NEW ZEALAND

EDICT OF GOVERNMENT

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AS-NZS 2243-3 (2010) (English): Safety in laboratories - Microbiological safety and containment [By Authority of New Zealand Fire Safety and Evacuation of Buildings Regulations 2006 (SR 2006/123)]

We will sell to no man,
we will not deny or defer to any man either justice or right.
Magna Carta—Tūtohinga Nui
Kore rawa e hoko ki te tangata, e kore e whakakāhoretia,
e tautuku rānei te tangata ki te ture, tika ranei.

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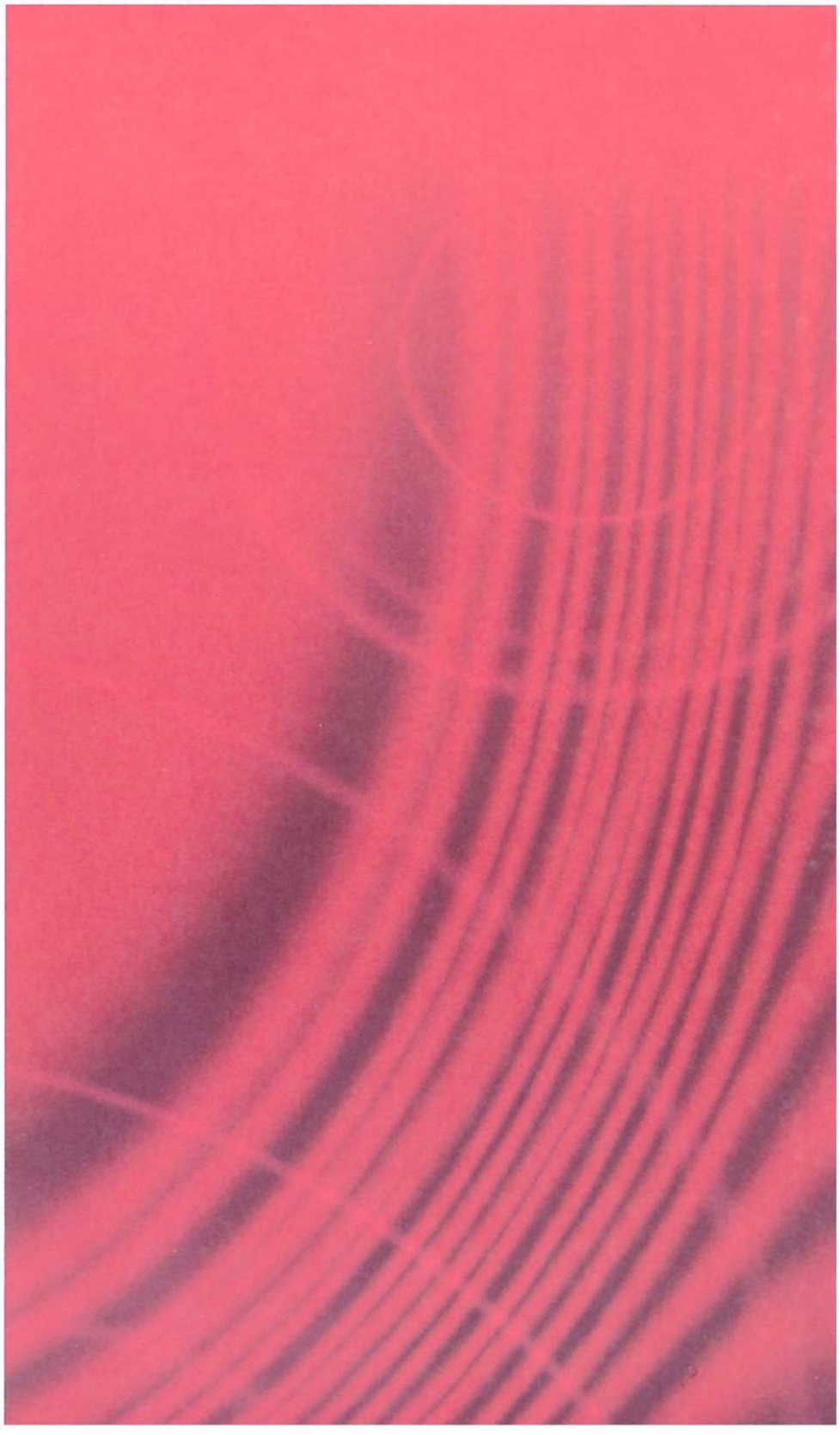
STANDARDS NEW ZEALAND
PAEREWA AOTEAROA

Safety in laboratories

Part 3: Microbiological safety and containment



STANDARDS Australia

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee CH-026, Safety in Laboratories. It was approved on behalf of the Council of Standards Australia on 13 May 2010 and on behalf of the Council of Standards New Zealand on 27 August 2010.
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The following are represented on Committee CH-026:

Australian Industry Group
Australian Institute of Occupational Hygienists
CSIRO
Department of Labour, New Zealand
Department of Primary Industries, Vic.
Environmental Science and Research, New Zealand
Ministry of Agriculture and Forestry, New Zealand
Ministry of Economic Development, New Zealand
National Association of Testing Authorities, Australia
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Additional Interests:

Australasian Plant Pathology Society
Australian National University
Australian Quarantine and Inspection Service
Australian Society for Microbiology
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CSIRO, Division of Livestock Industries
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Office of The Gene Technology Regulator
Sterilizing Research Advisory Council of Australia, Vic.
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Australian/New Zealand Standard™

Safety in laboratories

Part 3: Microbiological safety and containment

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee CH-026, Safety in Laboratories, to supersede AS/NZS 2243.3:2002, *Safety in laboratories*, Part 3: *Microbiological aspects and containment facilities*.

Major changes in this edition are as follows:

(a) Revision of the requirements for laboratories dealing with infectious diseases and the classifications of microorganisms into the four risk groups.

(b) Separate definitions are provided for the four risk groups for plant infectious microorganisms and for microorganisms carried by invertebrates.

(c) The plant and invertebrate sections have been revised to acknowledge the different types of hazards associated with plant and invertebrate microorganisms.

(d) The presentation of requirements for animal, plant and invertebrate containment facilities has been revised to make them independent of the requirements for laboratories.

(e) Addition of a requirement for a pressure steam sterilizer to be accessible from within all PC3 facilities.

The Committee is currently addressing the need to develop a section for containment of water based species, including fish and aquatic invertebrates. Some applicable information may be found in the laboratory and animal facility sections of this Standard.

The containment of plant pathogens is primarily concerned with minimizing hazards due to inadvertent spread to the environment. This is in contrast to the containment of human and animal pathogens, where the principal aim is to avoid risk of infection or contamination of facility workers and the community.

The containment of invertebrate pathogens may involve the minimization of hazards associated with inadvertent spread to the environment or microbiological hazards associated with exposure to people or animals. It may involve both of these hazards simultaneously. Where hazards to personnel are present in an invertebrate facility, the invertebrates and laboratory work will need to be carried out in a laboratory of appropriate microbiological containment level to protect the personnel, along with the additional containment features associated with invertebrate containment.

The Parts of the series promoting safety in laboratories are as follows:

Part 1: Planning and operational aspects
Part 2: Chemical aspects
Part 3: Microbiological safety and containment (this Part)
Part 4: Ionizing radiations
Part 5: Non-ionizing radiations—Electromagnetic, sound and ultrasound
Part 6: Mechanical aspects
Part 7: Electrical aspects
Part 8: Fume cupboards
Part 9: Recirculating fume cabinets
Part 10: Storage of chemicals

Although many of the safety aspects of working in laboratories are addressed in other Parts of the series, some are repeated here in Part 3 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 occupational health and safety legislation to take care of both themselves and others in the workplace. It should not be assumed that compliance 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.

It should be noted that nothing in this Standard is required by law in any jurisdiction unless the Standard has been specifically incorporated by an Act or regulation in that jurisdiction. The exact manner of incorporation will determine whether the whole document, or specific sections or provisions, are made legal requirements or whether the Standard becomes an Approved Code of Practice. However, it should also be noted that this Standard is recognized in common law as defining current knowledge in microbiological safety practice. The provisions in a Code are not mandatory but give practical guidance on how to comply with the relevant provisions of the Act or regulation. Provided an alternative method also fulfils the requirements of the Act or regulation, it may be used. Users will need to consult the relevant authority to determine if this Standard has been incorporated and the manner of incorporation, if any.

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. Compliance 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' have been used in this Standard to define the application of the appendix to which they apply. A 'normative' appendix is an integral part of a Standard and contains requirements that have to be met for compliance with the objectives and intent of this Standard. An 'informative' appendix is only for information and guidance.

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FOREWORD

Safety in all laboratories is primarily a management responsibility, but is also an individual responsibility. It is the responsibility of 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 staff 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. Staff training must 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 staff, 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.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard
Safety in laboratories

Part 3: Microbiological safety and containment

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. It includes animal, plant and invertebrate 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. This Standard should be read in conjunction with AS/NZS 2243.1, AS/NZS 2982.1, building codes in Australia and New Zealand and other relevant Parts of the AS/NZS 2243 series.

NOTES:

1 This Standard uses the term 'containment facility' instead of historical terms such as plant houses, glass houses, insectaries and animal houses. For example, an animal house is referred to as an animal containment facility.

2 This Standard is not intended for genetic modification work not involving microorganisms, for which the appropriate body should be consulted. See Clause 2.3.

3 In addition to referenced documents, Appendix A contains references and related documents that are included in this Standard for additional information and guidance.

4 This Standard does not address aquatic containment facilities.

1.2 OBJECTIVE

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

1.3 REFERENCED DOCUMENTS

Documents referred to in this Standard are listed in Appendix A.

1.4 DEFINITIONS

For the purpose of this Standard, the definitions below apply.

1.4.1 Aerosol

Suspension in air of finely dispersed solids or liquids.

NOTE: Any procedure that disrupts the surface of a liquid has potential to produce aerosols. Procedures such as shaking, mixing and ultrasonic disruption are particularly common examples for microbiological work.

1.4.2 Airlock

A separate, fully-enclosable space with two doors designed to limit 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 exit procedures.

1.4.3 Anteroom

A separate, fully-enclosable space used during access and egress that has specific containment functions.

1.4.4 Antiseptic

Substance capable of destroying or preventing growth of microorganisms under prescribed conditions of use, and specifically for application to living tissues.

1.4.5 Aseptic technique

The 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.

1.4.6 Biohazard

The potential microbiological source of harm.

1.4.7 Biological safety cabinets

1.4.7.1 *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 high-efficiency particulate air (HEPA) filtration of exhaust air.

1.4.7.2 *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.

1.4.7.3 *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.

1.4.8 Biosafety

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

1.4.9 Biosafety committee (BC)

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

NOTE: An institutional biosafety committee (IBC) is specific to gene technology. An institutional biological safety committee (IBSC) is the New Zealand equivalent of an IBC.

1.4.10 Change room

1.4.10.1 *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.

1.4.10.2 *Outer change room*

Space used by personnel to remove personal clothing as appropriate to facility level prior to entry and to don personal clothing on exit, e.g. from shower airlock.

1.4.11 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.

1.4.12 Containment

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

1.4.13 Containment facility

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

NOTE: This definition is distinct from that used in the MAF Biosecurity New Zealand and ERMA New Zealand Standard *Facilities for Microorganisms and Cell Cultures: 2007a.*

1.4.14 Cross-contamination

The undesirable transfer of microorganisms from one source to another.

1.4.15 Decontamination

A physical or chemical process that kills or removes pathogenic microorganisms, but does not necessarily result in sterility.

1.4.16 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.

1.4.17 Disinfectant

A substance capable of killing a wide range of microorganisms; its use is usually confined to hard surfaces.

1.4.18 Exposure standard

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

1.4.19 HEPA filter

A 'high-efficiency particulate air' (HEPA) filter complying with the requirements in Clause 10.9.1.

1.4.20 Infectious microorganism

A microorganism capable of invading a susceptible host and multiplying in it, which may or may not cause a disease.

1.4.21 Invertebrates

Includes all multi-cellular animal species without backbones that are land based as adults. This includes annelids, cnidarians, echinoderms, flatworms, nematodes, molluscs and arthropods. Protozoans are not included due to their microscopic size and single cellular nature.

1.4.22 Microbiological hazard

The potential microbiological source of harm, often called a 'biohazard'.

1.4.23 Microbiological spill

An incident where control of infectious material has been lost inadvertently.

1.4.24 Microorganisms

Microscopic organisms including protozoa and other parasites, fungi, archaea, bacteria, unicellular algae, viruses and viroids.

1.4.25 Pathogen

An infectious organism, usually microscopic, capable of causing disease in a host.

1.4.26 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.

1.4.27 Prions

Proteinaceous infectious particles that lack nucleic acids, which can cause scrapie and other related neurodegenerative diseases of humans and animals.

1.4.28 Risk assessment

A process of estimating the potential of a hazard (source of harm) to give rise to an adverse outcome. 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.

1.4.29 Shall

Indicates a statement is mandatory.

1.4.30 Sharps

Objects or devices having sharp points or protuberances or cutting edges, capable of cutting or piercing the skin.

NOTE: See AS 4031 for information on sharps containers.

1.4.31 Should

Indicates a recommendation.

1.4.32 Sterile

The state of being free from viable microorganisms.

NOTE: In practice, no such absolute statement regarding the absence of microorganisms can be proven.

1.4.33 Sterilization

A validated process used to render a product free from viable microorganisms.

NOTE: 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.

1.4.34 Viable

Living: capable of growth even though resuscitation procedures may be required, e.g. when microorganisms are sub-lethally damaged by being frozen, dried, heated or affected by chemicals and disinfectants.

1.5 ABBREVIATIONS

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

AQIS	Australian Quarantine and Inspection Service
BC	Biosafety committee
BSC	Biological safety cabinet
CWA	CEN Workshop Agreement
DNA	Deoxyribonucleic acid
ERMA	Environmental Risk Management Authority
GMO	Genetically modified organism
HEPA	High-efficiency particulate air
HSNO	Hazardous Substances and New Organisms
IATA	International Air Transport Association
IBC	Institutional biosafety committee
IBSC	Institutional biological safety committee
IMO	International Maritime Organization
MAF BNZ	Ministry of Agriculture and Forestry Biosecurity New Zealand
NHMRC	National Health and Medical Research Council
NRL	National Radiation Laboratory
NTAC	National Tuberculosis Advisory Committee
OGTR	Office of Gene Technology Regulator
OHS	Occupational health and safety
PC	Physical containment
PPE	Personal protective equipment
RPE	Respiratory protective equipment

SECTION 2 ORGANIZATION AND RESPONSIBILITY

2.1 RESPONSIBILITY

2.1.1 Management policy

Management shall provide staff with a policy statement on laboratory safety that recognizes the special hazards associated with microorganisms.

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. See 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.

(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 staff/workers with the particular microorganisms proposed for the work.

(i) Any health considerations for staff, e.g. vaccinations, medical monitoring.

(j) The capability to deal with a spill, such as by facility gaseous decontamination.

All risk assessments that involve biological systems are 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 occupational health and safety (OHS) laws, the employer is responsible for ensuring that the workplace is safe and free from risks to health.

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

(a) the applicable statutory regulations for the composition and operation of overall OHS 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 terms of reference of the BC in relation to biohazards should be as follows:

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

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

(iii) Review of safety audits.

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

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

(vi) Inspection, audits and any licensing of laboratories.

(vii) Ensuring appropriate records are kept, including staff training, immunizations and relevant, OHS-related medical advice given.

2.1.4 Safety officer(s)

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

2.1.5 Laboratory or facility supervisor

The supervisor shall ensure that safe procedures are documented and put into practice. The supervisor shall implement initial and continuing training programs, ensure staff are supervised and ensure maintenance is carried out in accordance with safe procedures. The supervisor should also ensure that casual visitors do not have unrestricted access to the laboratory.

2.1.6 Personal responsibility

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

(a) Individuals shall familiarize themselves with the recommendations and requirements 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 Australian Quarantine and Inspection Service (AQIS) approves places where post-entry quarantine requirements apply for a wide range of human, plant and animal pathogens and human, plant and animal products, so that it can be sure that these activities are performed with a minimal degree of risk.

To gain approval as a quarantine approved premises (QAP), there are conditions that the premises must meet to assure AQIS that the risk of any quarantine 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, animal, plant and invertebrate facilities.

Further information on the approval process for quarantine approved premises is available at http://www.daff.gov.au/aqis/import/general-info/qap.

AQIS will also require institutions to obtain a permit for work conducted in containment facilities. Such permits contain special conditions. The import conditions database (ICON) should be consulted at http://www.aqis.gov.au/icon32/asp/homecontent.asp.

2.2.2 New Zealand

In New Zealand, Ministry of Agriculture and Forestry Biosecurity New Zealand (MAF BNZ) controls the import of biological risk goods, establishes Standards for laboratories receiving and holding such goods and enforces the compliance to those standards.

For further information, contact—

Import Standards Group
MAF BNZ
Box 2526
Wellington New Zealand
Website: www.maf.govt.nz

2.3 LABORATORIES USING GENETICALLY MODIFIED ORGANISMS (GMOs)

2.3.1 Australia

Under the Commonwealth gene technology legislation, certain dealings with genetically modified organisms (GMOs) are required to be conducted in facilities that meet and are certified as complying with OGTR *Guidelines for the certification of physical containment facilities*.

Organizations seeking information about the regulatory requirements that apply to work with GMOs should contact the OGTR for further information at the following address:

Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
CANBERRA ACT 2601
Website: www.ogtr.gov.au

2.3.2 New Zealand

Under the *Hazardous Substances and New Organisms (HSNO) Act 1996*, work with genetically modified organisms is regulated by the Environment Risk Management Authority (ERMA). In general, all work involving the holding or development of GMOs shall be carried out in accordance with controls set by ERMA, or an IBSC or the Chief Executive of ERMA New Zealand in containment facilities approved by MAF BNZ. Work involving GMOs shall be carried out in accordance with MAF BNZ and ERMA New Zealand Standard: *Facilities for Microorganisms and Cell Cultures:2007a*.

Laboratories should consult—

ERMA New Zealand
PO Box 131
Wellington
Email: enquiries@ermanz.govt.nz
Website: www.ermanz.govt.nz

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

2.4 LABORATORY BIOSECURITY

Laboratory biosecurity, 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 laboratory biosecurity program 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 biosecurity measures.

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

2.5 COMMISSIONING

On completion of the construction of a containment facility or major changes to a containment facility, the surrounding building, environment, associated air supply or exhaust systems, the facility shall be assessed for overall compliance with this Standard. An itemized checklist should be developed to assist in ensuring all requirements of the Standard relevant to the particular facility are taken into account when conducting the assessment.

2.6 HEALTH MANAGEMENT

2.6.1 General

All personnel shall be advised of the risk of occupational exposure to microorganisms to which they may not be immune.

When working with human pathogens of Risk Group 3 or Risk Group 4, each person working in the laboratory or animal, plant or invertebrate facility shall be subjected to an initial medical examination, including a chest X-ray where relevant, and periodic examinations. A baseline serum sample should be obtained from at risk personnel and stored for future reference. (See also Clauses 2.6.3 and 2.6.5.)

When working with human pathogens of Risk Group 4, a system 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.

2.6.2 Injuries and infections

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. All injuries that occur in the workplace shall be reported to the supervisor (see Clause 2.7). Immediate medical action is required after human blood or body fluid exposure and contaminated sharps injuries. (See the Department of Health and Ageing publication, *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting.*) 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.

If samples are collected, procedures shall be documented defining who owns the serum, how it is stored, who can access it for testing, who may order tests, who evaluates the tests and who can have access to the results.

2.6.4 Immunization

For those working with human or zoonotic pathogens, or samples that may contain human or zoonotic pathogens, the latest editions of *The Australian Immunisation Handbook* published by the NHMRC or the *Immunisation Handbook* published by the New Zealand Ministry of Health, as appropriate, should be consulted and implemented.

All new staff working with specimens and cultures potentially containing *Mycobacterium tuberculosis* (TB) complex are recommended to 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 (see Reference 1.1). Staff with negative test results should be retested on an annual basis (see the NTAC *Guidelines for Australian Mycobacteriology Laboratories* or *Guidelines for Tuberculosis Control in New Zealand 2003*, as appropriate).

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

Consideration should be given to the immunization of support staff 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 person responsible for microbiological safety of their condition so that appropriate 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

Laboratory management shall inform all female employees of the risk to the unborn child or the pregnant woman of occupational exposure to certain microorganisms (e.g. *Toxoplasma gondii*, *Listeria monocytogenes*, cytomegalovirus, parvovirus B19, rubella virus, human immunodeficiency virus (HIV), *Coxiella burnetii* and hepatitis B, C and E viruses) and some fungi. The precise steps taken for protection will vary, depending on the microorganisms to which the woman may be exposed. 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 should be given to the Risk Group if a microorganism is involved, how it might be transmitted and if any hosts, the environment or processes 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, it should be reported verbally to the supervisor as soon as reasonably possible. The incident should be documented once the appropriate clean-up procedure has been implemented. (See Section 9 dealing with spill clean-up.)

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

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

Personnel should be encouraged to report all overt exposures or 'near hits', so that they may be documented, investigated and, if necessary, procedures changed. This may prevent another or a similar circumstance producing an incident, injury or illness.

NOTE: Appendix B 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.

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: Reference should be made 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, animals, plants 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 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 were 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 and harvesting of infected tissues from animals and eggs.

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, physical containment equipment, laboratory design and procedures to be followed when working in laboratories with microorganisms classified at the various risk groups.

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

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 References 1.3, 1.4 and 1.5). The World Health Organization (WHO) suggests each country draw up risk groups according to the microorganisms encountered within its boundaries (see Reference 1.6). Unless otherwise stated, references to particular risk groups, e.g. Risk Group 1, refers to human and animal, plant and invertebrate risk groups.

3.2.2 Human and animal infectious microorganisms

The following classification has been drawn up for microorganisms that are infectious for humans and 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:

(a) *Risk Group 1 (low individual and community risk)*—a microorganism that is unlikely to cause human or 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 four risk groups are used to manage risks posed by plant infectious microorganisms:

(i) *Plant Risk Group 1*—a microorganism that is unlikely to be a risk to plants, industry, a community or region and is already present and widely distributed.

(ii) *Plant Risk Group 2*—a microorganism that is a low to moderate risk to plants, industry, a community or region and is present but not widely distributed.

(iii) *Plant Risk Group 3*—a microorganism that is 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.

(iv) *Plant Risk Group 4*—a microorganism that is 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:

(A) *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.

(B) *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.

(C) *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.

(D) *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.

