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DR AS/NZS 2243.3:2019, Safety in laboratories, Part 3: Microbiological safety and containment

Revision of AS/NZS 2243.3:2010

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Comments are welcome on the technical content, wording and general arrangement of the draft. How the requirements of this draft coordinate with other Standards is of particular importance and you are invited to point out any areas where changes or additions to this draft may be necessary. Editorial matters (i.e. spelling, punctuation, grammar, etc.) will be corrected before final publication.

Please provide supporting reasons and suggested wording for each comment. Where you consider that specific content is too simplistic, too complex or too detailed please provide an alternative.

If the proposed Standard is acceptable for Australia or New Zealand without change, an acknowledgement to this effect would be appreciated.

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Only comments submitted via the Standards Australia Standards Hub site before midnight on the closing date will be reviewed by the committee. The Hub automatically submits comments to the committee. Any other communication will not be considered by the committee.

At the expiry of the comment period, the committee responsible for the document is obliged to give serious consideration to all comments received. However, normally no acknowledgement of comment is sent.
Preface

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee CH-026, Safety in Laboratories, to supersede AS/NZS 2243.3—2010, Safety in laboratories, Part 3: Microbiological aspects and containment.

The objective of this Standard is to provide management and personnel of an institute’s laboratories and containment facilities with requirements and guidelines that promote microbiological safety and prevent the unintended spread of microorganisms and prions.

The major change in this edition is the addition of a section for the containment of water-based species, including fish and aquatic invertebrates.

This Standard is part of a series promoting safety in laboratories. The series is as follows:

AS/NZS 2243.1.2010, Safety in laboratories, Part 1: Planning and operational aspects
AS/NZS 2243.2.2010, Safety in laboratories, Part 2: Chemical aspects
AS/NZS 2243.3.2010, Safety in laboratories, Part 3: Microbiological safety and containment (this Standard)
AS/NZS 2243.4.2010, Safety in laboratories, Part 4: Ionizing radiations
AS/NZS 2243.5.2010, Safety in laboratories, Part 5: Non-ionizing radiations — Electromagnetic, sound and ultrasound
AS/NZS 2243.6.2010, Safety in laboratories, Part 6: Mechanical aspects
AS/NZS 2243.7.2010, Safety in laboratories, Part 7: Fume cupboards
AS/NZS 2243.8.2010, Safety in laboratories, Part 8: Recirculating fume cabinets

Although many of the safety aspects of working in laboratories are addressed in other parts of the series, some are repeated in this Standard because there is an increase in the risk in containment facilities.

This Standard is intended to cover safety and containment aspects of work with microorganisms, including genetically modified microorganisms. However, it does not cover the additional security requirement that may be implemented in response to community interest and concerns in genetic modification work. For these, the relevant regulatory authority should be consulted. Also, the Standard is not primarily intended to address containment of organisms for work that does not involve microorganisms.

This Standard is intended to assist in addressing the obligations placed on employers and employees under WHS legislation to take care of both themselves and others in the workplace. It should not be assumed that conformance with this Standard means that all aspects of appropriate legislation or all legal obligations are being fulfilled. This Standard is not intended to provide for compliance with a specific act or regulation.

Australian/New Zealand Standards are voluntary. They do not include contractual, legal or statutory requirements. Voluntary Standards do not replace laws, with which Standards users are understood to comply and which take precedence.

In recognition of the changes made to this Standard during its revision, existing facilities should be assessed for risk and interim control measures should be implemented.

Current facilities and procedures should be updated to conform to this Standard. Conformance improvements should be made within a time frame that takes into consideration the cost of upgrading and the severity of the associated risk.

The terms “normative” and “informative” are used in Standards to define the application of the appendices to which they apply. A “normative” appendix is an integral part of a Standard, whereas an “informative” appendix is only for information and guidance.
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Introduction

Safety in all laboratories is primarily a management responsibility, but is also an individual responsibility. It is the responsibility of an institute’s management to provide and maintain protective equipment and containment areas, a policy relating to safe work practices within a laboratory and to promote the training in, and institution of, those practices. It is the responsibility of the laboratory personnel to carry out the safe work practices and to use protective equipment to minimize injury or prevent occupational illness, not only to themselves, but also to their colleagues. It is also a responsibility of managers to ensure that consideration is given to hazards to the general environment when dispensing or handling biological material. Personnel training needs to be directed toward making safety an attitude of mind and an integral part of all laboratory procedures, so that a constant, purposeful control of the laboratory environment will result. Accidents such as spillages are an obvious hazard, but the production of aerosols during some routine procedures is a less obvious hazard that can be a serious source of contamination. In addition to the many problems commonly encountered in chemical laboratories, microbiological laboratories can pose the following specific problems:

(a) Infection of laboratory personnel, the general public, animals and plants by dissemination of microorganisms inside and outside the laboratory.

(b) Cross-contamination of research and diagnostic materials or animals.

(c) Contamination with adventitious microorganisms.

The basic approach to working with microorganisms is to regard them as potential pathogens and to handle them with standard microbiological techniques. Nevertheless, microorganisms vary markedly in their pathogenicity. This Standard includes the classification of microorganisms into four risk groups and specifies work requirements for the corresponding four physical containment levels.
Section 1 Scope and general

1.1 Scope

This Standard sets out requirements, responsibilities and general guidelines relating to safe handling and containment of microorganisms and prions in laboratories, including pathology and diagnostic laboratories. It includes provisions for terrestrial animal, plant, invertebrate and aquatic containment facilities (these may be integral or separate to the laboratory) where microbiological work such as research, teaching, diagnosis, quality control and regulatory analysis, e.g. of foodstuffs, water and effluents, pharmaceuticals and cosmetics, is undertaken. It may also provide assistance to other laboratories where specimens that may contain pathogenic microorganisms and prions are handled, e.g. biochemistry and soil laboratories.

NOTE 1 This Standard uses the term “containment facility” instead of historical terms such as “plant house”, “glass house”, “insectary” and “animal house”. For example, an animal house is referred to as a terrestrial animal containment facility.

NOTE 2 This Standard is not intended to include work that involves the generation or use of genetic modified microorganisms for which the appropriate body should be consulted (see Clause 2.3).

NOTE 3 The principles of containment detailed in this Standard apply regardless of the scale or quantity of microbiological material being used (see also Clause 2.3).

1.2 Application

This Standard should be read in conjunction with AS/NZS 2243.1, AS/NZS 2982, the Building Codes of Australia (BCA), other relevant parts of the AS 2243 series, and other relevant standards and legislation.

NOTE Refer to relevant Standards and regulations, where applicable, for specialist applications, e.g. post-mortem facilities.

1.3 Objective

The objective of this Standard is to provide management and personnel of laboratories and containment facilities with requirements and guidelines that promote microbiological safety and prevent the unintended spread of microorganisms and prions.

1.4 Normative documents

The following documents are referred to in this text in such a way that some or all of their context constitutes requirements of this document.

NOTE Documents for informative purposes are listed in the Bibliography.

AS 1319, Safety signs for the occupational environment

AS 1324.1, Air filters for use in general ventilation and airconditioning, Part 1: Application, performance and construction

AS 1324.2, Air filters for use in general ventilation and airconditioning, Part 2: Methods of test

AS 1807.6, Cleanrooms, workstations, safety cabinets and pharmaceutical isolators —Methods of test, Method 6: Determination of integrity of terminally mounted HEPA filter installations
1.5 Terms and definitions

For the purpose of this Standard, the following terms and definitions apply.
1.5.1  
aerosol  
suspension in air of finely dispersed solids or liquids

Note 1 to entry: Any procedure that disrupts the surface of a liquid has potential to produce aerosols. Procedures such as shaking, mixing, ultrasonic disruption, and removing a needle from a rubber seal are particularly common examples for microbiological work.

1.5.2  
airlock  
a separate, fully-enclosable space with two doors designed to limit the air transfer and pressure fluctuations during entry and exit. A shower airlock is an airlock that incorporates full body shower capability, which can be used as part of egress procedures

1.5.3  
animals  
also referred to as terrestrial animals

Note 1 to entry: See 1.5.42.

1.5.4  
anteroom  
a separate, fully-enclosable space used during access and egress that has specific containment functions

1.5.5  
antiseptic  
substance capable of destroying or preventing growth of microorganisms under prescribed conditions of use, and specifically for application to living tissues

1.5.6  
aquatic organism  
a plant or animal species that is water-based

Note 1 to entry: This includes vertebrate or invertebrate animals which live most of their life in water and animals which move readily from water to land and vice versa (e.g. amphibians).

Note 2 to entry: Aquatic animals include annelids (e.g. aquatic segmented worms), cnidarians (e.g. jelly fish), echinoderms (e.g. starfish), monotremes (e.g. platypus), amphibians (e.g. frogs, toads, newts, salamanders, axolotl), fish (e.g. zebra fish), molluscs (e.g. snails), crustaceans (e.g. crab, shrimp, krill), reptiles (e.g. crocodiles), and other marine and freshwater animals such as otters.

1.5.7  
aseptic technique  
exercise of special procedures for maintaining —

(a) the sterility of equipment, media, and other materials;
(b) the purity of cultures, by eliminating adventitious contamination; and
(c) protection of the operator and environment from microorganisms.

1.5.8  
biohazard  
potential microbiological source of harm
1.5.9 **biological safety cabinets**

**BSC**

1.5.9.1 **class I**
cabinets intended to provide protection from hazardous biological agents for personnel and the environment. The cabinets are exhaust ventilated, with an inward flow of air away from the operator and HEPA filtration of exhaust air.

1.5.9.2 **class II**
cabinets intended to provide protection from hazardous biological agents for personnel and the environment and also to protect the material used in the cabinet from exogenous contamination. The cabinets provide this protection by inducing an inflow of air through the work access opening, by delivering recirculated, filtered, laminar flow air downwards through the work zone and by HEPA filtration of exhaust air.

1.5.9.3 **class III**
totally enclosed, ventilated cabinets that allow work to be performed through the use of attached gloves. These cabinets are gas-tight, maintained under a negative air pressure, have their supply air HEPA-filtered and have their exhaust air passed through two HEPA filters in series. Transfer boxes allow passage of materials into and out of the work zone while maintaining the negative pressure.

1.5.10 **biological safety office**

**BSO**
a person who is competent in the assessment and control of biological hazards and has responsibility and authority for oversight of the control of biological hazards.

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

1.5.12 **biosafety committee**

**BC**
a committee that provides advice, resources and facilities as are necessary for safe working in laboratories.

1.5.13 **calibration**
operation that, under specified conditions, in the first step establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in the second step uses this information to establish a relation for obtaining a measurement result from an indication.


1.5.14 **change room**

1.5.14.1 **inner change room**
a separate, fully-enclosable space used by personnel for donning facility clothing and PPE on entry and for removing it on exit.
1.5.14.2 outer change room
space used by personnel to remove personal clothing as appropriate to facility level prior to entry and
to put on personal clothing upon egress, e.g. from shower airlock

1.5.15 competent person
a person who has acquired through training, qualifications or experience, or a combination of these, the
knowledge and skills enabling that person to perform a specified task

1.5.16 containment
combination of buildings, engineering function, equipment, and worker practices used to handle
microorganisms and prions safely

1.5.17 containment facility
may comprise a combination of laboratories, terrestrial animal, plant, invertebrate and aquatic
organism facilities and associated rooms within a physical containment barrier. This may include
airlocks, access and support rooms and interconnecting corridors

Note 1 to entry: This definition is distinct from that used in the MPI (NZ) requirements.

Note 2 to entry: Tertiary ducts, pipes, and decontamination equipment which remove contaminated material
from containment facilities are often located in tertiary containment spaces which do not usually form part of
the containment facility (see Clause 4.4). See Section 10 and Clause 13.3 for information related to protection of
these systems against breach of containment.

1.5.18 cross-contamination
undesirable transfer of microorganisms from one source to another

1.5.19 decontamination
a physical or chemical process that kills or removes pathogenic microorganisms, but does not
necessarily result in sterility

1.5.20 diagnostic specimen
any human, animal, plant or invertebrate material including, but not limited to, excreta, secreta, blood
and its components, tissue and tissue fluids submitted for purposes of diagnosis or analysis

1.5.21 disinfectant
a substance capable of killing a wide range of microorganisms

1.5.22 exposure standard
airborne concentration of a particular substance (not microorganisms) in the worker's breathing zone,
exposure to which, according to current knowledge, should not cause adverse health effects nor cause
undue discomfort to nearly all workers

Note 1 to entry: The exposure standard can be of three forms: time-weighted average (TWA), peak limitation, or
short-term exposure limit (STEL).

1.5.23 HEPA filter
a high-efficiency particulate air (HEPA) filter conforming with the requirements in Clause 11.10.1
1.5.24 **immunisation**
process where a person is made immune or resistant to infectious microorganism through administration of a vaccine

1.5.25 **infectious microorganism**
a microorganism capable of invading a susceptible host and multiplying in it, which may or may not cause a disease

1.5.26 **invertebrates**
includes all multi-cellular animal species without backbones that are land based as adults

   Note 1 to entry: This includes annelids, cnidarians, echinoderms, flatworms, nematodes, molluscs and arthropods. Protozoans are not included due to their microscopic size and single cellular nature.

1.5.27 **institute**
an organization with the authority for undertaking specific work related to microbiology and who has responsibility for microbiological safety

1.5.28 **may**
indicates the existence of an option

1.5.29 **microbiological hazard**
potential microbiological source of harm

   Note 1 to entry: Also referred to as a biohazard, see 1.5.8.

1.5.30 **microbiological spill**
an incident where control of biological material has been lost inadvertently

1.5.31 **microorganisms**
microscopic organisms including protozoa and other parasites, fungi, archaea, bacteria, unicellular algae, viruses and viroids

1.5.32 **pathogen**
an infectious organism, usually microscopic, capable of causing disease in a host

1.5.33 **personal protective equipment**

   **PPE**
any devices or equipment, including clothing, designed to be worn or held by a person on its own, or as part of a system, to protect against one or more health and safety hazards

1.5.34 **plants**
all land-based plant species

   Note 1 to entry: See 1.5.6 for aquatic-based plants definition.

1.5.35 **prions**
proteinaceous infectious particles that lack nucleic acids, which can cause scrapie and other related neurodegenerative diseases of humans and animals
1.5.36  
**risk assessment**  
process of estimating the potential of a hazard (source of harm) to give rise to an adverse outcome

Note 1 to entry: This estimation is based on a combination of the likelihood of the hazard occurring and the consequences if the hazard occurs. Control measures are used to limit the risk.

1.5.37  
**shall**  
indicates a statement is mandatory

1.5.38  
**sharps**  
objects or devices having sharp points or protuberances or cutting edges, capable of cutting or piercing the skin

Note 1 to entry: Refer to AS 4031 for information on sharps containers.

1.5.39  
**should**  
indicates a recommendation

1.5.40  
**sterile**  
state of being free from viable microorganisms

Note 1 to entry: In practice, no such absolute statement regarding the absence of microorganisms can be proven.

1.5.41  
**sterilization**  
a validated process used to render a product free from viable microorganisms

Note 1 to entry: The number of microorganisms that survive a sterilization process can be expressed in terms of probability. While the probability may be reduced to a very low number, it can never be reduced to zero.

1.5.42  
**terrestrial animals**  
all terrestrial vertebrate animals

Note 1 to entry: This includes imported small laboratory animals such as mice, rats, rabbits, guinea-pigs and/or other rodents, or large non-laboratory animals (non-imported animals) such as pigs, sheep, goats, deer, camels, cattle, and horses. Other terrestrial animals included are primates and some marsupials.

1.5.43  
**vaccination**  
ad ministers a vaccine in order to make a person immune or resistant to infectious microorganism

1.5.44  
**viable**  
capable of growth even though resuscitation procedures may be required

Note 1 to entry: For example, when microorganisms are sub-lethally damaged by being frozen, dried, heated or affected by chemicals and disinfectants.

### 1.6 Abbreviations

For the purpose of this Standard, the abbreviations below apply:

- **BC**  
  Biosafety committee

- **BCG**  
  Bacille Calmette-Guérin
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>BSC</td>
<td>Biological safety cabinet</td>
</tr>
<tr>
<td>CDSC</td>
<td>Cytotoxic drug safety cabinets</td>
</tr>
<tr>
<td>CWA</td>
<td>CEN Workshop Agreement</td>
</tr>
<tr>
<td>DNA</td>
<td>Deoxyribonucleic acid</td>
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<tr>
<td>DAWR</td>
<td>Department of Agriculture and Water Resources</td>
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<tr>
<td>EPA</td>
<td>Environmental Protection Agency</td>
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<tr>
<td>GMO</td>
<td>Genetically modified organism</td>
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<tr>
<td>HEPA</td>
<td>High-efficiency particulate air</td>
</tr>
<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<tr>
<td>HSNO</td>
<td>Hazardous Substances and New Organisms</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association</td>
</tr>
<tr>
<td>IBSC</td>
<td>Institutional biological safety committee</td>
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<tr>
<td>IMO</td>
<td>International Maritime Organization</td>
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<tr>
<td>MPI</td>
<td>Ministry of Primary Industries (NZ)</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
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<td>NOHSC</td>
<td>National Occupational Health and Safety Commission</td>
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<tr>
<td>NRL</td>
<td>National Radiation Laboratory</td>
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<td>NTAC</td>
<td>National Tuberculosis Advisory Committee</td>
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<tr>
<td>OGTR</td>
<td>Office of Gene Technology Regulator</td>
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<tr>
<td>OIE</td>
<td>World Organization for Animal Health</td>
</tr>
<tr>
<td>PC</td>
<td>Physical containment</td>
</tr>
<tr>
<td>PCD</td>
<td>Process challenge devices</td>
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<tr>
<td>PPE</td>
<td>Personal protective equipment</td>
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<tr>
<td>QAC</td>
<td>Quaternary ammonium compounds</td>
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<tr>
<td>RPE</td>
<td>Respiratory protective equipment</td>
</tr>
<tr>
<td>SCBA</td>
<td>Self-contained breathing apparatus</td>
</tr>
<tr>
<td>SDS</td>
<td>Safety data sheets</td>
</tr>
<tr>
<td>SPF</td>
<td>Specific pathogen free</td>
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<tr>
<td>SSBA</td>
<td>Security sensitive biological agents</td>
</tr>
<tr>
<td>STEL</td>
<td>Short-term exposure limit</td>
</tr>
<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
</tbody>
</table>
Section 2  Organization and responsibility

2.1  Responsibility

2.1.1  Laboratory safety policy
The institute management shall provide personnel with a policy statement on laboratory safety that recognizes the special hazards associated with microorganisms to ensure personnel are fully informed during the course of their duties.

2.1.2  Risk assessment
Research, teaching or operational work with biohazards shall only be undertaken after a risk assessment of the work has been conducted and it has been demonstrated that any hazards are controlled. This process shall be documented and regularly reviewed to ensure its ongoing validity. Review shall be undertaken whenever a change to the parameters of the original risk assessment is planned.

NOTE  Refer to CWA 15793 and AS/NZS ISO 31000.

The risk assessment shall be done prior to commencement of any work to determine the appropriate type and level of containment facility. The risk assessment should include consideration of the following:

(a) The microorganisms involved, their presence or absence in Australia and New Zealand, their source, risk group, volume, concentration, mode of transmission, host range, minimum infectious dose, vectors and the nature of the proposed work.

Regulatory conditions for imported organisms, GMOs, in vivo work and SSBAs (see Clauses 2.2, 2.3 and 2.4).

(b) The processes and equipment to be used.

(c) Storage requirements and safe handling between work areas and storage areas.

(d) The containment performance of the facility construction, including the seal quality of the facility, air pressure and directional control mechanisms, treatment and filtration of air leaving the facility and emergency backup systems, where applicable.

(e) The suitability of containment equipment such as biological safety cabinets, for the intended work.

(f) Provisions for handling, decontamination and disposal of potentially contaminated waste, including liquid waste from drains.

(g) The availability and suitability of PPE for the intended work.

(h) The training and experience of personnel with the particular microorganisms proposed for the work.

(i) Any health considerations for personnel including cleaning staff, e.g. vaccinations and medical monitoring.

(j) The capability to deal with a spill, such as by facility gaseous decontamination.
All risk assessments that involve biological systems shall be subject to a level of uncertainty due to a lack of experimental evidence. The level of uncertainty should be considered when conducting the risk assessment.

2.1.3 Organizational arrangements for the implementation and monitoring of biosafety

As an overall principle under WHS laws, the employer shall be responsible for ensuring that the workplace is safe and risks to health are minimized.

Organizational arrangements put in place to meet management responsibilities will depend on —

(a) the applicable statutory regulations for the composition and operation of overall WHS committees in the workplace; and

(b) the size and activities of the institution.

The central element of such arrangements is a Biosafety Committee (BC). The BC should consider the following aspects:

(i) Ensure a system is in place for training and assessment of personnel.

(ii) Overall monitoring and surveillance of the continuing implementation of Standards and guidelines.

(iii) Review of risk assessments before the work commences.

(iv) Consideration of the implications of microbiological components of research proposals.

(v) Inspection, inspection frequency, audits and any licensing of laboratories.

(vi) Review of safety audits.

(vii) Ensuring that appropriate records are kept, including personnel training, immunisations, and relevant, WHS-related medical advice.

2.1.4 Biological safety officer(s)

A biological safety officer shall be contactable to provide advice and guidance on microbiological safety.

2.1.5 Laboratory or facility supervisor

The supervisor shall ensure that safe procedures are documented, put into practice, and reviewed and updated regularly. The supervisor shall implement initial and continuing training programs, ensure personnel are supervised and that maintenance is carried out in accordance with safe procedures. The supervisor should also ensure that casual visitors have restricted access to the laboratory.

2.1.6 Personal responsibility

All laboratory work shall be carried out with regard to the safety of laboratory personnel. The following requirements shall apply to all laboratory personnel:

(a) Individuals shall familiarize themselves with the requirements and recommendations in the laboratory safety manual.

(b) Individuals shall be familiar with, and shall use, the appropriate safety equipment provided.

(c) Individuals, who alone know the nature and contents of their experimental materials and apparatus, shall ensure that the apparatus (or the remains, if broken) is decontaminated before maintenance or disposal, and that materials are processed in accordance with laboratory policy before disposal.
2.2 Quarantine materials

2.2.1 Australia

The Department of Agriculture and Water Resources (DAWR) approves places where post-entry quarantine requirements apply for a wide range of human, terrestrial animal, plant, aquatic organism, pathogens and products, so that it can be sure that these activities are performed with a minimal degree of risk.

To gain approval as an Approved Arrangement (refer to Biosecurity Act 2015), there are conditions that the premises needs to meet to ensure the DAWR that the risk of any biosecurity breach is minimal. These conditions detail the requirements and responsibilities for containment facilities where the premises are utilized for research, analysis or testing of imported material, including microorganisms, animal and human products and soil. Premises of this type include microbiological, terrestrial animal, plant, invertebrate and aquatic facilities.

NOTE For further information on the approval process for Approved Arrangement premises is available at the DAWR website, refer to www.agriculture.gov.au.

DAWR will also require institutions to obtain a permit for work with exotic organisms even if conducted in containment facilities. Such permits contain special conditions. The Australian biosecurity import conditions (BICON) database should be consulted on the DAWR website.

2.2.2 New Zealand

In New Zealand, the Ministry of Primary Industries (MPI) controls the import of biological risk goods, establishes Standards for laboratories receiving and holding such goods and enforces the conformance to those standards.

2.3 Laboratories using Genetically Modified Organisms (GMOs)

2.3.1 Australia

Under the Commonwealth Gene Technology Act 2000 and Gene Technology Regulations 2001, certain dealings with GMOs are required to be conducted in facilities that meet and are certified as complying with Office of Gene Technology Regulator (OGTR) Guidelines for the certification of physical containment facilities.

NOTE Organizations seeking information about the regulatory requirements that apply to work with GMOs should contact the OGTR for further information.

2.3.2 New Zealand

Under the Hazardous Substances and New Organisms Act 1996, work with GMOs is regulated by the EPA. In general, all work involving the holding or development of GMOs are carried out in accordance with controls set by the EPA, an IBSC, or the Chief Executive of EPA New Zealand in containment facilities approved by the MPI. Work involving GMOs shall be carried out in accordance with MPI and EPA New Zealand Standards.

Work involving GMOs shall be carried out in accordance with controls set by HSNO Act Approvals. Such work shall be carried out in an MPI approved containment facility to the appropriate Standard.

2.4 Security of biological material

Security of biological material, as opposed to laboratory biosafety, refers to the institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens and toxins. Facilities holding pathogens or toxins should prepare and implement a specific program for the security of biological material according to the requirements of the facility, the nature of the pathogens(s) or toxins(s), the type of laboratory work conducted and the local conditions. Measures
should include a secure inventory of all microorganisms, including such information as location and access. All personnel in such facilities should be trained in security measures of biological material.

NOTE 1 In Australia, the regulation of security sensitive biological agents (SSBA) is governed by the National Health Security Act 2007 administered by the Department of Health (www.health.gov.au/ssba).

NOTE 2 In Australia, other State and Territory governments may have requirements for the security of biological material that needs to be met.

NOTE 3 In New Zealand, the MPI and EPA, as well as regional councils and agencies that manage Crown Land, may also have requirements for the security of biological material that needs to be met.

2.5 Commissioning

A containment facility shall be assessed for conformance with this Standard when construction or major alteration is completed on one of the following:

(a) Containment facility.
(b) Surrounding building(s).
(c) Environment.
(d) Associated air supply.
(e) Exhaust systems.

Assessment shall include confirmation checks, such as utility supply failures and individual pressure controlling equipment failures, where these are critical for containment performance. An itemized checklist should be developed to assist in ensuring all requirements of this Standard relevant to the particular facility are taken into account when conducting the assessment.

2.6 Health management

2.6.1 General

The institute shall inform all personnel of the risk of occupational exposure to microorganisms to which they may not be immune. Health monitoring of exposure should be put in place and be relevant to the risks associated with the microorganisms.

When working with human pathogens, personnel working in the containment shall be offered, and be encouraged to undertake an initial medical examination which shall include a chest X-ray, as well as periodic examinations, where clinically relevant, i.e. unless a risk assessment has been undertaken to show that these are not required.

NOTE 1 See Clause 2.6.3 for further information on obtaining serum samples.

When working with human pathogens, systems shall be set up for reporting accidents and exposures to microorganisms, for monitoring employee absenteeism and for the medical surveillance of illnesses that are potentially laboratory associated.

The institute shall inform all personnel of the risks to an unborn child or pregnant woman of occupational exposure to certain microorganisms (e.g. Toxoplasma gondii, Listeria monocytogenes, Cytomegalovirus, Parvovirus B19, Rubella virus, Zika virus, HIV, Coxiella burnetii, and Hepatitis B, C and E viruses) and some fungi.

NOTE 2 See Clause 2.6.5 for further information on at-risk persons.
2.6.2 Injuries and infections

All injuries that occur in the workplace shall be reported to the supervisor (see Clause 2.7). Minor cuts and abrasions, which provide routes for infection from contaminated surfaces, should be adequately covered and kept dry. Infections (especially respiratory or wound) can provide sources of contamination for experimental materials and fellow workers. Individual cases should be assessed in relation to the particular laboratory’s work.

Immediate medical action shall be required after human blood or body fluid exposure and contaminated sharps injuries.


Consideration should be given to whether any infection was laboratory acquired.

2.6.3 Blood samples

A serum bank can be invaluable when there are questions of work-related infection. Subject to privacy and informed consent considerations, baseline serum samples should be collected from “at-risk” personnel, to be stored for future reference. Additional serum samples may be collected periodically, depending on the risk of exposure to agents handled in the laboratory.

A baseline serum sample should be obtained as soon as possible from personnel involved in a potential or known laboratory exposure. A second serum sample should be collected at an appropriate interval following the exposure event to establish whether the worker(s) have been exposed to an infectious agent following a laboratory incident.

NOTE Consult State, Territory, and/or Commonwealth legislation in regard to the collection, storage, and use of blood samples.

2.6.4 Immunization

All new personnel working with specimens and cultures potentially containing *Mycobacterium tuberculosis* (*M. tuberculosis*) complex should have a tuberculin skin test (TST) or TB gamma-interferon assay. Prior vaccination with Bacille Calmette-Guérin (BCG) confounds TST testing but not the TB gamma interferon assay.

NOTE 1 See Bibliography, Reference 1.1.

Personnel with negative test results should be retested on an annual basis.

NOTE 2 For further guidance, refer to the NTAC, Guidelines for Australian Mycobacteriology Laboratories or Ministry of Health, Guidelines for Tuberculosis Control in New Zealand 2003 as in force from time to time.

Vaccination against *M. tuberculosis* is not generally recommended. However, BCG vaccination should be considered for personnel with high risk of exposure to TB and as recommended by State and Territory TB control authorities.

Consideration should be given to the immunization of support personnel where appropriate.

NOTE 3 For those working with human or zoonotic pathogens, or samples that may contain human or zoonotic pathogens, refer to *The Australian Immunization Handbook* published by the NHMRC or the Immunization Handbook published by the New Zealand Ministry of Health. These documents should be consulted and implemented where appropriate.
2.6.5 At-risk persons

Persons who are immuno-suppressed, immuno-compromised, or otherwise unduly vulnerable to infection (such as persons who are diabetic) should inform their supervisor or personnel responsible for microbiological safety of their condition so that appropriate precautionary action may be taken. Medical opinion may be required if working with human pathogens. Some microorganisms that are regarded as part of the normal flora of humans or animals may be pathogenic for immuno-compromised persons.

2.6.6 Precautions for women

Pregnant women should inform their supervisor or personnel responsible for microbiological safety of their condition so that appropriate action (i.e. safety precautions) may be taken. Pregnant women with gestational diabetes should be regarded in the same sense as persons who are diabetic and may be unduly vulnerable to infection. The precise steps taken for protection will vary, depending on the microorganisms to which the woman may be exposed, based on a risk assessment. A medical opinion may be required.

2.7 Incident reporting

Where an incident has occurred resulting in an injury or illness, priority shall be given to the care of the injured or ill person. The project risk assessment should be consulted and consideration given to the risk group if a microorganism is involved, i.e. how the microorganism may be transmitted and if any hosts, the environment or processes that are at risk as a result of the accident. First aid should be applied by trained personnel, ensuring that they do not risk being infected. If necessary, medical aid should then be sought (see also Clause 2.6.2).

The incident should be reported verbally to the supervisor as soon as reasonably possible, documented using the institution’s health and safety report form and referred to the BC (or referred as required by the equivalent institutional procedures).

Where an incident occurs with potential for contamination from infectious material, a verbal report shall be made to the supervisor as soon as reasonably possible. The incident should be documented once the appropriate clean-up procedure has been implemented.

NOTE 1 See Section 10 for guidance in response to microbiological spills.

Incidents involving GMOs or quarantine materials resulting in a breach of containment shall be reported to the relevant authorities.

For certain infections, notification of local public health authorities may be necessary.

Personnel should be encouraged to report all overt exposures or incidents that have the potential to cause harm so that they may be documented and investigated. If necessary, the procedures shall be changed to prevent further similar incidents producing injuries or illness.

NOTE 2 Appendix A provides an example of an incident/illness reporting form.

2.8 Emergency response and contingency plans

2.8.1 Emergency plan

An emergency evacuation plan shall be developed in accordance with AS/NZS 2243.1. The plan shall address emergency microbiological issues and shall include minimization of the microbiological risk associated with any emergency evacuation. The plan should take into account the different arrangements for entry and exit associated with the containment level of the facility.

NOTE Refer to AS 3745.
2.8.2 Contingency plan

Contingency plans shall be developed for the spillage of microorganisms and breaches of containment caused by the release of microorganisms outside the laboratory through accident, deliberate action, natural disaster, fire, sabotage, theft, or any other event.

2.8.3 First aid kit

A readily accessible first aid kit shall be provided in an unlocked and clearly labelled container. The contents of the kit shall be appropriate to the needs of the laboratory and maintained in a satisfactory condition.

NOTE Refer to national, State and Territory legislation for first aid treatment in the workplace.

Section 3 Degree of hazard from microorganisms

3.1 General

All work with microorganisms requires the use of standard techniques to minimize risk to people and the environment. Such techniques also maintain the purity of strains of isolates in the laboratory.

Microorganisms vary widely in their ability to infect humans, terrestrial animals, plants, aquatic organisms, and invertebrates, or to spread in the environment. There is obvious, but varied, risk to people from work with microorganisms isolated from or infecting humans. With regard to microorganisms infecting animals, many do not cause human disease, but some zoonotic microorganisms are responsible for serious human infections and can be responsible for serious harm to the economy and the environment.

Some microorganisms that infect arthropods are capable of causing human disease. The arthropods are then said to be vectors of disease, for example, mosquitoes may transmit arboviruses and lice may transmit rickettsiae.

Certain soil microorganisms, while not pathogenic to humans, may cause diseases in plants and be spread to new locations from improper handling or practices. In general, microorganisms from plant and fish diseases rarely infect humans. Certain microorganisms infecting plants or animals are subject to strict quarantine control in Australia and New Zealand, to protect the environment and primary industry.

Certain microorganisms, e.g. Clostridium botulinum, produce small molecules termed toxins that account for their pathogenicity. Some of the microorganisms that produce toxins are listed in Risk Groups 2 and 3. Toxins are also produced by certain plants and animals such as ricin from castor beans and saxitoxin from shell fish. The safety considerations for working with toxins from these sources are not discussed in this Standard.

The basic approach to working with microorganisms is to regard them as potential pathogens and to handle them with standard microbiological techniques which, in the main, protect the environment and the operator and maintain the purity of the strain or isolate.

Microorganisms vary widely in their infectivity. This is partly due to differences in the portal of entry of the organism (e.g. by skin penetration, ingestion, entry via the respiratory tract or entry via the conjunctiva), the physiology of the microorganism, the infectious dose and the ability of the microorganism to overcome intrinsic immune and other defences of the host.

Surveys of the causes of laboratory-acquired infections (see Bibliography, Reference 1.2) have shown that only about 20% of cases followed known accidents with infectious material, the most common being skin penetration accidents, e.g. with a needle and syringe and injury from broken glass. Spillage, mouth pipetting, leakage during centrifugation and bites from infected animals are other causes. Simple precautions can reduce the likelihood of such accidents occurring.
Many of the remaining 80% of infections are believed to be due to inhalation of aerosols that may be produced from common laboratory operations. Such operations include vortexing, sonicating, homogenizing, dropping cultures of high-titre material, blowing out the last few drops in a pipette, removing a needle from a rubber seal, centrifuging, grinding, vigorous shaking or mixing, opening containers of infectious material whose internal pressure may be different from ambient pressure, intranasal inoculation of animals harvesting of infected tissues from animals and eggs, cell counters, and unprotected or open robotics sampling operations.

The probability that an aerosol will contain an infectious dose of an organism is broadly related to the concentration (titre) of the organism in the material being handled. The risk is therefore increased when handling bacterial or viral isolates propagated to high titre in culture or in animals, as compared with clinical specimens, food, water and other samples which may contain fewer organisms. Indeed, high titre cultures of some microorganisms (e.g. some arboviruses) may be infectious by the aerosol-respiratory tract route or through broken skin in the laboratory even though in nature they are normally transmitted by insect bite.

Special containment equipment and procedures have been designed to protect laboratory workers from infection with those microorganisms with a "track record" of transmission by the aerosol-respiratory tract route.

Clause 3.2 describes the classification of microorganisms by risk group based, when possible, on past experience with the infectious potential of the microorganism or on microbiologically-informed prudence when a newly-discovered microorganism of uncertain infectious potential has to be handled.

Section 4 provides the principles on which the requirements for containment facilities are based and requirements common to all types of containment laboratories and facilities.

Section 5 sets out the classification of laboratories, PC equipment, laboratory design and procedures to be followed when working in laboratories with microorganisms classified at the various risk groups.

Sections 6, 7, 8 and 9 describe the classification of terrestrial animal, plant, invertebrate and aquatic organism containment facilities, PC equipment, facility design and procedures to be followed when working with microorganisms classified at the various risk groups.

When handling human blood, serum, or other body fluids and substances that are visibly contaminated with blood, appropriate publications shall be consulted.


This risk extends to human sera and derivatives used as control reagents (both positive and negative) in diagnostic and other procedures.

NOTE 2 Although existing test methods for viruses are sensitive, they do not entirely preclude the possibility of viral contamination. The fact that a serum sample is used as a negative control for some particular tests does not necessarily mean that it is free of viruses.

3.2 Classification of microorganisms by risk group

3.2.1 General

Classifications of infectious microorganisms according to degree of risk have been published in the USA, Canada and the UK, together with recommendations for appropriate laboratory facilities for working with them (see Bibliography, References 1.3 and 1.4).

The World Health Organization (WHO) suggests each country draw up risk groups according to the microorganisms encountered within its boundaries (see Bibliography, Reference 1.5).

Unless otherwise stated, references to particular risk groups, e.g. Risk Group 1, refers to human, terrestrial animal, plant, invertebrate and aquatic organism risk groups.
3.2.2 Human and terrestrial animal infectious microorganisms

The following classification has been drawn up for microorganisms that are infectious for humans and terrestrial animals for Australia and New Zealand by modification of the WHO guidelines, and is based on the pathogenicity of the agent, the mode of transmission and host range of the agent, the availability of effective preventive measures, and the availability of effective treatment. The classification is as follows:

(a) **Risk Group 1 (low individual and community risk)** — A microorganism that is unlikely to cause human or terrestrial animal disease.

(b) **Risk Group 2 (moderate individual risk, limited community risk)** — A microorganism that is unlikely to be a significant risk to laboratory workers, the community, livestock, or the environment; laboratory exposures may cause infection, but effective treatment and preventive measures are available, and the risk of spread is limited.

(c) **Risk Group 3 (high individual risk, limited to moderate community risk)** — A microorganism that usually causes serious human or animal disease and may present a significant risk to laboratory workers. It could present a limited to moderate risk if spread in the community or the environment, but there are usually effective preventive measures or treatment available.

(d) **Risk Group 4 (high individual and community risk)** — A microorganism that usually produces life-threatening human or animal disease, represents a significant risk to laboratory workers and may be readily transmissible from one individual to another. Effective treatment and preventive measures are not usually available.

3.2.3 Plant infectious microorganisms

The risk grouping of plant infectious microorganisms is primarily concerned with containment of plant pathogens to avoid risk to the environment. Plant pathogens are infectious agents capable of causing disease in plants and include fungi, bacteria, viruses, viroids, rickettsiae, phytoplasmas and nematodes.

Factors considered in relation to the risk from plant infectious microorganisms are —

(a) the economic or ecological impact;

(b) the infectious microorganism’s presence in Australia or New Zealand;

(c) ease of spread;

(d) use in the facility, *in vitro* or *in vivo*; and

(e) the host range.

The following three risk groups are used to manage risks posed by plant infectious microorganisms:

(i) **Plant Risk Group 1** — A microorganism that is a low to moderate risk to plants, industry, a community or region and is present but not widely distributed.

(ii) **Plant Risk Group 2** — A microorganism that is a significant risk to plants, industry, a community or region and is exotic but with a limited ability to spread without the assistance of a vector.

(iii) **Plant Risk Group 3** — A microorganism that is a highly significant risk to plants, industry, a community or region and is exotic and readily spread naturally without the assistance of a vector.

3.2.4 Invertebrates carrying microorganisms

The risks posed by invertebrates are based on the nature of the microorganism that they may be carrying and the nature of the invertebrate itself.

Examples include viruses in mosquitoes, midges and biting flies, *Borrelia* in soft ticks, trypanosomes in Triatomid bugs, and tospoviruses in thrips.
Factors considered in relation to the risk are —

(a) the risk to facility personnel;
(b) the potential economic or ecological impact;
(c) geographical distribution;
(d) suitable climatic conditions for development;
(e) host range;
(f) the size of the organism, and consequent ease of detection;
   NOTE In some cases, the invertebrate may be microscopic in size.
(g) ability to disperse;
(h) use in the facility, *in vitro* or *in vivo*;
(i) resistance to pesticides, especially for exotic invertebrates; and
(j) potential to be carrying exotic or pesticide-resistant parasites and microorganisms.

The following four groups are used to identify the risks posed by infectious microorganisms carried by invertebrates:

(i) *Invertebrate Risk Group 1* — Microorganisms that are carried by invertebrates where the microorganisms are unlikely to be a risk to humans or to the environment and are already present and widely distributed.

(ii) *Invertebrate Risk Group 2* — Microorganisms that are carried by invertebrates where the microorganisms are a low to moderate risk to humans or to the environment and are present but not widely distributed. They have a limited ability to disperse because of low persistence of the microorganism outside the host. They are carried by invertebrates that are unlikely to be able to disperse or can be readily controlled.

(iii) *Invertebrate Risk Group 3* — Microorganisms that are carried by invertebrates where the microorganisms are a significant risk to humans or to the environment and are exotic and have the ability to disperse with or without the aid of a vector. They are carried by invertebrates that are able to disperse.

(iv) *Invertebrate Risk Group 4* — Microorganisms that are carried by invertebrates where the microorganisms are a highly significant risk to humans or to the environment and are exotic and readily able to disperse with or without the aid of a vector. The microorganisms may be carried by invertebrates that are difficult to detect visually.

### 3.2.5 Aquatic infections microorganisms

The risks posed by aquatic infectious microorganisms are based on the nature of the microorganism that they may be carrying and the nature of the aquatic animal itself. The risk grouping of aquatic animal infectious microorganisms is primarily concerned with containment of aquatic pathogens to avoid risk to humans, animals and the environment. Aquatic pathogens are infectious agents capable of causing disease in aquatic animals and include fungi, bacteria, and viruses, rickettsiae, protozoan and metazoan parasites.

Factors considered in relation to the risk from aquatic infectious microorganisms are —

(a) the economic or ecological impact;
(b) the infectious microorganism’s presence in Australia or New Zealand;
(c) ease and effectiveness of spread;
(d) use in the facility, in vitro or in vivo; and

(e) the host range.

The following two groups are used to identify the risks posed by infectious microorganisms carried by aquatic animals:

(i) **Aquatic Risk Group 1** — Microorganisms that are carried by aquatic animals and plants where the microorganisms are a significant risk to humans, animals, primary industries, or to the environment. They have the ability to disperse with or without the aid of a vector. They are carried by aquatic animals and plants that are able to disperse.

(ii) **Aquatic Risk Group 2** — Microorganisms that are carried by aquatic animals where the microorganisms are a highly significant risk to humans or to the environment. They are exotic, targeted for eradication or subject to specific import controls and readily able to disperse with or without the aid of a vector. The microorganisms may be carried by aquatic animals that are difficult to detect visually.

NOTE A number of “transitional” pathogens or “notifiable pathogens subject to control” but whose presence in Australia is confirmed but have not been eradicated have been omitted from Tables 3.11 and 3.12. State and Territory Regulations in respect of organisms that have been detected vary between jurisdictions. As such, in instances where there is doubt as to whether an organism is exotic, advice should be sought from relevant State and Territory agencies.

3.3 Risk-grouping of microorganisms by type

3.3.1 General

Tables 3.1 to 3.12 are indicative examples of microorganisms categorized into risk groupings and can be used for a documented risk assessment (see Clause 2.1.2).

A documented risk assessment shall be conducted on all microorganisms to determine if the work needs to be conducted with additional precautions or in a higher level of PC. The risk assessment should include a review of recent literature to determine if any additional information may warrant changes to the risk grouping or the level of PC. It should also consider in vivo work and work with imported organisms, GMOs and SSBAs (see Clauses 2.2, 2.3 and 2.4).

No tables are provided for microorganisms belonging in Risk Group 1, as the number of relevant microorganisms is large.

3.3.2 Human and animal infectious microorganism risk group examples

3.3.2.1 Bacteria

Tables 3.1 and 3.5 list examples of bacteria of Risk Group 2 and Risk Group 3 respectively and additional information is indicated in footnotes. Currently, no bacteria are classified in Risk Group 4. In addition to the information in the tables, reference should be made to the work practices specified for the relevant level of PC.

NOTE Refer to the *Tuberculosis Laboratory Biosafety Manual* published by the World Health Organization, for specific recommendations related to handling mycobacteria tuberculosis.

3.3.2.2 Parasites

Many parasites are regarded as Risk Group 2, with respect to their infectious stages. Preparations that are known to be free of infectious stages may not require a containment level corresponding to this risk group. Table 3.2 lists examples of Risk Group 2 parasites.
3.3.2.3 Fungi

Tables 3.3 and 3.6 list examples of fungi of Risk Group 2 and Risk Group 3 respectively.

3.3.2.4 Viruses

Tables 3.4, 3.7 and 3.8 list examples of viruses for Risk Groups 2, 3 and 4 respectively.

The additional containment requirements for poliovirus set out in Appendix B shall be applied.

3.3.3 Plant pathogen risk group examples

Tables 3.9 and 3.11 list examples of plant pathogens of Plant Risk Groups 2 and 3 respectively.

3.3.4 Invertebrate risk group examples

Invertebrates are able to act as vectors for human, terrestrial animal and plant disease. Pathogens that use invertebrates as vectors are not listed in separate tables. Instead, examples of pathogens of Risk Groups 2, 3 and 4 that are vectored by invertebrates are included in Tables 3.1, 3.2, 3.4, 3.5 and 3.7 to 3.10.

3.3.5 Aquatic risk group examples

Table 3.11 lists examples of aquatic organism pathogens of Risk Group 2.

3.4 Human, terrestrial and aquatic animal clinical and diagnostic specimens

Such specimens would normally be regarded as Risk Group 2 and shall be handled in PC Level 2 facilities unless a higher risk group is indicated by the clinical or diagnostic notes. This applies in all microbiology and other pathology laboratories, e.g. for haematology and biochemistry. Once a microorganism of a higher risk group than originally suspected is suspected through accumulation of reasonable evidence, isolated or confirmed from a specimen, the isolate and all infectious samples from that source shall be handled according to the corresponding risk group, and at the appropriate PC level.

All clinical and diagnostic specimens shall be treated with care as they may contain multiple types of infectious agents. Examples of precautions that should be adopted are provided in the NHMRC publication, Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010), the Department of Health Infection Control Guideline, Infection prevention and control procedures to minimize the risk of transmission of Creutzfeldt-Jakob disease (CJD) in health care settings, and the NOHSC publication National Code of Practice for the Control of Work-related Exposure to Hepatitis and HIV (Blood-borne) Viruses [NOHSC:2010 (2003)].

3.5 Quality assurance of cultures and materials

Cultures and materials containing microorganisms are regularly transferred within and between institutions and PC levels. Laboratory-acquired infections have occurred because of cross-contamination and ineffective attenuation or inactivation.

It is strongly recommended that prior to despatch and upon receipt of “pure” cultures, tests are carried out to ensure purity.

If infectious microorganisms are attenuated or inactivated prior to removal to a lower PC level or prior to transfer between institutions, the attenuation or inactivation processes shall be verified and documented. The identity and purity of cultures shall be confirmed before they are transferred to lower containment levels or between institutions.

Routine quality control testing of registered live vaccine strains should be carried out in a BSC.
3.6 Work with human, animal or plant cells

Work with cells has the potential to be hazardous to laboratory workers and the environment, depending on the source of the cells and the likelihood that they contain infectious microorganisms. However, the preparation of primary cells from human organs or tissues shall be conducted in PC2 containment. The manipulation of these cell lines should be done in Class II BSCs.

Some cell lines contain Mycoplasma and although they can be “cleaned up”, the cells can become reinfected and again pose a hazard to the laboratory worker. Cell lines from an animal source can also contain microorganisms that are capable of causing disease in humans and animals. In some instances, PC1 laboratories can be adequate if good microbiological practices are followed, e.g. work with standard human cell lines.

Plant cells and tissue cultures can contain plant infectious microorganisms that have the potential to spread in the environment if inadvertently released and cause economic and environmental damage.

A documented risk assessment shall be carried out to determine what level of containment is required for the cells proposed for use.

All cells shall be decontaminated before disposal.

3.7 Prions

Prions are resistant to most traditional methods of inactivation used for other microorganisms such as formaldehyde, ultraviolet light, ethylene oxide, ionizing radiation and moist heat at 121 °C. Because of the difficulties in inactivating the infectivity, these agents pose particular laboratory problems. However, they are not easily spread from host to host and the usual mechanism of spread appears to be by the ingestion or grafting of infectious material.

When working with material that definitely or potentially contains infectious prions, a class 2 biosafety cabinet shall be used. Consideration should be given to the use of a laminar flow cytotoxic drug safety cabinet if the procedure involves higher-infectivity tissue or a risk assessment of the procedure identifies large volumes of material of any infectivity or high frequency handling of material of any infectivity. Table 3.4 lists examples of prions of Risk Group 2 (see also Clauses 11.9 and 13.2.1). Table E.2 provides guidance on disinfection of equipment or surfaces contaminated with prions.

For diagnostic samples which may have the potential to be infectious, see Clause 3.4.

3.8 Scale of cultures

The risk group classifications listed in Tables 3.1 to 3.7 are appropriate for small-scale laboratory operations with microorganisms of Risk Groups 2 and 3. Where larger volumes or very high concentrations of the microorganisms are to be handled, the risk of infection or inadvertent release from containment can be higher and additional precautions or an increase in PC level may be appropriate. See also Clause 2.3 for large scale GMO work.
Table 3.1 — Examples\textsuperscript{a} of bacteria of risk group 2

<table>
<thead>
<tr>
<th>Organism</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acidovorax spp.</td>
<td>Kingella kingae</td>
</tr>
<tr>
<td>Acinetobacter spp.</td>
<td>Klebsiella spp.</td>
</tr>
<tr>
<td>Actinoimyces spp.</td>
<td>Legionella spp.</td>
</tr>
<tr>
<td>Aeromonas spp.</td>
<td>Leptospira interrogans (all serovars)\textsuperscript{e}</td>
</tr>
<tr>
<td>Afipia spp.</td>
<td>Listeria spp., Listeria monocytogenes\textsuperscript{f}</td>
</tr>
<tr>
<td>Arcanobacterium haemolyticum</td>
<td>Moraxella spp.</td>
</tr>
<tr>
<td>Bacillus cereus</td>
<td>Mycobacterium spp. other than M. tuberculosis complex\textsuperscript{g}</td>
</tr>
<tr>
<td>Bacterioides fragilis</td>
<td>Mycobacterium tuberculosis complex (except multi-drug resistant strains\textsuperscript{g,h,i})</td>
</tr>
<tr>
<td>Bartonella spp. (except B. bacilliformis)</td>
<td>Mycoplasma spp. M. pneumoniae\textsuperscript{g}</td>
</tr>
<tr>
<td>Bordetella pertussis</td>
<td>Neisseria gonorrhoeae, Unspecified</td>
</tr>
<tr>
<td>Borrelia spp. (serology)</td>
<td>Neisserias\textsuperscript{a-g}, N. meningitidis\textsuperscript{a-g}</td>
</tr>
<tr>
<td>Brucella spp. (serology)</td>
<td>Nocardiia spp.</td>
</tr>
<tr>
<td>Burkholderia spp (except B. mallei) Burkholderia pseudomallei\textsuperscript{g}</td>
<td>Pasteurellia spp.</td>
</tr>
<tr>
<td>Campylobacter spp.</td>
<td>Pseudomonas spp.</td>
</tr>
<tr>
<td>Capnocytophaga spp.</td>
<td>Rhodococcus equi</td>
</tr>
<tr>
<td>Chlamydia spp. (except C. psittaci)</td>
<td>Salmonella enterica serovars</td>
</tr>
<tr>
<td>Clostridium spp. (except C. botulinum)</td>
<td>Salmonella Paratyphi A and B\textsuperscript{c}</td>
</tr>
<tr>
<td>Corynebacterium diphtheria, C. pseudotuberculosis</td>
<td>Serratia spp.</td>
</tr>
<tr>
<td>Coxiella burnetii (serology)</td>
<td>Shigella spp.c</td>
</tr>
<tr>
<td>Dermatophilus congoensis</td>
<td>Staphylococcus spp.</td>
</tr>
<tr>
<td>Eikenella corrodens</td>
<td>Stenotrophomonas maltophilia</td>
</tr>
<tr>
<td>Enterococcus spp.</td>
<td>Streptobacillus moniliformis</td>
</tr>
<tr>
<td>Erysipelothrix rhusiopathiae</td>
<td>Streptococcus spp.</td>
</tr>
<tr>
<td>Escherichia coli (except genetically modified strains) includes enteropathogenic (ETEC), enteroaggregative (EAEC), enterotoxigenic (ETEC), and Shiga-like toxin producing (STEC)\textsuperscript{c}</td>
<td>Treponema pallidum (serology, darkfield microscopy, PCR)</td>
</tr>
<tr>
<td>Fusobacterium spp.</td>
<td>Ureaplasma urealyticum</td>
</tr>
<tr>
<td>Gardnerella vaginalis</td>
<td>Vibrio cholerae, V. parahaemolyticus, V. vulnificus</td>
</tr>
<tr>
<td>Haemophilus spp.</td>
<td>Yersinia spp. (except Y. pestis)</td>
</tr>
<tr>
<td>Helicobacter spp.</td>
<td></td>
</tr>
</tbody>
</table>

\textsuperscript{a} This list is not exhaustive. Some species of some genera may be classified as Risk Group 1 subject to a risk assessment and check of current literature.

\textsuperscript{b} Work with exotic organisms requires regulatory approval.

\textsuperscript{c} Low infectious dose, high pathogenicity, common source of laboratory-acquired infections.

\textsuperscript{d} For genetically crippled strains, refer to Commonwealth legislation.

\textsuperscript{e} Can penetrate intact skin.

\textsuperscript{f} May be dangerous for pregnant women.

\textsuperscript{g} Should be handled in a BSC due to high risk of aerosol spread.

\textsuperscript{h} Vaccination, see Clause 2.6.4.

\textsuperscript{i} Less than 5000 cultures per year. See references in Clause 3.3.2.1. Clostridium botulinum (botulism toxin-producing strains) — SSBA see Note, Clause 2.4.
Table 3.2 — Examples\textsuperscript{a} of parasites of risk group 2

<table>
<thead>
<tr>
<th>Organism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acanthamoebae spp.</td>
</tr>
<tr>
<td>Angiostrongylus cantonensis</td>
</tr>
<tr>
<td>Anasakis spp.</td>
</tr>
<tr>
<td>Ascaris lumbricoides</td>
</tr>
<tr>
<td>Babesia spp.</td>
</tr>
<tr>
<td>Balamuthia mandrillaris</td>
</tr>
<tr>
<td>Brugia spp.</td>
</tr>
<tr>
<td>Clonorchis sinensis</td>
</tr>
<tr>
<td>Cryptosporidium spp.</td>
</tr>
<tr>
<td>Cyclospora cayetanensis</td>
</tr>
<tr>
<td>Cystoisospora belli</td>
</tr>
<tr>
<td>Diphyllobothrium latum</td>
</tr>
<tr>
<td>Echinococcus spp.</td>
</tr>
<tr>
<td>Entamoeba histolytica</td>
</tr>
<tr>
<td>Enterobius vermicularis</td>
</tr>
<tr>
<td>Fasciola hepatica</td>
</tr>
<tr>
<td>Giardia spp.</td>
</tr>
<tr>
<td>Hookworm spp.</td>
</tr>
<tr>
<td>Hymenolepis spp.</td>
</tr>
<tr>
<td>Leishmania spp.</td>
</tr>
<tr>
<td>Loa loa</td>
</tr>
<tr>
<td>Naegleria fowleri</td>
</tr>
<tr>
<td>Opisthorchis spp.</td>
</tr>
<tr>
<td>Plasmodium spp. (human and simian)</td>
</tr>
<tr>
<td>Schistosoma spp.</td>
</tr>
<tr>
<td>Strongyloides stercoralis\textsuperscript{c}</td>
</tr>
<tr>
<td>Taenia saginata</td>
</tr>
<tr>
<td>Taenia solium\textsuperscript{d}</td>
</tr>
<tr>
<td>Toxocara spp.</td>
</tr>
<tr>
<td>Toxoplasma gondii\textsuperscript{e}</td>
</tr>
<tr>
<td>Trichinella spp.</td>
</tr>
<tr>
<td>Trichuris trichiura</td>
</tr>
<tr>
<td>Trypanosoma spp.</td>
</tr>
<tr>
<td>Wuchereria bancrofti</td>
</tr>
</tbody>
</table>

\textsuperscript{a} This list is not exhaustive.
\textsuperscript{b} Work with exotic organisms requires regulatory approval.
\textsuperscript{c} Filariform larvae may cross intact skin.
\textsuperscript{d} Accidental ingestion of eggs may lead to cysticercosis.
\textsuperscript{e} May be teratogenic.
Table 3.3 — Examples\textsuperscript{a} of fungi or fungal-like organisms of risk group 2\textsuperscript{b}

<table>
<thead>
<tr>
<th>Organism</th>
</tr>
</thead>
<tbody>
<tr>
<td>\textit{Aspergillus fumigatus}</td>
</tr>
<tr>
<td>and \textit{A. flavus}</td>
</tr>
<tr>
<td>\textit{Candida albicans}</td>
</tr>
<tr>
<td>\textit{Cladophialophora} spp.</td>
</tr>
<tr>
<td>\textit{Cryptococcus gattii}</td>
</tr>
<tr>
<td>\textit{Cryptococcus neoformans}</td>
</tr>
<tr>
<td>\textit{Epidermophyton} floccosum</td>
</tr>
<tr>
<td>\textit{Microsporum} spp.</td>
</tr>
<tr>
<td>\textit{Scedosporium} spp.</td>
</tr>
<tr>
<td>\textit{Sporothrix schenckii}</td>
</tr>
<tr>
<td>\textit{Trichophyton} spp.</td>
</tr>
<tr>
<td>\textit{Zika virus}c</td>
</tr>
</tbody>
</table>

\textsuperscript{a} This list is not exhaustive.
\textsuperscript{b} Work with exotic organisms requires regulatory approval.
\textsuperscript{c} May be dangerous for pregnant women.

