COMMITTEE CH-026

DR 07335

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Draft for Public Comment Australian/New Zealand Standard

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AS/NZS 2243.3:200X
Safety in laboratories
Part 3: Microbiological aspects and containment facilities
(Revision of AS/NZS 2243.3:2002)

STANDARDS Australia

STANDARDS NEW ZEALAND Paerewa Aotearoa

Draft for Public Comment
Australian/New Zealand Standard

The committee responsible for the issue of this draft comprised representatives of organizations interested in the subject matter of the proposed Standard. These organizations are listed on the inside back cover.

Comments are invited on the technical content, wording and general arrangement of the draft.

The preferred method for submission of comment is to download the MS Word comment form found at *http://www.standards.com.au/Catalogue/misc/Public Comment Form.doc*. This form also includes instructions and examples of comment submission.

When completing the comment form ensure that the number of this draft, your name and organization (if applicable) is recorded. Please place relevant clause numbers beside each comment.

Editorial matters (i.e. spelling, punctuation, grammar etc.) will be corrected before final publication.

The coordination of the requirements of this draft with those of any related Standards is of particular importance and you are invited to point out any areas where this may be necessary.

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

If the draft is acceptable without change, an acknowledgment to this effect would be appreciated.

When completed, this form should be returned to the Projects Manager, **Carol Foster** via email to **carol.foster@standards.org.au**.

Normally no acknowledgment of comment is sent. All comments received electronically by the due date will be put before the relevant drafting committee. Because Standards committees operate electronically we cannot guarantee that comments submitted in hard copy will be considered along with those submitted electronically. Where appropriate, changes will be incorporated before the Standard is formally approved.

If you know of other persons or organizations that may wish to comment on this draft Standard, could you please advise them of its availability. Further copies of the draft are available from the Customer Service Centre listed below and from our website at *http://www.standards.org.au/*.

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Draft for Public Comment

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Committee CH-026—Safety in Laboratories

Subcommittee CH-026-03 — Microbiology

DRAFT

Australian/New Zealand Standard

Safety in laboratories

Part 3: Microbiological aspects and containment facilities

(Revision of AS/NZS 2243.3:2002)

(To be AS/NZS 2243.3:200X)

This draft contains extensive revisions to provide specific risk groups for plant and invertebrate pathogens and to present requirements for animal, plant and invertebrate containment facilities separately to the requirements for laboratories. Major areas of change are listed in the Preface and the committee would appreciate specific comment on these areas of the draft.

Comment on the draft is invited from people and organizations concerned with this subject. It would be appreciated if those submitting comment would follow the guidelines given on the inside front cover.

This document is a draft Australian/New Zealand Standard only and is liable to alteration in the light of comment received. It is not to be regarded as an Australian/New Zealand Standard until finally issued as such by Standards Australia/Standards New Zealand.

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.

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 pathogens and for invertebrate pathogens.

(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 PC3 laboratory and PC3 animal facilities.

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 personnel hazards 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 aspects and containment facilities (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

The term ‘shall’ is used by Standards Australia and Standards New Zealand to indicate requirements that have to be met for compliance with this Standard. The term ‘should’ indicates a recommendation.

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.

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 aspects and containment facilities

SECTION 1 SCOPE AND GENERAL

1.1 SCOPE

This Standard sets out requirements, responsibilities and general guidelines relating to safety in laboratories and containment of microorganisms and prions where they are handled. It is intended for laboratories, including animal, plant and invertebrate containment facilities, whether 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 which may contain pathogenic microorganisms and prions are handled such as biochemistry and soil laboratories. This Standard should be read in conjunction with AS/NZS 2243.1, AS/NZS 2982.1, the Building Code of Australia and other relevant Parts of the AS/NZS 2243 series.

NOTES:

1 In this context, microorganism means protozoa, fungi, free-living bacteria, cell-dependent bacteria and viruses.

2 This Standard uses the term ‘containment facility’ when referring to ancillary sections of laboratories. Historical terms such as plant houses, glass houses, insectaries and animal houses are no longer used. For example, an animal house is referred to as an animal containment facility.

3 This Standard does not provide detailed guidance for genetic modification work for which the appropriate body should be consulted. See Clause 2.4.

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

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 safety when microbiological work is carried out and prevent the unintended spread of microorganisms.

1.3 REFERENCED DOCUMENTS

A list of referenced and related documents is given 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.

1.4.2 Airlock

Space with two doors designed to limit pressure fluctuations within a containment facility during entry and exit.

1.4.3 Anteroom

Space used during access and egress to a containment facility 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 for the operator and environment.

1.4.6 Biological containment for genetic modification

The use of particular strains of the organism which have a reduced ability to survive or reproduce in the open environment to prevent the spread of genetically modified organisms outside the laboratory. The objective of biological containment is to minimize both the survival of the host and vector outside the laboratory and the transmission of the vector from the propagation host to a non-laboratory host.

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 which 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 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 laboratories. An institutional biological safety committee (IBSC) is the New Zealand equivalent of an IBC.