3.3 RISK-GROUPING OF MICROORGANISMS BY TYPE

3.3.1 General

Tables 3.1 to 3.8 and 3.9 to 3.11 list examples of microorganisms in Risk Groups 2 to 4 and Plant Risk Groups 2 to 4 respectively. See Clause 3.3.4 in relation to invertebrate risk group examples. 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 physical containment level may be appropriate. This also applies to situations where the potential to cause environmental and economic damage is a significant concern.

A 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 physical containment. 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 physical containment.

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 physical containment.

Guidelines for Australian Mycobacteriology Laboratories published by the National Tuberculosis Advisory Committee or *Guidelines for Tuberculosis Control in New Zealand 2003* published by the Ministry of Health New Zealand, as appropriate, should be consulted for specific requirements for collection, handling and culture of specimens for mycobacteria.

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 C shall be applied.

3.3.3 Plant pathogen risk group examples

Tables 3.9, 3.10 and 3.11 list examples of plant pathogens of Plant Risk Groups 2, 3 and 4 respectively.

3.3.4 Invertebrate risk group examples

Invertebrates are able to act as vectors for human, 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 3.11.

3.4 HUMAN AND ANIMAL CLINICAL AND DIAGNOSTIC SPECIMENS

Such specimens would normally be regarded as Risk Group 2 and shall be handled in Physical Containment Level 2 facilities unless a higher risk group is indicated by the clinical notes. This applies in all microbiology and other pathology laboratories, e.g. for haematology and biochemistry. However, if a microorganism of a higher risk group is isolated from a specimen, the isolate and all samples from that source shall be handled according to the corresponding risk group, and at the appropriate physical containment level.

All clinical and diagnostic specimens shall be treated with care as they may contain multiple types of infectious microorganisms. Examples of precautions that should be adopted are provided in the Department of Health and Ageing publication, *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting* and NOHSC: 2010.

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. 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. In some instances, PC1 teaching labs can be adequate if good microbiological practices are followed, e.g. work with standard human cell lines. 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', 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.

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 infectious or potentially infectious prions, a laminar flow cytotoxic drug safety cabinet shall be used. Table 3.4 lists examples of prions of Risk Group 2. See also Clauses 10.8 and 12.2.1. Table F2 provides guidance on disinfection of equipment or surfaces contaminated with prions.

TABLE 3.1
EXAMPLES[a] OF BACTERIA OF RISK GROUP 2

Organism	
Abiotrophia spp.	*Haemophilus influenzae, H. ducreyi*
Acidovorax spp.	*Helicobacter pylori*
Acinetobacter spp.	*Kingella kingae*
Actinobacillus spp.	*Klebsiella* spp.
Actinomyces spp.	*Legionella* spp.
Aeromonas hydrophila	*Leptospira interrogans* (all serovars)[d]
Afipia spp.	*Listeria spp., Listeria monocytogenes*[e]
Arcanobacterium haemolyticum	*Moraxella* spp.
Bacillus cereus	*Mycobacterium* spp. other than *M. tuberculosis* complex[f]
Bartonella henselae, B. quintana, B. vinsonii, B. elizabethiae, B. weisii	*Mycobacterium tuberculosis* complex (except multi-drug resistant strains[f, g, h])
Bordetella pertussis	*Mycoplasma pneumoniae*[f]
*Borrelia (*mammalian*)* spp.	*Neisseria gonorrhoeae*, Unspeciated Neisseria[b, f], *N. meningitidis*[b, f]
Brucella ovis	*Nocardia* spp.
Brucella spp. serology only	*Oligella* spp.
Burkholderia spp. (except *B. mallei*), *Burkholderia pseudomallei*[b, f]	*Pasteurella* spp.
Campylobacter coli, C. fetus, C. jejuni	*Pseudomonas* spp.
Capnocytophaga canimorsus	*Rhodococcus equi*
Chlamydia spp. (except *C. psittaci*)	*Salmonella* serovars
Clostridium spp.	*Salmonella* Paratyphi A and B[b]
Corynebacterium diphtheriae, C. renale, C. pseudotuberculosis	*Salmonella* Typhi[b, e]
Coxiella burnetii serology, other tests on samples	*Serratia* spp.
Dermatophilus congolensis	*Shigella* spp.[b]
Edwardsiella tarda	*Sphaerophorus necrophorus*
Eikenella corrodens	*Staphylococcus aureus*
Enterococcus spp. (Vancomycin-resistant strains)	*Stenotrophomonas maltophilia*
Erysipelothrix rhusiopathiae	*Streptobacillus moniliformis*
Pathogenic *Escherichia coli* (except genetically crippled strains[c])	*Streptococcus pyogenes, S. pneumoniae*
Verocytotoxin-producing *Escherichia coli* (VTEC)[b]	*Treponema pallidum*
Fusobacterium spp.	*Ureaplasma ureolyticum*
Gardnerella vaginalis	*Vibrio cholerae, V. parahaemolyticus, V. vulnificus*
Gordona spp.	*Yersinia* spp. (except *Y. pestis*)

[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.

[b] Low infectious dose, high pathogenicity, common source of laboratory-acquired infections.

[c] For genetically crippled strains, refer to the gene technology regulations.

[d] Can penetrate intact skin.

[e] May be dangerous for pregnant women.

[f] High risk of aerosol spread.

[g] Vaccination, see Clause 2.6.4.

[h] Less than 5000 cultures per year. See references in Clause 3.3.2.1.

TABLE 3.2

EXAMPLES[a] OF PARASITES OF RISK GROUP 2— INFECTIOUS STAGES ONLY

Organism
Ancylostoma duodenale
Ascaris lumbricoides
Babesia divergens
Babesia microti
Brugia spp.
Clonorchis sinensis
Cryptosporidium spp.
Echinococcus spp.
Entamoeba histolytica
Giardia duodenalis (also known as *Giardia lamblia* and *Giardia intestinalis*)
Hymenolepis diminuta
Hymenolepis nana
Leishmania (mammalian) spp.
Loa loa
Naegleria fowleri
Necator americanus
Opisthorchis spp.
Plasmodium (human and simian)
Strongyloides stercoralis[b]
Taenia saginata
Taenia solium[c]
Toxocara canis
Toxoplasma gondii[d]
Trichinella spiralis
Trypanosoma brucei subspp.
Trypanosoma cruzi
Wuchereria bancrofti

[a] This list is not exhaustive.

[b] Filariform larvae may cross intact skin.

[c] Accidental ingestion of eggs may lead to cysticercosis

[d] May be teratogenic

TABLE 3.3

EXAMPLES[a] OF FUNGI OR FUNGAL-LIKE ORGANISMS OF RISK GROUP 2

Organism
Aspergillus fumigatus and *A. flavus*
Candida albicans
Cladophialophora spp.
Cryptococcus gattii
Cryptococcus neoformans
Epidermophyton floccosum
Microsporum spp.
Scedosporium spp.
Sporothrix schenckii
Trichophyton spp.

[a] This list is not exhaustive.

TABLE 3.4

EXAMPLES[a] OF VIRUSES AND PRIONS OF RISK GROUP 2

Virus or prion
Adenoviridae
Adenovirus
Arenaviridae
Arenavirus
Lymphocytic choriomeningitis (LCM) non-neurotropic strains
Tacaribe virus complex
Caliciviridae
Feline calicivirus
Norovirus
Sapporo-like
Largovirus
Rabbit haemorrhagic disease
Coronaviridae
Coronavirus other than SARS coronavirus
SARS coronavirus (tests not involving replication)[b]
Flaviviridae
Flavivirus
Dengue 1, 2, 3 and 4
Japanese encephalitis (Nakayama strain)[c]
Kokobera
Kunjin
Murray Valley encephalitis
West Nile (Sarafend strain)
Saumarez Reef
Yellow fever (strain 17D)[c]
Hepacivirus
Hepatitis C
Hepadnaviridae
Duck hepatitis B
Hepatitis B[c]
Herpesviridae
Alphaherpesvirinae
Simplex
Varicella[c]
Betaherpesvirinae
Cytomegalovirus[d]
Gammaherpesvirinae
Herpes 6 and 7
Lymphocryptovirus (EB-like viruses)
Orthomyxoviridae
Influenza (all strains and candidate vaccine strains except those specified in Table 3.7 [c,e]

(*continued*)

TABLE 3.4 (*continued*)

Virus or prion
Paramyxoviridae
Paramyxovirinae
Morbillivirus
Measles[c]
Rubulavirus
Menangle
Mumps[c]
Human parainfluenza 2 and 4
Avulavirus
Newcastle disease (non-virulent enzootic strains)
Avian paramyxoviruses 2 to 9
Respirovirus
Sendai
Human parainfluenza 1 and 3
Pneumovirinae
Pneumovirus
Respiratory syncytial
Metapneumovirinae
Metapneumovirus
Avian metapneumovirus
Human metapneumovirus
Parvoviridae
Human parvovirus[d]
Picornaviridae
Cardiovirus
Encephalomyocarditis virus
Hepatovirus
Hepatitis A virus[c]
Human Enterovirus
Coxsackievirus
Echovirus
Enterovirus
Poliovirus 1, 2 and 3 (see Appendix C)[c]
Parechovirus
Rhinovirus
Poxviridae
Orthopoxvirus
Vaccinia[c, f]
Parapoxvirus
Orf
Prions
Gertsmann-Sträussler syndrome,
Kuru and Creutzfeldt-Jakob agents (See Clauses 3.7 and 12.2.1)
Reoviridae
Orbivirus
Bluetongue viruses (endemic strains)
Epizootic haemorrhagic disease viruses of deer (endemic strains)
Rotavirus
Rotavirus
Retroviridae (serology, other tests on samples)
Oncovirinae
Human lymphotropic virus 1
Human lymphotropic virus 2
Lentivirinae
Human immunodeficiency virus

(*continued*)

TABLE 3.4 *(continued)*

Virus or prion
Togaviridae
Alphavirus
Barmah Forest
Ross River
Semliki Forest
Arterivirus
Equine viral arteritis
Rubivirus
Rubella[c,d]
Unclassified
Hepatitis D
Hepatitis E[f]

[a] This list is not exhaustive.

[b] While these agents are exotic to Australia, the AQIS permit determines the level of containment required.

[c] Vaccination available, see Clause 2.6.4.

[d] May be teratogenic.

[e] See also Tables 3.7.

[f] May be dangerous for pregnant women.

NOTE: Hepatitis G and hepatitis TT have been excluded from this Table as there is insufficient evidence that these agents are associated with disease.

TABLE 3.5

EXAMPLES[a] OF BACTERIA OF RISK GROUP 3

Organism
Bacillus anthracis
Bartonella bacilliformis
Burkholderia mallei
Brucella spp. (except serology (see Table 3.1) and *B. ovis*)
Chlamydia psittaci
Coxiella burnetii (cultures, animal work and concentrates)[b, c]
Francisella tularensis (type A)
Mycobacterium tuberculosis complex[c, d, e]
Rickettsia spp.
Yersinia pestis

[a] This list is not exhaustive.

[b] May be dangerous for pregnant women.

[c] Vaccination, see Clause 2.6.4.

[d] Respiratory protection should be considered.

[e] Greater than 5000 cultures per year, susceptibility testing, known multi-drug resistant strains. See references in Clause 3.3.2.1.

TABLE 3.6

EXAMPLES[a] OF FUNGI OR FUNGAL-LIKE ORGANISMS OF RISK GROUP 3

Organism
Blastomyces dermatitidis
Coccidioides immitis[b]
Coccidioides posadasii
Histoplasma spp.
Paracoccidioides brasiliensis
Penicillium marneffei

[a] This list is not exhaustive.

[b] 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

Virus
Arenaviridae
Arenavirus
Lymphochoriomeningitis (LCM) neurotropic strains
Bunyaviridae
Group C
Oropouche
Phlebovirus
Hantavirus
Hantaan and related viruses[b]
Coronaviridae
SARS coronavirus (from cultures and concentrates)[c]
Flaviviridae
Flavivirus
Japanese encephalitis[d]
St Louis encephalitis
Tick-borne viruses
West Nile
Yellow fever[d]
Orthomyxoviridae
Avian influenza (exotic pathogenic strains)[c, d]
Influenza (highly pathogenic strains)
Paramyxoviridae
Paramyxovirinae
Rubulavirus
Mapuera
Avulavirus
Newcastle disease (exotic strains)
Retroviridae (from cultures and concentrates)
Oncovirinae
Human lymphotropic virus 1
Human lymphotropic virus 2
Lentivirinae
Human immunodeficiency virus
Rhabdoviridae
Lyssavirus
Australian bat lyssavirus[d]
Rabies fixed strain (CVS II)[d]
Togaviridae
Alphavirus
Chikungunya
Eastern equine encephalitis
Western equine encephalitis
Venezuelan equine encephalitis[d]

[a] This list is not exhaustive.

[b] Animal inoculations to be performed under PC4 containment.

[c] While these agents are exotic in Australia, the AQIS permit determines the level of containment required.

[d] Vaccination available, see Clause 2.6.4.

TABLE 3.8

EXAMPLES[a] OF VIRUSES OF RISK GROUP 4

Virus
Arenaviridae
Arenavirus
Guanarito
Junin
Lassa
Machupo
Mopeia viruses
Sabia
Bunyaviridae
Nairovirus
Crimean-Congo hemorrhagic fever
Hazara
Filoviridae
Ebola
Marburg
Flaviviridae
Flaviviruses
Absettarov
Central European encephalitis
Hanzalova
Hypr
Kumlinge
Kyasanur Forest disease
Omsk hemorrhagic fever disease
Russian spring summer encephalitis
Tick-borne encephalitis
Herpesviridae
Alphaherpesvirinae
Herpes virus simiae (B virus)
Paramyxoviridae
Paramyxovirinae
Henipavirus
Hendra[b]
Nipah

[a] This list is not exhaustive.

[b] 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.

TABLE 3.9

EXAMPLES[a] OF PLANT PATHOGENS OF PLANT RISK GROUP 2

Organism
Grapevine fan leaf nepovirus
Asparagus stem blight (*Phomopsis asparagi*)
Tomato yellow leaf curl virus
Citrus tristeza virus
Onion smut (*Urocystis cepulae*)
Lettuce leaf blight (*Pythium tracheiphilum*)

[a] This list is not exhaustive.

TABLE 3.10

EXAMPLES[a] OF PLANT PATHOGENS OF PLANT RISK GROUP 3

Organism
Citrus canker (*Xanthomonas axonopodis*)
Fire blight (*Erwinia amylovora*)
Plum pox potyvirus
Potato cyst nematode (*Globodera pallida*)
Pierce's disease (*Xylella fastidiosa*)
Chestnut blight (*Cryphonectria parasitica*)
Pine pitch canker (*Fusarium circinatum*)

[a] This list is not exhaustive.

TABLE 3.11

EXAMPLES[a] OF PLANT PATHOGENS OF PLANT RISK GROUP 4

Organism
Guava rust (*Puccinia psidii*)
Karnal bunt (*Tilletia indica*)
Sudden oak death (*Phytophthora ramorum*)
Potato leaf blight (*Phytophthora infestans* exotic strains)
Grapevine rust (*Phakopsora euvitis*)

[a] This list is not exhaustive.

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 animals, plants or invertebrates inoculated with microorganisms from defined risk groups shall be used, stored or housed in corresponding or higher level containment facilities.

4.2 CONTAINMENT MEASURES

4.2.1 General

The three general descriptors 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 1), 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 leakproof container forming the inner receptacle of an approved IATA infectious materials transport container. Invariably, there is a primary barrier or other containment measure restricting the passage of infectious microorganisms.

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 physical containment measures are invariably supplemented by defined work practices, including PPE.

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 physical containment level used when working with microorganisms shall be at least the appropriate level for the risk group of the microorganism, i.e. Physical Containment Level 1 for Risk Group 1, Physical Containment Level 2 for Risk Group 2. Unless otherwise stated, Risk Group 1 to Risk Group 4 mean human and animal, plant and invertebrate Risk Group 1 to Risk Group 4 and PC1 to PC4 mean laboratory, animal, plant and invertebrate PC1 to PC4.

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 physical containment levels of laboratories corresponding to Risk Groups 1 to 4 defined in Clause 3.2.2 and include the laboratory structural requirements and facilities, PPE, safety equipment, practices, techniques and health monitoring procedures. The four classifications of laboratories are defined by the physical containment prefix 'PC'.

Sections 6, 7 and 8 contain the corresponding requirements for animal, plant and invertebrate facilities. The corresponding classifications for animal, plant and invertebrate facilities have 'Animal', 'Plant' or 'Invertebrate' 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 biological safety cabinet 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 biological safety cabinet 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.

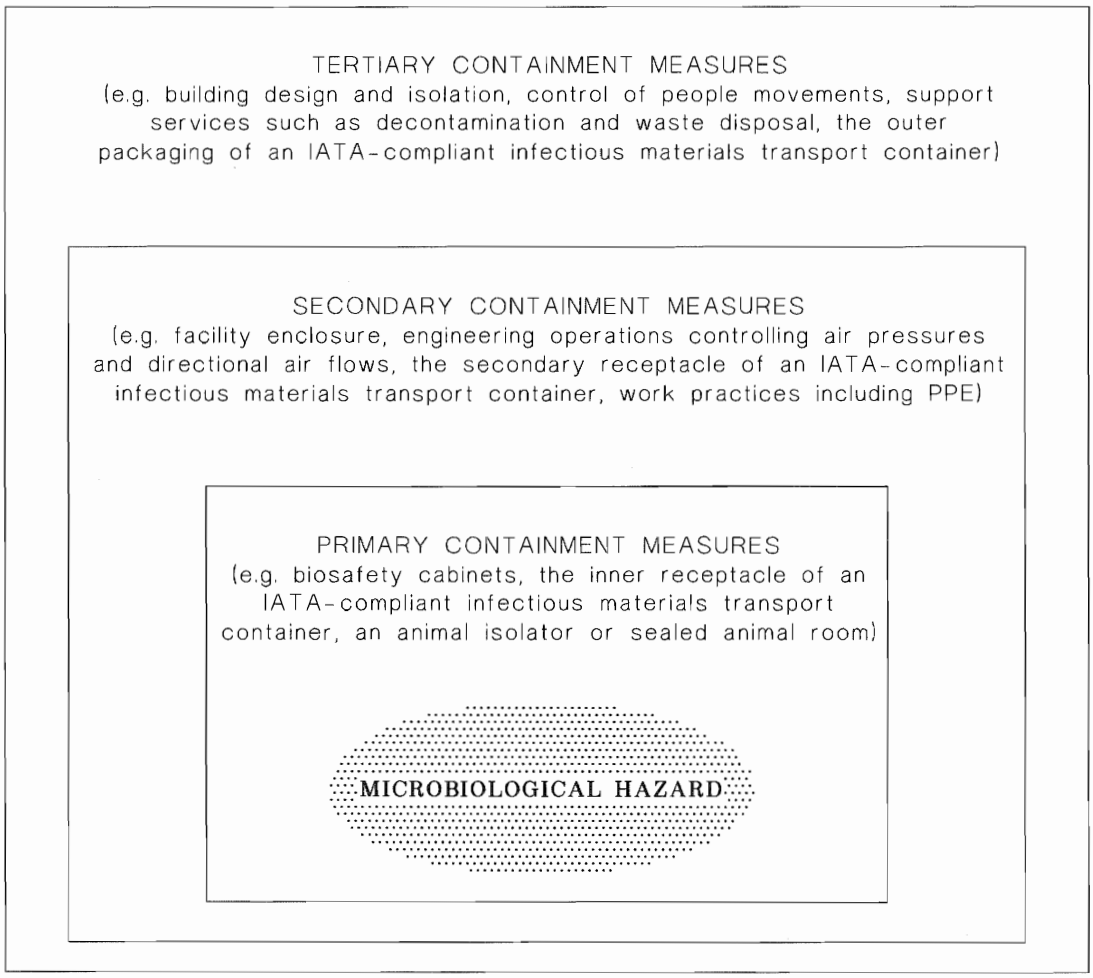


FIGURE 1 RELATIONSHIP BETWEEN CONTAINMENT MEASURES

SECTION 5 LABORATORY CONTAINMENT FACILITIES

5.1 LABORATORY PHYSICAL CONTAINMENT

The physical containment 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 physical containment.

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 2982.1 and the following requirements to facilitate microbiological safety and reduce the likelihood of microorganisms escaping from containment:

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

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

(c) 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.

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

(e) 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.

(f) Dedicated hand basins or an alternative means of decontaminating hands shall be provided inside each laboratory, near the exit.

(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 Paragraph E3.1 of Appendix E.

(i) Eyewash facilities in accordance with AS/NZS 2982.1 shall be provided.

(j) Storage for PPE shall be provided.

(k) 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: This includes offices within the containment facility boundary.

(c) PPE worn and used in the laboratory shall comply with the requirements in AS/NZS 2243.1. See also Clause 10.2 for detailed information on PPE.

Protective clothing to afford protection to the front part of the body shall be worn within the laboratory.

NOTE: A rear-fastening gown is preferable.

(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.

NOTES:

1 BSCs are not designed for this purpose (see Clause 10.1).

2 AS/NZS 2982.1 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 clean 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 9.)

(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 12.)

(p) Remove laboratory gowns and decontaminate hands before moving to areas outside laboratories.

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 biological safety cabinet 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 infectious materials from one floor to another, e.g. to a pressure steam sterilizer on another floor, the infectious materials shall be either double-bagged, the outer bag of which should be sealed during transport, or placed in a secondary sealable, unbreakable container for the 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 in stairs can be a source of cross-contamination. Infectious materials shall be double-bagged, the outer bag of which should be sealed during transport, or placed in a secondary sealable, unbreakable container for transport.

Where large areas are classified as PC2, including associated write-up areas, the prohibition of eating and drinking applies in these adjacent areas. See also Clause 5.3.3(i).

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 of 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.

NOTES:

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

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.

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 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 and utility pipes shall be selected and fitted to facilitate cleaning of any horizontal surfaces on which dust can settle.

NOTE: Where large spaces, such as ceiling voids, are used as part of return or exhaust air paths, care should be taken by personnel accessing such spaces due to the potential for long term build-up of laboratory dust.

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

(e) Containers in accordance with Section 12 shall be provided for collection, storage or disposal of 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 10.6 and Section 12.)

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 decontaminating hands shall be provided inside each laboratory, near the exit.

(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, near the exit.

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

(k) Gas supplies in the facility shall comply with the backflow prevention requirements specified in Paragraph E3.2 of Appendix E.

(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(e) or all openings to the laboratory shall be provided with screens in accordance with Clause 7.3.3(e).

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 near 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 D1 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.

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

NOTE: A risk assessment should be conducted to determine the duration of operating hours of the ventilation system based on the active work hours and the ongoing use of equipment such as incubators, water baths and warm rooms.

5.3.5 Containment equipment

5.3.5.1 *Biological safety cabinets*

A Class I or II biological safety cabinet (see Clause 10.7) shall be provided if work with microorganisms transmissible by the respiratory route or work producing a significant risk from aerosol production is anticipated.