Table 3.4 — Examples\textsuperscript{a} of viruses and prions of risk group 2

<table>
<thead>
<tr>
<th>Virus or prion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adenoviridae</strong></td>
</tr>
<tr>
<td>Adenovirus</td>
</tr>
<tr>
<td><strong>Arenaviridae</strong></td>
</tr>
<tr>
<td>Arenavirus</td>
</tr>
<tr>
<td>Lymphocytic Choriomeningitis virus (LCMV) non neurotropic and laboratory adapted strains\textsuperscript{d,g}</td>
</tr>
<tr>
<td>Tacaribe virus complex</td>
</tr>
<tr>
<td><strong>Astroviridae</strong></td>
</tr>
<tr>
<td>Astrovirus</td>
</tr>
<tr>
<td><strong>Caliciviridae</strong></td>
</tr>
<tr>
<td>Feline calicivirus</td>
</tr>
<tr>
<td>Norovirus</td>
</tr>
<tr>
<td>Sapporo-like</td>
</tr>
<tr>
<td>Largovirus</td>
</tr>
<tr>
<td>Rabbit haemorrhagic disease</td>
</tr>
<tr>
<td><strong>Hepevirus</strong></td>
</tr>
<tr>
<td>Hepatitis E\textsubscript{f}</td>
</tr>
<tr>
<td><strong>Coronaviridae</strong></td>
</tr>
<tr>
<td>Alphacoronavirus</td>
</tr>
<tr>
<td>\textit{229E}</td>
</tr>
<tr>
<td>Porcine Epidemic Diarrhoea Virus</td>
</tr>
<tr>
<td>Betacoronavirus</td>
</tr>
<tr>
<td>SARS — related coronavirus (serology, tests not involving replication)\textsuperscript{j}</td>
</tr>
<tr>
<td>MERS — related coronavirus (serology and tests not involving propagation or culture)\textsuperscript{b}</td>
</tr>
<tr>
<td>OC43</td>
</tr>
<tr>
<td>Mouse hepatitis virus</td>
</tr>
<tr>
<td><strong>Flaviridae</strong></td>
</tr>
</tbody>
</table>

\textsuperscript{a} May be dangerous for pregnant women.
### Table 3.4 (continued)

<table>
<thead>
<tr>
<th>Virus or prion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flavivirus</strong></td>
</tr>
<tr>
<td>Dengue 1, 2, 3 and 4</td>
</tr>
<tr>
<td>Japanese encephalitis (Nakayama strain)</td>
</tr>
<tr>
<td>Kokobera</td>
</tr>
<tr>
<td>West Nile (Kunjin strain)</td>
</tr>
<tr>
<td>Murray Valley encephalitis</td>
</tr>
<tr>
<td>West Nile (Sarafend strain)</td>
</tr>
<tr>
<td>Saumarez Reef</td>
</tr>
<tr>
<td>Yellow fever (strain 17D)</td>
</tr>
<tr>
<td>Zikad</td>
</tr>
<tr>
<td><strong>Hepacivirus</strong></td>
</tr>
<tr>
<td>Hepatitis C</td>
</tr>
<tr>
<td>Pegivirus (previously known as GB virus C or Hepatitis G)</td>
</tr>
<tr>
<td><strong>Hepadnaviridae</strong></td>
</tr>
<tr>
<td>Avihepadnavirus</td>
</tr>
<tr>
<td>Duck hepatitis B</td>
</tr>
<tr>
<td>Orthohepadnavirus</td>
</tr>
<tr>
<td>Hepatitis B</td>
</tr>
<tr>
<td><strong>Hepeviridae</strong></td>
</tr>
<tr>
<td>Orthohepevirus</td>
</tr>
<tr>
<td>Hepatitis E</td>
</tr>
<tr>
<td><strong>Herpesviridae</strong></td>
</tr>
<tr>
<td>Alphaherpesvirinae</td>
</tr>
<tr>
<td>Simplex</td>
</tr>
<tr>
<td>Varicella&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Betaherpesvirinae</td>
</tr>
<tr>
<td>Cytomegalovirus</td>
</tr>
<tr>
<td>Human beta herpes virus 5&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Rubelovirus</td>
</tr>
<tr>
<td>Human beta herpesvirus Herpes 6 and 7</td>
</tr>
<tr>
<td><strong>Gammaherpesvirinae</strong></td>
</tr>
<tr>
<td>Lymphocryptovirus</td>
</tr>
<tr>
<td>Human gammaherpesvirus 4 or EB virus</td>
</tr>
<tr>
<td>Rhadinovirus</td>
</tr>
<tr>
<td>Human gammaherpesvirus 8 (Kaposi's sarcoma associated virus)</td>
</tr>
<tr>
<td><strong>Orthomyxviridae</strong></td>
</tr>
<tr>
<td>Influenza (all strains and candidate vaccine strains except those specified in Table 3.7&lt;sup&gt;c&lt;/sup&gt;)</td>
</tr>
<tr>
<td><strong>Papillomaviridae</strong></td>
</tr>
<tr>
<td>Human Papillomavirus</td>
</tr>
<tr>
<td><strong>Paramyxoviridae</strong></td>
</tr>
<tr>
<td>Paramyxovirinae</td>
</tr>
<tr>
<td>Morbillivirus</td>
</tr>
<tr>
<td>Measles&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Rubulavirus</td>
</tr>
</tbody>
</table>
### Table 3.4 (continued)

<table>
<thead>
<tr>
<th>Virus or prion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Menangle</td>
</tr>
<tr>
<td>Mumps&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Human parainfluenza 2 and 4</td>
</tr>
<tr>
<td>Avulavirus</td>
</tr>
<tr>
<td>Newcastle disease (non-virulent enzootic strains)</td>
</tr>
<tr>
<td>Avian paramyxoviruses 2 to 9</td>
</tr>
<tr>
<td>Respirovirus</td>
</tr>
<tr>
<td>Sendai</td>
</tr>
<tr>
<td>Human parainfluenza 1 and 3</td>
</tr>
<tr>
<td>Pneumovirinae</td>
</tr>
<tr>
<td>Pneumovirus</td>
</tr>
<tr>
<td>Respiratory syncytial</td>
</tr>
<tr>
<td>Metapneumovirinae</td>
</tr>
<tr>
<td>Metapneumovirus</td>
</tr>
<tr>
<td>Avian metapneumovirus</td>
</tr>
<tr>
<td>Human metapneumovirus</td>
</tr>
<tr>
<td>Parvoviridae</td>
</tr>
<tr>
<td>Human parvovirusd</td>
</tr>
<tr>
<td>Picornaviridae</td>
</tr>
<tr>
<td>Cardiovirus</td>
</tr>
<tr>
<td>Encephalomyocarditis virus</td>
</tr>
<tr>
<td>Hepatovirus</td>
</tr>
<tr>
<td>Hepatitis A virus&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Human Enterovirus</td>
</tr>
<tr>
<td>Coxsackievirus</td>
</tr>
<tr>
<td>Echovirus</td>
</tr>
<tr>
<td>Enterovirus</td>
</tr>
<tr>
<td>Poliovirus 1, 2 and 3 (see Appendix C)&lt;sup&gt;h&lt;/sup&gt;</td>
</tr>
<tr>
<td>Parechovirus</td>
</tr>
<tr>
<td>Rhinovirus</td>
</tr>
<tr>
<td>Polyomaviridae</td>
</tr>
<tr>
<td>Polyomavirus</td>
</tr>
<tr>
<td>JC polyomavirus</td>
</tr>
<tr>
<td>BK polyomavirus</td>
</tr>
<tr>
<td>Simian virus 40 (SV40)</td>
</tr>
<tr>
<td>Poxviridae</td>
</tr>
<tr>
<td>Chordopoxvirinae</td>
</tr>
<tr>
<td>Molluscipox</td>
</tr>
<tr>
<td>Molluscum contagious virus</td>
</tr>
<tr>
<td>Orthopox</td>
</tr>
<tr>
<td>Vaccinia&lt;sup&gt;c-f&lt;/sup&gt;</td>
</tr>
<tr>
<td>Cowpox</td>
</tr>
<tr>
<td>Parapox</td>
</tr>
<tr>
<td>Orf</td>
</tr>
</tbody>
</table>
### Table 3.4 (continued)

<table>
<thead>
<tr>
<th>Virus or prion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pseudocowpox (Milkers nodes virus)</td>
</tr>
<tr>
<td>Prions</td>
</tr>
<tr>
<td>Gertmann-Sträussler syndrome, Kuru and Creutzfeldt-Jakob agents (see Clauses 3.7 and 12.2.1)</td>
</tr>
<tr>
<td>Reoviridae</td>
</tr>
<tr>
<td>Orbivirus</td>
</tr>
<tr>
<td>Bluetongue viruses (endemic strains)</td>
</tr>
<tr>
<td>Epizootic haemorrhagic disease viruses of deer (endemic strains)</td>
</tr>
<tr>
<td>Rotavirus</td>
</tr>
<tr>
<td>Human Rotavirus</td>
</tr>
<tr>
<td>Orthoreoviruses</td>
</tr>
<tr>
<td>Reoviruses 1 to 3</td>
</tr>
<tr>
<td>Mammalian reoviruses 1 to 3</td>
</tr>
<tr>
<td>Retroviridae (serology, tests not involving propagation or culture)</td>
</tr>
<tr>
<td>Orthoretrovirinae</td>
</tr>
<tr>
<td>Deltavirus</td>
</tr>
<tr>
<td>Primate T-cell lymphotropic viruses type 1 and 2 (synonyms)</td>
</tr>
<tr>
<td>Human T-cell lymphotropic virus type 1 and 2</td>
</tr>
<tr>
<td>Lentivirinae</td>
</tr>
<tr>
<td>Human immunodeficiency virus types 1 and 2</td>
</tr>
<tr>
<td>Simian immunodeficiency virus</td>
</tr>
<tr>
<td>Togaviridae</td>
</tr>
<tr>
<td>Alphavirus</td>
</tr>
<tr>
<td>Barmah Forest</td>
</tr>
<tr>
<td>Ross River</td>
</tr>
<tr>
<td>Semliki Forest</td>
</tr>
<tr>
<td>Arterivirus</td>
</tr>
<tr>
<td>Equine viral arteritis</td>
</tr>
<tr>
<td>Rubivirus</td>
</tr>
<tr>
<td>Rubella&lt;sup&gt;c,d&lt;/sup&gt;</td>
</tr>
<tr>
<td>Unassigned</td>
</tr>
<tr>
<td>Deltavirus</td>
</tr>
<tr>
<td>Hepatitis delta virus</td>
</tr>
</tbody>
</table>

Footnotes to Table 3.4:

a. This list is not exhaustive.

b. Work with exotic organisms will require regulatory approval.

c. Vaccination available, see Clause 2.6.4.

d. May be teratogenic.

e. See also Table 3.7.

f. May be dangerous for pregnant women.

g. All manipulations to be undertaken in a BSC.
Immunization against poliovirus mandatory.

SSBA refer Note, Clause 2.

Table 3.5 — Examples\(^a\) of bacteria of risk group 3

<table>
<thead>
<tr>
<th>Organism</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacillus anthracis</em></td>
</tr>
<tr>
<td><em>Bartonella bacilliformis</em></td>
</tr>
<tr>
<td><em>Burkholderia mallei</em></td>
</tr>
<tr>
<td><em>Brucella</em> spp. [except serology (see Table 3.1) and <em>B. ovis</em>]</td>
</tr>
<tr>
<td><em>Chlamydia psittaci</em></td>
</tr>
<tr>
<td><em>Coxiella burnetii</em> (cultures, animal work and concentrates)(^c,d)</td>
</tr>
<tr>
<td><em>Francisella tularensis</em> (Type A)(^g)</td>
</tr>
<tr>
<td><em>Mycobacterium tuberculosis</em> complex(^d,e,f)</td>
</tr>
<tr>
<td><em>Rickettsia</em> spp.</td>
</tr>
<tr>
<td><em>Yersinia pestis</em></td>
</tr>
</tbody>
</table>

\(^a\) This list is not exhaustive.

\(^b\) Work with exotic organisms requires regulatory approval.

\(^c\) May be dangerous for pregnant women.

\(^d\) Vaccination, see Clause 2.6.4.

\(^e\) Respiratory protection should be considered.

\(^f\) Greater than 5000 cultures per year, susceptibility testing, known multi-drug resistant strains. See references in Clause 3.3.2.1.

\(^g\) SSBA refer Note 1, Clause 2.4.

Table 3.6 — Examples\(^a\) of fungi or fungal-like organisms of risk group 3\(^b\)

<table>
<thead>
<tr>
<th>Organism</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Blastomyces dermatitidis</em></td>
</tr>
<tr>
<td><em>Coccidioides immitis</em></td>
</tr>
<tr>
<td><em>Coccidioides posadasii</em></td>
</tr>
<tr>
<td><em>Histoplasma</em> spp.</td>
</tr>
<tr>
<td><em>Paracoccidioides brasiliensis</em></td>
</tr>
<tr>
<td><em>Penicillium marneffei</em> (syn <em>Talaromyces marneffei</em>)</td>
</tr>
</tbody>
</table>

\(^a\) This list is not exhaustive.

\(^b\) Work with exotic organisms requires regulatory approval.

\(^c\) May be dangerous for pregnant women.

NOTE The mycelial forms of these fungi produce highly infectious conidia. The use of plate cultures should be avoided.
### Table 3.7 — Examples\(^a\) of viruses of risk group 3\(^b\)

<table>
<thead>
<tr>
<th>Virus</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Arenaviridae</strong></td>
</tr>
<tr>
<td>Arenavirus</td>
</tr>
<tr>
<td>Lymphochoriomeningitis (LCM) neurotropic strains</td>
</tr>
<tr>
<td><strong>Bunyaviridae</strong></td>
</tr>
<tr>
<td>Group C</td>
</tr>
<tr>
<td>Oropouche</td>
</tr>
<tr>
<td>Phlebovirus</td>
</tr>
<tr>
<td>Rift Valley Fever virus (Zinga virus)</td>
</tr>
<tr>
<td>Hantavirus</td>
</tr>
<tr>
<td>Hantaan and related viruses(^c)</td>
</tr>
<tr>
<td><strong>Coronaviridae</strong></td>
</tr>
<tr>
<td>Betacoronavirus</td>
</tr>
<tr>
<td>SARS coronavirus (from cultures and concentrates)(^e)</td>
</tr>
<tr>
<td>MERS — related coronavirus (propagative in vitro activities)</td>
</tr>
<tr>
<td><strong>Flaviviridae</strong></td>
</tr>
<tr>
<td>Flavivirus</td>
</tr>
<tr>
<td>Japanese encephalitis(^d)</td>
</tr>
<tr>
<td>St Louis encephalitis</td>
</tr>
<tr>
<td>Tick-borne viruses</td>
</tr>
<tr>
<td>West Nile</td>
</tr>
<tr>
<td>Yellow fever(^d, e)</td>
</tr>
<tr>
<td><strong>Orthomyxoviridae</strong></td>
</tr>
<tr>
<td>Avian influenza (exotic pathogenic strains)(^d)</td>
</tr>
<tr>
<td>Influenza (highly pathogenic strains)(^d, e)</td>
</tr>
<tr>
<td><strong>Paramyxoviridae</strong></td>
</tr>
<tr>
<td>Paramyxovirinae</td>
</tr>
<tr>
<td>Rubulavirus</td>
</tr>
<tr>
<td>Mapuera</td>
</tr>
<tr>
<td>Avulavirus</td>
</tr>
<tr>
<td>Newcastle disease (exotic strains)</td>
</tr>
<tr>
<td><strong>Retroviridae (propagative in vitro activities)</strong></td>
</tr>
<tr>
<td>Orthoretrovirinae</td>
</tr>
<tr>
<td>Deltavirus</td>
</tr>
<tr>
<td>Primate T-cell lymphotropic viruses type 1 and 2 (synonyms Human lymphotropic virus type 1 and 2)</td>
</tr>
<tr>
<td>Lentivirus</td>
</tr>
<tr>
<td>Human immunodeficiency virus types 1 and 2</td>
</tr>
<tr>
<td>Simian immunodeficiency virus</td>
</tr>
</tbody>
</table>

\(^a\) This list is not exhaustive.

\(^b\) Work with exotic organisms will require regulatory approval.

\(^c\) While these agents are exotic in Australia and New Zealand, the import permit determines the level of containment required.

\(^d\) Vaccination available, see Clause 2.6.4.

\(^e\) SSBA refer Note 1, Clause 2.4.
### Table 3.7 (continued)

<table>
<thead>
<tr>
<th>Virus</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lyssavirus</td>
</tr>
<tr>
<td></td>
<td>Australian bat lyssavirus[^d]</td>
</tr>
<tr>
<td></td>
<td>Rabies fixed strain (CVS II)[^d]</td>
</tr>
<tr>
<td><strong>Togaviridae</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Alphavirus</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chikungunya</td>
</tr>
<tr>
<td></td>
<td>Eastern equine encephalitis</td>
</tr>
<tr>
<td></td>
<td>Western equine encephalitis</td>
</tr>
<tr>
<td></td>
<td>Venezuelan equine encephalitis[^d]</td>
</tr>
</tbody>
</table>

[^a]: This list is not exhaustive.
[^b]: Work with exotic organisms will require regulatory approval.
[^c]: While these agents are exotic in Australia and New Zealand, the import permit determines the level of containment required.
[^d]: Vaccination available, see Clause 2.6.4.
[^e]: SSBA refer Note 1, Clause 2.4.

---

### Table 3.8 — Examples[^a] of viruses of risk group 4[^b]

<table>
<thead>
<tr>
<th>Virus</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Arenaviridae</strong></td>
</tr>
<tr>
<td>Arenavirus</td>
</tr>
<tr>
<td>Guanarito</td>
</tr>
<tr>
<td>Junin</td>
</tr>
<tr>
<td>Lassa</td>
</tr>
<tr>
<td>Machupo</td>
</tr>
<tr>
<td>Mopeia viruses</td>
</tr>
<tr>
<td>Sabia</td>
</tr>
<tr>
<td><strong>Bunyaviridae</strong></td>
</tr>
<tr>
<td>Nairovirus</td>
</tr>
<tr>
<td>Crimean-Congo haemorrhagic fever</td>
</tr>
<tr>
<td>Hazara</td>
</tr>
<tr>
<td><strong>Filoviridae</strong></td>
</tr>
<tr>
<td>Ebola[^d]</td>
</tr>
<tr>
<td>Marburgd</td>
</tr>
<tr>
<td><strong>Flaviviridae</strong></td>
</tr>
<tr>
<td>Flavivirus</td>
</tr>
<tr>
<td>Kyasanur Forest disease</td>
</tr>
<tr>
<td>Omsk haemorrhagic fever disease</td>
</tr>
<tr>
<td>Tick-borne encephalitis</td>
</tr>
<tr>
<td><strong>Herpesviridae</strong></td>
</tr>
</tbody>
</table>

[^a]: This list is not exhaustive.
[^b]: Work with exotic organisms will require regulatory approval.
[^c]: Although only a few cases of infection with Hendra have occurred, the death rate has been high. It is considered appropriate to include this virus in Risk Group 4 from the limited information available.
[^d]: SSBA refer Note 1, Clause 2.4.
### Table 3.8 (continued)

<table>
<thead>
<tr>
<th>Virus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alphaherpesvirinae</td>
</tr>
<tr>
<td>Herpes virus simiae (B virus)</td>
</tr>
<tr>
<td>Paramyxovirinae</td>
</tr>
<tr>
<td>Henipavirus</td>
</tr>
<tr>
<td>Hendra</td>
</tr>
<tr>
<td>Nipah</td>
</tr>
</tbody>
</table>

*a This list is not exhaustive.
*b Work with exotic organisms will require regulatory approval.
*c Although only a few cases of infection with Hendra have occurred, the death rate has been high. It is considered appropriate to include this virus in Risk Group 4 from the limited information available.
*d SSBA refer Note 1, Clause 2.4.

### Table 3.9 — Examples of plant pathogens of plant risk group 2b,c

<table>
<thead>
<tr>
<th>Organism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onion smut (<em>Urocystis colchici</em>) — soilborne, under control</td>
</tr>
<tr>
<td>Citrus canker (<em>Xanthomonas axonopodis</em>) — exotic, splash-dispersed</td>
</tr>
<tr>
<td>Fire blight (<em>Erwinia amylovora</em>) — exotic, needs vector</td>
</tr>
<tr>
<td>Plum pox potyvirus — exotic, needs vector</td>
</tr>
<tr>
<td>Potato cyst nematode (<em>Globodera rostochiensis</em> and <em>G. pallida</em>) — soilborne, under control or exotic</td>
</tr>
<tr>
<td>Pierce’s disease (<em>Xylella fastidiosa</em>) — exotic, needs vector</td>
</tr>
<tr>
<td>Chestnut blight (<em>Cryptonectria parasitica</em>) — under eradication, splash-dispersed</td>
</tr>
<tr>
<td>Pine pitch canker (<em>Fusarium circinatum</em>) — exotic, splash-dispersed</td>
</tr>
<tr>
<td>Onion smut (<em>Urocystis colchici</em>) — soilborne, under control</td>
</tr>
</tbody>
</table>

*a This list is not exhaustive.
*b Work with exotic organisms requires regulatory approval.
*c Use of plant pathogens may also be subject to regulation by State and Territory or relevant Australian or New Zealand Federal authorities.

### Table 3.10 — Examples of plant pathogens of plant risk group 3b

<table>
<thead>
<tr>
<th>Organism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Karnal bunt (<em>Tilletia indica</em>) — exotic, wind borne</td>
</tr>
<tr>
<td>Grapevine rust (<em>Phakopsora euvitis</em>) — exotic, wind borne borne</td>
</tr>
<tr>
<td>Guava rust (<em>Puccinia psidii</em>) — wind borne</td>
</tr>
<tr>
<td>Sudden oak death (<em>Phytophthora ramorum</em>) — exotic, wind borne</td>
</tr>
<tr>
<td>Potato late blight (<em>Phytophthora infestans</em>) exotic strains — wind borne</td>
</tr>
<tr>
<td>Guava rust/eucalyptus rust/myrtle rust (<em>Austropuccinia psidii</em>) — required for States not already affected, and for exotic strains, wind borne</td>
</tr>
</tbody>
</table>

*a This list is not exhaustive.
*b Work with exotic organisms requires regulatory approval.
*c Use of plant pathogens may also be subject to regulation by State and Territory or relevant Australian or New Zealand Federal authorities.
### Table 3.11 — Examples\(^a\) of aquatic pathogens of risk group 2\(^a,b\)

<table>
<thead>
<tr>
<th>Virus</th>
<th>Family</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abalone herpesvirus</td>
<td>Malacoherpesviridae</td>
</tr>
<tr>
<td>Aphanomyces invadansinvidans</td>
<td>Leptolegniaceae</td>
</tr>
<tr>
<td><em>Aeromonas salmonicida</em> subsp. (excluding subsp. salmonicida)</td>
<td>Aeromonadaceae</td>
</tr>
<tr>
<td>Batrachochytrium dendrobatidis</td>
<td>Not assigned</td>
</tr>
<tr>
<td><em>Bonamia exitiosa</em></td>
<td>Haplosporidiidae</td>
</tr>
<tr>
<td><em>Bonamia</em> sp.</td>
<td>Haplosporidiidae</td>
</tr>
<tr>
<td><em>Edwardsiella ictaluri</em></td>
<td>Enterobacteriaceae</td>
</tr>
<tr>
<td>Epizootic haematopoietic necrosis virus</td>
<td>Iridoviridae</td>
</tr>
<tr>
<td>Gill-associated virus</td>
<td>Roniviridae</td>
</tr>
<tr>
<td>Infectious hypodermal and haematopoietic necrosis virus</td>
<td>Paroviridae</td>
</tr>
<tr>
<td><em>Macrobrachium rosenbergii</em> nodavirus</td>
<td>Nodaviridae</td>
</tr>
<tr>
<td>Marteilia sydneyi</td>
<td>Marteiliidae</td>
</tr>
<tr>
<td>Nervous necrosis virus</td>
<td>Nodaviridae</td>
</tr>
<tr>
<td>Ostreid herpesvirus-1 including (\mu)Var</td>
<td>Malacoherpesviridae</td>
</tr>
<tr>
<td><em>Perkinsus olseni</em></td>
<td>Perkinsidae</td>
</tr>
<tr>
<td>Ranavirus</td>
<td>Iridoviridae</td>
</tr>
<tr>
<td>Abalone herpesvirus</td>
<td>Malacoherpesviridae</td>
</tr>
</tbody>
</table>

\(^a\) This list is not exhaustive.  
\(^b\) Use of aquatic pathogens may also be subject to regulation by State and Territory or relevant Australian or New Zealand Federal authorities.

### Table 3.12 — Examples\(^a\) of aquatic pathogens of risk group 3

<table>
<thead>
<tr>
<th>Organism</th>
<th>Family</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Aeromonas salmonicida</em> subsp. salmonicida</td>
<td>Aeromonadaceae</td>
</tr>
<tr>
<td><em>Aphanomyces astaci</em></td>
<td>Leptolegniaceae</td>
</tr>
<tr>
<td><em>Bonamia ostreae</em></td>
<td>Haplosporidiidae</td>
</tr>
<tr>
<td><em>Candidatus Hepatobacter penaei</em></td>
<td>Rhizobiaceae</td>
</tr>
<tr>
<td>Channel catfish virus</td>
<td>Alloherpesviridae</td>
</tr>
<tr>
<td>European catfish virus/ European sheatfish virus</td>
<td>Iridoviridae</td>
</tr>
<tr>
<td>Grouper iridovirus</td>
<td>Iridoviridae</td>
</tr>
<tr>
<td>Gyrodactylus salaris</td>
<td>Gyrodactylidae</td>
</tr>
<tr>
<td>Infectious haematopoietic necrosis virus</td>
<td>Rhabdoviridae</td>
</tr>
</tbody>
</table>

\(^a\) This list is not exhaustive.  
\(^b\) Use of aquatic pathogens may also be subject to regulation by State and Territory or Federal authorities.  
\(^c\) For diagnostic purposes, excluding culture of pathogens, organisms categorized as Risk Group 3 may be handled in containment level 2 facilities with permission from the relevant regulator.  
\(^d\) A number of examples of megalocytiviruses are listed on Page 7–8 of Biosecurity Australia (2010) “Importation of freshwater ornamental fish: review of biosecurity risks associated with gourami iridovirus and related viruses – Provisional final import risk analysis report”, Department of Agriculture, Canberra, Australia. At least one of the viruses listed in this publication have already been detected in Australia in aquaculture and others are recorded in imported ornamental fish. Before work commences with such viruses, advice should be sought from relevant State, Territory or Federal agencies, or in New Zealand, from relevant authorities (see Bibliography, Reference 1.40 and 1.41).  
\(^e\) AHPND is a newly emerging disease of farmed prawns in Asia — information on this disease is changing on a regular basis.
<table>
<thead>
<tr>
<th>Organism</th>
<th>Family</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious myonecrosis virus</td>
<td>Totiviridae</td>
</tr>
<tr>
<td>Infectious pancreatic necrosis virus</td>
<td>Birmnaviridae</td>
</tr>
<tr>
<td>Infectious salmon anaemia virus</td>
<td>Orthomyxoviridae</td>
</tr>
<tr>
<td>Koi herpesvirus</td>
<td>Alloherpesviridae</td>
</tr>
<tr>
<td>Laem-Singh virus</td>
<td>Not assigned</td>
</tr>
<tr>
<td>Marteilia refringens</td>
<td>Marteiliidae</td>
</tr>
<tr>
<td>Marteilioides chungmuensis</td>
<td>Marteiliidae</td>
</tr>
<tr>
<td>Mikrocytos mackini</td>
<td>Mikrocytidae</td>
</tr>
<tr>
<td>Myxobolus cerebralis</td>
<td>Myxobolidae</td>
</tr>
<tr>
<td>Perkinsus marinus</td>
<td>Perkinsidae</td>
</tr>
<tr>
<td>Piscirickettsia salmonis</td>
<td>Piscirickettsiaceae</td>
</tr>
<tr>
<td>Red sea bream iridovirus</td>
<td>Iridoviridae</td>
</tr>
<tr>
<td>Renibacterium salmoninarum</td>
<td>Micrococcaceae</td>
</tr>
<tr>
<td>Salmonid alphavirus</td>
<td>Togaviridae</td>
</tr>
<tr>
<td>Spring viraemia of carp virus</td>
<td>Rhadoviridae</td>
</tr>
<tr>
<td>Taura syndrome virus</td>
<td>Dicistroviridae</td>
</tr>
<tr>
<td>Vibrio parahaemolyticus (VPAMHND)</td>
<td>Vibrionaceae</td>
</tr>
<tr>
<td>Viral haemorrhagic septicaemia virus</td>
<td>Rhadoviridae</td>
</tr>
<tr>
<td>Xenohaliotis Californiens</td>
<td>Anaplasmataceae</td>
</tr>
<tr>
<td>Yellow head virus</td>
<td>Roniviridae</td>
</tr>
<tr>
<td>Yersinia ruckeri — Hagerman strain</td>
<td>Enterobacteriaceae</td>
</tr>
</tbody>
</table>

a This list is not exhaustive.
b Use of aquatic pathogens may also be subject to regulation by State and Territory or Federal authorities.
c For diagnostic purposes, excluding culture of pathogens, organisms categorized as Risk Group 3 may be handled in containment level 2 facilities with permission from the relevant regulator.
d A number of examples of megalocytiviruses are listed on Page 7 – 8 of Biosecurity Australia (2010) "Importation of freshwater ornamental fish: review of biosecurity risks associated with gourami iridovirus and related viruses – Provisional final import risk analysis report", Department of Agriculture, Canberra, Australia. At least one of the viruses listed in this publication have already been detected in Australia in aquaculture and others are recorded in imported ornamental fish. Before work commences with such viruses, advice should be sought from relevant State, Territory or Federal agencies, or in New Zealand, from relevant authorities see Bibliography, Reference 1.40 and 1.41).
e AHPND is a newly emerging disease of farmed prawns in Asia — information on this disease is changing on a regular basis.

### Section 4 Principles of containment

#### 4.1 General

Containment of microorganisms involves a combination of buildings, engineering function, equipment, and worker practices to handle microorganisms safely. Physical containment is the term used to describe procedures and structures designed to reduce or prevent the release of viable organisms into the outside environment. Four PC levels, PC1 to PC4, are assigned for work with microorganisms.

Viable microorganisms and terrestrial animals, plants, invertebrates, or aquatic organisms inoculated with microorganisms from defined risk groups shall be used, stored or housed in corresponding or higher level containment facilities.
Some facilities may be required to house animals, plants, invertebrates and aquatic species and also may be used simultaneously to carry out microbiological work. These facilities shall be constructed to meet the recommendations of multiple sections of this Standard.

4.2 Containment measures

4.2.1 General

The three general measures by which microbiological containment is achieved are known as primary, secondary and tertiary containment measures. Optimal microbiological containment is provided by the “box-within-a-box” principle (see Figure 4.4), where the highest hazards are enclosed by multiple containment measures.

4.2.2 Primary containment measures

Primary containment measures are the constraints immediately surrounding the source of infectious material, such as a BSC, a ventilated animal enclosure, a sealed animal room with appropriate air pressure controls, or the leak-proof container forming the inner receptacle of an approved IATA infectious materials transport container.

4.2.3 Secondary containment measures

Secondary containment measures include the design of a laboratory or device that encloses the primary containment. Facility design and engineering operations providing laboratories with air pressure control and directional air flow (supplemented by HEPA filtration of exhaust air) are examples of secondary containment measures. Another example is the secondary receptacle of an approved IATA transport container. In the laboratory or animal room, secondary PC measures are invariably supplemented by defined work practices, including PPE use.

4.2.4 Tertiary containment measures

Tertiary containment measures provide protection of the wider environment by supporting the secondary containment, e.g. using the outer packaging of an approved IATA transport container, an isolated building complex, control of people movements, and provision of support services such as decontamination and laundering of clothing and disposal of infectious wastes.

4.3 Physical containment classifications

4.3.1 General

The hazard and risk posed by different microorganisms varies greatly and this is reflected by the organization of microorganisms into the risk groups described in Section 3. The PC level used when working with microorganisms shall be at least the appropriate level for the risk group of the microorganism, i.e. PC Level 1 for Risk Group 1, PC Level 2 for Risk Group 2, etc. Unless otherwise stated, Risk Group 1 to Risk Group 4 mean human and terrestrial animal, plant, invertebrate and aquatic organism Risk Group 1 to Risk Group 4 and PC1 to PC4 mean laboratory, terrestrial animal, plant, invertebrate and aquatic organism PC1 to PC4.

NOTE All work done in a laboratory or facility of a specific level shall follow procedures prescribed for that level of physical containment.

Section 5 details the appropriate requirements and recommendations for four PC levels of laboratories corresponding to Risk Groups 1 to 4 defined in Clause 3.2 and include the laboratory structural requirements and facilities, PPE, safety equipment, practices, techniques and health monitoring procedures.

Sections 6, 7, 8, and 9 contain the corresponding requirements for terrestrial animal, plant, invertebrate, and aquatic organism containment facilities. The corresponding classifications for terrestrial animal,
plant, invertebrate and aquatic organism containment facilities have “Terrestrial Animal”, “Plant”, “Invertebrate” or “Aquatic Organism” preceding “PC” as appropriate.

4.3.2 Physical containment level 1 (PC1)

A PC1 laboratory or facility is suitable for work with microorganisms where the hazard levels are low, and where laboratory or facility personnel can be adequately protected by standard laboratory practice. This level of laboratory or facility with its practices and equipment is usually suitable for student and undergraduate teaching laboratories. The organisms used should generally be classified as Risk Group 1. Specimens that have been inactivated or fixed may be handled in PC1 facilities.

4.3.3 Physical containment level 2 (PC2)

This level of laboratory or facility with its practices and equipment is applicable to research, diagnostic and other premises where work is carried out with microorganisms or material likely to contain microorganisms that are classified as Risk Group 2 microorganisms. If working with specimens containing microorganisms transmissible by the respiratory route or if the work produces a significant risk to humans or the environment from the production of infectious aerosols, a BSC shall be used.

4.3.4 Physical containment level 3 (PC3)

This level of laboratory or facility with its practices and equipment is applicable to research, diagnostic and other premises where work is carried out with microorganisms or material likely to contain microorganisms that are classified as Risk Group 3 microorganisms.

A PC3 laboratory or facility provides additional building features and services to minimize the risk of infection to individuals, the community and the environment.

4.3.5 Physical containment level 4 (PC4)

This level of laboratory or facility with its practices and equipment is applicable to work with microorganisms classified as Risk Group 4 microorganisms.

A PC4 laboratory or facility is situated in a building separate from other laboratories or facilities or constructed as an isolated area within a building. The facility is maintained under negative pressure and includes secondary barriers such as sealable openings, airlocks or liquid disinfection barriers, a clothing-change and shower room contiguous to the laboratory or facility ventilation system, and exhaust air and liquid waste decontamination systems to prevent the escape of microorganisms to the environment.

A PC4 laboratory or facility may be of two types; one where work is conducted in a Class III BSC exhausting outside the facility or one where the work is conducted without being isolated in such a manner and staff wear fully encapsulated positive pressure suits.

4.4 Location

The design of the facility shall take into account the potential impact of severe environmental and climatic events (such as seismic events, flooding, snow, wind storms, fire, cyclones and hail storms) that are likely to occur in the area in which it is located so that the risk of damage to the containment barrier is minimized.
Section 5 Laboratory containment facilities

5.1 Laboratory physical containment

The PC level used when working with microorganisms in laboratories shall be at least the appropriate level for the risk group of the microorganism, as set out in Section 4. Requirements for laboratory PC1, PC2, PC3 and PC4 containment facilities are set out in Clauses 5.2, 5.3, 5.4 and 5.5 respectively.

All work done in a laboratory of a specific level shall follow procedures prescribed for that level of PC.

5.2 Requirements for PC1 laboratories

5.2.1 General

A Laboratory PC1 facility, in which laboratory personnel can be adequately protected by standard laboratory practice and no containment equipment is required, is suitable for work with microorganisms in Risk Group 1. Specimens that have been inactivated or fixed may be handled in a PC1 laboratory.

This level of facility with its practices and equipment is appropriate for student and undergraduate teaching laboratories. Work may be carried out on the open bench.

A sign complying with Appendix D showing the level of containment, together with hazard symbols as appropriate and any access restrictions, should be prominently displayed at the entrance.
5.2.2 Construction

Laboratory facilities shall be constructed in accordance with AS/NZS 2982 and the following requirements to facilitate microbiological safety and reduce the likelihood of microorganisms escaping from containment:

(a) The floors of the laboratory, doors, and any window furnishings shall be smooth, easy to clean, impermeable to liquids, and resistant to commonly used reagents and disinfectants.

(b) Where window furnishings exist in the laboratory, they shall not be located next to major sources of heat or potential fire hazards such as hot plates or Bunsen burners.

(c) Bench tops shall be able to withstand heat generated by general laboratory procedures, e.g. flaming loops and heating of media.

(d) Open spaces between and under benches, cabinets and equipment shall be accessible for cleaning to prevent build-up of material providing refuge for invertebrates and microorganisms.

(e) Facilities shall be designed to prevent infestation by vermin.

(f) Furniture shall be ergonomically suitable and appropriate for the specific purpose of the laboratory, the safety of laboratory users and the manipulation of microorganisms in containment. This shall include adjustable height stools and the use of smooth impervious seat coverings to facilitate cleaning.

(g) Dedicated hand basins or an alternative means of decontaminating the hands shall be provided inside each laboratory, in a position on the pathway towards the exit which supports appropriate use of the hand basins as part of the recommended exit procedure.

(h) Backflow prevention for water supplies shall comply with Appendix E.

(i) Gas supplies in the facility shall comply with the general requirements specified in Clause D3.1.

(j) Eyewash facilities in accordance with AS/NZS 2982 shall be provided.

(k) Storage for PPE shall be provided.

(l) Facilities outside the laboratory shall be provided for storing outer garments and personal items.

5.2.3 Work practices

Laboratory personnel shall observe the work practices in AS/NZS 2243.1 as well as the following (see also Clause 2.1.6):

(a) Access to the laboratory shall be limited to authorized personnel.

(b) Food and drink provide a means of microbial contamination and items for personal consumption shall not be brought into the laboratory or stored in laboratory refrigerators. Eating, drinking, smoking, shaving and the application of cosmetics shall be prohibited in laboratories.

   NOTE 1 This includes offices within the containment facility boundary.

   NOTE 2 The chewing of gum is also prohibited.

(c) PPE worn and used in the laboratory shall comply with the requirements in AS/NZS 2243.1.

The minimum PPE worn and used in the laboratory shall be protective clothing to afford protection to the front part of the body, and closed shoes, i.e. footwear that covers the toes, upper foot and heels, unless lesser requirements can be justified by a risk assessment. Protective eyewear shall be worn if a risk assessment of the task requires it. See also Clause 11.2 for detailed information on PPE.

NOTE A rear-fastening gown is preferable PPE for the front part of the body.
(d) Minimize the production of aerosols, particularly where work is carried out on the open bench (see also Clause 3.1).

(e) Minimize the dissemination of microbiological material while flaming a wire loop, by drawing the loop gradually from the cooler to the hotter parts of the Bunsen burner flame, or by using a hooded or an electric Bunsen burner.

NOTE Disposable loops may be used as an alternative.

(f) Clearly identify and date cultures. Minimize the time for which cultures are kept on the bench. Transfer them to a dedicated storage area, such as a refrigerator or part of a cold room.

(g) Do not mouth pipette. Blowing out residual volumes from pipettes creates aerosols; do not use pipettes that require forced expulsion to deliver the nominal volume.

(h) Diagnostic kits, control sera and products manufactured from microbiological sources shall be handled with care as infectious microorganisms may be still present.

(i) Because airborne fungal spores can spread in a similar manner to aerosols, cover or seal cultures of spore-producing fungi as appropriate to prevent dispersal.

(j) Ensure chemicals are stored in the laboratory in accordance with AS/NZS 2243.10.

(k) Always use local exhaust ventilation or a fume cupboard when determined appropriate by a risk assessment of any work with toxic, volatile, corrosive or odoriferous substances.

NOTE 1 BSCs are not designed for this purpose (see Clause 11.1).

NOTE 2 AS/NZS 2982 should be consulted for local exhaust ventilation requirements.

(l) Items such as door handles, fridges, telephones, keyboards, reading and writing materials shall be regularly decontaminated.

(m) Decontaminate work benches at least daily and after all work involving microorganisms.

(n) Staff shall be trained in the cleaning up of microbiological spills. Spills shall be contained, any affected personnel attended to and the area cleaned up and decontaminated with appropriate disinfectant (see Section 10).

(o) Segregate wastes (e.g. broken glassware, biological and radioactive substances) and dispose of according to applicable regulations, using the most appropriate and effective method for the materials concerned (see also Section 13).

(p) Remove laboratory gowns and decontaminate hands before moving to areas outside laboratories. Where personnel are moving directly to another laboratory that is not separated via public thoroughfare, they may continue to wear their laboratory gown, provided it is clean and free from contaminants.

(q) Mobile phones and other electronic devices with earphones, e.g. MP3 players and i-Pods, and wireless headsets shall not be used at the laboratory bench as they may become contaminated with organisms and laboratory reagents.

NOTE Where contamination occurs or is suspected, decontamination must take place prior to removal of the device from the laboratory.

5.3 Requirements for PC2 laboratories

5.3.1 General

A Laboratory PC2 facility is suitable for work with microorganisms in Risk Group 2 and incorporates all the requirements of a Laboratory PC1 facility with additional requirements relating to conditions of access, safety equipment and staff training requirements. With good microbiological techniques,
work with these microorganisms may be carried out on the open bench. If working with specimens containing microorganisms transmissible by the respiratory route or if the work produces a significant risk from the production of infectious aerosols, a BSC shall be used.

5.3.2 Multiple room PC2 facilities

Institutions with large areas such as entire floors, multiple floors or multiple buildings designated as PC2 areas shall ensure that safety is maintained for both laboratory workers and non-laboratory persons. There is a need to restrict access to the PC2 areas, including via lifts and stairs, preventing the use of laboratories as thoroughfares and ensuring that eating and drinking is prohibited in the entire PC2 area.

Where lifts operate through multiple PC2 levels, the lift itself shall not be classified as PC2 as it may be used by non-laboratory persons. The lift shaft and lift motor areas are required to be accessed by lift technicians and cannot be readily decontaminated. Where it is required to use the lift to transport potentially infectious or infectious materials from one floor to another, e.g. to a pressure steam sterilizer on another floor, the potentially infectious or infectious materials shall be either double-bagged or placed in a secondary sealable, unbreakable container for the transport. Where the potentially infectious or infectious materials are double bagged, the outer bag should be sealed during transport.

Potentially contaminated laboratory gowns and gloves shall not be worn in lifts.

Inward air flow to the PC2 areas from lifts and lift shafts shall be maintained. This requires attention to cater for the pressure fluctuations and air movements caused by movement of the lift car in the shaft (“piston effect”).

Where lift equipment is accessed via PC2 areas, care shall be taken to ensure that lift maintenance personnel are able to perform their work without compromising safety or containment.

Stairs that connect only to PC2 areas may be classified as PC2 spaces provided that they satisfy the PC2 construction requirements. Users shall be made aware that wearing potentially contaminated laboratory gowns and gloves on stairs can be a source of cross-contamination. Potentially infectious or infectious materials shall be double-bagged or placed in a secondary sealable, unbreakable container for transport. Where the potentially infectious or infectious materials are double bagged, the outer bag should be sealed during transport.

Where large areas are classified as PC2 and include associated write-up areas, the prohibition of eating and drinking applies in these associated areas [see also Clause 5.2.3(b)].

5.3.3 Construction

In addition to the construction requirements specified for PC1 laboratories in Clause 5.2.2, the following shall apply:

(a) In addition to floors, the walls, benches, and joinery within the laboratory shall be smooth, easy to clean, impermeable to liquids, and resistant to commonly used reagents and disinfectants. Floors shall be coved to walls and exposed plinths to facilitate cleaning. Benches shall be finished with a material that is impermeable to liquids, have any joints sealed, and be sealed to end walls and sinks where there is a wet area.

NOTE 1 Where ceilings have a textured finish, these should be easily cleanable.

NOTE 2 Non-particle-shedding acoustic tiles may be used for the ceiling, provided contaminants are not readily absorbed and can be removed easily by cleaning or washing.

NOTE 3 The use of the ceiling space as an unducted air path should be considered with caution. This can give rise to long term build-up of settled laboratory dusts in the ceiling space, which can be disturbed if tiles are removed.
(b) Structural joints, where required, shall be durable, impermeable, easy to clean and shall resist
deterioration due to commonly used cleaning agents, common disinfectants, and where applicable,
exposure to ultraviolet radiation.

NOTE Structural joints should be minimized in containment laboratories.

(c) Internal fittings and fixtures, such as lights, air ducts, pipes and conduits shall be selected and
fitted to enable cleaning of any surfaces.

(d) Windows in the laboratory shall be closed and sealed.

(e) Containers in accordance with Section 13 shall be provided for collection, storage or disposal of
potentially infectious or infectious materials.

(f) A pressure steam sterilizer shall be available where steam sterilizing of laboratory wastes is
required [see Clause 5.3.6(j), Clause 11.6 and Section 13].

NOTE The pressure steam sterilizer should be as close to the laboratory as possible.

(g) A single-outlet, hands-free operation type dedicated hand basin or alternative means of
decomcontaminating hands shall be provided inside each laboratory, in a position on the pathway
towards the exit which supports appropriate use of the hand basin as part of the recommended
exit procedure.

NOTE Exits which are only intended for emergency egress purposes are excluded.

(h) Storage space, e.g. shelving, within the laboratory, separate from the work bench, shall be provided
for reference documents and papers other than worksheets which may be used on the bench.

(i) Separate report writing and long-term write up areas, e.g. offices, shall not be provided within the
PC2 facility boundary.

(j) Hooks or storage facilities for laboratory gowns that prevent cross-contamination shall be
provided within the laboratory, in a position on the pathway towards the exit which supports
appropriate use of the hooks or storage facilities as part of the recommended exit procedure.

NOTE 1 Gowns should be hung or stored individually to prevent cross-contamination or contamination of
the inside of gowns.

NOTE 2 Gowns should not be stored on laboratory work benches or chairs.

(k) Gas supplies in the facility shall comply with the backflow prevention requirements specified in
Clause D3.2.

(l) Where plant growth cabinets are used in conjunction with microbiological work, all openings to
the cabinets shall be provided with screens in accordance with Clause 7.3.3(f) or all openings to
the laboratory shall be provided with screens in accordance with Clause 7.3.3(f).

NOTE Implementation of the second option will generally preclude the use of tiled ceilings for such
laboratories.

(m) A sign complying with Appendix D showing the biological hazard symbol and the level of
containment, together with hazard symbols as appropriate and any access restrictions, shall be
prominently displayed at each entrance to each individual laboratory.

(n) When situated outside the laboratory, freezers, refrigerators or other storage units used for
holding microorganisms shall be posted with the biological hazard symbol (see Figure D.1 of
Appendix D).

NOTE Where freezers or refrigerators are used by multiple personnel, it is recommended that the names
and telephone numbers of the users are displayed on the front of the unit.
5.3.4 Ventilation

An inward flow of air shall be maintained by forced extraction of laboratory air to minimize the spread of aerosols in the event of an inadvertent spill. Recirculation is permitted but not into areas outside the PC2 facility.

Recirculated air shall be filtered to remove airborne particulates. Where long term build-up of particulate material can be hazardous to personnel, filtration should occur before air leaves the laboratory, i.e. at or below ceiling level.

Ventilation system components such as filters and filter plenums can accumulate particulates. Any special precautions that are required for maintenance personnel should be noted at points of access to this equipment.

NOTE 1 Refer to AS 1668.2 for general filtration requirements and for locations of supply intakes and exhaust discharges outside buildings to ensure adequate ventilation air quality.

Ventilation air shall not be directed towards doors or located in positions that can disturb air flow at BSCs.

NOTE 2 If it is intended to reduce ventilation rates during unoccupied periods, there is the potential for airborne contamination build-up to pose a hazard when occupancy is resumed. A risk assessment is recommended to ensure that continuously operating equipment can be managed safely such that breathing air quality is not adversely affected. This should include considerations such as incubators, water baths, shakers, rollers, centrifuges, warm rooms, freezers and other equipment which have the potential to release contaminants or heat into the air.

5.3.5 Containment equipment

5.3.5.1 Biological safety cabinets

A Class I or Class II BSC (see Clause 11.7) shall be provided if there is a potential for personnel to become infected by aerosol generation.

NOTE 1 Refer to Figures 1 and 2 of Clause 5 of AS 2252.4 for guidance on installation and location of BSCs.

NOTE 2 See Appendix H for information and recommendations concerning safe use of the BSC.

NOTE 3 Refer to Clause ZZ14 of AS 2252.4 for information related to decontamination of the BSC.

NOTE 4 Class II BSCs shall be tested in situ with features, (e.g. supply ventilation), operating at the most significant potential disruptive effect.

Where requirements in AS 2252.4 conflict with requirements in this Standard, the requirements in this Standard shall take precedence.

5.3.5.2 Cytotoxic drug safety cabinets

A laminar flow CDSC (see also Clause 11.9) shall be provided if work involving prions is intended.

Installation and use, including the decontamination of the safety cabinet, shall be performed in accordance with the requirements of AS 2252.5.

5.3.5.3 Centrifuges

When potentially infections or infectious materials are used, a centrifuge fitted with either sealed rotors or sealed buckets shall be used (see also Clause 10.3).
5.3.6 Work practices

In addition to the work practices specified for PC1 (see Clause 5.2.3) laboratories, the following shall apply:

(a) Instruction and training in handling infectious microorganisms shall be provided to laboratory personnel with regular updates, e.g. annually or when new information is obtained (see also Clause 2.1.5).

(b) All clinical and diagnostic specimens shall be regarded as potentially hazardous. Leaking containers shall be handled in a BSC and the outside of the container decontaminated, see Table E.1. Where a replacement sample is readily obtained, the leaking specimen shall be decontaminated and discarded in accordance with Section 13.

(c) The use of sharps such as syringes, needles and scalpels shall be minimized, as sharps injuries constitute a large portion of laboratory accidents (see also Bibliography, Reference 1.6). Needles and syringes or other sharp instruments shall be restricted in the laboratory for use only when there is no alternative. Sharps shall be disposed of in sharps containers, see AS 4031. Before disposal, needles shall not be removed, bent, sheared, or replaced in a sheath or guard, unless the recapping/removal procedure can be carried out by a safe method with suitable equipment.

NOTE 1 Laboratory users should be aware of the potential for glass equipment such as pipettes and tissue grinders to become sharps during an accident. Plastic ware should be substituted for glassware whenever possible.

NOTE 2 Where infectious material is being injected under high pressure, Luer-lock fittings, or equivalent, should be used.

(d) For manipulations of Risk Group 2 microorganisms transmissible by the respiratory route or work producing a significant risk from aerosol production, a BSC or other equipment designed to contain the aerosol shall be used. A period of at least 5 min shall be allowed for aerosols to settle before opening homogenizer or sonicator containers in a BSC.

NOTE Large items of equipment can interfere with the airflow pattern in a Class II BSC and correct operation of the cabinet should be validated with the equipment in situ (see Clause 10.3.1).

(e) When working with infectious or potentially infectious prions, a BSC shall be used (see also Clause 3.7 and Clause 11.8).

(f) Bacterial cultures shall not be actively sniffed for odours.

NOTE This has been a common cause of laboratory acquired infections.

(g) Seal cultures of spore-producing fungi as appropriate to prevent dispersal.

(h) Any container of viable microorganisms, including any waste that may contain potentially infectious organisms, shall be transported outside the laboratory within a second unbreakable and closed container, which shall first be decontaminated on all outer surfaces. See Clause 13.1 for further information on identification and management of contaminated material and waste.

(i) Potentially contaminated re-usable laboratory ware shall be collected and disinfected or decontaminated in accordance with Section 13 prior to washing and re-use. For chemical disinfection, pipettes shall be placed vertically in an appropriate disinfectant solution, tip-first and fully immersed, to minimize the production of aerosols. If pipettes are to be thermally decontaminated in a steam sterilizer, they shall be fully immersed, vertically in a fluid, such as a detergent.

NOTE Thermal decontamination of pipettes that are not fully immersed in a liquid, i.e. are empty, can only be achieved in a pre-vacuum steam sterilizer.

(j) Microbiological waste shall be disposed of in accordance with Clause 13.2.

(k) The protective equipment specified in Clause 5.2.3(c) shall be used (see also Clause 11.2).
Reusable non-contaminated PPE shall be retained in the facility between uses, and kept segregated from unused PPE.

Appropriate eye protection (see Clause 11.2.4) shall be used to protect eyes from contaminated or hazardous materials or from ultraviolet light.

Gloves shall be worn when working in a BSC, when handling human blood and body fluids, and when conducting procedures with liquids that contain or potentially contain human Risk Group 2 microorganisms. These present a risk of spills or splashes that could otherwise result in direct skin contact.

PPE shall be removed and hands decontaminated in a predetermined appropriate order, before leaving the laboratory.

NOTE 1 The order is usually removal of gloves followed by hand decontamination, then eye protection and laboratory gown followed by a second hand decontamination.

NOTE 2 Appropriate protocols for laundering or decontaminating PPE should be implemented.

Laboratory staff shall advise maintenance and service personnel of the special microbiological hazards in the laboratory. All potentially contaminated equipment and adjacent surfaces shall be decontaminated prior to maintenance or removal from the area.

NOTE Appendix F provides information on disinfectants.

A control program against pest insects, birds and animals shall be instituted.

Where there is a floor drain installed within the laboratory, a standard operating procedure shall be prepared to manage microbiological contamination of the floor drain.

5.4 Requirements for PC3 laboratories

5.4.1 General

A Laboratory PC3 facility is suitable for work with infectious microorganisms in Risk Group 3 and incorporates all equipment and practices for PC1 (see Clause 5.2) and PC2 (see Clause 5.3) laboratories; however, additional conditions of access, safety equipment and staff training apply.

NOTE The design of a PC3 facility is complex and those planning its construction should seek specialized advice. See also Appendix G (Figures G.1 to G.5) for examples of recommended layouts for PC3 facilities showing the design principles involved and Appendix H for airtightness considerations.

5.4.2 Construction

In addition to the construction requirements specified for PC1 (see Clause 5.2.2) and PC2 (see Clause 5.3.3) laboratories, the following shall apply:

(a) The facility shall be physically separated from other areas, including offices used by laboratory personnel, and not accessible by the general public. This separation shall be achieved by a double-door system where entry to the facility is gained only through an airlock or shower airlock. For an airlock, the doors shall open outwards and the outer door shall be lockable. For a shower airlock, the outer door of the shower airlock shall open outward. Either the door to the outer change room or the outer door of the shower airlock shall be lockable. The outer shower door shall form the limit of PC3 containment for decontamination purposes. Airlock and shower airlock doors shall be self-closing and fitted with seals to limit air leakage.

NOTE 1 Where separate laboratories are contained within a PC3 facility, consideration should be given during the design of the air handling system to the use of a common system or the need for individual air exhaust systems, HEPA filters and duct isolation valves to facilitate gaseous decontamination of all or part of the facility.
NOTE 2  The airlock is provided to ensure the maintenance of the negative pressure within the PC3 facility and prevent airflow between the PC3 facility and areas external to the facility. It should not be used for any work, nor should it contain any equipment, washing facilities (apart from the shower where it is used as a shower airlock) or PPE which has been worn in the facility.

NOTE 3  Gaseous decontamination chambers and dunk tanks should be considered for facilities that require removal of equipment that cannot be steam sterilized. Decontamination chambers can reduce the need to decontaminate multi-room PC3 facilities.

NOTE 4  Decontamination chambers can also be used to support the entry of materials into a facility and the provision of a pass-through port can support entry of smaller materials. This needs to be included for animal, plant, invertebrate and aquatic, suitably adjusted.

NOTE 5  Depending on size, removable panels to allow for entry and exit of large items of equipment should be considered. These should be readily resealable to an airtight condition following use.

NOTE 6  Building regulations may require alternative egress in certain facility configurations. These exits are required to be accessible and easily usable without compromising facility seal integrity. Lockable doors need to permit emergency egress in accordance with building regulations.

(b) Means shall be provided for minimizing disturbance of pressure differentials by reducing the likelihood of both airlock doors being opened at the same time.

NOTE  Examples of suitable mechanisms include entry and egress “traffic light” alarm systems, door interlock control systems or viewing panels if suitable.

(c) Means shall be provided to prevent powered air lock doors from opening simultaneously in the event of power loss or emergency. Manual overrides may be used to address emergency egress requirements.

(d) The allocation of task zones and layout within the facility shall promote the movement of ventilation air from the entrance and towards the more contaminated zones such as BSCs and steam sterilizer loading trolleys.

Care shall be taken to avoid turbulence or ventilation system air movement within the vicinity of BSCs that could interfere with the stability of the work face air flow pattern.

(e) Equipment that requires direct contact with potentially contaminated material shall be located to minimize the risk of escape of organisms, taking into account the requirement to access components requiring service and maintenance.

NOTE 1  Wherever possible, valves control and supporting equipment (such as ventilation equipment, heating and cooling equipment) should be located outside the laboratory to minimize the need for service personnel to enter the laboratory.

NOTE 2  The provision of a gaseous decontamination chamber should be considered where it is necessary to remove items that cannot be steam sterilized.

(f) The facility shall have a high level of physical security including control of access (e.g. electronic access card) and shall not open onto a public thoroughfare.

(g) Doors, apart from those to areas used for showering and changing, shall contain viewing panels to minimize entry and exit incidents.

(h) Adequate arrangements for observation of laboratory occupants shall be provided.

NOTE  Examples of suitable arrangements are the viewing panels in doors specified in Item (g) provided they allow adequate viewing of laboratory occupants; viewing panels in walls; or electronic visual monitoring facilities (e.g. viewing cameras or closed circuit television).

(i) A pressure steam sterilizer for decontamination of laboratory wastes shall be provided in the facility. The pressure steam sterilizer shall not be located in the airlock.
NOTE 1 A double-ended type is preferred, positioned through the barrier wall of the facility and allowing adequate access for loading and unloading of the steam sterilizer and for maintenance of the associated plant from outside the facility.

NOTE 2 See also Clause 11.6.8.

(j) Provision shall be made for decontamination of liquid effluents in a manner appropriate to the composition, type and quantity of waste. The method of decontamination and disposal shall be determined using the results of a risk assessment based on the likely composition and volume of the waste and in accordance with applicable regulations. The risk assessment shall include the method of collection, design of drainage systems and transportation pipes to prevent leakage, and the types of decontamination systems, including the equipment rooms where the equipment is located. The risk assessment shall also consider the potential impact due to excess flow from water fixtures (e.g. tap left on condition) and the release of water from water based fire protection systems, where provided (see Section 11 and Section 13).

NOTE If all microbiological hazardous material is decontaminated prior to removal from a primary containment device, the risk assessment may deem that a town sewer provides adequate treatment for general wastes in secondary containment spaces.

(k) Provision shall be made for decontamination of the facility. The facility shall be constructed to contain any aerosols or gases used for decontamination. The surface finishes in the facility shall be compatible with the decontamination agents used.

NOTE The design of the facility should avoid inaccessible spaces. See Appendix H for recommendations on design for airtightness and periodical retesting.

(l) All room penetrations shall be sealed airtight to withstand pressures and movement due to pressure fluctuations. Penetrations shall be durable and capable of regular inspection to confirm ongoing performance see Appendix H).

5.4.3 Ventilation

A ventilation system that establishes a negative pressure in the laboratory shall be provided so that there is a directional airflow into the working area. Where laboratories have supply air systems, the supply air and exhaust air systems shall be interlocked, to ensure inward airflow at all times. The proper directional airflow into the laboratory shall be verified by airflow tests. The laboratory (including the airlock) shall be structurally designed to take account of the operation under negative pressures.