1.4.9 Change room

1.4.9.1 *Inner change room*

Space used by personnel for donning facility clothing and PPCE on entry and for removing it on exit.

1.4.9.2 *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.

1.4.10 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.

1.4.11 Containment

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

1.4.12 Containment facility

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

1.4.13 Cross-contamination

The undesirable transfer of microorganisms from one source to another.

1.4.14 Decontamination

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

1.4.15 Diagnostic specimen

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

1.4.16 Disinfectant

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

1.4.17 Environmental Risk Management Authority (ERMA)

The New Zealand Government statutory body responsible for new organisms (including genetically modified organisms), under the Hazardous Substances and New Organisms (HSNO) Act 1996 (Reference 1.1).

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 9.10.1.

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 Microbiological hazard

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

1.4.22 Office of the Gene Technology Regulator (OGTR)

The Australian regulatory agency responsible for a national scheme to regulate dealings with genetically modified organisms (GMOs).

NOTE: Technical advice is supplied to the OGTR by the Gene Technology Technical Advisory Committee (GTTAC).

1.4.23 Pathogen

A microorganism capable of causing disease in a host.

1.4.24 Risk assessment

Risk assessment is 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.

NOTES:

1 When conducting a risk assessment for adverse outcomes that may arise from the use of microorganisms that can infect humans, animals or plants, a number of contributory factors that may influence the risk estimate should also be considered. This list includes but is not limited to—

(a) the presence or absence of the organism in Australia and New Zealand;

(b) host range of the organism;

(c) pathogenicity, virulence and toxicity of the organism;

(d) route of infection and mode of transmission of the organism;

(e) concentration and volume of the organism;

(f) minimum infective dose of the organism;

(g) presence of a suitable host;

(h) stability and viability of the organism both inside and outside a suitable host;

(i) availability and efficacy of prophylaxis; and

(j) economic and environmental consequences.

2 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.

1.4.25 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.

1.4.26 Sterile

The state of being free from viable microorganisms.

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

1.4.27 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.

1.4.28 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.

SECTION 2 ORGANIZATION AND RESPONSIBILITY

2.1 RESPONSIBILITY

2.1.1 Management policy

Management shall provide staff with a policy statement on laboratory safety, and recognize the special hazards associated with microbiology laboratories.

2.1.2 Management responsibility for the implementation and monitoring of biocontainment procedures

As an overall principle under occupational health and safety (OHS) laws in the States, Territories and Commonwealth of Australia and under comparable law in New Zealand, the employer is responsible for ensuring that the workplace is safe and free from risks to health. In practice, the primary responsibility for this rests with senior management (e.g. the Director or Chief Executive Officer, and Executive in large clinical diagnostic laboratories or research institutes or the Vice Chancellor and Executive in university settings).

In the microbiology laboratory, meeting this responsibility requires that no research, teaching or operational work with biohazards be undertaken until a risk assessment of the work is conducted and it is demonstrated that any hazards are controlled.

The precise form of the 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.

Consequently, a universally applicable plan for these organizational arrangements is not offered but the following guidelines are presented to assist management's task of meeting workplace health and safety obligations. These guidelines are analogous to those devised by the OGTR for recombinant DNA work and are provided for consideration when setting in place arrangements tailored to the needs of a particular institution.

The central element of such arrangements is a Biosafety Committee (BC). In large institutions (e.g. multidisciplinary clinical diagnostic laboratories or teaching and research laboratories with substantial microbiological activity) an overarching BC might have three component, dependent subgroups or working parties, namely—

(i) infective biohazards;

(ii) gene technology affairs; and

(iii) physical, chemical and radiation safety.

The convenors of the subgroups should be *ex officio* members of the BC. The BC should have as its chair the senior manager or chief executive of the institution to ensure that —

(A) all reports to and from outside bodies (e.g. Health Department, the OGTR) are seen, accepted or progressed at senior level;

(B) the BC has equal standing with other core institutional committees to ensure high level advocacy to secure resources for development and maintenance of biocontainment facilities; and

(C) decision making is impartial, free of the conflict of interest which might arise with a committee chair based in a subdepartment or division of the institution.

In selecting other members of the BC, due regard should be taken of local OHS regulations requiring certain classes of membership (e.g. staff or union representatives, members of the public). Other members of the BC may comprise an engineer with experience of biocontainment facilities, a senior microbiologist and the person in charge of veterinary services (or another person in charge of animal facilities and concerned with the animal ethics committee). The microbiological safety officer (Clause 2.1.3) and the manager of the research secretariat for the institution might also attend BC meetings.

To reduce the staff time required for operations of a large BC of this type, meetings should be held regularly but infrequently to receive periodic reports from its subgroups. Provision should be made for extraordinary meetings to deal with unexpected problems. Close routine monitoring of infectious biohazards, at laboratory level, should be undertaken by the appropriate subgroup. While the structure of the gene technology subgroup and that for physical, chemical and radiation hazards are set out in OGTR regulations and guidelines and OHS regulations, the infectious biohazard subgroup should comprise a convenor, a bacteriologist, a virologist and a safety officer.