Installation and use, including the decontamination of the biological safety cabinet, shall be performed in accordance with the requirements of AS/NZS 2647.

5.3.5.2 *Cytotoxic drug safety cabinets*

A laminar flow cytotoxic drug safety cabinet (see also Clause 10.8) 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 2639.

5.3.5.3 *Centrifuges*

When 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 described in Clause 5.2.3 for PC1 laboratories, the following work practices shall be observed:

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

(b) 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.

(c) When handling human blood, serum, other body fluids and substances that are visibly contaminated with blood, appropriate publications shall be consulted (see Department of Health and Ageing publication, *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting*). This risk extends to human sera and derivatives used as control reagents (both positive and negative) in diagnostic and other procedures.

NOTE: 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 test does not necessarily mean that it is free of viruses.

(d) All clinical and diagnostic specimens shall be regarded as potentially hazardous. Leaking containers shall be handled in a biological safety cabinet and the outside of the container decontaminated (see Table F1). Where a replacement sample is readily obtained, the leaking specimen shall be decontaminated and discarded in accordance with Section 12.

(e) 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 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.

NOTES:

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

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

(f) For manipulations of Risk Group 2 microorganisms transmissible by the respiratory route or work producing a significant risk from aerosol production, a biological safety cabinet 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 biological safety cabinet (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.

(g) When working with infectious or potentially infectious prions, a laminar flow cytotoxic drug safety cabinet shall be used (see also Clause 10.8).

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

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

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

(j) 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 can be readily decontaminated.

(k) Potentially contaminated re-usable laboratory ware shall be collected and disinfected or decontaminated in accordance with Section 12 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.

(l) Microbiological waste shall be disposed of in accordance with Clause 12.2.

(m) The protective equipment specified in Clause 5.2.3(c) shall be used. (See also Clause 10.2).

(n) Appropriate eye protection (see Clause 10.2.4) shall be used to protect eyes from contaminated or hazardous materials or from ultraviolet light.

(o) Gloves shall be worn when working in a biological safety cabinet, 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.

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

NOTES:

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

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

(q) 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.

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

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 Physical Containment Levels 1 (Clause 5.2) and 2 (Clause 5.3); 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 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 construction requirements described for PC1 and PC2 in Clauses 5.2.2 and 5.3.3, 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.

NOTES:

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.

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 worn in the facility.

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

4 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.

5 Building regulations may require alternative egress in certain facility configurations. These are required to be accessible and easily usable without compromising facility seal integrity. Lockable doors should 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) The allocation of task zones and layout within the facility shall promote the movement of ventilation air from near the entry and towards the more contaminated zones such as biological safety cabinets and steam sterilizer loading trolleys.

(d) As much valve and control equipment as possible shall be located outside the laboratory boundary to minimize the need for service personnel to enter the laboratory.

(e) 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.

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

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

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

(h) 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.

(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.

NOTES:

1 A double-ended type is preferred, positioned through the barrier wall of the facility (see Note 2) and allowing adequate access for loading and unloading of the steam sterilizer and for maintenance of the associated plant from outside the facility.

2 The barrier wall of the PC3 facility should be sealed airtight to a purpose-constructed chamber barrier flange with all penetrations sealed airtight such that the steam sterilizer installation maintains the integrity of the seal of the containment facility.

3 See also Clause 10.6.8.

(j) Provision shall be made for decontamination of liquid effluents in a manner appropriate to the 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. See also Section 12.

(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 to ensure they are airtight.

NOTE: See Appendix H.

5.4.3 Multiple room PC3 facilities

Some institutions have PC3 facilities consisting of several laboratories within the negative pressure area.

Additional safety structures that may be incorporated into the barrier wall include a dunk tank for removal of containers and materials that can withstand immersion in liquid disinfectant, a decontamination chamber for gaseous decontamination or introduction of large items of equipment and a pass-through box for entry of materials into the facility.

5.4.4 Laboratory 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 airconditioning equipment such as fan coil units and split system airconditioning 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.

NOTES:

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.

2 The quantity of outside air supplied to the laboratory should comply with relevant health quality standards or regulations (see 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 biological safety cabinets.

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 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 10.9.1. An exhaust prefilter of the same standard as the supply filter shall be provided, and mounted upstream of the HEPA filter.

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 10.9.2.

(g) A differential pressure gauge shall be visible and readable from 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 button 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 emergency 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.

(k) Annual testing by competent persons shall include:

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

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

(C) 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.

(D) Calibration of pressure control and indicating devices.

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

(l) Exhaust air from Class III biological safety cabinets shall be discharged through the building exhaust system through direct ducting or a capture hood as described in AS/NZS 2647. It shall not be recirculated through the laboratory.

NOTES:

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

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

5.4.5 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.

5.4.6 Containment equipment

In addition to equipment specified for PC2 (Clause 5.3.5), 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 biological safety cabinets (see Clause 10.7.2).

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

5.4.7 Work practices

In addition to work practices specified for PC1 (Clause 5.2.3) and PC2 (Clause 5.3.6), the following practices 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 5.4.4 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 plan 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 with Risk Group 3 infectious materials, shall be conducted in a biological safety cabinet of Class I, Class II or Class III (see Clause 5.4.6).

(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) 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.

(k) Laboratory wastes shall be rendered safe, preferably by decontamination in a pressure steam sterilizer, before disposal in accordance with Clause 12.2.

(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.

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 hands again.

(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.

5.4.8 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 (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 of two types; a laboratory where work is conducted in a Class III biological safety cabinet 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 design features and facilities specified for PC1, PC2 and PC3, the following facilities shall be provided:

(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 on 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: 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.

NOTES:

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

2 A timer should be provided to permit personnel to shower for a defined period as part of the exit procedure.

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

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, and shall be sealed to the containment perimeter of 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 10.6.

(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 12.

(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 G5). The system shall be provided with an alarm to detect malfunction. The supply and exhaust airflow shall be interlocked to assure 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 10.9.1. The HEPA filters shall be installed and housed as specified in Clause 10.9.2. Prefilters to both the supply and exhaust HEPA filters shall be provided as specified in Clause 5.4.4 Items (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 biological safety cabinets shall be discharged through the facility exhaust system.

(d) The ventilation control system shall raise an audible alarm within the laboratory 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 a competent person shall include:

(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 biological safety cabinet (see Clause 5.5.4.1(i) and 10.7.1).

(b) A Class III biological safety cabinet (see Clause 10.7.2).

5.5.5 Work practices

5.5.5.1 *General*

In addition to the work practices specified for Physical Containment Levels 1 (Clause 5.2.3), 2 (Clause 5.3.6) and 3 (Clause 5.4.7), the following practices 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 biological safety cabinets, or alternatively Class I or Class II biological safety cabinets, 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 12.

(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. 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 (l)).

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.

(m) Viable biological materials to be removed from the 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. The secondary container shall be removed from the facility through the disinfectant dunk tank or gaseous decontamination chamber or an airlock designed for this purpose. No other materials shall be removed from the laboratory 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 laboratory.

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.

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

(o) 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 co-worker either inside the laboratory or observing the work from outside the laboratory should be considered.

(p) 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 ANIMAL CONTAINMENT FACILITIES

6.1 REQUIREMENT FOR ANIMAL CONTAINMENT FACILITIES

This Section sets out requirements to ensure that 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 animal containment can also be applied to 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 AQIS, 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 AQIS. 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 MAF. 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: 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.

6.2 PRINCIPLES OF ANIMAL CONTAINMENT

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 Animal PC1 facilities confine larger animals in a fenced enclosure, other 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 (Animal PC1 and Animal 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, specialised 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 12.) Animal containment facilities should have access to decontamination facilities within their own areas. Waste from low level (PC1 and PC2) 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 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 physical containment recommended for working with infectious agents 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 physical containment levels for work with microorganisms shall follow the containment levels appropriate for the microorganism. Requirements for Animal PC1, Animal PC2, Animal PC3 and Animal PC4 facilities are set out in Clauses 6.4, 6.5, 6.6 and 6.7.

6.3 OTHER CONSIDERATIONS ASSOCIATED WITH ANIMAL CONTAINMENT

6.3.1 Designing facilities for different aspects of 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 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 Reference 1.8.) 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 animal containment facilities

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.

NOTES:

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.

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

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

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 animal waste

Infectious bedding, cage wastes and cages from small animals shall be decontaminated prior to disposal or reuse as described in Section 12. 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 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 animals that are infected or suspected to be infected with pathogenic microorganisms shall be carried out under physical containment 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 ANIMAL PC1 FACILITIES

6.4.1 General

An 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

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.

NOTES:

1 The facility should be secure against incursions by feral or predatory animals.

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

(g) Gas supplies in the facility shall comply with the general requirements specified in Paragraph E3.1 of Appendix E.

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

(i) 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 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.

(f) PPE appropriate for the work being carried out shall be worn. See also Clause 10.2 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 animal containment facility.

NOTES:

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

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

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

4 Eye protection should be considered when working with animals.

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

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

(g) 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.

(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 organisms through the skin either by accidental self-inoculation or by contact with ecto-parasites is a real risk.

(i) Animals shall be restrained during experimental handling.

(j) 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.

(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 Item 6.4.2(i). 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 animal containment facility.

(p) 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 12.

6.5 REQUIREMENTS FOR ANIMAL PC2 FACILITIES

6.5.1 General

An Animal PC2 facility is suitable for work with infectious microorganisms in Risk Group 2 and incorporates all the requirements of an 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 Animal PC1 facilities in Clause 6.4.2, the following shall apply:

(a) Floors, ceilings 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.

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 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 airconditioning or ventilation inlets and outlets, 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;

(C) corrosion resistance; and

(D) resistance to attack by insects from either inside the containment facility or from the local environment outside the facility.

NOTES:

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.

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.

(f) 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.

NOTE: 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 12 shall be provided for collection, storage or disposal of infectious materials.

(h) A pressure steam sterilizer shall be available where steam sterilizing of facility wastes is required. See also Clause 10.6 and Section 12.

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

(i) A single outlet hands-free operation type dedicated hand basin or alternative means of decontaminating hands shall be provided inside each animal room or facility, near the exit.

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

(j) Gas supplies in the facility shall comply with the backflow prevention requirements specified in Paragraph E3.2 of Appendix E.

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

(l) 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 near the entrance to the facility.

(m) 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.

(n) 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. 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 10.7) shall be provided if work with microorganisms transmissible by the respiratory route or work producing a significant risk from aerosol production is anticipated.

Installation and use, including the decontamination of the biological safety cabinet, shall be performed in accordance with the requirements of AS/NZS 2647.

6.5.4.2 *Animal change stations*

Suitable containment equipment shall be provided to minimise personnel exposure to allergens where applicable.

6.5.5 Work practices

In addition to the work practices described in Clause 6.4.3 for Animal PC1 facilities, the following work practices shall be observed:

(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 manipulations with small animals that could result in an aerosol containing viable organisms, a biological safety cabinet or other equipment designed to contain the aerosol shall be used. For larger animals, the room becomes the primary containment measure.

(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.

NOTES:

1 Sharps use should be eliminated wherever possible.

2 Staff should be aware of the potential for glass equipment such as pipettes and tissue grinders to become sharps during an accident. Plasticware should be substituted for glassware whenever possible.

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: Appendix F provides information on disinfectants.

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

(i) PPE shall be removed and hands decontaminated in an appropriate, predetermined order before leaving the animal 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 9).

NOTES:

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

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

(k) Potentially contaminated re-usable laboratory ware shall be collected and disinfected or decontaminated in accordance with Section 12 prior to washing and reuse.

NOTES:

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

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

(l) Microbiological wastes, animal bedding, animal cages and animal carcasses shall be decontaminated. Waste should be disposed of in accordance with Section 12.

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

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

NOTE: Worksheets may be used on the bench.

6.6 REQUIREMENTS FOR ANIMAL PC3 FACILITIES

6.6.1 General

An Animal PC3 facility is suitable for work with infectious microorganisms in Risk Group 3 and incorporates equipment and practices for Animal PC1 facilities except Item 6.4.2(i) of Clause 6.4 and all equipment and practices for Animal PC2 facilities (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 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 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 Animal PC1 and Animal PC2 facilities also apply to Animal PC3 facilities, apart from the option to provide drinking water. In addition to construction requirements described for Animal PC1 and Animal PC2 facilities in Clauses 6.4.2 and 6.5.2, 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 Animal PC3 containment for decontamination purposes.

NOTES:

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.

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.

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.

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.

5 Building regulations may require alternative egress in certain facility configurations. These are required to be accessible and easily usable and should not compromise facility seal integrity. Lockable doors should 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) The allocation of task zones and layout within the facility shall promote the movement of ventilation air from near the entry and towards the more contaminated zones such as biological safety cabinets and steam sterilizer loading trolleys.

(d) 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.

(e) 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.

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

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

NOTE: Examples of suitable arrangements are the viewing panels in doors required in Item (f) if they allow adequate viewing of occupants, viewing panels in walls or electronic visual monitoring facilities (e.g. viewing cameras or closed circuit television).

(h) 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.

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

(j) 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.

NOTES:

1 A double-ended type of pressure steam sterilizer is preferred, positioned through the barrier wall of the facility (see Note 2) and allowing adequate access for loading and unloading of the steam sterilizer and for maintenance of the associated plant from outside the facility.

2 The barrier wall of the PC3 facility should be sealed airtight to a purpose-constructed chamber barrier flange with all penetrations sealed airtight such that the steam sterilizer installation maintains the integrity of the seal of the containment facility.

3 See also Clause 10.6.8.

(k) Provision shall be made for decontamination of liquid effluents in a manner appropriate to the 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. See also Section 12.

(l) 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.

(m) All room penetrations shall be sealed to ensure they are airtight.

NOTE: See Appendix H.

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 airconditioning equipment such as fan coil units and split system airconditioning 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.

NOTES:

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.

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 biological safety cabinets.

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 prefilter 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 10.9.1. An exhaust prefilter 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.

NOTES:

1 Prefilters should be located within animal rooms for ease of replacement.

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 10.9.2.

(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.

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) Annual testing by competent persons shall include:

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

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

(C) 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.

(D) Calibration of pressure control and indicating devices.

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

(l) Exhaust air from Class III biological safety cabinets shall be discharged through the building exhaust system through direct ducting or a capture hood as described in AS/NZS 2647. It shall not be recirculated through the facility.

NOTES:

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

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.

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 PC2 (Clause 6.5.4), a Class III Biological safety cabinet shall be provided where appropriate (see Clause 10.7.2).

6.6.6 Work practices

In addition to requirements for Animal PC1 and Animal PC2 facilities (see Clauses 6.4 and 6.5), the following work practices 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 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 infectious materials shall be done either in a Class I or II biological safety cabinet (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 12.2. Additionally, if floor drains are present, all effluents shall be rendered safe in accordance with Clause 12.2 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.

NOTE: In most circumstances, the appropriate removal procedure is removing the gloves then decontaminating 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 hands again.

(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 ANIMAL PC4 FACILITIES

6.7.1 General

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

An Animal PC4 facility may be one of two types—

(a) a facility where small animals are kept in individually ventilated isolators or Class III biological safety cabinets in the 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 animal containment measures cannot be used, the facility forms the primary containment measure.

NOTE: The design of an 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 biological safety cabinets 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 biological safety cabinets may be discharged into the facility or through the building exhaust system in accordance with AS/NZS 2647.

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 12.2.

(b) *Primary containment devices in Animal PC4 facilities* Animals may be kept in individually ventilated isolators or Class III biological safety cabinets in an Animal PC4 facility if the exhaust air from the Class III biological safety cabinets is discharged through the building exhaust system through a capture hood as described in AS/NZS 2647. The exhaust air shall not be recirculated. In such Animal PC4 facilities staff, do not need to wear positive pressure personnel suits.

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 biological safety cabinets 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) *Animal PC4 facilities where the room is the primary containment measure* In such 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 design features and facilities specified for Animal PC1, Animal PC2 and Animal PC3, the following shall be provided:

(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 on 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: 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.

NOTES:

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

2 A timer should be provided to permit personnel to shower for a defined period as part of the exit procedure.

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

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

5 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, and shall be sealed to the containment perimeter of 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 10.6.

(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 12.

(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 G5). The system shall be provided with an alarm to detect malfunction. The supply and exhaust airflow shall be interlocked to assure 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 10.9.1. The HEPA filters shall be installed and housed as specified in Clause 10.9.2. Prefilters 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:

(i) Testing of the pressure differentials in accordance with AS 1807.10 to ensure compliance with (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 biological safety cabinet (see Clause 6.7.6.1(h)) where the facility forms the primary containment measure.

(b) A Class III biological safety cabinet (see Clause 10.7).

6.7.6 Work practices

6.7.6.1 *General*

In addition to the work practices specified for Animal Physical Containment Levels 1 (Clause 6.4.3), 2 (Clause 6.5.4) and 3 (Clause 6.6.5), the following practices 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 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.

(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 agents assigned to Risk Group 4 shall be conducted in Class III biological safety cabinets in accordance with Clause 6.7.2(b) or alternatively in Class I or Class II biological safety cabinets used in conjunction with one-piece positive pressure personnel suits ventilated by a life-support system in accordance with Clause 6.7.2(c).

(j) Prior to disposal, all facility effluents, including those from the shower, shall be decontaminated by either heat or chemical treatment in accordance with Section 12.

(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 with one-piece positive pressure personnel suits ventilated by a life-support system, viable biological materials to be removed from Class III BSCs 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. 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 (l)).

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.

(m) Viable biological materials to be removed from the containment 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. The secondary container shall be removed from the facility through the disinfectant dunk tank or gaseous decontamination chamber or an airlock designed for this purpose.

(n) No other materials shall be removed from the maximum containment 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 be stored only 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 co-worker 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.

6.7.6.2 *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 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 12.2. Additionally, if floor drains are present, all effluents shall be decontaminated in accordance with Clause 12.2 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 4 require corresponding physical containment 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 physical containment (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, 7.4 and 7.5 cover Plant PC2, Plant PC3 and Plant PC4 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.

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 Paragraph E3.1 of Appendix E.

(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 biosafety committee, 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.

NOTES:

1 Procedures should be consistent with good agricultural and horticultural practice, including pest and disease control management.

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.

NOTES:

1 BSCs are not designed for this purpose (see Clause 10.1).

2 AS/NZS 2982.1 should be consulted for local exhaust ventilation requirements.

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

(i) Drinking and the storage of drink for human use shall only be permitted in the facility in accordance with Item 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.

(j) 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 12.

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.

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 and walls shall be smooth, easy to clean, impermeable to liquids and resistant to commonly used reagents and disinfectants.

(b) 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 and, where applicable, exposure to ultraviolet radiation.

NOTE: Structural joints should be minimized in containment facilities.

(c) 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.

(d) Outer door openings shall be fitted with seals to the top, bottom and sides. A self-closing device shall be fitted on each outer door. Suitable hooks for gowns shall be provided within the facility, near the exit.

(e) Any openings in the walls, ceiling or roof, such as windows, vents and air conditioning or ventilation inlets and outlets, 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.

NOTES:

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.

2 In locations where dust and debris can be generated, the use of roughing prefilters upstream of the mesh screens can result in safer and easier cleaning.

(f) 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 12.

(g) Suitable enclosed containers for storage of solid plant waste material shall be available within the containment facility.

(h) A pressure steam sterilizer shall be available where steam sterilizing of infectious facility wastes is required. See also Clause 10.6 and Section 12.

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

(i) A single outlet hands-free operation type dedicated hand basin or alternative means of decontaminating hands shall be provided within each facility, near the exit.

NOTE: Where a PC2 laboratory is directly connected to the Plant PC2 facility, the hand decontamination facilities may be in the laboratory.

(j) 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 near the entrance to the facility.

(k) Gas supplies in the facility shall comply with the backflow prevention requirements specified in Paragraph E3.2 of Appendix E.

(l) 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 biological safety cabinet (see Clause 10.7) shall be provided if work producing a significant risk from aerosol production is anticipated.

Installation and use, including the decontamination of the biological safety cabinet, shall be performed in accordance with the requirements of AS/NZS 2647.

7.3.4.2 *Centrifuges*

When infectious materials are used, a centrifuge fitted with either sealed rotors or sealed buckets shall be used. (See also Clause 10.3.)

7.3.5 Work practices

In addition to the work practices described in Clause 7.2.4 for Plant PC1 facilities, the following work practices shall be observed:

(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 be opened only within the containment facility. Packaging material shall be decontaminated as soon as possible. See also Section 12.

(c) Personnel shall wear appropriate protective clothing and footwear within the facility (see Clause 10.2). Gowns shall be kept in the facility between uses and shall be laundered at appropriate intervals. Gloves shall be worn when working in a BSC.

(d) 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.

(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.

NOTES:

1 Sharps use should be eliminated wherever possible.

2 Staff should be aware of the potential for glass equipment such as pipettes and tissue grinders to become sharps during an accident. Plasticware should be substituted for glassware whenever possible.

(f) Application of pesticides shall be performed utilizing appropriate PPE.

(g) 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.

(h) 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 13.

(i) 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 12.

NOTE: Soil substitutes that can be readily decontaminated should be used whenever possible. Use of soil is discouraged.

(j) Personnel shall remove PPE and decontaminate their hands in an appropriate, predetermined order after handling potentially infected material and prior to leaving the 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.

(k) 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 9).

7.4 REQUIREMENTS FOR PLANT PC3 FACILITIES

7.4.1 General

The following standard of plant physical containment facilities and work practices (Plant PC3) 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 but have limited natural ability to be transmitted outside the facility.

NOTE: The design of a PC3 facility is complex and those planning its construction should seek specialized advice. See also Appendix G 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 (see 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 and Plant PC2 facilities in Clauses 7.2.3 and 7.3.3, 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.

NOTES:

1 The preferred location of the footbath is immediately inside the work area.

2 The airlock or shower airlock takes the place of the anteroom required for Plant PC2 facilities.

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.

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.

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.

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.

7 Building regulations may require alternative egress in certain facility configurations. These are required to be accessible and easily usable without compromising facility seal integrity. Lockable doors should 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) The allocation of task zones and layout within the facility shall promote the movement of ventilation air from near the entry and towards the more contaminated zones such as biological safety cabinets and steam sterilizer loading trolleys.

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

(e) Supporting equipment (such as ventilation equipment, pumps and irrigation equipment, heating and cooling equipment, shading devices) shall be located outside the facility wherever possible to minimize the requirements for repair and maintenance inside the facility. 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 serviceable and maintainable components.

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

(f) 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.

(g) 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.

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

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

NOTE: Examples of suitable arrangements are the viewing panels in doors required in Item (h) if they allow adequate viewing of occupants, viewing panels in walls or electronic visual monitoring facilities (e.g. viewing cameras or closed circuit television).

(j) 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.