Failure of a single component, such as an exhaust fan or a supply fan, can result in extremely high positive or negative pressures in the laboratory. Alarms and failure mode operations of ventilation systems shall address this risk to ensure that interlocks operate rapidly to stop systems. The laboratory shall be constructed to withstand, without cracking or deterioration, the maximum positive and negative pressures that can be generated until failure mode safeguards operate. Automatic and manual failure mode sequences shall be independent of any automated control system that may, itself, be the primary cause of a failure situation.

All air that leaves the laboratory shall be exhausted in accordance with the requirements of this Clause.

Air may be recirculated within each laboratory. If air is recirculated, this shall be achieved utilizing internally-mounted air conditioning equipment such as fan coil units and split system air conditioning units. Any internally-mounted equipment shall be provided with removable panels as required to ensure the complete penetration of gas or vapour during room decontamination.

NOTE 1 Ventilation equipment should be located to ensure a flow of incoming air from the vicinity of the entry door towards the highest risk microbiological work areas.

NOTE 2 The quantity of outside air supplied to the laboratory should comply with relevant health quality standards or regulations (refer to AS 1668.2) and should dilute laboratory airborne contaminants.

Ventilation equipment and outlets shall be located to minimize the disturbance to the open faces of Class I and Class II BSCs.
The laboratory ventilation shall incorporate the following features:

(a) The laboratory shall be maintained at an air pressure of at least 50 Pa below the pressure of areas outside the PC3 containment barrier when both doors of the airlock are closed. When either door is open, the laboratory pressure shall remain at least 25 Pa below that of areas outside the PC3 containment barrier. The 0 Pa reference pressure shall be measured to minimize the effects of fluctuations due to wind and other building ventilation systems.

NOTE Additional precautions should be considered when one or more surfaces are external and exposed to fluctuations of pressure due to wind effect. Suitable precautions include the use of an interstitial space that can be maintained at the zero reference pressure and the use of solid walls such as concrete with minimal joints, which are unlikely to be perforated or leak.

(b) The pressure differential shall be achieved by means of an independent room exhaust fan located downstream of a HEPA filter and discharging to the outside atmosphere.

NOTE A variable speed drive on the exhaust fan is preferred to facilitate room pressure control adjustments.

(c) Supply or replacement air to the room shall be filtered using Type 1 Class A or Class B filters complying with AS 1324.1 and have a minimum arrestance efficiency of 90% when tested in accordance with AS 1324.2 with Test Dust No. 4. Where replacement air is drawn from adjacent areas, adjustable dampers shall be provided in the transfer aperture to assist in setting up the reduced room pressure. This aperture and filter shall not be mounted in the door.

(d) Exhaust air shall be filtered and discharged to the outside atmosphere in such a manner that it is dispersed away from occupied buildings and outside air intakes (refer to AS 1668.2).

(e) The exhaust filter shall be a HEPA type as specified in Clause 11.10.1. An exhaust prefilter of the same standard as the supply filter shall be provided, and mounted upstream of the HEPA filter [see Clause 5.4.3(c)].

NOTE The prefilter may be installed in the exhaust HEPA filter housing or in the laboratory. Installation within the laboratory can facilitate access and changing.

(f) The HEPA filter shall be installed, housed and maintained as specified in Clause 11.10.2.

(g) A differential pressure gauge shall be provided, visible, and readable from inside and immediately outside the laboratory.

(h) Any tubing that forms part of the laboratory pressure sensing and control equipment shall be fitted with a 0.2 μm hydrophobic membrane filter (such as a miniature disk filter), located as close as possible to the PC3 containment barrier. Filters and tubing shall be protected against mechanical damage.

(i) An emergency ventilation stop button shall be provided outside the laboratory, adjacent to the exit. The emergency stop mechanism shall operate independently of the main ventilation control and main laboratory pressure control system such that emergency isolation of the ventilation can be implemented in event of central control system malfunction.

(j) An audible alarm shall be provided within the laboratory to indicate a loss of negative pressure and a visible alarm shall be provided outside the laboratory to indicate the same. Alarms shall be sufficiently sensitive to occur before any laboratory pressure becomes positive and before any pressure reversal occurs between different pressure zones within the facility laboratory. Alarm set-points should have sufficient tolerance such that false nuisance alarms do not occur. The alarms shall be generated within 2 min of such loss of pressure control.

(k) In multiple room and multiple zone applications, sufficient monitoring points and alarms shall be provided to capture a loss of pressure control in any space within the facility.

NOTE Additional pressure gauges and emergency stop mechanisms should be considered where applicable.
Annual testing by competent persons shall include the following:

(i) Testing of the pressure differentials in accordance with AS 1807.10 to ensure compliance with the requirements in Item (a).

(ii) Integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7, as applicable.

(iii) Checking that the control system is operating correctly and verifying alarms are set to operate in accordance with Item (j) on a loss of room pressure.

(iv) Calibration of pressure control and indicating devices.

(v) A report of the testing in Items (i) to (iv) and of any maintenance conducted shall be provided to the appropriate person for the facility.

(m) Exhaust air from Class III biological safety cabinets shall be discharged through the building exhaust system through direct ducting or a capture hood. It shall not be recirculated through the laboratory.

Capture hood air flow shall exceed cabinet discharge air flow by sufficient margin to ensure full entrainment of cabinet discharge air into the exhaust air stream. Discharges shall be designed and located outside of the building to ensure external air velocities do not adversely affect containment air flows and pressures within the cabinets.

NOTE 1 Care should be exercised with direct ducting with respect to pressure fluctuations.

NOTE 2 The exhaust air from Class I or Class II BSCs may be discharged into the laboratory or through the building exhaust system (see also Clause 11.7.1).

NOTE 3 Capture hoods may be inappropriate for toxic gases and vapours.

5.4.4 Access to services

Access to voids surrounding the immediate perimeter of the laboratory and to the ventilation equipment that serves the laboratory shall be restricted to authorized persons. Items of equipment, ducts and access panels to contained sections of the ventilation system shall be marked with biohazard labels to minimize the risk of accidental exposure to air or to contaminated surfaces. The installation of services shall ensure proper access to equipment such as HEPA filters for maintenance and testing personnel and their equipment.

5.4.5 Containment equipment

In addition to the equipment specified for PC2 (see Clause 5.3.5) laboratories, the following shall be provided:

(a) Where a central reticulated vacuum system or portable vacuum pumps are used, 0.2 μm hydrophobic membrane-type filters, and liquid disinfectant traps shall be installed at the point of use.

(b) Where required, Class III BSCs (see Clause 11.7.2).

NOTE The provision of an uninterruptible power supply should be considered for BSCs.

5.4.6 Work practices

In addition to the work practices specified for PC1 (see Clause 5.2.3) and PC2 (see Clause 5.3.6) laboratories, the following shall be observed:

(a) All containment features of the completed facility shall be tested, commissioned and the results documented, before use.
(b) The facility shall be inspected at least annually by the BC or operator to ensure that its containment requirements comply with Clause 5.4.3 by reviewing records, including HEPA filter integrity test reports, and room pressure readings.

c) The laboratory management shall establish policies and written procedures whereby only persons who have been advised of the biohazard, and who meet any medical requirements, shall enter the laboratory (see Clause 2.6).

d) An effective emergency evacuation plan shall be devised, and information on the action shall be available to all laboratory staff and local emergency services.

e) All laboratory staff shall have specific training in handling pathogenic organisms and in the use of safety equipment and controls. The laboratory staff shall be supervised by senior scientists who are experienced in working with pathogenic microorganisms.

(f) The facility door shall be locked when the room is unoccupied by personnel [see Clause 5.4.2(a)].

g) All laboratory procedures involving opened containers of potentially infectious and infectious material shall be conducted in a biological safety cabinet of Class I, Class II or Class III (see Clause 5.4.6). Work with multiple organisms infectious microorganisms shall not occur within the same BSC at the same time unless required for the procedure.

(h) Outer clothing and personal effects shall not be taken into the containment facility.

(i) No one shall enter the laboratory for cleaning, servicing of equipment, repairs or other activities before the relevant, potentially contaminated laboratory surfaces have been decontaminated and authorization has been obtained from the laboratory supervisor or the safety officer. Dedicated cleaning equipment shall be stored within the laboratory.

(j) Potentially infectious materials shall be placed in a non-breakable, leak-proof container during transport within the facility.

(k) Laboratory wastes shall be rendered safe, preferably by decontamination in a pressure steam sterilizer, before disposal in accordance with Clause 13.2.

(l) If a double-ended pressure steam sterilizer is installed across the barrier, it shall be decontaminated after each exposure to the laboratory environment.

(m) Protective clothing shall not be worn outside the facility and shall be decontaminated by pressure steam sterilization prior to laundering or disposal.

(n) Protective clothing shall be removed in a predetermined appropriate order.

(o) Measures shall be taken to ensure no microbiological contamination is removed from the facility on footwear.

NOTE Suitable measures include the use of dedicated facility footwear, the use of overshoes or a combination of these measures.

(p) In the event of a power failure, entry to the facility shall be restricted until services have been restored.

(q) Laboratory doors shall be closed when the laboratory is operating.

(r) Instruction and training in handling infectious microorganisms shall be provided to laboratory personnel with regular updates, e.g. annually or when new information is obtained (see also Clause 2.1.5).

(s) When handling human blood, serum, or other body fluids and substances that are visibly contaminated with blood, appropriate publications shall be consulted.
NOTE 1 Refer to Department of Health Infection Control Guidelines (providing recommendations for infection prevention and control procedures to minimize the risk of transmission of Creutzfeldt-Jakob disease (CJD) in health care settings) and the NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010).

This risk extends to human sera and derivatives used as control reagents (both positive and negative) in diagnostic and other procedures.

NOTE 2 Although existing test methods for viruses are sensitive, they do not entirely preclude the possibility of viral contamination. The fact that a serum sample is used as a negative control for some particular tests does not necessarily mean that it is free of viruses.

(t) All clinical and diagnostic specimens shall be regarded as potentially hazardous. Leaking containers shall be handled in a BSC and the outside of the container decontaminated (see Table E.1). Where a replacement sample is readily obtained, the leaking specimen shall be decontaminated and discarded in accordance with Section 13.

(u) The use of sharps such as syringes, needles and scalpels shall be minimized, as sharps injuries constitute a large portion of laboratory accidents (see also Bibliography, Reference 1.7). Needles and syringes or other sharp instruments shall be restricted in the laboratory for use only when there is no alternative. Sharps shall be disposed of in sharps containers (see AS 4031). Before disposal, needles shall not be removed, bent, sheared, or replaced in a sheath or guard, unless the recapping/removal procedure can be carried out by a safe method with suitable equipment.

NOTE 1 Laboratory users should be aware of the potential for glass equipment such as pipettes and tissue grinders to become sharps during an accident. Plastic ware should be substituted for glassware whenever possible.

NOTE 2 Where infectious material is being injected under high pressure, Luer-lock fittings should be used.

(v) When working with infectious or potentially infectious prions, a laminar flow cytotoxic drug safety cabinet shall be used when required (see also Clauses 11.8 and 11.9).

(w) Bacterial cultures shall not be actively sniffed for odours.

NOTE This has been a common cause of laboratory acquired infections.

(x) Seal cultures of spore-producing fungi as appropriate to prevent dispersal.

(y) Any container of viable microorganisms, including any waste that may contain viable organisms, shall be transported outside the laboratory within a second unbreakable and closed container, which shall first be decontaminated on all outer surfaces.

(z) Potentially contaminated re-usable laboratory ware shall be collected and disinfected or decontaminated in accordance with Section 13 prior to washing and re-use. For chemical disinfection, pipettes shall be placed vertically in an appropriate disinfectant solution, tip-first and fully immersed, to minimize the production of aerosols. If pipettes are to be thermally decontaminated in a steam sterilizer, they shall be fully immersed, vertically in a fluid, such as a detergent.

NOTE Thermal decontamination of pipettes that are not fully immersed in a liquid, i.e. are empty, can only be achieved in a pre-vacuum steam sterilizer.

(aa) Microbiological waste shall be disposed of in accordance with Clause 13.2.

(bb) The protective equipment specified in Clause 5.2.3(c) shall be used (see also Clause 11.2).

(cc) Reusable non-contaminated PPE shall be retained in the facility between uses, and kept segregated from unused PPE.

(dd) Appropriate eye protection (see Clause 11.2.4) shall be used to protect eyes from contaminated or hazardous materials or from ultraviolet light.
Gloves shall be worn when working in a BSC, when handling human blood and body fluids, and when conducting procedures with liquids that contain or potentially contain human Risk Group 2 microorganisms. These present a risk of spills or splashes that could otherwise result in direct skin contact.

PPE shall be removed and hands decontaminated in a predetermined appropriate order, before leaving the laboratory.

NOTE 1 The order is usually removal of gloves followed by hand decontamination, then eye protection and laboratory gown followed by a second hand decontamination.

NOTE 2 Appropriate protocols for laundering or decontaminating PPE should be implemented.

Laboratory staff shall advise maintenance and service personnel of the special microbiological hazards in the laboratory. All potentially contaminated equipment and adjacent surfaces shall be decontaminated prior to maintenance or removal from the area.

NOTE Appendix F provides information on disinfectants.

A control program against pest insects, birds and animals shall be instituted.

5.4.7 Health monitoring

See Clause 2.6.

5.5 Requirements for PC4 laboratories

5.5.1 General

A Laboratory PC4 facility is suitable for work with infectious microorganisms in Risk Group 4 and incorporates all equipment and practices for PC1, PC2 and PC3 laboratories (see Clauses 5.2, 5.3 and 5.4); however, additional requirements on conditions of access and egress, safety equipment and staff training apply.

A PC4 laboratory may be one of two types: a laboratory where work is conducted in a Class III BSC exhausting outside the laboratory or one where the work is conducted without being isolated in such a manner and staff wear fully encapsulated positive pressure suits.

NOTE The design of a PC4 facility is complex and those planning its construction should seek specialized advice. See also Appendix G for examples of recommended layouts for PC4 facilities showing the design principles involved and Appendix H for airtightness considerations.

5.5.2 Construction

5.5.2.1 General

In addition to the construction requirements specified for PC1 (see Clause 5.2.2), PC2 (see Clause 5.3.3) and PC3 (see Clause 5.4.2) laboratories, the following facilities shall apply:

(a) The facility shall be housed in a separate building or shall form an isolated part of a building. Full access to all exterior surfaces of the contained structure and service penetrations shall be provided to facilitate periodic integrity testing. The perimeter of the facility shall be protected against adverse pressure fluctuations due to wind or other external factors. The facility negative pressure shall be maintained across the floor, wall and ceiling boundaries at all times.

NOTE Recommendations for achieving acceptable room airtightness are given in Appendix H.

(b) Any transparent sections shall be constructed of impact-resistant materials.
(c) An outer and inner change room, separated by a shower airlock with interlocking, self-closing
doors, shall be provided for personnel entering and leaving the facility. The outer door of the
facility shall be lockable.

NOTE 1 A security card access procedure, with additional numerical pad or biometric access control, is
preferred as a means of entry.

The outer shower door shall form the laboratory containment boundary for
decontamination purposes.

The four doors of each entry/exit path shall raise an alarm if left open.

An entry and egress “traffic light” alarm system or door interlock control system shall be provided
to prevent the simultaneous opening of the doors on each side of the shower.

NOTE 2 The use of pneumatically sealed doors should be considered on both sides of the shower.

NOTE 3 Privacy for changing and showering may require door access features and interlocks or alarms
additional to the above biocontainment requirements.

NOTE 4 The use of interlocks requires the provision of manual overrides in case of emergencies.

(d) Walls, floors and ceilings of the facility shall be constructed in such a manner as to form a sealed
internal shell which facilitates gaseous decontamination. The internal surfaces of the shell shall
be resistant to liquids and chemicals used in the facility and shall facilitate easy cleaning and
decontamination. All apertures in the structures and surfaces shall be sealed to prevent vermin or
insects from entering the area. Glazing in windows shall be of laminated security glass selected to
withstand the maximum pressure differential imposed during all operating conditions, including
all possible failure modes, and during testing.

(e) A double-ended pressure steam sterilizer shall be provided to decontaminate materials from the
facility and from the inner clothing change room. The outer sterilizer door shall open to the area
external to the facility. The inner door shall automatically interlock with the outer door in such a
manner that the outer door can be opened only after the sterilization cycle has been completed.
The sterilizer shall comply with the requirements of Clause 11.6.

(f) A pass-through dunk tank, decontamination chamber or equivalent decontamination equipment
shall be provided, so that materials and equipment that cannot be decontaminated in the pressure
steam sterilizer can be rendered safe for removal from the facility.

(g) A suitable decontamination system shall be provided for handling all laboratory effluents,
including those from any showering facility, in accordance with Section 13.

(h) An automatic changeover emergency power source, emergency lighting and communication
systems shall be provided. The emergency power source shall be adequate to operate the
ventilation systems, BSCs, room access and shower controls. An uninterruptible power supply
shall be provided to ensure uninterrupted operation of the ventilation control system.

5.5.2.2 Positive pressure suit area

For certain requirements, a specially designed suit area may be provided within the facility.
Personnel who enter this area shall wear a one-piece positive pressure suit that is ventilated by a life
support system. If provided, positive pressure suit areas shall comply with the following additional
requirements:

(a) Entry shall be via an outer change room that leads to an airlock fitted with a personal body shower
then into an anteroom leading to a second airlock fitted with a chemical disinfectant shower
provided to decontaminate the surface of the suit before the worker leaves the area.

(b) A breathing quality air supply for connection to the positive pressure suit shall be provided in the
anteroom, chemical shower and experimental area. Quick-connect fittings shall be provided on the
suit and the air supply lines to ensure prompt disconnect and reconnect when moving between the anteroom, chemical shower and experimental areas.

c) All penetrations into the internal shell of the suit area shall be sealed.

d) An alarm and emergency back-up breathing air system shall be provided.

5.5.3 Ventilation

5.5.3.1 General

The facility ventilation shall comply with the following:

(a) A separate supply and exhaust, non-recirculating air ventilation system shall be provided. The system shall maintain such pressure differentials and directional airflow to ensure airflows toward areas of highest potential risk within the facility. There shall be a differential pressure of at least 25 Pa between each area (see Figure F.5). The system shall be provided with an alarm to detect malfunction. The supply and exhaust airflow shall be interlocked to ensure inward (or zero) airflow at all times. Differential air pressures between laboratory zones shall be monitored by use of a differential pressure gauge as specified in Clause 5.4.4(g).

(b) Both supply and exhaust air shall be filtered through HEPA filters as specified in Clause 11.10.1. The HEPA filters shall be installed and housed as specified in Clause 11.10.2. Prefilters to both the supply and exhaust HEPA filters shall be provided as specified in Clause 5.4.4(c) and (e).

The supply air HEPA filter shall prevent the outflow of contaminated air if air pressures become imbalanced within the facility.

c) The filtered air from Class III BSCs shall be discharged through the facility exhaust system.

d) Annual testing by a competent person shall include the following:

(i) Testing of the pressure differentials in accordance with AS 1807.10 to ensure compliance with Item (a).

(ii) Integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7, as applicable.

(iii) Checking that the control system is operating correctly and verifying alarms are set to operate in accordance with Item (d).

(iv) A report of the testing in Items (i) to (iii) and of any maintenance conducted shall be provided to the appropriate person for the facility.

5.5.3.2 Positive pressure suit area

In addition to the requirements in Clause 5.5.3.1, positive pressure suit areas shall comply with the following:

(a) The exhaust air shall be filtered through two HEPA filters installed in series.

(b) Duplicate ventilation equipment shall be provided to automatically re-establish laboratory ventilation and pressure conditions in event of equipment failure. Controls and equipment operation shall prevent a positive pressure occurring within the laboratory at all times, including the failure of an exhaust fan.

(c) The air pressure within the suit area shall be lower than that of the adjacent entry, exit and non-suit areas.

NOTE A 25 Pa differential is recommended.
5.5.4 Containment equipment

For work with agents of Risk Group 4, one of the following shall be provided:

(a) A Class I or Class II BSC (see Clauses 5.5.5.1(i) and 11.7.1).
(b) A Class III BSC (see Clause 11.7.2).

5.5.5 Work practices

5.5.5.1 General

In addition to the work practices specified for PC1 (see Clause 5.2.3), PC2 (see Clause 5.3.6) and PC3 (see Clause 5.4.6) laboratories, the following shall be observed:

(a) All staff shall be trained in the specific working aspects of the facility, including the safety equipment, the operation of the laboratory and containment and clean-up of infectious spills. Staff shall use the safety equipment provided. Staff shall receive specific training, with written instructions and information in the handling of the relevant infectious microorganisms.
(b) Staff shall be supervised by senior scientists who are trained and experienced in working with the relevant infectious microorganisms. A facility operations manual shall be prepared.
(c) Access shall be controlled to allow entry by authorized staff only. A list of contact names and phone numbers shall be provided outside the laboratory entry point.
(d) Personnel shall enter and leave the facility through the clothing change and shower rooms, except in cases of emergency, where alternative exits may be used.
(e) Complete facility clothing, including shoes, shall be provided by the organization.
(f) On entering the facility, personnel shall don complete facility clothing, including shoes. All street clothing, including underwear, shall be removed and retained in the outer clothing change room.
(g) Before leaving the facility, a full body shower shall be taken. Personnel shall remove their laboratory clothing and store or discard it in the inner change room before showering.
(h) Personnel entering or leaving the laboratory shall indicate, either manually or electronically, the time of each exit and entry.
(i) All procedures within the facility involving agents assigned to Risk Group 4 shall be conducted in Class III BSCs, or alternatively Class I or Class II BSCs, used in conjunction with one-piece positive pressure personnel suits ventilated by a life-support system in accordance with Clause 5.5.5.2.
(j) Prior to disposal, all laboratory effluents, including those from the shower facility, shall be decontaminated by either heat or chemical treatment (see also Section 13).
(k) The double-ended pressure steam sterilizer and decontamination chamber opening across the barrier shall be decontaminated after each exposure to the laboratory environment.
(l) Unless working in one-piece positive pressure suits ventilated by a life support system, viable biological materials to be removed from Class III BSC shall be transferred to a non-breakable, sealed primary container, the external surface of which is decontaminated before enclosure in a non-breakable, sealed secondary container, which is decontaminated on removal from the isolator. A primary container holding viable or intact biological materials shall be opened only in another Class III BSC in the PC4 laboratory or another PC4 laboratory [see Item (m)].

NOTE Containers may be opened in non-PC4 laboratories only if the biological material has been rendered non-infectious or non-toxic, and the space in the primary and secondary containers has been decontaminated.
Viable biological materials to be removed from the laboratory shall be removed from the facility in a sealed secondary container [see Item (l)] and by passing through a disinfectant dunk tank or gaseous decontamination chamber or airlock designed for this purpose. No other materials shall be removed from the facility unless they have been decontaminated. Equipment or materials which might be damaged by high temperatures or steam shall be decontaminated in an airlock or specially designed chamber by means of sterilizing gas or vapour.

**NOTE** Containers may be opened in non-PC4 laboratories only if the biological material has been rendered non-infectious provided they are opened within a Class II BSC.

Risk Group 4 material shall only be stored within the facility.

A risk assessment of the working environment shall be undertaken encompassing all matters influencing the personal safety of staff. Monitoring and emergency procedures shall be prepared and implemented at a level commensurate with the outcome of the risk assessment.

**NOTE** The presence of a coworker either inside the laboratory or observing the work from outside the laboratory should be considered.

Checks shall be carried out to ensure monitoring and communication arrangements result in the emergency procedures being initiated in a timely manner and to ensure the procedures are adequate.

### 5.5.5.2 Positive pressure suit area

In addition, the following work practices apply for positive pressure suit areas:

(a) Upon entering the anteroom, the person shall don a positive pressure suit prior to entering the second (chemical shower) airlock.

(b) When exiting the suit area, a chemical disinfectant shower shall be taken to decontaminate the outer surface of the suit. The disinfectant shall be effective against the microorganisms used in the suit area at the concentration at which it is used in the shower taking into account the time and temperature defined for the shower. The suit and clothing shall be removed in the anteroom and a full body shower shall be taken before leaving the facility.

### 5.5.6 Health monitoring

See Clause 2.6.

### Section 6 Terrestrial animal containment facilities

#### 6.1 Requirements for terrestrial animal containment facilities

This Section sets out requirements to ensure that terrestrial animals that are infected with or that may contain infectious microorganisms are contained in facilities that will prevent the escape of the animals and the microorganisms. The general principles of terrestrial animal containment can also be applied to terrestrial animals that do not contain any infectious microorganisms, such as specific pathogen free (SPF) animals and genetically modified or transgenic animals. This Section is not intended to be used as a substitute for other regulations or guidelines that apply to these animals, such as those issued by DAWR, OGTR or equivalent New Zealand regulatory agencies.

In Australia, animals exposed to exotic microorganisms shall be housed in containment facilities that meet the requirements of DAWR. Animals exposed to genetically modified microorganisms shall be housed in accordance with OGTR requirements. Disposal of such animals shall be in accordance with the relevant regulations or guidelines.
In New Zealand, animals exposed to exotic microorganisms and animals exposed to genetically modified microorganisms shall be housed in facilities approved by MPI. Disposal of such animals shall be in accordance with the relevant regulations or guidelines.

Facilities and arrangements for animal husbandry and management shall be consistent with good animal welfare practices and in accordance with either the Australian code of practice for the care and use of animals for scientific purposes or the New Zealand Animal Welfare Act 1999, as appropriate.

NOTE 1 The Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals should also be consulted.

Facilities and arrangements for terrestrial animal care and management shall be consistent with good terrestrial animal welfare practices and in accordance with either the Australian code of practice for the care and use of animals for scientific purposes (see Bibliography, Reference 1.34) or the New Zealand Animal Welfare Act 1999, as appropriate.

NOTE 2 The Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals should also be consulted (see Bibliography, Reference 1.35).

NOTE 3 Refer to Guide for the care and use of laboratory animals (see Bibliography, Reference 1.36) for specific information related to aquatic animal husbandry.

NOTE 4 The USDA-ARS (United States Department of Agriculture, Agricultural Research Service), national agricultural library has some excellent reference material related to the care and use of species such as molluscs (see Bibliography, Reference 1.34).

### 6.2 Principles of terrestrial animal containment

Terrestrial animals can be held in a variety of containment facilities that are designed to ensure that the animals, and the microorganisms that may be being used in conjunction with the animals, do not escape from containment. Animals under experiment may be either small laboratory animals (e.g. mice or rabbits) or large domestic animals (e.g. pigs, sheep or cattle). The requirements for housing and maintenance of the animals may differ in scale as a result but the overall principles that apply are the same. While some Terrestrial Animal PC1 facilities confine larger animals in a fenced enclosure, other Terrestrial Animal PC1 facilities are designed to contain smaller animals such as rodents.

Facilities may be designed and constructed in the same way as a laboratory and may be integral to, and inseparable from, the laboratory itself. At lower containment levels (PC1 and PC2), there may be little difference between the design and construction of animal and laboratory containment facilities.

Where smaller animals may be infected with, or exposed to, Risk Group 3 or Risk Group 4 microorganisms, it is preferable that they are kept in some form of primary containment device, such as ventilated cages fitted with exhaust HEPA filters. The use of primary containment devices should be considered at all levels of animal facilities to prevent cross-contamination and to prevent exposure of personnel to allergens and microorganisms.

In cases where it is not possible to keep animals in primary containment devices (e.g. for cattle and sheep), or the animal cages or enclosures do not prevent the spread of aerosols, the room itself will form the primary containment. In this situation, in addition to the room exhaust HEPA filters, other measures such as additional construction requirements, specialized PPE, work practices and training may be required to ensure the protection of both human health and the environment. Measures for consideration include the use of dedicated PPE that remains in the facility and showering of personnel before leaving the facility.

Waste shall be segregated, decontaminated where necessary and disposed of according to applicable regulations (see also Section 13). Terrestrial animal containment facilities should have access to decontamination facilities within their own areas. Waste from low level (PC1 and PC2) terrestrial animal containment facilities can be decontaminated outside the facility. However, waste shall be contained to prevent dissemination of any infectious microorganisms. Waste from higher level terrestrial animal containment facilities shall either be pressure steam sterilized in the facility or decontaminated in a closed system to ensure that all infectious microorganisms are destroyed.
As a general principle, the biological and PC recommended for working with infectious agents and agents of biosecurity interest in vivo and in vitro are comparable. Infected animals should only be handled by trained staff using procedures designed to protect staff and the environment from exposure to the microorganisms. When housing animals in which microorganisms are to be used, the PC levels for work with microorganisms shall follow the containment levels appropriate for the microorganism. Requirements for Terrestrial Animal PC1, Terrestrial Animal PC2, Terrestrial Animal PC3 and Terrestrial Animal PC4 facilities are set out in Clauses 6.4, 6.5, 6.6 and 6.7 respectively.

6.3 Other considerations associated with terrestrial animal containment

6.3.1 Designing facilities for different aspects of terrestrial animal handling

Prior to designing facilities, separate areas should be considered for different activities, for example for animal housing, experiments, post-mortem examinations, disposal of wastes and associated maintenance.

Infected, non-infected and quarantined animals should be separately housed, and precautions taken to prevent cross-infection. Even animals that have not been deliberately infected may harbour organisms that are dangerous to humans.

Training staff in animal handling is the best method of preventing injury, both to staff members and to animals (see the Australian code of practice for the care and use of animals for scientific purposes or the New Zealand Animal Welfare Act 1999, as appropriate).

6.3.2 The occurrence of allergic reactions in personnel handling terrestrial animals

Exposure to animals or animal products (scurf, dander, hair or urine components) can cause allergies and asthma. About 33% of animal handlers have allergic symptoms (e.g. rhinitis) and approximately 10% have animal-induced asthma. Inhalation is one of the most common ways for allergens to enter the body. Some workers develop allergic symptoms fairly quickly, while others can take longer to become sensitized (usually within three years) (see Bibliography, Reference 1.87.). To reduce the incidence of these conditions, adequate ventilation, including an increased number of air changes per hour, should be ensured and local exhaust systems provided where necessary (see Clause 6.3.3). In addition, animal handlers, technical and scientific staff should take appropriate precautions to prevent the development of allergies.

It is recommended that respiratory protection is worn to prevent the development of laboratory animal allergies. Usually P2 particulate respirators are adequate but fit testing of the respirator is important to ensure that it is appropriate for the individual and advice from an occupational hygienist or similar should be sought.

Any unusual personal reaction or allergy to animals or animal products should be reported so that appropriate action can be taken.

6.3.3 Air change rates for terrestrial animal containment facilities

Terrestrial animal containment facilities require relatively high rates of fresh air ventilation to control odours and contaminants such as animal detritus and ammonia (from waste products). The fresh air ventilation rate shall be sufficient to keep odour and contaminant levels below acceptable threshold limits for the long-term exposure of personnel. The use of purpose-designed allergen exposure reducing change stations and similar devices shall be used where these can be demonstrated to reduce human allergen exposure. Such devices shall be cleaned and maintained in such a way that maintenance persons are not exposed.

NOTE 1 The required fresh air ventilation rate depends on a number of factors, including —

(a) the type of animal caging;
(b) the nature of animals to be accommodated;
(c) the stocking density in relation to room volume;
(d) the animal husbandry, particularly the frequency of bedding changes;
(e) temperature, humidity and air movement in the animal environment; and
(f) the ventilation effectiveness.

NOTE 2 Guideline minimum fresh-air ventilation rates for terrestrial animal containment facilities are as follows:

<table>
<thead>
<tr>
<th>Animal housing</th>
<th>Fresh airflow (air changes per hour)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open cages, i.e. the room forms the primary containment barrier</td>
<td>15</td>
</tr>
<tr>
<td>Isolators fitted with HEPA exhaust filtration and activated carbon or equivalent odour controlling mechanisms</td>
<td>12</td>
</tr>
<tr>
<td>Isolators fitted with HEPA exhaust filtration and exhaust air is completely removed from the occupied space by capture hood or direct-ducting</td>
<td>8</td>
</tr>
</tbody>
</table>

NOTE 3 The rate may need to be increased for animal welfare reasons or to reduce concentrations of airborne substances such as pheromones.

6.3.4 Decontamination and disposal of terrestrial animal waste

Infectious bedding, cage wastes and cages from animals shall be decontaminated prior to disposal or reuse as specified in Section 13. Infected carcasses shall be decontaminated prior to disposal. This may be achieved by methods such as alkali digestion, autoclaving, incineration or rendering. All instruments and containers that have been used in procedures with infectious microorganisms should be decontaminated before cleaning. Any special precautions that are needed, such as decay of radioisotopes, should be taken.

NOTE Decontamination requirements apply for Animal PC2 and higher facilities (see Clauses 6.5 to 6.7).

6.3.5 Transport of terrestrial animals and animal tissues between facilities

Where it is necessary to transport animals or animal tissues from the containment facility, the appropriate precautions shall be determined. Tissues fixed to inactivate infectious materials may be removed from the facility. Live animals and animal tissues shall not be moved to a facility of a lower level of containment, e.g. from PC3 to PC2 (see Clause 3.5).

6.3.6 Dissection and post-mortem examinations

Post-mortem examinations of terrestrial animals that are infected or suspected to be infected with pathogenic microorganisms shall be carried out under PC conditions equivalent to the risk group of the microorganism present or suspected to be present.

During post-mortems, appropriate PPE such as gloves, aprons and eye protection should be worn. Where there is a risk of infection by the respiratory route, respiratory protection shall be used.

6.4 Requirements for terrestrial animal PC1 facilities

6.4.1 General

An Terrestrial Animal PC1 facility is suitable for work with microorganisms in Risk Group 1 and uninfected animals. Microbiological containment is generally addressed by good work practices.

A sign complying with Appendix D showing the level of containment, together with hazard symbols as appropriate and any access restrictions, should be prominently displayed at the entrance.
6.4.2 Construction

Terrestrial Animal PC1 facilities shall comply with the following:

(a) Facilities for laboratory and experimental animals shall be separated from other areas such as those used for animal production or animal quarantine.

(b) Facilities shall be constructed to prevent the escape of the animal species being contained.
   
   **NOTE 1** The facility should be secure against incursions by feral or predatory animals.
   
   **NOTE 2** For facilities with fences, electric fencing and buried fencing should be used where appropriate.

(c) Facilities shall be designed to prevent the access of unauthorized personnel.

(d) Constructed facilities shall be designed to prevent infestation by vermin.

(e) Facilities shall be constructed in a manner that allows regular cleaning and, if appropriate, decontamination.

(f) Dedicated hand basins or an alternative means of decontaminating the hands shall be provided inside each laboratory, in a position on the pathway towards the exit which supports appropriate use of the hand basins as part of the recommended exit procedure.

(g) Backflow prevention for water supplies shall comply with **Appendix E**.

(h) Gas supplies in the facility shall comply with the general requirements specified in Clause D3.1.

(i) Dissection tables shall be impermeable to liquids and be covered with a washable material.

(j) Two independent communications systems shall be provided. Two way communication shall be able to be conducted on at least one system, the other shall allow a person in the facility to draw the attention of persons outside.

(k) Where human pathogens are not present and there is a risk to the health of workers through dehydration, due to circumstances such as heat stress, heavy work or long shifts in response to emergencies, drinking facilities may be provided to the facility. This shall be subject to approval by the BC, following a risk assessment of the particular situation. If drinking facilities are provided, they shall be via a hands-free operation drinking fountain in a designated area.
   
   **NOTE** This option is only for Animal PC1 and Animal PC2 facilities, provided the room is not the primary containment measure.

6.4.3 Work practices

The work practices for Terrestrial Animal PC1 facilities shall be as follows:

(a) Access to the facility shall be restricted to authorized personnel.

(b) All means of access to the facility shall be locked when animals are not under direct supervision.

(c) For containment of grazing animals, the external perimeter fence shall be checked at least every three months and after storms for any breaks or holes in the fence. Any breach shall be repaired immediately.

(d) Other provisions such as feed and water supplies and regular inspections shall meet requirements for animal husbandry and welfare purposes.

(e) Animals shall be prevented from escaping, with reasonable contingencies in place for accidents such as during handling.
   
   **NOTE** The doors should be kept closed when experimental animals are present, and for those periods when work is being carried out within the facility.
PPE appropriate for the work being carried out shall be worn. See also Clause 11.2 for detailed information on PPE. For all work with animals, personal clothing shall be covered by a laboratory coat or gown as a minimum. Closed footwear shall be worn, preferably separate shoes or boots that remain within the terrestrial animal containment facility.

NOTE 1 Overalls should be considered as an alternative to a laboratory coat or gown.

NOTE 2 Gloves should be considered when working with animals and when working in a BSC.

NOTE 3 Double gloves should be considered when working with multiple animals.

NOTE 4 Eye protection should be considered when working with animals.

NOTE 5 Protection against inhalation of aerosols and scratches or bites should be considered.

NOTE 6 Gowns or other protective clothing should be laundered at appropriate intervals.

Staff handling animals shall be trained in fundamental aspects of good animal husbandry. Staff shall be familiar with safe handling procedures for the animal species involved, including appropriate restraint procedures; staff shall understand the nature and hazards of any infectious agent involved and how it can be transmitted, the inoculation method to be used, how subsequent sampling is to be done, safe disposal of liquid effluents and animal waste, and emergency procedures.

Staff shall be competent in inoculation procedures designed to prevent self-inoculation and to minimize aerosol formation.

NOTE When handling or inoculating animals, the introduction of organisms through the skin either by accidental self-inoculation or by contact with ecto-parasites is a real risk.

Animals shall be restrained during experimental handling.

Animals shall be properly identified (e.g. by tattooing, microchip, ear tags, permanent branding or labels on cages of individually caged animals) and accounting procedures shall be established.

NOTE A record should be maintained to provide an up-to-date inventory of the animals present and a chronological record of procedures performed.

During post-mortem examinations, spillage trays and containers for used instruments shall be used. Procedures shall be followed to avoid cuts with the instruments used.

Eating, smoking and the storage of food for human use shall not be permitted in the facility.

Drinking and the storage of drink for human use shall only be permitted in the facility in accordance with Clause 6.4.2(k). If drinking facilities are provided, work practices shall be instituted to ensure gloves are removed and hands are decontaminated prior to drinking.

Chemicals shall be stored in the facility in accordance with AS/NZS 2243.10.

PPE shall be removed and hands shall be decontaminated in a predetermined appropriate order, before leaving the terrestrial animal containment facility.

NOTE 1 The order is usually removal of gloves followed by hand decontamination, then eye protection and laboratory gown followed by a second hand decontamination.

NOTE 2 Appropriate protocols for laundering or decontaminating PPE should be implemented.

Wastes shall be segregated (e.g. broken glassware, biological and radioactive substances) and disposed of according to applicable regulations, using the most appropriate and effective method for the materials concerned (see also Section 13).
(q) The facility shall be inspected at least annually by the BC or operator to ensure that its containment requirements comply with Clause 6.4.2 by reviewing records, including HEPA filter integrity test reports and room pressure readings.

6.5 Requirements for terrestrial animal PC2 facilities

6.5.1 General

A Terrestrial Animal PC2 facility is suitable for work with infectious microorganisms in Risk Group 2 and incorporates all the requirements of a Terrestrial Animal PC1 facility with additional requirements of construction, access, safety equipment and staff training.

6.5.2 Construction

In addition to the construction requirements specified for Terrestrial Animal PC1 facilities in Clause 6.4.2, the following shall apply:

(a) Floors, ceilings, benches and walls of the facility shall be smooth, easy to clean, impermeable to liquids and resistant to commonly used reagents and disinfectants. Floors shall be coved to walls and exposed plinths to facilitate cleaning. Benches shall be finished with a material that is impermeable to liquids, have any joints sealed, and be sealed to end walls and sinks where there is a wet area.

NOTE The doorway and room structure should be rodent-proof.

(b) Structural joints, where required, shall be durable, impermeable, easy to clean and shall resist deterioration due to commonly used cleaning agents, common disinfectants and, where applicable, exposure to ultraviolet radiation.

NOTE Structural joints should be minimized in containment facilities.

(c) Access doors shall be self-closing and be designed and installed to minimize the possibility of any animals escaping.

(d) Windows shall be closed and sealed.

(e) Any openings in the walls, roof or ceiling, such as vents and air conditioning or ventilation inlets and outlets, and any other specialist ventilation openings, shall be screened at the containment boundary with fine mesh screens having apertures of sufficiently small gauge to prevent entry or egress of invertebrates. The mesh shall be —

   (i) stainless steel; or

   (ii) a suitable material with regards to its —

      (A) mechanical strength under the airflow load;

      (B) ability to remain undamaged with the regular vigorous cleanings needed to remove dust, scurf, dander, hair or plant fibre; and

      (C) corrosion resistance; and resistance to attack by insects from either inside the containment facility or from the local environment outside the facility.

NOTE 1 The recommended maximum aperture size for general applications is 0.25 mm (250 μm). Standard stainless steel mesh with an aperture of 0.25 mm and wire gauge of 0.16 mm satisfies this requirement. Smaller aperture sizes of 0.10 mm (100 μm) may be required for work which involves some arthropod varieties such as mites and thrips.

NOTE 2 In locations where dust and debris can be generated, the use of roughing filters upstream of the mesh screens can result in safer and easier cleaning.
NOTE 3 It is recommended that ducted fume cupboards are not installed within animal facilities so that the requirement for mesh screening of the exhaust path can be avoided. Fume cupboards should be installed in adjacent microbiological laboratories where required. If installation within an animal facility is required, the use of a recirculating type fume cupboard can be considered.

(f) Where the animal room forms the primary containment measure, consideration should be given to the provision of liquid effluent decontamination. This may be plumbing the effluent directly into the sewer, where local authorities permit.

(g) Containers in accordance with Section 13 shall be provided for collection, storage or disposal of potentially infectious or infectious materials.

(h) A pressure steam sterilizer shall be available where steam sterilizing of facility wastes is required (see also Clause 11.6 and Section 13).

NOTE The pressure steam sterilizer should be as close to the facility as possible.

(i) Each facility shall be equipped with a hand basin with hands-free mixing taps, in a position on the pathway towards the exit which supports appropriate use of the hand basin as part of the recommended exit procedure.

NOTE 1 Shower facilities should be provided within the same building as the animal facility.

NOTE 2 Consideration should be given to the provision of a hand basin or a hands-free dispenser providing appropriate disinfectant hand rub in individual animal rooms to reduce cross-contamination risk (see Bibliography, Reference 1.8).

(j) Two independent communications systems shall be provided. Two way communication shall be able to be conducted on at least one system, the other shall allow a person in the facility to draw the attention of persons outside.

(k) Gas supplies in the facility shall comply with the backflow prevention requirements specified in Clause D3.2.

(l) Where required, storage space, e.g. shelves, shall be provided for reference documents and papers within the facility and separate from the work surface.

(m) A sign complying with Appendix D showing the biological hazard symbol and the level of containment, together with hazard symbols as appropriate, emergency contacts and any access restrictions, shall be posted at the entrance to the facility.

(n) An area in which protective clothing and footwear can be stored shall be provided. If animals are not in primary containment devices, this area shall be in an anteroom situated within the facility.

(o) Where the animal room itself forms the primary containment measure, and if determined necessary on the basis of a risk assessment, the following shall be provided:

(i) An anteroom, to allow changing of clothes on entry and exit and the storage of specialized PPE.

and

(ii) A shower facility, to allow appropriate cleaning of staff exiting the room.

6.5.3 Ventilation

An inward flow of air shall be maintained by forced extraction of air to minimize the spread of aerosols in the event of an inadvertent spill.

NOTE Refer to AS 1668.2 for general filtration requirements to provide indoor air contaminant control in buildings.
Air shall not be recirculated unless animals are kept in primary containment devices that are separately exhausted. If air is recirculated, it shall not be supplied to areas outside the Animal PC2 facility.

Ventilation air shall not be directed towards doors or located in positions that can disturb air flow at a BSC or an animal isolator.

### 6.5.4 Containment equipment

#### 6.5.4.1 Biological safety cabinets

A Class I or II biological safety cabinet (see Clause 11.7) shall be provided if there is a potential for personnel to become infected by aerosol generation.

**NOTE 1** Refer to Figures 1 and 2 of Clause 5 of AS 2252.4 for guidance on installation and location of BSCs.

**NOTE 2** See Appendix H for information and recommendations concerning safe use of the BSC.

**NOTE 3** Refer to Clause ZZ14 of AS 2252.4 for information related to decontamination of the BSC.

Where requirements in AS 2252.4 conflict with requirements in this Standard, the requirements in this Standard shall take precedence.

#### 6.5.4.2 Animal change stations

Animal change stations should be routinely maintained, and the cleaning of the change stations shall be done so as not to expose the workers to the allergens. Suitable containment equipment shall be provided to minimize personnel exposure to allergens where applicable.

### 6.5.5 Work practices

In addition to the work practices specified for Terrestrial Animal PC1 (see Clause 6.4.3) facilities, the following shall apply:

(a) Protective clothing and footwear shall be worn in the facility. Gloves and eye protection shall be worn when handling animals or material containing Risk Group 2 microorganisms.

(b) Maintenance personnel shall be advised of potential hazards before entering the facility. Areas or equipment being maintained shall be decontaminated before the maintenance is carried out. Equipment shall be decontaminated prior to removal from the facility.

**NOTE** Appendix F provides information on disinfectants.

(c) Animals shall be restrained appropriately when not held in cages or pens.

(d) For animal work with Risk Group 2 microorganisms transmissible by the respiratory route or work producing a significant risk from aerosol production, a BSC or other equipment designed to contain the aerosol shall be used. A period of at least 5 min shall be allowed for aerosols to settle before opening homogenizer or sonicator containers in a BSC.

**NOTE** Large items of equipment can interfere with the airflow pattern in a Class II BSC and correct operation of the cabinet should be validated with the equipment in situ (see Clause 10.3.1).

(e) Care shall be taken in the use of syringes, needles and other sharps. Sharps containers shall be provided at each point of use. Precautions shall always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes and scalpels. Needles and syringes or other sharp instruments shall be restricted for use only when there is no alternative, such as for parenteral injection, phlebotomy or aspiration of fluids from animals and diaphragm bottles.

**NOTE 1** Sharps use should be eliminated wherever possible.
NOTE 2  Staff should be aware of the potential for glass equipment such as pipettes and tissue grinders to become sharps during an accident. Plastic ware should be substituted for glassware whenever possible.

NOTE 3  Where infectious material is being injected under high pressure, Luer-lock fittings should be used.

(f) Viable microorganisms or animal tissues being transported out of the facility shall be double-contained. The second container shall be closed and unbreakable and the surface shall be decontaminated before removal. If taking live animals out of the facility, they shall be contained in a manner that prevents dissemination of the microorganism and escape of the animal.

(g) Work surfaces shall be decontaminated after use, after any spill of viable material, and before maintenance is carried out in the area.

NOTE  Appendices provides information on disinfectants.

(h) Personnel shall decontaminate their hands after handling cultures or animals.

(i) PPE shall be removed and hands decontaminated in an appropriate, predetermined order before leaving the terrestrial animal containment facility.

NOTE  The order is usually removal of gloves followed by hand decontamination, then eye protection and laboratory gown followed by a second hand decontamination.

NOTE  Appropriate protocols for laundering or decontaminating PPE should be implemented.

(j) Reusable non-contaminated PPE shall be retained in the facility between uses, and kept segregated from unused PPE.

(k) Gowns or other protective clothing shall be laundered at appropriate intervals. If potentially infectious or infectious materials have been spilled on gowns or protective clothing, these items shall be decontaminated, preferably by steam pressure sterilization prior to laundering or disposal. (See Section 10.)

NOTE  Appropriate protocols for laundering or decontaminating PPE should be implemented.

(l) Potentially contaminated re-usable laboratory ware shall be collected and disinfected or decontaminated in accordance with Section 13 prior to washing and reuse.

NOTE  For chemical disinfection, pipettes placed vertically in an appropriate disinfectant solution, tip-first and fully immersed, minimize production of aerosols.

NOTE  Thermal decontamination of pipettes that are not fully immersed in a liquid, can only be achieved in a pre-vacuum steam sterilizer.

(m) Microbiological wastes, animal bedding, animal cages and animal carcasses shall be decontaminated.

NOTE  Waste should be disposed of in accordance with Section 13.

(n) Animal rooms shall be cleaned and decontaminated after use.

(o) Report writing and long-term write up shall occur outside the facility.

NOTE  Worksheets may be used on the bench.

6.6 Requirements for terrestrial animal PC3 facilities

6.6.1 General

A Terrestrial Animal PC3 facility is suitable for work with infectious microorganisms in Risk Group 3 and incorporates equipment and practices for Terrestrial Animal PC1 facilities except Clause 6.4.2(k), and all equipment and practices for Terrestrial Animal PC2 facilities (see Clause 6.5). However, additional requirements for construction, conditions of access, safety equipment and staff training apply.
When pathogenic microorganisms of Risk Group 3 are being used in association with small animals, primary containment devices such as BSCs or individually ventilated isolators fitted with HEPA exhaust filters should be used wherever practicable. Where primary terrestrial animal containment devices cannot be used, the facility forms the primary containment measure.

NOTE The design of a PC3 facility is complex and those planning its construction should seek specialized advice. See also Appendix G (Figures G.1 to G.5) for examples of recommended layouts for PC3 facilities showing the design principles involved and Appendix H for airtightness considerations.

6.6.2 Construction

Similar requirements to those applying to Terrestrial Animal PC1 and PC2 facilities also apply to Terrestrial Animal PC3 facilities, apart from the option to provide drinking water. In addition to construction requirements specified for Terrestrial Animal PC1 (see Clause 6.4.2) and PC2 (see Clause 6.5.2) facilities, the following shall apply:

(a) The facility shall be physically separated from non-PC3 areas, including offices used by facility personnel, and areas accessible by the general public. This separation shall be achieved by a double-door system where entry to the facility is gained only through an airlock or shower airlock. For an airlock, the doors shall open outwards and the outer door shall be lockable. For a shower airlock, the outer door of the shower airlock shall open outward. Either the door to the outer change room or the outer door of the shower airlock shall be lockable. Airlock and shower airlock doors shall be self-closing and fitted with seals to limit air leakage.

Where the facility forms the primary containment measure, an outer and inner change room, separated by a shower airlock shall be provided. The outer shower door shall form the limit of Terrestrial Animal PC3 containment for decontamination purposes.

NOTE 1 Where separate animal rooms are contained within a PC3 facility, consideration should be given during the design of the air handling system to the use of a common system or the need for individual air exhaust systems, HEPA filters and duct isolation valves to facilitate gaseous decontamination of all or part of the facility.

NOTE 2 The airlock is provided to ensure the maintenance of the negative pressure within the facility and prevent airflow between the facility and areas external to the facility. It should not be used for any work, nor should it contain any equipment, washing facilities (apart from the shower where it is used as a shower airlock) or PPE worn in the facility.

NOTE 3 Consideration should be given to the provision of a gaseous decontamination chamber for facilities that require removal and installation of equipment that cannot be steam sterilized. This facilitates removal of such items without the need to decontaminate the complete facility.

NOTE 4 Depending on the need, removable panels to allow for entry and exit of large items of equipment should be considered. These should be readily resealable to an airtight condition following use.

NOTE 5 Building regulations may require alternative egress in certain facility configurations. These exits are required to be accessible and easily usable and should not compromise facility seal integrity. Lockable doors need to permit emergency egress in accordance with building regulations.

(b) Means shall be provided for minimizing disturbance of pressure differentials by reducing the likelihood of both airlock doors being opened at the same time.

NOTE Examples of suitable mechanisms include entry and egress “traffic light” alarm systems, door interlock control systems or viewing panels if suitable.

(c) Means shall be provided to prevent powered air lock doors from opening simultaneously in event of power loss or emergency. Manual overrides may be used to address emergency egress requirements.
(d) The allocation of task zones and layout within the facility shall promote the movement of ventilation air from the entrance and towards the more contaminated zones such as BSCs and steam sterilizer loading trolleys.

Care shall be taken to avoid turbulence or ventilation system air movement within the vicinity of BSCs that could interfere with the stability of the work face air flow pattern.

(e) Wherever possible, valves control equipment and supporting equipment (such as ventilation equipment, heating and cooling equipment) should be located outside the facility laboratory to minimize the need for service personnel to enter the laboratory. Equipment that requires direct contact with potentially contaminated material shall be located to minimize the risk of escape of organisms, taking into account the requirement to access components requiring service and maintenance.

NOTE The provision of a gaseous decontamination chamber should be considered where it is necessary to remove items that cannot be steam sterilized.

(f) The facility shall have a high level of physical security including control of access (e.g. electronic access card) and shall not open onto a public thoroughfare.

(g) Doors, apart from those to areas used for showering and changing, shall contain viewing panels to minimize entry and exit incidents.

(h) Adequate arrangements for observation of occupants shall be provided.

NOTE Examples of suitable arrangements are the viewing panels in doors specified in Item (g) provided they allow adequate viewing of occupants; viewing panels in walls; or electronic visual monitoring facilities (e.g. viewing cameras or closed circuit television).

(i) Two independent communications systems shall be provided. These shall allow a person in the facility to draw the attention of persons outside.

(j) The facility shall include provisions to change animal cages, bedding, feed and water without compromising microbiological containment.

(k) A pressure steam sterilizer for decontamination of wastes shall be provided in the facility. The pressure steam sterilizer shall not be located in the airlock.

NOTE 1 A double-ended type of pressure steam sterilizer is preferred, positioned through the barrier wall of the facility and allowing adequate access for loading and unloading of the steam sterilizer and for maintenance of the associated plant from outside the facility.

NOTE 2 See also Clause 11.6.8.

(l) Provision shall be made for decontamination of liquid effluents in a manner appropriate to the composition, type and quantity of waste. The method of decontamination and disposal shall be determined using the results of a risk assessment based on the likely composition and volume of the waste and in accordance with applicable regulations. The risk assessment shall include the method of collection, design of drainage systems and transportation pipes to prevent leakage, and the types of decontamination systems, including the equipment rooms where the equipment is located. The risk assessment shall also consider the potential impact due to excess flow from water fixtures (e.g. tap left on condition) and the release of water from water based fire protection systems, where provided (see Section 11 and Section 13).

(m) Provision shall be made for decontamination of the facility. The facility shall be constructed to contain any aerosols or gases used for decontamination. The surface finishes in the facility shall be compatible with the decontamination agents used.

NOTE The design of the facility should avoid inaccessible spaces. See Appendix H for recommendations on design for airtightness and periodical retesting.

(n) All room penetrations shall be sealed to ensure they are airtight.
6.6.3 Ventilation

A ventilation system that establishes a negative pressure in the facility shall be provided so that there is a directional airflow into the working area. Where facilities have supply air systems, the supply air and exhaust air systems shall be interlocked, to ensure inward airflow at all times. The proper directional airflow into the facility shall be verified by airflow tests. The facility (including the airlock) shall be structurally designed to take account of the operation under negative pressures.

Failure of a single component, such as an exhaust fan or a supply fan, can result in extremely high positive or negative pressures in the facility. Alarms and failure mode operations of ventilation systems shall address this risk to ensure that interlocks operate rapidly to stop systems. The facility shall be constructed to withstand, without cracking or deterioration, the maximum positive and negative pressures that can be generated until failure mode safeguards operate. Automatic and manual failure mode sequences shall be independent of any automated control system that may, itself, be the primary cause of a failure situation.

All air that leaves the facility shall be exhausted in accordance with the requirements of this Clause.

Air may be recirculated within each facility. If air is recirculated, this shall be achieved utilizing internally-mounted air conditioning equipment such as fan coil units and split system air conditioning units. Any internally-mounted equipment shall be provided with removable panels as required to ensure the complete penetration of gas or vapour during room decontamination.

NOTE 1 Ventilation equipment should be located to ensure a flow of incoming air from the vicinity of the entry door towards the highest risk microbiological work areas.

NOTE 2 The quantity of outside air supplied to the facility should comply with relevant health quality standards or regulations (see AS 1668.2) and should dilute airborne contaminants.

Ventilation equipment and outlets shall be located to minimize the disturbance to the open faces of Class I and Class II BSCs.

The facility ventilation shall incorporate the following features:

(a) The facility shall be maintained at an air pressure of at least 50 Pa below the pressure of areas outside the PC3 containment barrier when both doors of the airlock are closed. When either door is open, the facility pressure shall remain at least 25 Pa below that of areas outside the PC3 containment barrier. The 0 Pa reference pressure shall be measured to minimize the effects of fluctuations due to wind and other building ventilation systems.

NOTE Additional precautions should be considered when one or more surfaces are external and exposed to fluctuations of pressure due to wind effect. Suitable precautions include the use of an interstitial space that can be maintained at the zero reference pressure and the use of solid walls such as concrete with minimal joints, which are unlikely to be perforated or leak.

(b) The pressure differential shall be achieved by means of an independent room exhaust fan located downstream of a HEPA filter and discharging to the open air through a pre-filter and HEPA exhaust filter.

NOTE A variable speed drive on the exhaust fan is preferred to facilitate room pressure control adjustments.

(c) Supply or replacement air to the room shall be filtered using Type 1 Class A or Class B filters complying with AS 1324.1 and having a minimum arrestance efficiency of 90 % when tested in accordance with AS 1324.2 with Test Dust No. 4. Where replacement air is drawn from adjacent areas, adjustable dampers shall be provided in the transfer aperture to assist in setting up the reduced room pressure. This aperture and filter shall not be mounted in the door.

(d) Exhaust air shall be filtered and discharged to the outside atmosphere in such a manner that it is dispersed away from occupied buildings and outside air intakes.
(e) The exhaust filter shall be a HEPA type as specified in Clause 11.10.1. An exhaust pre-filter of the same standard as the supply filter shall be provided and mounted upstream of the HEPA filter. Filters shall be selected to meet the expected quantity and type of animal debris, e.g. animal dander, hair, dusts and down.

NOTE 1 Pre-filters should be located within animal rooms for ease of replacement.

NOTE 2 Ventilation rates should ensure an acceptable atmosphere quality for animal welfare. If air cooling is required, this should be achieved through cooling coils mounted external to the occupied rooms.

(f) The HEPA filter shall be installed, housed and maintained as specified in Clause 11.10.2.

(g) For each ventilation system a differential pressure gauge shall be visible and readable from immediately outside the facility.

(h) Any tubing that forms part of the facility pressure sensing and control equipment shall be fitted with a 0.2 μm hydrophobic membrane filter (such as a miniature disk filter), located as close as possible to the PC3 containment barrier. Filters and tubing shall be protected against mechanical damage.

(i) An emergency stop button shall be provided for each ventilation system outside the facility, adjacent to the exit.

The emergency stop button shall operate independently of the main ventilation control and main facility pressure control system such that emergency isolation of the ventilation can be implemented in event of central control system malfunction.