In smaller institutions, the two layers of the BC and subgroups are likely to be combined into one committee with membership supplemented as needed by microbiologists and other experts from outside the institution.

The terms of reference of the BC in relation to infective biohazards should be—

(1) assessment of the microbiological training of newly-recruited staff along with arrangement of any remedial training;

(2) through its subgroups, overall monitoring and surveillance of the continuing implementation of Standards and guidelines;

(3) review, via the infective biohazard subgroup, of safety audits organized by the microbiological safety officer;

(4) consideration of the implications of microbiological components of research proposals for grant funding of groups in the institution;

(5) inspection, audit and any licensing of laboratories working with Risk Group 2, Risk Group 3 and Risk Group 4 organisms;

NOTE: The involvement of an external consultant for the design and approval of Physical Containment Level 3 and 4 facilities is advisable.

(6) review of accident reports; and

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

2.1.3 Safety officer responsible for microbiology

In a self-contained microbiology laboratory, the general safety officer might carry out the tasks of the microbiological safety officer. The safety officer or the person responsible for OHS, in association with the laboratory supervisor, shall ensure the following actions are carried out:

(a) Advising management on the need for safety equipment.

(b) Advising management on the design of new laboratory facilities.

(c) Coordinating and organizing the safety program.

(d) Preparing a laboratory safety manual detailing safe procedures relevant to the type of work in the laboratory.

(e) Investigating accidents in the laboratory.

NOTE: See Appendix B and AS 1885.

(f) Ensuring that new members of staff are given clear directions on safety matters as part of their induction.

(g) Advising management, in accordance with specialized medical advice, on the need for prophylactic inoculation of staff (see Clause 2.2.4).

(h) Training and advising staff in safety regulations and decontamination procedures.

(i) Providing the names and after-hours telephone numbers of senior staff and the safety officer.

The general safety officer, who may lack knowledge of microbiology, may be advised on specialized matters by the senior microbiologist or the microbiology safety adviser on the biosafety committee.

2.1.4 Laboratory supervisor

The laboratory supervisor shall ensure that safe procedures are documented and put into practice. The laboratory supervisor shall implement initial and continuing training programs, ensure laboratory staff are supervised and ensure maintenance is carried out in accordance with safe procedures. The laboratory supervisor should also ensure that casual visitors do not have unrestricted access to the laboratory. See also Clause 4.5.7.

2.1.5 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 HEALTH MANAGEMENT

2.2.1 General

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

2.2.2 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 laboratory supervisor (see Clause 2.6). 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.

2.2.3 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, who can access it for testing, who may order tests, who evaluates the tests and who can have access to the results.

2.2.4 Immunization

The latest edition of *The Australian Immunisation Handbook* published by the NHMRC should be consulted. It is recommended that vaccination to Australian recommendations should apply. This includes immunization against diphtheria, tetanus, measles, mumps, rubella and poliomyelitis. Staff working with agents infectious for humans should also be vaccinated against hepatitis B.

Where additional appropriate vaccination is available, this should be considered and discussed with staff, with acknowledgement of any potential side effects. Recommendations should be based on levels and frequency of potential exposures. Vaccines are available against influenza, hepatitis A, meningococcal infection (excluding type B), typhoid, Q fever, plague, yellow fever, anthrax, Australian bat lyssavirus (ABL) and rabies, and Japanese encephalitis.

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 BCG confounds TST testing but not the TB gamma interferon assay (see Reference 1.2). Staff members with negative test results should be retested on an annual basis (see the NTAC *Guidelines for Australian Mycobacteriology Laboratories*).

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

2.2.5 High risk persons

Persons who are immuno-suppressed, immuno-compromised, or otherwise unduly vulnerable to infection, such as persons who are pregnant or 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.

2.2.6 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). The precise steps taken for protection will vary, depending on the microorganisms to which the woman may be exposed. Medical opinion may be required.

2.3 QUARANTINE MATERIALS

2.3.1 Australia

The Australian Quarantine and Inspection Service (AQIS) requires that all institutions wanting to import biological materials obtain a permit for all *in-vitro* work, and *in-vivo* work with laboratory animals.

For work involving *in-vivo* use of imported biological materials in non-laboratory animals, an additional permit is required. Also, AQIS carries out audits of premises where such work is to be conducted and register the premises if they fulfil requirements.

For further information, contact—

Biologicals Unit

Australian Quarantine and Inspection Service

GPO Box 858

CANBERRA ACT 2601

Website: www.aqis.gov.au

2.3.2 New Zealand

In New Zealand, the Ministry of Agriculture and Forestry (MAF) Biosecurity Authority controls the import of biological materials and post-entry conditions (see Reference 1.3).