NOTES:

1 A double-ended type of pressure steam sterilizer is preferred, positioned through the barrier wall of the facility (see Note 2) and allowing adequate access for loading and unloading of the steam sterilizer and for maintenance of the associated plant from outside the facility.

2 The barrier wall of the PC3 facility should be sealed airtight to a purpose-constructed chamber barrier flange with all penetrations sealed airtight such that the steam sterilizer installation maintains the integrity of the seal of the containment facility.

3 See also Clause 10.6.8.

(k) A single outlet dedicated hand basin of the hands-free operation type or alternative means of decontaminating hands shall be provided within each containment facility, near the exit to the anteroom.

(l) 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.

(m) Provision shall be made for decontamination of liquid effluents in a manner appropriate to the type of waste (see Section 12). 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.

(n) 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.

(o) The floor of the facility shall be designed such that all waste water is collected and drained appropriately.

(p) 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.

(q) 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.

NOTES:

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.

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 biological safety cabinets.

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 10.9.1. An exhaust prefilter of the same standard as the supply filter shall be provided, and mounted upstream of the HEPA filter.

NOTE: The prefilter 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 10.9.2.

(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.

(k) Annual testing by competent persons shall include:

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

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

(C) 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.

(D) Calibration of pressure control and indicating devices.

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

(l) Exhaust air from Class III biological safety cabinets shall be discharged through the building exhaust system through direct ducting or a capture hood as described in AS/NZS 2647. It shall not be recirculated through the facility.

NOTES:

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

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.

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 and Plant PC2 facilities, the following work practices 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 12.2.

(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 12.

(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 12.

(o) Protective clothing shall be removed in an appropriate, predetermined order before leaving the Plant PC3 facility.

NOTE: In most circumstances, the appropriate removal procedure is removing the gloves then decontaminating 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 hands again.

(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.

7.5 REQUIREMENTS FOR PLANT PC4 FACILITIES

7.5.1 General

The following standard of plant physical containment facilities and work practices (Plant PC4) is regarded as a suitable minimum for work with plants infected with plant microorganisms in Plant Risk Group 4. Plant PC4 facilities incorporate equipment and practices for Plant PC1, Plant PC2 and Plant PC3 (Clauses 7.2, 7.3 and 7.4); however, additional requirements on conditions of access and egress, safety equipment and staff training apply.

Plant PC4 facilities include permanent greenhouse structures with inward directional airflow to prevent microorganism escape. Plant PC4 facilities are suitable for use with plants infected with exotic plant microorganisms that present a significant hazard to plants and can readily spread outside the facility in the absence of a vector.

NOTE: The design of a Plant 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.

7.5.2 Construction

In addition to the construction requirements specified for Plant PC1, Plant PC2 and Plant PC3, a Plant PC4 facility shall incorporate the following features:

(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 on acceptable room airtightness are given in Appendix H.

(b) The 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 of the facility shall be lockable. The inner change room shall be fitted with a sticky pest strip or alternative automatic device designed to kill invertebrates that may gain entry.

NOTE: 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.

NOTES:

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

2 A timer should be provided to permit personnel to shower for a defined period as part of the exit procedure.

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

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

5 The inner change room may provide the functions of the anteroom as set out in Clause 7.3.3(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, and the chamber shall be sealed to the containment perimeter of 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 10.6.

(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) All drains in the facility and anteroom shall empty into collecting tanks and the effluent shall be decontaminated by a method that renders plant microorganisms and plant propagules non-viable prior to leaving the containment facility. Disposal after treatment shall be in accordance with Section 12.

(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, BSCs, 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.

7.5.3 Ventilation

The plant 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 plant microorganisms from the facility. Testing of HEPA filters and systems by a competent person shall be completed in accordance with recommended standards.

(b) 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. The system shall be provided with an alarm that activates upon detection of a malfunction. The supply and exhaust airflow shall be interlocked to assure inward (or zero) airflow at all times. Differential air pressures between plant facility zones shall be monitored by use of a differential pressure gauge as specified in Clause 7.4.4(g).

(c) Both supply and exhaust air shall be filtered through HEPA filters as specified in Clause 10.9.1. The HEPA filters shall be installed and housed as specified in Clause 10.9.2. Prefilters to both the supply and exhaust HEPA filters shall be provided as specified in Clause 7.4.4 Items (c) and (e).

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:

(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 (d) on a loss of room pressure.

(iv) Calibration of pressure control and indicating devices.

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

7.5.4 Work practices

In addition to work practices specified for Plant PC1, Plant PC2 and Plant PC3, the following work practices 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) Prior to disposal, all facility effluents, including those from the shower facility, shall be decontaminated by either heat or chemical treatment. See also Section 12.

(j) The double-ended pressure steam sterilizer and fumigation chamber opening across the barrier shall be decontaminated after each exposure to the facility environment.

(k) 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. The secondary container shall be removed from the facility through the disinfectant dunk tank or gaseous decontamination chamber or an airlock designed for this purpose.

(l) 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.

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

(n) 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 co-worker either inside the facility or observing the work from outside the facility should be considered.

(o) 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.

7.5.5 Health monitoring

See Clause 2.6.

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 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 physical containment (Invertebrate PC) for containing invertebrates. 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 physical containment (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 Paragraph E3.1 of Appendix E.

(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 biosafety committee, 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.

NOTES:

1 BSCs are not designed for this purpose (see Clause 10.1).

2 AS/NZS 2982.1 should be consulted for local exhaust ventilation requirements.

(h) PPE appropriate for the work being carried out shall be worn. See also Clause 10.2 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.

NOTES:

1 A rear-fastening gown affording protection to the front part of the body is preferable.

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

(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 8.2.3, Item (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 regulation, using the most appropriate and effective method for the materials concerned. See also Section 12.

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 and, where applicable, exposure to ultraviolet radiation.

NOTE: 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. Appropriate devices may include sticky pest strips, air curtains, cold space temperature control or other automatic traps or killing devices. The anteroom shall allow materials, equipment and trolleys to pass through, ensuring one door can be closed at all times.

(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) Outer door openings shall be fitted with seals to the top, bottom and sides. A self-closing device shall be fitted on each outer door. Suitable hooks for gowns shall be provided within the facility, near the exit and hand decontamination facility.

(f) Any openings in the walls, ceiling or roof, such as windows, vents and air conditioning or ventilation inlets and outlets, 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.

NOTES:

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.

2 In locations where dust and debris can be generated, the use of roughing prefilters upstream of the mesh screens can result in safer and easier cleaning.

(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 12.

(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 10.6 and Section 12.

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 hands shall be provided within each facility, near the exit.

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 near the entrance to the facility.

(l) Gas supplies in the facility shall comply with the backflow prevention requirements specified in Paragraph E3.2 of Appendix E.

8.3.4 Containment equipment

8.3.4.1 *Biological safety cabinets*

A Class I or II biological safety cabinet (see Clause 10.7) shall be provided if work producing a significant risk from aerosol production is anticipated.

Installation and use, including the decontamination of the biological safety cabinet, shall be performed in accordance with the requirements of AS/NZS 2647.

8.3.4.2 *Centrifuges*

When infectious materials are used, a centrifuge fitted with either sealed rotors or sealed buckets shall be used. (See also Clause 10.3.)

8.3.5 Work practices

In addition to work practices specified in Clause 8.2.4 for Invertebrate PC1, the following work practices shall be observed:

(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) Personnel shall wear appropriate PPE within the facility. PPE shall be removed prior to leaving and kept in the facility between uses.

(c) 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.

(d) Mobile invertebrates shall be contained to prevent escape. Access for research, feeding and cleaning shall be designed to minimize the risk of escape.

(e) 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.

(f) All packages containing invertebrates shall be opened only within the facility. Packaging material shall be decontaminated as soon as possible. See also Section 12.

(g) All doors to the facility shall be locked whenever microbiological hazards are potentially present, except when personnel are working in the facility.

(h) Personnel shall remove PPE and decontaminate their hands in an appropriate, predetermined order after handling potentially infected material and prior to leaving the 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.

(i) 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 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 9).

(j) 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 13.

(k) 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 colonised 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 12.

NOTE: Soil substitutes which can be readily decontaminated should be used whenever possible. Use of soil is discouraged.

(l) 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 physical containment facilities and work practices (Invertebrate PC3) 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 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 and Invertebrate PC2 facilities in Clauses 8.2.3 and 8.3.3, 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).

NOTES:

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.

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.

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 should 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.

NOTES:

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.

2 See Appendix G for examples of recommended layouts for PC3 facilities showing the design principles involved and Appendix H for airtightness considerations.

3 The anteroom should be located between the airlock and the work area of the facility. See Figure G4.

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) The allocation of task zones and layout within the facility shall promote the movement of ventilation air from near the entry and towards the more contaminated zones such as biological safety cabinets and steam sterilizer loading trolleys.

(f) The layout within the facility shall promote the movement of ventilation air from the clean side of the facility near the entry and towards the more contaminated zones such as biological safety cabinets and steam sterilizer loading trolleys.

Care shall be taken to avoid turbulence or ventilation system air movement within the vicinity of biological safety cabinets 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) 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.

(i) Supporting equipment (such as ventilation equipment, heating and cooling equipment) shall be located outside the facility wherever possible to minimize the need for repair and maintenance inside the facility. 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.

(j) The facility shall have a high level of physical security including barrier fencing and restricted access provided by a controlled access system (e.g. electronic access card).

(k) A single outlet dedicated hand basin of the hands-free operation type or alternative means of decontaminating hands shall be provided within each invertebrate containment facility, near the exit to the anteroom.

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

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

NOTE: Examples of suitable arrangements are the viewing panels in doors required in Item (l) if they allow adequate viewing of occupants, viewing panels in walls or electronic visual monitoring facilities (e.g. viewing cameras or closed circuit television).

(n) 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.

NOTES:

1 A double-ended type of pressure steam sterilizer is preferred, positioned through the barrier wall of the facility (see Note 2) and allowing adequate access for loading and unloading of the steam sterilizer and for maintenance of the associated plant from outside the facility.

2 The barrier wall of the PC3 facility should be sealed airtight to a purpose-constructed chamber barrier flange with all penetrations sealed airtight such that the steam sterilizer installation maintains the integrity of the seal of the containment facility.

3 See also Clause 10.6.8.

(o) 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.

(p) Provision shall be made for decontamination of liquid effluents in a manner appropriate to the type of waste (see Section 12). 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. 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.

(q) The floor of the facility shall be designed such that all waste water is collected and drained appropriately.

(r) 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.

(s) 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.

(t) 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 airconditioning units, shall be provided with removable panels as required to ensure the complete penetration of gas or vapour during room decontamination.

NOTES:

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.

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 biological safety cabinets.

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.

NOTES:

1 The nominal set-point for the airlock should be 25 Pa below the 0 Pa reference pressure.

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 10.9.1. An exhaust prefilter of the same standard as the supply filter shall be provided, and mounted upstream of the HEPA filter.

NOTE: The prefilter 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 10.9.2.

(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.

(k) Annual testing by competent persons shall include:

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

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

(C) 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.

(D) Calibration of pressure control and indicating devices.

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

(l) Exhaust air from Class III biological safety cabinets shall be discharged through the building exhaust system through direct ducting or a capture hood as described in AS/NZS 2647. It shall not be recirculated through the facility.

NOTES:

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

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.

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 (Clause 8.3.4), a Class III Biological safety cabinet shall be provided where appropriate (see Clause 10.7.2).

8.4.7 Work practices

In addition to work practices specified for Invertebrate PC1 and Invertebrate PC2 facilities, the following work practices 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 disposable gloves and full coverage protective clothing (e.g. hooded, long-sleeved overalls plus hair covering). 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 12.2.

(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 12.

(o) 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 12.

(p) Protective clothing shall be removed and hands decontaminated in an appropriate, predetermined order before leaving the facility.

NOTE: In most circumstances, the appropriate removal procedure is removing the gloves then decontaminating 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 hands again.

(q) 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 physical containment facilities and work practices (Invertebrate PC4) 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 (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, Invertebrate PC2 and Invertebrate PC3 facilities, an Invertebrate PC4 facility shall incorporate the following features:

(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 on 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: 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.

NOTES:

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

2 A timer should be provided to permit personnel to shower for a defined period as part of the exit procedure.

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

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

5 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 out of the facility and out of the inner clothing change room. The outer sterilizer door shall open to the area external to the facility, and the chamber shall be sealed to the containment perimeter of 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 10.6.

(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 12.

(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 assure 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 10.9.1. The HEPA filters shall be installed and housed as specified in Clause 10.9.2. Prefilters to both the supply and exhaust HEPA filters shall be provided as specified in Clause 8.4.4 Items (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:

(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 (A) to (D) 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, Invertebrate PC2 and Invertebrate PC3 facilities, the following work practices 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 biological safety cabinets, or alternatively Class I or Class II biological safety cabinets, 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 12.

(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) 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. 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 (l)).

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.

(m) 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. The secondary container shall be removed from the facility through the disinfectant dunk tank or gaseous decontamination chamber or an airlock designed for this purpose.

(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 be stored only 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 co-worker 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 MICROBIOLOGICAL SPILLS

9.1 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 are categorized as follows:

(a) Spills inside BSCs (all PC levels)—see Clause 9.3.

(b) Spills in PC2 facilities outside BSCs that can be cleaned up by workers — see Clause 9.4.2.

(c) Spills in PC2 facilities outside BSCs with clean up performed by a trained spills clean-up team—see Clause 9.4.3.

(d) Spills in PC3 facilities outside BSCs, which are cleaned up by PC3 workers or, if necessary, by a spills clean-up team—see Clause 9.4.4.

(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 9.4.5.

(f) Spills in PC4 facilities where workers wear positive pressure suits, which are cleaned up by the PC4 workers themselves—see Clause 9.4.6.

The recommended 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.

9.2 PLANNING

9.2.1 General

Planning for the control of a spill within the facility involves—

(a) ensuring staff 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 should be employed for cleaning up of spills where determined to be necessary by the risk assessment. This team shall have training in the correct response procedure for PC2 and PC3 containment facilities in the institution, the risk groups of the microorganisms handled and the correct use of any PPE, particularly respiratory protective equipment (RPE). Response procedures in PC4 facilities are best managed by the specialist scientific staff handling the infectious microorganisms.

With large volume or highly hazardous microbiological spills, minimizing the spread of the contamination and preventing the production of aerosols are the guiding principles for protecting personnel. Leaving the area to avoid inhalation of infectious aerosols is the primary consideration. Allow at least 30 min for aerosols to settle or be removed by the air handling system before attempting to clean up the spill. Any contaminated PPE is left in the area where the spill occurred.

Refresher training for both staff and the spills clean-up team shall be done on a regular basis to ensure competence is maintained.

9.2.2 Emergency provisions for personnel

Emergency showers that are provided for chemical spills in laboratories are not suitable for decontamination of personnel who have been exposed to biological material. Such showers will spread the contamination and create more aerosols. This can be exacerbated by the lack of drains underneath most emergency showers.

Eyewash stations or hand-held drench hoses can be used when there is contamination of the eyes/face/mucous membranes with infectious material or chemicals, as waste can be contained in a sink. If the level of contamination necessitates a shower, then this can be taken in a regular shower after initial rinsing with a hand-held drench hose.

9.2.3 Clean-up materials and equipment

Clean-up materials and equipment should be kept at an appropriate location and should include the following:

(a) 'Biohazard' signs with 'DO NOT ENTER' written underneath the symbol.

(b) Suitable disinfectant supplies.
NOTE: Appendix F lists suitable disinfectants.

(c) Absorbent materials.

(d) Protective clothing including spare gowns, gloves and RPE.

(e) Appropriate waste containers.

(f) Spare clothing for contaminated personnel.

9.3 SPILLS INSIDE BIOLOGICAL SAFETY CABINETS

9.3.1 General

This procedure applies to spills that occur inside all types of biological safety cabinets, irrespective of the level or type of containment facility.

Spills inside a biological safety cabinet are generally considered to be a lower hazard than those outside the cabinet 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 the workers themselves.

9.3.2 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. Allow adequate time for the disinfectant to take effect.

9.3.3 Larger spills

The suggested procedure for a larger spill or breakage is as follows:

(a) Ensure that the cabinet 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.

NOTES:

1 The three parameters that affect the efficacy of the disinfectant are concentration, time and temperature.

2 Appendix F lists suitable disinfectants.

(c) Disinfect gloved hands and remove protective gloves in the cabinet. Remove any contaminated clothing for decontamination and wash hands and arms. 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, cabinet work zone and remaining items of equipment with fresh disinfectant solution. For Class II cabinets, disinfect both sides of the front grille and work floor within the cabinet. 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) Consider whether the cabinet should be decontaminated before further use. The safety officer should be consulted for guidance.

(g) Complete an incident report in accordance with any institutional requirements.

NOTE: An example incident report form is given in Appendix B.

9.4 SPILLS OUTSIDE BIOLOGICAL SAFETY CABINETS

9.4.1 General

Spills outside biological safety cabinets may be of varying degrees of complexity, ranging from spills where a limited number of persons 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 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.

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.

All staff shall learn the basic procedure 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 airconditioning system and air flow direction. General spills, such as from liquid cultures or culture plates, shall be treated with a suitable disinfectant.

NOTE: For spills at colder temperatures, longer contact times for disinfectants are required.

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: An example incident report form is given in Appendix B.

9.4.2 Spills in PC2 facilities that can be cleaned up by the worker

Spills inside BSCs should be dealt with as described in Clause 9.3.

In spills external to BSCs, low hazard (as determined by the risk assessment) infectious material that is spilled without generating significant aerosol, and does not contain a human pathogen spread by the respiratory route, 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. If it is suspected that shoes are contaminated, remove 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.

9.4.3 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 9.3.

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) If safe to do so, contain the source of the spill. Move away from the spill.

(b) Remove the laboratory gown and any other garment suspected of being contaminated, and place in a biohazard bag for subsequent decontamination. If it is suspected that shoes are contaminated, remove and place in a separate biohazard bag.

(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 9.2.)

(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: Appendix F provides a list of disinfectants.

(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.

9.4.4 Spills in PC3 facilities

Spills inside BSCs should be dealt with as described in Clause 9.3.

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: 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) Notify staff external to the PC3 facility via the emergency communication system.

(b) If safe to do so, contain the source of the spill. Move away from the spill.

(c) If contamination is superficial, remove PPE and place in a biohazard bag for subsequent decontamination. If it is suspected that shoes are contaminated, remove and place in a separate biohazard bag. Decontaminate hands and leave the PC3 facility.

(d) If spilled material has soaked through clothing, remove PPE and clothing, including shoes, and place in a biohazard bag for subsequent decontamination and put on emergency clothing. Decontaminate hands and leave the spill area.

(e) Place a biohazard sign with 'DO NOT ENTER' on the door of the area where the spill has occurred.

(f) Discuss the nature of the spill with the clean-up team.

The response for the spills clean-up team (who may be the workers themselves) should be as follows:

NOTES:

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.

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.

(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 9.2.)

(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 9.2).

(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: Appendix F provides a list of disinfectants.

(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.

9.4.5 Spills in PC4 facilities where no positive pressure suit is worn

Spills inside BSCs are less hazardous and should be dealt with as described in Clause 9.3.

Spills that occur in PC4 facilities outside BSCs where no positive pressure suits are 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 staff 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) Don normal PC4 clothing and any additional protective clothing and equipment, such as gowns, gloves, boots, eye and respiratory protection (see Clause 9.2). 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: Appendix F provides a list of disinfectants.

(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.

9.4.6 Spills in PC4 facilities where a positive pressure suit is worn

Spills inside BSCs should be dealt with as described in Clause 9.3.

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 9.4.5), 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 9.4.5.

Complete an incident report form after exiting the PC4 facility.

9.5 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 9.1) 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* Thermally decontaminate intact at 121°C for a minimum of 15 min. See Appendix F.

(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 F). 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 10 CHEMICALS, PPE AND SPECIAL EQUIPMENT

10.1 CHEMICALS

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 material safety data sheet (MSDS) should be consulted for every chemical used to ensure that appropriate safety precautions are implemented to minimize the risk to health. AS/NZS 2243.2 and AS/NZS 2243.10 should be referred to 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.

10.2 PERSONAL PROTECTIVE EQUIPMENT (PPE)

10.2.1 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.

10.2.2 Laboratory coats, gowns, coveralls and aprons

Long-sleeved, back-opening gowns or coveralls should be used as they give better protection than laboratory coats. Where necessary to give further protection against spillage of chemicals or biological materials such as blood or culture fluids, aprons should be worn over gowns or laboratory coats.

10.2.3 Footwear

Closed footwear shall be worn, i.e. footwear that covers the toes 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.

10.2.4 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 overglasses 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. Units with chin guards are preferable. AS/NZS 1336, AS/NZS 1337 and the AS/NZS 1338 series shall be consulted when choosing the type of eye protection to be used.

10.2.5 Respiratory protection

Microbiological work should be planned to limit the reliance on respiratory protective equipment (RPE). Most laboratory work with microorganisms transmissible to humans by the respiratory route is conducted in containment equipment such as a BSC. Respiratory protective equipment 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 afford 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, are 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 References 1.10, 1.11 and 1.12), but similar values are obtained (see Table 10.1) when RPE is tested against aerosolized bacteria and fungal spores (see Reference 1.13). 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 judgments are needed to evaluate particular exposure hazards, the level of protection required, 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 facepiece penetration (e.g. face seal protection, valve leakage). (By way of contrast, some current overseas publications quote higher protection factors for respirator classes by not taking all these factors into account.)

TABLE 10.1

TYPES OF RESPIRATORY PROTECTIVE EQUIPMENT THAT WILL PROVIDE REQUIRED PROTECTION FACTORS (MODIFIED FROM REFERENCE 1.13)

MPF*	Respirator type	Comment
10	Half-facepiece (P2 or N95)	Respirator needs to be fit tested to the individual
50	Powered air purifying respirator (PAPR) with half-facepiece	Devices covering half-face provide lower levels of protection
50	Full-facepiece respirator with P3 or HEPA filter	Respirator needs to be fit tested to the individual
100	PAPR with P3 or HEPA filter and head-covering hood	Considered to provide high protection. Fit testing to the individual not required
10 000	Self-contained breathing apparatus (SCBA) with positive pressure demand	Not practical for most microbiological applications

* Minimum protection factor that could be assigned to the respirator type

Air-purifying RPE is 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 facepiece (includes disposable type), a full facepiece 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 covered in AS 4381. They are not for use 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.

10.2.6 Gloves

Contamination of 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.

After handling infectious materials, working in a biological safety cabinet and before leaving the laboratory, gloves shall be removed and hands decontaminated. Used gloves shall be discarded with infected laboratory waste.

Allergic reactions such as dermatitis and immediate hypersensitivity have been reported in laboratory and other workers wearing latex gloves (powdered and non-powdered). Alternatives such as nitrile or vinyl gloves should be made available.