(j) An audible emergency alarm shall be provided within the facility to indicate a loss of negative pressure and a visible alarm shall be provided outside the facility to indicate the same. Alarms shall be sufficiently sensitive to occur before any facility pressure becomes positive and before any pressure reversal occurs between different pressure zones within the facility. Alarm set-points should have sufficient tolerance such that false alarms do not occur. The alarms shall be generated within 2 min of such loss of pressure control.

NOTE The selection of alarm type and the provision of mute switches should be considered to address animal welfare concerns associated with sudden or prolonged noises.

(k) In multiple room and multiple zone applications, sufficient monitoring points and alarms shall be provided to capture a loss of pressure control in any space within the facility.

NOTE Additional pressure gauges and emergency stop buttons should be considered where applicable.

(l) Annual testing by competent persons shall include the following:

(i) Testing of the pressure differentials in accordance with AS 1807.10 to ensure compliance with the requirements in Item (a).

(ii) Integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7, as applicable.

(iii) Checking that the control system is operating correctly and verifying alarms are set to operate in accordance with Item (j) on a loss of room pressure.

(iv) Calibration of pressure control and indicating devices.

(v) A report of the testing in Items (i) to (iv) and of any maintenance conducted shall be provided to the appropriate person for the facility.

(m) Exhaust air from Class III BSCs shall be discharged through the building exhaust system through direct ducting or a capture hood. It shall not be recirculated through the facility.

Capture hood air flow shall exceed cabinet discharge air flow by sufficient margin to ensure full entrainment of cabinet discharge air into the exhaust air stream. Discharges shall be designed and
located outside of the building to ensure external air velocities do not adversely affect containment air flows and pressures within the cabinets.

NOTE 1 Care should be exercised with direct ducting with respect to pressure fluctuations. Capture hoods may be inappropriate for gases and vapours.

NOTE 2 The exhaust air from Class I or Class II biological safety cabinets may be discharged into the facility or through the building exhaust system in accordance with AS/NZS 2647.

NOTE 3 Capture hoods may be inappropriate for toxic gases and vapours.

6.6.4 Access to services

Access to voids surrounding the immediate perimeter of the facility and to the ventilation equipment that serves the facility shall be restricted to authorized persons. Items of equipment, ducts and access panels to contained sections of the ventilation system shall be marked with biohazard labels to minimize the risk of accidental exposures to air or to contaminated surfaces. The installation of services shall ensure proper access to equipment such as HEPA filters for maintenance and testing personnel and their equipment.

6.6.5 Containment equipment

In addition to equipment specified for Terrestrial Animal PC2 (see Clause 6.5.4), a Class III BSC shall be provided where appropriate (see Clause 11.7.2).

6.6.6 Work practices

In addition to work practices specified for Terrestrial Animal PC1 (see Clause 6.4.3) and PC2 (see Clause 6.5.5) facilities, the following shall apply:

(a) All containment features of the completed facility shall be tested, commissioned and the results documented, before use.

(b) The facility shall be inspected at least annually by the BC or operator to ensure that its containment requirements comply with Clauses 6.6.2(a) and 6.6.3 by reviewing records including HEPA filter integrity test reports and room pressure readings.

(c) The facility management shall establish policies and written procedures whereby only persons who have been advised of the biohazard, and who meet any medical requirements, shall enter the facility (see Clause 2.6).

(d) An effective emergency evacuation plan shall be devised and information on the plan shall be available to all facility staff and local emergency services.

(e) All facility staff shall have specific training in handling pathogenic organisms and in the use of safety equipment and controls. The staff shall be supervised by senior scientists who are experienced in working with pathogenic microorganisms.

(f) Only trained people authorized by the BC or operator shall enter the animal facility, and then only after they have been advised of the hazard and met all specific requirements, such as immunization.

(g) The facility door shall be locked when the room is unoccupied by personnel [see also Clause 6.6.2(a)].

(h) Outer clothing and personal effects shall not be taken into the facility.

(i) No one shall enter the facility for cleaning, servicing of equipment, repairs, room maintenance or other activities before the relevant, potentially contaminated surfaces have been decontaminated and authorization has been obtained from the facility supervisor or the safety officer. Dedicated cleaning equipment shall be stored within the facility.
(j) If the animal facility does not form the primary containment measure, all animal handling procedures with potentially infectious or infectious materials shall be done either in a Class I or II BSC (or the equivalent).

NOTE The provision of an uninterruptible power supply should be considered for BSCs.

(k) All equipment used in the facility shall be decontaminated prior to maintenance, service or removal.

(l) If a double-ended pressure steam sterilizer is installed across the barrier, it shall be decontaminated after each exposure to the facility environment.

(m) Microbiological wastes, animal excrement, liquid effluents, animal bedding, animal cages and animal carcasses shall be decontaminated in a pressure steam sterilizer. Waste material shall then be disposed of in accordance with Clause 13.2. Additionally, if floor drains are present, all effluents shall be rendered safe in accordance with Clause 13.2 before discharge.

(n) Live animals or viable biological material shall only be taken to an equivalent or higher level of containment.

(o) Viable biological materials to be removed from the containment laboratory shall be transferred to a non-breakable, sealed primary container, the external surface of which is decontaminated before enclosure in a non-breakable, sealed secondary container.

(p) Protective clothing shall be removed in a predetermined appropriate order before leaving the animal facility.

(q) Protective clothing shall not be worn outside the facility and shall be decontaminated by pressure steam sterilization prior to laundering or disposal.

(r) Where the animal facility forms the primary containment measure, and there is a risk of infectious material adhering to personnel, a full body shower shall be taken upon exiting the facility.

(s) Measures shall be taken to ensure no microbiological contamination is removed from the facility on footwear.

NOTE Suitable measures include the use of dedicated facility footwear, the use of overshoes or a combination of these measures.

(t) In the event of a power failure, entry to the facility shall be restricted until services have been restored.

6.6.7 Health monitoring

See Clause 2.6.

6.7 Requirements for terrestrial animal PC4 facilities

6.7.1 General

A Terrestrial Animal PC4 facility is suitable for work with infectious microorganisms in Risk Group 4 and incorporates all equipment and practices for Terrestrial Animal PC1 (see Clause 6.4), PC2 (see Clause 6.5) and PC3 (see Clause 6.6). However, additional requirements on conditions of access and egress, safety equipment and staff training apply, as listed below.

A Terrestrial Animal PC4 facility may be one of two types —

(a) a facility where small animals are kept in individually ventilated isolators or Class III BSCs in the Terrestrial Animal PC4 facility; or

(b) a facility set up for the use of fully-encapsulated, positive pressure personnel suits ventilated by a life-support system.
When pathogenic microorganisms of Risk Group 3 or 4 are being used in association with small animals, primary containment measures such as BSCs or individually ventilated isolators fitted with HEPA exhaust filters shall be used. Where primary terrestrial animal containment measures cannot be used, the facility forms the primary containment measure.

NOTE The design of a Terrestrial Animal PC4 facility is complex and those planning its construction should seek specialized advice. See also Appendix G for examples of recommended layouts for PC4 facilities showing the design principles involved and Appendix H for airtightness considerations.

6.7.2 Alternative locations for animal work

Animals may be kept in PC4 facilities in the following ways:

(a) **PC4 laboratories** — Small animals in appropriate cages or containers may be kept in Class I or Class II BSCs in a PC4 laboratory where staff wear one-piece positive pressure personnel suits ventilated by a life-support system.

NOTE The exhaust air from Class I or Class II BSCs may be discharged into the facility or through the building exhaust system (see also Clause 11.7.1).

In addition to the work practices used in PC4 laboratories (see Clause 5.5.5), the following work practices apply:

(i) All staff shall have specific training in handling Risk Group 4 organisms in the relevant animal species and in the use of safety equipment and operation of the facility.

(ii) Microbiological wastes, animal excrement, liquid effluents, shower effluents, animal bedding, small animal cages and animal carcasses shall be decontaminated, preferably by pressure steam sterilization, before disposal in accordance with Clause 13.2.

(b) **Primary containment devices in Animal PC4 facilities** — Animals may be kept in individually ventilated isolators or Class III BSCs in a Terrestrial Animal PC4 facility if the exhaust air from the Class III BSCs is discharged through the building exhaust system. In such Animal PC4 facilities, operators may not need to wear positive pressure personnel suits.

The exhaust from the Class III BSC may be direct-ducted or a capture hood may be used. The exhaust air shall not be recirculated. Capture hood air flow shall exceed cabinet discharge air flow by sufficient margin to ensure full entrainment of cabinet discharge air into the exhaust air stream. Discharges shall be designed and located outside of the building to ensure external air velocities do not adversely affect containment air flows and pressures within the cabinets.

NOTE 1 Care should be exercised with direct ducting with respect to pressure fluctuations.

NOTE 2 See also Clause 11.7.2.

In addition to the requirements in Clauses 6.7.3 to 6.7.7 (other than those in Clauses 6.7.3.2, 6.7.4.2 and 6.7.6.2), procedures for handling animals in individually ventilated isolators or Class III BSCs fitted with an exhaust HEPA filter shall be documented following a risk assessment of the hazards involved with the infectious agent and animal species.

(c) **Terrestrial Animal PC4 facilities where the room is the primary containment measure** — In such Terrestrial Animal PC4 facilities staff wear one-piece positive pressure personnel suits ventilated by a life-support system and additional requirements specified in Clauses 6.7.3 to 6.7.7 apply, including those in Clauses 6.7.3.2, 6.7.4.2 and 6.7.6.2.
6.7.3 Construction

6.7.3.1 General

In addition to the construction requirements specified for Terrestrial Animal PC1 (see Clause 6.4.2), PC2 (see Clause 6.5.2) and PC3 (see Clause 6.6.2) facilities, the following shall apply:

(a) The facility shall be housed in a separate building or shall form an isolated part of a building. Full access to all exterior surfaces of the contained structure and service penetrations shall be provided to facilitate periodic integrity testing. The perimeter of the facility shall be protected against adverse pressure fluctuations due to wind or other external factors. The facility negative pressure shall be maintained across the floor, wall and ceiling boundaries at all times.

NOTE Recommendations for achieving acceptable room airtightness are given in Appendix H.

(b) Any transparent sections shall be constructed of impact-resistant materials.

(c) An outer and inner change room, separated by a shower airlock with interlocking, self-closing doors, shall be provided for personnel entering and leaving the facility. The outer door of the facility shall be lockable.

NOTE 1 A security card access procedure, with additional numerical pad or biometric access control, is preferred as a means of entry.

The outer shower door shall form the facility containment boundary for decontamination purposes.

The four doors of each entry/exit path shall raise an alarm if left open.

An entry and egress "traffic light" alarm system or door interlock control system shall be provided to prevent the simultaneous opening of the doors on each side of the shower.

NOTE 2 The use of pneumatically sealed doors should be considered on both sides of the shower.

NOTE 3 A timer should be provided to permit personnel to shower for a defined period as part of the exit procedure.

NOTE 4 Privacy for changing and showering may require door access features and interlocks or alarms additional to the above biocontainment requirements.

NOTE 5 The use of interlocks requires the provision of manual overrides in case of emergencies.

NOTE 6 The inner change room may provide the functions of the anteroom as set out in Clause 6.5.2(n).

(d) Walls, floors and ceilings of the facility shall be constructed in such a manner as to form a sealed internal shell which facilitates gaseous decontamination. The internal surfaces of the shell shall be resistant to liquids and chemicals used in the facility and shall facilitate easy cleaning and decontamination. All apertures in the structures and surfaces shall be sealed to prevent vermin or insects from entering the area. Glazing in windows shall be of laminated security glass selected to withstand the maximum pressure differential imposed during all operating conditions, including all possible failure modes, and during testing.

(e) A double-ended pressure steam sterilizer shall be provided to decontaminate materials from the facility and from the inner clothing change room. The outer sterilizer door shall open to the area external to the facility. The inner door shall automatically interlock with the outer door in such a manner that the outer door can be opened only after the sterilization cycle has been completed. The sterilizer shall comply with the requirements of Clause 11.6.

(f) A pass-through dunk tank, decontamination chamber or equivalent decontamination equipment shall be provided, so that materials and equipment that cannot be decontaminated in the pressure steam sterilizer can be rendered safe for removal from the facility.
(g) A suitable decontamination system shall be provided for handling all effluents, including those from any showering facility, in accordance with Section 13.

(h) An automatic changeover emergency power source, emergency lighting and communication systems shall be provided. The emergency power source shall be adequate to operate the ventilation systems, BSCs, room access and shower controls. An uninterruptible power supply shall be provided to ensure uninterrupted operation of the shower controls and ventilation control system.

6.7.3.2 Positive pressure suit area

For certain requirements, a specially designed suit area may be provided within the facility. Personnel who enter this area shall wear a one-piece positive pressure suit that is ventilated by a life support system. If provided, positive pressure suit areas shall comply with the following additional requirements:

(a) Entry shall be via an outer change room that leads to an airlock fitted with a personal body shower then into an anteroom leading to a second airlock fitted with a chemical disinfectant shower provided to decontaminate the surface of the suit before the worker leaves the area.

(b) A breathing quality air supply for connection to the positive pressure suit shall be provided in the anteroom, chemical shower and experimental area. Quick-connect fittings shall be provided on the suit and the air supply lines to ensure prompt disconnect and reconnect when moving between anteroom, chemical shower and experimental areas.

(c) All penetrations into the internal shell of the suit area shall be sealed.

(d) An alarm and emergency back-up breathing air system.

6.7.4 Ventilation

6.7.4.1 General

The facility ventilation shall comply with the following:

(a) A separate supply and exhaust, non-recirculating air ventilation system shall be provided. The system shall maintain such pressure differentials and directional airflow to ensure airflows toward areas of highest potential risk within the facility. There shall be a differential pressure of at least 25 Pa between each area (see Figure F.5). The system shall be provided with an alarm to detect malfunction. The supply and exhaust airflow shall be interlocked to ensure inward (or zero) airflow at all times. Differential air pressures between facility zones shall be monitored by use of a differential pressure gauge as specified in Clause 6.6.3(g).

(b) Both supply and exhaust air shall be filtered through HEPA filters as specified in Clause 11.10.1. The HEPA filters shall be installed and housed as specified in Clause 11.10.2. Pre-filters to both the supply and exhaust HEPA filters shall be provided as specified in Clause 6.6.3(c) and (e).

The supply air HEPA filter shall prevent the outflow of contaminated air if air pressures become imbalanced within the facility.

(c) The ventilation control system shall raise an audible alarm within the facility and at an attended location when room differential air pressures depart from set points by more than 15 Pa for a period of greater than 2 min.

(d) Annual testing by a competent person shall include the following:

(i) Testing of the pressure differentials in accordance with AS 1807.10 to ensure compliance with Item (a).
(ii) Integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7, as applicable.

(iii) Checking that the control system is operating correctly and verifying alarms are set to operate in accordance with Item (c).

(iv) A report of the testing in Items (i) to (iii) and of any maintenance conducted shall be provided to the appropriate person for the facility.

6.7.4.2 Positive pressure suit area

In addition to the requirements in Clause 6.7.4.1, the following ventilation system features shall be provided for a positive pressure suit area:

(a) The exhaust air shall be filtered through two HEPA filters installed in series.

(b) Duplicate ventilation equipment shall be provided to automatically re-establish facility ventilation and pressure conditions in event of equipment failure. Controls and equipment operation shall prevent a positive pressure occurring within the facility at all times, including the failure of an exhaust fan.

(c) The air pressure within the experimental area shall be lower than that of the chemical shower airlock which, in turn, shall be lower than the adjacent entry/exit and non-suit areas.

NOTE A 25 Pa differential for each airlock is recommended.

6.7.5 Containment equipment

For work with agents of Risk Group 4, either of the following shall be provided:

(a) A Class I or Class II BSC [see Clause 6.7.6.1(h)] where the facility forms the primary containment measure.

(b) A Class III BSC (see Clause 11.7).

6.7.6 Work practices

6.7.6.1 General

In addition to the work practices specified for Terrestrial Animal PC1 (see Clause 6.4.3), PC2 (see Clause 6.5.4), and PC3 (see Clause 6.6.5) facilities, the following shall apply:

(a) All staff shall be trained in the specific working aspects of the facility, including the safety equipment, the operation of the facility and containment and clean-up of infectious spills. Staff shall use the safety equipment provided. Staff shall receive specific training, with written instructions and information in the handling of the relevant microorganisms in the relevant animal species.

(b) Staff shall be supervised by senior scientists who are trained and experienced in working with the relevant microorganisms and animal species. A facility operations manual shall be prepared.

(c) Access shall be controlled to allow entry by authorized staff only. A list of contact names and phone numbers shall be provided outside the entry point.

(d) Personnel shall enter and leave the facility through the clothing change and shower rooms, except in cases of emergency, where alternative exits may be used.

(e) Complete facility clothing, including shoes, shall be provided by the organization.

(f) On entering the facility, personnel shall don complete facility clothing, including shoes. All street clothing, including underwear, shall be removed and retained in the outer clothing change room.
Before leaving the facility, a full body shower shall be taken. Personnel shall remove their facility clothing and store or discard it in the inner change room before showering.

Personnel entering or leaving the facility shall indicate, either manually or electronically, the time of each exit and entry.

All procedures within the facility involving agents assigned to Risk Group 4 shall be conducted in Class III BSCs in accordance with Clause 6.7.2(h) or alternatively in Class I or Class II BSCs used in conjunction with one-piece positive pressure personnel suits ventilated by a life-support system in accordance with Clause 6.7.2(c).

Prior to disposal, all facility effluents, including those from the shower, shall be decontaminated by either heat or chemical treatment in accordance with Section 13.

The double-ended pressure steam sterilizer and decontamination chamber opening across the barrier shall be decontaminated after each exposure to the facility environment.

Unless working in one-piece positive pressure suits ventilated by a life support system, viable biological materials to be removed from Class III BSC shall be transferred to a non-breakable, sealed primary container, the external surface of which is decontaminated before enclosure in a non-breakable, sealed secondary container, which is decontaminated on removal from the isolator. A primary container holding viable or intact biological materials shall be opened only in another Class III BSC in the PC4 laboratory or another PC4 laboratory [see Item (m)].

NOTE Containers may be opened in non-PC4 laboratories only if the biological material has been rendered non-infectious, and the space in the primary and secondary containers has been decontaminated.

Viable biological materials to be removed from the laboratory shall be removed from the facility in a sealed secondary container [see Item (l)] and by passing through a disinfectant dunk tank or gaseous decontamination chamber or airlock designed for this purpose. No other materials shall be removed from the facility unless they have been decontaminated. Equipment or materials which might be damaged by high temperatures or steam shall be decontaminated in an airlock or specially designed chamber by means of sterilizing gas or vapour.

NOTE Containers may be opened in non-PC4 laboratories only if the biological material has been rendered non-infectious provided they are opened within a Class II BSC.

Risk Group 4 material shall only be stored within the facility.

A risk assessment of the working environment shall be undertaken encompassing all matters influencing the personal safety of staff. Monitoring and emergency procedures shall be prepared and implemented at a level commensurate with the outcome of the risk assessment.

NOTE The presence of a coworker either inside the facility or observing the work from outside the facility should be considered.

Checks shall be carried out to ensure monitoring and communication arrangements result in the emergency procedures being initiated in a timely manner and to ensure the procedures are adequate.

6.7.6.2 Positive pressure suit area

In addition, the following work practices apply for positive pressure suit areas:

Upon entering the anteroom, the person shall don a positive pressure suit prior to entering the second (chemical shower) airlock.

When exiting the suit area, a chemical disinfectant shower shall be taken to decontaminate the outer surface of the suit. The disinfectant shall be effective against the microorganisms used in the suit area at the concentration at which it is used in the shower taking into account the time and temperature defined for the shower. The suit and clothing shall be removed in the anteroom and a full body shower shall be taken in the shower airlock.
(c) Microbiological wastes, animal excrement, liquid effluents, shower effluents, animal bedding, small animal cages and animal carcasses shall be decontaminated, preferably by pressure steam sterilization, before disposal in accordance with Clause 13.2. Additionally, if floor drains are present, all effluents shall be decontaminated in accordance with Clause 13.2 before discharge.

6.7.7 Health monitoring

See Clause 2.6.

Section 7 Plant containment facilities

7.1 General

Plant microorganisms are not usually directly hazardous to humans. They may, however, pose a significant hazard to the environment, agriculture and forestry. Plants infected with microorganisms classified into Plant Risk Groups 1 to 3 require corresponding PC level facilities. Selection of the level of containment required to prevent escape will depend on the biology of the organism and the impact that escape might have on the environment.

Hazards associated with plant facilities include propagules, such as seeds and pollen, tiny invertebrates and plant microorganisms. Compliance with microbiological, animal and invertebrate sections of this Standard shall be included where applicable.

Plant containment facilities are intended to prevent the escape of plants and seeds and limit the entry and escape of invertebrate vectors in order to prevent dissemination of plant infectious microorganisms.

This Section sets out requirements for four levels of plant PC facilities for plants infected with microorganisms. The appropriate location, construction requirements and work practices are shown in Clause 7.2 for Plant PC1 facilities, while Clauses 7.3 and 7.4 cover Plant PC2 and Plant PC3 facilities respectively.

NOTE This Section is not intended to cover the use of plant growth cabinets within laboratories.

7.2 Requirements for plant PC1 facilities

7.2.1 General

The following standard of plant containment facilities and work practices (Plant PC1) is regarded as a suitable minimum for work with plants infected with plant microorganisms in Plant Risk Group 1. Plant PC1 facilities provide the most basic containment and include open fields and structures comprising greenhouses, screen houses and flexible film plastic structures.

7.2.2 Location

Plant PC1 facilities have no special location requirements. For location considerations for aquatic containment facilities, see Clause 9.3.7.

7.2.3 Construction

Plant PC1 facility structures shall comply with the following:

(a) The floor, walls, ceiling and roof shall be suitable for the plant species and appropriate for the local climate. Transparent sections of the walls and roof covering shall be made out of a suitable material that resists deterioration from the elements.

   NOTE Suitable materials include glass, polycarbonate, flexible film plastics such as polythene or screens.

(b) All work surfaces shall be easily cleaned.
(c) Ventilation and shading shall be provided to maintain adequate light and internal conditions for research and to maintain plants in good health.

(d) Backflow prevention for water supplies shall comply with Appendix E.

(e) Gas supplies in the facility shall comply with the general requirements specified in Clause D3.1.

(f) Where human pathogens are not present and there is a risk to the health of workers through dehydration, due to circumstances such as heat stress, heavy work or long shifts in response to emergencies, drinking facilities may be provided in the facility. This shall be subject to approval by the BC, following a risk assessment of the particular situation. If drinking facilities are provided, they shall be via a drinking fountain in a designated area with work practices instituted to ensure gloves are removed and hands are washed prior to drinking.

NOTE The drinking fountain should be the hands-free operation type.

7.2.4 Work practices

The work practices for Plant PC1 facilities shall be as follows:

(a) Access to the facility shall be restricted to authorized personnel. All such personnel shall be appropriately trained.

NOTE 1 Procedures should be consistent with good agricultural and horticultural practice, including pest and disease control management.

NOTE 2 Plants should be raised off the floor on non-absorptive benches to minimize disease contamination.

(b) All means of access to the facility shall be closed and locked when the facility is not under direct supervision.

(c) The production of aerosols shall be minimized, particularly where work is carried out on the open bench (see also Clause 3.1).

(d) Cultures shall be clearly identified and dated.

(e) Because airborne fungal spores can be easily spread in a similar manner to aerosols, cultures of spore-producing fungi shall be covered or sealed, as appropriate, to prevent dispersal.

(f) Chemicals shall be stored in the facility in accordance with AS/NZS 2243.10.

(g) Local exhaust ventilation or a fume cupboard shall be used when determined appropriate by a risk assessment of any work with toxic, volatile, corrosive or odoriferous substances.

NOTE 1 BSCs are not designed for this purpose (see Clause 11.1).

NOTE 2 AS/NZS 2982 should be consulted for local exhaust ventilation requirements.

(h) Reusable non-contaminated PPE shall be retained in the facility between uses, and kept segregated from unused PPE.

(i) Eating, smoking and the storage of food for human use shall not be permitted in the facility.

(j) Drinking and the storage of drink for human use shall only be permitted in the facility in accordance with Clause 7.2.3(f). If drinking facilities are provided, work practices shall be instituted to ensure gloves are removed and hands are decontaminated prior to drinking.

(k) Waste shall be segregated and disposed of according to applicable regulations, using the most appropriate and effective method for the materials concerned (see also Section 13).
7.3 Requirements for plant PC2 facilities

7.3.1 General

The following level of plant containment facilities and work practices (Plant PC2) is regarded as a suitable minimum for work with plants infected with plant microorganisms in Plant Risk Group 2. Plant PC2 facilities incorporate all the appropriate requirements of Plant PC1 containment facilities as well as the additional requirements relating to location, construction and work practices specified in Clauses 7.3.2 to 7.3.4.

Plant PC2 facilities include permanent greenhouse structures with an anteroom or a corridor with self-closing doors to restrict access. Containment is achieved primarily through the creation of a physical barrier. Windows and ventilation inlets and outlets are screened and effective pest control procedures are in place.

7.3.2 Location

The Plant PC2 facility should have a buffer zone of at least 3 m free of primary or alternative hosts that may be susceptible to infection from the plant microorganisms being used in the containment facility. For location considerations for aquatic containment facilities, see Clause 9.3.7.

7.3.3 Construction

In addition to the construction requirements specified for Plant PC1 facilities in Clause 7.2.3, the following shall apply:

(a) Floors, ceilings, benches and walls of the facility shall be smooth, easy to clean, impermeable to liquids and resistant to commonly used reagents and disinfectants. Floors shall be coved to walls and exposed plinths to facilitate cleaning. Benches shall be finished with a material that is impermeable to liquids, have any joints sealed, and be sealed to end walls and sinks where there is a wet area. Materials, services and equipment shall be designed and installed such that infestation by invertebrates or vermin can be managed and eradicated when required.

(b) Where the facility contains plant holding platforms, they shall be smooth, impermeable to liquids and resistant to commonly used reagents and disinfectants.

(c) Transparent sections of the walls and roof covering shall be made out of glass, polycarbonate or similar suitable material which resists deterioration from the elements, environmental and climatic events and attack by vermin and invertebrates. Screen material shall not be used as the primary construction covering. Where required, structural joints shall be durable, impermeable, easy to clean and shall resist deterioration due to commonly used cleaning agents, common disinfectants and, where applicable, exposure to ultraviolet radiation. The seal of the facility shall be maintained during thermal expansion and contraction of building elements.

NOTE Structural joints should be minimized in containment facilities.

(d) If the Plant PC2 facility is freestanding, it shall have an anteroom for entry and exit. The anteroom shall be fitted with a properly-maintained sticky pest strip or other automatic device designed to attract and kill invertebrates that may gain entry. The anteroom shall allow materials, equipment and trolleys to pass through, ensuring one door can be closed at all times. Anteroom doors shall be fitted with self-closing devices and seals to top, bottom and sides. Openings directly to the outside, such as emergency egress doors, shall be sealed to an equivalent maximum aperture size as specified in Clause 7.3.3(f).

(e) Doors between plant PC2 facilities and adjacent spaces shall be fitted with self-closing devices and seals to top, bottom and sides. Suitable storage for gowns shall be provided within the facility, located adjacent to the exit.

(f) Any openings in the walls, ceiling or roof, such as windows, vents and air conditioning or ventilation inlets and outlets, and any other specialist ventilation openings, shall be screened at
the containment boundary with fine mesh screens having apertures of sufficiently small gauge to prevent entry or egress of invertebrates. The mesh shall be —

(i) stainless steel; or

(ii) suitable material with regards to its —

(A) mechanical strength under the airflow load;

(B) ability to remain undamaged with the regular vigorous cleaning needed to remove dust and plant fibre;

(C) corrosion resistance; and

(D) resistance to attack by insects from either inside the containment facility or from the local environment outside the facility.

NOTE 1 The recommended maximum aperture size for general applications is 0.25 mm (250 μm). Standard 0.25 mm aperture/0.16 mm wire gauge stainless steel mesh satisfies this requirement. Smaller aperture sizes of 0.10 mm (100 μm) may be required for work that involves some invertebrates such as mites and thrips.

NOTE 2 In locations where dust and debris can be generated, the use of roughing pre-filters upstream of the mesh screens can result in safer and easier cleaning.

NOTE 3 Care is recommended to ensure that equipment requiring regular cleaning and maintenance are located in safely accessible locations, especially in constructions such as greenhouses.

NOTE 4 Refer to AS 1668.2 for general filtration requirements to provide indoor air contaminant control in buildings.

NOTE 5 Ducted fume cupboards should not be installed within plant facilities so that the requirement for mesh screening of the exhaust path can be avoided. Fume cupboards should be installed in adjacent microbiological laboratories where required. Where installation within a plant facility is required, the use of a recirculating type fume cupboard can be considered.

NOTE 6 Inward air flow is not normally a requirement for PC2 plant facilities. However, where microbiological material may become airborne a risk assessment may be necessary to identify if filtration and exhaust is required, and to identify any aspects of microbiological containment listed in Section 5 which may apply, such as inward air flow.

(g) The drainage exits shall conform to local council standards with all wastewater draining to an approved disposal system, such as a sewerage or septic system. Liquid drainage exits shall be protected against entry or exit of rodents and invertebrates by the use of adequately replenished traps or by an equivalent effective method. Soil traps shall be installed in drains in locations where drainage inflow is likely to contain soil or sand (see also Section 13).

(h) Suitable enclosed containers for storage of solid plant waste material shall be available within the containment facility.

(i) A pressure steam sterilizer shall be available where steam sterilizing of infectious facility wastes is required (see also Clause 11.6 and Section 13).

NOTE The pressure steam sterilizer should be as close to the facility as possible.

(j) A dedicated, single-outlet hand basin of a hands-free operation type, or alternative means of decontaminating the hands, shall be provided inside each facility, in a position on the pathway towards the exit which supports appropriate use of the hand basin as part of the recommended exit procedure.
NOTE Where a PC2 laboratory is directly connected to the Plant PC2 facility, the hand decontamination facilities may be in the laboratory.

(k) A sign complying with Appendix D showing the biological hazard symbol and the level of containment, together with hazard symbols as appropriate, emergency contacts and any access restrictions, shall be posted at each entrance to the facility.

(l) Gas supplies in the facility shall comply with the backflow prevention requirements specified in Clause D3.2.

(m) If drinking facilities are provided, they shall be via a hands-free operation drinking fountain.

7.3.4 Containment equipment

7.3.4.1 Biological safety cabinets

A Class I or II BSC (see Clause 11.7) shall be provided if there is a potential for personnel to become infected by aerosol generation.

NOTE 1 Refer to Figures 1 and 2 of Clause 5 of AS 2252.4 for guidance on installation and location of BSCs.

NOTE 2 See Appendix H for information and recommendations concerning safe use of the BSC.

NOTE 3 Refer to Clause ZZ14 of AS 2252.4 for information related to decontamination of the BSC.

Where requirements in AS 2252.4 conflict with requirements in this Standard, the requirements in this Standard shall take precedence.

7.3.4.2 Centrifuges

When potentially infectious or infectious materials are used, a centrifuge fitted with either sealed rotors or sealed buckets shall be used (see also Clause 11.3).

7.3.5 Work practices

In addition to the work practices specified for Plant PC1 facilities in Clause 7.2.4, the following shall apply:

(a) The facility shall be inspected at least annually to ensure that its containment features are intact. The buffer zone surrounding the facility shall be free of debris, rubbish, overhanging trees and shrubs. Screens, filters and similar equipment shall be cleaned in accordance with manufacturer's specified frequency and procedures.

(b) Packages of containers of plant microorganisms shall only be opened within the containment facility. Packaging material shall be decontaminated as soon as possible (see also Section 13).

(c) For plant work producing a significant risk from aerosol production, a BSC or other equipment designed to contain the aerosol shall be used. A period of at least 5 min shall be allowed for aerosols to settle before opening homogenizer or sonicator containers in a BSC.

NOTE Large items of equipment can interfere with the airflow pattern in a Class II BSC and correct operation of the cabinet should be validated with the equipment in situ (see Clause 10.3.1).

(d) Personnel shall wear appropriate protective clothing and footwear within the facility (see Clause 11.2). Gloves shall be worn when working in a BSC.

(e) Gowns shall be kept in the facility between uses, kept segregated from unused PPE, and shall be laundered at appropriate intervals.
(f) Measures shall be taken to ensure no plant or microbiological contamination enters or leaves the facility on footwear. Suitable measures include the use of dedicated facility footwear, the use of overshoes and the use of footbaths containing effective disinfectant.

(g) Care shall be taken in the use of syringes, needles and other sharps. Sharps containers shall be provided at each point of use. Precautions shall always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes and scalpels. Needles and syringes or other sharp instruments shall be restricted for use only when there is no alternative.

NOTE 1 Sharps use should be eliminated wherever possible.

NOTE 2 Staff should be aware of the potential for glass equipment such as pipettes and tissue grinders to become sharps during an accident. Plastic ware should be substituted for glassware whenever possible.

(h) Application of pesticides shall be performed utilizing appropriate PPE.

(i) The facility shall have an effective rodent and invertebrate control program in place. Plants shall be inspected at appropriate intervals for signs of infestation or unwanted disease infections.

NOTE If the work permits, plants should be sprayed regularly with an appropriate insecticide.

(j) Living plants or tissues shall not be taken from the facility except to a facility of the same PC level or higher. Transport of Plant PC2 materials shall comply with Section 14.

(k) Potting of plants that have been infected with PC2 organisms or potentially contaminated plants shall occur within the containment boundary.

(l) Waste plants, tissues, soil, soil substitutes and planting pots shall be collected in a sealed insect-proof container and decontaminated. Pruning and other equipment shall be decontaminated prior to removal from the facility. Dead or unwanted plant material and spilled growing medium shall be cleaned up immediately followed by decontamination of affected areas (see also Section 13).

NOTE Soil substitutes that can be readily decontaminated should be used whenever possible. Use of soil is discouraged.

(m) PPE shall be removed and hands decontaminated in a predetermined appropriate order, after handling potentially infected material and prior to leaving the facility.

NOTE 1 The order is usually removal of gloves followed by hand decontamination, then eye protection and laboratory gown followed by a second hand decontamination.

NOTE 2 Appropriate protocols for laundering or decontaminating PPE should be implemented.

(n) If potentially infectious or infectious materials have been spilled on gowns or protective clothing, these items shall be decontaminated, preferably by steam pressure sterilization prior to laundering or disposal (see Section 10).

7.4 Requirements for plant PC3 facilities

7.4.1 General

The following standard of Plant PC3 facilities and work practices is regarded as a suitable minimum for work with plants infected with plant microorganisms in Plant Risk Group 3. Plant PC3 facilities shall incorporate all the appropriate requirements of Plant PC1 and Plant PC2 facilities as well as those of Clauses 7.4.2 to 7.4.6.

Plant PC3 facilities include permanent greenhouse structures with sealed windows and all ventilation inlets and outlets fitted with appropriate screens and filters to prevent ingress and egress of unwanted invertebrates. Containment is achieved primarily through good operational practices, the use of protective clothing and effective sanitation. Supporting containment is achieved by solid construction, negative pressure within the contained environment, and the use of HEPA exhaust air filters. Plant
PC3 facilities are suitable for use with plants infected with exotic plant microorganisms that present a significant hazard to plants and can spread naturally without the assistance of a vector.

NOTE The design of a PC3 facility is complex and those planning its construction should seek specialized advice. See also Appendix G (Figures G.1 to G.5) for examples of recommended layouts for PC3 facilities showing the design principles involved and Appendix H for airtightness considerations.

### 7.4.2 Location

Plant PC3 facilities shall be protected against flooding and storm surges.

Structural design for wind loads shall take into account wind region maps (refer to AS/NZS 1170.2).

Where Plant PC3 facilities are proposed to be located in active seismic zones, the structural design shall take into account the potential for seismic damage.

### 7.4.3 Construction

In addition to the construction requirements specified for Plant PC1 (see Clause 7.2.3) and Plant PC2 (see Clause 7.3.3) facilities, the following shall apply:

(a) The facility shall be constructed with a rigid reinforced frame with walls, floors and glazing forming a shell. Floors shall be slip resistant. Transparent sections shall be made of impact-resistant material such as methyl-methacrylate ("perspex") or reinforced glass. Impact resistance shall include hailstone protection. Additional protection shall be provided where required to protect against extreme climatic events (see Clause 4.4).

(b) The facility shall be physically separated from other areas, including offices used by facility personnel, by a double-door system where entry to the facility is gained only through an airlock or shower airlock. For an airlock, the doors shall open outwards and the outer door shall be lockable. For a shower airlock, the outer door of the shower airlock shall open outward. Either the door to the outer change room or the outer door of the shower airlock shall be lockable. Airlock and shower airlock doors shall be self-closing and fitted with seals to limit air leakage and entry/egress of invertebrates when closed. The airlock or shower airlock shall allow materials, equipment and trolleys to pass through, ensuring one door can be closed at all times. The airlock or shower airlock shall be fitted with a sticky pest strip or alternative automatic device designed to kill invertebrates that may gain entry. Provisions, such as drop down door seals fitted to both inner and outer doors of the airlock or shower airlock, shall be made to deter vermin and invertebrates from entering or exiting the plant containment facility. The facility shall be provided with a footbath containing a suitable disinfectant.

Where the facility forms the primary containment measure and there is a risk of microorganism escape via plant material adhering to personnel, an outer and inner change room, separated by a shower airlock shall be provided. The outer shower door shall form the limit of Plant PC3 containment for decontamination purposes.

NOTE 1 The preferred location of the footbath is immediately inside the work area.

NOTE 2 The airlock or shower airlock takes the place of the anteroom required for Plant PC2 facilities.

NOTE 3 Where separate plant rooms are contained within a PC3 facility, consideration should be given during the design of the air handling system to the use of a common system or the need for individual air exhaust systems, HEPA filters and duct isolation valves to facilitate gaseous decontamination of all or part of the facility.

NOTE 4 The airlock or shower airlock is provided to ensure the maintenance of the negative pressure within the facility and prevent airflow between the facility and areas external to the facility. It should not be used for any work, nor should it contain any equipment, washing facilities (apart from the shower where it is used as a shower airlock) or PPE worn in the facility.
NOTE 5 Consideration should be given to the provision of a gaseous decontamination chamber for facilities that require removal and installation of equipment that cannot be steam sterilized. This facilitates removal of such items without the need to decontaminate the complete facility.

NOTE 6 Depending on size, removable panels to allow for entry and exit of large items of equipment should be considered. These should be readily resealable to an airtight condition following use.

NOTE 7 Building regulations may require alternative egress in certain facility configurations. These exits are required to be accessible and easily usable without compromising facility seal integrity. Lockable doors need to permit emergency egress in accordance with building regulations.

(c) Means shall be provided for minimizing disturbance of pressure differentials by reducing the likelihood of both airlock doors being opened at the same time.

NOTE Examples of suitable mechanisms include entry and egress “traffic light” alarm systems, door interlock control systems or viewing panels if suitable.

(d) Means shall be provided to prevent powered air lock doors from opening simultaneously in the event of power loss or emergency. Manual overrides may be used to address emergency egress requirements.

(e) The allocation of task zones and layout within the facility shall promote the movement of ventilation air from the entrance and towards the more contaminated zones such as BSCs and steam sterilizer loading trolleys.

Care shall be taken to avoid turbulence or ventilation system air movement within the vicinity of BSCs that could interfere with the stability of the work face air flow pattern.

(f) Wherever possible, valves control equipment and supporting equipment (such as ventilation equipment, heating and cooling equipment) should be located outside the laboratory to minimize the need for service personnel to enter the laboratory. Equipment that requires direct contact with potentially contaminated material shall be located to minimize the risk of escape of organisms, taking into account the requirement to access components requiring service and maintenance.

NOTE The provision of a gaseous decontamination chamber should be considered where it is necessary to remove items that cannot be steam sterilized.

(g) As much valve and control equipment as possible shall be located outside the facility boundary to minimize the need for service personnel to enter the facility.

(h) The facility shall have a high level of physical security including control of access (e.g. electronic access card) and shall not open onto a public thoroughfare.

(i) Doors, apart from those to areas used for showering and changing, shall contain viewing panels to minimize entry and exit incidents.

(j) Adequate arrangements for observation of occupants shall be provided.

NOTE Examples of suitable arrangements are the viewing panels in doors specified in Item (i) provided they allow adequate viewing of occupants, viewing panels in walls or electronic visual monitoring facilities (e.g. viewing cameras or closed circuit television).

(k) A pressure steam sterilizer for decontamination of plant facility wastes shall be provided in the facility. The pressure steam sterilizer shall not be located in the airlock.

NOTE 1 A double-ended type of pressure steam sterilizer is preferred, positioned through the barrier wall of the facility and allowing adequate access for loading and unloading of the steam sterilizer and for maintenance of the associated plant from outside the facility.

NOTE 2 See also Clause 11.6.8.

(l) A single outlet dedicated hand basin of the hands-free operation type or alternative means of decontaminating the hands shall be provided within each containment facility, in a position on
the pathway towards the exit which supports appropriate use of the hand basin as part of the recommended exit procedure.

(m) Two independent communications systems shall be provided. These shall allow a person in the facility to draw the attention of persons outside.

(n) Provision shall be made for decontamination of liquid effluents in a manner appropriate to the composition, type and quantity of waste. The method of decontamination and disposal shall be determined using the results of a risk assessment based on the likely composition and volume of the waste and in accordance with applicable regulations. The risk assessment shall include the method of collection, design of drainage systems and transportation pipes to prevent leakage, and the types of decontamination systems, including the equipment rooms where the equipment is located. The risk assessment shall also consider the potential impact due to excess flow from water fixtures (e.g. tap left on condition) and the release of water from water based fire protection systems, where provided (see Section 11 and Section 13).

(o) Where propagules (such as seeds, pollen, or invertebrate life stages) could potentially survive the liquid effluent treatment system, liquid waste outlets shall be fitted with strainers of adequately fine gauge to prevent escape.

(p) The floor of the facility shall be designed such that all waste water is collected and drained appropriately (see Section 11).

(q) Provision shall be made for decontamination of the facility. The facility shall be constructed to contain any aerosols or gases used for decontamination. The surface finishes in the facility shall be compatible with the decontamination agents used.

NOTE The design of the facility should avoid inaccessible spaces. See Appendix H for recommendations on design for airtightness and periodical retesting.

(r) If voids are present in the facility, these shall either be fully sealed to a gas-tight standard or able to be decontaminated by gaseous decontamination.

(s) All room penetrations shall be sealed to ensure they are airtight.

NOTE See Appendix H.

7.4.4 Ventilation

A ventilation system that establishes a negative pressure in the facility shall be provided so that there is a directional airflow into the working area. Where facilities have supply air systems, the supply air and exhaust air systems shall be interlocked, to ensure inward airflow at all times. The proper directional airflow into the facility shall be verified by airflow tests. The facility (including the airlock) shall be structurally designed to take account of the operation under negative pressures.

Failure of a single component, such as an exhaust fan or a supply fan, can result in extremely high positive or negative pressures in the facility. Alarms and failure mode operations of ventilation systems shall address this risk to ensure that interlocks operate rapidly to stop systems. The facility shall be constructed to withstand, without cracking or deterioration, the maximum positive and negative pressures that can be generated until failure mode safeguards operate. Automatic and manual failure mode sequences shall be independent of any automated control system that may, itself, be the primary cause of a failure situation.

Air may be recirculated in plant facilities where there are no airborne risks to humans. All air leaving the facility shall be filtered with HEPA filters prior to recirculation. Air leaving the facility that is intended for recirculation shall firstly meet all applicable requirements of exhaust air in Items (d) to (h) inclusive prior to recirculation. Provision shall be made to isolate any unsealed sections of duct and equipment during gaseous decontamination and during post-gaseous decontamination purging.
Where air is recirculated within a plant facility, equipment used for this purpose, such as fan coil units and split system air conditioning units, shall be provided with removable panels as required to ensure the complete penetration of gas or vapour during room decontamination.

NOTE 1 Ventilation equipment should be located to ensure a flow of incoming air from the vicinity of the entry door towards the highest risk microbiological work areas.

NOTE 2 The quantity of outside air supplied to the facility should comply with relevant health quality standards or regulations (see AS 1668.2) and should dilute airborne contaminants.

Ventilation equipment and outlets shall be located to minimize the disturbance to the open faces of Class I and Class II BSCs.

The facility ventilation shall incorporate the following features:

(a) The facility shall be maintained at an air pressure of at least 50 Pa below the pressure of areas outside the PC3 containment barrier when both doors of the airlock are closed. When either door is open, the facility pressure shall remain at least 25 Pa below that of areas outside the PC3 containment barrier. The 0 Pa reference pressure shall be measured to minimize the effects of fluctuations due to wind and other building ventilation systems.

NOTE Additional precautions should be considered when one or more surfaces are external and exposed to fluctuations of pressure due to wind effect. Suitable precautions include the use of an interstitial space that can be maintained at zero reference pressure and the use of solid walls such as concrete with minimal joints, which are unlikely to be perforated or leak.

(b) The pressure differential shall be achieved by means of an independent room exhaust fan located downstream of a HEPA filter and discharging to the outside atmosphere.

NOTE A variable speed drive on the exhaust fan is preferred to facilitate room pressure control adjustments.

(c) Supply or replacement air to the room shall be filtered using Type 1 Class A or Class B filters complying with AS 1324.1 and having a minimum arrestance efficiency of 90 % when tested in accordance with AS 1324.2 with Test Dust No. 4. Where replacement air is drawn from adjacent areas, adjustable dampers shall be provided in the transfer aperture to assist in setting up the reduced room pressure. This aperture and filter shall not be mounted in the door.

(d) Exhaust air shall be filtered and discharged to the outside atmosphere in such a manner that it is dispersed away from occupied buildings and outside air intakes.

(e) The exhaust filter shall be a HEPA type as specified in Clause 11.10.1. An exhaust pre-filter of the same standard as the supply filter shall be provided, and mounted upstream of the HEPA filter.

NOTE The pre-filter may be installed in the exhaust HEPA filter housing or in the facility. Installation in the facility can facilitate access and changing.

(f) The HEPA filter shall be installed, housed and maintained as specified in Clause 11.10.2.

(g) A differential pressure gauge shall be visible and readable from immediately outside the facility.

(h) Any tubing that forms part of the facility pressure sensing and control equipment shall be fitted with a 0.2 μm hydrophobic membrane filter, (such as a miniature disk filter), located as close as possible to the PC3 containment barrier. Filters and tubing shall be protected against mechanical damage.

(i) An emergency ventilation stop button shall be provided outside the facility, adjacent to the exit.

The emergency stop button shall operate independently of the main ventilation control and main facility pressure control system such that emergency isolation of the ventilation can be implemented in event of central control system malfunction.
(j) An audible emergency alarm shall be provided within the facility to indicate a loss of negative pressure and a visible alarm shall be provided outside the facility to indicate the same. Alarms shall be sufficiently sensitive to occur before any facility pressure becomes positive and before any pressure reversal occurs between different pressure zones within the facility. Alarm set-points should have sufficient tolerance such that false alarms do not occur. The alarms shall be generated within 2 min of such loss of pressure control.

(k) In multiple room and multiple zone applications, sufficient monitoring points and alarms shall be provided to capture a loss of pressure control in any space within the facility.

NOTE Additional pressure gauges and emergency stop buttons should be considered where applicable.

(l) Annual testing by competent persons shall include the following:

(i) Testing of the pressure differentials in accordance with AS 1807.10 to ensure compliance with the requirements in Item (a).

(ii) Integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7, as applicable.

(iii) Checking that the control system is operating correctly and verifying alarms are set to operate in accordance with Item (j) on a loss of room pressure.

(iv) Calibration of pressure control and indicating devices.

(v) A report of the testing in Items (i) to (iv) and of any maintenance conducted shall be provided to the appropriate person for the facility.

(m) Exhaust air from Class III BSCs shall be discharged through the building exhaust system through direct ducting or a capture hood. It shall not be recirculated through the facility.

Capture hood air flow shall exceed cabinet discharge air flow by sufficient margin to ensure full entrainment of cabinet discharge air into the exhaust air stream. Discharges shall be designed and located outside of the building to ensure external air velocities do not adversely affect containment air flows and pressures within the cabinets.

NOTE 1 Care should be exercised with direct ducting with respect to pressure fluctuations.

NOTE 2 The exhaust air from Class I or Class II BSCs may be discharged into the facility or through the building exhaust system (see also Clause 11.7.1).

7.4.5 Access to services

Access to voids surrounding the immediate perimeter of the facility and to the ventilation equipment that serves the facility shall be restricted to authorized persons. Items of equipment, ducts and access panels to contained sections of the ventilation system shall be marked with biohazard labels to minimize the risk of accidental exposure to air or to contaminated surfaces. The installation of services shall ensure proper access to equipment such as HEPA filters for maintenance and testing personnel and their equipment.

7.4.6 Work practices

In addition to work practices specified for Plant PC1 (see Clause 7.2.4) and Plant PC2 (see Clause 7.3.5) facilities, the following shall apply:

(a) All containment features of the completed facility shall be tested, commissioned and the results documented, before use.

(b) The facility shall be inspected at least annually by the BC or operator to ensure that its containment features comply with Clauses 7.4.3(a) and 7.4.4 by reviewing records including HEPA filter integrity.
test reports and room pressure readings. Screens, filters and similar equipment shall be cleaned or replaced in accordance with manufacturer’s specified procedures.

(c) The facility management shall establish policies and written procedures whereby only persons who have been advised of the biohazard, and who meet any medical requirements, shall enter the facility (see Clause 2.6).

(d) An effective emergency evacuation plan shall be devised, and information on the plan shall be available to all facility staff and local emergency services.

(e) All facility staff shall have specific training in handling pathogenic organisms and in the use of safety equipment and controls. The staff shall be supervised by senior scientists who are experienced in working with pathogenic microorganisms.

(f) Appropriate signage indicating the plant microorganisms present in the facility and any special entry requirements shall be posted on the outer entry door.

(g) Personnel shall put on overshoes or dedicated footwear on entry to the plant facility. Personnel shall wear disposable gloves and full coverage protective clothing (e.g. boiler suit, hair covering).

(h) Plants shall be treated prior to entry to the facility to destroy or remove unwanted invertebrates.

(i) No one shall enter the facility for cleaning, servicing of equipment, repairs or other activities before the relevant, potentially contaminated facility surfaces have been decontaminated and authorization has been obtained from the facility supervisor or the safety officer. Dedicated cleaning equipment shall be stored within the facility.

(j) Equipment taken out of the plant containment facility shall be treated by a technique demonstrated to be effective in destroying or removing all stages of the plant microorganism life-cycle and invertebrates.

(k) Facility wastes shall be rendered safe, preferably by decontamination in a pressure steam sterilizer, before disposal in accordance with Clause 13.2.

(l) If a double-ended pressure steam sterilizer is installed across the barrier, it shall be decontaminated after each exposure to the facility environment.

(m) All solid wastes including plant material, pots, soil and soil substitutes shall be collected and treated to render the plant microorganism non-viable (e.g. sterilization). Wastes shall not be allowed to accumulate and shall not be stored outside the facility (see also Section 13).

(n) All liquid wastes shall be treated in a manner deemed to minimize the risk of escape of viable plant material and microorganisms (see Clause 7.4.3(n) and Section 13).

(o) Protective clothing shall be removed in an appropriate, predetermined order before leaving the Plant PC3 facility.

(p) Protective clothing shall not be worn outside the plant facility and shall be decontaminated by pressure steam sterilization prior to laundering or disposal.

(q) In the event of a power failure, entry to the facility shall be restricted until services have been restored.

Section 8 Invertebrate containment facilities

8.1 General

This Section provides requirements for containment of microorganisms associated with invertebrates. This necessarily includes containment requirements for the invertebrates themselves. The levels of containment defined in this Section relate to the risks posed by the microorganisms, not necessarily the risks posed by the invertebrate. Levels of invertebrate containment facilities correspond to the four
Invertebrate Risk Groups. Selection of the level of containment required to prevent escape will depend on the nature of the invertebrate itself, any associated infectious microorganisms and its potential to act as a vector for human, animal or plant microorganisms. Any or all of these factors need to be considered to assess the impact on personnel and the environment.

NOTE The principles and considerations relating to terrestrial animal containment set out in Clauses 6.2 and 6.3 provide guidance on factors that may be relevant for some invertebrates.

Hazards associated with invertebrate facilities include escape of invertebrates and escape of microorganisms using vectors other than the invertebrates themselves. Compliance with microbiological, plant and animal sections of this Standard shall be included where applicable.

This Section sets out requirements for four levels of (Invertebrate PC) for containing invertebrates infected with microorganisms. The appropriate location, construction requirements and operating procedures are shown in Clause 8.2 for minimum level Invertebrate PC1 facilities, while Clauses 8.3, 8.4 and 8.5 cover Invertebrate PC2, Invertebrate PC3 and Invertebrate PC4 facilities respectively.

Invertebrate PC3 is the minimum recommended level when dealing with invertebrates that may be carrying exotic microorganisms until the microorganism risk has been satisfactorily assessed. The invertebrates may be relocated to a lower or higher level of facility following analysis.

8.2 Requirements for invertebrate PC1 facilities

8.2.1 General

The following standard of Invertebrate PC1 facilities and work practices is regarded as a suitable minimum for work with Invertebrate Risk Group 1 microorganisms.

8.2.2 Location

Invertebrate PC1 facilities have no special location requirements.

8.2.3 Construction

The Invertebrate PC1 facility shall comply with the following:

(a) The floor, walls, ceiling and roof shall be durable, suitable for the invertebrate species and appropriate for the local climate.

(b) All work surfaces shall be easily cleaned.

(c) Ventilation and shading shall be provided to maintain adequate light and internal conditions for research and to maintain invertebrates in good health.

(d) Backflow prevention for water supplies shall comply with Appendix E.

(e) Gas supplies in the facility shall comply with the general requirements specified in Clause D.3.1.

(f) Where human pathogens are not present and there is a risk to the health of workers through dehydration due to circumstances such as heat stress, heavy work or long shifts in response to emergencies, drinking facilities may be provided in the facility. This shall be subject to approval by the BC, following a risk assessment of the particular situation. If drinking facilities are provided, they shall be via a hands-free operation drinking fountain in a designated area with work practices instituted to ensure gloves are removed and hands are decontaminated prior to drinking.
8.2.4 Work practices

The work practices for Invertebrate PC1 facilities shall be as follows:

(a) Access to the facility shall be restricted to authorized personnel. All such personnel shall be appropriately trained.

(b) All means of access to the facility shall be closed and locked when the facility is not under direct supervision.

NOTE Mobile invertebrates should be contained to prevent escape.

(c) Appropriate pest and disease control management procedures shall be implemented.

(d) The production of aerosols shall be minimized, particularly where work is carried out on the open bench (see also Clause 3.1).

(e) Cultures shall be clearly identified and dated.

(f) Chemicals shall be stored in the facility in accordance with AS/NZS 2243.10.

(g) Local exhaust ventilation or a fume cupboard shall be used when determined appropriate by a risk assessment of any work with toxic, volatile, corrosive or odoriferous substances.

NOTE 1 BSCs are not designed for this purpose (see Clause 11.1).

NOTE 2 AS/NZS 2982 should be consulted for local exhaust ventilation requirements.

(h) PPE appropriate for the work being carried out shall be worn. See also Clause 11.2 for detailed information on PPE. Gloves shall be worn when working in a BSC. PPE shall be removed and hands shall be decontaminated prior to leaving the facility.

NOTE 1 A rear-fastening gown affording protection to the front part of the body is preferable.

NOTE 2 Long sleeved gowns should be worn when handling invertebrates that penetrate the skin by biting or burrowing.

(i) Gowns shall be kept in the facility between uses, kept segregated from unused PPE, and shall be laundered at appropriate intervals.

(j) Eating, smoking and the storage of food for human use shall not be permitted in the facility.

(k) Drinking and the storage of drink for human use shall only be permitted in the facility in accordance with Clause 8.2.3(f). If drinking facilities are provided, work practices shall be instituted to ensure gloves are removed and hands are decontaminated prior to drinking.

(l) Waste shall be segregated and disposed of according to applicable regulations, using the most appropriate and effective method for the materials concerned (see also Section 13).

8.3 Requirements for invertebrate PC2 facilities

8.3.1 General

The following standard of invertebrate containment facilities and work practices is suitable for work with Invertebrate Risk Group 2 microorganisms. Invertebrate PC2 facilities incorporate all appropriate requirements of Invertebrate PC1 containment facilities as well as the additional requirements relating to location, construction and work practices specified in Clauses 8.3.2 to 8.3.5.

Invertebrate PC2 facilities include permanent structures with an anteroom with self-closing doors to restrict access. Containment is achieved primarily through the creation of a physical barrier. Windows and ventilation inlets and outlets are screened and effective pest control procedures are in place.
8.3.2 Location

The potential impact of severe environmental events such as flood, fire, earthquake and high winds should be considered when selecting sites for Invertebrate PC2 facilities.

The Invertebrate PC2 facility should have a buffer zone free of primary or alternative hosts that may be susceptible to infection from microorganisms potentially being carried by the invertebrates in the containment facility. The extent of the buffer zone should be determined through consideration of the risks posed by a potential escape. Large distances or location of the facility in areas where there are no potential hosts may be appropriate.

8.3.3 Construction

In addition to the construction requirements specified for Invertebrate PC1 facilities in Clause 8.2.3, the following shall apply:

(a) The facility shall have a washable and impermeable floor.

(b) The walls and roof shall be made out of a suitable rigid material that resists deterioration from the elements and resists attack by invertebrates such as insects and arthropods. Where required, structural joints shall be durable, impermeable, easy to clean and shall resist deterioration due to commonly used cleaning agents, common disinfectants and, where applicable, exposure to ultraviolet radiation. Benches shall be finished with a material that is impermeable to liquids, have any joints sealed, and be sealed to end walls and sinks where there is a wet area.

NOTE 1 All exposed surfaces should be of contrasting colour to invertebrates for ease of identification, so that they can be easily, locate, recaptured or killed.

NOTE 2 The presence of dark and inaccessible spaces should be avoided to minimize hiding places for invertebrates, where applicable.

NOTE 3 Structural joints should be minimized in containment facilities.

(c) The facility shall have an anteroom for entry and exit. The anteroom shall be fitted with at least one type of appropriate device designed to attract and kill invertebrates that may gain entry. The anteroom shall allow materials, equipment and trolleys to pass through, while ensuring one door can be closed at all times.

NOTE Deterrent devices such as air curtains should also be considered for use to deter entry of insects into the anteroom. Appropriate trap and kill devices may include sticky pest strips, cold space temperature control or other automatic traps or killing devices.

(d) Suitable mechanisms shall be provided to minimize the likelihood of both anteroom doors being opened at the same time.

NOTE Examples of suitable mechanisms include entry and egress “traffic light” alarm systems, door interlock control systems or viewing panels if suitable.