For further information, contact—

Import Management

Biosecurity Authority

Ministry of Agriculture and Forestry

Box 2526

Wellington New Zealand

Website: www.maf.govt.nz

2.4 LABORATORIES FOR GENETIC MODIFICATION

2.4.1 Australia

Under the *Gene Technology Act (Commonwealth) 2000*, work with genetically modified organisms (GMOs) in Australia is regulated. In general, the regulations require work with GMOs to be conducted in facilities that meet and are certified as complying with OGTR *Guidelines for the certification of facilities/Physical containment requirements.*

Organizations that are proposing to undertake work of this type shall contact OGTR at the following address before any work is commenced:

Office of the Gene Technology Regulator

MDP 54

PO Box 100

WODEN ACT 2606

Website: www.ogtr.gov.au

2.4.2 New Zealand

In New Zealand, genetically modified organisms are regulated by the Environmental Risk Management Authority. The *Hazardous Substances and New Organisms (Low-risk Genetic Modifications) Regulations* and the *Hazardous Substances and New Organisms Amendment Act* shall be consulted (References 1.4 and 1.5).

Laboratories should consult—

ERMA New Zealand

PO Box 131

Wellington

Email: enquiries@ermanz.govt.nz

Website: www.ermanz.govt.nz

Work involving genetically modified organisms shall be carried out in accordance with controls set by ERMA or the IBSC and MAF Biosecurity Authority Standard 154.02.17 (Reference 1.6). Such work shall be carried out in MAF-approved containment facilities complying with this Standard.

2.5 LABORATORY BIOSECURITY

Global events in the recent past have highlighted the need to protect laboratories and the materials they contain from being intentionally compromised in ways that may harm people, livestock, agriculture or the environment. 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. A specific laboratory biosecurity program should be prepared and implemented for each facility according to the requirements of the facility, the type of laboratory work conducted and the local conditions. This should have input from all staff. Measures should include a secure inventory of all microorganisms, including such information as location and access. All personnel should be trained in biosecurity measures. Regular reviews and updating of procedures should be carried out with checks for compliance.

2.6 INCIDENT/ILLNESS REPORTING

Where an incident has occurred in the laboratory and an injury or illness occurs, priority shall be given to the care of the injured or ill person. Consideration should then 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. The incident should be reported verbally to the supervisor as soon as 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 in the laboratory with no injury to personnel, but with potential for contamination from infectious material, it should immediately be reported verbally to the supervisor. The incident should be documented once the appropriate clean-up procedure has been implemented. (See Section 8 dealing with spill clean-up.)

Incidents involving genetically modified organisms or recombinant-DNA shall be reported to the OGTR in Australia or ERMA in New Zealand.

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 that can be used for this purpose.

2.7 EMERGENCY PREPAREDNESS

2.7.1 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.

2.7.2 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.

SECTION 3 DEGREE OF HAZARD FROM MICROORGANISMS

3.1 GENERAL

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

Microorganisms vary widely in their ability to infect humans and animals or to spread in the environment. There is obvious, but varied, risk to laboratory staff from work with microorganisms isolated from or infecting humans. With regard to microorganisms infecting animals, many do not cause human disease, but some, the zoonoses, are responsible for serious human infections.

While most microorganisms infecting arthropods do not cause human disease, there are some that are capable of causing infection following transmission by bites or from excreta. The arthropods are then said to be vectors of disease, for example, mosquitoes may transmit arboviruses and lice may transmit rickettsia.

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.

Different families or genera of microorganisms vary widely in their infectivity for the operator when handled in the laboratory. In part this reflects, among other factors, 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 size of the minimal dose required to produce infection and the ability of the microorganism to overcome intrinsic immune and other defences of the host.

Historically, surveys of the causes of laboratory-acquired infections 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 such risks.

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 infective 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 infective by the aerosol-respiratory tract route 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 and route.

Clauses 3.2 to 4.7 describe—

(a) the classification of microorganisms by risk group based, when possible, on past experience with laboratory infections or on microbiologically-informed prudence when a newly-discovered microorganism of uncertain infective potential has to be handled; and

(b) the classification of laboratories, physical containment equipment, laboratory design and procedures to be followed when working with microorganisms classified at the various risk groups.

3.2 CLASSIFICATION OF INFECTIVE MICROORGANISMS BY RISK GROUP

3.2.1 Human and animal pathogens

Classifications of 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 1.7, 1.8, and 1.9). The World Health Organization (WHO) suggests each country draw up risk groups according to the microorganisms encountered within its boundaries (see Reference 1.10). The following classification has been drawn up 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 pathogen that can cause human or animal disease, but is unlikely to be a serious hazard 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 community risk)*—a pathogen that usually causes serious human or animal disease and may present a serious hazard to laboratory workers. It could present a 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 pathogen that usually produces life-threatening human or animal disease, represents a serious hazard to laboratory workers and is readily transmissible from one individual to another. Effective treatment and preventive measures are not usually available.