Heat-insulating gloves should be worn when conducting procedures involving liquid nitrogen, sterilizers and microwave ovens.

Stainless steel mesh gloves should be worn when there is a potential exposure to cuts from sharp instruments, e.g. during post-mortem examinations.

Further information on occupational protective gloves is available in the AS/NZS 2161 series.

10.3 CENTRIFUGES

10.3.1 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 staff, 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 II biological safety cabinets 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.

10.3.2 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 9.5.

(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.

10.3.3 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 biological safety cabinet.

(c) The use and maintenance of a continuous-flow centrifuge shall be in strict compliance with manufacturer's instructions.

NOTE: This type of equipment is a potential producer of aerosols.

10.3.4 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.

10.4 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 biological safety cabinet. The ampoules shall be wrapped in material such as a gauze square to protect the operator from being cut. Commercial ampoule breakers are 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 12.2).

10.5 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. 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 shall be used for storing materials. Certain hard glass ampoules are suitable, but cryogenic plastic containers are safer. If liquid nitrogen leaks into a glass container, an explosion is likely when it is removed as the liquid is rapidly converted into gaseous nitrogen.

NOTE: The wearing of hearing protection should be considered.

(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 19.5%. Failure of the ventilation system can cause the nitrogen gas concentration to rise. If oxygen reduction becomes severe, complete physical collapse can occur. The victim can be unaware that anything is wrong until beyond self-rescue or the summoning of aid. Where asphyxia develops by gradual reduction of the oxygen content in the air, early outward signs are the inability to think clearly, disturbance of muscular coordination, rapid fatigue and easy arousal of emotions, particularly of ill-temper.

(g) If Dewar flasks are transported by lift between floors, the containers shall not be accompanied by passengers.

10.6 PRESSURE STEAM STERILIZERS

10.6.1 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. Relevant regulations for pressure vessels shall be consulted for information about regular certification of the sterilizer.

Persons using 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. Such areas should also have provision for the separate storage of infectious waste in impermeable plastic bags or lidded containers. Bags should be opened prior to commencement of the sterilization cycle.

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.

10.6.2 Air removal methods for steam sterilizers

For efficient sterilization, all air shall be removed from the load and from the chamber of the sterilizer. This can be achieved by—

(a) downward displacement of air by steam; or

(b) the use of an evacuation pump to remove air prior to entry of steam.

10.6.3 Downward-displacement steam sterilizers

Downward-displacement cycles are used for the sterilization of articles, culture media and fluids. 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. On the other hand, 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. Persons using 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.

AS 2192 should be consulted for requirements for downward-displacement steam sterilizers.

10.6.4 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.

AS 1410 should be consulted for requirements for pre-vacuum steam sterilizers.

10.6.5 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.

10.6.6 Monitoring of sterilization cycles

Some visual indicators, such as sensitive papers or tapes, give only 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 (see AS 1410) 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.

Sterilizer cycles should be validated. Validation is 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 a trained competent person using measuring equipment that has a current certificate of calibration issued by a body with third-party accreditation for conducting such calibrations. Calibration should be performed on a regular basis and, as 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. Table 10.2 lists commonly-used biological indicators and has been based on information in Reference 1.14.

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 to ensure that the sterilizer cycle is maintained within calibration specifications.

10.6.7 Chamber pressure relief valves

Pressure relief valves shall discharge in a safe place outside and away from the containment structure because of the potential for a saturated atmosphere to damage the integrity of the containment facility.

10.6.8 Barrier wall steam sterilizers

The inner door shall automatically interlock with the outer door in such a manner that the outer door can be opened only 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.

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 10.2

COMMONLY-USED BIOLOGICAL INDICATORS

Process	Species	Incubation temperature
Steam under pressure	*Geobacillus stearothermophilus*	56°C Rapid enzyme BI (60°C)
Dry heat	*Bacillus atrophaeus*	37°C
Ethylene oxide	*Bacillus atrophaeus*	37°C
Subatmospheric steam and formaldehyde	*Geobacillus stearothermophilus*	56°C

10.7 BIOLOGICAL SAFETY CABINETS

10.7.1 Class I and II BSCs

Two classes of biological safety cabinets are in common use, Class I and Class II, see Clause 1.4.7.

To enhance containment of hazardous materials in Class I or Class II cabinets, both AS 2252.1 and AS 2252.2 require that all potentially contaminated zones under positive air pressure are surrounded by zones of negative air pressure relative to the facility. Cabinets without this design feature may not provide the same degree of safety for the user and the environment.

In addition, Class II biological safety cabinets meeting 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 required by AS/NZS 2647.

Class I and Class II cabinets, complying with AS 2252.1 and AS 2252.2 respectively, offer an equivalent degree of protection to the operator. Class I and Class II cabinets 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 biological safety cabinets, 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 cabinets (see AS/NZS 2647). Information on the installation and use of biological safety cabinets is provided in AS/NZS 2647.

All cabinets 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 cabinets 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.

Cabinets shall be decontaminated with formaldehyde gas or an equivalent decontaminant before testing when they have been used for handling Risk Group 2, 3 or 4 microorganisms. Penetration of the decontaminant throughout all sections of the cabinet is essential.

When a cabinet 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 1386.5 do not provide operator protection as do biological safety cabinets. 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 Groups 2, 3 or 4 or hazardous materials.

NOTE: Aspects of location, use, decontamination and outline of testing of biological safety cabinets are covered in an audiovisual presentation prepared by the WHO Collaborating Centre for Biosafety in Microbiology at the Victorian Infectious Diseases Reference Laboratory. The presentation is available from the publications list on the Victorian Infectious Diseases Reference Laboratory web site, www.vidrl.org.au. It includes the following parts:

(a) Part 1: Types of cabinets and their proper location;

(b) Part 2: Using the Class II cabinet;

(c) Part 3: Decontamination and testing of cabinets; and

(d) Part 4: Summary.

Class I and II biological safety cabinets shall not be used for the handling of infectious materials which also contain volatile hazardous chemicals, unless the exhaust air from the cabinets 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.

Fume cupboards shall not be used when working with infectious materials.

10.7.2 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. Class III BSCs include flexible film isolators and some powder containment chambers used for handling powders suspected of being bioterrorist agents.

NOTES:

1 The operator works in gloves attached to sleeves which are part of the BSC, or in gauntlets attached to the BSC envelope.

2 Class III BSCs operate at a pressure below that of the room in which they are located. The entry and escape of air-borne particles is prevented by a HEPA filtered inlet and exhaust air system.

3 Material is introduced and removed from the Class III BSC through supply and sample ports without compromising microbiological security.

4 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.

10.8 LAMINAR FLOW CYTOTOXIC DRUG SAFETY CABINETS

Laminar flow cytotoxic drug safety cabinets are suitable for work with materials containing prions. These cabinets, in contrast to laminar flow biological safety cabinets (Class II BSC), provide protection for cabinet maintenance staff in addition to protection of the environment, the material being handled and the operator. See AS 2567 and AS 2639.

As it is not possible to gaseously inactivate material containing prions, the design of the laminar flow cytotoxic drug safety cabinet 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. 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.

10.9 HEPA FILTERS

10.9.1 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 is available demonstrating full compliance with AS 4260 and, in particular, the requirements for filter efficiency, leak testing, fire performance, structural strength and resistance to vibration.

10.9.2 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 permit 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.

NOTE: Recommendations for airtightness of HEPA filter housings and the duct connections between the facility and the housings can be found in the section on the air handling system in Agriculture and Agri-Food Canada Veterinary Biologics Guideline 4.7E, *Containment Standards for Veterinary Facilities*, available from the Canadian Food Inspection Agency web site at www.inspection.gc.ca/english/sci/lab/convet/convete.shtml.

HEPA filters shall be tested in accordance with AS 1807.6 or AS 1807.7, as applicable, at least annually. Prior to testing, the HEPA filter shall be decontaminated. See AS/NZS 2647 for information on gaseous decontamination of biological safety cabinets and their HEPA filters.

SECTION 11 CLEANING

11.1 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.

Clean surroundings facilitate clean work. Staff shall clean and tidy work benches and shelves as they work, and provide a complete clean-up at the end of the working day.

Work areas shall be kept free from physical hazards that might cause spillages or breakages. Items for sterilization shall be regularly collected. This collection shall be independent of the regular collection of uncontaminated waste.

11.2 CLEANING PERSONNEL

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. Only laboratory or facility staff shall handle infectious materials.

11.3 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.

11.4 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.

11.5 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 12 CONTAMINATED MATERIALS AND WASTE

12.1 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 (see 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 12.2.5.1.)

(g) *Imported biological material* In Australia, consult AQIS prior to disposing and, in New Zealand, consult the relevant MAF BNZ Standard along with any conditions in the relevant permit to import.

(h) *Non-contaminated waste* Waste paper, plastics, and paper products shall be collected.

(i) *Prions* Waste that contains or could contain prions shall be collected for decontamination by the appropriate method. (See Clause 12.2.4.)

NOTE: See also AS/NZS 3816 and NZS 4304 for clinical and healthcare waste and AS/NZS 2243.1 for other types of waste.

12.2 DECONTAMINATION AND DISPOSAL OF WASTES

12.2.1 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.

12.2.2 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.

12.2.3 Decontamination methods

12.2.3.1 *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 Clauses 10.6.5 and 10.6.6).

NOTE: See also Clause 10.6 for correct use of pressure steam sterilizers.

12.2.3.2 *Chemical disinfection*

Following decontamination with appropriate disinfectant (see Appendix F), waste shall be disposed of in accordance with AS/NZS 2243.2 and relevant authority requirements.

12.2.3.3 *Incineration*

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. Transport of materials by surface to such incinerators in Australia shall be done in approved packaging and according to the requirements of AS 4834 (see also Clause 13.4.2 (c)). Transport by air shall be according to IATA requirements (see Section 13).

NOTE: EPA-approved incineration for cytotoxic drugs exceeds the requirements for microbial destruction (see also Reference 1.17).

12.2.3.4 *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 12.2.3 to 12.2.5. Relevant authorities shall be consulted for advice.

12.2.4 Prions

Current recommendations for the sterilization of articles or specimens that could be contaminated by prions are 18 min at 134°C to 138°C in a pre-vacuum pressure steam

sterilizer (UK) or 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.

Pressure steam sterilizer/chemical methods for decontaminating heat-resistant instruments are either—

(a) 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

(b) 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 Clauses 1.15 and 1.16).

12.2.5 Secondary contamination considerations

12.2.5.1 *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. Seek advice from the Radiation Protection Officer.

In New Zealand, radioactive waste shall be treated and disposed in accordance with the requirements of the National Radiation Laboratory Code of safe practice for the use of unsealed radioactive materials, NRL C1.

12.2.5.2 *Chemical waste*

Chemical waste shall be disposed of in accordance with AS/NZS 2243.2 and Government requirements where applicable.

12.2.6 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. All waste from PC3 and PC4 facilities shall be treated as potentially contaminated.

SECTION 13 TRANSPORT OF INFECTIOUS AND OTHER BIOLOGICAL MATERIALS

13.1 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 specifies required training for packing dangerous goods for transport by air. All persons 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, Australia.

This Section summarises the requirements of the various regulatory bodies and is based on United Nations *Recommendations on the Transport of Dangerous Goods. Model Regulations*, which are adopted by the International Air Transportation Association (IATA) and AS 4834.

Facilities should be provided for after-hours delivery of samples. After hours staff shall be warned of any hazards.

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 12.)

13.2 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* (Reference 1.18).

(c) *Australian Code for the Transport of Dangerous Goods by Road and Rail*.

(d) *Transport of Dangerous Goods on Land* (NZS 5433).

(e) New Zealand Post, *Postal Users Guide* (Reference 1.19).

(f) The International Maritime Organization (IMO), *International Maritime Dangerous Goods Code* (IMDG Code).

(g) The Office of the Gene Technology Regulator (OGTR), *Guidelines for the transport of GMOs*.

(h) *Packaging for surface transport of biological material that may cause disease in humans, animals and plants* (AS 4834).

(i) United Nations *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 Shippers Declaration for Dangerous Goods. AS 4834 covers packaging for surface transport of biological material that may cause disease in humans, animals and plants in Australia.

13.3 TRANSPORT DEFINITIONS OF BIOLOGICAL MATERIALS

The following 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.

(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, 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 microoganisms are microorganisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

13.4 CLASSIFICATION AND PACKAGING

13.4.1 General

Clauses 13.4.2 to 13.4.5 provide details of the classifications that apply within the different types of biological materials and the corresponding packing requirements.

Figure 2 provides a flow chart 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.

13.4.2 Infectious substances

Infectious substances shall be classified as Division 6.2 dangerous goods and assigned the appropriate UN number, UN 2814, UN 2900, UN 3291 or UN 3373 using 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 13.1 provides a list of indicative examples of substances that meet these criteria.

NOTE: 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 judgment concerning individual circumstances of the source human or animal.

NOTES:

1 The proper shipping name for UN 2814 is INFECTIOUS SUBSTANCE, AFFECTING HUMANS.

2 The proper shipping name for UN 2900 is INFECTIOUS SUBSTANCE, AFFECTING ANIMALS ONLY.

Packing instruction P620 (UN) or PI 602 (IATA) apply to these substances.

NOTE: Figure 3 shows examples of triple packaging systems for Category A and Category B infectious substances.

Table 13.1 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.

TABLE 13.1

INDICATIVE EXAMPLES OF MICROORGANISMS ASSIGNED AS UN 2814 OR UN 2900 INCLUDED IN CATEGORY A (IN ANY FORM UNLESS OTHERWISE INDICATED)

UN 2814 Infectious substance affecting humans	
Bacillus anthracis (cultures only)	Human immunodeficiency virus (cultures only)
Brucella abortus (cultures only)	Japanese Encephalitis virus (cultures only)
Brucella melitensis (cultures only)	Junin virus
Brucella suis (cultures only)	Kyasanur Forest disease virus
Burkholderia mallei, Pseudomonas mallei, Glanders (cultures only)	Lassa virus
Burkholderia pseudomallei, Pseudomonas pseudomallei (cultures only)	Machupo virus
Chlamydia psittaci, avian strains (cultures only)	Marburg virus
Clostridium botulinum (cultures only)	Monkeypox virus
Coccidioides immitis (cultures only)	*Mycobacterium tuberculosis* (cultures only)
Coxiella burnetti (cultures only)	Nipah virus
Crimean-Congo haemorrhagic fever virus	Omsk haemorrhagic fever virus
Dengue virus (cultures only)	*Poliovirus* (cultures only)
Eastern equine encephalitis virus (cultures only)	Rabies virus (cultures only)
Ebola virus	*Rickettsia prowazekii* (cultures only)
Escherichia coli, verotoxigenic (cultures only)	*Rickettsia rickettsii* (cultures only)
Flexal virus	Rift Valley fever virus (cultures only)
Francisella tularensis (cultures only)	Russian spring-summer encephalitis virus (cultures only)
Guanarito virus	Sabia virus
Hantaan virus	*Shigella dysenteriae type 1* (cultures only)
Hantavirus causing haemorrhagic fever with renal syndrome	Tick-borne encephalitis virus (cultures only)
Hendra virus	Variola virus
Hepatitis B virus (cultures only)	Venezuelan equire encephalitis virus (cultures only)
Herpes B virus (cultures only)	West Nile virus (cultures only)
Highly pathogenic avian influenza virus (cultures only)	Yellow fever virus (cultures only)
	Yersinia pestis (cultures only)
UN 2900 Infectious substance affecting animals	
African swine fever virus (cultures only)	Peste des petits ruminants virus (cultures only)
Avian paramyxovirus Type I, Velogenic Newcastle disease virus (cultures only)	Rinderpest virus (cultures only)
Classical swine fever virus (cultures only)	Sheep-pox virus (cultures only)
Foot and mouth disease (cultures only)	Goat-pox virus (cultures only)
Lumpy skin disease virus (cultures only)	Swine vesicular disease virus (cultures only)
Mycoplasma mycoides, Contagious bovine pleuropneumonia (cultures only)	Vesicular stomatitis virus (cultures only)

(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: 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: Figure 3 shows examples of triple packaging systems for Category A and Category 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*

The current edition of the IATA Dangerous Goods Regulations shall be consulted.

13.4.3 Biological products

Biological products are divided into 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 present a biohazard only 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.

13.4.4 Genetically modified microorganisms and organisms

Genetically modified microorganisms shall be transported according to the guidelines or standards published by the OGTR or MAF, as appropriate.

13.4.5 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: 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 are not subject to the UN Model Regulations unless they meet the criteria for inclusion in another class.

NOTE: AS/NZS 3816 should also be consulted.

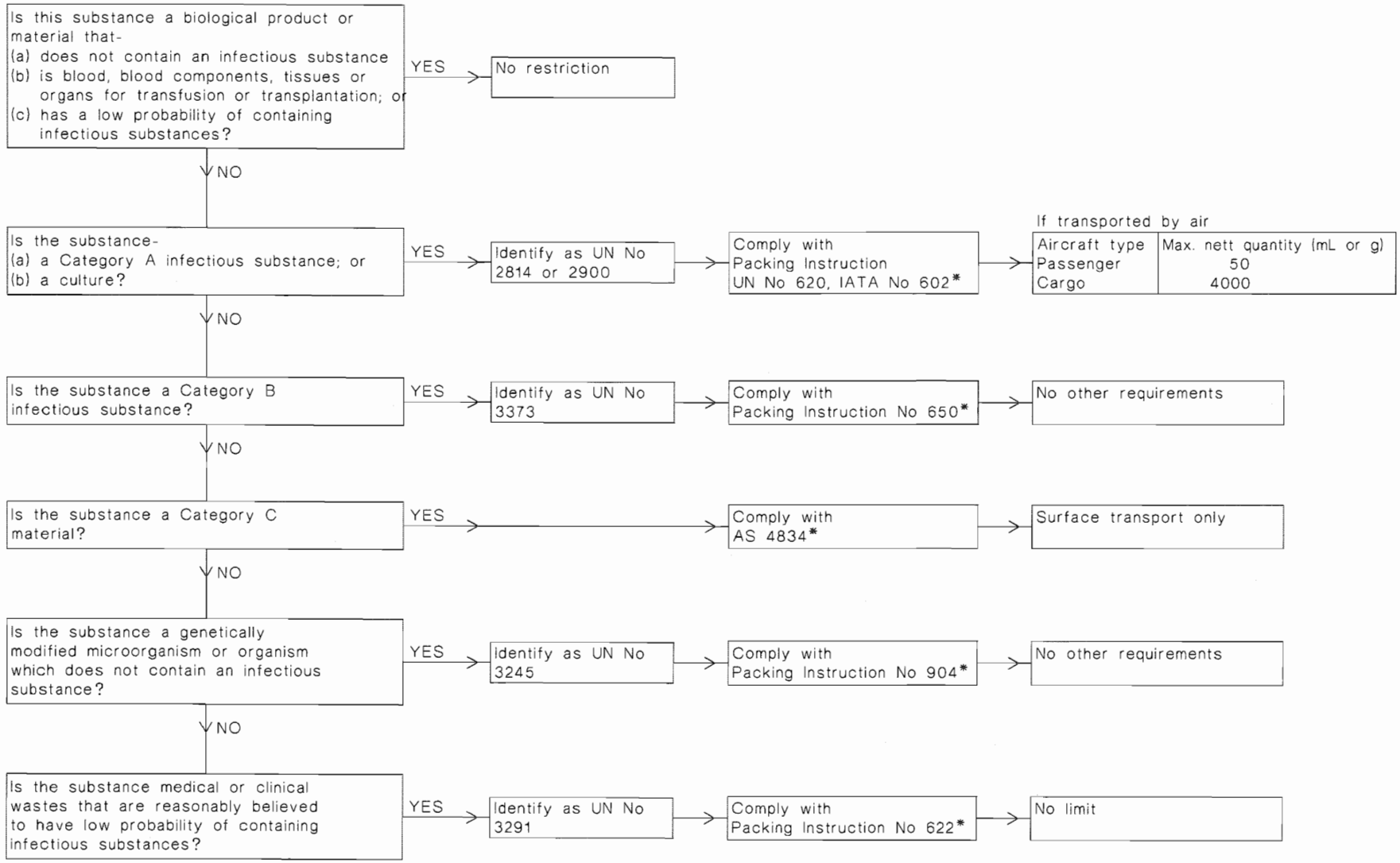
13.5 TRANSPORT OF INFECTED ANIMALS

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.

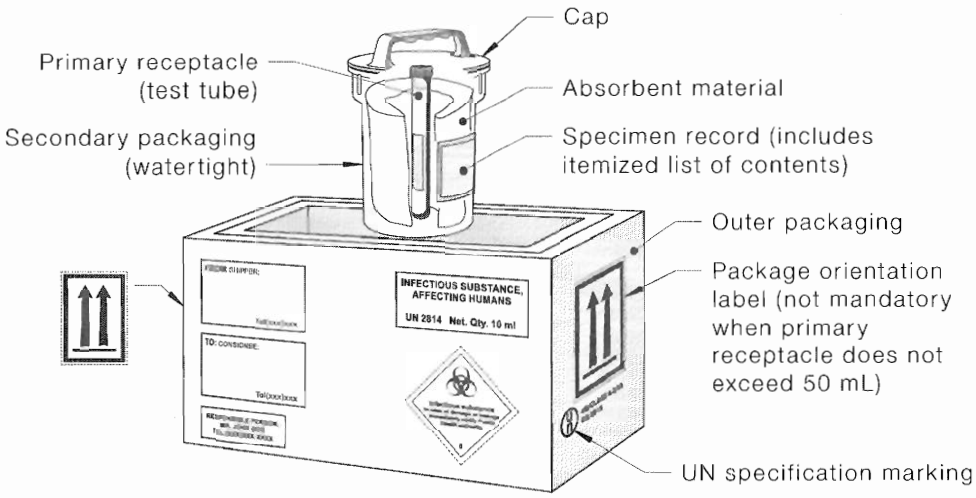
13.6 DOCUMENTATION

When infectious material is being transported, a Shipper's Declaration for Dangerous Goods 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 primary and secondary packages, 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.