(e) Anteroom doors shall be fitted with door closers, and seals shall be fitted to top, bottom and sides for both anteroom doors. The quality of anteroom door seals shall be adequate to contain the invertebrate species being housed in the facility. Suitable hooks or storage for laboratory gowns shall be provided within the facility, in a position on the pathway towards the exit which supports appropriate use of the hooks or storage, as part of the recommended exit procedure.

(f) Any openings in the walls, ceiling or roof, such as windows, vents and air conditioning or ventilation inlets and outlets, and any other specialist ventilation openings, shall be screened at the containment boundary with fine mesh screens having apertures of sufficiently small gauge to prevent entry or egress of invertebrates. The mesh shall be —

(i) stainless steel; or
(ii) suitable material with regards to its —

(A) mechanical strength under the airflow load;

(B) ability to remain undamaged with the regular vigorous cleaning needed to remove deposited material;

(C) corrosion resistance; and

(D) resistance to attack by insects from either inside the containment facility or from the local environment outside the facility.

NOTE 1 The recommended maximum aperture size for general applications is 0.25 mm (250 μm). Standard 0.25 mm aperture/0.16 mm wire gauge stainless steel mesh satisfies this requirement. Smaller aperture sizes of 0.10 mm (100 μm) may be required for work that involves some invertebrates such as mites and thrips.

NOTE 2 In locations where dust and debris can be generated, the use of roughing pre-filters upstream of the mesh screens can result in safer and easier cleaning.

NOTE 3 Refer to AS 1668.2 for general filtration requirements to provide indoor air contaminant control in buildings.

It is recommended that ducted fume cupboards are not installed within invertebrate facilities so that the requirement for mesh screening of the exhaust path can be avoided. Fume cupboards should be installed in adjacent microbiological laboratories where required. If installation within an invertebrate facility is required, the use of a recirculating type fume cupboard can be considered.

(g) The drainage exits shall conform to local council standards with all wastewater draining to an approved disposal system, such as a sewerage or septic system. Liquid drainage exits shall be protected against entry or exit of rodents and invertebrates by the use of adequately replenished traps or by an equivalent effective method. Soil traps shall be installed in drains in locations where drainage inflow is likely to contain soil or sand (see also Section 13).

NOTE For work involving invertebrate species which breed using water (e.g. mosquitoes) additional protection may be required to provide containment at drainage exits.

(h) Suitable enclosed containers for storage of solid waste material shall be available within the containment facility.

(i) A pressure steam sterilizer shall be available where steam sterilizing of infectious facility wastes is required (see also Clause 11.6 and Section 13).

NOTE The pressure steam sterilizer should be as close to the facility as possible.

(j) A single outlet hands-free operation type dedicated hand basin or alternative means of decontaminating the hands shall be provided within each facility, in a position on the pathway towards the exit which supports appropriate use of the hand basin as part of the recommended exit procedure.

NOTE Where a PC2 laboratory is directly connected to the Invertebrate PC2 facility, the hand decontamination facilities may be in the laboratory.

(k) A sign complying with Appendix D showing the biological hazard symbol and the level of containment, together with hazard symbols as appropriate, emergency contacts and any access restrictions, shall be posted at the entrance to the facility.

(l) Gas supplies in the facility shall comply with the backflow prevention requirements specified in Clause D.3.2.
A mechanism for detection and removal of invertebrates from personnel, e.g. a full height mirror and vacuum device shall be provided. This shall be located either in the facility adjacent to the exit or in the anteroom, adjacent to the hand decontamination facility and gown hooks.

8.3.4 Containment equipment

8.3.4.1 Biological safety cabinets

A Class I or Class II BSC (see Clause 11.7) shall be provided if there is a potential for personnel to become infected by aerosol generation. Alternatively, other equipment designed to contain the aerosol shall be used.

NOTE 1 Refer to Figures 1 and 2 of Clause 5 of AS 2252.4 for guidance on installation and location of BSCs.

NOTE 2 See Appendix H for information and recommendations concerning safe use of the BSC.

NOTE 3 Refer to Clause ZZ14 of AS 2252.4 for information related to decontamination of the BSC.

Where requirements in AS 2252.4 conflict with requirements in this Standard, the requirements in this Standard shall take precedence.

8.3.4.2 Centrifuges

When potentially infectious or infectious materials are used, a centrifuge fitted with either sealed rotors or sealed buckets shall be used (see also Clause 11.3).

8.3.5 Work practices

In addition to work practices specified for Invertebrate PC1 in Clause 8.2.4, the following shall apply:

(a) Personnel shall take precautions to minimize the hazards of working with invertebrates that are able to penetrate the skin. This may include the use of special PPE, the use of physical barriers and means of rapidly destroying any escaped invertebrates. Effective measures shall be in place to deal with an accident such as a spilled cage.

(b) For invertebrate work producing a significant risk from aerosol production, a BSC or other equipment designed to contain the aerosol shall be used. A period of at least 5 min shall be allowed for aerosols to settle before opening homogenizer or sonicator containers in a BSC.

NOTE 1 Large items of equipment can interfere with the airflow pattern in a Class II BSC and correct operation of the cabinet should be validated with the equipment in situ (see Clause 10.3.1).

NOTE 2 For some work with invertebrate species the use of a sealed glove box may be more appropriate than a BSC.

(c) Personnel shall wear appropriate PPE within the facility. PPE shall be removed prior to leaving and kept in the facility between uses.

(d) Measures shall be taken to ensure no invertebrate or microbiological contamination enters or leaves the facility on footwear. Suitable measures include the use of dedicated facility footwear, the use of overshoes and the use of footbaths containing effective disinfectant.

(e) Mobile invertebrates shall be contained to prevent escape. Access for research, feeding and cleaning shall be designed to minimize the risk of escape.

(f) The facility shall be inspected at least annually to ensure that its containment features are intact. The area surrounding the facility shall be free of debris, rubbish, overhanging trees and shrubs. Screens, filters and similar equipment shall be cleaned in accordance with manufacturer's specified frequency and procedures.
(g) All packages containing invertebrates shall only be opened within the facility. Packaging material shall be decontaminated as soon as possible (see also Section 13).

(h) All doors to the facility shall be locked whenever microbiological hazards are potentially present, except when personnel are working in the facility.

(i) PPE shall be removed and hands decontaminated in a predetermined appropriate order after handling potentially infected material and prior to leaving the facility.

NOTE 1 The order is usually removal of gloves followed by hand decontamination, then eye protection and laboratory gown followed by a second hand decontamination.

NOTE 2 Appropriate protocols for laundering or decontaminating PPE should be implemented.

(j) Used PPE shall be decontaminated at appropriate intervals. Precautions shall be taken to prevent the escape of invertebrates where laundry facilities are not in the invertebrate facility. Precautions may include decontamination inside the facility, double bagging, freezing or alternative suitable means depending on the invertebrate species.

NOTE If potentially infectious or infectious materials have been spilled on gowns or protective clothing, they should be decontaminated, preferably by steam pressure sterilization prior to laundering or disposal. (See Section 10.)

(k) Living invertebrates or tissues shall not be taken from the facility except to a facility of the same PC level or higher. Transport of Invertebrate PC2 materials shall comply with Section 14.

(l) Dead invertebrates, host plants and plant tissues, soil, soil substitutes and planting pots shall be collected in a sealed insect-proof container and decontaminated to render any microorganisms that have colonized the material non-viable. Pruning and other equipment shall be decontaminated prior to removal from the facility. Dead or unwanted invertebrate material and spilled growing medium shall be cleaned up immediately followed by decontamination of affected areas (see also Section 13).

NOTE Soil substitutes which can be readily decontaminated should be used whenever possible. Use of soil is discouraged.

(m) The facility shall have an effective insect and rodent control program in place. Any host plants shall be inspected at appropriate intervals for signs of infestation or unwanted disease infections. The inspection regimen shall pay particular attention to mites as they would not normally be excluded by the window and vent screens.

NOTE If the work permits, host plants should be sprayed regularly with an appropriate insecticide.

8.4 Requirements for invertebrate PC3 facilities

8.4.1 General

The following standard of Invertebrate PC3 facilities and work practices is regarded as a suitable minimum for work with Invertebrate Risk Group 3 microorganisms. Invertebrate PC3 facilities incorporate all the appropriate requirements of Invertebrate PC1 and Invertebrate PC2 facilities as well as those of Clauses 8.4.2, 8.4.3 and 8.4.4.

Invertebrate PC3 facilities include permanent structures with sealed windows and all ventilation inlets and outlets fitted with appropriate screens and filters to prevent ingress and egress of unwanted invertebrates. Containment is achieved primarily through good operational practices, the use of protective clothing and effective sanitation. Supporting containment is achieved by solid construction, negative pressure within the contained environment, and the use of HEPA exhaust air filters.

NOTE The design of a PC3 facility is complex and those planning its construction should seek specialized advice. See also Appendix G (Figures G.1 to G.5) for examples of recommended layouts for PC3 facilities showing the design principles involved and Appendix H for airtightness considerations.
8.4.2 Location

Where located in areas that suffer from extreme climatic events (e.g. storms, cyclones), the design of the facility shall take these factors into account to minimize the risk of damage. Invertebrate PC3 facilities shall not be located in areas that are subject to flooding.

Structural design for wind loads shall take into account wind region maps. See AS/NZS 1170.2.

Where Invertebrate PC3 facilities are proposed to be located in active seismic zones, the structural design shall take into account the potential for seismic damage.

Invertebrate PC3 facilities shall not be located in areas that are geologically unstable or prone to land slippage.

8.4.3 Construction

In addition to the construction requirements specified for Invertebrate PC1 (see Clause 8.2.3) and Invertebrate PC2 (see Clause 8.3.3) facilities, the following shall apply:

(a) The facility shall be constructed with a rigid reinforced frame with walls, floors and glazing forming a shell. Floors shall be slip resistant. Any transparent sections shall be made of impact-resistant material such as methyl-methacrylate (“perspex”) or reinforced glass. Impact resistance shall include hailstone protection. Additional protection shall be provided where required to protect against extreme climatic events (see Clause 8.4.2).

NOTE 1 Where separate facility rooms are contained within an invertebrate PC3 facility, consideration should be given during the design of the air handling system to the use of a common system or the need for individual air exhaust systems, HEPA filters and duct isolation valves to facilitate gaseous decontamination of all parts of the facility.

NOTE 2 Depending on the size, removable panels to allow for entry and exit of large items of equipment should be considered. These should be readily resealable to an airtight condition following use.

NOTE 3 Building regulations may require alternative egress in certain facility configurations. The regulations require such alternative egress to be accessible and easily usable. The design should ensure this without compromising facility seal integrity. Lockable doors need to permit emergency egress in accordance with building regulations.

(b) In addition to the anteroom [see Clause 8.3.3(c)], the facility shall have an airlock or shower airlock for entry and exit. For an airlock, the doors shall open outward and the outer door shall be lockable. For a shower airlock, the outer door of the shower airlock shall open outwards. Either the door to the outer change room or the outer door of the shower airlock shall be lockable. Airlock and shower airlock doors shall be self-closing and fitted with seals to limit air leakage.

Where the facility forms the primary containment measure and there is a risk of viable invertebrates adhering to personnel, an outer and inner change room, separated by a shower airlock shall be provided.

The outer airlock door shall form the limit of Invertebrate PC3 containment for decontamination purposes.

NOTE 1 The airlock is provided to ensure the maintenance of the negative pressure within the PC3 facility and prevent airflow between the PC3 facility and areas external to the facility. It should not be used for any work, nor should it contain any equipment, washing facilities (apart from the shower where it is used as a shower airlock) or PPE worn in the facility.

NOTE 2 See Appendix G (Figures G.1 to G.5) for examples of recommended layouts for PC3 facilities showing the design principles involved and Appendix H for airtightness considerations.

NOTE 3 The anteroom should be located between the airlock and the work area of the facility. See Figure F.4.
NOTE 4 If the invertebrate facility connects via its anteroom to another containment facility of the same level, an airlock is not required between the two containment facilities.

(c) The anteroom shall be fitted with —

(i) drop down door seals fitted to both inner and outer doors to deter vermin and invertebrates from entering or exiting the invertebrate containment facility;

(ii) no source of natural light; and

(iii) capability to be maintained in a darkened state or a lit state depending on which state offers the best discouragement to the invertebrates of concern.

(d) Means shall be provided for minimizing disturbance of pressure differentials by reducing the likelihood of both airlock doors being opened at the same time.

NOTE Examples of suitable mechanisms include entry and egress “traffic light” alarm systems, door interlock control systems or viewing panels if suitable.

(e) Means shall be provided to prevent powered air lock doors from opening simultaneously in the event of power loss or emergency. Manual overrides may be used to address emergency egress requirements.

(f) The allocation of task zones and layout within the facility shall promote the movement of ventilation air from the entrance and towards the more contaminated zones such as BSCs and steam sterilizer loading trolleys.

Care shall be taken to avoid turbulence or ventilation system air movement within the vicinity of BSCs that could interfere with the stability of the work face air flow pattern.

(g) Provision shall be made for materials, equipment and trolleys to pass into and out of the facility while ensuring one door can be closed at all times.

NOTE Consideration should be given to the provision of a gaseous decontamination chamber for facilities that require removal and installation of equipment that cannot be steam sterilized. This facilitates removal of such items without the need to decontaminate the whole facility.

(h) Wherever possible, valves control and supporting equipment (such as ventilation equipment, heating and cooling equipment) should be located outside the laboratory to minimize the need for service personnel to enter the laboratory. Equipment that requires direct contact with potentially contaminated material shall be located to minimize the risk of escape of organisms, taking into account the requirement to access components requiring service and maintenance.

NOTE The provision of a gaseous decontamination chamber should be considered where it is necessary to remove items that cannot be steam sterilized.

(i) The facility shall have a high level of physical security including restricted access provided by a controlled access system (e.g. electronic access card).

(j) A dedicated, single-outlet hand basin of the hands-free operation type, or alternative means of decontaminating the hands, shall be provided within each invertebrate containment facility, in a position on the pathway towards the exit which supports appropriate use of the hand basin as part of the recommended exit procedure.

(k) Doors, apart from those to areas used for changing, shall contain viewing panels to minimize entry and exit incidents.

(l) Adequate arrangements for observation of occupants shall be provided.

NOTE Examples of suitable arrangements are the viewing panels in doors specified in Item (k) provided they allow adequate viewing of occupants; viewing panels in walls; and electronic visual monitoring facilities (e.g. viewing cameras or closed circuit television).
(m) A pressure steam sterilizer for decontamination of wastes shall be provided in the facility. The pressure steam sterilizer shall not be located in the airlock or the anteroom.

NOTE 1 A double-ended type of pressure steam sterilizer is preferred, positioned through the barrier wall of the facility and allowing adequate access for loading and unloading of the steam sterilizer and for maintenance of the associated plant from outside the facility.

NOTE 2 See also Clause 11.6.8.

(n) Two independent communications systems shall be provided. These shall allow a person in the facility to draw the attention of persons outside.

(o) Provision shall be made for decontamination of liquid effluents in a manner appropriate to the composition, type and quantity type of waste. The method of decontamination and disposal shall be determined using the results of a risk assessment based on the likely composition and volume of the waste and in accordance with applicable regulations. The risk assessment shall include the method of collection, design of drainage systems and transportation pipes to prevent leakage, and the types of decontamination systems, including the equipment rooms where the equipment is located. The risk assessment shall also consider the potential impact due to excess flow from water fixtures (e.g. tap left on condition) and the release of water from water based fire protection systems, where provided. Where invertebrate life stages could potentially survive the liquid effluent treatment system, liquid waste outlets shall be fitted with strainers of adequately fine gauge to prevent escape (see also Section 11 and Section 13).

(p) The floor of the facility shall be designed such that all waste water is collected and drained appropriately.

(q) Provision shall be made for decontamination of the facility. The facility shall be constructed to contain any aerosols or gases used for decontamination. The surface finishes in the facility shall be compatible with the decontamination agents used.

NOTE The design of the facility should avoid inaccessible spaces. See Appendix H for recommendations on design for airtightness and periodical retesting.

(r) All room penetrations shall be sealed to ensure they are airtight.

NOTE See Appendix H.

8.4.4 Ventilation

A ventilation system that establishes a negative pressure in the facility shall be provided so that there is a directional airflow into the working area. Where facilities have supply air systems the supply air and exhaust air systems shall be interlocked, to ensure inward airflow at all times. The proper directional airflow into the facility shall be verified by airflow tests. The facility, including the airlock shall be structurally designed to take account of the operation under negative pressures.

Failure of a single component, such as an exhaust fan or a supply fan, can result in extremely high positive or negative pressures in the facility. Alarms and failure mode operations of ventilation systems shall address this risk to ensure that interlocks operate rapidly to stop systems. The facility shall be constructed to withstand, without cracking or deterioration, the maximum positive and negative pressures that can be generated until failure mode safeguards operate. Automatic and manual failure mode sequences shall be independent of any automated control system that may, itself, be the primary cause of a failure situation.

Air may be recirculated in invertebrate facilities where there are no airborne risks to humans. All air leaving the facility shall be filtered with HEPA filters prior to recirculation. Air leaving the facility that is intended for recirculation shall firstly meet all applicable requirements of exhaust air in Items (d) to (h) inclusive prior to recirculation. Provision shall be made to isolate any unsealed sections of duct and equipment during gaseous decontamination and during post gaseous decontamination purging.
When air is recirculated within an invertebrate facility, equipment used for this purpose, such as fan coil units and split system air conditioning units, shall be provided with removable panels as required to ensure the complete penetration of gas or vapour during room decontamination.

NOTE 1 Ventilation equipment should be located to ensure a flow of incoming air from the vicinity of the entry door towards the highest risk microbiological work areas.

NOTE 2 The quantity of outside air supplied to the facility should comply with relevant health quality standards or regulations (see AS 1668.2) and should dilute airborne contaminants.

Ventilation equipment and outlets shall be located to minimize the disturbance to the open faces of Class I and Class II BSCs.

The facility ventilation shall incorporate the following features:

(a) The facility shall be maintained at an air pressure of at least 50 Pa below the pressure of areas outside the PC3 containment barrier when both doors of the airlock are closed. When either door is open, the facility pressure shall remain at least 25 Pa below that of areas outside the PC3 containment barrier. The 0 Pa reference pressure shall be measured to minimize the effects of fluctuations due to wind and other building ventilation systems. The airlock shall remain at a defined pressure between the reference pressure and the facility pressure when both doors are closed.

NOTE 1 The nominal set-point for the airlock should be 25 Pa below the 0 Pa reference pressure.

NOTE 2 No specific air pressure requirements are nominated for the anteroom.

(b) The pressure differential shall be achieved by means of an independent room exhaust fan located downstream of a HEPA filter and discharging to the outside atmosphere.

NOTE A variable speed drive on the exhaust fan is preferred to facilitate room pressure control adjustments.

(c) Supply or replacement air to the room shall be filtered using Type 1 Class A or Class B filters complying with AS 1324.1 and having a minimum arrestance efficiency of 90 % when tested in accordance with AS 1324.2 with Test Dust No. 4. Where replacement air is drawn from adjacent areas, adjustable dampers shall be provided in the transfer aperture to assist in setting up the reduced room pressure. This aperture and filter shall not be mounted in the door.

(d) Exhaust air shall be filtered and discharged to the outside atmosphere in such a manner that it is dispersed away from occupied buildings and outside air intakes.

(e) The exhaust filter shall be a HEPA type as specified in Clause 11.10.1. An exhaust pre-filter of the same standard as the supply filter shall be provided, and mounted upstream of the HEPA filter.

NOTE The pre-filter may be installed in the exhaust HEPA filter housing or in the facility. Installation within the facility can facilitate access and changing.

(f) The HEPA filter shall be installed, housed and maintained as specified in Clause 11.10.2.

(g) A differential pressure gauge shall be visible and readable from immediately outside the facility.

(h) Any tubing that forms part of the facility pressure sensing and control equipment shall be fitted with a 0.2 μm hydrophobic membrane filter, (such as a miniature disk filter), located as close as possible to the PC3 containment barrier. Filters and tubing shall be protected against mechanical damage.

(i) An emergency ventilation stop button shall be provided outside the facility, adjacent to the exit.

The emergency stop button shall operate independently of the main ventilation control and main facility pressure control system such that emergency isolation of the ventilation can be implemented in event of central control system malfunction.
(j) An audible emergency alarm shall be provided within the facility to indicate a loss of negative pressure and a visible alarm shall be provided outside the facility to indicate the same. Alarms shall be sufficiently sensitive to occur before any facility pressure becomes positive and before any pressure reversal occurs between different pressure zones within the facility. Alarm set-points should have sufficient tolerance such that false alarms do not occur. The alarms shall be generated within 2 min of such loss of pressure control.

(k) In multiple room and multiple zone applications, sufficient monitoring points and alarms shall be provided to capture a loss of pressure control in any space within the facility.

NOTE Additional pressure gauges and emergency stop buttons should be considered where applicable.

(l) Annual testing by competent persons shall include the following:

(i) Testing of the pressure differentials in accordance with AS 1807.10 to ensure compliance with the requirements in Item (a).

(ii) Integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7, as applicable.

(iii) Checking that the control system is operating correctly and verifying alarms are set to operate in accordance with Item (j) on a loss of room pressure.

(iv) Calibration of pressure control and indicating devices.

(v) A report of the testing in Items (i) to (iv) and of any maintenance conducted shall be provided to the appropriate person for the facility.

(m) Exhaust air from Class III BSCs shall be discharged through the building exhaust system through direct ducting or a capture hood. It shall not be recirculated through the facility.

Capture hood air flow shall exceed cabinet discharge air flow by sufficient margin to ensure full entrainment of cabinet discharge air into the exhaust air stream. Discharges shall be designed and located outside of the building to ensure external air velocities do not adversely affect containment air flows and pressures within the cabinets.

NOTE 1 Care should be exercised with direct ducting with respect to pressure fluctuations.

NOTE 2 The exhaust air from Class I or Class II biological safety cabinets may be discharged into the facility or through the building exhaust system (see Clause 11.7.1).

NOTE 3 Capture hoods may be inappropriate for gases and vapours.

8.4.5 Access to services

Access to voids surrounding the immediate perimeter of the facility and to the ventilation equipment that serves the facility shall be restricted to authorized persons. Items of equipment, ducts and access panels to contained sections of the ventilation system shall be marked with biohazard labels to minimize the risk of accidental exposure to air or to contaminated surfaces. The installation of services shall ensure proper access to equipment such as HEPA filters for maintenance and testing personnel and their equipment.

8.4.6 Containment equipment

In addition to equipment specified for PC2 (see Clause 8.3.4), a Class III BSC shall be provided where appropriate (see Clause 11.7.2).
8.4.7 Work practices

In addition to work practices specified for Invertebrate PC1 (see Clause 8.2.4) and Invertebrate PC2 (see Clause 8.3.5) facilities, the following shall apply:

(a) All containment features of the completed facility shall be tested, commissioned and the results documented, before use.

(b) The facility shall be visually inspected at least annually by the BC or operator to ensure that its containment features are intact. Screens, filters and similar equipment shall be cleaned or replaced in accordance with manufacturers’ specified procedures.

(c) The facility management shall establish policies and written procedures whereby only persons who have been advised of the biohazard, and who meet any medical requirements, shall enter the facility (see Clause 2.6).

(d) An effective emergency evacuation plan shall be devised, and information on the plan shall be available to all facility staff and local emergency services.

(e) All facility staff shall have specific training in handling pathogenic organisms and in the use of safety equipment and controls. The staff shall be supervised by senior scientists who are experienced in working with pathogenic microorganisms.

(f) Appropriate signage indicating the nature of the invertebrates present in the facility and any special entry requirements shall be posted on the outer entry door.

(g) Measures shall be taken to ensure no biological contamination enters or leaves the facility on footwear.

   NOTE Suitable measures include the use of dedicated facility footwear, the use of overshoes and the use of footbaths containing effective disinfectant.

(h) Personnel shall wear PPE appropriate to the potential hazards and invertebrate species. PPE to be considered includes disposable gloves, fully covering clothing including hair nets, hoods, and long sleeved coveralls. These garments shall be removed prior to leaving the Invertebrate PC3 facility and placed into sealed containers within the facility prior to decontamination by pressure steam sterilization followed by laundering or disposal. Personnel shall decontaminate their hands prior to exiting the containment facility.

(i) No one shall enter the facility for cleaning, servicing of equipment, repairs or other activities before the relevant, potentially contaminated facility surfaces have been decontaminated and authorization has been obtained from the facility supervisor or the safety officer. Dedicated cleaning equipment shall be stored within the facility.

(j) Equipment taken out of the invertebrate containment facility shall be treated by a technique demonstrated to be effective in destroying or removing all life stages of the invertebrate and possible microbial contaminants.

(k) Facility wastes shall be rendered safe, preferably by decontamination in a pressure steam sterilizer, before disposal in accordance with Clause 13.2.

(l) If a double-ended pressure steam sterilizer is installed across the barrier, it shall be decontaminated after each exposure to the facility environment.

(m) Support materials such as soil and plants transported into the facility shall be treated prior to entry to destroy or remove unwanted contaminants.

(n) All solid waste including plant material, pots, soil and soil substitutes shall be collected and treated to render invertebrates and any associated microorganisms non-viable (e.g. sterilization). Wastes shall not be allowed to accumulate and shall not be stored outside the facility (see also Section 13).
All liquid wastes shall be treated in a manner deemed to minimize the risk of escape of invertebrates and microorganisms (see Clause 8.4.3(q) and Section 13).

Protective clothing shall be removed and hands decontaminated in an appropriate, predetermined order before leaving the facility.

In the event of a power failure, entry to the facility shall be restricted until services have been restored.

8.5 Requirements for invertebrate PC4 facilities

8.5.1 General

The following standard of Invertebrate PC4 facilities and work practices is regarded as a suitable minimum for work with Invertebrate Risk Group 4 microorganisms. Invertebrate PC4 facilities incorporate all equipment and practices for Invertebrate PC1, Invertebrate PC2 and Invertebrate PC3 (see Clauses 8.2, 8.3 and 8.4); however, additional requirements on conditions of access and egress, safety equipment and staff training apply.

Invertebrate PC4 facilities include permanent structures with inward directional airflow to prevent the escape of invertebrates.

NOTE The design of an Invertebrate PC4 facility is complex and those planning its construction should seek specialized advice. See also Appendix G for recommended layouts for PC4 facilities showing the design principles involved and Appendix H for airtightness considerations.

8.5.2 Construction

In addition to the construction requirements specified for Invertebrate PC1 (see Clause 8.2.3), PC2 (see Clause 8.3.3) and PC3 (see Clause 8.4.3) facilities, the following shall apply:

(a) The facility shall be housed in a separate building or shall form an isolated part of a building. Full access to all exterior surfaces of the contained structure and service penetrations shall be provided or suitable protocols devised to facilitate periodic integrity testing. The perimeter of the facility shall be protected against adverse pressure fluctuations due to wind or other external factors. The facility negative pressure shall be maintained across the floor, wall and ceiling boundaries at all times.

NOTE Recommendations for achieving acceptable room airtightness are given in Appendix H.

(b) Any transparent sections shall be constructed of impact-resistant materials. Ordinary window glass shall not be used, irrespective of whether it is proposed to install hail-screens.

(c) An outer and inner change room, separated by a shower airlock, with interlocking, self-closing doors, shall be provided for personnel entering and leaving the facility. The outer door shall be lockable.

NOTE 1 A security card access procedure, with additional numerical pad entry or similar, is preferred as a means of entry.

The outer shower door shall form the laboratory containment boundary for decontamination purposes.

The inner change room shall be fitted with a sticky pest strip or alternative automatic device designed to kill invertebrates that may gain entry.

The four doors of each entry/exit path shall raise an alarm if left open.

An entry and egress “traffic light” alarm system or door interlock control system shall be provided to prevent the simultaneous opening of the doors on each side of the shower.
NOTE 2 The use of pneumatically sealed doors should be considered on both sides of the shower.

NOTE 3 A timer should be provided to permit personnel to shower for a defined period as part of the exit procedure.

NOTE 4 Privacy for changing and showering may require door access features and interlocks or alarm additional to the above biocontainment requirements.

NOTE 5 The use of interlocks requires the provision of manual overrides in case of emergencies.

NOTE 6 The inner change room may provide the functions of the anteroom as set out in Clause 8.3.3(c).

(d) Walls, floors and ceilings of the facility shall be constructed in such a manner as to form a sealed internal shell which facilitates gaseous decontamination. The internal surfaces of the shell shall be resistant to liquids and chemicals used in the facility and shall facilitate easy cleaning and decontamination. All apertures in the structures and surfaces shall be sealed to prevent vermin or insects from entering the area. Glazing in windows shall be of laminated security glass selected to withstand the maximum pressure differential imposed during all operating conditions, including all possible failure modes, and during testing.

(e) A double-ended pressure steam sterilizer shall be provided to decontaminate materials from the facility and from the inner clothing change room. The outer sterilizer door shall open to the area external to the facility. The inner door shall automatically interlock with the outer door in such a manner that the outer door can be opened only after the sterilization cycle has been completed. The sterilizer shall comply with the requirements of Clause 11.6.

(f) A pass-through dunk tank, gaseous decontamination chamber or equivalent decontamination system shall be provided, so that materials and equipment that cannot be decontaminated in the pressure steam sterilizer can be rendered safe for removal from the facility.

(g) All drains in the facility and anteroom shall empty into collecting tanks and shall be decontaminated by a method that renders invertebrate life stages and microorganisms non-viable prior to leaving the containment facility. Disposal after treatment shall be in accordance with Section 13.

(h) The floor of the facility, the lower parts of the walls and the sills under doors shall be constructed and sealed to ensure that liquids drain only into the collecting tanks.

(i) An automatic changeover emergency power source, emergency lighting and communication systems shall be provided. The emergency power source shall ensure continuing operation of the ventilation systems, BSC, room access and shower controls. An uninterruptible power supply shall be provided to ensure uninterrupted operation of the shower door controls and ventilation control systems.

8.5.3 Ventilation

The invertebrate facility ventilation system shall comply with the following:

(a) The air pressure in the facility shall be maintained at a level 50 Pa below the external air pressure. There shall be a gauge showing the pressure differential and an audible alarm and light that operates when this differential is not maintained. Heating and cooling air supply ducts and ventilation and exhaust ducts shall be fitted with HEPA filters to prevent entry of invertebrates and escape of microorganisms from the facility. Testing of HEPA filters and systems by a competent person shall be completed in accordance with recommended standards.

(b) If the microorganisms are of risk to humans, a separate supply and exhaust, non-recirculating air ventilation system shall be provided. If the microorganisms are not of risk to humans and the ventilation system is configured to allow recirculation of air, the requirements in Clause 8.4.4 shall be applied. The ventilation system shall maintain such pressure differentials and directional airflow to ensure airflows toward areas of highest potential risk within the facility. There shall be a differential pressure of at least 25 Pa between each area. The system shall be provided with an alarm that activates on detection of a malfunction. The supply and exhaust airflow shall be
interlocked to ensure inward (or zero) airflow at all times. Differential air pressures between invertebrate facility zones shall be monitored by use of a differential pressure gauge as specified in Clause 8.4.4(g).

(c) Both supply and exhaust air shall be filtered through HEPA filters as specified in Clause 11.10.1. The HEPA filters shall be installed and housed as specified in Clause 11.10.2. Pre-filters to both the supply and exhaust HEPA filters shall be provided as specified in Clause 8.4.4(c) and (e). Where the room forms the primary containment barrier for invertebrate microorganisms, the exhaust air (and any recirculated air) shall be filtered through two sets of HEPA filters installed in series. The supply air HEPA filter shall prevent the outflow of contaminated air if air pressures become imbalanced within the facility.

(d) The ventilation control system shall raise an audible alarm within the facility and at an attended location when room differential air pressures depart from set points by more than 15 Pa for a period of greater than 2 min.

(e) Annual testing by competent persons shall include the following:

(i) Testing of the pressure differentials in accordance with AS 1807.10 to ensure compliance with the requirements in Item (a).

(ii) Integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7, as applicable.

(iii) Checking that the control system is operating correctly and verifying alarms are set to operate in accordance with Item (b) and (d) on a loss of room pressure.

(iv) Calibration of pressure control and indicating devices.

(v) A report of the testing in Items (i) to (iv) and of any maintenance conducted shall be provided to the appropriate person for the facility.

8.5.4 Work practices

In addition to work practices specified for Invertebrate PC1 (see Clause 8.2.4), PC2 (see Clause 8.3.5) and PC3 (see Clause 8.4.7) facilities, the following shall apply:

(a) All staff shall be trained in the specific working aspects of the facility, including the safety equipment, the operation of the facility and containment and clean-up of infectious spills. Staff shall use the safety equipment provided. Staff shall receive specific training, with written instructions and information in the handling of the relevant infectious microorganisms.

(b) Staff shall be supervised by senior scientists who are trained and experienced in working with the relevant infectious microorganisms. A facility operations manual shall be prepared.

(c) Access shall be controlled to allow entry by authorized staff only. A list of contact names and phone numbers shall be provided outside the facility entry point.

(d) Personnel shall enter and leave the facility through the clothing change and shower rooms, except in cases of emergency, where alternative exits may be used.

(e) Complete facility clothing, including shoes, shall be provided by the organization.

(f) On entering the facility, personnel shall don complete facility clothing, including shoes. All street clothing, including underwear, shall be removed and retained in the outer clothing change room.

(g) Before leaving the facility, a full body shower shall be taken. Personnel shall remove their facility clothing and store or discard it in the inner change room before showering.

(h) Personnel entering or leaving the facility shall indicate, either manually or electronically, the time of each exit and entry.
(i) All procedures within the facility involving Risk Group 4 microorganisms of risk to humans shall be conducted in Class III BSCs, or alternatively Class I or Class II BSCs, used in conjunction with one-piece positive pressure personnel suits ventilated by a life-support system.

(j) Prior to disposal, all facility effluents, including those from the shower facility, shall be decontaminated by either heat or chemical treatment (see also Section 13).

(k) The double-ended pressure steam sterilizer and decontamination chamber opening across the barrier shall be decontaminated after each exposure to the facility environment.

(l) Unless working in one-piece positive pressure suits ventilated by a life support system, viable biological materials to be removed from Class III BSC shall be transferred to a non-breakable, sealed primary container, the external surface of which is decontaminated before enclosure in a non-breakable, sealed secondary container, which is decontaminated on removal from the isolator. A primary container holding viable or intact biological materials shall be opened only in another Class III BSC in the PC4 facility or another PC4 facility [see Item (m)].

NOTE Containers may be opened in non-PC4 facility only if the biological material has been rendered non-infectious, and the space in the primary and secondary containers has been decontaminated.

(m) Viable biological materials to be removed from the facility shall be removed from the facility in a sealed secondary container [see Item (l)] and by passing through a disinfectant dunk tank or gaseous decontamination chamber or airlock designed for this purpose. No other materials shall be removed from the facility unless they have been decontaminated. Equipment or materials which might be damaged by high temperatures or steam shall be decontaminated in an airlock or specially designed chamber by means of sterilizing gas or vapour.

NOTE Containers may be opened in non-PC4 facilities only if the biological material has been rendered non-infectious provided they are opened within a Class II BSC.

(n) No other materials shall be removed from the facility unless they have been decontaminated. Equipment or materials which might be damaged by high temperatures or steam shall be decontaminated in an airlock or specially designed chamber, by means of sterilizing gas or vapour.

A primary container holding viable or intact biological materials shall be opened only in a Class III BSC in another PC4 facility.

NOTE Containers may be opened in non-PC4 facilities only if the biological material has been rendered non-infectious or non-toxic, and the space in the primary and secondary containers has been decontaminated.

(o) Risk Group 4 material shall only be stored within the facility.

(p) A risk assessment of the working environment shall be undertaken encompassing all matters influencing the personal safety of staff. Monitoring and emergency procedures shall be prepared and implemented at a level commensurate with the outcome of the risk assessment.

NOTE The presence of a coworker either inside the facility or observing the work from outside the facility should be considered.

(q) Checks shall be carried out to ensure monitoring and communication arrangements result in the emergency procedures being initiated in a timely manner and to ensure the procedures are adequate.

8.5.5 Health monitoring

See Clause 2.6.
Section 9  Aquatic organism containment facilities

9.1  General

This Section sets out requirements to ensure that aquatic organisms that are infected with, or which may contain, hazardous or infectious microorganisms, are contained in facilities that will prevent the escape of those microorganisms. This is primarily done through ensuring the aquatic organisms, and any life stages thereof, are contained. The general principles of aquatic organism containment can also be applied to aquatic organisms that do not necessarily require microbiological containment, e.g. specific pathogen free (SPF) aquatic organisms and genetically modified aquatic organisms. This Section is not intended to be used as a substitute for other regulations or guidelines that apply to these aquatic organisms, such as those issued by the DAWR and the OGTR in Australia or such as those issued by the MPI and the EPA in New Zealand. The aquatic environment can contain many organisms other than the aquatic organisms of interest. This can be intentional or unintentional and may include plants, invertebrates and microorganisms of unknown, unwanted or exotic status or organisms which have been intentionally introduced into the aquatic environment for specific purposes. These considerations shall be borne in mind when considering appropriate containment measures.

Aquatic organism handling can be uniquely hazardous for research, care and management personnel. Hazards can include injury from physical impact, biting, stinging, exposure to toxins, and puncture wounds from fins or spines. Some species of sea organisms are amongst the most toxic in the world. These can include aquatic animals, some marine reef organisms and some species of aquatic plants. Personnel may need to enter the water in larger aquatic containment environments, adding hazards such as drowning and requiring operators to use specialist breathing equipment.

For the purposes of this Standard, aquatic organism containment applies to aquatic animals and aquatic plants together with their aquatic environment. Aquatic animals include vertebrate, non-vertebrate animals and amphibious species. For some applications, additional containment requirements apply. For example, animal facility containment and plant containment requirements apply where amphibious animals move out of water and where plants are exposed to insects or other land-based invertebrates. Frozen material, e.g. cored ice samples, shall be considered as appropriate for any viable microbiological material at the appropriate risk level.

In Australia, aquatic organisms exposed to exotic microorganisms shall be housed in containment facilities that meet the requirements of DAWR. Aquatic organisms exposed to genetically modified microorganisms shall be housed in accordance with OGTR requirements. Disposal of such aquatic organisms, including aquatic organisms at early reproductive stages, such as eggs, and including potentially contaminated water, shall be in accordance with the relevant regulations or guidelines.

In New Zealand, aquatic organisms exposed to exotic microorganisms that are classified as new organisms (including GMOs) under the Hazardous Substances and New Organisms (HSNO) Act 1996 shall be held in containment facilities approved by MPI. In addition, aquatic organisms that are classified as unwanted organisms under the Biosecurity Act 1993 may also be required to be held in such facilities. Disposal of such aquatic organisms, including aquatic organisms at early reproductive stages, such as eggs, and including potentially contaminated water, shall be in accordance with the relevant regulations or guidelines.

Facilities and arrangements for aquatic animal care and management shall be consistent with good aquatic animal welfare practices and in accordance with either the Australian code of practice for the care and use of animals for scientific purposes (see Bibliography, Reference 1.34) or the New Zealand Animal Welfare Act 1999, as appropriate.

Aquatic facilities can result in the potential for loss of containment in event of flood, inundation or major leakage. The following location-specific issues can arise for aquatic facilities:

(a) The likelihood of flooding due to weather events.

(b) Location of the facility near water features such as rivers or lakes.
The potential for water drainage systems to “back up” into containment areas under certain failure scenarios.

The above issues shall be addressed by an appropriate risk assessment at the time of planning of the aquatic facility (see also Clause 4.4).

NOTE 1 The Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals should also be consulted (see Bibliography, Reference 1.35).

NOTE 2 Refer to Guide for the care and use of laboratory animals (see Bibliography, Reference 1.36) for specific information related to aquatic animal husbandry.

NOTE 3 The USDA-ARS (United States Department of Agriculture, Agricultural Research Service), national agricultural library has some excellent reference material related to the care and use of species such as molluscs (see Bibliography, Reference 1.37).

9.2 Principles of aquatic organism containment

Aquatic organisms can be held in a variety of containment facilities that are designed to ensure that the aquatic organisms, and the microorganisms that are associated with them, or may be being used in conjunction with them, do not escape from containment. Aquatic organisms used for research may be either small laboratory aquatic organisms (e.g. zebrafish, snails, marine plankton and corals) or larger animals (e.g. crocodiles, sharks). The requirements for housing and maintenance of aquatic organisms may differ in scale as a result but the overall principles that apply are the same. While some Aquatic Organism PC1 facilities confine larger aquatic organisms in a secure and fenced off pond or pool, other Aquatic Organism PC1 facilities are designed to contain smaller aquatic species such as zebrafish and Xenopus in aquatic environments such as tanks or aquaria.

Facilities may be designed and constructed in the same way as a standard laboratory and may be integral to, and inseparable from, the laboratory itself. At lower containment levels (Aquatic Organism PC1 and Aquatic Organism PC2), there may be little difference between the design and construction of aquatic organism containment and laboratory containment facilities.

The use of primary containment devices should be considered at all levels of aquatic organism facilities. Separate primary containment supports the prevention of contaminant spread, assists with the control of cross-contamination, and may help to reduce personnel exposure.

For the purposes of this Section, primary containment for aquatic organisms shall be taken to be a level of protection such that —

(a) aquatic organisms are unable to escape the primary containment environment;

(b) operation of normal support equipment, such as aerators, does not result in liquid escaping from the primary containment device;

(c) lids, caps or seals are provided so that the normal behaviour of the aquatic organisms, including surface-breaking activity, jumping and spraying, does not result in liquid escaping from the primary containment device;

(d) if primary containers are designed to be moved or carried, measures are in place to minimize the likelihood and quantity of spillage if the container is dropped or tipped; and

   NOTE Such measures can include sealing lids with restraints to hold them in place.

(e) routine maintenance of the aquatic organism environment can be carried out with minimal opening and closing of the primary containment devices.

   NOTE Routine maintenance includes features such as automated water circulation, automated aeration and facilities for the introduction of feed and disposal of waste.

In situations where it is not possible to keep aquatic organisms in primary containment devices (e.g. for large aquatic species such as crocodiles or sharks), or in situations where the enclosures are unable to
be designed to prevent the spread of water spray or aerosols, the aquatic organism enclosure itself will form the primary containment environment. In these situations, additional measures shall be taken to provide containment based on the hazards associated with the microorganisms that may be present. All of these features shall be supported by good work practices and training to ensure the protection of personnel and the environment.

Measures for consideration shall include the following:

(i) General measures applicable at all levels of containment include:

(A) Bunding and other liquid escape mechanisms.
(B) Additional construction standards to control spillage, leakage and ease of cleaning.
(C) The use of dedicated PPE that remains in the facility. And the use of specialized training and work practices for some species.
(D) The use of moisture resistant outer clothing and footwear.
(E) The use of specialized PPE for some species.
(F) The use of specialized training and work practices for some species.

(ii) For higher levels of containment, such as PC3, additional measures for consideration include:

(A) Aerosol escape prevention mechanisms, including HEPA exhaust filters.
(B) Showering of personnel before leaving the facility.

Liquid waste from aquatic organism facilities will often be a major containment risk. Liquid waste from low level (PC1 and PC2) aquatic organism containment facilities can often be decontaminated inside or adjacent to the facility using proprietary filtration and chemical or UV technologies. Liquid waste from higher containment level aquatic organism containment facilities shall either be pressure steam sterilized in a closed batch heat treatment system or shall be effectively decontaminated by some equivalent means to ensure that all potentially hazardous microorganisms are destroyed. When liquid waste is transported for treatment at locations remote from the facility, measures shall be taken to address the risks of leakage or spillage such that effective containment is maintained until liquid waste is decontaminated.

Solid waste shall be segregated, decontaminated where necessary and disposed of according to applicable regulations (see also Section 13). Aquatic organism containment facilities should have access to decontamination facilities within their own areas. Waste from low level (PC1 and PC2) aquatic organism containment facilities can be decontaminated outside the facility. However, waste shall be contained to prevent dissemination of any potentially hazardous microorganisms. Waste from higher level aquatic organism containment facilities shall either be pressure steam sterilized in the facility or decontaminated in a closed system to ensure that all infectious microorganisms are destroyed.

As a general principle, the biological and PC recommended for working with infectious agents and agents of biosecurity interest in vivo and in vitro are comparable. Infected aquatic organisms should only be handled by trained staff using appropriate procedures designed to protect staff and the environment from exposure to the microorganisms. When housing aquatic organisms in which microorganisms are to be used, the PC levels for work with microorganisms shall follow the containment levels appropriate for the microorganism. Requirements for Aquatic Organism PC1, Aquatic Organism PC2, Aquatic Organism PC3 and Aquatic Organism PC4 facilities are set out in Clauses 9.4, 9.5, 9.6 and 9.7.

9.3 Other considerations associated with aquatic organism containment

9.3.1 Designing facilities for different aspects of aquatic organism handling

Managers and operators shall obtain information from qualified and reliable sources to ensure that the facility can be built and operated to both good design and good practice methods. Such information
relates to materials used, ability to contain, animal husbandry, inspection and monitoring for disease or illness, appropriate response to incidents involving the species being cared for, and taking care to optimize the health of animals.

Prior to designing facilities, separate areas should be considered for different activities, for example housing, experiments, post-mortem examinations, disposal of wastes and associated maintenance. This separation is dependent on species and type of aquatic organism. Applicable aquatic animal welfare guidelines need to be consulted and followed.

Infected aquatic organisms, aquatic organisms suspected of being infected and aquatic organisms in quarantine shall be segregated from non-infected and non-quarantined aquatic organisms and precautions shall be taken to prevent cross-infection. As a minimum, segregation shall be in separate containers with independent water systems to prevent infection of non-infected aquatic organisms.

Even aquatic organisms that have not been deliberately infected may harbour organisms that are dangerous to other aquatic organisms and, in some instances, humans.

Training staff in aquatic organism handling is the best method of preventing injury, both to staff members and the aquatic organisms themselves.

NOTE See Clause 9.1 for some useful references associated with the handling of aquatic organisms.

9.3.2 The occurrence of allergic reactions in personnel handling aquatic organisms

Some aquatic organisms (both plant and animal) can cause allergic reaction and this hazard should be considered when applicable. Inhalation and direct contact are two of the most common ways for allergens to enter the body. To reduce the incidence of the former, adequate ventilation, including an increased number of air changes per hour, should be provided where necessary and local exhaust systems should be provided where necessary (see Clause 9.3.3). In addition, aquatic environment handlers, technical and scientific staff should take appropriate precautions to prevent the development of allergies, including the use of appropriate PPE, especially when handling aquatic organisms directly.

Any unusual bodily reaction or allergy to the aquatic species present in the facility shall be immediately reported so that appropriate action can be taken and to preclude such reaction being the result of infection.

It is recommended that respiratory protection is worn in situations where allergenic material may be present in the aquatic facility to prevent the development of allergies. Usually P2 particulate respirators are adequate, but fit testing of the respirator is important to ensure that it is appropriate for the individual and advice from an occupational hygienist or similar should be sought.

9.3.3 Air change rates for aquatic organism containment facilities

Aquatic organism containment facilities require rates of fresh air ventilation to control containment levels, moisture build-up and odours. In consideration of the long term exposure of personnel, the fresh air ventilation rate shall be sufficient to keep moisture, odour and contaminant levels below acceptable threshold limits. See Note 2 and AS 1668.2 for information related to the use of ventilation for indoor air contaminant control.

NOTE 1 The required fresh air ventilation rate depends on a number of factors, including —

(a) the type of aquatic organism containers;
(b) the nature, quantity and of aquatic organisms to be accommodated;
(c) density of aquatic organisms to be accommodated;
(d) temperature, humidity and air movement; and
(e) the ventilation effectiveness.

NOTE 2 Guideline minimum fresh air ventilation rates for organism containment facilities are as follows:
Organism housing

<table>
<thead>
<tr>
<th></th>
<th>Fresh airflow (air changes per hour)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open tanks, i.e. the room forms the primary containment barrier</td>
<td>10 – 15, species dependent</td>
</tr>
<tr>
<td>Aquaria tanks or containers fitted with lids</td>
<td>8 – 12, species dependent</td>
</tr>
<tr>
<td>Isolation devices where all exhaust air is completely removed from the aquatic organism environment by capture hood or direct-ducting. These include HEPA filtered isolators at higher levels of containment.</td>
<td>8</td>
</tr>
</tbody>
</table>

NOTE 3 The rate may need to be increased for animal welfare reasons or to reduce concentrations of airborne substances. This can be important in facilities housing multiple animal species.

NOTE 4 Many aquatic facilities can involve significant areas of exposed water surface. The evaporation rate from these surfaces can vary markedly depending on the temperature and humidity of the air, and the nature and directional flow of any ventilation systems. These evaporation rates can, in turn, affect the temperature profiles, heat loss and water loss from tanks. These factors should be considered carefully when designing these systems.

9.3.4 Decontamination and disposal of aquatic organism waste

Liquid waste related to aquatic organisms can result in contamination exposure of equipment such as housing containers, water treatment systems, filters, water containers, pumps, tubing, recreational accessories and dead aquatic organisms (or parts thereof), etc. This equipment shall be appropriately decontaminated prior to maintenance, disposal or re-use. Contaminated and potentially contaminated waste shall be decontaminated prior to disposal or reuse as specified in Section 13. Decontamination of infected carcasses and body parts may be achieved by methods such as alkali digestion, steam sterilizing, incineration or rendering. All instruments and containers that have been used in procedures with infectious microorganisms should be decontaminated before cleaning. Any special precautions that are needed, such as decay of radioisotopes, should be taken.

Liquid waste discharged from aquatic containment facilities shall be decontaminated according to the risk group of the aquatic organisms and in accordance with local authority requirements.

NOTE 1 Decontamination requirements apply for Aquatic Organism PC2 facilities and higher facilities (see Clauses 9.5 to 9.6).

NOTE 2 See also Clauses 1.5.6.

9.3.5 Transport of aquatic organisms and organism tissues between facilities

Where it is necessary to transport aquatic organisms or aquatic organism tissues from the containment facility, the appropriate precautions to prevent spread of microorganisms shall be determined. Tissues fixed to inactivate infectious materials may be removed from the facility, provided that inactivation is ensured. Live aquatic organisms and potentially infected aquatic organism tissues shall not be moved to a facility of a lower level of containment, e.g. from PC3 to PC2.

9.3.6 Dissection and post-mortem examinations

Post-mortem examinations of aquatic organisms that are infected or suspected to be infected with microorganisms shall be carried out under PC conditions equivalent to the risk group of the microorganism present or suspected to be present. If the microorganism is unknown, such examinations shall be carried out under a minimum of PC2 level conditions unless a risk analysis provides sufficient assurance that indicates that a different level is appropriate.

During post-mortems, appropriate PPE such as gloves, aprons and respiratory and eye protection shall be worn.
9.3.7 Location considerations for aquatic containment facilities

The following location-specific issues can arise for aquatic facilities:

(a) The likelihood of flooding due to weather events.
(b) Location of the facility near water features such as rivers or lakes.
(c) The potential for water drainage systems to "back up" into containment areas under certain failure scenarios.

The above issues shall be addressed by an appropriate risk assessment at the time of planning of the aquatic facility (see also Clause 4.4).

9.4 Requirements for aquatic ORGANISM PC1 facilities

9.4.1 General

An Aquatic Organism PC1 facility is suitable for work with microorganisms in Risk Group 1 and uninfected aquatic organisms. Microbiological containment is generally addressed by good work practices.

A sign complying with Appendix D showing the level of containment, together with hazard symbols as appropriate and any access restrictions, should be prominently displayed at the entrance.

9.4.2 Construction

Aquatic Organism PC1 facilities shall comply with the following:

(a) Facilities for different activities shall be appropriately segregated, considering containment, cross-contamination and animal welfare aspects. Separate areas shall be provided for the following:
   (i) Quarantine.
   (ii) Breeding and production.
   (iii) Experimental work and procedures.

   NOTE In some cases, separate rooms should be provided for different activities. However, these requirements are species dependent.

(b) Facilities shall be constructed to prevent the escape of the aquatic organism species and microorganisms of interest being contained.

   NOTE Where fencing is required, electric fencing and buried fencing should be used where appropriate (applicable to large amphibious facilities, such as reptiles).

(c) Facilities shall be designed to prevent incursions by feral or predatory organisms.

(d) Facilities shall be designed to prevent the access of unauthorized personnel.

(e) Facilities shall be designed and constructed to prevent infestation by undesirable organisms, including vermin.

(f) Facilities shall be constructed in a manner that facilitates regular cleaning and, if appropriate, decontamination.

(g) Dedicated hand basins or an alternative means of decontaminating the hands shall be provided inside each laboratory, in a position on the pathway towards the exit which supports appropriate use of the hand basins as part of the recommended exit procedure.

(h) Backflow prevention for water supplies shall comply with Appendix E.
(i) Gas supplies in the facility shall comply with the general requirements specified in Clause D.3.1.

(j) Dissection tables shall be impermeable to liquids and be covered with a washable material that is resistant to disinfectants and cleaning solutions.

(k) Where no recognized human pathogens are present and workers are at risk of dehydration due to circumstances such as heat stress, heavy work or long shifts in response to emergencies, drinking facilities may be provided in the facility. This shall be subject to approval by the BC, following a risk assessment of the particular situation. If drinking facilities are provided, they shall be via a hands-free operation drinking fountain in a designated area.

NOTE This option is only for aquatic organism PC1 and aquatic organism PC2 facilities.

(l) Equipment rooms containing potentially exposed contaminated material, such as liquid from aquatic storage tanks, can be integral to and part of the containment facility, such as recirculating, filtration and treatment systems for zebra fish installations; or can be separately housed, such as for some sealed liquid waste treatment systems.

NOTE See Section 13 for fully sealed treatment processes which are located remote from the facility. Fully sealed treatment processes may be considered in equipment rooms of a lower containment standard provided that suitable measures are in place to safely and securely manage a failure, leak, or breach of containment.

9.4.3 Work practices

The work practices for Aquatic Organism PC1 facilities shall be as follows:

(a) Access to the facility shall be restricted to authorized personnel.

(b) All means of access to the facility shall be locked when aquatic organisms are not under direct supervision.

(c) For containment of open pond or amphibious habitats, the external perimeter fence shall be checked at least every three months and after storms or other inclement weather events for any breaks or holes in the fence. Any breach shall be repaired immediately.

(d) Other provisions, such as feed and water supplies and regular inspections, shall meet requirements for aquatic organism husbandry and welfare purposes, where applicable.

(e) Aquatic organisms shall be prevented from escaping, with reasonable contingencies in place for accidents, such as during handling.

NOTE The doors should be kept closed when aquatic organisms are present, and for those periods when work is being carried out within the facility.

(f) PPE appropriate for the work being carried out shall be worn. See also Clause 11.2 for detailed information on PPE. Often in aquatic facilities PPE needs to be water-resistant and appropriate for the activities being carried out.

NOTE 1 Gloves, reinforced if necessary, should be considered when working with aquatic organisms and when working in a BSC.

NOTE 2 Eye protection should be considered when working with aquatic organisms.

NOTE 3 Protection against stings, scratches and bites should be considered.

NOTE 4 Protection against inhalation of aerosols or skin exposure to toxins should be considered, if applicable.

NOTE 5 Facility clothing should be laundered at appropriate intervals.

(g) Staff handling aquatic organisms shall be trained in fundamental aspects of good animal husbandry. Staff shall be familiar with safe handling procedures for the aquatic organism species involved, including appropriate restraint procedures. Staff shall understand the nature and
hazards of any infectious agent involved and how it can be transmitted, the inoculation method to be used, how subsequent sampling is to be done, safe disposal of liquid effluents and organism waste, and emergency procedures.

(h) Staff shall be competent in inoculation procedures designed to prevent self-inoculation and to minimize aerosol formation.

NOTE When handling or inoculating animals, the introduction of microorganisms through the skin, either by accidental self-inoculation or by contact with ecto-parasites, is a real risk.

(i) Aquatic organisms shall be appropriately restrained during handling and procedures.

(j) Aquatic organisms shall be properly identified (e.g. by tattooing, microchip, tags, permanent branding or labels on aquaria) and accounting procedures shall be established.

NOTE A record should be maintained to provide an up-to-date inventory of the aquatic organisms present and a chronological record of procedures performed.

(k) During post-mortem examinations, spillage trays and containers for used instruments shall be used. Procedures shall be followed to avoid cuts with the instruments used.

(l) Eating, smoking and the storage of food for human use shall not be permitted in the facility.

(m) Drinking and the storage of drink for human use shall only be permitted in the facility in accordance with Clause 6.4.2(k). If drinking facilities are provided, work practices shall be instituted to ensure gloves are removed and hands are decontaminated prior to drinking.

(n) Chemicals shall be stored in the facility in accordance with AS/NZS 2243.10.

(o) PPE shall be removed and hands shall be decontaminated before leaving the aquatic organism containment facility.

(p) Waste shall be segregated (e.g. broken glassware, biological and radioactive substances) and disposed of in accordance with applicable regulations, using the most appropriate and effective method for the materials concerned (see also Section 13).

9.5 Requirements for aquatic organism PC2 facilities

9.5.1 General

An Aquatic Organism PC2 facility is suitable for work with infectious microorganisms in Risk Group 2 and incorporates all the requirements of an Aquatic Organism PC1 facility with additional requirements of construction, access, safety equipment and staff training.

9.5.2 Construction

In addition to the construction requirements specified for Aquatic Organism PC1 facilities in Clause 9.4.2, the following shall apply:

(a) Floors, ceilings, walls and internal furnishings, such as blinds and curtains, shall be smooth, easy to clean, and resistant to commonly used reagents and disinfectants. Surfaces shall be impervious and shall support regular and vigorous cleaning procedures that can be associated with wet areas. Floor-to-wall joints shall be provided with continuous waterproof coving to facilitate cleaning.

(b) Where this coving forms part of the bunded facility volume, there shall be mechanisms in place to ensure the bunding requirement is not compromised at openings such as doors. Some aquatic facilities include aquatic environments containing salt water or chemically treated water. Facility construction, surfaces, finishes and ducts and pipes carrying air and water shall be suitable for the required environments.

NOTE The doorway and room structure should be rodent-proof.
(c) Structural joints, where required, shall be durable, impermeable, easy to clean and shall resist deterioration due to commonly used cleaning agents and, where applicable, exposure to ultraviolet radiation.

NOTE Structural joints should be minimized in facilities.

(d) Access doors shall be self-closing and be designed and installed to minimize the possibility of aquatic organisms escaping.

(e) Windows shall be closed and sealed.

(f) Suitable structural provision shall be made to deter the entry and exit of invertebrates. This will depend on the types of invertebrates attracted to the facility and the location of the facility itself.

NOTE Provisions that should be considered include electric/UV insect killers, air curtains, foot baths, sticky strips, an anteroom, a light-controlled anteroom, seals and drop-down seals to doors.

