virus challenge can be carried out whereby a bacteriophage (for example, Phi-X174) is put on a piece of glove material and the underside assessed for breakthrough.

Similar tests specified in relevant ISO standards are also performed to determine the resistance of protective clothing against biological agents.

14.3.2 Chemical protection

While the fourth edition of the *Laboratory biosafety manual (5)* is primarily concerned with biological hazards, chemical protection is an important consideration for most laboratory facilities. PPE must offer adequate protection against the chemicals being handled in the laboratory. Failure to consider the chemical hazards can lead to incorrect PPE being used. In turn, such chemicals, if PPE is exposed to them, can permeate and/or degrade the PPE material. If this happened, skin would be exposed directly to those chemicals and to the biological agents being handled that could have been carried through the material by the chemicals. This is particularly relevant for glove use as hands are the most likely area to become exposed during the handling of biological agents and chemicals.

ISO 374:2016+A1:2018 (Protective gloves against dangerous chemicals and microorganisms) is the international standard against which gloves are tested against chemicals. It is important to note that gloves specified as being tested against this standard do not protect the wearer against all chemicals at an absolute/undiluted concentration. The types and concentrations of the chemicals from which the PPE protects the wearer are represented by a letter placed underneath the chemical protection symbol. These letters represent different chemicals (Table 14.4). The types of chemicals to be used and hence the type of PPE required (for example, type of glove material) to protect personnel against the chemicals to be used must be identified before use. It is important to note that a lower case “i” in the symbols indicates that reference to manufacturers’ instructions is required. This is of particular importance where protection is required against a chemical not listed in the standard or the chemical is used at a higher concentration than noted in the standard. While this list is based on a standard for gloves, it also applies to other PPE.

Table 14.4: Code letters for chemicals, and their CAS number and class (ISO 374:2016+A1:2018)

CODE LETTER	CHEMICAL	CAS NUMBER	CLASS
A	Methanol	67-56-1	Primary alcohol
B	Acetone	67-64-1	Ketone
C	Acetonitrile	75-05-8	Nitrile compound
D	Dichloromethane	75-09-2	Chlorinated hydrocarbon
E	Carbon disulfide	75-15-0	Sulfur-containing organic compound
F	Toluene	108-88-3	Aromatic hydrocarbon
G	Diethylamine	109-89-7	Amine
H	Tetrahydrofuran	109-99-9	Heterocyclic and ether compound
I	Ethyl acetate	141-78-6	Ester
J	n-Heptane	142-82-5	Saturated hydrocarbon
K	Sodium hydroxide 40%	1310-73-2	Inorganic base
L	Sulfuric acid 96%	7664-93-9	Inorganic mineral acid, oxidizing
M	Nitric acid 65%	7697-37-2	Inorganic mineral acid, oxidizing
N	Acetic acid 99%	64-19-7	Organic acid
O	Ammonium hydroxide 25%	1336-21-6	Organic base
P	Hydrogen peroxide 30%	7722-84-1	Peroxide
S	Hydrofluoric acid 40%	7664-39-3	Inorganic mineral acid
T	Formaldehyde 37%	50-00-0	Aldehyde

CAS = Chemical Abstract Services.

PPE is often categorized based on the number of chemicals against which it provides protection as well as the measured breakthrough times and other standards. An example of such categorization for gloves is shown in Table 14.5 based on ISO 374-1:2016+A1:2018.

Where PPE has been tested against a standard and has been shown to provide protection against some of the chemicals in Table 14.4, the chemical code letter will be displayed under the protection symbol, and the standard against which the PPE has been tested will be noted above the protection symbol. If the PPE has also been categorized, such as for gloves as shown in Table 14.5, this will also be displayed (Figure 14.1).

Table 14.5 Example of categorization and associated requirements for personal protective equipment (gloves) based on ISO 374-1:2016+A1:2018

CATEGORIZATION	REQUIREMENTS
Type A	<ul style="list-style-type: none"> ▪ Passed permeation test: minimum of six test chemicals (listed in Table 14.4) to a breakthrough time of at least level 2, that is > 30 min ▪ Passed general requirements (EN 420:2009)^a ▪ Passed penetration test (ISO 374-2:2014)^a
Type B	<ul style="list-style-type: none"> ▪ Passed permeation test: minimum of three test chemicals (listed in Table 14.4) to a breakthrough time of at least level 2, that is > 30 min ▪ Passed general requirements (EN 420:2009)^a ▪ Passed penetration test (ISO 374-2:2014)^a
Type C	<ul style="list-style-type: none"> ▪ Passed permeation test: minimum of one test chemical (listed in Table 14.4) to a breakthrough time of at least level, 1, that is >10 min ▪ Passed general requirements (EN 420:2009)^a ▪ Passed penetration test (ISO 374-2:2014)^a

ISO = International Organization for Standardization

^a ISO 374-1:2016+A1:2018 stipulates that these tests need to be passed.