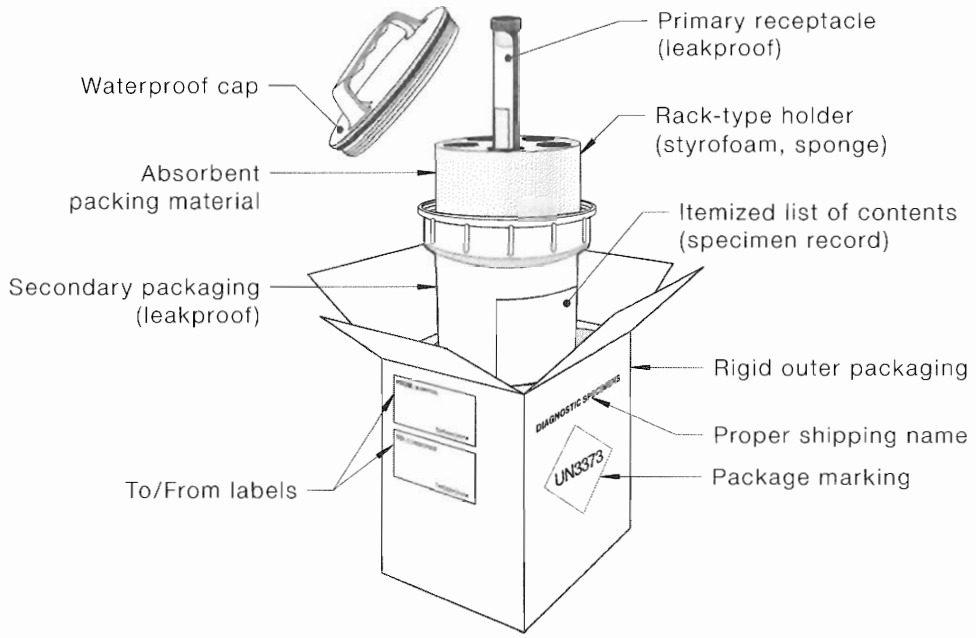


*Refer to IATA, UN Recommendations on the Transport of Dangerous Goods or AS 4834 for more detail

FIGURE 2 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 3 EXAMPLES OF TRIPLE PACKAGING SYSTEMS

APPENDIX A

REFERENCED AND RELATED DOCUMENTS

(Normative)

A1 SCOPE

This Appendix provides lists of documents and publications referred to in this Standard, as well as a list of related publications.

A2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS

1319 Safety signs for the occupational environment

1324 Air filters for use in general ventilation and airconditioning
1324.1 Part 1: Application, performance and construction
1324.2 Part 2: Methods of test

1386 Cleanrooms and clean workstations
1386.5 Part 5: Clean workstations

1410 Sterilizers—Steam—Pre-vacuum

1668 The use of ventilation and airconditioning in buildings
1668.2 Part 2: Ventilation design for indoor air contaminant control

1807 Cleanrooms, workstations, safety cabinets and pharmaceutical isolators—Methods of test
1807.6 Method 6: Determination of integrity of terminally mounted HEPA filter installations
1807.7 Method 7: Determination of integrity of HEPA filter installations not terminally mounted
1807.10 Method 10: Determination of air pressure of cleanrooms and pharmaceutical isolators

2192 Sterilizers—Steam—Downward-displacement

2243 Safety in laboratories
2243.4 Part 4: Ionizing radiations

2252 Biological safety cabinets
2252.1 Part 1: Biological safety cabinets (Class I) for personnel and environment protection

2252 Controlled environments
2252.2 Part 2: Biological safety cabinets (Class II)—Design

2567 Laminar flow cytotoxic drug safety cabinets

2639 Laminar flow cytotoxic drug safety cabinets—Installation and use

4031 Non-reusable containers for the collection of sharp medical items used in health care areas

AS
4260 High efficiency particulate air (HEPA) filters—Classification, construction and performance

4381 Single-use face masks for use in health care

4834 Packaging for surface transport of biological material that may cause disease in humans, animals and plants

AS/NZS
1170 Structural design actions
1170.2 Part 2: Wind actions

1336 Recommended practices for occupational eye protection

1337 Personal eye protection (series)

1338 Filters for eye protectors (series)

1715 Selection, use and maintenance of respiratory protective devices

2161 Occupational protective gloves (series)

2210 Occupational protective footwear (series)

2243 Safety in laboratories
2243.1 Part 1: Planning and operational aspects
2243.2 Part 2: Chemical aspects
2243.8 Part 8: Fume cupboards
2243.9 Part 9: Recirculating fume cabinets
2243.10 Part 10: Storage of chemicals

2647 Biological safety cabinets—Installation and use

2982 Laboratory design and construction
2982.1 Part 1: General requirements

3500 Plumbing and drainage (series)

3816 Management of clinical and related wastes

AS/NZS ISO
31000 Risk management—Principles and guidelines

ISO
3864 Graphical symbols—Safety colours and safety signs (series)

NZS
4304 Management of healthcare waste

5433 Transport of dangerous goods on land

ACTDG (Advisory Committee on the Transport of Dangerous Goods, Australia)
ADG Code, Australian Code for the Transport of Dangerous Goods by Road and Rail

CWA (CEN Workshop Agreement)
15793 Laboratory Biorisk Management Standard (available from www.cen.eu/cenorm/businessdomains/technicalcommitteesworkshops/workshops/ws31.asp)

CIVIL AVIATION SAFETY AUTHORITY (Australia)
Civil Aviation Safety Regulations 1998

COMMONWEALTH OF AUSTRALIA
National Health Security Act 2007

DEPARTMENT OF HEALTH AND AGEING, AUSTRALIA
Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting

IATA (International Air Transport Association)
Dangerous Goods Regulations

IMO (International Maritime Organization)
International Maritime Dangerous Goods Code

MAF BNZ—ERMA, New Zealand
Facilities for Microorganisms and Cell Cultures:2007a

MINISTRY OF HEALTH NEW ZEALAND
Guidelines for Tuberculosis Control in New Zealand 2003
Immunisation Handbook 2006

NHMRC (National Health and Medical Research Council, Australia)
Australian code of practice for the care and use of animals for scientific purposes
The Australian Immunisation Handbook
Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals

NOHSC (National Occupational Health and Safety Commission)
2010 National Code of Practice for the control of work related exposure to hepatitis and HIV (blood-borne) viruses

NRL (National Radiation Laboratory, NZ)
C1 Code of safe practice for the use of unsealed radioactive materials

NTAC (National Tuberculosis Advisory Committee, Australia)
Guidelines for Australian Mycobacteriology Laboratories

New Zealand Animal Welfare Act 1999
New Zealand Hazardous Substances and New Organisms Act 1996

OGTR (Office of the Gene Technology Regulator, Australia)
Guidelines for the certification of physical containment facilities
Guidelines for the transport of GMOs

UNITED NATIONS
Recommendations on the Transport of Dangerous Goods. Model Regulations

A3 OTHER REFERENCED PUBLICATIONS

The following publications are referred to in this Standard:

1.1 CENTERS FOR DISEASE CONTROL AND PREVENTION, Guidelines for the investigation of contacts of persons with infectious tuberculosis: recommendations from the National Tuberculosis Controllers Association and CDC, and Guidelines for using the QuantiFERON-TB Gold test for detecting *Mycobacterium tuberculosis* infection. *Morbidity and Mortality Weekly Review* 54 (Recommendations and Reports 15) 2005; p. 1-62.

1.2 COLLINS, C.H. and KENNEDY, D.A. (eds.) *Laboratory-acquired infections: history, incidence, causes and prevention.* 4th ed. Oxford: Butterworth Heinemann, 1999.

1.3 US DEPARTMENT OF HEALTH AND HUMAN SERVICES. *Biosafety in microbiological and biomedical laboratories.* 5th ed. Washington D.C.: US Government Printing Office, 2007.

1.4 UK ADVISORY COMMITTEE ON DANGEROUS PATHOGENS. *The management, design and operation of microbiological containment laboratories*. London: HSE Books, 2001.

1.5 PUBLIC HEALTH AGENCY CANADA. *Laboratory biosafety guidelines*. 3rd ed. Ottawa: Population and Public Health Branch, Centre for Emergency Preparedness and Response, 2004.

1.6 WORLD HEALTH ORGANIZATION. WHO/CDS/CSR/LYO/2004.11 *Laboratory biosafety manual*. 3rd ed. Geneva: World Health Organization, 2004. (Available from WHO web site at www.who.int/csr/resources/publications).

1.7 DR VRIES, B. and COSSART, Y.E. Needlestick injury in medical students. *Medical Journal of Australia*. 1994; vol. 160: p. 398-400.

1.8 NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH. *Preventing Asthma in Animal Handlers*. Publication No.97-116, January 1998.

1.9 BOYCE J.M. and PITTET M.D., Guideline for Hand Hygiene in Health Care Settings *Morbidity and Mortality Weekly Review* 51(Recommendations and Reports 16) 25 October 2002; p. 1-44.

1.10 LENHART, S.W., SEITZ, T., TROUT, D. and BOLLINGER, N. Issues affecting respirator selection for workers exposed to infectious aerosols: Emphasis on healthcare settings. *Applied Biosafety* 2004; vol. 9(1): p. 20-36.

1.11 McCULLOUGH, N. Personal respiratory protection. In FLEMING, D.O. and HUNT, D.L. (eds.). *Biological safety: Principles and practices*. 4th ed. Washington D.C.: American Society for Microbiology, 2006.

1.12 NATIONAL OCCUPATIONAL HEALTH AND SAFETY COMMISSION. *Adopted National exposure standards for atmospheric contaminants in the occupational environment*. 3rd ed. Canberra: Australian Government Publishing Service, 1995.

1.13 LAVOIE, J., CLOUTIER, Y., LARA, J. and MARCHAND, G. Technical Guide RG-501: *Guide on respiratory protection against bioaerosols: Recommendations on its selection and use*. Montreal: Occupational Health and Safety Research Institute Robert-Sauvé, 2007.

1.14 GARDNER, J.F. and PEEL, M.M. *Sterilization, disinfection and infection control*. 3rd ed. Melbourne: Churchill Livingstone, 1998.

1.15 GARLAND, A.J.M. A review of BSE and its inactivation. *European Journal of Parenteral Sciences*. 1999; vol. 4: p. 86-93.

1.16 WORLD HEALTH ORGANIZATION. *WHO Infection Guidelines for Transmissible Spongiform Encephalopathies*. Report of a Consultation, March 1999. Geneva: World Health Organization, 2000.

1.17 BARBEITO, M.S. and SHAPIRO, M. Microbiological safety evaluation of a solid and liquid pathological incinerator. *Journal of Medical Primatology*. 1977; vol. 6: p. 264-73.

1.18 AUSTRALIA POST. *Dangerous and prohibited goods packaging guide*. Post Guide. Section 2.5.15, Melbourne: Australia Post, 1996.

1.19 NEW ZEALAND POST. *Postal users guide*. Wellington: New Zealand Post, 1994.

1.20 BLOOMFIELD, S.F., SMITH-BURCHNELL, C.A. and DALGLEISH, A.G. Evaluation of hypochlorite-releasing disinfectants against the human immunodeficiency virus (HIV). *Journal of Hospital Infection*. 1990; vol. 15: p. 273-8.

1.21 ABRAHAM, G., LE BLANC SMITH, P.M. and NGUYEN, S. The effectiveness of gaseous formaldehyde decontamination assessed by biological monitoring. *Journal of the American Biological Safety Association* 1997; vol. 2(1): p. 30-8.

1.22 DRUCE, J.D., JARDINE, D., LOCARNINI, S.A., and BIRCH, C.J. Susceptibility of HIV to inactivation by disinfectants and ultraviolet light. *Journal of Hospital Infection*. 1995; vol. 30: p. 167-80.

1.23 BROADLEY, S.J., FURR, J.R., JENKINS, P.A., and RUSSELL, A.D. Antimycobacterial activity of 'Virkon'. *Journal of Hospital Infection.* 1993; vol 23: p. 189-97.

1.24 MONTEFIORI, D.C., ROBINSON, W.E.Jr., MODLISZEWSKI, A. and MITCHELL, W.M. Effective inactivation of human immunodeficiency virus with chlorhexidine antiseptics containing detergents and alcohol. *Journal of Hospital Infection*. 1990; vol. 15: p. 279-82.

1.25 RUTALA, W. and WEBER, D. New Disinfection and Sterilisation Methods. *Emerging Infectious Diseases*. 2001; vol. 7 (2): p. 348-353.

1.26 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): p. 4-11.

1.27 MCGURK, G.B. *A study of of air-tightness in Australian high-level bio-containment facilities*. Journal of the American Biological Safety Association 2009; vol. 14 (2):p. 72-80.

1.28 CZARNESKI, M. A. *Microbial Decontamination of a New 65-Room Pharmaceutical Research Facility*. Journal of the American Biological Safety Association 2009; vol. 14(2): pp. 81-88.

1.29 CETA *Application Guide for the use of Surface Decontaminants in Biosafety Cabinets*, CAG-004-2007, www.cetainternational.org/reference/CAG0042007i.pdf

1.30 BABB, J.R., BRADLEY, C.R. and AYLIFFE G.A.J. *Sporicidal activity of glutaraldehydes and hypochlorites and other factors influencing their selection for the treatment of medical equipment*, J Hosp Infect.1980; vol 1:p 63-75.

1.31 FICHET, G., ANTLOGA, K., COMOY, E., DESLYS, J.P.and MCDONNELL G. *Prion inactivation using a new gaseous hydrogen peroxide sterilisation process*. J Hosp Infect. 2007 Nov; vol. 67(3):p 278-86.

1.32 BEST,M., SATTAR, S.A., SPRINGTHORPE ,V. S. and KENNEDY, M.E. *Efficacies of selected disinfectants against Mycobacterium tuberculosis*, J Clin Microbiol. (1990) October; vol. 28 (10):p 2234-2239.

1.33 FICHET, G., COMOY, E., DUVAL, C., ANTLOGA, K., DEHEN, C., CHARBONNIER, A., MCDONNELL, G., BROWN, P., LASMÉZAS, C.I.,and DESLYS, J.P., *Novel methods for disinfection of prion-contaminated medical devices*. Lancet . 2004; Aug 7-13:364(9433):p 521-6.

A4 RELATED DOCUMENTS

Attention is drawn to the following related documents:

2.1 ABRAHAM, G. and DELLA-PORTA, A.J. Microbiological containment and biosafety in medical and veterinary laboratories. *Recent advances in microbiology*. 1993; vol. 1: p. 228-58.

2.2 AYLIFFE, G.A.J., COATES, D. and HOFFMAN, P.N. *Chemical disinfection in hospitals*. 2nd ed. London: Public Health Laboratory Service, 1993.

2.3 BLOCK, S.S. (ed.). *Disinfection, sterilization, and preservation*. 5th ed. Philadelphia: Lippincott Williams and Wilkins, 2001.

2.4 FLEMING, D.O. and HUNT, D.L. (eds.). *Biological safety: Principles and practices*. 4th ed. Washington D.C.: American Society for Microbiology, 2006.

2.5 FURR, A.K. (ed.). CRC *Handbook of laboratory safety*. 3rd ed. Boca Raton, Florida: CRC Press, 1990.

2.6 LAUER, J.L., BATTLES, D.R. and VESLEY, D. Decontaminating infectious laboratory waste by autoclaving. *Applied and Environmental Microbiology*. 1982; vol. 44: no 3, p. 690-4.

2.7 NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL. *National guidelines for the management of clinical and related wastes*. Canberra: Australian Government Publishing Service, 1989.

2.8 RUSSELL, A.D., HUGO, W.B. and AYLIFFE, G.A. (eds.). *Principles and practices of disinfection, preservation and sterilization*. 3rd ed. Oxford: Blackwell Scientific Publications, 1999.

2.9 SAX, N.I. *Dangerous properties of industrial materials*. 10th ed. New York: Van Nostrand Reinhold, 2000.

2.10 POOLE, T. (ed.). *The UFAW Handbook on the care and management of laboratory animals*. 6th ed. Great Britain, Bath Press, 1987.

2.11 RICHMOND, J.Y. (ed.). *Anthology of Biosafety* (series). American Biological Safety Association, 1999-.

2.12 PHILBEY, A.W., KIRKLAND, P.D., ROSS, A.D., DAVIS, R.J., GLEESON, A.B., LOVE, R.J., DANIELS, P.W., GOULD, A.R. and HYATT, A.D. An apparently new virus (Family *Paramyxoviridae*) infectious for pigs, humans and fruit bats. *Emerging Infectious Diseases*. 1998; vol. 4, no. 2: p. 269–71.

2.13 UK ADVISORY COMMITTEE ON DANGEROUS PATHOGENS. *Guidance on the use, testing and maintenance of laboratory and animal flexible film isolators*. London: HSE Books, 1985.

NOTE: Information on risk groups from the UK health and Safety Executive is continually being updated and may be found at their website, e.g. www.hse.gov.uk/pubns/misc208.pdf

2.14 COMMONWEALTH OF AUSTRALIA. *Gene Technology Act 2000.*

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2.16 STANDARDS AUSTRALIA. AS/NZS 4187. *Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities*. Sydney: Standards Australia 2003.

2.17 BUCHEN-OSMOND, C., CRABTREE, K., GIBBS, A. and MCLEAN, G. (eds.). *Viruses of plants in Australia*. Canberra: The Australian National University Printing Service, 1988.

2.18 KAHN, R.P. and MATHUR, S.B. *Containment facilities and safeguards for exotic plant pathogens and pests.* American Phytopathological Society, 1999.

2.19 CSL Limited. *Q fever: your questions answered.* Sydney: MediMedia Communications, 1999.

2.20 WORLD HEALTH ORGANIZATION. *Guidance on regulations for the transport of infectious substances.* WHO/CDS/CSRL/LYO/2005.22. Lyons: World Health Organization, 2005.

APPENDIX B

EXAMPLE MICROBIOLOGICAL INCIDENT/ILLNESS REPORT FORM

(Informative)

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 C

ADDITIONAL CONTAINMENT REQUIREMENTS FOR POLIOVIRUS

(Normative)

C1 SCOPE

This Appendix sets out additional requirements for working with poliovirus.

C2 REQUIREMENTS

The World Health Organization (WHO) has issued guidance documents* related to work with wild poliovirus in the near and long-term future.

People wishing to work with wild poliovirus during containment Phase I, Laboratory Survey and Inventory, during which wild polioviruses are decreasing world-wide, shall do so under PC2/polio containment. PC2/polio containment follows traditional PC2 requirements for facilities, practices and procedures, with the additional requirements that—

(a) access to the laboratory is restricted;

(b) all persons entering the laboratory are fully immunized against polio in a manner that includes a single booster dose of polio vaccine every 10 years;

(c) all open manipulations with wild poliovirus infectious or potential infectious materials are performed using a certified Class I or II biological safety cabinet;

(d) all wild poliovirus infectious and potential infectious materials are stored in secure areas with limited access;

(e) freezers and refrigerators are locked with limited access to the key mechanism and clearly marked as containing wild poliovirus materials;

(f) freezer inventories are current and complete, including nature of material, volume or amount, location in freezer;

(g) documentation is current on all materials, including geographical source and date of collection;

(h) all materials are transferred to and from the freezer in leak-proof, unbreakable secondary containers;

(i) standard operating procedures (SOP) are established and regular training provided on responses to all spills, breakage of virus-containing vessels and accidents where virus may have been released.

Unless there are strong scientific reasons for working with virulent polioviruses, laboratories should use the attenuated Sabin oral poliovirus vaccine (OPV) strains. Authenticated OPV strains can be supplied on application to the National Polio Reference Laboratory, Victorian Infectious Diseases Reference Laboratory, Australia or Environmental Science and Research, New Zealand. Further information on the eradication and containment of wild polioviruses is available at www.polioeradication.org and www.polioeradication.org/content/publications/WHO-VB-03-729.pdf.

All laboratories retaining wild poliovirus infectious materials or potential wild poliovirus infectious materials should be listed on the inventory held by the national government. The

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* WORLD HEALTH ORGANIZATION. *WHO global action plan for laboratory containment of wild polioviruses*. 2nd ed. WHO/V and B/03/11 Geneva: World Health Organization, 2003.

purpose of the inventory is to meet the country requirements defined by WHO for the certification of regions as polio-free, and to maintain a current list of laboratories to be notified about initiating the appropriate containment procedures one year after the global detection of the last wild poliovirus. The inventory is updated regularly and submitted for review and endorsement to the National and Regional Commissions for Certification of Polio Eradication. The Australian inventory also includes laboratories using OPV strains. The contacts are for Australia: www.health.gov.au and for New Zealand: www.moh.gov.nz.

Phase II, Global Certification, begins one year after no case has been detected globally. At this time, all laboratories wishing to retain wild poliovirus infectious or potentially infectious materials shall begin implementing biosafety measures appropriate for the laboratory procedures being performed (PC2/polio or PC3/polio containment procedures). All activities involving wild polio infectious materials, including storage, shall be carried out under PC3/polio containment. All activities that involve inoculating poliovirus-permissive cells or animals with potential wild polio infectious materials shall also be performed under PC3/polio containment. Other activities involving potential wild polio infectious materials may be conducted safely in a certified class I or II biological safety cabinet in a PC2/polio laboratory. Centrifuging such materials may be done in an open laboratory if sealed rotors or safety cups are used and these are only loaded and opened in a biological safety cabinet. A PC3/polio laboratory shall incorporate all the microbiological practices and procedures described for the PC2/polio laboratory. Major facility requirements are described in Clause 5.4.2. Alternatively, laboratories may contact a laboratory capable of meeting the required biosafety standards to arrange for transfer and storage of selected materials.

After two years passes with no reported cases globally, containment should be completed and documentation of implementation submitted. Global polio eradication will be certified after three years with no cases reported.

Phase III, Post Global Certification refers to a time in the future when post-eradication data and experiences suggest to some countries the need to consider the option of discontinuing polio immunization. When oral poliovirus vaccine immunization stops, with or without universal replacement with inactivated polio vaccine (IPV), the biosafety requirements for both wild and oral polio vaccine (OPV) viruses will become more stringent than those outlined in the second edition of the Global Action Plan, consistent with the consequences of inadvertent transmission of poliovirus from the laboratory to an increasingly susceptible community.

APPENDIX D

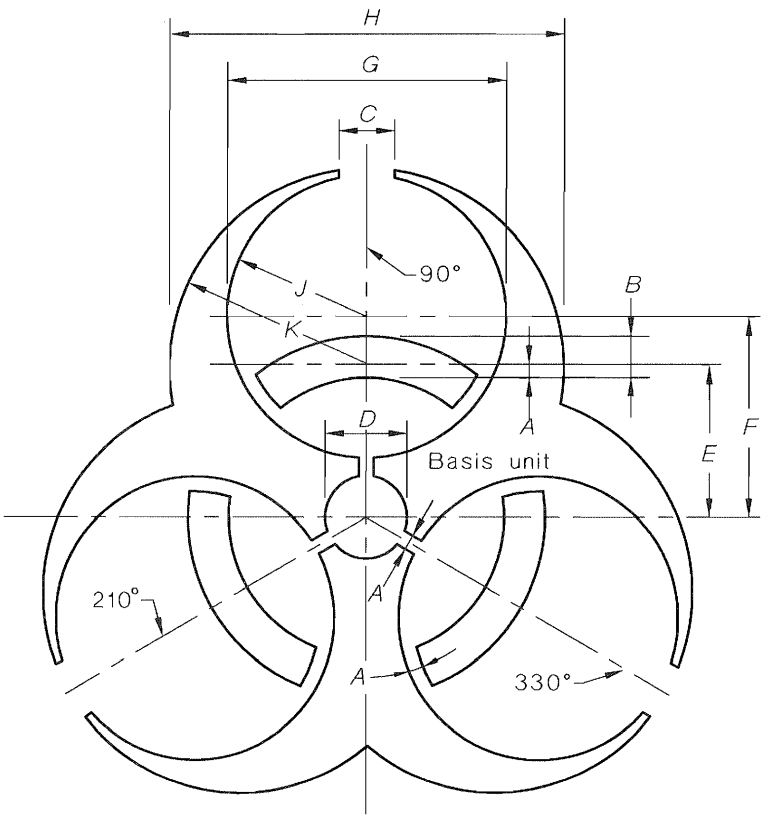
BIOLOGICAL HAZARD SIGNS

(Normative)

D1 BIOLOGICAL HAZARD SYMBOL

The biological hazard symbol shown in Figure D1 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 for all warning signs.