(g) Any openings in the walls, roof or ceiling, such as vents and air conditioning, ventilation inlets and outlets, and specialist exhaust systems, shall be screened at the containment boundary with fine mesh screens having apertures of sufficiently small gauge to prevent entry or egress of any invertebrates which may result in a compromise to containment. The mesh shall be —

(i) stainless steel; or

(ii) a suitable material with regards to its —

(A) mechanical strength under the airflow load;

(B) ability to remain undamaged with regular vigorous cleaning;

(C) corrosion resistance; and

(D) resistance to attack by insects from either inside the containment facility or from the local environment outside the facility.

(iii) It is recommended that ducted fume cupboards are not installed within aquatic facilities so that the requirements for mesh screening of the exhaust path can be avoided.

NOTE 1 For aquatic facilities, the requirements should be based on a suitable risk assessment and there is no specific recommendation. Conventional fly screening, with filters to ventilation supplies and exhausts, may be adequate in many facilities.

NOTE 2 For applications where hazards are unknown, or for future flexibility, the recommended maximum aperture size is 0.25 mm (250 μm). Standard stainless steel mesh with an aperture of 0.25 mm and wire gauge of 0.16 mm satisfies this requirement. Smaller aperture sizes of 0.10 mm (100 μm) may be required for work which involves some arthropod varieties such as mites and thrips.

NOTE 3 In locations where dust and debris can be generated, the use of roughing filters upstream of the mesh screens can result in safer and easier cleaning.

NOTE 4 Refer to AS 1668.2 for general filtration requirements to provide indoor air contaminant control in buildings.

NOTE 5 It is recommended that ducted fume cupboards are not installed within aquatic facilities so that the requirement for mesh screening of the exhaust path can be avoided. Fume cupboards should be installed in adjacent microbiological laboratories where required. If installation within an aquatic facility is required, the use of a recirculating type fume cupboard can be considered.

(h) Bunds or containers shall be provided to capture any potential spillage or overflow from aquatic organism containers. The bunding shall be of sufficient capacity to contain the largest single aquatic organism container, or group of containers where interconnection could result in leakage.
from multiple containers. The potential for leakage to occur from pipes, filters, pumps and other
liquid handling equipment shall be considered when assessing bunding requirements. If the floor
is used as the bunding zone, any waste openings located at or below the bund fill level, such as floor
wastes or low level tundishes, shall be sealed closed or otherwise protected during normal facility
operation. This is to prevent unintentional release of potentially contaminated material. Seals are
not required if the liquid waste is connected to an effective liquid decontamination system during
normal operation.

(i) Liquid drainage exits shall be protected against entry or exit of rodents and invertebrates by the
use of adequately replenished traps or by an equivalent effective method.

(j) Provision shall be made for decontamination of liquid effluents in a manner appropriate to the
composition, type and quantity of waste. The method of decontamination and disposal shall be
determined using the results of a risk assessment based on the likely composition and volume of
the waste and in accordance with applicable regulations. The risk assessment shall include the
method of collection, design of drainage systems and transportation pipes to prevent leakage,
and the types of decontamination systems, including the equipment rooms where the equipment
is located. The risk assessment shall also consider the potential impact due to excess flow from
water fixtures (e.g. tap left on condition) and the release of water from water based fire protection
systems, where provided. Liquid waste treatment, where provided, shall be located as close to the
aquatic containment facility as possible to minimize the transport or carrying requirements, the
length of potentially contaminated pipes and to reduce the likelihood of spillages.

Provisions shall be put in place to prevent and manage any potential liquid waste backup and to
prevent discharge of untreated liquid in event of a failure. This includes any failure or leakage
within the room housing the liquid waste treatment equipment. Any such failure shall be alarmed
to warn the facility staff.

Liquid waste treatment systems, where provided, shall incorporate sampling ports and monitoring
capability to permit testing of system efficacy with logging and recording of treatment processes.
Waste treatment pipes and equipment components which may contain contaminated material
shall incorporate means for effective decontamination prior to service, repair and maintenance.

Any pipes carrying potentially contaminated liquids outside the aquatic facility boundary shall
have provisions for leakage testing, inspection and maintenance.

All liquid waste components outside the aquatic facility shall be secure against unauthorized entry
or access and shall be labelled to minimize the risk of the accidental breach of containment (see
also Sections 11 and 13).

(k) Containers in accordance with the requirements of Section 13 shall be provided for collection,
storage or disposal of infectious materials.

(l) A pressure steam sterilizer shall be available where steam sterilizing of facility wastes is required
(see also Clause 11.6 and Section 13).

NOTE  The pressure steam sterilizer should be as close to the facility as possible.

(m) A hand basin with hands-free mixing taps shall be provided in a position on the pathway towards
the exit which supports appropriate use of the hand basin as part of the recommended exit
procedure. The hand basin may be shared with other PC2 areas if a risk assessment deems this to
be appropriate.

NOTE 1  Shower facilities should be provided within the same building as the facility.

NOTE 2  Consideration should be given to the provision of a hand basin or a hands-free dispenser
providing appropriate disinfectant hand rub in individual aquatic organism holding rooms to reduce cross-
contamination risk (see Bibliography, Reference 1.8). Note that this option can be appropriate in individual
rooms for situations where waterborne microorganisms may be present.
NOTE 3 Hand washing in a hand basin is considered essential prior to exiting the facility. Disinfectant hand rubs are not considered appropriate substitutes because of the potential requirement to remove contaminants such as dirt, and other solids.

(n) Where required, storage space (e.g. shelving) separate from work surfaces shall be provided for documentation within the facility.

(o) A sign complying with Appendix D showing the biological hazard symbol and the level of containment, together with hazard symbols as appropriate, emergency contacts and any access restrictions, shall be posted at each entrance to the facility.

(p) An area in which protective clothing and footwear can be stored shall be provided. If aquatic organisms are not in primary containment devices, this area shall be an anteroom situated within the facility.

(q) Where the room itself forms the primary containment measure and, if determined necessary on the basis of a risk assessment, the following shall be provided:

(i) an anteroom, to allow changing of clothes on entry and exit and the storage of specialized PPE; and

(ii) a shower facility for persons exiting the room; or

(iii) an inner and outer change room on each side of the shower facility to allow staff to fully change clothing on entry and exit to the room.

9.5.3 Ventilation

Where an aquatic organism facility forms the primary containment measure, air shall not be recirculated.

Ventilation air shall not be directed towards doors or located in positions that can disturb air flow at a BSC.

Ventilation systems shall take account of the increased moisture burden that can occur in aquatic containment facilities.

9.5.4 Containment equipment

9.5.4.1 Biological safety cabinets

A Class I or II BSC (see Clause 11.7) shall be provided if there is a potential for personnel to become infected by aerosol generation. Alternatively, other equipment designed to contain the aerosol shall be used.

Installation and use, including the decontamination of the biological safety cabinet, shall be performed in accordance with the requirements of AS 2252.4.

9.5.5 Work practices

In addition to the work practices specified for Aquatic Organism PC1 facilities in Clause 9.4.3, the following shall apply:

(a) Dedicated facility clothing shall be worn or personal clothing shall be effectively covered by suitable overalls, or a laboratory coat or gown. Closed footwear shall be worn, preferably separate shoes or boots that remain within the aquatic organism containment facility. Gloves and eye protection shall be worn when handling aquatic organisms or material containing Risk Group 2 microorganisms. Where splashing of potentially contaminated material may extend to the user’s clothing, precautions shall be taken to ensure this does not contaminate personal clothing or skin.
(b) Maintenance personnel shall be advised of potential hazards and required applicable work practices before entering the facility. Areas or equipment being maintained shall be decontaminated before the maintenance is carried out. Equipment shall be decontaminated prior to removal from the facility.

NOTE Appendix F provides information on disinfectants.

(c) All clinical and diagnostic specimens shall be regarded as potentially hazardous. See Clause 3.4 for aquatic organism work with Risk Group 2.

(d) Microorganisms transmissible by the respiratory route or work producing a significant risk from aerosol production, a BSC or other equipment designed to contain the aerosol shall be used. A period of at least 5 min shall be allowed for aerosols to settle before opening homogenizer or sonicator containers in a BSC.

NOTE 1 Large items of equipment can interfere with the airflow pattern in a Class II BSC and correct operation of the cabinet should be validated with the equipment in situ (see Clause 10.3.1).

NOTE 2 For larger aquatic organisms, environments, the room becomes the primary containment measure can extend outside containment devices and a risk assessment should be carried out if there are potential aerosol hazards. This may require specialist PPE personnel protective equipment.

(e) Care shall be taken in the use of syringes, needles and other sharps. Sharps containers shall be provided at each point of use. Precautions shall be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes and scalpels. Needles and syringes or other sharp instruments shall be restricted for use only when there is no alternative, such as for parenteral injection, phlebotomy or aspiration of fluids from aquatic organisms and diaphragm bottles.

NOTE 1 Sharps use should be eliminated wherever possible.

NOTE 2 Staff should be aware of the potential for glass equipment such as pipettes and tissue grinders to become sharps during an accident. Plastic ware should be substituted for glassware whenever possible.

NOTE 3 Where infectious material is being injected under high pressure, Luer-lock fittings (or equivalent) should be used.

(f) Viable microorganisms or aquatic organism tissues being transported out of the facility shall be double-contained. The second container shall be closed and unbreakable and the surface shall be decontaminated before removal. If taking live aquatic organisms out of the facility, they shall be contained in a manner that prevents dissemination of the microorganism and prevents escape of the aquatic organism.

(g) Work surfaces shall be decontaminated after use, after any spill of viable material, and before maintenance is carried out in the area.

NOTE Appendix F provides information on disinfectants.

(h) Personnel shall decontaminate their hands after handling cultures and aquatic organisms.

(i) PPE shall be removed and hands decontaminated in an appropriate, pre-determined order before leaving the aquatic organism containment facility.

(j) Gowns or other protective clothing shall be laundered at appropriate intervals. If infectious materials have been spilled on gowns or protective clothing, these items shall be decontaminated, preferably by steam pressure sterilization prior to laundering or disposal. (See Section 10.)

NOTE 1 The order is usually removal of gloves followed by hand decontamination, then eye protection and laboratory gown followed by a second hand decontamination.

NOTE 2 Appropriate protocols for laundering or decontaminating PPE should be implemented.
Potentially contaminated re-usable laboratory ware shall be collected and disinfected or decontaminated in accordance with Section 13 prior to washing and reuse.

NOTE 1 For chemical disinfection, pipettes placed vertically in an appropriate disinfectant solution, tip-first and fully immersed, minimize production of aerosols.

NOTE 2 Thermal decontamination of pipettes that are not fully immersed in a liquid can only be achieved in a pre-vacuum steam sterilizer.

Microbiological wastes, aquatic organism environmental enrichment material, aquatic organism cages and aquatic organism carcasses and tissues shall be decontaminated prior to disposal.

NOTE Waste should be disposed of in accordance with Section 13.

Facility rooms shall be cleaned and decontaminated after use.

NOTE Worksheets may be used within the facility in areas away from work benches and dedicated for that purpose.

9.6 Requirements for aquatic organism PC3 facilities

9.6.1 General

An Aquatic Organism PC3 facility is suitable for work with infectious microorganisms in Risk Group 3. It shall incorporate the construction provisions and work practices for Aquatic Organism PC1 facilities, except Clause 9.4.2(i), and all equipment and practices for Aquatic Organism PC2 facilities listed under Clause 9.5. Additional requirements for construction, conditions of access, safety equipment and staff training apply, as specified below.

The risks of escape for aquatic microorganisms are different to those for microorganisms in non-aquatic Organism PC3 laboratories. This is because aerosol risks are less likely to be of significance for aquatic species, but liquid waste risks are likely to be greater. Although the capability of gaseous decontamination is considered essential in the event of an accident or spill, the requirement for HEPA exhaust air filtration for aquatic PC3 microorganisms shall be based on an appropriate risk assessment.

When pathogenic microorganisms of Risk Group 3 are being used in association with small aquatic animals and plants, primary containment devices shall be used. Where primary containment devices cannot be used, the facility forms the primary containment measure.

NOTE The design of a PC3 facility is complex and those planning its construction should seek specialized advice. See also Appendix G (Figures G.1 to G.5) for examples of recommended layouts for PC3 facilities showing the design principles involved and Appendix H for airtightness considerations.

9.6.2 Construction

Construction requirements applying to Aquatic Organism PC1 and Aquatic Organism PC2 facilities also apply to Aquatic Organism PC3 facilities, but with the removal of the option to provide drinking water [see Clause 9.4.2(i)]. In addition to the construction requirements specified for aquatic organism PC1 (see Clause 9.4.2) and Aquatic Organism PC2 (see Clause 9.5.2) facilities, the following shall apply:

(a) The facility shall be physically separated from non-PC3 areas, including offices used by facility personnel, and areas accessible by the general public. This separation shall be achieved by a double-door system where entry to the facility is gained only through an airlock or shower airlock. For an airlock, the doors shall open outwards and the outer door shall be lockable. For a shower airlock, the outer door of the shower airlock shall open outward. Either the door to the outer change room
or the outer door of the shower airlock shall be lockable. Airlock and shower airlock doors shall be self-closing and fitted with seals to limit air leakage.

Where the facility forms the primary containment measure, an outer and inner change room, separated by a shower airlock shall be provided. The outer shower door shall form the limit of the Aquatic Organism PC3 containment for decontamination purposes.

NOTE 1 The use of gas-tight and liquid-tight primary containment devices to prevent escape of liquid or droplets may be justified in certain high risk applications. These devices will require special filtration for air and water connections.

NOTE 2 Where separate aquatic organism rooms are contained within a PC3 facility, consideration should be given during the design of the air handling system to the use of a common system or the need for individual air exhaust systems and duct isolation valves to facilitate gaseous decontamination of all or part of the facility.

NOTE 3 The airlock is provided to ensure the maintenance of the negative pressure within the facility and prevent airflow between the facility and areas external to the facility. It should not be used for any work, nor should it contain any equipment, washing facilities (apart from the shower where it is used as a shower airlock) or PPE worn in the facility.

NOTE 4 Consideration should be given to the provision of a gaseous decontamination chamber for facilities that require removal and installation of equipment that cannot be steam sterilized. This facilitates removal of such items without the need to decontaminate the complete facility.

NOTE 5 Depending on the need, removable panels to allow for entry and exit of large items of equipment should be considered. These should be readily resealable to an airtight condition following use.

NOTE 6 Building regulations may require alternative egress in certain facility configurations. These exits are required to be accessible and easily usable and should not compromise facility seal integrity. Lockable doors need to permit emergency egress in accordance with building regulations.

(b) Means shall be provided for minimizing disturbance of pressure differentials by reducing the likelihood of both airlock doors being opened at the same time.

NOTE Examples of suitable mechanisms include entry and egress “traffic light” alarm systems, door interlock control systems or viewing panels if suitable.

(c) Means shall be provided to prevent powered air lock doors from opening simultaneously in the event of power loss or emergency. Manual overrides may be used to address emergency egress requirements.

(d) The allocation of task zones and layout within the facility shall promote the movement of ventilation air from the entrance and towards the more contaminated zones such as BSCs and steam sterilizer loading trolleys.

Care shall be taken to avoid turbulence or ventilation system air movement within the vicinity of BSCs that could interfere with the stability of the work face air flow pattern.

(e) As much fresh water handling and pre-treatment equipment, valve and control equipment as possible shall be located outside the facility boundary to minimize the need for service personnel to enter the facility.

(f) The facility shall have a high level of physical security including control of access (e.g. electronic access card) and shall not open directly onto a public thoroughfare.

(g) Doors, apart from those to areas used for showering and changing, shall contain viewing panels to minimize entry and exit incidents.

(h) Adequate arrangements for observation of occupants shall be provided.

NOTE Examples of suitable arrangements are the viewing panels in doors specified in Item (g) provided they allow adequate viewing of occupants; viewing panels in walls; and electronic visual monitoring facilities (e.g. viewing cameras or closed circuit television).
Two independent communications systems shall be provided. These shall allow a person in the facility to draw the attention of persons outside.

The facility shall include provisions to change aquatic organism cages, bedding, feed and water without compromising microbiological containment.

A pressure steam sterilizer for decontamination of wastes shall be provided in the facility. The pressure steam sterilizer shall not be located in the airlock.

NOTE 1: A double-ended type of pressure steam sterilizer is preferred, positioned through the barrier wall of the facility and allowing adequate access for loading and unloading of the steam sterilizer and for maintenance of the associated plant from outside the facility.

NOTE 2: See also Section 11 and Section 13.

All liquid effluent from the facility shall be decontaminated to ensure that no viable microorganisms leave the facility. For aquatic organisms, liquid effluent treatment is a complex process. The design and installation of these systems requires the use of suitably qualified professionals.

The liquids to be decontaminated include all liquids potentially exposed to aquatic microorganisms, equipment discharges, tundishes, floor wastes, facility sink effluent, hand basin effluent and shower effluent.

NOTE: See also Section 11 and Section 13.

Provision shall be made for decontamination of the facility. The facility shall be constructed to contain any aerosols or gases used for decontamination. The surface finishes in the facility shall be compatible with the decontamination agents used.

NOTE: The design of the facility should avoid inaccessible spaces. See Appendix H for recommendations on design for airtightness and periodical retesting.

All room penetrations shall be sealed to ensure they are airtight.

NOTE: See Appendix H.

### 9.6.3 Ventilation

A ventilation system that establishes a negative pressure in the facility shall be provided so that there is a directional airflow into the working area. Where facilities have supply air systems, the supply air and exhaust air systems shall be interlocked to ensure inward airflow at all times. The proper directional airflow into the facility shall be verified by airflow tests. The facility, including the airlock shall be structurally designed to take account of the operation under negative pressures.

Failure of a single component, such as an exhaust fan or a supply fan, can result in extremely high positive or negative pressures in the facility. Alarms and failure mode operations of ventilation systems shall address this risk to ensure that interlocks operate rapidly to stop systems. The facility shall be constructed to withstand, without cracking or deterioration, the maximum positive and negative pressures that can be generated until failure mode safeguards operate. Automatic and manual failure mode sequences shall be independent of any automated control system that may, itself, be the primary cause of a failure situation.

The requirements for exhaust specified in this Clause shall apply to all air that leaves the facility.

Air may be recirculated within the facility. If air is recirculated, this shall be achieved utilizing internally-mounted air conditioning equipment, such as fan coil units and split system air conditioning units. Any internally-mounted equipment shall be provided with removable panels, as required, to ensure the complete penetration of gas or vapour during room decontamination.

NOTE 1: Ventilation equipment should be located to ensure a flow of incoming air from the vicinity of the entry door towards the highest risk microbiological work areas.
NOTE 2 The quantity of outside air supplied to the facility should comply with relevant health quality standards or regulations (see AS 1668.2) and should be adequate to dilute airborne contaminants.

Ventilation equipment and outlets shall be located to minimize the disturbance to the open faces of Class I and Class II BSCs.

The facility ventilation shall incorporate the following features:

(a) The facility shall be maintained at an air pressure of at least 50 Pa below the pressure of areas outside the PC3 containment barrier when both doors of the airlock are closed. When either door is open, the facility pressure shall remain at least 25 Pa below that of areas outside the PC3 containment barrier. The 0 Pa reference pressure shall be measured to minimize the effects of fluctuations due to wind and other building ventilation systems.

NOTE Additional precautions should be considered when one or more surfaces are external and exposed to fluctuations of pressure due to wind effect. Suitable precautions include the use of an interstitial space that can be maintained at the zero reference pressure and the use of solid walls, such as concrete with minimal joints, which are unlikely to be perforated or leak.

(b) The pressure differential shall be achieved by means of an independent room exhaust fan discharging to the open air through a filter.

NOTE A variable speed drive on the exhaust fan is preferred to facilitate room pressure control adjustments.

(c) Supply or replacement air to the room shall be filtered using Type 1 Class A or Class B filters complying with AS 1324.1 and having a minimum arrestance efficiency of 90 % when tested in accordance with AS 1324.2 with Test Dust No. 4.

If adjustable dampers are provided in transfer apertures to assist in setting up the reduced room pressure, these devices shall not be mounted in the door.

(d) Exhaust air shall be filtered and discharged to the outside atmosphere in such a manner that it is dispersed away from occupied buildings and outside air intakes.

(e) For normal applications, the exhaust filter shall be Type 1 Class A or Class B filter complying with AS 1324.1 and having a minimum arrestance efficiency of 90 % when tested in accordance with AS 1324.2 with Test Dust No. 4.

NOTE Where hazards from PC3 aquatic microorganisms are solely waterborne, and no potential for hazardous aerosol generation has been confirmed, filtration of exhaust air to a HEPA standard is not always required.

(f) Where a potential risk of hazardous aerosol generation has been identified or anticipated in future potential work in the aquatic organism facility, the exhaust filter shall be a HEPA type as specified in Clause 11.10.1. An exhaust pre-filter of the same standard as the supply filter shall be provided and mounted upstream of the HEPA filter. Filters shall be selected to meet the expected quantity and type of aquatic organism debris.

NOTE 1 Pre-filters should be located within aquatic organism rooms for ease of replacement.

NOTE 2 Ventilation rates should ensure an acceptable atmosphere quality for aquatic organism welfare. If air cooling is required, this should be achieved through cooling coils mounted external to the occupied rooms.

NOTE 3 If HEPA exhaust filtration is omitted, the Aquatic Organism PC3 facility will not be suitable for other types of work at PC3 level.

(g) Where required in Item (f) above, the HEPA filter shall be installed, housed and maintained as specified in Clause 11.10.2.

(h) For each ventilation system, a differential pressure gauge shall be visible and readable from immediately outside the facility.
(i) Where HEPA filtration is required by Item (f) above, any tubing that forms part of the facility pressure sensing and control equipment shall be fitted with a 0.2 μm hydrophobic membrane filter (such as a miniature disk filter), located as close as possible to the PC3 containment barrier. Filters and tubing shall be protected against mechanical damage.

(j) An emergency stop button shall be provided for each ventilation system. This shall be located outside the facility, adjacent to the exit.

The emergency stop button shall operate independently of the main ventilation control and main facility pressure control system such that emergency isolation of the ventilation can be implemented in the event of a central control system malfunction.

(k) An audible emergency alarm shall be provided within the facility to indicate a loss of negative pressure and a visible alarm shall be provided outside the facility to indicate the same. Alarms shall be sufficiently sensitive to occur before any facility pressure becomes positive and before any pressure reversal occurs between different pressure zones within the facility. Alarm set-points should have sufficient tolerance such that false nuisance alarms do not occur. The alarms shall be generated within 2 min of such loss of pressure control.

NOTE The selection of alarm type and the provision of mute switches should be considered to address aquatic organism welfare concerns associated with sudden or prolonged noises.

(l) In multiple room and multiple zone applications, sufficient monitoring points and alarms shall be provided to capture a loss of pressure control in any space within the facility.

NOTE Additional pressure gauges and emergency stop buttons should be considered where applicable.

(m) Annual testing by qualified and competent persons shall include the following:

(i) Testing of the pressure differentials in accordance with AS 1807.10 to ensure compliance with the requirements in Item (a).

(ii) Integrity testing of any installed HEPA filters in accordance with AS 1807.6 or AS 1807.7, as applicable.

(iii) Checking that the control system is operating correctly and verifying alarms are set to operate in accordance with Item (k) on a loss of room pressure.

(iv) Calibration of pressure control and indicating devices.

(v) A report of the testing in Items (i) to (iv) and of any maintenance conducted shall be provided to the appropriate person for the facility.

(n) Exhaust air from Class III BSCs shall be discharged through the building exhaust system through direct ducting or a capture hood as described in AS 2252.3. It shall not be recirculated through the facility.

NOTE 1 Care should be exercised with direct ducting with respect to pressure fluctuations. Capture hoods may be inappropriate for gases and vapours.

NOTE 2 The exhaust air from Class I or Class II BSCs may be discharged into the facility or through the building exhaust system in accordance with AS 2252.4.

9.6.4 Access to services

Access to voids surrounding the immediate perimeter of the facility and to the ventilation equipment that serves the facility shall be restricted to authorized persons. Items of equipment, ducts and access panels to contained sections of the ventilation system shall be marked with biohazard labels to minimize the risk of accidental exposures to air or to contaminated surfaces. The installation of services shall be done in a way that facilitates access to equipment, such as HEPA filters, for maintenance and testing personnel and their equipment.
9.6.5 Containment equipment

Class III BSCs (see Clause 11.7.2) should be considered for applications which are hazardous to the operator and for applications which could be highly hazardous to the environment in event of escape. Where these hazards potentially exist a risk assessment shall be carried out to confirm appropriate containment measures.

9.6.6 Work practices

In addition to the work practices specified for Aquatic Organism PC1 (see Clause 9.4.3) and PC2 (see Clause 9.5.5) facilities, the following shall apply:

(a) All containment features of the completed facility shall be tested, commissioned and the results documented, before use.

(b) The facility shall be inspected at least annually by the BC or operator to ensure that its containment requirements comply with Clauses 9.6.2(a) and 9.6.3 by reviewing records including any HEPA filter integrity test reports and room pressure readings.

(c) The facility management shall establish policies and written procedures whereby only persons who have been advised of the biohazard, and who meet any medical requirements, shall enter the facility (see Clause 2.6).

(d) An effective emergency evacuation plan shall be devised and information on the plan shall be available to all facility staff and local emergency services.

(e) All facility staff shall have specific training in handling pathogenic aquatic organisms and in the use of safety equipment and controls. The staff shall be supervised by qualified personnel who are experienced in working with pathogenic microorganisms.

(f) Only trained people authorized by the BC or operator shall enter the aquatic organism facility, and then only after they have been advised of the specific hazard(s) and met all specific requirements, such as immunization.

(g) The facility door shall be locked when the room is unoccupied by personnel [see also Clause 9.6.2(a)].

(h) Outer clothing and personal effects shall not be taken into the facility.

(i) No one shall enter the facility for cleaning, servicing of equipment, repairs or other activities before the relevant, potentially contaminated surfaces have been decontaminated and authorization has been obtained from the facility supervisor or the safety officer. Dedicated cleaning equipment shall be stored within the facility.

(j) If the facility does not form the primary containment measure, and there is the potential for an aerosol hazard, all aquatic organism handling procedures with potentially infectious materials shall be done either in a Class I or II BSC (or the equivalent).

NOTE The provision of an uninterruptible power supply should be considered for BSCs.

(k) All equipment used in the facility shall be decontaminated prior to maintenance, service or removal.

(l) If a double-ended pressure steam sterilizer is installed across the barrier, the chamber shall be decontaminated after exposure to the facility environment before the discharge side can be opened. See Clause 11.6.8 for door interlocking requirements.

(m) Microbiological wastes, aquatic organism excrement, liquid effluents, organism bedding, organism cages and aquatic organism carcasses and tissues shall be decontaminated in a pressure steam sterilizer. Waste material shall then be disposed of in accordance with Clause 13.2.

(n) Live aquatic organisms or viable biological material shall only be taken to the same or higher level of containment.
(o) Viable biological materials to be removed from the facility shall be transferred to a non-breakable, sealed primary container, the external surface of which is decontaminated before enclosure in a non-breakable, sealed secondary container.

(p) Protective clothing shall not be worn outside the facility and shall be decontaminated by pressure steam sterilization prior to laundering or disposal.

NOTE In most circumstances, the appropriate removal procedure is removing the gloves then decontaminating the hands followed by removal of eye protection, gown and respiratory protection, taking care not to touch potentially contaminated parts of PPE when doing so, then decontaminating the hands again.

(q) Where the aquatic organism facility forms the primary containment measure, and there is a risk of infectious material being directly present on personnel (e.g. hair or skin), a full body shower shall be taken prior to exiting the facility.

(r) Measures shall be taken to ensure no microbiological contamination is removed from the facility on footwear.

NOTE Suitable measures include the use of dedicated facility footwear, the use of overshoes or a combination of these measures.

(s) In the event of a power failure, entry to the facility shall be restricted until services have been restored.

9.6.7 Health monitoring

See Clause 2.6.

Section 10 Microbiological spills

10.1 General

The response for an inadvertent spill of biohazardous material in any type of containment facility (hereafter referred to in this Section as “spills”) will depend upon various factors such as the risk group of the microorganisms handled or if it is a human pathogen.

A risk assessment is an essential part of addressing microbiological hazards. This includes the determination of the correct response to any microbiological spill (see Clause 2.1.2).

Spills shall be categorized as follows:

(a) Spills inside BSCs (all PC levels) (see Clause 10.3).

(b) Spills in PC1 and PC2 facilities outside BSCs that can be cleaned up by workers (see Clause 10.4.2).

(c) Spills in PC2 facilities outside BSCs with clean up performed by a trained spills clean-up team (see Clause 10.4.3).

(d) Spills in PC3 facilities outside BSCs, which are cleaned up by PC3 workers or, if necessary, by a trained spills clean-up team (see Clause 10.4.4).

(e) Spills in PC4 facilities where workers do not wear positive pressure suits, and which are cleaned up by the PC4 workers themselves (see Clause 10.4.5).

(f) Spills in PC4 facilities where workers wear positive pressure suits, which are cleaned up by the PC4 workers themselves (see Clause 10.4.6).

(g) Spills in aquatic facilities if large volumes are involved.
NOTE The response for each category is described in the clauses indicated. If unsure at any time of the correct procedure, ensure the safety of yourself and other workers, make the workplace as safe as possible and seek assistance.

In addition, procedures shall be developed and implemented for the following:

(i) The handling of personnel whose skin or mucous membrane have been exposed to Risk Group 3 or Risk Group 4 human pathogens, particularly those infectious by the respiratory route.

(ii) The protection of emergency personnel, particularly from aerosol inhalation, when treatment/evacuation of injured workers is necessary.

10.2 Planning

10.2.1 General

Planning for the control of a spill within the facility shall include —

(a) ensuring personnel are competent in the correct response to incidents, which may vary according to the risk group of the microorganism involved;

(b) the provision of written instructions and suitable equipment for clean-up; and

(c) having available those sources of information which will help a trained spills clean-up group to select the correct approach for the particular circumstances.

A spills clean-up team shall be employed for the cleaning up of spills where determined to be necessary by the risk assessment. This clean-up team shall have training in —

(i) the correct response procedure for PC2 and PC3 containment facilities in the institution;

(ii) the risk groups of the microorganisms handled; and

(iii) the correct use of any PPE, particularly respiratory protective equipment (RPE).

Scientific personnel trained in the handling of relevant infectious microorganisms shall respond to emergencies in PC4 facilities using documented procedures.

With large volume or highly hazardous microbiological spills, minimizing the spread of the contamination and preventing the production of aerosols shall be the major factors for protecting personnel. Leaving the area to avoid inhalation of infectious aerosols shall be the primary concern. Before attempting to clean up the spill a minimum of 30 min shall be allowed for aerosols to settle or be removed by the air handling system. At PC1 and PC2 containment levels, some air handling systems are designed for recirculation of air. In these situations activation of an emergency alarm system may be required to ensure all air is exhausted (refer Clause 2.4 of AS/NZS 2243.1). Any contaminated PPE shall be left in the area where the spill occurred.

Refresher training for both personnel and the spills clean-up team shall be scheduled and implemented to ensure competence is maintained.

10.2.2 Emergency provisions for personnel

Eyewashers (refer to AS 4774 series and AS/NZS 2982) or an equivalent decontaminating treatment shall be used to remove biological contamination of the eyes, face, or mucous membranes where deemed effective by risk assessment.
Safety showers (refer to AS 4775 and AS/NZS 2982) shall not be used for decontamination of personnel exposed to biological material.

NOTE 1 Safety showers are designed to wash off and dilute hazardous substances and have the potential to spread microbiological contamination and create more aerosols. Safety showers can generate large quantities of liquid waste which can be difficult to manage unless floor wastes have been provided directly under the discharge roses.

NOTE 2 Personnel exposed to biological material should utilize a safety or regular shower where the assessed level of contamination deems it safe.

10.2.3 Clean-up materials and equipment
Clean-up materials and equipment shall be kept at an easily accessible location and include the following:
(a) "Biohazard" signs with "DO NOT ENTER" written underneath the symbol.
(b) Suitable disinfectant supplies.
   NOTE For suitable disinfectants, see Appendix E.
(c) Absorbent materials.
(d) Protective clothing including spare gowns, gloves and RPE.
(e) Appropriate waste containers.
(f) Spare clothing for contaminated personnel.

10.3 Spills inside biological safety cabinets

10.3.1 General
These procedures shall apply to spills that occur inside all types of BSCs, irrespective of the level or type of containment facility.

Spills inside a BSC are generally considered to be a lower hazard than those outside the BSC as they are contained and aerosols are swept away by the cabinet air stream. Clean-up may be commenced immediately and may be done by laboratory personnel.

NOTE Class II BSCs do not offer 100 % protection from aerosols. Protection factors of log 5 or log 6 mean that larger spills or high titred aerosols generated inside an open Class II BSC may contaminate the front of the operator and possibly nearby items (see Bibliography, References 1.36 and 1.37).

10.3.2 Small spills
Small spills, i.e. droplet-size spills or those up to 1 mL, may be treated easily by wiping with disinfectant-soaked absorbent material or flooding with a suitable disinfectant solution.

NOTE 1 Refer to the disinfectant manufacturer’s specifications to ensure the recommended freshness, concentration and exposure time are allowed for the disinfecting procedures to be effective.

NOTE 2 For suitable disinfectants, see Appendix E.

10.3.3 Larger spills
The procedure for cleaning larger spills or breakages should be as follows:
(a) Ensure that the BSC remains operating to retain aerosols during Steps (b), (c), (d) and (e).

(b) Place absorbent material wetted with suitable disinfectant or proprietary absorbent materials that release hypochlorite over the spill. Allow approximately 10 min to effect disinfection.
NOTE 1 The three parameters that affect the efficacy of the disinfectant are concentration, time and temperature.

NOTE 2 For suitable disinfectants, see Appendix E.

(c) Disinfect gloved hands and protective gloves in the BSC. Remove any clothing for decontamination and wash hands and arms. Decontaminate items immediately in front of the open Class II BSC which may have been contaminated by any infectious material escaping the front of the BSC. Replace with clean gloves and protective clothing for carrying out the remainder of the clean-up.

(d) After initial disinfection of the spill, remove any sharp objects with forceps and discard as contaminated sharps then remove excess fluid with absorbent material and discard into a container for decontamination. Discard culture bottles, petri dishes and solid material associated with the spill into the appropriate container. Decontaminate cultures, media and disposable materials adjacent to the spill.

(e) Wipe down the work floor, BSC work zone and remaining items of equipment with fresh disinfectant solution. For Class II BSCs, disinfect both sides of the front grille and work floor within the BSC. Check that the spillage has not contaminated the sump. If the sump is contaminated, add sufficient disinfectant solution to completely cover the sump floor. If the spill is large, use sufficient disinfectant to dilute and inactivate the infectious material.

(f) Take into account whether the BSC needs to be decontaminated before further use. Consult the safety officer for guidance.

(g) Complete an incident report in accordance with any institutional requirements.

NOTE An example incident report form is given in Appendix A.

10.4 Spills outside biological safety cabinets

10.4.1 General

Spills outside BSCs may be of varying degrees of complexity, ranging from spills where a limited number of personnel work to those occurring in high access areas such as corridors. All efforts should be directed towards minimizing the chance of a spill occurring. For PC2 and higher levels of containment, material containing microorganisms that is being moved in or between facilities or service areas shall be contained in secondary sealed, unbreakable containers.

Spills can involve amounts of material ranging from 1 mL or less, to more than 100 mL. The amount spilled, the physical characteristics of the material and how the spill occurred are important factors in determining the area of involvement.

When liquid is spilled, it is generally dispersed as the following three spill fractions:

(a) The bulk of the liquid that remains in an irregular puddle.

(b) The portion that separates as splashes and rivulets.

(c) The small portion that is separated as airborne particles.

NOTE The larger airborne particles settle rapidly, whereas the smaller particles can remain suspended in air for a considerable time and can be transported from the spill site by a ventilation system. In the event of a spill of liquid, it shall be assumed that an aerosol has been generated.

The institute shall be responsible for the training of all personnel in the basic procedures for the control of microbiological spills. Decontamination procedures for spills of infectious material shall contain the contamination in the affected area. Spills in confined areas, especially cold-rooms, require special
considerations, e.g. the air conditioning system and air flow direction. General spills, such as from liquid cultures or culture plates, shall be treated with a suitable disinfectant.

NOTE 1 For spills at colder temperatures, longer contact times for disinfectants are required (see Appendix E, Table E.1).

The treatment of microbiological spills in all levels and types of containment facilities shall be determined by the risk assessment.

After a spill has been cleaned up, an incident report shall be completed in accordance with any institutional requirements.

NOTE 2 An example incident report form is given in Appendix A.

10.4.2 Spills in PC1 and PC2 facilities that can be cleaned up by the worker

Spills inside BSCs should be dealt with as described in Clause 10.3.

In spills external to BSCs, low hazard (as determined by the risk assessment) infectious material that is spilled without generating significant aerosol should be cleaned up with a paper towel or other absorbent material soaked with an effective chemical disinfectant.

The response should be as follows:

(a) Remove the laboratory gown and any other garment suspected of being contaminated and place in a biohazard bag for subsequent decontamination. Remove footwear suspected of being contaminated and place in a separate biohazard bag.

(b) Put on appropriate protective clothing such as gowns, gloves and eye protection.

(c) Place absorbent material wetted with suitable disinfectant over the spill. Alternatively, proprietary absorbent materials which release hypochlorite may be used. Allow at least 10 min to effect disinfection. Remove any sharp objects with forceps and discard as contaminated sharps.

(d) Use the same disinfectant solution to wipe over the area likely to have been contaminated, allowing 10 min for disinfection time.

(e) Carefully mop up the spill and disinfection solution, and transfer all contaminated materials for decontamination by pressure steam sterilization.

(f) Remove protective clothing and decontaminate hands.

(g) Complete an incident report form in accordance with any institutional requirements.

10.4.3 Spills in PC2 facilities that should be cleaned up by a dedicated spills clean-up team

Spills inside BSCs should be dealt with as described in Clause 10.3.

A spill external to a BSC of a large volume of high risk (as determined by the risk assessment) infectious material with the generation of aerosols will require evacuation of the area and clean-up by a trained spills clean-up team. This team shall wear protective clothing and RPE if the spill is hazardous to humans by the respiratory route.

Once a spill of this type has occurred, the area shall be evacuated immediately and sufficient time allowed (generally 30 min) for aerosol particles to be dispersed before contaminated surfaces are disinfected.

NOTE Although in certain circumstances respirators with P2 filters can provide adequate respiratory protection, the higher protection offered by HEPA filters with a full face respirator is recommended for spill clean-up operations. Goggles should be worn where full face respirators are not used.
The response for the worker should be as follows:

(a) Move away from the spill warning others to exit the laboratory.

(b) Remove potentially contaminated laboratory gown, shoes and any other garments and place on the floor away from the spill during the exit procedure from the laboratory.

(c) Warn others to keep out of the area of the spill.

(d) If contamination of the worker is superficial, wash exposed skin and put on a clean laboratory gown. Use an eyewash station if the eyes or face have been exposed.

(e) Leave the area and place a biohazard sign with “DO NOT ENTER” on the door.

(f) Notify the area supervisor or biosafety officer of the spill.

(g) If spilled material has soaked through clothing, take a complete body shower in a regular, i.e. not an emergency, shower wherever possible.

The response for the spills clean-up team should be as follows:

(i) Stay out of the spill area for at least 30 min.

NOTE Consideration should be given to isolation of recirculating ventilation systems.

(ii) Assemble a clean-up team consisting of three people: one to observe and direct the clean-up procedure, and the other two to carry out the procedure. Check all necessary equipment is available (see Clause 10.2).

(iii) Before entering the area of the spill, put on appropriate protective clothing and equipment, such as gowns, gloves, boots, eye and respiratory protection.

(iv) Determine the extent of contamination.

(v) Place absorbent material, such as paper towels, wetted with disinfectant, over the spill. Allow at least 10 min to effect disinfection.

NOTE For suitable disinfectants, see Appendix E.

(vi) Carefully remove any sharp objects with forceps and dispose of as contaminated sharps then clean up the spill and disinfectant solution. Starting from the outside, wipe towards the centre of the spill. Transfer all contaminated materials for decontamination.

NOTE Waste that includes chlorine-containing materials should not be decontaminated by pressure steam sterilization due to the likelihood of toxic fumes being produced.

(vii) Use the same disinfectant solution to wipe over surrounding areas likely to have been contaminated with aerosols. Allow 10 min for disinfection time then discard waste for decontamination.

(viii) Ensure that each member of the clean-up team decontaminates PPE used to clean up the spill.

(ix) Complete an incident report form.

(x) Notify people that the area is safe for them to return to work.

10.4.4 Spills in PC3 facilities

Spills inside BSCs should be dealt with as described in Clause 10.3.

Spills in PC3 facilities that occur outside BSCs can be dealt with either by the workers themselves, as they have experience with the microorganisms handled, or by a specialist trained spills clean-up team.

NOTE 1 The spills clean-up team should be trained and familiar with PC3 entry and exit procedures and satisfy any health requirements, such as vaccinations.
NOTE 2 The spills clean-up team should consist of three people: one to observe from outside the PC3 area and direct the clean-up procedure, and the other two to carry out the procedure.

NOTE 3 The clean-up team may require vaccinations to enable entry into the PC3 facility.

The response will vary with the design of the facility but should follow the basic procedures detailed in this Clause.

The response for the worker should be as follows:

(a) Move away from the spill warning others to exit the laboratory.

(b) Remove the laboratory gown and any other garment (including personal clothing or shoes) suspected of being contaminated and place on the floor away from the spill as you exit the laboratory.

(c) If spilled material has soaked through clothing then wash area well or shower as soon as possible and change into alternative clothing.

(d) Discuss the nature of the spill with the clean-up team.

(e) Notify personnel external to the PC2 facility via the emergency communication system.

The response for the spills clean-up team (who may be the workers themselves) should be as follows:

(i) Discuss the nature of the spill with the worker who was involved in the spill.

(ii) Leave the ventilation system on and stay out of the spill area for at least 30 min.

(iii) Check all necessary equipment is available (see Clause 10.2).

(iv) Before entering the area where the spill has occurred, put on appropriate protective clothing and equipment, such as gowns, gloves, boots, eye and respiratory protection (see Clause 10.2).

(v) Determine the extent of contamination.

(vi) Place absorbent material, such as paper towels, wetted with disinfectant, over the spill. Allow at least 10 min to effect disinfection.

NOTE For suitable disinfectants, see Appendix E.

(vii) Carefully remove any sharp objects with forceps and dispose of as contaminated sharps then clean up the spill and disinfectant solution. Starting from the outside, wipe towards the centre of the spill. Transfer all contaminated materials for decontamination.

NOTE Waste that includes chlorine-containing materials should not be decontaminated by pressure steam sterilization due to the likelihood of toxic fumes being produced.

(viii) Use the same disinfectant solution to wipe over surrounding areas likely to have been contaminated with aerosols. Allow 10 min for disinfection time, then discard waste for decontamination.

(ix) Discard all clothing and PPE for decontamination or pressure steam sterilizing before leaving the PC3 facility. If a shower is present in the facility, shower before leaving the facility. If there is no shower in the facility, put on emergency clothing, exit via the airlock and take a regular, i.e. not an emergency, shower.

(x) Complete an incident report form.

10.4.5 Spills in PC4 facilities where positive pressure suits are not worn

Spills inside BSCs are less hazardous and should be dealt with as described in Clause 10.3.
Spills that occur in PC4 facilities outside BSCs, where positive pressure suits are not worn, are particularly hazardous due to the nature of Risk Group 4 microorganisms. It is imperative that exposure to aerosols is minimized.

The clean-up procedure should be carried out by the specialist scientists working in the PC4 facility, who have been trained to deal with this situation. The procedure should be as follows:

(a) Notify personnel external to the PC4 facility via the emergency communication system.

(b) If safe to do so, contain the source of the spill. Take measures to avoid breathing the aerosol and warn others in the area and all leave immediately. If safe to do so, exit via the shower as per standard procedure.

(c) Leave the area for at least 30 min.

(d) Put on normal PC4 clothing and any additional protective clothing and equipment, such as gowns, gloves, boots, eye and respiratory protection (see Clause 10.2). This emergency clothing and equipment should be stored in the outer change room of the PC4 facility.

(e) Re-enter the area of the spill and determine the extent of contamination.

(f) Place absorbent material, such as paper towels, wetted with disinfectant, over the spill. Allow at least 10 min to effect disinfection.

   NOTE For suitable disinfectants, see Appendix E.

(g) Carefully remove any sharp objects with forceps and dispose of as contaminated sharps then clean up the spill and disinfectant solution. Starting from the outside, wipe towards the centre of the spill. Transfer all contaminated materials for decontamination.

   NOTE Waste that includes chlorine-containing materials should not be decontaminated by pressure steam sterilization due to the likelihood of toxic fumes being produced.

(h) Use the same disinfectant solution to wipe over surrounding areas likely to have been contaminated with aerosols. Allow 10 min for disinfection time, then discard waste for decontamination.

(i) Discard all clothing and equipment used for cleaning up the spill for pressure steam sterilization. Non-disposable RPE should be decontaminated chemically.

(j) Complete incident report form after exiting the PC4 facility.

10.4.6 Spills in PC4 facilities where positive pressure suits are worn

Spills inside BSCs should be dealt with as described in Clause 10.3.

Spills that occur in PC4 facilities outside BSCs, where positive pressure suits are worn, are less hazardous than those where no suits are worn (see Clause 10.4.5), as the workers are fully protected against any aerosols.

Clean-up of the spill may begin immediately and should be carried out by the specialist scientists working in the PC4 facility who have been trained to deal with this situation, following similar principles to those described in Clause 10.4.5.

An incident report form should be completed after exiting the PC4 facility.
10.5 Centrifuge spills

Where a spill or leak is detected within a centrifuge, the procedure will depend upon the risk group of the agent involved (see Clause 10.1) as well as the construction of the equipment. The clean-up procedure should be as follows:

(a) Sealed rotors or buckets that can withstand high temperatures — Steam sterilize at 121 °C for a minimum of 15 min (see Clause 11.6).

(b) Rotors and buckets not able to withstand high temperatures — Where breakage or spillage is observed, allow 30 min for aerosols to settle. Place the rotor or bucket in an appropriate non-corrosive disinfectant solution (see Appendix E). If the disinfectant is corrosive, wipe internal surfaces with water or detergent at the end of the contact time. The use of glass centrifuge tubes should be avoided. If a glass centrifuge tube has broken, remove larger pieces of broken glass to the sharps container with forceps and use material such as cotton wool moistened with disinfectant to pick up the finer pieces. Wipe internal surfaces of the centrifuge bowl with disinfectant.

Section 11 Chemicals, PPE and special equipment

11.1 Chemicals

11.1.1 General

Many media components, chemicals and reagents used in the microbiological laboratory are hazardous to health, however, the effects of some of these have not been fully characterized. The relevant safety data sheet (SDS) should be consulted for every chemical used to ensure that appropriate safety precautions are implemented to minimize the risk to health. Refer to AS/NZS 2243.2 and AS/NZS 2243.10 for the safe use and storage of chemicals in laboratories and AS/NZS 2243.8 and AS/NZS 2243.9 should be referred to for the use of fume cupboards and recirculating fume cabinets respectively.

Fume cupboards and recirculating fume cabinets shall not be used when working with infectious materials. Conversely, fume cupboards, recirculating fume cabinets or local exhaust ventilation shall be used when determined appropriate by a risk assessment for work with toxic, odoriferous, volatile or corrosive substances.

11.1.2 Chemical disinfection — Disinfectant dunk tanks, footbaths and dispensers

Pass through dunk tanks are provided in PC4 and some PC3 enhanced facilities to decontaminate the outside of secondary containers prior to their removal to other facilities. If the primary containers, whose external surfaces have been previously decontaminated, contain infectious materials, they shall only be opened in a physical containment facility of the same level. Those containing inactivated materials may be opened at a lower level within a BSC provided the surfaces of both the primary and secondary containers have been decontaminated.

Footbaths are provided in plant and invertebrate facilities to ensure that no plant or microbiological contaminants enter or leave the facility on footwear. Dedicated footwear or over-boots may be more effective than footbaths to decontaminate footwear during entry and exit. It is often challenging to achieve the required disinfectant exposure time using footbaths.

Disinfectant dispensers are used in many facilities as an alternative or additional method to soap and water for decontaminating hands. If hands are obviously soiled, they shall be thoroughly washed with soap and water.

Chemicals selected for dunk tanks, footbaths and hand decontamination shall be suitable for the purpose and shall be selected after considering their efficacy against likely potential contaminants. Recommended contact times shall be adhered to. The disinfectants shall be replenished according to manufacturer’s instructions or when soiled, whichever occurs first.

NOTE 1 For detailed information concerning chemical disinfectants, see Appendix E.
NOTE 2 The efficacy of the disinfectants may be diminished by many factors including exposure to sunlight, rain or organic material.

NOTE 3 Consideration should be given to the corrosive properties of disinfectants selected.

11.2 Personal protective equipment (PPE)

11.2.1 General

Personal protective equipment and clothing can act as a barrier to minimize the risk of exposure to aerosols, splashes and accidental inoculation and shall be worn when working in microbiological containment facilities. The equipment shall be selected to suit the type of work being performed and the potential risk of exposure. AS/NZS 2243.1 should be consulted for detailed information on the types and use of PPE.

All PPE shall be removed and hands decontaminated prior to leaving the laboratory or containment facility.

11.2.2 Laboratory coats, gowns, coveralls and aprons

Long-sleeved, back-opening gowns or coveralls should be used as they give better protection than laboratory coats. Those with adjustable or elasticized closures at the wrists or the use of oversleeves are recommended. Where necessary, to give further protection against spillage of chemicals or biological materials such as blood or culture fluids, fluid resistant gowns or aprons should be worn over gowns or laboratory coats.

NOTE For PPE associated with BSCs, see also Appendix H.

11.2.3 Footwear

Closed footwear shall be worn, i.e. footwear that covers the toes, upper foot, and heels, unless lesser requirements can be justified by a risk assessment. Where specific safety footwear is required for a particular hazard, it shall be selected in accordance with AS/NZS 2210.

NOTE Dedicated facility footwear for over-boots should be considered where there is a risk of contaminated material being removed on footwear.

11.2.4 Eye and face protection

Protective eyewear shall be worn unless a documented risk assessment can justify a lesser requirement. The choice of equipment to protect the eyes and face from splashes and impacting objects is dependent on the activity performed. Prescription or plain eye protectors are manufactured using shatterproof material and either curved or fitted with side shields. Goggles or over-glasses, including eye shields, may be worn over normal prescription spectacles. Contact lenses do not provide protection against laboratory hazards. Face shields are made of shatterproof plastic, fit over the face and are held in place by head straps or caps. Face shields with chin guards should be used. Eye protection in accordance with AS/NZS 1336, AS/NZS 1337 and the AS/NZS 1338 series shall be used.

11.2.5 Respiratory protection

Microbiological work should be planned to limit the reliance on RPE. Most laboratory work with microorganisms transmissible to humans by the respiratory route is conducted in containment equipment such as a BSC. RPE shall be used when carrying out highly hazardous procedures, e.g. when cleaning up a spill of material containing microorganisms transmissible by the aerosol route and handling animals infected with zoonotic agents transmissible by the respiratory route. Where possible, animals infected with zoonotic agents transmissible to humans by the respiratory route are housed in ventilated cages fitted with exhaust HEPA filters.
The various types of RPE available provide different levels of respiratory protection. To protect against contaminants in the atmosphere, exposure standards have been determined for particulates and specific chemicals. AS/NZS 1715 provides information on the types of RPE, types of filters and the selection of appropriate RPE for a particular situation. AS/NZS 1715 also describes the two ways of providing personal respiratory protection, i.e. purifying the air that a person breathes and supplying the person with respirable air.

Protection factors (PFs), which are a measure of the degree of protection afforded by a particular respirator, shall be used to determine the reduction in exposure that a particular respirator type can be expected to provide. These can be used to assist in the selection of RPE. These values have been determined mainly for particulates and chemicals (see Bibliography, References 1.9, 1.10 and 1.11), but similar values shall be obtained (see Table 11.1) when RPE is tested against aerosolized bacteria and fungal spores (see Bibliography, Reference 1.12).

The determination of precise PFs for infectious agents is difficult because air concentrations of infectious agents are often impossible to measure and infectious doses (exposure limits) are not available for most diseases. The lack of exposure standards for microorganisms means that the concept of minimum protection factors (MPF), as described in AS/NZS 1715, cannot be easily applied. Therefore, although imprecise, qualitative professional judgements are needed to evaluate particular exposure hazards, the convenience of a device in a particular circumstance, the type of work to be done and other relevant factors. A minimum protection factor is defined in AS/NZS 1715 as the level of respiratory protection that an item of properly functioning RPE or class of RPE would be expected to provide to properly fitted and trained users in the workplace, when used in accordance with the manufacturer’s information and instruction. The MPF takes into account all expected sources of face piece penetration (e.g. face seal protection, valve leakage).

NOTE By way of contrast, some current overseas publications quote higher protection factors for respirator classes by not taking all these factors into account.

<table>
<thead>
<tr>
<th>MPFa</th>
<th>Respirator type</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Half-face piece (P2 or N95)</td>
<td>Respirator needs to be fit tested to the individual</td>
</tr>
<tr>
<td>50</td>
<td>Powered air purifying respirator (PAPR) with half-face piece</td>
<td>Devices covering half-face provide lower levels of protection</td>
</tr>
<tr>
<td>50</td>
<td>Full-face piece respirator with P3 or HEPA filter</td>
<td>Respirator needs to be fit tested to the individual</td>
</tr>
<tr>
<td>100</td>
<td>PAPR with P3 or HEPA filter and head-covering hood</td>
<td>Considered to provide high protection. Fit testing to the individual not required</td>
</tr>
<tr>
<td>10 000</td>
<td>Self-contained breathing apparatus (SCBA) with positive pressure demand</td>
<td>Not practical for most microbiological applications</td>
</tr>
</tbody>
</table>

a Minimum protection factor that could be assigned to the respirator type.

NOTE Table 11.1 is modified from Bibliography, Reference 1.13.

Air-purifying RPE shall be available with interchangeable filters for protection against gases, vapours, particulates and microorganisms. SCBA and supplied air respirators provide the highest level of protection but are impractical in most microbiological applications. RPE employing a HEPA filter (P3 filter) provides the best practical respiratory protection against aerosolized microorganisms. Air-purifying RPE can be powered (where air is drawn through the filter by means of a fan) or non-powered (where air is drawn through the filter by wearer inhalation). In either case, the RPE may be in the form of a half face piece (includes disposable type), a full face piece or a head covering. The performance of full face and half face respirators is critically dependent on fit testing as described in AS/NZS 1715.

The term “face masks” is used to describe masks designed for use in health care, such as in operating rooms, medical and dental procedures. These types of masks are specified in AS 4381. They shall not
be used where an additional degree of respiratory protection is required from the risk of airborne transmission of infection, and they do not meet the requirements for RPE specified in AS/NZS 1715.

11.2.6 Gloves

Contamination of the hands may occur when laboratory procedures are performed. Hands are also vulnerable to "sharps" injuries. Disposable latex, nitrile or vinyl surgical-type gloves are used widely for general laboratory work, particularly when blood and body fluids are being handled or to protect laboratory materials from human contamination.

Where allergic reactions such as dermatitis and immediate hypersensitivity are reported in a laboratory from wearing latex gloves (powdered and non-powdered), alternatives such as nitrile or vinyl gloves, or accelerator-free nitrile gloves shall be made available.

After handling infectious materials, working in a BSC and before leaving the laboratory, gloves shall be removed and hands decontaminated. Used gloves shall be discarded with infected laboratory waste.

Heat-insulating gloves shall be worn when conducting procedures involving liquid nitrogen, sterilizers and microwave ovens.

Stainless steel mesh gloves shall be worn when there is a potential exposure to cuts from sharp instruments, e.g. during post-mortem examinations.

NOTE Further information on occupational protective gloves is available in the AS/NZS 2161 series.

11.3 Centrifuges

11.3.1 General

While centrifuges are essential pieces of laboratory equipment, equipment failure, such as the breakage of centrifuge tubes or buckets, can pose a hazard to operators, to other personnel, to the environment and to other experimental work through the release of contaminated aerosols. To reduce the potential for aerosol release, aerosol-tight, sealed buckets or sealed rotors should be used.

NOTE The life of some types of seals or tubes can be shortened by repeated steam sterilization (consult the manufacturer’s guidelines).

The following measures shall be implemented when using centrifuges:

(a) Tubes and buckets with aerosol-tight caps or lids that can be sealed securely shall be used when centrifuging infectious materials.

(b) Centrifuges shall not be used in Class I or Class II BSCs unless the combination of BSC and centrifuge has been tested and it has been found that air turbulence caused by the centrifuge does not compromise containment.

(c) Centrifuges with vacuum pumps shall be fitted with a 0.2 μm hydrophobic type membrane filter between the chamber and the vacuum pump.

11.3.2 Centrifuge use and maintenance

The following procedures shall be implemented:

(a) Centrifuge tubes and buckets shall be periodically inspected before use and those showing damage shall be discarded. Rotors shall be inspected for damage, cracking or corrosion and, if evident, withdrawn from service (consult the manufacturer’s guidelines).

(b) Loaded tubes and buckets shall be carefully balanced before centrifuging.

(c) After completion of centrifuging, check for any evidence of leaks or breakages before opening sealed rotors or buckets.
NOTE For the management of centrifuge spills, see Clause 10.5.

(d) The centrifuge bowl, rotors and buckets shall be decontaminated with appropriate disinfectant on a regular basis and before servicing.

NOTE Consult the manufacturer’s handbook to check for compatibilities of disinfectants.

11.3.3 Centrifuges lacking aerosol containment

Where sealed-bucket or sealed-rotor centrifuges are not available, the following precautions shall be taken:

(a) Centrifuge tube compartments in angle rotors and buckets or carriers in horizontal rotors shall be cleaned regularly and inspected for damage, cracking or corrosion. If damage becomes significant, the unit shall be discarded.

(b) Rotors of some medium and high speed centrifuges, although equipped with O-ring seals, may not retain material if a leak occurs from a tube. When centrifuging infectious material of Risk Group 2 or higher risk in any medium and high speed centrifuges, the tubes shall be loaded, and the tubes and rotors unloaded, in a BSC.

(c) The use and maintenance of a continuous-flow centrifuge shall be in strict conformance with manufacturer’s instructions.

NOTE This type of equipment is a potential producer of aerosols.

(d) Centrifuges of this type shall not be used in PC3 and PC4 facilities unless contained within the BSC.

11.3.4 Centrifuge rooms

Laboratories using a number of large, medium-speed and high-speed centrifuges often install them in a dedicated centrifuge room. To allow for the possibility of a rotor failure or leakage with a resultant production of an aerosol, the centrifuge room ventilation shall be treated according to the requirements of its physical containment level.