3.2.2 Plant pathogens

The containment of plant pathogens is primarily concerned with avoiding risk to the environment. Plant pathogens are infectious agents that attack plants and include fungi, bacteria, viruses, viroids, rickettsiae, phytoplasmas and nematodes.

Factors considered in relation to the risk from plant pathogens are—

(a) the economic or ecological impact;

(b) the pathogen'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 different risk groups are used to manage risks posed by plant infective microorganisms:

(i) *Risk Group 1*—a plant infective microorganism that is endemic and widely distributed. Effective treatment and preventive measures are available.

(ii) *Risk Group 2*—a plant infective microorganism that presents a moderate hazard to plants. Risk Group 2 microorganisms include plant infective microorganisms that are endemic but not widely distributed and those that are exotic but have a limited ability to spread without the assistance of a vector.

(iii) *Risk Group 3*—a plant infective microorganism that is exotic and presents a significant hazard to plants and has the potential to have a significant economic impact on an industry, an ecological community or a region. Risk Group 3 microorganisms have a limited ability to spread without the assistance of a vector.

(iv) *Risk Group 4*—a plant infective microorganism that presents a highly significant hazard to plants and has the potential to have a significant economic or ecological impact on the national economy or the environment. Risk Group 4 microorganisms are exotic and may be readily spread naturally without the assistance of a vector (e.g. via wind-borne propagules).

3.2.3 Invertebrate pathogens

There are two critical aspects to invertebrate containment—

(a) prevention of the escape of invertebrates and invertebrate pathogens, at any life stage where this presents a hazard; and

(b) prevention of the spread of human, animal or plant pathogens by invertebrates capable of acting as vectors.

Invertebrate pathogens 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 from invertebrates are—

(i) the risk to facility personnel;

(ii) the potential economic or ecological impact;

(iii) geographical distribution;

(iv) suitable climatic conditions for development;

(v) host range;

(vi) the size of the organism, and consequent ease of detection;

(vii) ability to disperse;

(viii) use in the facility, *in-vitro* or *in-vivo*;

(ix) resistance to pesticides, especially for exotic invertebrates; and

(x) potential to be carrying exotic or pesticide resistant parasites.

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

(A) *Risk Group 1*—invertebrates that are endemic and widely distributed. These invertebrates do not present any risk of infection to facility personnel and do not present a hazard to the environment. Invertebrates in this risk group would not be acting as vectors for any human, animal or plant pathogens that are themselves above Risk Group 1. Effective treatment and preventive measures are available.

(B) *Risk Group 2*—invertebrates that present a moderate hazard to facility personnel or to the environment. Invertebrates in this risk group would not be acting as vectors for any human, animal or plant pathogens that are themselves above Risk Group 2. These include invertebrates that are endemic but are not widely distributed and invertebrates that are exotic but have a limited ability to disperse and are easily detected visually.

(C) *Risk Group 3*—invertebrates that are exotic and present a significant hazard to either facility personnel or the environment or both. Invertebrates in this risk group would not be acting as vectors for any human, animal or plant pathogens that are themselves above Risk Group 3. These invertebrates are readily able to disperse but would easily be detected visually, and have the potential to have a significant economic impact on an industry, an ecological community or a region or to cause harm to facility personnel. Risk Group 3 is the minimum recommended level when dealing with exotic invertebrates of unknown pathogenicity, insecticide resistance or that may be carrying unknown exotic parasites.

(D) *Risk Group 4*—invertebrates that are exotic and present a highly significant hazard to facility personnel, the environment or both. These invertebrates may be readily able to disperse and may be difficult to detect visually. They may have the potential to have a significant economic or ecological impact on the national economy or the environment or to cause major harm to facility personnel.

3.3 DIAGNOSTIC SPECIMENS

Diagnostic specimens from humans or animals would normally be regarded as Risk Group 2 and shall be handled in Physical Containment Level 2 facilities. This applies in all microbiology and other pathology laboratories, e.g. for haematology and biochemistry. If a microbial pathogen of a higher risk group is isolated from a specimen, it shall be handled according to the corresponding risk group, and at the appropriate physical containment level. All diagnostic samples shall be treated with care as they may contain multiple types of pathogens. For a description of ‘Standard Precautions’, see Clause 4.5.8.

3.4 CULTURES—TRANSFER BETWEEN INSTITUTIONS AND PC LEVELS

Cultures are regularly transferred between institutions and PC levels and problems have occurred relating to cross-contamination and inactivation.

It is strongly recommended that upon receipt of ‘pure’ cultures, tests are carried out prior to use to ensure they are in fact pure cultures. There have been instances where these cultures have been cross-contaminated with other higher risk organisms and other instances of laboratory-acquired infections caused by transfer of ‘vaccine’ or ‘inactivated’ strains that contained virulent strains of cross-contaminating microorganisms.

Also, if infectious materials are inactivated prior to removal to a lower Physical Containment (PC) level or prior to transfer between institutions, the 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.

3.5 WORK WITH HUMAN OR ANIMAL CELL LINES

Work with cell lines has the potential to be hazardous to laboratory workers, depending on the source of the cells and the work that is being carried out. 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.