Dimension	A	B	C	D	E	F	G	H	J	K
Proportion	1	3.5	4	6	11	15	21	30	11.5	15

FIGURE D1 BIOLOGICAL HAZARD SYMBOL

D2 GENERAL MICROBIOLOGICAL LABORATORY SIGN

The sign for general microbiological laboratories shall be in the format shown in Figure D2, i.e. it shall show the biological hazard symbol shown in Figure D1 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.

FIGURE D2 LAYOUT FOR GENERAL MICROBIOLOGICAL LABORATORY WARNING SIGN (EXAMPLE FOR PC2 LABORATORY)

APPENDIX E

WATER AND GAS SUPPLIES TO CONTAINMENT FACILITIES

(Normative)

E1 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.

E2 WATER SUPPLIES

E2.1 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 E1:

(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. Protection may be shared for PC1 and PC2 facilities.

(c) To outlets within Class II BSC. 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. Protection may be shared for PC1 and PC2 facilities. Separate protection shall be provided to each PC3 or PC4 facility.

NOTE: 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.

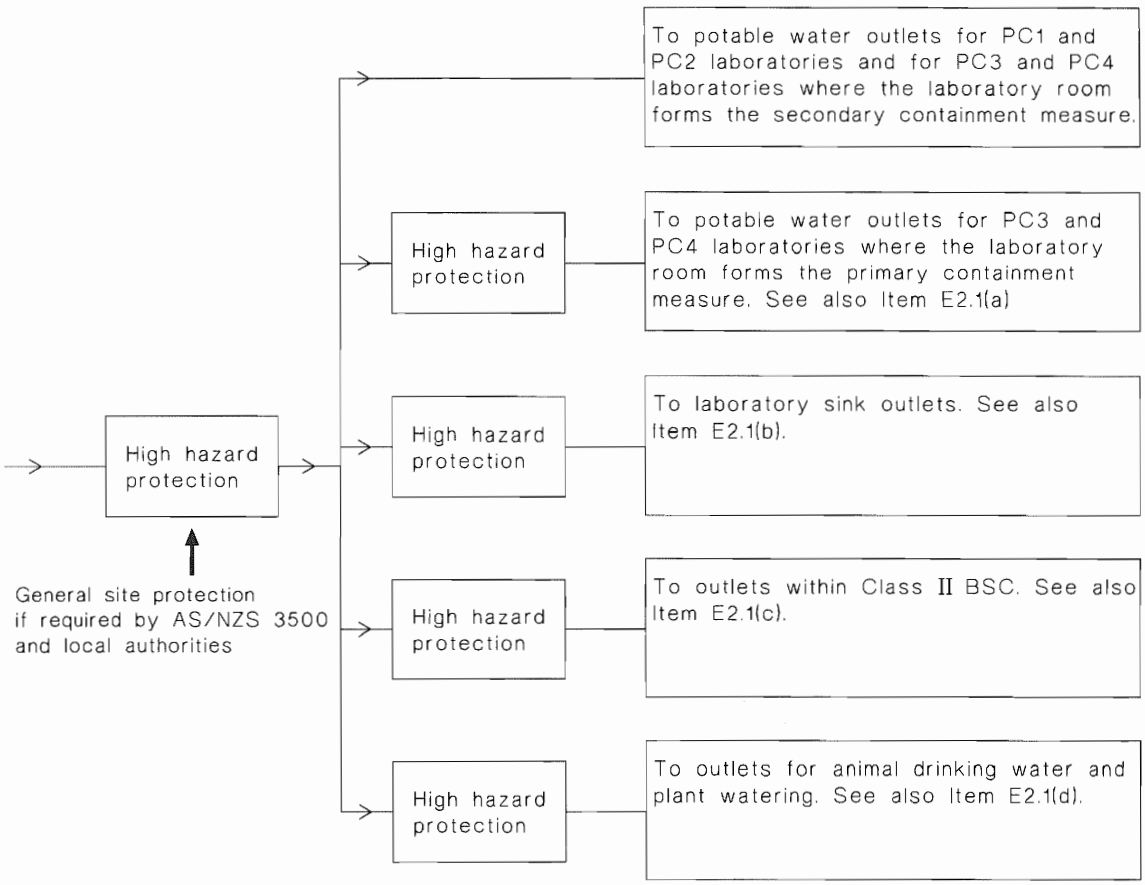


FIGURE E1 BACKFLOW PREVENTION FOR LABORATORY WATER SUPPLIES

E2.2 Looped services (e.g. water from reverse osmosis systems or demineralized water)

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.

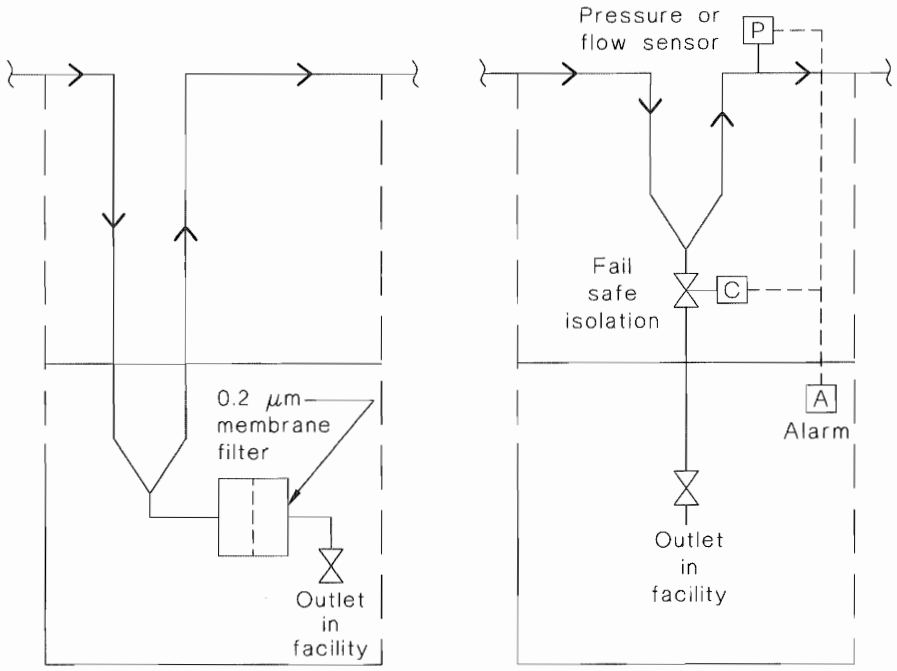
For BSC Class II and within PC3 and PC4 facilities where the room forms the primary containment measure (e.g. large animal facilities, plant facilities), looped service outlets should be avoided. The preferred method of supplying water is by carrying it in using containers that can be decontaminated 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 E2(a).

(b) Reverse flow protection including alarms shall be provided. See Figure E2(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 least 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.



(a) Filter option (b) Isolation option

FIGURE E2 BACKFLOW PREVENTION FOR LOOPED SERVICE OUTLETS

E3 GAS SERVICES

E3.1 General gas service requirements

The following general requirements 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.

E3.2 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 E3:

(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 Item E3.1(c).

(b) To outlets within Class II BSC. Protection may be shared within a single room. Separate protection shall be provided for each room.

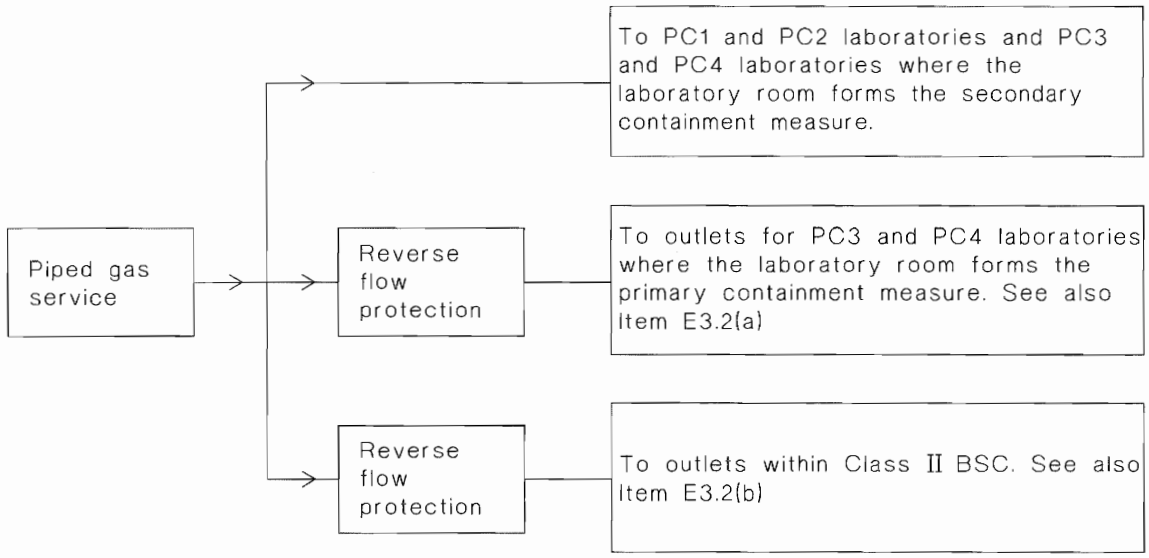


FIGURE E3 BACKFLOW PREVENTION FOR GAS SERVICES

APPENDIX F

CHEMICAL DISINFECTANTS

(Informative)

F1 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 Ref 1.14.

F2 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 Clauses 3.7 and 12.2.1).

F3 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.

F4 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.

F5 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.

Material safety data sheets (MSDS) should be obtained from the supplier or distributor for any chemical disinfectant used in the workplace. A request for the relevant MSDS should automatically accompany the initial order for materials. MSDS 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 persons have access to MSDS for the substances that are used in the workplace and that these are read and understood by those concerned. MSDS, as obtained from suppliers, should not be altered although additional information may be appended and clearly marked as such.

Tables F1 and F2 should be consulted for assistance when selecting disinfectants. Table F1 provides recommended applications for chemical disinfectants in microbiological facilities.

Table F2 provides a guide to the effectiveness of different classes of disinfectant against a range of microorganisms (see Reference 1.29). The disinfectants in Table F2 have been categorised according to the range of microorganisms that they are able to inactivate under optimum conditions:

(a) *Sterilants* Kill all viruses, fungi and bacteria, including their spores, given enough time.

(b) *High level disinfectants* Kill most microbial pathogens except large numbers of bacterial endospores.

(c) *Intermediate level disinfectants* Destroy vegetative cells including Mycobacteria, fungi and most viruses.

(d) *Low level disinfectants* Destroy vegetative bacteria and enveloped viruses.

Tables F1 and F2 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.

F6 PROPERTIES OF COMMONLY-USED DISINFECTANTS

F6.1 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 5000–10 000 p.p.m. (0.5–1%) available chlorine is required for the inactivation of HIV and hepatitis viruses in blood or serum (see 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.

NOTE: Information on diluting chlorine-containing solutions for disinfection purposes is provided in Attachment 4 to the Victorian Department of Human Services publication '*Guidelines for the investigation of gastrointestinal illness*' available at web address: www.health.vic.gov.au/ideas/diseases/gas_ill_index.htm.

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.

F6.2 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.

F6.3 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/m^3 (see 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 biological safety cabinets; 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: Further information on formaldehyde decontamination is available from Reference 1.21 and, for BSC, AS/NZS 2647 should be consulted.

F6.4 Glutaraldehyde

Glutaraldehyde (1,5-pentanedial) 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/m^3. 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.

F6.5 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.

F6.6 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 References 1.22 and 1.23). It is corrosive to metalware and damaging to fabrics but less so than is sodium hypochlorite of equivalent activity.

F6.7 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 (vapourised hydrogen peroxide) in air. A 30% to 35% aqueous solution of liquid hydrogen peroxide is typically flash vapourised 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.

F6.8 Chlorine dioxide

Chlorine dioxide is an oxidising 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. For further information see Reference 1.28.

F6.9 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 biological safety cabinets and not with equipment that is likely to produce sparks. In biological safety cabinets, alcohol disinfectants may be used from a dispensing bottle but should not be sprayed.

F6.10 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.

F6.11 Quaternary ammonium compounds

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.

F6.12 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 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.

F6.13 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.

F6.14 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 References 1.25 and 1.26.

F7 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'.

TABLE F1

SUMMARY OF RECOMMENDED APPLICATIONS FOR CHEMICAL DISINFECTANTS IN MICROBIOLOGICAL LABORATORIES

Site or equipment	Routine or preferred method or usage	Acceptable alternative
Benches and surfaces (not obviously contaminated)	Alcohols e.g. 70% *w/w* (= 80% *v/v*) ethyl or 60–70% *v/v* isopropyl—swabbed (See paragraph F6.9)	Synthetic phenolics* (See paragraph F6.10)
Biological safety cabinet (BSC) work surfaces	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 paragraph F6.1) *or* other disinfectant depending on the organism	For BSC with capture hoods, glutaraldehyde† (with cabinet fan operating)—swabbed (see AS/NZS 2647)(See paragraph F 6.4)
Room space eg laboratory or animal room, BSC before servicing or testing or after major spill	Formaldehyde vapour (see Paragraph F6.3)	Vaporised hydrogen peroxide (see paragraph F6.7) or Chlorine dioxide (see paragraph F6.8)
Centrifuge rotor or sealable bucket after leakage or breakage	Disinfection not the preferred method. Pressure steam sterilizing at 121°C for 15 min recommended (See Clause 10.6)	Glutaraldehyde† for 10 min *or* synthetic phenolics* for bacterial spills for 10 min(See paragraph F 6.10)
Centrifuge bowl after leakage or breakage	Glutaraldehyde† for 10 min (swabbed twice within the 10 min period then wiped with water))(See paragraph F 6.4)	Synthetic phenolics* for bacterial spills for 10 min)(See paragraph F 6.10)
Discard containers (pipette jars)	Chlorine disinfectant at 2 000–2 500 p.p.m. (0.2–0.25%),	Synthetic phenolics* for bacteriological work (changed weekly) *or* detergent with pressure steam sterilizing for virus work
Equipment surfaces before services or testing	Surfaces disinfected according to manufacturers' instructions	Alcohol (80% *v/v* ethyl or 60–70% *v/v* isopropyl) except when its flammability poses a hazard (See F 6.9)*or* glutaraldehyde† then water(see F6.4)
Gnotobiotic animal isolators	Peracetic acid at 2% *v/v* —swabbed (see F6.5)	
Hand disinfection	Chlorhexidine (0.5–4% *w/v*) in alcoholic formulations for 2 min(See F6.12)	Isopropyl (60–70% *v/v*) or ethyl alcohol (80% *v/v*)) (See F 6.9) with emollients or Povidone-iodine (0.75–1% av I) for 2 min(See F6.2)
Hygienic handwash	Chlorhexidine (4% *w/v*) in detergent formulation (or alcoholic formulations) for 15 s (See F6.12)	Detergent cleansers *or* soap for 15 s
Spills of blood/serum (or viral cultures)	High concentration chlorine at 5000–10 000 p.p.m. (0.5–1%) (See F6.1) for 10 min (active against hepatitis viruses and HIV)	Glutaraldehyde† for 10 min (See F6.4)
Spills of bacterial cultures	High concentration chlorine disinfectant at 5 000–10 000 p.p.m. (0.5–1%) *or* Iodophor* for 10 min (See F6.2)	Synthetic phenolics*(unaffected by organic load) for 10 min (See F6.10)

(continued)

TABLE F1 *(continued)*

Site or equipment	Routine or preferred method or usage	Acceptable alternative
Spills of bacterial cultures	High concentration chlorine disinfectant at 5000-10 000 p.p.m. (0.5 – 1%)* (See F6.1) *or* Iodophor* for 10 min (See F6.2)	Synthetic phenolics* (unaffected by organic load) for 10 min (See F6.10)
Animal cages	Wash with detergent followed by pressure steam sterilizing at 121°C for 15 min if infected (See Clause 10.6)	
Drains and animal rooms (surfaces)	Sodium hydroxide 1M	

* Dilute according to manufacturer's instructions.

† Glutaraldehyde as 2% *w/v* activated aqueous or 1% *w/v* glycol-complexed formulations.

TABLE F2

EFFECTIVENESS OF LIQUID OR GASEOUS DISINFECTANTS LISTED IN APPENDIX F6 AGAINST MICROORGANISMS AND PATHOGENIC AGENTS

Disinfectant/ Decontaminant	Optimum concentration	Minimum Contact time (min)[1]	Reference	Bacteria				Fungi	Viruses		Prions
				Gram positive	Gram negative	Endospores	Mycobacteria		Enveloped	Non-enveloped	
	Sterilants										
Formaldehyde (F6.3)	8%v/v in 80% ethanol	10	1.21	+	+	+	+	+	+	+	-
Glutaraldehyde (F6.4)	2%	10	1.30	+	+	+	+	+	+	+	-
Peracetic acid (F6.5)	2%	10		+	+	+	+	+	+	+	-
Vapourised Hydrogen peroxide (F6.7)	700 ppm = 1 mg/l	120	1.31	+	+	+	+	+	+	+	+[2]
Chlorine dioxide (F6.8)	1 mg/l	60		+	+	+	+	+	+	+	-
	High level disinfectants										
Peroxygen biocides (F6.6)	1%	10	1.22, 1.23	+	+	+	-	+	+	+[3]	-
Chlorine-releasing compounds (F6.1)	0.01-5%	10	1.20, 1.16	+	+	-	+[4]	+	+	+	+[4]
Ortho-phthalaldehyde (F6.14)	0.55%	5	1.25, 1.26	+	+	-	+	+	+	+	-

(continued)

TABLE F2 (*continued*)

Disinfectant/ Decontaminant	Optimum concentration	Minimum Contact time (min)[1]	Reference	Bacteria				Fungi	Viruses		Prions
				Gram positive	Gram negative	Endospores	Mycobacteria		Enveloped	Non-enveloped	
	Intermediate level disinfectants										
Iodine/Iodophor (F6.2)	0.5–2.5%	10		+	+	-	-	+	+	-	-
Alcohol (F6.9)	70–85%	10	1.32	+	+	-	+[5]	-	+	+	-
Phenolics (F6.10)	0.2-3%	10	1.33	+	+	-	+	+	+	-	+[6]
	Low level disinfectants										
Quaternary ammonium compounds (F6.11)	0.1%	10		+	+	-	-	-	+	-	-
Chlorhexidine (F6.12)	2%	1	1.24	+	+	-	-	-	+	-	-

1 For bacterial endospores, a contact time of up to 720 mins is required for inactivation

2 See 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 mins to achieve an effective level of decontamination

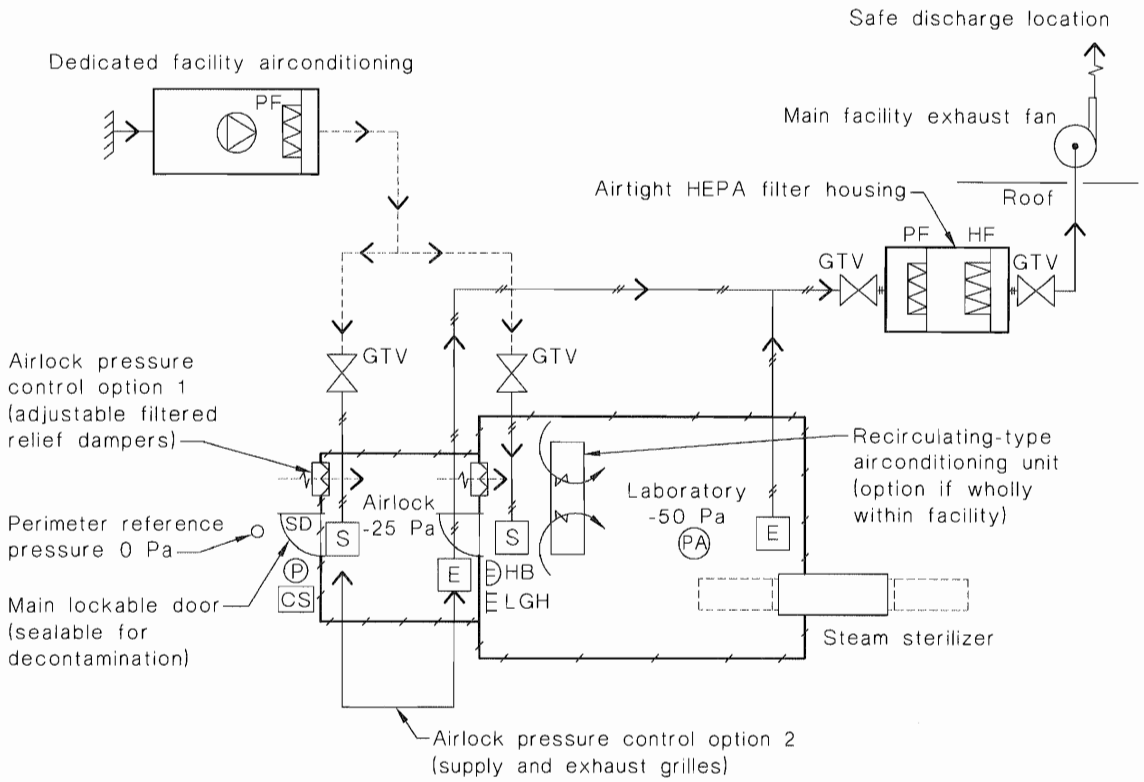
5 Only effective in the absence of sputum (See Reference 1.32)