11.4 Freeze-drying and reconstitution of cultures

Freeze-drying is an operation that is potentially hazardous, both to susceptible hosts and to the laboratory environment. Freeze-drying shall be carried out in containment levels appropriate to the risk group of the microorganism being handled (see Section 4). To minimize the risks, the following points shall be observed:

(a) The manufacturer’s instructions shall be strictly followed when operating the freeze-drier.

(b) The freeze-drier shall be fitted with a 0.2 μm hydrophobic membrane type filter in the chamber exhaust line to protect the oil in the vacuum pump from contaminated aerosols.

(c) Appropriate procedures shall be used when using cryogenic agents, such as liquid nitrogen or dry ice in ethanol.

(d) Ampoules containing infectious freeze-dried material shall be opened in a BSC. The ampoules shall be wrapped in material such as a gauze square to protect the operator from being cut. Commercial ampoule breakers shall be available.

(e) Unwanted ampoules shall be sterilized by heating to 160 °C for 2 h, prior to discarding, or shall be discarded into a sharps container for incineration (see Clause 13.2).

11.5 Liquid nitrogen

Liquid nitrogen is commonly used for storing and transporting materials and cultures of microorganisms at low temperature. The very low temperature of the liquid, −196 °C, will cause injury similar to high
temperature thermal burns following very brief contact with body surfaces. The eyes are especially vulnerable to exposure.

NOTE Refer to AS 1894 for information related to the storage and handling of cryogenic and refrigerated liquids.

The following precautions shall be taken when handling liquid nitrogen and when adding or removing materials from low temperature storage:

(a) A full face shield and impervious insulating gloves of cotton-lined heavy duty rubber, that give protection without being clumsy, shall be worn. When the liquid is being poured, an impervious apron shall be used to prevent spilled liquid nitrogen becoming trapped in clothing.

NOTE The possibility of splashes entering shoes should be considered.

(b) Cryogenic containers specifically designed or approved for such work shall be used for storing materials. If liquid nitrogen leaks into a container, an explosion is likely when it is removed as the liquid is rapidly converted into gaseous nitrogen.

NOTE The wearing of hearing protection is recommended.

(c) If cryogenic vials or glass ampoules leak, the contents will remain viable and contaminate the liquid nitrogen. Precautions shall be taken to avoid cross-contaminating material being removed.

(d) Containers of liquid nitrogen shall not be tightly closed, as one volume of the liquid produces nearly 700 volumes of gaseous nitrogen. Only approved vessels shall be used for the storage and transport of liquid nitrogen.

(e) Liquid nitrogen shall not be stored in unventilated rooms such as cold rooms.

(f) The atmosphere in rooms containing liquid nitrogen refrigerators, storage vessels or Dewars shall be monitored for oxygen concentration where the capacity of liquid nitrogen containers is sufficient to deplete the oxygen level to less than 18%. Failure of the ventilation system can cause the nitrogen gas concentration to rise.

NOTE Oxygen depletion sensors should be selected, adjusted and calibrated at suitable intervals to minimize the occurrence of false alarms.

(g) If Dewar flasks are transported by lift between floors, the containers shall not be accompanied by passengers.

11.6 Pressure steam sterilizers

11.6.1 General

Pressure steam sterilizers are used in facilities both for sterilization of media and equipment required for the culture of microorganisms, and for decontamination of discarded cultures and waste materials. Pressure steam sterilizers operate at high pressures and temperatures, and appropriate measures shall be taken for personnel safety.

NOTE 1 Refer to AS 1210 and state pressure vessel registration requirements to ensure steam sterilizers meet and maintain safe operational requirements.

Personnel operating a pressure steam sterilizer shall be trained so they understand that correct loading of the sterilizer is essential to ensure sterilization or decontamination of the load. Operators shall be trained so they understand the hazards associated with heat, steam and pressure. Operators shall be provided with protective clothing, including heat-insulating gloves, for use when loading and unloading sterilizers. Use of a face shield is recommended when unloading the sterilizer.
Areas for the temporary holding of material awaiting sterilization shall provide appropriate storage conditions and adequate protection from unauthorized access and vermin.

NOTE 2 Such areas should also have provision for the separate storage of infectious waste in impermeable plastic bags or lidded containers. Bags should allow the exit of air and entry of steam into the bag to contact all parts of the waste during the sterilization cycle. There are technologies available which provide for automatic opening of containers at the commencement of the steam sterilization cycle to prevent exposure of operators to contaminate material (see Clause 11.6.4).

Sterilization facilities shall be equipped with local exhaust ventilation with air capture vents or extraction systems for the removal of heat, steam and odours. Wire racks or perforated metal shelving shall be provided in the vicinity of heat sterilizers for the cooling of sterilized materials and loads. Adequate space shall be provided for the movement of large loads and trolleys.

Appropriate chemical disinfectants shall be provided for spills and leaks. Easy access to hand washing facilities, safety showers and eyewash facilities shall also be provided.

11.6.2 Air removal methods for steam sterilizers

For efficient sterilization, all air shall be removed from the load and from the chamber of the sterilizer by —

(a) downward displacement of air by steam; or
(b) the use of an evacuation pump to remove air prior to entry of steam.

11.6.3 Downward-displacement steam sterilizers

Downward-displacement cycles are used for the sterilization of articles, culture media and fluids. They are not usually appropriate for waste decontamination without special precautions and cycle validation. Small articles such as test tubes or bottles should be packed in open mesh baskets or similar containers allowing easy displacement of air. Screw caps should be loosened. Large containers, such as buckets, trap air in downward-displacement cycles and should not be used to hold small articles for sterilization. If such large containers are to be sterilized when empty, they shall be placed on their sides in the chamber. Admission of steam at a controlled rate may be necessary to prevent damage to glassware. When using autoclave bags, extra water may be carefully added to the opened bag to assist in reaching the correct temperature for decontamination.

The timing of the sterilization stage of the cycle commences when the set temperature is recorded by the thermocouples in the drain line and in the densest part of the materials to be sterilized or decontaminated. Constituents of the load may not have reached this temperature and additional time for heating should be allowed especially where large containers of liquids or solids are to be sterilized. However, materials that may be damaged by excessive heat over an extended period should not form part of a load containing large volumes of liquid.

Procedures used shall address the dangers of removing containers of fluid from the hot sterilizer chamber. Sufficient time should be allowed for cooling before they are handled. Personnel operating the sterilizer shall ensure that the sterilization cycle is complete and the pressure has returned to zero before attempting to open the sterilizer door. Care should be taken when removing large containers of liquid after completion of sterilization, as sudden changes in pressure and temperature may occur and they may break or boil over when moved. Before removal of the load, the sterilizer door should be partly opened and sufficient time allowed for the load to cool. Avoid inhaling harmful vapours when opening a sterilizer if the load contains chemicals, e.g. biochemical test reagents such as amyl alcohol (1-pentanol) from the indole test.

NOTE Refer to EN 285 and EN 13060 for requirements for downward-displacement steam sterilizers.
11.6.4 Pre-vacuum (porous load) steam sterilizers

Penetration of steam into the load is inhibited in a downward-displacement cycle if air is trapped among cavities or in gaps in porous materials. The attainment of effective sterilizing temperatures at such sites is consequently delayed, or even prevented. Porous loads such as clothing should therefore be processed in a sterilizer fitted with a pump for air removal in a pre-vacuum stage of the cycle. If drying of the load is required, the same pump is also used in a post-vacuum stage, after sterilization. Pre-vacuum sterilizers can also be used to sterilize large empty containers that would trap air in downward-displacement cycles. Where there is a risk of microbial contamination in the evacuated chamber air, a 0.2 μm hydrophobic membrane type filter shall be fitted between the chamber and the vacuum pump and periodically maintained.

NOTE Refer to EN 285 and EN 13060 for requirements for pre-vacuum steam sterilizers.

11.6.5 Times for sterilization

Sufficient penetration time should be allowed for all parts of the load to reach the desired temperature. Minimum holding times after attainment of temperature shall be —

(a) 15 min at 121 °C and 103 kPa; or
(b) 3 min at 134 °C and 203 kPa.

11.6.6 Monitoring of sterilization cycles

Some visual indicators, such as sensitive papers or tapes, only give an indication that the sterilizer load has reached a specified temperature and do not give an indication of how long the load has been exposed to that temperature. Such visual indicators may be used as a check that materials have been processed, but shall not be used to monitor the efficacy of the sterilization procedure. Other chemical indicators progressively change colour with the time exposed at specified temperatures, and their use is recommended as they give an immediate indication of the efficacy of treatment.

Biological indicators should be used at regular intervals (e.g. monthly) to monitor the microbial killing power of the sterilization process. They shall be placed in several positions in a load, including those least likely to attain accepted sterilization parameters. Bacterial enzyme indicators may be used instead of biological indicators for the monitoring of sterilization cycles. These indicators are designed so that the loss of enzyme activity parallels the loss of spore viability. Their advantage is that enzyme inactivation can be easily and rapidly determined, e.g. within minutes or hours, by the addition of a substrate and observation for absence of a coloured or fluorescent end-point. In contrast, biological indicators require incubation for growth for periods of days.

The Bowie-Dick test (refer to Section 17 of EN 285) is designed for the daily monitoring of air removal from standard towel packs sterilized in pre-vacuum sterilizers, and is not suitable for downward-displacement sterilizers. Process challenge devices (PCDs) have been developed to demonstrate air removal and steam penetration of hollow bore/cannulated instruments. The Helix test is a type of PCD. Either the Bowie-Dick or the Helix test could be used to demonstrate air removal and steam penetration (refer to ISO 11140-1).

Sterilizer cycles should be validated. Validation shall be achieved by demonstrating that pre-determined physical and biological parameters can be met. Physical parameter validation involves demonstration that the pre-determined temperature can be reached in the coolest part of the sterilizer and the densest part of the load. This may be achieved by the use of thermocouples or resistance thermometers to demonstrate that the sterilization temperature selected is achieved. All gauges including temperature, pressure and time shall be calibrated. Calibration of gauges shall be performed by competent personnel using measuring equipment that has documentation confirming the calibration accuracy against a referenced Standard. Calibration should be performed on a regular basis and, at a minimum, annually. Biological validation involves successful demonstration of biological lethality through the placement of biologic/ enzymatic indicators in the coolest part of the sterilizer (usually the drain) and in the densest part of a load. Generally, biologic/ enzymatic indicators should be placed adjacent to the temperature sensors (see Table 11.2 for commonly-used biological indicators).
A logbook recording details of sterilizer load and cycle should be maintained. The chart records of temperature and duration of sterilization cycles should be assessed and checked regularly by the safety officer.

11.6.7 Chamber pressure relief valves

Pressure relief valves shall discharge in a safe place, preferably outside and away from the containment structure because of the potential for a saturated atmosphere to damage the integrity of the containment facility.

11.6.8 Barrier wall steam sterilizers

The inner door shall automatically interlock with the outer door in such a manner that the outer door can only be opened after the sterilization cycle has been completed. In addition, all displaced or evacuated air, steam and liquid shall be regarded as potentially contaminated and shall be filtered or heat treated appropriately. Pressure sensing instruments shall be protected by filters that can be steam sterilized. All potentially contaminated pipework that is not steam sterilized shall be arranged to facilitate chemical decontamination.

NOTE It should be noted that the liquid in liquid ring vacuum pumps is potentially contaminated and would require heat or chemical decontamination unless the evacuated air or gases have been filtered through an appropriate membrane filter.

The barrier wall steam sterilizer shall be sealed gas-tight to PC3 and PC4 facility boundaries using a purpose-constructed chamber barrier flange. All penetrations shall be sealed gas-tight such that the installation of the steam sterilizer does not compromise the seal integrity of the containment facility. The inner door shall automatically interlock with the outer door in such a manner that the outer door can only be opened after a successful sterilization cycle has been completed. In addition, sterilizers used in PC3 and PC4 facilities shall be fitted with sealed bonnet pressure relief valves and be preceded with appropriately rated bursting discs. The interspace shall be monitored for pressure rise.

### Table 11.2 — Commonly-used biological indicators

<table>
<thead>
<tr>
<th>Process</th>
<th>Species</th>
<th>Incubation temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam under pressure</td>
<td><em>Geobacillus stearothermophilus</em></td>
<td>56 °C Rapid enzyme B1 (60 °C)</td>
</tr>
<tr>
<td>Dry heat</td>
<td><em>Bacillus atrophaeus</em></td>
<td>37 °C</td>
</tr>
<tr>
<td>Ethylene oxide</td>
<td><em>Bacillus atrophaeus</em></td>
<td>37 °C</td>
</tr>
<tr>
<td>Subatmospheric steam and formaldehyde</td>
<td><em>Geobacillus stearothermophilus</em></td>
<td>56 °C</td>
</tr>
</tbody>
</table>

NOTE Table 11.2 is based on information provided in Bibliography, Reference 1.14.

11.7 Biological safety cabinets

11.7.1 Classes I and II BSCs

Class I and Class II are the two most commonly used BSCs (see Clause 1.5.9).

To enhance containment of hazardous materials in Class I or Class II BSCs, both AS 2252.1 and AS 2252.2 require that all potentially contaminated zones under positive air pressure shall be surrounded by zones of negative air pressure relative to the facility. BSCs without this design feature may not provide the same degree of safety for the user and the environment.

In addition, Class II BSCs conforming with AS 2252.2 are required to pass an air barrier containment test. This test is a direct determination of the effectiveness of containment by the air barrier and is part of the certification done regularly in the facility as described within Appendix H.
Class I and Class II BSCs, conforming with AS 2252.1 and AS 2252.2 respectively, offer an equivalent degree of protection to the operator. Class I and Class II BSCs are designed to be freestanding units, and shall not be connected directly to ducting that vents to the atmosphere, as wind effects may interfere with containment. Exhaust air from Class I or Class II BSCs, which has been passed through a HEPA filter, may be discharged either into the facility or exhausted through the building exhaust system.

When the building exhaust system is used, the connections shall be made in a manner that avoids any interference with the air balance of the BSCs. Capture hood air flow shall exceed cabinet discharge air flow by sufficient margin to ensure full entrainment of cabinet discharge air into the exhaust air stream. Discharges shall be designed and located outside of the building to ensure external air velocities do not adversely affect containment air flows and pressures within the BSCs.

NOTE 1 Refer to Figures 1 and 2 of Clause 5 of AS 2252.4 for guidance on installation and location of BSCs.

NOTE 2 For information and recommendations concerning safe use of the BSC, see Appendix H.

NOTE 3 Refer to Clause ZZ14 of AS 2252.4 for information related to decontamination of the BSC.

Where requirements in AS 2252.4 conflict with requirements in this Standard, the requirements in this Standard shall take precedence.

NOTE 4 Capture hoods may be inappropriate for toxic gases and vapours.

All BSCs shall be checked for containment efficiency and safety before initial use, after any modification including change of HEPA filters, after relocation and on an annual basis. The use of Bunsen burners in Class II BSCs is not recommended as it disrupts the laminar flow and the barrier air. An alternative means, such as disposable implements or electrical heating, is preferred.

BSCs shall be decontaminated with formaldehyde gas or an equivalent decontaminant before testing when they have been used for handling Risk Group 2, Risk Group 3 or Risk Group 4 microorganisms. Penetration of the decontaminant throughout all sections of the BSC is essential.

When a BSC is used for handling Risk Group 1 microorganisms or uninfected cell lines, a thorough wipe-down of all work area surfaces, including the inner surface of the viewing window, with a detergent/disinfectant cleaner shall be done before servicing and testing.

Clean workstations (laminar flow clean benches) conforming to AS 2252.6 do not provide operator protection as do BSCs. Clean workstations provide HEPA filtered air to protect the work in a vertical (downflow) direction or in a horizontal (crossflow) direction. Part or all of this air moves towards the operator. These workstations shall not be used when handling microorganisms of Risk Group 2, Risk Group 3 or Risk Group 4 or hazardous materials.


Classes I and II BSCs shall not be used for the handling of infectious materials which also contain volatile hazardous chemicals, unless the exhaust air from the BSCs is removed via the building exhaust system and is not discharged into the room or specialist advice is sought on how to also capture the volatile hazardous chemicals. Where a central vacuum system or portable vacuum pumps are used, 0.2 μm hydrophobic membrane-type filters, and liquid disinfectant traps shall be installed at the point of use.

Fume cupboards shall not be used when working with infectious materials.

11.7.2 Class III BSCs

A Class III BSC is a self-contained, totally enclosed chamber incorporating an isolator envelope and gloves attached to sleeves, for the performance of laboratory work with infectious material and for housing infected animals.

NOTE 1 Class III BSCs include flexible film isolators and some powder containment chambers used for handling powders suspected of being bioterrorist agents.
NOTE 2  The operator works in gloves attached to sleeves which are part of the BSC, or in gauntlets attached to the BSC envelope.

NOTE 3  Class III BSCs operate at a pressure below that of the room in which they are located. The entry and escape of airborne particles is prevented by a HEPA filtered inlet and exhaust air system.

NOTE 4  Material is introduced and removed from the Class III BSC through supply and sample ports without compromising microbiological security.

NOTE 5  The flexible film isolator envelope is constructed of plastic film which is flexible, puncture and tear-resistant and optically clear and attached to a rigid supporting frame.

### 11.8 Vacuum systems

When vacuum systems or pumps are used, there is the potential for aerosols to be released into the surrounding environment. This is particularly relevant where working with materials which contain or potentially contain infectious microorganisms. Vacuum systems are often connected to the internal environments in Classes I, II and III BSCs.

Liquid disinfectant traps and 0.2 μm hydrophobic membrane-type filters shall be installed at each point of use for any vacuum connections within biological safety cabinets.

Liquid disinfectant traps and 0.2 μm hydrophobic membrane-type filters shall be installed at points of use for work with potentially infectious material at PC1 and PC2 level and for all vacuum connections at PC3 and PC4 level.

Centrifuges with vacuum pumps shall be fitted with a 0.2 μm hydrophobic membrane-type filter between the chamber and the vacuum pump. Installation of vacuum line air filters and liquid disinfectant traps shall ensure that maintenance can be achieved safely to this equipment without exposing maintenance personnel to contamination.

### 11.9 Laminar flow cytotoxic drug safety cabinets

Laminar flow CDSCs are suitable for work with materials containing cytotoxic agents and with other infectious agents that are difficult to inactivate such as prions. These cabinets, in contrast to laminar flow BSCs (Class II BSCs), provide protection for cabinet maintenance personnel in addition to protection of the environment, the material being handled and the operator (see AS 2252.5 and AS 2639).

The design of the laminar flow CDSC enables this material to be captured in an exhaust filter located under the work floor. This arrangement prevents the contamination of the airflow paths within the cabinet. The procedure for sealing and safe removal of the cabinet exhaust HEPA filter is described in AS 2639.

NOTE  For further information on prions, see Clause 3.7.

The labelling of the encapsulated filter shall be “CAUTION: PRION CONTAMINATED WASTE. DISPOSE BY HIGH TEMPERATURE INCINERATION ONLY”. Packaging shall also include the biological hazard symbol.

### 11.10 HEPA filters

#### 11.10.1 Specification

HEPA filters for containment facilities shall be either of the following:

(a) Type 1, Class A filters as specified in AS 1324.1 with separators and elastomeric compression seals or gel seals that do not support microbiological growth, which meet all requirements of AS 4260 with a minimum performance of Grade 2.

(b) Separatorless filters that meet all requirements of AS 4260 with a minimum performance of Grade 2 provided accredited data are available demonstrating full conformance with AS 4260 and, in
particular, the requirements for filter efficiency, leak testing, fire performance, structural strength and resistance to vibration.

11.10.2 Installation and maintenance

HEPA filters for containment facilities shall be mounted in gastight housing(s) located as close as possible to the containment facility to minimize the length of potentially contaminated ductwork. The interconnecting ductwork between the containment room and the HEPA filter housing shall also be of gastight construction.

The design of the filter housing shall facilitate the testing of the integrity of the HEPA filter element and mounting, and the periodic gaseous decontamination of the filter element and associated mounting surfaces independently of the gaseous decontamination of the facility.

Housings shall be placed in fully accessible locations outside the facility with clear access to facilitate filter integrity testing, physical handling of filter elements and operation of isolating valves. Installations in false ceiling spaces should be avoided.

Filter housings shall incorporate the following features:

(a) Gastight construction with sealed access doors for filter maintenance and integrity testing.

(b) Gastight isolating valves on the air inlet and outlet ducts to allow independent gaseous decontamination of the housings.

(c) Secure filter element clamping and mounting tracks ensuring damage-free handling.

(d) Upstream and downstream valved ports to facilitate gaseous decontamination.

(e) Upstream and downstream valved pressure tappings to facilitate monitoring of the filter air flow pressure drop. The upstream tapping shall be fitted with a 0.2 μm hydrophobic membrane type filter of either stainless steel construction with a serviceable membrane or a disposable plastic housing and filter membrane. This filter housing shall be protected from physical impact.

(f) A differential pressure gauge.

(g) A facility to introduce a test airflow and cold generated aerosol to establish the integrity of the filter element and its mounting in accordance with the test protocol in AS 1807.6 or AS 1807.7, as applicable.


HEPA filters shall be tested in accordance with AS 1807.6 or AS 1807.7, as applicable, at a minimum, annually. Prior to testing, the HEPA filter shall be decontaminated.

NOTE 2 See Appendix H and Clause ZZ14 of AS 2252.4 for information on gaseous decontamination of BSCs and their HEPA filters.

11.11 Liquid effluent decontamination systems

11.11.1 General

Liquid waste generated from within microbiological laboratories and containment facilities cannot always be discharged directly to local sewers or external waste streams. In some situations local authorities will require liquid waste to be appropriately treated prior to discharge.

Liquid waste can be relatively low risk, such as from showers or hand basins, or can be heavily contaminated with infectious organisms. Liquid waste can also contain substantial amounts of suspended solids, such as liquid wastes from large animal facilities.

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Liquid effluent decontamination systems typically use equipment and materials that either operate at high temperature and pressure or which use corrosive and toxic chemicals. A breach, leakage or spillage can result in operational exposure to hazardous microbiological, chemical or high temperature liquid, vapour or gas.

11.11.2 Safety considerations

The following safety considerations shall apply:

(a) Personnel operating and maintaining liquid effluent decontamination systems shall be trained for both the hazards which may be present in the waste and for the hazards which may be present when operating and maintaining the equipment so that the hazards are fully understood prior to carrying out any work.

(b) Personal protective clothing shall be worn at all times.

(c) Safety showers and eyewashers shall be provided to manage hazards associated with splashes from contaminated effluent or chemicals where applicable in accordance with AS 4775 and AS/NZS 2982.

(d) Hand basins or an alternative means of decontaminating hands shall be provided at the exit of each room where liquid effluent decontamination equipment is located.

(e) Pressure vessels shall be constructed and maintained in accordance with AS/NZS 1200 and AS 1210.

(f) Liquid effluent decontamination systems shall be housed in secure dedicated spaces and access shall be restricted to authorized personnel.

(g) Appropriate biohazard and chemical safety signage alerting operators to the potential hazards shall be provided, visible immediately outside access doors.

(h) Viewing capability shall be provided immediately outside the equipment housing space so that operators are able to confirm it is safe to enter.

(i) Adequate ventilation shall be provided for human safety and comfort and to remove heat, odours and vapours.

(j) All air removed from the spaces shall be exhausted to safe locations outside the building using sealed ducts and fans (refer to Clause of 5.6 of AS/NZS 2982).

(k) Precautions shall be taken to ensure that no air can re-enter other internal spaces during normal or failure situations.

(l) A risk assessment shall be carried out to assess if exhaust air needs to be HEPA filtered prior to discharge.

(m) Floors shall be bunded to retain the volume of the largest liquid storage vessel plus the volume of any disinfectant that would need to be added as part of a clean-up procedure.

(n) The facility shall be designed and constructed to enable safe decontamination of untreated liquid effluent that has escaped the containment system.

NOTE Services, pipes and cables unrelated to the function of the liquid effluent decontamination systems or the associated room should not be located within the spaces.

11.11.3 Methods of liquid effluent decontamination

The following are a number of methods of decontaminating liquid effluent from containment facilities:

(a) Heat-based batch systems.
Continuous flow systems operate at elevated temperatures or higher chemical concentrations to reduce the required decontamination exposure time. Continuous flow technology is not usually appropriate for liquid effluent containing solids or particulates unless precautions are taken to limit particulate sizes. This is necessary to ensure that heat penetration and time exposure parameters are met. Otherwise, heat may not effectively penetrate particulate material during the short time exposure. It is important to seek appropriate technical advice if continuous flow systems are being considered.

11.11.4 Requirements for liquid effluent decontamination systems

11.11.4.1 Performance requirements

The following performance requirements shall apply:

(a) The system technology and operational parameters (temperature, time, chemical concentration) shall be effective against the microorganisms of concern which are potentially present in the waste.

(b) The design of the system shall take into account the possible presence of sediment, surface scum and frothing to ensure that the decontamination process penetrates all the potentially contaminated material.

(c) Where solids may be present, the decontamination shall penetrate the thickness of the solid material to ensure complete decontamination is achieved.

NOTE This requirement means that some chemical systems and continuous flow heat-based systems are not appropriate for liquid effluent containing solids unless the particulate size is managed and a suitable analysis is carried out to confirm their effectiveness.

(d) Discharge of decontaminated liquid effluent shall meet local regulations with respect to parameters including temperature, chemicals, solids and organic material.

(e) For heat-based systems, the temperature shall be measured at sufficient locations within the system to ensure that all of the effluent is maintained at or above decontamination temperature throughout the decontamination cycle exposure time.

NOTE The coolest part of some systems can be connections at the top or underside of vessels.

(f) For chemical-based systems, the effectiveness of the proposed chemical treatment system shall be validated for the microorganisms of concern. Adequate chemical quantity and mixing shall ensure chemical concentration is evenly distributed and maintained at or above the required level for the required duration to successfully decontaminate the effluent. This shall be verified by a suitable methodology for every cycle.

11.11.4.2 Operational requirements

The following operation requirements shall apply:

(a) Liquid effluent decontamination system functions shall be verified prior to use to ensure that the equipment operates in accordance with requirements. Critical operational functions shall be checked periodically to confirm ongoing performance.

(b) Instruments used to manage and monitor critical process parameters shall be regularly calibrated to ensure ongoing performance characteristics are reliably achieved.

(c) There shall be provision to record and log critical parameters for a minimum period of 1 year, or as required by applicable authorities.
(d) There shall be provision to insert or mount biological indicators and these shall be used to validate the treatment cycle at suitable intervals.

(e) Errors and failed cycles shall be alarmed and a failed cycle shall have mechanisms in place such that discharge of incomplete or untreated liquid effluent cannot occur.

(f) For automated liquid effluent decontamination systems, or systems which could operate, fill or leak when unattended, there shall be an alarm mechanism which shall alert appropriate operators in event of a failure.

11.11.4.3 Construction requirements

The following construction requirements shall apply:

(a) The materials of construction shall be suitable for the liquid being treated and for the elevated temperatures, pressures and chemicals which may be present. A risk assessment shall be carried out to identify chemicals, cleaning agents, waste composition which may be present and at what concentrations. This information shall be used to support the selection of materials for all pipes, vessels, fittings and fixtures which could come into contact with the liquid waste.

(b) The installed equipment shall include provisions to decontaminate all components, including collection vessels, pipes, fixtures and fittings for periodical maintenance.

(c) The installed equipment shall include provisions to decontaminate untreated liquid effluent and to decontaminate components of the liquid effluent decontamination system in the event of a failure where access may be required by maintenance personnel.

(d) Care shall be taken to avoid dead-legs, capillary tubing and other features connected directly to treatment systems where these could harbour contaminated material.

(e) Precautions shall be taken to ensure that untreated, or partially treated, liquid effluent cannot leak or “weep” past valves or connections exposed to liquid waste systems before or during treatment.

(f) Venting of air from spaces containing potentially contaminated material shall incorporate filters. Vent filters shall be suitable for the hazards applicable to the installation. As a guide, membrane filters rated to 0.2 µ for liquids and to 0.003 µ for gases are typical for liquid waste system vents. Filters shall be periodically tested for integrity and shall be decontaminated prior to inspection, testing, maintenance, and replacement.

(g) Mechanisms shall be in place to prevent overloading of liquid effluent systems. This can occur, for example, if a water supply is left on or if a valve fails without closing properly. Overload due to activation of a fire sprinkler system shall be taken into account, where such a system is fitted.

(h) In situations where a spill could result in the release of PC3 or PC4 aerosol hazards, a risk assessment shall be carried out to assess the requirements for the space housing the equipment (see Clause 13.3).

11.11.5 Storage and handling of chemicals

Where chemicals are required for chemical-based liquid effluent decontamination systems or for clean-in-place processes, chemicals shall be stored —

(a) outside the effluent decontamination room; and

(b) in accordance with relevant regulatory requirements.

11.11.6 Pressure relief valves

Pressure relief valves shall be provided for all vessels which may operate above atmospheric pressure. Pressure relief valves shall discharge in a manner that minimizes the risk to personnel.
In addition pressure relief valves used for liquid effluent decontamination systems serving PC3 and PC4 facilities shall be preceded by appropriately rated bursting discs. The interspace shall be monitored for pressure rise.

NOTE Overfilling of liquid effluent decontamination systems can result in high pressures at locations such as vent filters. This should be assessed carefully when designing such systems.

11.11.7 Biological indicators for heat-based liquid effluent decontamination systems
Commonly used biological indicators for thermal-based liquid effluent decontamination systems include:
(a) *Geobacillus stearothermophilus* incubated at 56 °C. Rapid enzyme BI (60 °C).
(b) *Bacillus Atrophaeus* incubated at 37 °C.

NOTE This is based on information provided in the Bibliography, Reference 1.14.

Section 12 Cleaning

12.1 General
The facility's physical containment level shall be considered when setting out cleaning arrangements and services. Dedicated cleaning equipment shall be provided for PC3 and PC4 facilities. Such equipment shall be stored within the containment facility.

Personnel shall clean and tidy work benches and shelves as work proceeds, and provide a complete clean-up at the end of the working day.

Work areas shall be kept free from physical hazards that may cause spillages or breakages. Items for sterilization shall be regularly collected. This collection shall be independent of the regular collection of uncontaminated waste.

12.2 Cleaning personnel handling infectious material
Special instructions for the cleaning of microbiological facilities shall be issued (particularly to cleaning contractors). Cleaning shall be carried out by trained personnel engaged for this purpose. Where cleaning contractors are used, their work should be confined to floor and window cleaning and removal of clearly marked uncontaminated waste.

The institute shall provide training on safe handling of infectious materials to cleaning personnel that handle infectious material (see Clause 2.1.2(f)) and Clause 2.6.4).

12.3 Cleaning of equipment
Apparatus such as centrifuges, water baths, incubators, refrigerators, deep freeze cabinets and liquid nitrogen storage vessels shall be cleaned and, if necessary, decontaminated at regular intervals and before being sent for repair or disposal.

12.4 Walls and shelves
Walls shall be cleaned periodically, or when visibly dirty, by washing with a detergent solution. Unnecessary or too-vigorous cleaning is not recommended, as it may cause damage to paint surfaces and provide a surface that is difficult to decontaminate.

Open shelves collect dust and shall be cleaned routinely. Frequently used reagent bottles and books collect little dust, but those seldom used may become dusty, and should be stored in closed cupboards.
12.5 Floor cleaning

The time of the day allocated for floor cleaning shall be specified. General floor cleaning should not be done during normal working hours, as it may produce dust and aerosols which contaminate work. The various floor cleaning methods are as follows:

(a) Wet mopping — Wet mopping, with a solution having detergent properties, is the most practical method of cleaning floors. The use of two mops and two buckets with wringers is convenient, one bucket with a clean solution to treat the floor and the second bucket to collect the dirty solution from the floor.

(b) Dry mopping — Dry mopping, if used, shall be carried out with a mop that has dust-retaining properties.

(c) Vacuum cleaning — Vacuum cleaning shall only be used where a vacuum cleaner is fitted with a disposable bag for retention of coarse material, and a HEPA filter fitted to the exhaust. The disposable bag shall be removed and deposited directly into a plastic bag to minimize exposure of the operator to collected dust. A household-type vacuum cleaner, which produces aerosols, shall not be used in microbiological facilities.

(d) Sweeping — Brooms shall not be used, as they produce airborne dust that can increase contamination of work in the facility.

Section 13 Contaminated materials and waste

13.1 Collection

Contaminated materials and non-contaminated waste shall be collected in segregated containers, clearly identified according to the following categories:

(a) Sharps — Examples are syringes with needles, broken glass, scalpel blades and glass Pasteur pipettes. These shall be collected in a rigid, puncture-proof container (refer to AS 4031) that is also capable of withstanding pressure steam sterilization without losing its integrity.

(b) Contaminated or potentially contaminated solid materials for disposal — Examples are diagnostic samples, used Petri dishes, animal carcasses, plants, invertebrates, bedding materials, potting mix, cultures, gloves and other disposable PPE.

(c) Contaminated or potentially contaminated solid materials for reuse — Examples are instruments, glass and some plastic laboratory ware, gowns and other reusable PPE.

(d) Contaminated or potentially contaminated liquids for disposal — Examples are culture media, buffers, liquid effluent.

NOTE These may be collected in disposable containers (e.g. plastic), reusable containers (e.g. glass, plastic) that can withstand appropriate treatment or purpose-built containers for effluent from animal facility cleaning or plant irrigation activities.

(e) Co-mingled material — The disposal of co-mingled waste, such as contaminated and radioactive waste, or contaminated and chemical wastes shall be conducted in a manner that addresses both hazards.

(f) Radioactive contaminated material — Collect solid waste into robust plastic containers, labelled with isotope and date, within a secondary solid container. Collect liquid waste into container for decontamination (see Clause 13.2.5.1).

(g) Imported biological material — In Australia, consult DAWR prior to disposing. In New Zealand, consult the relevant MPI NZ Standard along with any conditions in the relevant permit to import.
(h) **Non-contaminated waste** — Waste paper products, plastics, paper products and other discarded material shall be collected and disposed of prior to entry into containment facilities in order to reduce the quantity of contaminated waste.

(i) **Prions** — Waste that contains or could contain prions shall be collected for decontamination by the appropriate method (see Clause 13.2.4).

NOTE Refer to AS/NZS 3816 and NZS 4304 for clinical and healthcare waste and AS/NZS 2243.1 for other types of waste.

### 13.2 Decontamination and disposal of wastes

#### 13.2.1 General

All types of contaminated or potentially contaminated wastes, both liquid and solid, shall be decontaminated by one or more of the following methods:

(a) Pressure steam sterilization.
(b) Chemical disinfection.
(c) High temperature, high efficiency EPA-approved (Australia) or regional council-approved (New Zealand) incineration.
(d) Any other process approved by the relevant regulatory authority.

After decontamination or chemical treatment, waste shall be disposed of in accordance with relevant authority requirements.

NOTE Section 7 should also be consulted for specific requirements for plant materials.

#### 13.2.2 Validation of waste decontamination processes

Waste processes that include heat, pressure, chemicals, or a combination of these parameters, to achieve decontamination shall be periodically validated to ensure ongoing efficacy.

This validation shall form part of the waste decontamination risk assessment. The following should be carried out on a regular basis:

(a) Calibration of all instruments that control or monitor critical process parameters.
(b) Confirmation that all functional aspects of the waste treatments system are operating within the specified limits.
(c) Checking and maintenance of equipment to ensure optimal operating condition.
(d) Checking of all safety and relief equipment.
(e) Efficacy assessments of the complete process using a biological indicator or equivalent.

#### 13.2.3 Decontamination methods

**13.2.3.1 Pressure steam sterilization**

The following measures shall be adopted:

(a) Contain contaminated or potentially contaminated waste at the point of generation prior to transport to the pressure steam sterilizer.
(b) Ensure that wastes that melt during steam sterilization do not block sterilizer drain holes.
(c) Use only validated steam sterilizer cycles (see Clause 11.6.5 and Clause 11.6.6).

NOTE See also Clause 11.6 for correct use of pressure steam sterilizers.

13.2.3.2 Chemical disinfection

Following decontamination with appropriate disinfectant (see Appendix E), waste shall be disposed of in accordance with AS/NZS 2243.2, local authority requirements, and relevant authority requirements (see also Clause 11.11).

13.2.3.3 Incineration/high heat treatment

Incineration of contaminated or potentially contaminated materials, e.g. sharps containers, shall be done using a high-temperature, high efficiency EPA-approved (Australia) or regional council-approved (New Zealand) incineration facility.

In Australia, transport of materials by surface to such incinerators shall be done in approved packaging and according to the requirements of AS 4834 [see also Clause 14.4.2(c)]. Transport by air shall be according to IATA requirements (see Section 14).

NOTE 1 Refer to local authority and applicable regulatory authorities for additional transportation requirements where applicable.

NOTE 2 EPA-approved incineration for cytotoxic drugs exceeds the requirements for microbial destruction (see also Bibliography, Reference 1.16).

13.2.3.4 Dry heat sterilization

Where dry heat sterilization is proposed, the following measures shall be adopted:

(a) The process shall be validated for the potential microbiological hazards which may be present.

(b) Each process shall be monitored for temperature and time to provide documented confirmation of exposure requirements.

(c) Critical temperature measuring devices shall be calibrated in accordance with manufacturer's recommendations.

(d) Operators shall be trained to deal with the high temperatures involved with accessing the equipment.

13.2.3.5 Other methods

In some States in Australia, contaminated or potentially contaminated waste may be decontaminated and disposed of by approved methods other than those described in Clauses 13.2.3 to 13.2.5, including continuous flow sterilization (see also Clause 11.11). Relevant authorities shall be consulted for advice on proper disposal of contaminated or potential contaminated waste.

13.2.4 Prions

Current recommendations for the sterilization of articles or specimens that could be contaminated by prions are —

(a) 18 min at 134 °C to 138 °C in a pre-vacuum pressure steam sterilizer (UK); or

(b) 1 h at 132 °C in a downward displacement pressure steam sterilizer (USA).

The recommended chemical disinfectant for effective decontamination of prions is 20 000 p.p.m. available chlorine for 1 h with sodium hypochlorite as the chlorine releasing agent.

NOTE See Appendix E, Clause E6.1 for general guidance on use of chlorine.
Pressure steam sterilizer/chemical methods for decontaminating heat-resistant instruments are either —

(i) immerse in 1 M sodium hydroxide and heat in a downward displacement pressure steam sterilizer at 121 °C for 30 min, clean, rinse in water then subject to routine sterilization; or

(ii) immerse in 1 M sodium hydroxide or 20 000 p.p.m. sodium hypochlorite for 1 h, transfer instruments to water, heat in a downward displacement pressure steam sterilizer at 121 °C for 1 h, clean and subject to routine sterilization.

If the materials have already been fixed in formalin, then these steam sterilizing processes will not decontaminate them. The most effective chemical treatment for decontaminating formalin-fixed tissue is 96 % formic acid for 1 h. For destruction of formalin-fixed tissues, steam sterilization in 1 M sodium hydroxide at 121 °C for 1 h is effective for disposal (see Bibliography, Reference 1.14 and Reference 1.15.)

13.2.5 Secondary contamination considerations

13.2.5.1 Radioactive waste

Radioactive waste should not be pressure steam sterilized.

In Australia, radioactive waste shall be treated in accordance with AS 2243.4 and Commonwealth, State or Territory requirements. The method used for the treatment and disposal of radioactive infectious waste depends on the isotope being used and whether the waste is liquid or solid.

NOTE Seek advice from the institute’s Radiation Protection Officer.

In New Zealand, radioactive waste shall be treated and disposed in accordance with the requirements of the National Radiation Laboratory, NRL C1, Code of Safe Practice for the Use of Unsealed Radioactive Materials (see Bibliography, Reference 1.35).

13.2.5.2 Chemical waste

Chemical waste shall be disposed of in accordance with AS/NZS 2243.2, local authority requirements and applicable regulatory authority requirements.

13.2.6 Uncontaminated waste

General uncontaminated waste, e.g. paper towels from PC1 and PC2 facilities, may be disposed of in the same manner as household waste, subject to any additional local authority requirements. All waste from PC3 and PC4 facilities shall be treated as potentially contaminated.

13.3 Decontamination of liquid wastes

This Clause applies to contaminated liquid waste which is removed from containment facilities for decontamination outside the boundary of the facility.

Precautions shall be taken to ensure the seal integrity of liquid waste transport and untreated holding components, such as drain pipes, holding tanks and vent lines.

Construction material shall be —

(a) robust;

(b) suitable for the fluids being transported; and

(c) be capable of being decontaminated for inspection and maintenance.

Components such as pipes and collection tanks shall be located and protected where necessary to minimize the likelihood of physical damage.
Biohazard labels shall be provided to clearly identify all sections of pipes, valves, components and vessels which may contain contaminated liquid. Where concealment is unavoidable, technologies such as interstitial-monitored double-wall construction may be employed.

Screening shall be provided at the facility boundary to limit solids carried by piped systems.

Where liquid waste is collected in a location remote from the facility boundary, precautions shall be taken to prevent release or spillage of contaminated waste.

These precautions shall include —

(i) physical security of the location to prevent unauthorized access;
(ii) bunding or an equivalent mechanism to contain liquid in the event of a spill or leak; and
(iii) provision for decontamination and removal of liquid in the event of a spill or leak.

The waste collection space shall be a room, constructed to PC2 standard as a minimum, with all air exhausted. Higher levels of containment performance may be required in some instances and shall be subject to a risk assessment.

Where liquid waste potentially contains contaminated aerosols, all vents to pipes, tanks, etc. shall be fitted with 0.2 μm membrane filters. Filters shall be —

(A) regularly monitored for performance;
(B) shall be replaced in accordance with the manufacturer’s recommendations; and
(C) shall be decontaminated safely prior to removal.

NOTE See also Clause 11.11 for information on related to specialist liquid effluent decontamination systems.

Section 14 Transport of infectious and other biological materials

14.1 General

International and national procedures have been established for the safe transport of biological materials by air, rail and road. Different packaging and transport arrangements apply depending on whether the materials are infectious substances, biological products, cultures, genetically modified microorganisms, medical or clinical wastes or exempt substances. It is the responsibility of the sender to ensure compliance with all packaging and transport regulations.

NOTE In Australia, Item 92.120 of the Civil Aviation Safety Regulations 1998 (refer to http://www.icao.int/safety/DangerousGoods/Pages/technical-instructions.asp) specifies required training for packing dangerous goods for transport by air. All personnel who pack dangerous goods for transport by air (including enclosing the goods in packaging, marking or labelling the consignment or preparing a shipper’s declaration) are required to successfully complete a course approved by the Civil Aviation Safety Authority.

This Section summarizes the requirements of the various regulatory bodies and is based on the United Nations, Recommendations on the Transport of Dangerous Goods — Model Regulations (refer to http://www.unece.org/trans/danger/publi/unrec/rev13/13nature_e.html), which are adopted by IATA and AS 4834.

Where required, facilities shall be provided for after-hours delivery of samples. Personnel handling after-hours deliveries shall be informed of any hazards associated with the sample.

Precautions taken during unpacking procedures shall be consistent with the risk posed by the stated contents of the package.

If contaminated waste is to be removed from a facility, the relevant agricultural, veterinary, quarantine and local public health regulations shall be followed (see also Section 13).
14.2 Transport regulations

The transport of biological materials is regulated by the following documents:

(a) The IATA Dangerous Goods Regulations.

(b) The Australia Post, Dangerous and Prohibited Goods Packaging Guide (see Bibliography, Reference 1.17).

(c) Australian Code for the Transport of Dangerous Goods by Road and Rail.

(d) Transport of Dangerous Goods on Land [refer to NZS 5433 (series)].

(e) New Zealand Post, Postal Users Guide (see Bibliography, Reference 1.18).


(g) Guidelines for the transport, storage and disposal of GMOs.

(h) Packaging for surface transport of biological material that may cause disease in humans, animals and plants (refer to AS 4834).

(i) UN Recommendations on the Transport of Dangerous Goods — Model Regulations.

The IATA Dangerous Goods Regulations are the most comprehensive regulations and, in general, include the requirements of the other regulations. These regulations define the requirements for certification, packing instructions, the maximum quantities that can be transported by cargo or passenger aircraft, the external labelling requirements (including the identifying UN number), and the details to be included in the attached Shipper’s Declaration for Dangerous Goods. AS 4834 specifies packaging for surface transport of biological material that may cause disease in humans, animals and plants in Australia.

14.3 Transport definitions of biological materials

The following transport definitions align with the UN Model Regulations and are used in this Section:

(a) Infectious substances

Infectious substances are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

(b) Biological products

Biological products are those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines.

(c) Cultures

Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens.

(d) Patient specimens

Patient specimens are those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.
(e) **Medical or clinical wastes**

Medical or clinical wastes are wastes derived from the medical treatment of animals or humans or from bioresearch.

(f) **Genetically modified microorganisms**

Genetically modified microorganisms are microorganisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. Genetically modified microorganisms not meeting the definition of infectious substance are classified in Class 9 (miscellaneous dangerous substances and articles, including environmentally hazardous substances). GMMOs and GMOs are not subject to dangerous goods regulations when authorized for use by the competent authorities of the countries of origin, transit and destination. Genetically modified live animals are to be transported under terms and conditions of the competent authorities of the countries of origin and destination.

14.4 Classification and packaging

14.4.1 General

Clauses 14.4.2 to 14.4.5 provide details of the classifications that apply within the different types of biological materials and the corresponding packing requirements.

Figure 14.1 provides a flowchart summarizing the IATA, UN and AS 4834 requirements for the transport of biological materials by air, sea and land.

NOTE The IATA Dangerous Goods Regulations are updated annually with occasional amendments. The categories and flow chart are based on the 2005 edition. As requirements are likely to vary, the current edition and any amendments should be consulted.

14.4.2 Infectious substances

Infectious substances shall be classified as "Division 6.2 dangerous goods" and assigned the appropriate UN number (e.g. UN 2814, UN 2900, UN 3291 or UN 3373), in accordance with the following categories and classification criteria:

(a) **Category A**

An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Table 14.1 provides a list of indicative examples of substances that meet these criteria.

NOTE 1 An exposure occurs when an infectious substance is released outside its protective packaging, resulting in physical contact with humans or animals.

Infectious substances meeting these criteria which cause disease in humans or both in humans and animals shall be assigned to UN 2814. Infectious substances which cause disease only in animals shall be assigned to UN 2900.

Assignment to UN 2814 or UN 2900 shall be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

NOTE 2 The proper shipping name for UN 2814 is INFECTIOUS SUBSTANCE, AFFECTING HUMANS.

NOTE 3 The proper shipping name for UN 2900 is INFECTIOUS SUBSTANCE, AFFECTING ANIMALS ONLY.

Packing instruction P620 apply to these substances.

NOTE 4 Figure 14.2 shows examples of triple packaging systems for Categories A and B infectious substances.
Table 14.1 is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria shall be assigned to Category A. In addition, if there is any doubt as to whether or not a substance meets the criteria, it shall be included in Category A.

(b) **Category B**

An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B shall be assigned to UN 3373.

**NOTE 1** The proper shipping name of UN 3373 is BIOLOGICAL SUBSTANCE, CATEGORY B. The shipping name DIAGNOSTIC SPECIMENS, CLINICAL SPECIMENS has been phased out.

Packing instruction P650 (UN) or PI 650 (IATA) apply to these substances.

**NOTE 2** Figure 14.2 shows examples of triple packaging systems for Categories A and B infectious substances.

(c) **Category C**

Category C applies to surface transport in Australia only. Patient specimens including excreta, secreta, blood and its components, tissues and tissue fluids and biological materials with a low probability of causing disease in humans, animals and plants that could cause community concerns if the specimen was to leak from its packaging fall into Category C in AS 4834 and, if transported by land, shall be packaged, marked, documented and transported according to the requirements in AS 4834. If transported by air, IATA regulations for exempt patient specimens shall be followed.

(d) **Exempt substances**

Exempt substances shall be in accordance with the current edition of the IATA Dangerous Goods Regulations.

<table>
<thead>
<tr>
<th>UN 2814 Infectious substance affecting humans</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Bacillus anthracis</em> (cultures only)</td>
<td>Human immunodeficiency virus (cultures only)</td>
</tr>
<tr>
<td><em>Brucella abortus</em> (cultures only)</td>
<td>Japanese Encephalitis virus (cultures only)</td>
</tr>
<tr>
<td><em>Brucella melitensis</em> (cultures only)</td>
<td>Junin virus</td>
</tr>
<tr>
<td><em>Brucella suis</em> (cultures only)</td>
<td>Kyasanur Forest disease virus</td>
</tr>
<tr>
<td><em>Burkholderia mallei, Pseudomonas mallei, Glanders</em> (cultures only)</td>
<td>Lassa virus</td>
</tr>
<tr>
<td><em>Burkholderia pseudomallei, Pseudomonas pseudomallei</em> (cultures only)</td>
<td>Machupo virus</td>
</tr>
<tr>
<td><em>Chlamydia psittaci, avian strains</em> (cultures only)</td>
<td>Marburg virus</td>
</tr>
<tr>
<td><em>Clostridium botulinum</em> (cultures only)</td>
<td>Monkeypox virus</td>
</tr>
<tr>
<td><em>Coccidioides immitis</em> (cultures only)</td>
<td>Mycobacterium tuberculosis (cultures only)</td>
</tr>
<tr>
<td><em>Coxiella burnetti</em> (cultures only)</td>
<td>Nipah virus</td>
</tr>
<tr>
<td>Crimean-Congo haemorrhagic fever virus</td>
<td>Omsk haemorrhagic fever virus</td>
</tr>
<tr>
<td>Dengue virus (cultures only)</td>
<td>Poliovirus (cultures only)</td>
</tr>
<tr>
<td>Eastern equine encephalitis virus (cultures only)</td>
<td>Rabies virus (cultures only)</td>
</tr>
<tr>
<td><em>Ebola virus</em></td>
<td><em>Rickettsia prowazekii</em> (cultures only)</td>
</tr>
<tr>
<td><em>Escherichia coli</em>, verotoxigenic (cultures only)</td>
<td><em>Rickettsia rickettsii</em> (cultures only)</td>
</tr>
</tbody>
</table>
14.4.3 Biological products

Biological products shall be divided into one of the following groups:

(a) Those which are manufactured and packaged in accordance with the requirements of appropriate national authorities and transported for the purposes of final packaging or distribution, and use for personal health care by medical professionals or individuals. Substances in this group are not subject to specific transport regulations, such as the UN Model Regulations.

(b) Those which do not fall under Item (a) and are known or reasonably believed to contain infectious substances and which meet the criteria for inclusion in Category A or Category B, shall be assigned to UN 2814, UN 2900 or UN 3373, as appropriate.

NOTE Some licensed biological products may only present a biohazard in certain parts of the world. In that case, competent authorities may require these biological products to be in compliance with local requirements for infectious substances or may impose other restrictions.

14.4.4 Genetically modified microorganisms and organisms

Genetically modified microorganisms (GMMOs) shall be transported according to the guidelines or standards published by the OGTR or MPI NZ, as appropriate. GMMOs or GMOs that do not meet the definition of toxic substances or infectious substances shall be assigned to UN 3245. GMMOs and GMOs assigned to UN 3245 shall be shipped following Packing Instruction P904 (ICAO/IATA P959).

NOTE 1 The proper shipping name for UN 3245 is GENETICALLY MODIFIED MICRO- ORGANISMS or GENETICALLY MODIFIED ORGANISMS OIATA P1959.
NOTE 2 The proper shipping name for UN 3245 is GENETICALLY MODIFIED MICRO-ORGANISMS or GENETICALLY MODIFIED ORGANISMS.

14.4.5 Medical or clinical wastes

Medical or clinical wastes containing Category A infectious substances shall be assigned to UN 2814 or UN 2900 as appropriate. Medical or clinical wastes containing infectious substances in Category B shall be assigned to UN 3291.

Medical or clinical wastes which are reasonably believed to have a low probability of containing infectious substances shall be assigned to UN 3291.

NOTE 1 The proper shipping name for UN 3291 is CLINICAL WASTE, UNSPECIFIED, N.O.S. or (BIO) MEDICAL WASTE, N.O.S. or REGULATED MEDICAL WASTE, N.O.S.

Packing instruction P622 applies to medical or clinical wastes.

Decontaminated medical or clinical wastes that previously contained infectious substances shall not be subject to the UN Model Regulations unless they meet the criteria for inclusion in another class.

NOTE 2 Refer also to AS/NZS 3816.

14.5 Transport of infected animals

A live animal that is known or suspected to contain an infectious substance shall not be transported by air unless the infectious substance contained cannot be transported by any other means. Infected animals may only be transported under terms and conditions approved by the competent authority.

Animal carcasses affected by pathogens of Category A or which would be assigned to Category A in cultures only, shall be assigned UN 2814 or UN 2900 as appropriate. Other animal carcasses affected by pathogens included in Category B shall be transported in accordance with provisions determined by the competent authority.

14.6 Documentation

In Australia, transportation of imported animals and animal products shall be still subject to biosecurity control measures and require a permit from DAWR.

NOTE The BICON database should also be consulted on the BICON website.

When infectious material is being transported, a Shipper’s Declaration for Dangerous Goods (refer to http://www.iata.org) shall be completed indicating origin, contents and date of dispatch, and shall be attached to the external surface of the package. Documentation enclosed in a package shall be placed between the secondary package, and inside outer packaging, in a separate impervious bag to protect it from contamination by contents of the package. Recipients shall be informed of all known hazards associated with the material in advance of delivery.
Is this substance a biological product or material that-
(a) does not contain an infectious substance
(b) is blood, blood components, tissues or organs for transfusion or transplantation;
or
(c) has a low probability of containing infectious substances?

YES  No restriction

NO  If transported by air

Is the substance-
(a) a Category A infectious substance; or
(b) a culture?

YES  Identify as UN No 2814 or 2900  Conform with Packing Instruction UN No 620, IATA No 602*

NO  Conform with Packing Instruction No 650*

NO  Identify as UN No 3373  Conform with Packing Instruction No 650*

NO  No other requirements

Is the substance a Category B infectious substance?

YES  Identify as UN No 3373  Conform with Packing Instruction No 650*

NO  No other requirements

NO  Conform with AS 4834*

Is the substance a Category C material?

YES  Surface transport only

NO  Identify as UN No 3245  Conform with Packing Instruction No 904*

NO  No other requirements

NO  Identify as UN No 3291  Conform with Packing Instruction No 622*

NO  No limit

Is the substance a genetically modified microorganism or organism which does not contain an infectious substance?

Is the substance medical or clinical wastes that are reasonably believed to have low probability of containing infectious substances?

* Refer to IATA, UN Recommendations on the Transport of Dangerous Goods or AS 4834 for more detail

Figure 14.1 — Summary of biological material packaging instruction classification
(a) Packing and labelling of Category A infectious substances

(b) Packing and labelling of Category B infectious substances

Figure 14.2 — Examples of triple packaging systems
Example of microbiological incident/illness report form

1. DATE AND LOCATION OF INCIDENT EXPOSURE:

2. NATURE OF INCIDENT:
   What was the employee doing and how did the incident exposure occur? (Describe the work being performed, list sequence of events.)

Name of microorganism(s):
Risk group:
Nature of genetic modification:

3. PERSONNEL INVOLVED:
   (Names) 1. 2.

4. NATURE OF INJURY, FIRST AID/MEDICAL TREATMENT/ILLNESS:

5. SPILLS CLEAN-UP PROCEDURE:
   (Include names of personnel involved, personal protective equipment and disinfectant used.)

6. WITNESSES:
   (Names) 1. 2.
   State what witness saw happen.

7. SUPERVISOR:
   Name: Signature: Date:

8. FOLLOW UP PREVENTATIVE ACTION:
   Actioning officer Completion date: Signature:
Appendix B
(normative)

Additional containment requirements for poliovirus

B.1 Scope

This Appendix outlines background information about containment and eradication of wild poliovirus. It also sets out the additional requirements for working with poliovirus.

B.2 General

The World Health Organization (WHO) recommends all laboratories that work or have worked with poliovirus, enterovirus, norovirus, rhinovirus or rotavirus should confirm the identity of all virus stocks, reference strains and derivatives of such viruses grown in poliovirus permissive cell cultures to exclude the presence of poliovirus.

If necessary, virus stocks of uncertain history shall be replaced by stocks with documented authenticity.

NOTE Laboratories wishing to retain historic collections of clinical material should explore options for their handling and storage with designated poliovirus essential facilities.

Currently, Afghanistan, Nigeria and Pakistan remain the only polio endemic countries with circulation of wild poliovirus type 1. Wild poliovirus type 2 was last detected in 1999 and was declared eradicated by WHO in 2015. Wild poliovirus type 3 was last detected in 2012 but has not been certified as eradicated.

Poliovirus potentially infectious material includes the following items from countries known or suspected to have circulating wild poliovirus or vaccine-derived poliovirus (VDPV) or countries where oral polio vaccine (OPV) was in use:

(a) Faecal or respiratory secretion samples collected for any purpose.
(b) Products of such materials in poliovirus permissive cells or animals.
(c) Uncharacterized enterovirus-like cell culture isolates.
(d) Respiratory and enteric virus stocks handled under conditions where wild poliovirus, VDPV or OPV/Sabin poliovirus contamination or replication was possible.

From 2016, the number of laboratories permitted to work with poliovirus type 2 will be restricted in order to minimize the risk of facility-associated poliovirus infection.

B.3 Phases of poliovirus containment

B.3.1 Phase I: Preparation for containment of poliovirus type 2

This initially involved a national laboratory survey and inventory of wild poliovirus materials, which has been completed in Australia and New Zealand. In preparation for Phase II, wild poliovirus type 2, VDPV2 and OPV2/Sabin2 materials were destroyed or transferred to a designated poliovirus essential facility that complies with the third edition of the WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (GAP III) (see Bibliography, Reference 1.42).
In Australia, the National Enterovirus Reference Laboratory located at the Victorian Infectious Diseases Reference Laboratory, was designated as a poliovirus essential facility for the handling of both wild and OPV/Sabin poliovirus type 2.

B.3.2 Phase II: Poliovirus type 2 containment period

WHO implemented a serotype-specific strategy for poliovirus containment beginning with poliovirus type 2.

At the commencement of Phase IIa, all wild poliovirus type 2 and VDPV type 2 stocks were either transferred to a wild poliovirus-holding essential facility or destroyed, in readiness for the global withdrawal of Sabin poliovirus type 2 from OPV in April 2016.

Phase IIb began three months after the switch from trivalent to bivalent OPV, by which time all OPV2/Sabin2 poliovirus stocks shall have been transferred to a poliovirus essential facility or destroyed. From August 2016, all laboratories that isolate or detect poliovirus type 2, whether wild, VDPV or OPV/Sabin strains, from any source, shall immediately notify the national health authorities and transfer the material to a poliovirus essential facility, without retaining any original or laboratory derived material.