EN ISO 374-1 2016/type A



UVWXYZ

Figure 14.1 Example of chemical protection demarcations for personal protective equipment

14.3.3 Protection provided by respirators

Many countries have their own performance standards and methods for assessing respiratory protective equipment. The classification of respiratory protective equipment can therefore vary considerably between countries. The existence of many different standards and the resulting classification systems can make selection of respirators confusing.

For example, the filter efficiency requirements for two products might be the same but measured differently depending on the standard method used to test the product. This may result in slightly different laboratory performance. This means that a respirator sold throughout the world may be identical in its manufacture, but different countries assign a different level of protection to it.

ISO have introduced a new set of standards that allow a single series of tests and one classification system for respirators that could be adopted worldwide. This would enable manufacturers to adhere to one set of standards for distributing the same product between countries and hence reduce confusion for end users. This will enable respirators to be classified within a single system. Therefore, an N95 or FFP2, which are broadly equivalent based on their percentage minimum filtration efficiency, might become collectively a single respirator type, for example, PC3W1bTF2 RPD. This classification system is based on the information outlined in Table 14.6. While this system may seem more complicated initially, overall it should simplify selection of respiratory protective equipment.

14.4 National regulations and requirements

Often, national authorities establish national policies, legislation and regulations and/or guidance documents which stipulate the type of risk control measures that must be implemented by a laboratory in order to be authorized to operate. PPE is often included as part of those risk control measures. An oversight system has generally been developed to ensure compliance with such regulations. Development of national regulations for biosafety begins with risk assessment – a systematic process of gathering and evaluating information to support the development of a regulatory framework that is risk- and evidence-based. It is important that these regulations achieve a balance between ensuring national risk mitigation and allowing laboratories enough flexibility to operate sustainably and within their means, and continue their work to benefit the communities they serve. Rapid disease diagnostics, innovative treatments and new knowledge about biological agents are all essential activities to improve local and global health care and should always be prioritized.

14.5 Local practices

Practices such as putting on a laboratory coat before entering a laboratory are common in many laboratory facilities. It is important to note that local practices, which are based on local risk assessments, may differ between organizations and even between different laboratories within the same organization. For example, some laboratories might have a requirement for putting on eye protection before entering the laboratory in the same way that laboratory coats are required. Others may require eye protection only for certain procedures, such as handling biological agents outside a primary containment device. It is important to know and understand local practices and norms for the laboratory before starting any work.

Table 14.6 Basic classification for all respiratory protective equipment based on: ISO/TS 16973:2016 Respiratory protective devices – Classification for respiratory protective device (RPD), excluding RPD for underwater application.

BASIC CLASSIFICATION FOR RPD			
PROTECTION CLASS	WORK RATE CLASS	RESPIRATORY INTERFACE CLASS	
PC1 (20% TIL _{max})	W1 Moderate (35 L/min and lower)	a Mouth only	T tight L loose
PC2 (5% TIL _{max})	W2 Very heavy and lower (135 L/min and lower)	b Mouth and nose	T tight L loose
PC3 (1% TIL _{max})	W3 Extremely heavy (105 L/min and lower)	c Face	T tight L loose
PC4 (0.1% TIL _{max})	W4 Maximal (135 L/min and lower)	d Head	T tight L loose
PC5 (0.01% TIL _{max})		e Body	T tight L loose

TIL = total inward leakage.

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Further information

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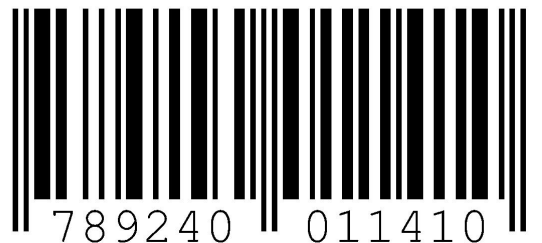
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