6 See Reference 1.33

APPENDIX G

EXAMPLES OF RECOMMENDED LAYOUTS FOR PC3 AND PC4 FACILITIES

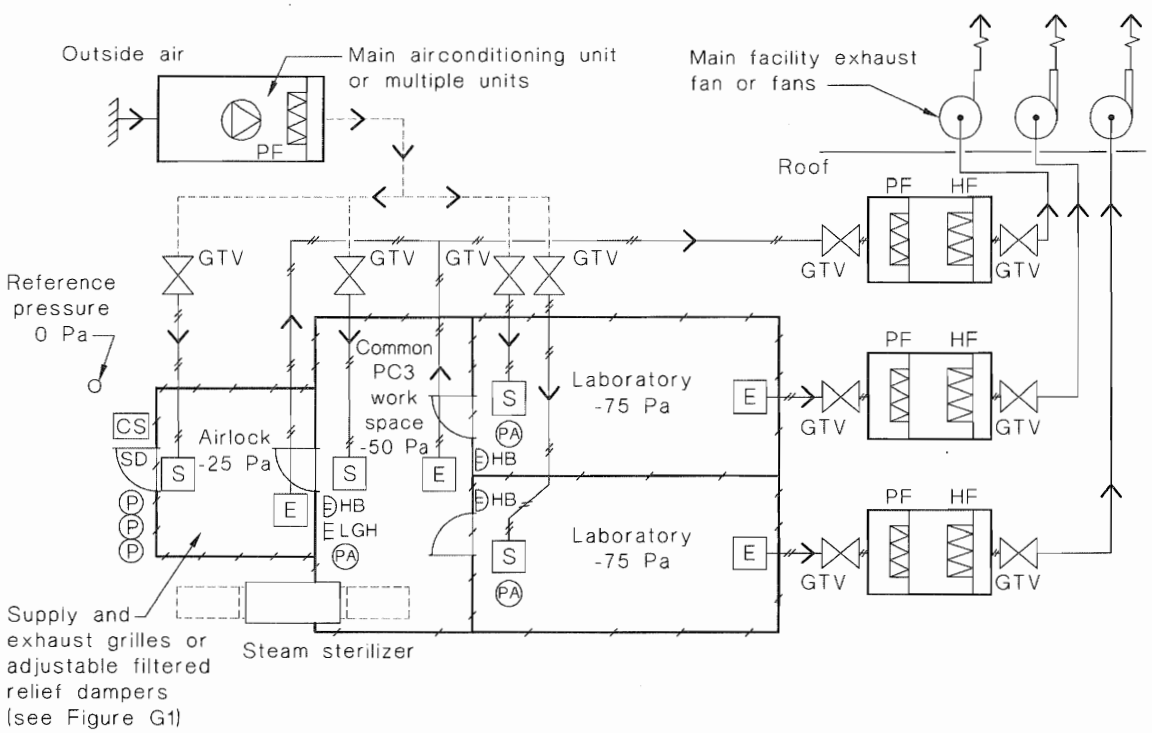
(Informative)



LEGEND:

- CS — Emergency airconditioning and exhaust system isolation switch
- GTV — Gastight air valve in duct
- Gastight duct (weld sealed)
- Well sealed duct
- Conventional duct
- S — Sealed supply air fitting (seal to room)
- E — Sealed exhaust air fitting (seal to room)
- P — Local indicating pressure gauge
- HB — Hand basin with hands-free mixer tap
- LGH — Laboratory gown hooks
- PF — Prefilter
- HF — HEPA filter
- PA — Audible pressure alarm
- Boundary of sealed PC3 facility (Airtight construction for decontamination capability)
- SD — Sealable door for decontamination purposes
- Adjustable filtered relief dampers (airlock pressure control option 1)

FIGURE G1 SIMPLE PC3 LABORATORY LAYOUT SHOWING DESIGN PRINCIPLES



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- CS — Emergency airconditioning and exhaust system isolation switch
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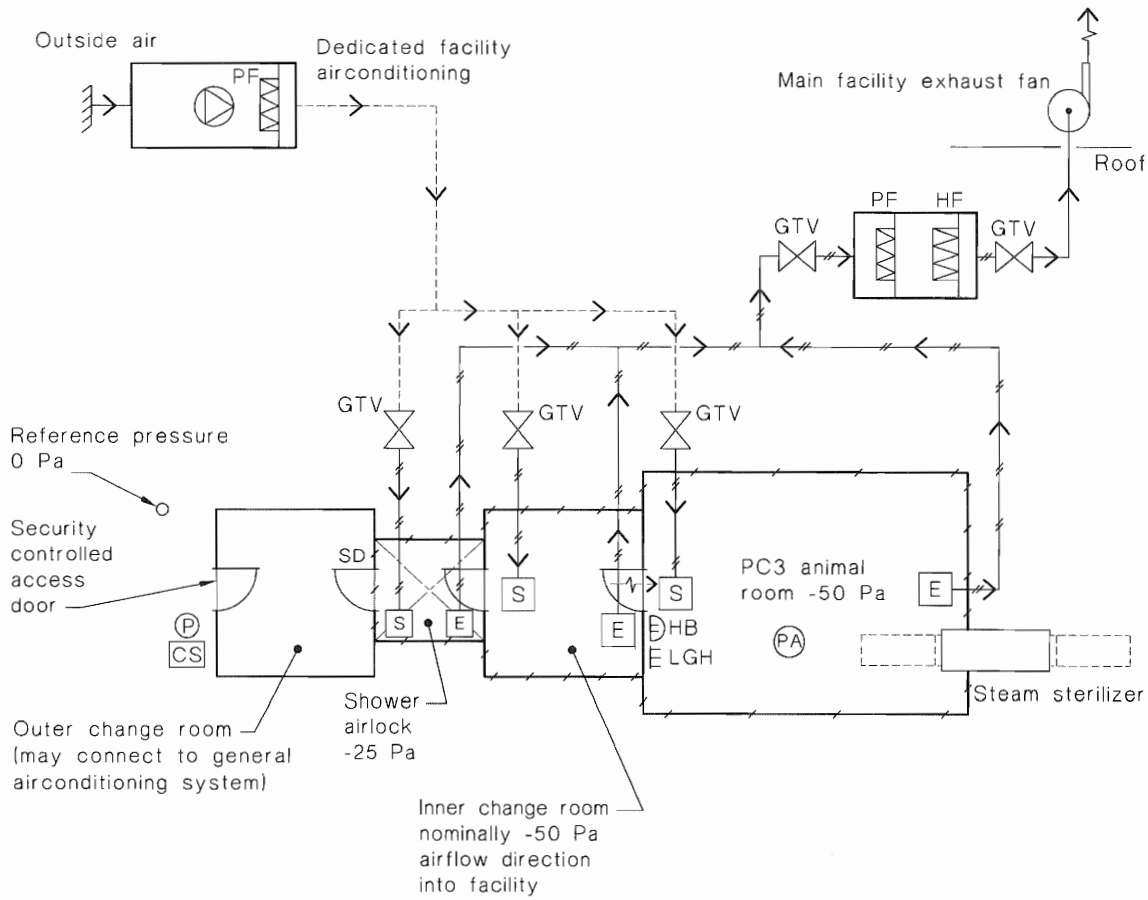
- Boundary of sealed PC3 facility (Airtight construction for decontamination capability)
- SD — Sealable door for decontamination purposes

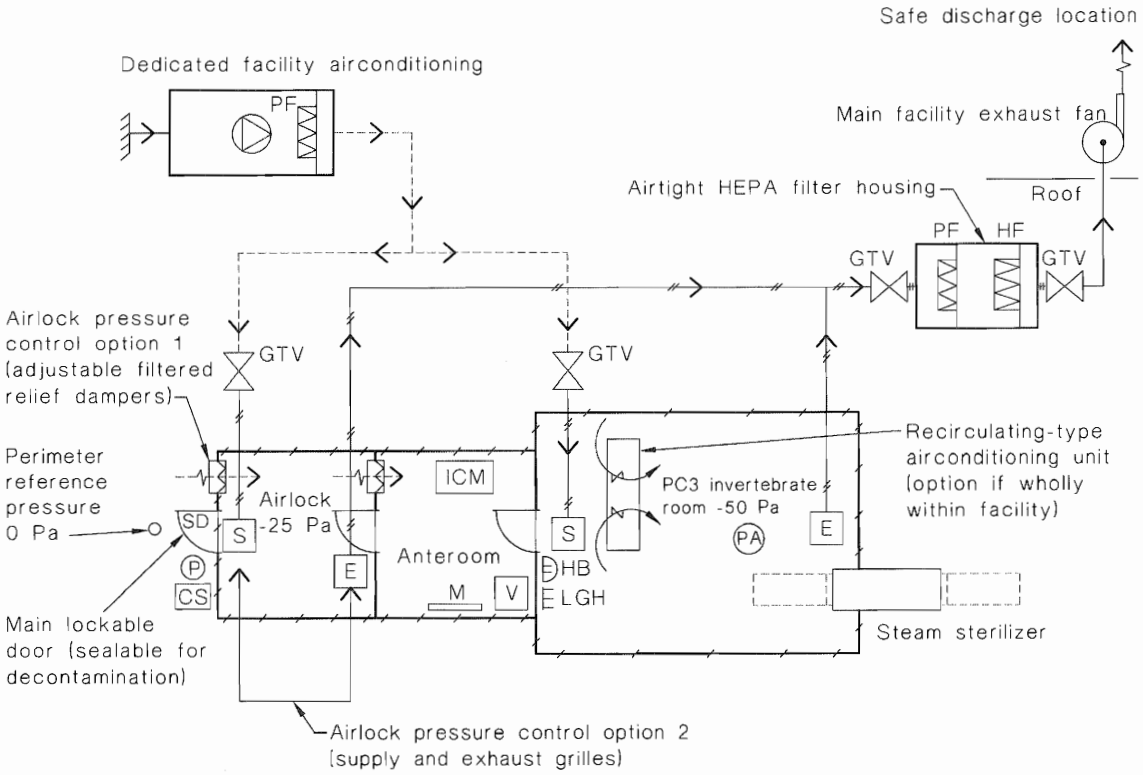
FIGURE G2 ADDITIONAL FEATURES FOR A MULTIPLE ROOM PC3 FACILITY



LEGEND:

- CS — Emergency airconditioning and exhaust system isolation switch
- GTV — Gastight air valve in duct
- Gastight duct (weld sealed)
- Well sealed duct
- Conventional duct
- S — Sealed supply air fitting (seal to room)
- E — Sealed exhaust air fitting (seal to room)
- P — Local indicating pressure gauge
- HB — Hand basin with hands-free mixer tap
- LGH — Laboratory gown hooks
- PF — Prefilter
- HF — HEPA filter
- PA — Audible pressure alarm
- Boundary of sealed PC3 facility (Airtight construction for decontamination capability)
- SD — Sealable door for decontamination purposes

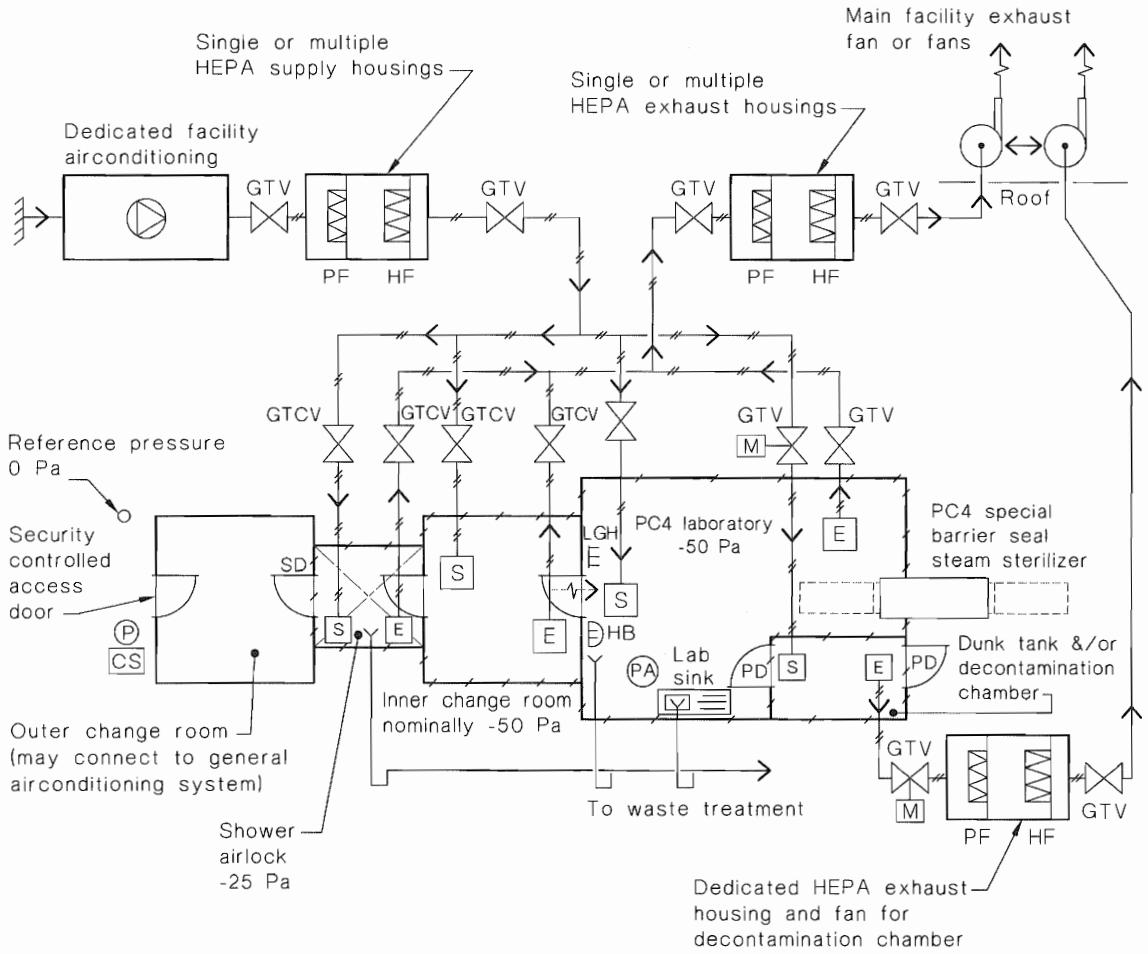
FIGURE G3 PC3 FACILITY WITH SHOWER (appropriate for animal facilities where the room is the primary containment measure)



LEGEND:

- CS — Emergency airconditioning and exhaust system isolation switch
- GTV — Gastight air valve in duct
- Gastight duct (weld sealed)
- Well sealed duct
- Conventional duct
- S — Sealed supply air fitting (seal to room)
- E — Sealed exhaust air fitting (seal to room)
- P — Local indicating pressure gauge
- HB — Hand basin with hands-free mixer tap
- ELGH — Laboratory gown hooks
- M — Mirror
- PF — Prefilter
- HF — HEPA filter
- PA — Audible pressure alarm
- Boundary of sealed PC3 facility (Airtight construction for decontamination capability)
- SD — Sealable door for decontamination purposes (outside door lockable)
- Adjustable filtered relief dampers (airlock pressure control option 1)
- ICM — Invertebrate control measure
- V — Vacuum device

FIGURE G4 PC3 FACILITY WITH ANTEROOM (appropriate for invertebrate facilities)



LEGEND:

- CS — Emergency airconditioning and exhaust system isolation switch
- GTV — Gastight air valve in duct
- Gastight duct (weld sealed)
- Well sealed duct
- Conventional duct
- S — Sealed supply air fitting (seal to room)
- E — Sealed exhaust air fitting (seal to room)
- P — Local indicating pressure gauge
- HB — Hand basin with hands-free mixer tap
- LGH — Laboratory gown hooks
- SD — Sealable door for decontamination purposes
- PD — Pneumatic (inflatable seal) door for containment and decontamination purposes
- GTCV — Gastight controllable air valve in duct
- GTV M — Actuated or motorized gastight air valve in duct
- PF — Prefilter
- HF — HEPA filter
- PA — Audible pressure alarm
- Boundary of sealed PC4 facility (Airtight construction for decontamination capability

FIGURE G5 PC4 FACILITY LAYOUT SHOWING DESIGN PRINCIPLES

APPENDIX H

RECOMMENDATIONS ON ACCEPTABLE ROOM AIRTIGHTNESS

(Informative)

H1 SCOPE

This Appendix provides recommendations on how to achieve acceptable room airtightness and a method for measuring air leakage.

H2 INTRODUCTION

All PC3 and PC4 facilities have a requirement for containment of aerosols and of gases used in decontamination.

H3 AEROSOL CONTAINMENT

Aerosols generated in the facilities listed in Paragraph H2 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 biological safety cabinets, 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 Reference 1.27.

(c) The containment facility structure provides a static barrier by being constructed of materials having a low permeability to air and decontaminating gases.

H4 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.

H5 DETERMINATION OF CONTAINMENT STRUCTURE INTEGRITY

Structural leakage theory for microbiological containment was developed by Graham W. Pickering* for the CSIRO Australian Animal Health Laboratory (AAHL). The theory allows leakage rates of aerosols containing microorganisms or decontamination gas to be simulated. The leakage coefficient β (m^3/Pa.s) is used to quantify structural air tightness. Smaller values of β result in more airtight structures. Figure H1 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*—described in the publication by G.W. Pickering.

(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 biological safety cabinets that act as the primary containment device within the laboratory structure.

H6 PRACTICAL APPLICATION OF CRITERIA

The recommended maximum leakage rate, β, for PC3 and PC4 laboratories is 10^{-5}, at a test pressure of 200 Pa (see Figure H1 and Paragraph H7). 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.

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* G.W. PICKERING. *ANAHL Analysis of Containment* Commonwealth of Australia: Department of Transport and Construction, 1982.

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. 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 600–800 p.p.m. (depending on the temperature) and an exposure period of 15 hours. This has been tested for space volumes up to 300 m^3. The methodology described in Paragraph F6.3 of Appendix F and 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.

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.

H7 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.

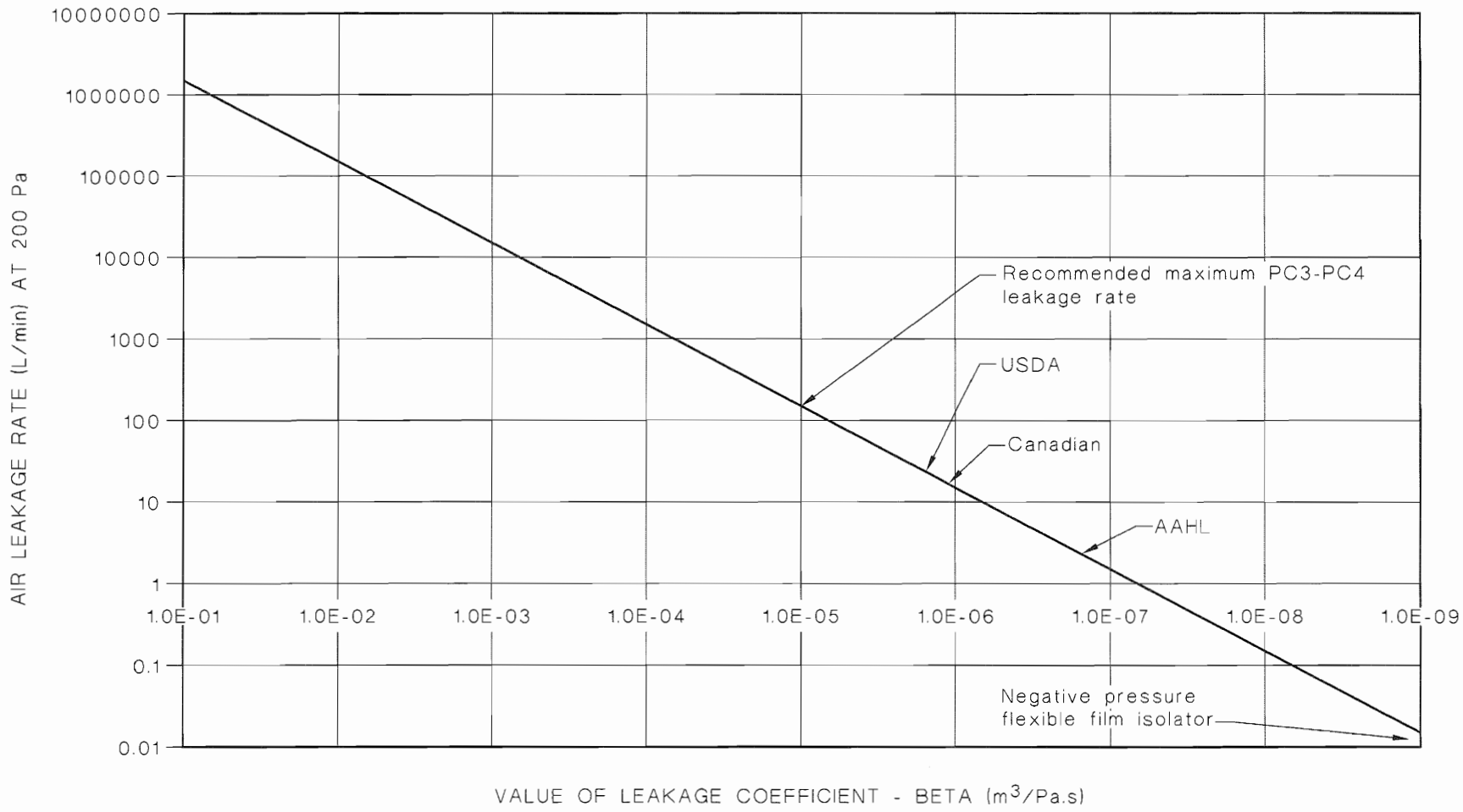

FIGURE H1 LABORATORY AIR LEAKAGE RATES AT 200 Pa DIFFERENTIAL PRESSURE

NOTE

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Standards Australia

Standards Australia is an independent company, limited by guarantee, which prepares and publishes most of the voluntary technical and commercial standards used in Australia. These standards are developed through an open process of consultation and consensus, in which all interested parties are invited to participate. Through a Memorandum of Understanding with the Commonwealth government, Standards Australia is recognized as Australia's peak national standards body.

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The first national Standards organization was created in New Zealand in 1932. The Standards Council of New Zealand is the national authority responsible for the production of Standards.
Standards New Zealand is the trading arm of the Standards Council established under the Standards Act 1988.

Australian/New Zealand Standards

Under a Memorandum of Understanding between Standards Australia and Standards New Zealand, Australian/New Zealand Standards are prepared by committees of experts from industry, governments, consumers and other sectors. The requirements or recommendations contained in published Standards are a consensus of the views of representative interests and also take account of comments received from other sources. They reflect the latest scientific and industry experience. Australian/New Zealand Standards are kept under continuous review after publication and are updated regularly to take account of changing technology.

International Involvement

Standards Australia and Standards New Zealand are responsible for ensuring that the Australian and New Zealand viewpoints are considered in the formulation of international Standards and that the latest international experience is incorporated in national and Joint Standards. This role is vital in assisting local industry to compete in international markets. Both organizations are the national members of ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission).

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