All cells should be autoclaved or chemically inactivated before disposal.

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

3.6 RISK-GROUPING OF MICROORGANISMS BY TYPE

3.6.1 General

Tables 3.1 to 3.8 list examples of microorganisms in Risk Groups 2 to 4. The Risk Group classifications are appropriate for small-scale laboratory operations with microorganisms of Risk Groups 2 and 3 listed in Tables 3.1 to 3.7. Where larger volumes or very high concentrations of the microorganisms are to be handled, the risk of infection can be higher and additional precautions or an increase in physical containment level may be appropriate. A risk assessment shall be conducted to determine if the work needs to be conducted with additional precautions or in a higher level of physical containment.

No table is provided for microorganisms belonging in Risk Group 1, as the number of relevant microorganisms is large. To assist those wishing to use safe microorganisms for student work, typical examples are microorganisms living in soil, such as *Azotobacter* sp., the vinegar-producing microorganism *Acetobacter* sp. and brewer's and baker's yeast. Some microorganisms that are regarded as part of the normal flora of humans or animals may be pathogenic for immuno-compromised persons.

3.6.2 Bacteria, Chlamydiae, Rickettsiae and Mycoplasmas

Most of these 'pathogenic' microorganisms belong to Risk Group 2 with a small number in Risk Group 3. Table 3.1 sets out a list of examples of Risk Group 2 microorganisms and special precautions are indicated in footnotes to the Table. Table 3.5 sets out examples of Risk Group 3 microorganisms and relevant special precautions. In addition to these special precautions, reference should be made to the work practices specified for each level of physical containment, PC1, PC2 and PC3 in Clauses 4.4.4, 4.5.7 and 4.6.8 respectively.

Guidelines for Australian Mycobacteriology Laboratories published by the National Tuberculosis Advisory Committee specifies requirements for collection, handling and culture of specimens for mycobacteria. PC2 containment with additional equipment and work practices is allowed for laboratories performing less than 5000 cultures a year. Those laboratories undertaking more than 5000 cultures per year, performing susceptibility tests or knowingly handling multidrug resistant tuberculosis strains should have PC3 facilities.

3.6.3 Parasites

Many parasites are regarded as Risk Group 2, with respect to their infective 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 sets out a list of examples of Risk Group 2 parasites.

3.6.4 Fungi

Risk Group 2 and Risk Group 3 are restricted to fungi that may pose a hazard for healthy persons. Fungi that infect following traumatic inoculation, e.g. *Phialophora verrucosa*, and *Pseudoallescheria boydii*, together with a large number of fungi normally saprophytic but which cause infections in the compromised host, are excluded and are classified in Risk Group 1. Unless otherwise stated, all fungi from clinical specimens should be handled at Physical Containment Level 2. Table 3.3 lists fungi of Risk Group 2 and Table 3.6 lists those of Risk Group 3.

3.6.5 Viruses

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

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

3.6.6 Exotic animal viruses

Table 3.9 lists some animal viruses which are exotic to Australia. Some of these viruses are potentially infectious to humans. In Australia, viruses in the list currently shall be handled only at the CSIRO Australian Animal Health Laboratory.

3.6.7 Plant and fish pathogens

Plant and fish pathogens are an infrequent cause of disease in humans but should be handled with good microbiological practices. While the majority of endemic plant pathogens may be classified as Risk Group 1 or 2, other classification groups may be appropriate for some plant pathogens, e.g. those not already present in that country. For plant pathogen work in New Zealand, the registers of unwanted organisms prepared by MAF shall be consulted.

NOTE: These registers are available electronically at the web address:

www.biosecurity.govt.nz/commercial-imports/unwanted-organisms-register-

For information on the classification of plant pathogens in Australia, the Office of the Chief Plant Protection Officer (OCPPO) should be consulted. The OCPPO web site can be reached via the web address www.daff.gov.au. For imported plant pathogens, see Clause 2.3.1.

3.7 PRIONS

Infectious agents called prions, the cause of scrapie and other transmissible spongiform encephalopathies, all produce slow, progressive and fatal diseases of the central nervous system. Agents of this type are known to infect humans as well as many other mammalian species including sheep, cattle and cats.

Prions are smaller than the smallest known viruses, appear not to contain any nucleic acid and may be satisfactorily described as self-replicating infectious proteins. They are resistant to most traditional methods of inactivation used for other microorganisms such as formalin, 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 most usual mechanism of spread appears to be by the ingestion or grafting of infectious material. Table 3.4 lists examples of prions of Risk Group 2.

TABLE 3.1
EXAMPLES* OF BACTERIA OF RISK GROUP 2

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

* This list is not exhaustive.

† These organisms are common causes of serious laboratory acquired infections because of their low infectious dose and handling them in BSC is particularly important (see Clauses 4.5.6.1 and 4.5.7(g)). (See Reference 1.11.)

‡ For genetically crippled strains, refer to the OGTR regulations.