B.3.3 Phase III: Final poliovirus containment

In preparation for Phase III, enhanced containment of all wild polioviruses at essential facilities will be instigated and compliance with provisions for OPV/Sabin poliovirus containment will be assessed.

Phase IIIa will commence three years after the isolation of the last wild poliovirus and all six WHO regions have certified eradication of wild poliovirus. Only facilities that have been certified for enhanced wild poliovirus containment will be permitted to handle and store wild poliovirus material.

Phase IIIb is planned for one year after the global declaration of wild poliovirus eradication with the recall and destruction of bivalent OPV stocks and the containment of all OPV/Sabin polioviruses at certified essential facilities.

B.4 Additional requirements for working with poliovirus

All personnel entering laboratories containing poliovirus shall be vaccinated against poliovirus.

B.5 Contacts for the national polio inventory and notification of matters relating to poliovirus

The following are contacts for national polio inventory and notification of matters relating to poliovirus:


Appendix C
(normative)

Biological hazard signs

C.1 Biological hazard symbol

The biological hazard symbol shown in Figure C.1 is specified in AS 1319, and is recognized worldwide, e.g. by the World Health Organization and the United Nations Committee on the Transport of Dangerous Goods. These signs are readily available from commercial sources of laboratory or medical supplies.

The colour scheme for signs incorporating the biological hazard symbol shall be a black symbol on a yellow background, as specified in AS 1319 and ISO 3864 series for all warning signs.

![Figure C.1 — Biological hazard symbol](image)

<table>
<thead>
<tr>
<th>Dimension</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>J</th>
<th>K</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proportion</td>
<td>1</td>
<td>3.5</td>
<td>4</td>
<td>6</td>
<td>11</td>
<td>15</td>
<td>21</td>
<td>30</td>
<td>11.5</td>
<td>15</td>
</tr>
</tbody>
</table>

C.2 General microbiological laboratory sign

The sign for general microbiological laboratories shall be in the format shown in Figure C.2, i.e. the sign shall show the biological hazard symbol shown in Figure C.1 and the laboratory containment level. The colours used in the sign shall be black for the symbol and writing on a yellow background as specified for safety signs in AS 1319 and ISO 3864 series.
Figure C.2 — Layout for general microbiological laboratory warning sign for PC2 laboratory
Appendix D
(normative)

Water and gas supplies to containment facilities

D.1 Scope
This Appendix provides requirements for the prevention of contamination of water and gas supplies, prevention of cross-contamination between different level facilities and general gas supply requirements.

D.2 Water supplies

D.2.1 Backflow prevention
In addition to high hazard rating boundary containment protection in accordance with AS/NZS 3500 and local authority requirements, individual backflow prevention devices to suit a high hazard rating situation shall be installed in the following water supply lines as illustrated in Figure D.1:

(a) To potable water outlets, including hand basins, safety showers, eyewash stations and body showers for PC3 and PC4 laboratories where the laboratory room forms the primary containment measure, e.g. large animal rooms. Separate protection shall be provided to each laboratory or facility.

(b) To laboratory sink outlets. Separate protection shall be provided to each PC3 or PC4 laboratory facility.

NOTE Protection may be shared for PC1 and PC2 facilities.

(c) To outlets within Class II BSCs.

NOTE Protection may be shared within a single room.

Separate protection shall be provided for each room.

(d) To outlets for animal drinking water and plant watering and for aquatic facility water supplies.

NOTE 1 Protection may be shared for PC1 and PC2 facilities.

Separate protection shall be provided to each PC3 or PC4 facility.

NOTE 2 No additional protection is required between the general site protection and potable water outlets including hand basins, safety showers, eyewash stations and body showers for PC1 and PC2 laboratories and for PC3 and PC4 laboratories where the laboratory room forms the secondary containment measure.
D.2.2 Looped services

For PC1, PC2, PC3 and PC4 facilities where the room forms the secondary containment measure, looped service outlets other than those outlets connected to primary containment equipment and those in BSC Class II should be provided with the minimum piping inside the facility.

NOTE Examples of looped services include water from reverse osmosis systems and demineralized water.

For BSC Class II and within PC3 and PC4 facilities where the room forms the primary containment measure (e.g. large animal facilities, plant facilities), looped service outlets should be avoided. The preferred method of supplying water is by carrying it in using containers that can be decontaminated using pressure steam sterilization. If outlets are provided they shall have backflow prevention in the form of one of the following options, preferably that in Item (a):

(a) A 0.2 µm membrane filter shall be inserted in the piping just prior to the outlet [see Figure D.2(a)].

(b) Reverse flow protection including alarms shall be provided [see Figure D.2(b)].

All looped service outlets shall be accompanied by a sign containing the wording “Looped service outlet: Maintain an air gap at all times “.

For sealed loop services, such as cooling water loops and sealed steam/condensate circuits, no backflow prevention is required. Systems shall be tested, at a minimum, annually to confirm that the seal is maintained. Isolation shall be provided within the facility for service and maintenance. For facilities that require gaseous decontamination capability, systems shall be capable of withstanding gaseous decontamination in both assembled and dismantled states.
D.3 Gas services

D.3.1 General gas service requirements

The following general requirements shall apply to gas services in microbiological containment facilities:

(a) All gases shall be reticulated at the lowest practical pressure.

(b) Systems shall incorporate flow limiting or free flow protection devices in situations where excessive flow could be a health hazard (poison or asphyxiation risk).

(c) The provision of gas outlets shall be minimized in laboratories where breathing apparatus is used. A risk assessment shall be undertaken to determine the need for —

(i) fail safe isolation of laboratory gas in the event of ventilation system failure;

(ii) flow restriction, such as through a calibrated orifice; and

(iii) gas leakage detection.

D.3.2 Backflow prevention

Reverse flow protection shall be provided between the facility's piped gas service and outlets in the following gas services as illustrated in Figure D.3:

(a) To outlets in PC3 and PC4 laboratories where the laboratory room forms the primary containment measure. Separate protection shall be provided to each laboratory or facility [see also Clause D.3.1(c)].

(b) To outlets within Class II BSC. Protection may be shared within a single room. Separate protection shall be provided for each room.
Piped gas service

Reverse flow protection

To PC1 and PC2 laboratories and PC3 and PC4 laboratories where the laboratory room forms the secondary containment measure

Reverse flow protection

To outlets for PC3 and PC4 laboratories where the laboratory room forms the primary containment measure [See also Clause E3.2(a)]

To outlets within Class II BSC [See also Clause E3.2(b)]

Figure D.3 — Backflow prevention for gas services
Appendix E
(Informative)

Chemical disinfectants

E.1 Introduction

Prior to any form of disinfection or decontamination, equipment and surfaces should where possible be cleaned and free from organic material and grease. Pressure steam sterilization (autoclaving) is the most reliable means of decontamination. However, this method is not applicable in all situations. Chemical disinfection is often the only practical method of decontamination for large spaces or surface areas and for heat-labile materials or equipment. Mechanical brushing and rubbing facilitate the action of chemical disinfectants and other forms of decontamination. Where time permits, heat-labile materials and equipment may be sterilized by gaseous chemicals such as ethylene oxide or by ionizing radiation. For a general guide to the use of disinfectants, see Bibliography, Reference 1.14. For disinfection of aquatic facilities, equipment and surfaces see the OIE website.

E.2 Susceptibility of microorganisms

Microorganisms vary in their susceptibility to chemical disinfectants. Lipid-containing viruses and the vegetative forms of most bacteria are relatively susceptible. Fungi, acid-fast bacteria (*Mycobacterium* spp.) and non-lipid-containing viruses are less susceptible while bacterial spores are resistant to the action of many chemical disinfectants. The agents of scrapie, Creutzfeldt-Jakob disease and other prions are extremely resistant to chemical disinfection (see Clause 3.7 and Clause 13.2.1).

E.3 Types of chemical disinfectants

Many chemical disinfectants are available under a variety of trade names. Examples of chemical disinfectants with a broad spectrum of activity against a range of microorganisms, including some sporicidal activity, are as follows:

(a) Halogens, e.g. chlorine and iodine.

(b) Aldehydes, e.g. formaldehyde and glutaraldehyde.

(c) Oxidizing agents, e.g. peracetic acid, peroxygen biocide and hydrogen peroxide and chlorine dioxide.

Chemical disinfectants with a more limited antimicrobial spectrum include the following:

(i) Alcohols, e.g. ethyl and isopropyl alcohols.

(ii) Phenolics.

(iii) Quaternary ammonium compounds.

(iv) Chlorhexidine.

(v) Acids and alkalis.

E.4 Factors affecting activity of disinfectants

Variables that may affect the action of chemical disinfectants include the following:

(a) Concentration and formulation of the disinfectant.
(b) Effective period of contact time.
(c) Temperature.
(d) pH.
(e) Relative humidity.
(f) Inactivation by organic matter or cellulosic and synthetic materials.

### E.5 Choice of disinfectant

The choice of a chemical disinfectant often represents a compromise between the requirement for a broad antimicrobial spectrum, the limitations imposed by the situation or type of materials being disinfected, and any disadvantages of particular disinfectants. A chemical disinfectant which is suitable for a particular purpose or situation depends not only on the types of microorganisms likely to be present but also on the control or provision of the conditions that can promote its effectiveness in that situation. Other properties of the disinfectant also need to be considered, such as possible corrosive, bleaching or staining effects and its flammability. In addition, the effect it can have on personnel as a toxic irritant, any sensitizing action and its carcinogenic potential need to be taken into account.

Safety data sheets (SDS) should be obtained from the supplier or distributor for any chemical disinfectant used in the workplace. A request for the relevant SDS should automatically accompany the initial order for materials. SDS provide information on the identity, physical characteristics, potential health hazards and precautions to be taken for safe storage, use and disposal of chemicals. The laboratory supervisor should ensure that all personnel have access to SDS for the substances that are used in the workplace and that these are read and understood by those concerned. SDS, as obtained from suppliers, should not be altered although additional information may be appended and clearly marked as such.

Tables E.1 and E.2 should be consulted for assistance when selecting disinfectants. Table E.1 provides recommended applications for chemical disinfectants in microbiological facilities.

Table E.2 provides a guide to the effectiveness of different classes of disinfectant against a range of microorganisms (see Bibliography, Reference 1.29). The disinfectants in Table E.2 have been categorized according to the range of microorganisms that they are able to inactivate under optimum conditions:

- **Sterilants** — Kills all viruses, fungi and bacteria, including their spores, given enough time.
- **High level disinfectants** — Kills most microbial pathogens except large numbers of bacterial endospores.
- **Intermediate level disinfectants** — Destroys vegetative cells including Mycobacteria, fungi and most viruses.
- **Low level disinfectants** — Destroys vegetative bacteria and enveloped viruses.

Tables E.1 and E.2 are informative only. Although the disinfectants are considered to be effective against all the microorganisms within a particular group where stated, the contact time required to inactivate different microorganisms within a group can vary. This is particularly so where inactivation of bacterial endospores is required. The effectiveness of any disinfection processes should be validated against the microorganism of choice and under the conditions in which the disinfection should occur.

**NOTE** Proprietary disinfectants may utilize a combination of activities.

### E.6 Properties of commonly-used disinfectants

See Clause 1.5 for definitions of the actions of agents and processes used for decontamination.
E.6.1 Chlorine

In the form of sodium hypochlorite or other chlorine-releasing compounds, chlorine is active against vegetative forms of bacteria and viruses and is the preferred chemical disinfectant for HIV and hepatitis viruses. It is less effective against spores. Chlorine combines rapidly with proteins, so, in the presence of organic materials, the concentration of chlorine needs to be increased to overcome this organic demand. For example, an equal volume of 5000 p.p.m to 10 000 p.p.m. (0.5 % – 1 %) available chlorine is required for the inactivation of HIV and hepatitis viruses in blood or serum (see Bibliography, Reference 1.20).

Commercially available chlorine solutions vary in the concentration of available chlorine they contain. For example, some solutions contain 4 % (e.g. household bleach) while others contain 12.5 % available chlorine. Care should be taken when diluting these solutions to ensure the correct final working concentration is achieved.


As the effective strength of chlorine solutions decreases on storage, working solutions should be freshly prepared each day. Stabilized solutions of sodium hypochlorite with added sodium chloride are preferred as these solutions maintain a greater effective chlorine concentration. For effective biocidal action, a pH range of 6 – 8 is optimum. High concentrations of hypochlorite solutions are corrosive to stainless steel and other metal surfaces and tend to bleach and damage fabrics.

A cheap and useful decontaminant with good wetting properties can be prepared by adding a non-ionic detergent to a solution containing about 500 p.p.m. (0.05 %) of available chlorine to give a detergent concentration of 0.7 % v/v. This solution is suitable for disinfecting contaminated pipettes.

E.6.2 Iodine

Iodine, in aqueous or alcoholic solution, has a wide spectrum of antimicrobial activity including some sporicidal action. It has the disadvantage of staining skin and may cause irritation and sensitization.

Iodophors are organic compounds of surface active agents and iodine which rely on the slow release of iodine for activity. Free iodine reacts more slowly with organic matter than does chlorine but inactivation may be significant in dilute iodine solutions. The optimum pH for activity is in the neutral to acid range. Decomposition occurs at temperatures above 40 °C with the release of iodine vapour which is toxic on absorption. Povidone-iodine is used as a skin disinfectant (see Bibliography, Reference 1.39).

E.6.3 Formaldehyde

A solution of about 37 % w/v formaldehyde gas in water is known as formalin. A solution of 5 % w/v formaldehyde, i.e. about 13 % v/v formalin, is a good decontaminant but it has a strong, irritating odour. Solutions of 8 % v/v formalin in 80 % v/v alcohol are considered to be very good for disinfection purposes because of their effectiveness against vegetative bacteria, spores and viruses. Formaldehyde is also available in polymerized form, known as paraformaldehyde, which, on heating, decomposes to formaldehyde gas.

Precautions are necessary for handling formaldehyde and when entering rooms which have been decontaminated by gaseous formaldehyde as it is a highly toxic gas and is classified as a known human carcinogen. The Australian National Exposure Standard, expressed as a TWA, for formaldehyde is specified as 1 p.p.m. or 1.2 mg/m³ (see Bibliography, Reference 1.12) and is currently under review. Formaldehyde and paraformaldehyde should only be opened or weighed in a fume cupboard. Under certain conditions, formaldehyde can react with free chlorine or chloride ions to form an unstable compound, bis (chloromethyl) ether, which is a potent carcinogen. Hypochlorite solutions and hydrochloric acid should therefore be removed from equipment or spaces being decontaminated by formaldehyde.
Formaldehyde is a useful space decontaminant for rooms, cubicles and BSCs; however, for proper effectiveness, it should only be used when the relative humidity (RH) is between 70% and 90%. Below this range, formaldehyde is less active; and, above it, difficult-to-remove polymers are deposited on surfaces. This procedure should only be used by trained personnel.

NOTE See Bibliography, Reference 1.21 for further information on formaldehyde decontamination.

E.6.4 Glutaraldehyde

Glutaraldehyde (1,5-pentanediol) is available as a 2% (w/v) aqueous solution which is activated as a disinfectant by the addition of an alkaline buffer. After activation, its useful life may be restricted to 14 d or 28 d, depending upon the formulation used. It is also available in a stable, glycol-complexed formulation (2% w/v) which does not require activation and which has reduced odour and irritancy. Glutaraldehyde is active against a wide range of microorganisms, including sporing bacteria, although a time period of between 3 h and 10 h (depending upon the manufacturer’s recommendations) is required for reliable sporicidal action. Its main advantages are that it is non-corrosive to metalware and does not harm plastics, rubber or the cement mounting of lenses. Glutaraldehyde is used for the disinfection of certain types of medical equipment. After disinfection, such instruments need to be rinsed well to remove the glutaraldehyde.

Glutaraldehyde is irritating to the eyes and mucous membranes, but less so than is formaldehyde, and may cause dermatitis and respiratory problems in some handlers. The Australian National Exposure Standard, expressed as a TWA, for glutaraldehyde is specified as 0.1 p.p.m. or 0.41 mg/m³. Measures should be taken to protect handlers from exposure to its liquid or vapour. These include the wearing of waterproof, impervious, protective gloves for handling instruments that have been immersed in glutaraldehyde. Containers of glutaraldehyde disinfectant should always be covered and good ventilation, preferably mechanical exhaust ventilation over the container, should be provided. Care should be taken to avoid contamination of the work area by glutaraldehyde solutions.

E.6.5 Peracetic acid

Peracetic acid (2% v/v) is used as a decontaminant when material is being transferred into plastics isolators containing gnotobiotic animals. It can also be used in disinfectant showers for personnel who are completely covered in waterproof protective clothing. Peracetic acid (2% v/v) is also a good decontaminant for clean, grease-free surfaces.

Peracetic acid solutions have a pungent odour and are irritating to the mucous membranes and highly corrosive. Protective face and respiratory protection should be worn and adequate extractive ventilation provided when the chemical disinfectant is used. A stabilized, non-corrosive formulation has been developed for use in a self-contained system of high-level disinfection of instruments (see Bibliography, Reference 1.48).

E.6.6 Peroxygen biocides

The peroxygen system consists of potassium peroxymonosulfate, sodium chloride and an inorganic surfactant acting at a low (acid) pH level. In a 1% w/v concentration, this strongly oxidizing disinfectant is active against a range of microorganisms, including fungi and viruses. However, it has been shown to be ineffective against Mycobacterium spp. and against HIV in the presence of blood (see Bibliography, Reference 1.22 and Reference 1.23). It is corrosive to metalware and damaging to fabrics but less so than is sodium hypochlorite of equivalent activity.

E.6.7 Hydrogen peroxide

Hydrogen peroxide is active against a range of microorganisms although fungi are relatively resistant and bacterial spores and enteric viruses require a higher concentration than the 3% w/v generally used for disinfection. A major advantage is the absence of toxic end products of decomposition.

Hydrogen peroxide can also be used as an effective space decontaminant when converted to a vapour (vaporized hydrogen peroxide) in air. A 30% to 35% aqueous solution of liquid hydrogen peroxide
is typically flash vaporized and then introduced into the space that is to be decontaminated. The concentration of the vapour in air is typically near 700 ppm, which corresponds to approximately 1.0 mg/litre. Typical exposure time is 120 – 240 min. As a vapour, hydrogen peroxide competes with water vapour in the air, so humidity may need to be controlled, depending on the equipment used. Standing water should be avoided in the area to be decontaminated. Vapour-phase hydrogen peroxide can be used for the decontamination of containment facilities and primary containment devices such as BSCs. A significant benefit of hydrogen peroxide is that it readily breaks down to oxygen and water. Additional sensing equipment can be a safety requirement due to the fact that hydrogen peroxide vapour at low concentrations is not readily detected visually, by odour or by taste.

E.6.8 Chlorine dioxide

Chlorine dioxide is an oxidizing agent that can be used as a gaseous decontaminant of containment facilities and BSCs. It is a gas at room temperature and unlike VHP, it does not condense. This enables it to be easily distributed in containment facilities and also facilitates penetration. Like VHP it has the advantage that it is non-carcinogenic and there are no residues resulting from its use. Although it is a gas at normal room temperatures, the relative humidity of the space to be decontaminated is critical for its effectiveness. Decontamination using chlorine dioxide is accomplished at a relative humidity of 65 % to 70 %, followed by injecting the gas to a typical concentration of 1 mg/litre and exposing the space to be decontaminated for 60 – 120 min.

NOTE See Bibliography, Reference 1.28 for further information.

E.6.9 Alcohols

A 70 % w/w (approximately 80 % v/v) solution of ethyl alcohol or a 60 % – 70 % v/v solution of isopropyl alcohol provides a useful disinfectant for clean surfaces and the skin. As a skin disinfectant, alcohols are used either alone or in combination with other disinfectants. Emollients, such as glycerol, are also added to counteract the drying effect of alcohols on skin.

Alcohols are active mainly against vegetative bacteria and the lipid-containing viruses and are inactive against spores. However, they are ineffective against *Mycobacterium* spp. and HIV dried on surfaces in the presence of sputum or serum. Alcohols evaporate from surfaces leaving no residues. However, they may cause swelling of rubber, hardening of plastics and weakening of the cement around lenses in instruments. The alcohols are unsuitable for application to proteinaceous material as they tend to coagulate and precipitate surface proteins which may then result in protection of the microorganisms present. Because of their flammability, alcohol disinfectants should be used sparingly in BSCs and not with equipment that is likely to produce sparks. In BSCs, alcohol disinfectants may be used from a dispensing bottle but should not be sprayed.

E.6.10 Phenolics

The synthetic phenolics do not have the pungent odours, highly corrosive and skin irritancy properties of the crude parent compounds, phenol and lysol. They are active against bacteria and lipid-containing viruses but are inactive against spores and the non-lipid-containing viruses. A major advantage of the phenolics is that they are not deactivated by organic matter. They may cause toxic effects if ingested.

E.6.11 Quaternary ammonium compounds

QACs are cationic detergents with powerful surface-active properties. They are effective against Gram-positive bacteria and lipid-containing viruses, e.g. herpes and influenza, but are less active against Gram-negative bacteria and non-lipid-containing viruses and are inactive against *Mycobacterium* spp. and bacterial spores. QACs tend to be inactivated by protein adsorption, anionic soaps and detergents, and cellulosic and synthetic plastics materials. However, they are non-toxic, inexpensive, non-corrosive to metals and non-staining. Because of their detergent properties, they have been used mainly in formulations of cleaning agents in the food industries (see Bibliography, Reference 1.48).
E.6.12 Chlorhexidine

Various formulations of chlorhexidine (as chlorhexidine gluconate) with compatible detergents and ethyl alcohol, or ethyl and isopropyl alcohols, are used as skin disinfectants. The alcoholic formulations have shown to be effective against HIV (see Bibliography, Reference 1.24). In general, aqueous chlorhexidine is active against Gram-positive bacteria, only moderately active against Gram-negative bacteria and inactive against sporing bacteria, *Mycobacterium* spp. and non-lipid-containing viruses. Alcohols in the skin disinfectant formulations extend the spectrum of activity of chlorhexidine. Chlorhexidine is of low toxicity, except for neurological tissues, and rarely causes hypersensitivity. It is compatible with quaternary ammonium compounds but is incompatible with soap and anionic detergents. Chlorhexidine is widely used in skin disinfectant formulations, but is not recommended as a general disinfectant.

E.6.13 Acids and alkalis

All acids are corrosive and care needs to be taken with their use. Acids are effective against a wide range of microorganisms. Hydrochloric acid solution of 2 % concentration can be used in places contaminated with urine, blood, faeces, and in sewage collection areas. Acetic and citric acids are effective for general use against many viruses. A solution of 0.2 % citric acid is recommended for personal decontamination. Phosphoric and sulfamic acids are used in food processing areas.

Alkalis have activity against a wide range of microorganisms even in the presence of heavy organic loads in such places as drains and areas contaminated by sewage.

Alkalis are disinfectants of choice for many animal holding areas or animal facilities. 1M sodium hydroxide is a very effective and readily available decontaminant. It retains a high level of activity in the presence of organic matter and is recommended in many situations, such as decontamination of drains and animal houses. Sodium carbonate 4 % solution can be used as a wash for animal cages and animal transport vehicles. Sodium metasilicate 5 % solution is used as a wash for aircraft and air transport crates.

E.6.14 Ortho-phthalaldehyde (OPA)

Ortho-phthalaldehyde (OPA) is an aqueous solution used at 0.55 % for high level disinfection of heat sensitive medical instruments. OPA was cleared by the US Food and Drug Administration in October 1999 and has subsequently been frequently used as an alternative to glutaraldehyde, particularly for high level disinfection of flexible endoscopes.

OPA has a rapid anti-mycobacterial effect and is a faster biocidal agent than glutaraldehyde for most common human pathogens. OPA has the potential to cause skin and respiratory sensitivity and therefore, the use of gloves is recommended. Good ventilation in the area of OPA use will assist in reducing respiratory sensitivity.

Medical equipment disinfected with OPA needs to be thoroughly rinsed as there is evidence that residual disinfectant can cause severe allergic reactions. For further information on OPA, see Bibliography, References 1.25 and 1.26.

E.7 Contamination of disinfectants

Working solutions of disinfectants should be frequently replaced with freshly prepared dilutions from stock solutions. This applies particularly to those disinfectants which are subject to inactivation by organic or other materials, loss of stability or significant dilution through the introduction of wet instruments. Otherwise, the inactivated, exhausted or diluted disinfectants may become contaminated and may even support the growth of the bacterial contaminants. The containers or dispensers used should also be emptied and decontaminated between batches and their contents not merely “topped up”.

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<table>
<thead>
<tr>
<th>Site, equipment or function</th>
<th>Routine or preferred method or usage</th>
<th>Acceptable alternative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benches and surfaces (not obviously contaminated)</td>
<td>Alcohols suitable for swabbing, e.g. 70 % w/w (= 80 % v/v) ethyl or 60 % – 70 % v/v isopropyl) (see Clause E6.9)</td>
<td>Synthetic phenolics&lt;sup&gt;a&lt;/sup&gt; (see Clause E6.10)</td>
</tr>
<tr>
<td>Biological safety cabinet (BSC) work surfaces</td>
<td>Alcohols, e.g. 70 % w/w (= 80 % v/v) ethyl — swabbed or high concentration chlorine disinfectant at 5000 – 10 000 p.p.m. (0.5 % – 1 %) (see Clause E6.1) or other disinfectant depending on the organism</td>
<td>For BSC with capture hoods, glutaraldehyde&lt;sup&gt;b&lt;/sup&gt; (with cabinet fan operating) — swabbed (see Appendix H and Clause ZZ14 of AS/NZS 2252.4) (see Clause E6.4)</td>
</tr>
<tr>
<td>Room space, e.g. laboratory or animal room, BSC before servicing or testing or after major spill</td>
<td>Vaporized hydrogen peroxide (see Clause E6.7) or chlorine dioxide (see Clause E6.8)</td>
<td>Formaldehyde vapour (see Clause E6.3); however, alternative effective methods should be explored due to increasing concern with human exposure to formaldehyde</td>
</tr>
<tr>
<td>Centrifuge rotor or sealable bucket after leakage or breakage</td>
<td>Disinfection not the preferred method. Pressure steam sterilizing at 121 °C for 15 min recommended (see Clause 11.6)</td>
<td>Glutaraldehyde&lt;sup&gt;b&lt;/sup&gt; for 10 min or synthetic phenolics&lt;sup&gt;a&lt;/sup&gt; for bacterial spills for 10 min (see Clause E6.10)</td>
</tr>
<tr>
<td>Centrifuge bowl after leakage or breakage</td>
<td>Glutaraldehyde&lt;sup&gt;b&lt;/sup&gt; for 10 min (swabbed twice within the 10 min period then wiped with water) (see Clause E6.4)</td>
<td>Synthetic phenolics&lt;sup&gt;a&lt;/sup&gt; for bacterial spills for 10 min) (see Clause E6.10)</td>
</tr>
<tr>
<td>Discard containers (pipette jars)</td>
<td>Chlorine disinfectant at 2 000 – 2 500 p.p.m. (0.2 % – 0.25 %)</td>
<td>Synthetic phenolics&lt;sup&gt;a&lt;/sup&gt; for bacteriological work (changed weekly) or detergent with pressure steam sterilizing for virus work</td>
</tr>
<tr>
<td>Equipment surfaces before services or testing</td>
<td>Surfaces disinfected according to manufacturer’s instructions</td>
<td>Alcohol (80 % v/v ethyl or 60 % – 70 % v/v isopropyl) except when its flammability poses a hazard (see Clause E6.9) or glutaraldehyde&lt;sup&gt;b&lt;/sup&gt; then water (see Clause E6.4)</td>
</tr>
<tr>
<td>Gnotobiotic animal isolators</td>
<td>Peracetic acid at 2 % v/v — swabbed (see Clause E6.5)</td>
<td></td>
</tr>
<tr>
<td>Hand decontamination</td>
<td>Alcohol-based handrub (waterless); Chlorhexidine (0.5 % w/v) in alcoholic formulations for 30 s (see Clause E6.12) OR Chlorhexidine (4 % w/v) in detergent formulations (or alcoholic formulations) for 2 min</td>
<td>Isopropyl (60 % – 70 % v/v) or ethyl alcohol (80 % w/v) (see Clause E6.9) with emollients or Povidone-iodine (0.75 % – 1 % av I) for 2 min (see Clause E6.2)</td>
</tr>
<tr>
<td>Spills of blood/serum (or viral cultures)</td>
<td>High concentration chlorine at 5000 – 10 000 p.p.m. (0.5 % – 1 %) (see Clause E6.1) for 10 min (active against hepatitis viruses and HIV)</td>
<td>Glutaraldehyde&lt;sup&gt;b&lt;/sup&gt; for 10 min (see Clause E6.4) or quaternary ammonium compounds&lt;sup&gt;c&lt;/sup&gt;</td>
</tr>
<tr>
<td>Spills of bacterial cultures</td>
<td>High concentration chlorine disinfectant at 5 000 – 10 000 p.p.m. (0.5 % – 1 %) or Iodophor&lt;sup&gt;a&lt;/sup&gt; for 10 min (see Clause E6.2)</td>
<td>Synthetic phenolics&lt;sup&gt;a&lt;/sup&gt; (unaffected by organic load) for 10 min (see Clause E6.10)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Dilute according to manufacturer’s instructions.

<sup>b</sup> Glutaraldehyde as 2 % w/v activated aqueous or 1 % w/v glycol-complexed formulations.

<sup>c</sup> QIV NH4 as acceptable alternative that is effective against enveloped viruses and blood.
**Table E.1 (continued)**

<table>
<thead>
<tr>
<th>Site, equipment or function</th>
<th>Routine or preferred method or usage</th>
<th>Acceptable alternative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal cages</td>
<td>Wash with detergent followed by pressure steam sterilizing at 121 °C for 15 min if infected (see <strong>Clause 11.6</strong>).</td>
<td></td>
</tr>
<tr>
<td>Drains and animal rooms</td>
<td>Sodium hydroxide 1M</td>
<td></td>
</tr>
<tr>
<td>(surfaces)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a</td>
<td>Dilute according to manufacturer's instructions.</td>
<td></td>
</tr>
<tr>
<td>b</td>
<td>Glutaraldehyde as 2 % w/v activated aqueous or 1 % w/v glycol-complexed formulations.</td>
<td></td>
</tr>
<tr>
<td>c</td>
<td>QIV NH4 as acceptable alternative that is effective against enveloped viruses and blood.</td>
<td></td>
</tr>
</tbody>
</table>
### Table E.2 — Effectiveness of liquid or gaseous disinfectants listed in Clause E.6 against microorganisms and pathogenic agents

<table>
<thead>
<tr>
<th>Disinfectant/Decontaminant</th>
<th>Optimum concentration</th>
<th>Minimum contact time (min)</th>
<th>Bibliography Reference</th>
<th>Bacteria</th>
<th>Fungi</th>
<th>Viruses</th>
<th>Prions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Gram positive</td>
<td>Gram negative</td>
<td>Endospores</td>
<td>Mycobacteria</td>
</tr>
<tr>
<td>Sterilants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formaldehyde (E6.3)</td>
<td>8 % v/v in 80 % ethanol</td>
<td>10</td>
<td>1.20</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Glutaraldehyde (E6.4)</td>
<td>2 %</td>
<td>10</td>
<td>1.29</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Peracetic acid (E6.5)</td>
<td>2 %</td>
<td>10</td>
<td>1.30</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Vaporized hydrogen peroxide (E6.7)</td>
<td>700 ppm = 1 mg/l</td>
<td>120</td>
<td>1.30</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Chlorine dioxide (E6.8)</td>
<td>1 mg/l</td>
<td>60</td>
<td></td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>High level disinfectants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peroxygen biocides (E6.6)</td>
<td>1 %</td>
<td>10</td>
<td>1.21, 1.22</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>−</td>
</tr>
<tr>
<td>Chlorine-releasing compounds (E6.1)</td>
<td>0.01–5 %</td>
<td>10</td>
<td>1.15, 1.19</td>
<td>+</td>
<td>+</td>
<td>−</td>
<td>+4</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde (E6.14)</td>
<td>0.55 %</td>
<td>5</td>
<td>1.24, 1.25</td>
<td>+</td>
<td>+</td>
<td>−</td>
<td>+</td>
</tr>
<tr>
<td>Intermediate level disinfectants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iodine/Iodophor (E6.2)</td>
<td>0.5 % – 2.5 %</td>
<td>10</td>
<td>1.31</td>
<td>+</td>
<td>+</td>
<td>−</td>
<td>−</td>
</tr>
<tr>
<td>Alcohol (E6.9)</td>
<td>70 % – 85 %</td>
<td>10</td>
<td>1.32</td>
<td>+</td>
<td>+</td>
<td>−</td>
<td>+</td>
</tr>
<tr>
<td>Phenolics (E6.10)</td>
<td>0.2 % – 3 %</td>
<td>10</td>
<td>1.32</td>
<td>+</td>
<td>+</td>
<td>−</td>
<td>+</td>
</tr>
<tr>
<td>Low level disinfectants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quaternary ammonium compounds (E6.11)</td>
<td>0.1 %</td>
<td>10</td>
<td></td>
<td>+</td>
<td>+</td>
<td>−</td>
<td>−</td>
</tr>
<tr>
<td>Chlorhexidine (E6.12)</td>
<td>2 %</td>
<td>1</td>
<td>1.24</td>
<td>+</td>
<td>+</td>
<td>−</td>
<td>−</td>
</tr>
</tbody>
</table>

1. For bacterial endospores, a contact time of up to 720 min is required for inactivation.
2. See Bibliography, Reference 1.31.
3. Not in the presence of blood.
4. Sodium hypochlorite required a higher concentration of available chlorine (2 %) and a contact time of 60 min to achieve an effective level of decontamination.
5. Only effective in the absence of sputum (see Bibliography, Reference 1.32).
6. See Bibliography, Reference 1.33.
Appendix F
(informative)

Examples of recommended layouts for PC3 and PC4 facilities

Figure F.1 — Simple PC3 laboratory layout showing design principles
Figure F.2 — Additional features for a multiple room PC3 facility
NOTE This example is appropriate for animal facilities where the room is the primary containment measure.

**Figure F.3 — PC3 Facility with shower**
Figure F.4 — PC3 Facility with anteroom

NOTE  This example is appropriate for invertebrate facilities.
Figure F.5 — PC4 facility layout showing design principles
Appendix G
(informative)

Recommendations for achieving acceptable room airtightness

G.1 Scope
This Appendix provides information and guidance on achieving acceptable room airtightness and a method for measuring air leakage.

G.2 Introduction
All PC3 and PC4 facilities have a requirement for containment of aerosols and of gases used in decontamination.

G.3 Aerosol containment
Aerosols generated in the facilities listed in Clause G2 are contained using a combination of the following three ways:

(a) Where possible, aerosols are captured at the source by the use of equipment forming a primary barrier, such as BSCs, capture hoods and HEPA filter top animal cages.

(b) The containment facilities are provided with a dynamic air barrier in that the space is maintained at a negative air pressure in relation to the surrounding atmosphere. This barrier is maintained by the mechanical ventilation system with HEPA filtered exhausts (see Bibliography, Reference 1.26).

(c) The containment facility structure provides a static barrier by being constructed of materials having a low permeability to air and decontaminating gases.

G.4 Loss of aerosol and gaseous containment
Loss of aerosol and gaseous containment can occur due to one or more of the following:

(a) HEPA filter integrity failure.

(b) Biological safety cabinet air balance failure.

(c) Facility exhaust fan failure with continuing supply fan operation.

(d) Facility overpressurization due to temperature rise with all ventilation systems inoperative.

(e) High external wind velocities causing localized low pressure variations at external building openings.

(f) Overpressurization caused by the generation of decontaminating gases with ventilation systems inoperative.

(g) Changes in atmospheric pressure during gaseous decontamination.

(h) Deterioration of seals.

Regular routine testing and maintenance in conjunction with incorporation of appropriate design features can mitigate against loss of containment caused by most of these scenarios. However, there are
three issues that influence the degree of structural integrity required of these containment facilities and that form the basis of related risk assessment criteria. These are —

(i) the risk and consequence of the microorganism escaping through the structure;
(ii) the acceptable leakage rate of decontamination process gases through the structure, commensurate with maintaining a gas concentration within the contained space for an appropriate time to effect a biological kill; and
(iii) the acceptable leakage rate of decontamination process gases through the structure, determined by the risk of gas exposure occurring outside the structure.

G.5 Determination of containment structure integrity

Structural leakage theory allows leakage rates of aerosols containing microorganisms or decontamination gas to be simulated. The leakage coefficient $\beta \text{(m}^3/\text{Pa.s)}$ is used to quantify structural air tightness. Smaller values of $\beta$ result in more airtight structures.

NOTE Structural leakage theory for microbiological containment was developed by Graham W. Pickering for the CSIRO Australian Animal Health Laboratory (AAHL).

Figure G.1 suggests acceptable air leakage values and also identifies the following leakage rates:

(a) Negative pressure flexible film isolator — This value was calculated from the integrity test method specified by the manufacturer for the particular isolator.

(b) CSIRO AAHL — see DEPARTMENT OF TRANSPORT AND CONSTRUCTION, COMMONWEALTH OF AUSTRALIA, ANAHL Analysis of Containment by G.W. PICKERING., 1982.

(c) United States Department of Agriculture value — Found in government publications on high containment laboratories.

(d) Canadian Government value — From the Agriculture and Agri-food Canada containment standards for veterinary facilities.

The values in Items (b) and (c) refer to leakage rates for high containment animal rooms. The room structure in this instance is the primary containment barrier. These facilities are used to contain exotic disease agents that may have significant political, economic, human health and animal health risk if an outbreak of the exotic disease occurred. This is the reason these facilities are constructed to very stringent leakage criteria.

Many PC3 and PC4 research laboratories do not need to meet the same level of air tightness as they are not dealing with animals and all work is performed in BSCs that act as the primary containment device within the laboratory structure.

G.6 Practical application of criteria

The recommended maximum leakage rate, $\beta$, for PC3 and PC4 laboratories is $10^{-5}$, at a test pressure of 200 Pa (see Figure G.1 and Clause G7). This corresponds to a leakage rate of 120 L per minute, or 2.0 L per second at this test pressure. This is achievable provided designers and builders pay special attention to joints, penetrations and openings for services.

Metal faced sandwich panel construction or stud wall construction (utilizing two overlapped layers of plasterboard or utilizing two overlapped layers of reinforced cement sheet) can provide a similarly effective well-sealed laboratory finish.

The solution should take into account the requirement for the finished structure to tolerate pressure differentials during normal operation as well as during situations of extreme pressure fluctuation in the event of partial ventilation system failure. This usually requires studs to be positioned at close centres, panelling to be supported at frequent intervals and to be capable of withstanding pressure-
generated forces in positive as well as negative directions. The worst case is often immediately after an exhaust fan failure but before the supply fan has been automatically stopped.

It is recommended that facilities be retested periodically to ensure that the appropriate leakage rate has been maintained during normal use of the laboratory. Facilities should be retested whenever any modifications take place that could affect the integrity of the seal.

As an absolute minimum, facilities should be retested every 5 years. It is recommended that consideration be given to test at intervals between 1 year and 5 years, depending on the nature of the surfaces and the observed deterioration of seal performance. This should be discussed during facility design. The design should incorporate the ability to connect suitable leakage testing equipment.

Effective decontamination with formaldehyde gas has been achieved successfully in practice with a leakage rate of $10^{-5}$ at 200 Pa using formaldehyde concentrations of 600 p.p.m to 800 p.p.m. (depending on the temperature) and an exposure period of 15 h. This has been tested for space volumes up to 300 m$^3$. The methodology described in Clause E6.3 of Appendix E and Bibliography, Reference 1.21 will normally achieve these concentrations and permits —

(a) adequate exposure time to reduce the microbial load with minimal loss of decontaminant gas concentration; and

(b) minimization of unacceptable levels of decontaminant gas in adjacent areas, provided those areas are reasonably well ventilated.

Existing laboratories may be capable of achieving successful and safe decontamination with tested leakage rates that exceed the recommended $10^{-5}$ at 200 Pa differential pressure. It is not recommended that a laboratory be designed for gaseous decontamination if the leakage rate exceeds $10^{-4}$ at 200 Pa differential pressure, without specialist advice. A leakage rate of $\beta = 10^{-4}$ corresponds to a leakage rate of 1200 l per minute, or 20.0 l per second at this test pressure.

If gaseous decontamination is proposed within a space that has a leakage coefficient within the range of $10^{-5}$ to $10^{-4}$ at 200 Pa test pressure, the following additional precautions should be undertaken:

(i) Attention should be given to the potential for decontaminant gas to accumulate in areas adjacent to the decontaminated space. This will involve an assessment of the size of these areas and the quality of the ventilation that would limit the build-up of concentration of leaked decontaminant gas.

(ii) The possibility that people could be present in any adjacent spaces and the ease with which these areas can be evacuated quickly should be considered. This can particularly apply to any confined plant areas or voids that are located adjacent to or near the decontamination space.

(iii) Consideration should be given to any likely ambient or fan-induced pressure variations between the decontaminated space and adjacent areas that could accelerate leakage.

(iv) The decrease in decontaminant gas concentration during the required exposure time should be measured and steps taken to ensure this does not fall below the recommended value for the duration of the exposure interval.

(v) Appropriate biological testing is carried out to assess the effectiveness of decontamination.

G.7 Structural air leakage testing

Air leakage can be quantified by using an equilibrium pressure/flow test. This test usually involves the introduction of clean, dry compressed air into the space while monitoring the pressure in the space through a separate pressure tapping. When the pressure is stabilized at the required test pressure (200 Pa or other selected pressure), the inflow of air required to maintain this pressure is measured using a flow meter such as a variable gap meter. The leakage is then recorded in litres per minute.

Prior to this test, care needs to be taken to ensure that all sources of air or gas pressure within the space are isolated. Doors should be taped with PVC tape and physically restrained to prevent movement under the positive room pressure.
This test can also be performed by extraction of air from the room, thus placing the room under negative pressure. Either of these procedures provides rapid results, freedom from some experimental variable such as the effects of temperature change and requires a low cost test apparatus. All instruments should be appropriately calibrated by an accredited laboratory.

Other test methods involving pressure decay can be adapted to provide a measure of air leakage but have been found less satisfactory.
Figure G.1 — Laboratory air leakage rates at 200 Pa differential pressure
Appendix H
(normative)

Safe use of Class I and Class II Biological safety cabinets (BSC)

H.1 Primary barrier: the BSC

H.1.1 General

The primary barrier is created by a BSC specified in either AS 2252.1 or AS 2252.2.

H.1.2 User instruction

The user shall be instructed in the degree of protection afforded by the BSC. In particular, the user shall be made fully conversant with the controls, alarms and air flow systems.

Written standard operating procedures shall be prepared and made readily available to the user.

H.1.3 Personal protective equipment (PPE)

The user shall wear a continuous-fronted garment with adjustable or elasticized closures at the wrists. The use of excessively bulky garments should be avoided as they may interfere with the barrier containment. The use of oversleeves is recommended. Thin protective gloves are required and should be pulled over the wrists of the gown.

NOTE See Section 11 for general advice regarding laboratory PPE.

H.1.4 Germicidal ultraviolet lamps

The installation of ultraviolet (UV) lamps should not be used unless required for a specific application. If used, the UV light intensity shall be verified when the BSC is recertified and the bulb regularly wiped to remove the build-up of dust. Previously it was common practice to fit UV lamps in the work zone of BSCs. However, users of such BSCs may not be aware of the following potential hazards and limitations that are inherent in this practice:

(a) Personnel exposed to UV radiation may suffer eye damage and erythema.

(b) UV lamps may generate ozone which may be an inhalation hazard.

(c) Radiation not penetrating and is ineffective on dry or shielded organisms.

(d) Radiation intensity reduces over time due to degradation and surface staining of lamps.

(e) UV radiation causes degradation of certain materials that may be used in BSC construction. The breakdown of some materials within the work zone may result in the emission of toxic vapours.

H.1.5 Electric power regulation

Power fluctuations may cause disturbance of air balance and trigger alarms. The issue of fluctuation, where applicable, shall be taken into account with electrical line conditioning.
H.1.6 Functional checks

The following functional checks shall be made:

(a) The unit is connected to a suitable power supply.
(b) The exhaust air outlet is free from obstructions which may affect air flow.
(c) The viewing window is firmly closed and the work access opening is free from obstructions.
(d) The BSC is switched on and the following is inspected:
   (i) Blower operation and audible alarm operation.
   (ii) The manometer, to ensure that the balance between the laminar flow and exhaust system is within the normal operating range.
   (iii) Work space lamp operation.
   (iv) Any services, where fitted.
   (v) All removable grilles for obstructions, e.g. tissues, cotton wool plugs.

NOTE Check to ensure the BSC test certificate is less than 12 months old. The circumstances of installation and use may dictate more frequent testing.

H.1.7 Location

The integrity of the air barrier can be disrupted by air currents generated by people walking past the BSC, by air vents, and the opening of equipment or room doors. BSCs shall be sited in a location to avoid such disruptions in accordance with the requirements of AS 2252.4, Section 5.

H.1.8 Pre-operational measures

The pre-operational measures shall be as follows:

(a) Clear the BSC of unnecessary items so as to preserve proper air flow.
(b) Before placing required materials in the BSC, check that the work zone is clean and, if necessary, wipe down with an appropriate disinfectant solution.
(c) A comprehensive guide for disinfectants is given in Appendix E.

CAUTION — ALCOHOLIC SOLUTIONS MAY POSE A FIRE HAZARD AND SHOULD BE USED SPARINGLY AND ONLY WHEN THE BSC IS OPERATING. HYPOCHLORITES AND SOME OTHER SOLUTIONS MAY CAUSE CORROSION IF LEFT IN CONTACT WITH STAINLESS STEEL. IT IS ESSENTIAL THAT LIQUIDS DO NOT COME IN CONTACT WITH THE HEPA FILTER.

NOTE Plastic-backed, absorbent sheeting may be laid on solid work floors to facilitate clean-ups between procedures.

(d) Where the BSC is used intermittently and has been switched off, it shall be allowed to operate for a minimum of 5 min before use in order to establish stable airflows and to purge the work zones of aerosols.

(e) All planned work and assembly of all required materials and equipment shall be located inside, or in proximity to, the BSC and within easy reach of the operator. Where appropriate, decontaminate the external surface of all materials before placement into the BSC. Place working items towards the centre of the work floor as the obstruction of the work access opening interferes with barrier air.

(f) Allow the BSC to operate for a further 5 min before use.
NOTE 1  Bunsen burners should not be used in Class II BSCs as they disrupt the laminar flow and the barrier air. The use of disposable loops or an alternative means of heating is preferred. If gas burners are used, they should be placed to the rear of the BSC and hoses for connecting them to BSC service taps should be of the reinforced, two-ply type. Portable gas cylinders should not be used inside BSCs.

NOTE 2  Service hoses or power leads should not be introduced into the BSC through the work access opening.

NOTE 3  Where reticulated vacuum services are connected to the unit, suitable measures, such as fitting a 0.2 μm hydrophobic filter, should be taken to provide microbiological containment.

NOTE 4  Untreated discharge from vacuum-producing devices should be confined to the work zone.

NOTE 5  Centrifuges, other than small, low speed centrifuges, should not be used in BSCs.

NOTE 6  The assembly of all required materials and equipment should be completed on a smooth and impervious trolley.

H.2  Use of the BSC

H.2.1  General

The following general procedures for work within the BSC shall apply:

(a) Follow good biological practice when handling materials in the BSC.
(b) Avoid unnecessary hand and arm movements within the work zone. Slow arm movements, perpendicular to the front opening assist in maintaining the integrity of the air curtain.
(c) Take precautions to avoid cross-contamination between successive specimens especially when these are homogenized in BSCs before culturing. Do not process two specimens in the BSC at the same time.

After completion of the work, the following procedures shall be performed with the BSC operating:

(i) Transfer cultures to a container for incubation or storage.
(ii) Remove unwanted material for sterilization taking appropriate precautions to contain hazardous materials.
(iii) If equipment is to be removed, wipe it over with a disinfectant solution suitable for use on the types of microorganisms being contained, as it is likely to have been contaminated.

NOTE  BSCs should not be used for storage of items not required for immediate use. However, certain small pieces of equipment in regular use, such as electrically-operated loop sterilizers, may be left inside the work zone.
(iv) Wipe the work zone over with an appropriate disinfectant solution. A second wiping with sterile or distilled water is needed when a corrosive disinfectant is used.
(v) Remove gloves (if worn) and discard as infectious waste. Wash hands.
(vi) Allow the BSC to remain operating for at least 5 min to purge air spaces before switching it off. Fit work access opening cover.

In Class II BSCs, the sump shall be cleaned regularly (e.g. weekly) or following a known spillage. With the BSC operating, the work floor shall be lifted and the following areas cleaned with disinfectant:

(A) Under-surface.
(B) Rear grille.
(C) Air intake grille.
(D) Sump floor.

(E) Accessible surfaces.

NOTE Recommended procedures for cleaning up following spillage are described in Section 10.

H.2.2 Breakdown procedure

If the BSC stops operating or the alarm sounds, the following steps shall be taken:

(a) Leaving BSC switched on, stop all work, and secure hazardous material.

(b) Turn off all services within the BSC, such as power to appliances.

(c) Remove gloves if worn, withdraw the hands and wash.

(d) Close the work access opening with the cover.

(e) Switch BSC off and then turn off its power supply.

(f) Notify supervisor.

(g) Call service and clearly mark to show that the BSC is unsafe and not to be used.

For Class II BSCs, if laminar flow failure is suspected or indicated, check the manometer. If failure is confirmed, the clean-up procedures described in (d), (e), (f) and (g) shall be followed.

BSCs shall not be used for microbiological manipulations or storage of infectious materials when the BSC is not operating.

H.2.3 Decontamination

Decontamination shall be performed —

(a) prior to maintenance or testing;

(b) prior to relocation;

(c) when occupational health and safety requirements make it appropriate;

(d) in special circumstances requiring increased assurance of sterility;

(e) after spillage where appropriate (see Section 10 and Bibliography, References 1.36 and 1.37); and

(f) as indicated by the workload and the nature of hazardous material being handled.

A prerequisite for effective decontamination shall be the cleaning of visible residues from surfaces. Special attention shall be paid to the sump of Class II BSCs.

Decontamination shall be carried out by suitable qualified and experienced personnel using a gas or vapour which is effective against the microorganisms which may be present.

NOTE 1 Decontamination should be carried out in strict accordance with equipment manufacturer's recommendations having due regard for environmental conditions of temperature and humidity, and concentration recommendations of the decontaminant chemical. Ensure purging is carried out safely on completion of decontamination. See Bibliography, Reference 1.21 for information related to the use of gaseous formaldehyde.

NOTE 2 Refer to Clause ZZ14 of AS 2252.4 for additional information related to safety precautions when using various decontaminant gases.

The effectiveness of the decontamination shall be monitored periodically by using biological indicators, and shall be performed whenever the decontamination methodology is changed. Test slides and chemical indicators may be used to augment biological indicator tests.
H.2.4 Inspection and testing

Inspection and testing, in accordance with appropriate methods of the AS 1807 series, shall be conducted —

(a) on site immediately prior to initial use (because of the possibility of stress during delivery, installation and effects of site conditions);

(b) after relocation of the BSC;

(c) after mechanical or electrical maintenance; and

(d) after HEPA filters are replaced.

In any case, the inspection and testing shall be completed at a minimum, annually.

Cleaning and gaseous decontamination shall be required before routine testing to confirm that the cabinet is safe for use. Testing shall occur with the room operating at normal conditions, e.g. with the room ventilation system in operation and ancillary equipment and furniture in place. The user should specify more frequent testing if circumstances warrant, e.g. if there is a major change in the use of the BSC or if there is a suspected mechanical fault, or where continued conformance is critical to human safety.

Non-rechargeable batteries should be replaced at each inspection.

Inspection and testing shall include the following:

(i) Filter installation integrity (Classes I and II).

(ii) Inward air velocity (Class I).

(iii) Air velocity and uniformity in work zone (Class II).

(iv) Air barrier containment (Class II).

(iv) Work zone integrity (Class II).

Alarm system function.

NOTE 1 Replacement of batteries does not constitute a part of test procedures.

A test report detailing the results of all tests conducted shall be provided to the owner. A summary of these results, shall be affixed to the BSC.

NOTE 2 A summary of these results may be in the form of a test certificate.

Where testing has shown that the performance requirements for inward air velocity or HEPA filter integrity (Class I), or air barrier containment or exhaust HEPA filter integrity (Class II) are not met and the defect has not been corrected, the BSC shall be clearly marked to show that it is unsafe and shall not be used.

H.2.5 Occupational health and safety

Service personnel shall wear suitable protective clothing, including gloves. Access panels to contaminated zones shall be removed only after the whole BSC has been decontaminated.

Service personnel shall ensure that decontamination has taken place before proceeding with work on the BSC.
H.3 Radiation protection

H.3.1 Hazards to operator

The handling of unsealed sources of radioactivity within a biological safety BSC requires special consideration of hazards to the operator. The biological effects of ionizing radiation are reviewed briefly in Bibliography, Reference 1.36. Hazards to the operator may arise as follows:

(a) External exposure, from sources which can irradiate the whole or part of the body with sufficient energy to affect the skin or underlying tissues. Practical control measures are —

(i) use of adequate shielding;

(ii) maximizing the distance between the radioactive source and the operator, including hands; and

(iii) limiting the time of exposure.

(b) Internal exposure, from radioactive material taken into the body by ingestion, inhalation or absorption through the skin. Practical control measures are similar to those employed in infection control by —

(i) containment of the material;

(ii) scrupulous attention to cleanliness and tidiness; and

(iii) use of the least harmful radionuclide and the smallest quantity of activity which will suffice for the purpose of work being undertaken.

H.3.2 Working practices

Safe working practices and facilities are described in AS 2243.4. Personnel should have a high level of competence and training in the handling of radionuclides. Stringent protective measures are required.

H.3.3 Legislative requirements

The Commonwealth of Australia, the government of New Zealand and all Australian States and Territories have enacted legislation controlling the safe possession, use and sale of radioactive substances. Laboratories shall comply with legislative requirements. Operators shall either hold an appropriate licence or work under the supervision of a licensee. The relevant regulatory authorities should be consulted.

H.3.4 Classification of laboratories

The amount of radioactivity which can be handled in a given laboratory will depend on the toxicity of the radionuclide, and the type and form of the manipulation. Information on the classification of laboratories can be obtained from Bibliography, Reference 1.37 or Reference 1.38 as appropriate.

H.3.5 Modification of BSCs

The use of an appropriately modified BSC can minimize the risks from handling radioactive sources associated with the biological materials. Class I BSCs may be adapted where no product protection is required. Class II BSCs may be adapted where both product and operator protection are required.

H.3.6 Gaseous or volatile radio-nuclides

BSCs are unsuitable for handling gaseous or volatile radionuclides, unless coupled to an approved exhaust system. Their use should be restricted to low levels of radioactivity only, and requires the approval of the appropriate regulatory authorities on the discharge levels of airborne waste. Ductwork shall conform with the provisions of AS 2243.8. Design of facilities for handling higher levels of radioactivity requires specialist advice, for example, in the installation of filters and exhaust systems.
H.4 Shielding

Shielding requirements will depend on the type and amount of radiation emitted. Alpha emissions do not require any shielding additional to that provided by the source container. Beta-emitting sources should be kept in containers which reduce radiation to negligible levels. Plastic or glass up to 8 mm thick is usually adequate, though large activity sources may require additional lead shielding for bremsstrahlung radiation. Gamma-emitting sources will usually require additional shielding of the container, in lead or equivalent.

Shielding against gamma radiation may be attached to the BSC or to a separate fixed or mobile frame. Advice on specific shielding requirements may be sought from the regulatory authorities in each State. For some purposes, a removable L-shaped shield comprising a base and stand may be used in a BSC, Class II only. A viewing window in lead glass or lead acrylic, as appropriate, should be incorporated in the shield. Placement of the shield shall not interfere with the uniformity and velocity of air flow above the workbench, air distribution and air barrier containment. Prior to using the BSC, the critical performance requirements as specified in AS 2252.2 shall be met with the shield in position in the work zone, as the shield may disturb the airflow.

H.4.1 Handling procedures

The operator should minimize direct handling of unshielded sources by the use of forceps or similar, while maintaining full control of the manipulative procedure.

H.4.2 Working practices

As described in AS 2243.4, safe working practices shall be adopted to prevent contamination of the BSC, the equipment, and the operator.
Bibliography

The following Standards are referenced in this Standard in an informative manner:

AS 1668.2, The use of ventilation and airconditioning in buildings, Part 2: Mechanical ventilation in buildings

AS 1894, The storage and handling of non-flammable cryogenic and refrigerated liquids

AS 2252.1, Controlled environments, Part 1: Biological safety cabinets (Class I) for personnel and environment protection

AS 2252.6, Controlled environments, Part 6: Clean workstations — Design, installation and use

AS 3745, Planning for emergencies in facilities

AS 4031, Non-reusable containers for the collection of sharp medical items used in health care areas

AS 4381, Single-use face masks for use in health care

AS 4834, Packaging for surface transport of biological material that may cause disease in humans, animals and plants

AS 4774, Work in compressed air and hyperbaric facilities (series)

AS/NZS 1170.2, Structural design actions, Part 2: Wind actions

AS/NZS 1715, Selection, use and maintenance of respiratory protective equipment

AS/NZS 2161, Occupational protective gloves (series)

AS/NZS 2243.9, Safety in laboratories, Part 9: Recirculating fume cabinets

AS/NZS 3816, Management of clinical and related wastes

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Further reading

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RIDEOUT, K., TESCHKE, K., DIMICH-WARD, H. and KENNEDY, S. Considering the risk to healthcare workers from glutaraldehyde alternatives in high-level disinfection. *Journal of Hospital Infection*. 2005; vol. 59(1): pp. 4–11


1.28 CETA Application Guide for the use of Surface Decontaminants in Biosafety Cabinets, CAG-004-2007, available on the CETA website


1.34 United States Department of Agriculture, Agricultural Research Services, National Agricultural Library, Animal Welfare Center. Refer in particular to 'Fish Welfare' and 'Care and Use of Molluscs' information resources.


1.38 OIE Terrestrial Manual oie.int/en/internationalstandardsetting/terrestrialmanual/access-online


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Committee CH-026, Safety In Laboratories, consisting of the following, is responsible for the issue of this draft:

- Association of Biosafety for Australia and New Zealand
- Australian Chamber of Commerce and Industry
- Australian Industry Group
- Australian Institute of Occupational Hygienists
- Australian Nuclear Science & Technology Organisation
- Bureau of Steel Manufacturers of Australia
- CSIRO
- Environmental Science and Research New Zealand
- Institution of Chemical Engineers
- Ministry for Primary Industries (NZ)
- National Measurement Institute
- New Zealand Institute of Architects
- New Zealand Microbiological Society
- Responsible Care New Zealand
- Royal Australian Chemical Institute
- Worksafe New Zealand
- WorkSafe Victoria

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