§ May be dangerous for pregnant women.

** Vaccination, see Clause 2.2.4.

†† Less than 5000 cultures per year. See Clause 3.6.2.

TABLE 3.2

EXAMPLES* OF PARASITES OF RISK GROUP 2— INFECTIVE STAGES ONLY

Organism
Ancylostoma duodenale
Ascaris lumbricoides
Babesia divergens
Babesia microti
Brugia spp.
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. (including *Clonorchis sinensis*)
Plasmodium (human and simian)
Strongyloides stercoralis
Taenia saginata
Taenia solium
Toxocara canis
Toxoplasma gondii†
Trichinella spiralis
Trypanosoma brucei subspp.
Trypanosoma cruzi
Wuchereria bancrofti

* This list is not exhaustive.
† May be teratogenic.

TABLE 3.3

EXAMPLES* OF FUNGI OR FUNGAL-LIKE ORGANISMS OF RISK GROUP 2

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

* This list is not exhaustive.

TABLE 3.4

EXAMPLES* 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
Norwalk-like
Sapporo-like
Largovirus
Rabbit haemorrhagic disease
Coronaviridae
Coronavirus other than SARS coronavirus
SARS coronavirus (tests not involving replication)†
Flaviviridae
Flavivirus
Dengue 1, 2, 3 and 4
Japanese encephalitis (Nakayama strain)‡
Kokobera
Kunjin
Murray Valley encephalitis
Sarafend
Saumarez Reef
Yellow fever (strain 17D)‡
Hepacivirus
Hepatitis C
Hepadnaviridae
Duck hepatitis B
Hepatitis B‡
Herpesviridae
Alphaherpesvirinae
Simplex
Varicella‡
Betaherpesvirinae
Cytomegalovirus§
Gammaherpesvirinae
Herpes 6 and 7
Lymphocryptovirus (EB-like viruses)
Orthomyxoviridae
Influenza (currently circulating endemic strains and candidate vaccine strains) ‡**
Paramyxoviridae
Paramyxovirinae
Morbillivirus
Measles‡
Rubulavirus
Menangle
Mumps‡
Avulavirus
Newcastle disease (non-virulent enzootic strains)
Respirovirus
Sendai
Pneumovirinae
Pneumovirus
Respiratory syncytial

(continued)

TABLE 3.4 (*continued*)

Virus or prion
Parvoviridae
Human parvovirus§
Picornaviridae
Encephalomyocarditis
Encephalomyocarditis virus
Enterovirus
Coxsackie
Echo
Entero
Parecho
Polio 1, 2 and 3 (see Clause 3.6.5) ‡
Rhinovirus
Hepatovirus
Hepatitis A‡
Poxviridae
Orthopoxvirus
Vaccinia‡
Parapoxvirus
Orf
Prions
Gerstmann-Sträussler syndrome, Kuru and Creutzfeldt-Jakob agents (See Note 1 and Clause 3.7)
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
Togaviridae
Alphavirus
Barmah Forest
Ross River
Semliki Forest
Arterivirus
Equine viral arteritis
Rubivirus
Rubella‡§
Unclassified
Hepatitis D
Hepatitis E††

* This list is not exhaustive.

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

‡ Vaccination available, see Clause 2.2.4.

§ May be teratogenic.

** See also Tables 3.7 and 3.9.

†† May be dangerous for pregnant women.

NOTES TO TABLE 3.4:

1 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 gravity displacement autoclave 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 gravity displacement autoclave 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 References 1.12 and 1.13.)

2 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* OF BACTERIA OF RISK GROUP 3

Organism
Bacillus anthracis
Bartonella bacilliformis
Burkholderia mallei
Brucella spp. (except *B. ovis*)
Chlamydia psittaci
Coxiella burnetii (cultures, animal work and concentrates) †‡
Francisella tularensis (type A)
Mycobacterium tuberculosis complex‡§**
Rickettsia spp.
Yersinia pestis

* This list is not exhaustive.

† May be dangerous for pregnant women.

‡ Vaccination, see Clause 2.2.4.

§ Respiratory protection should be considered.

** Greater than 5000 cultures per year, susceptibility testing, known multi-drug resistant strains. See Clause 3.6.2.

TABLE 3.6

EXAMPLES* OF FUNGI OR FUNGAL-LIKE ORGANISMS OF RISK GROUP 3

Organism
Blastomyces dermatitidis
Coccidioides immitis
Histoplasma spp.
Paracoccidioides brasiliensis

* This list is not exhaustive.

NOTE: The mycelial forms of these dimorphic fungi produce highly infective conidia. The use of plate cultures should be avoided.

TABLE 3.7

EXAMPLES* OF VIRUSES OF RISK GROUP 3

Virus
Arenaviridae
Arenavirus
Lymphochoriomeningitis (LCM) neurotropic strains
Bunyaviridae
Group C
Oropouche
Phlebovirus
Hantavirus
Hantaan and related viruses†
Coronaviridae
SARS coronavirus (from cultures and concentrates) ‡
Flaviviridae
Flavivirus
Japanese encephalitis§
St Louis encephalitis
Tick-borne viruses
West Nile
Yellow fever§
Orthomyxoviridae
Avian influenza (exotic pathogenic strains)‡§
Influenza (endemic strains not currently in circulation)
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§
Rabies fixed strain (CVS II) §
Togaviridae
Alphavirus
Eastern equine encephalitis
Western equine encephalitis
Venezuelan equine encephalitis§

* This list is not exhaustive.

† Animal inoculations to be performed under Risk Group 4 requirements.

§ Vaccination available, see Clause 2.2.4.

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

TABLE 3.8

EXAMPLES* 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*
Nipah

* 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

EXOTIC ANIMAL VIRUSES AND PRIONS HELD UNDER QUARANTINE CONDITIONS AT THE CSIRO AUSTRALIAN ANIMAL HEALTH LABORATORY

Virus or prion
Birnaviridae
Infectious pancreatic necrosis
Infectious bursal disease virus (virulent strain)
Bunyaviridae
Bunyavirus
Cache Valley
Phlebovirus
Rift Valley fever (vaccine strain)
Caliciviridae
San Miguel sea lion viruses
Vesicular exanthema
Coronaviridae
Transmissible gastroenteritis
Flaviviridae
Pestivirus
Classical swine fever (hog cholera)
Herpesviridae
Aujeszky's disease
Duck virus enteritis
Malignant catarrhal fever
Orthomyxoviridae
Equine influenza virus
Swine influenza (human isolate)
Paramyxoviridae
Henipavirus
Nipah
Morbillivirus
Peste-des-petits-ruminants
Rinderpest
Rubalavirus
Pathogenic strains of Newcastle disease
Porcine rubulavirus
Picornaviridae
Enterovirus
Swine vesicular disease
Unassigned
Duck hepatitis 1 and 3
Prion
Mouse Scrapie
Reoviridae
Orbivirus
African horsesickness
Bluetongue (exotic serotypes)
Epizootic haemorrhagic disease (exotic serotypes)
Retroviridae
Lentivirinae
Maedi-visna
Simian immunodeficiency virus (SIV)

(*continued*)

TABLE 3.9 (*continued*)

Virus or prion
Rhabdoviridae
Infectious haemopoietic necrosis
Viral haemorrhagic septicaemia
Lyssavirus
Rabies fixed strain (CVS II)
Bat rabies virus
Duvenhage
Mokola
Fin
Kotonkan
Lagos bat
Obodhiang
Eptesicus I
Vesiculovirus
Vesicular stomatitis virus-New Jersey
Vesicular stomatitis virus-Indiana
Vesicular stomatitis virus-Indiana 2 (Cocal)
Vesicular stomatitis virus-Indiana 3 (Alagoas)
Vesicular stomatitis virus-Indiana 4 (Maraba)
Vesicular stomatitis virus-Porton S
Vesicular stomatitis virus-Piry
Vesicular stomatitis virus-Chandipura
Togaviridae
Arterivirus
Porcine reproductive and respiratory syndrome
Unclassified
African swine fever

SECTION 4 CLASSIFICATION OF LABORATORIES, PRACTICES AND PROCEDURES

4.1 PRINCIPLES OF CONTAINMENT

4.1.1 General

Containment of microorganisms involves a combination of buildings, engineering function, equipment, and worker practices to handle hazardous microorganisms safely. Physical containment is the term used to describe the provision of infrastructure and equipment in the laboratory, together with safe laboratory practices.

The four classifications of laboratory facilities (see Clause 4.2) are defined by the physical containment prefix ‘PC’.

4.1.2 Containment measures

4.1.2.1 *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.

4.1.2.2 *Primary containment measures*

Primary containment measures are the constraints immediately surrounding the source of infectious material, such as a biosafety cabinet, 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.

4.1.2.3 *Secondary containment measures*

Secondary containment measures include the physical 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. The secondary receptacle of an approved IATA transport container is another. In the laboratory or animal room, secondary physical containment measures are invariably supplemented by defined work practices, including PPCE.

4.1.2.4 *Tertiary containment measures*

Tertiary containment measures provide protection of the wider environment by enclosing 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.

4.2 PHYSICAL CONTAINMENT CLASSIFICATIONS

4.2.1 General

The hazard and risk posed by different microorganisms varies greatly and this is reflected by the organization of microorganisms into the four Risk Groups described in Section 3. Clauses 4.4 to 4.7 detail the appropriate requirements and recommendations for the four

physical containment levels and include the laboratory structural requirements and facilities, PPCE, safety equipment, practices, techniques and health monitoring procedures.

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

Sections 5, 6 and 7 contain the corresponding requirements for animal, plant and invertebrate facilities.

Viable microorganisms, animals, plants or invertebrates inoculated with microorganisms from defined risk groups shall be stored or housed in containment facilities appropriate to the particular physical containment level.

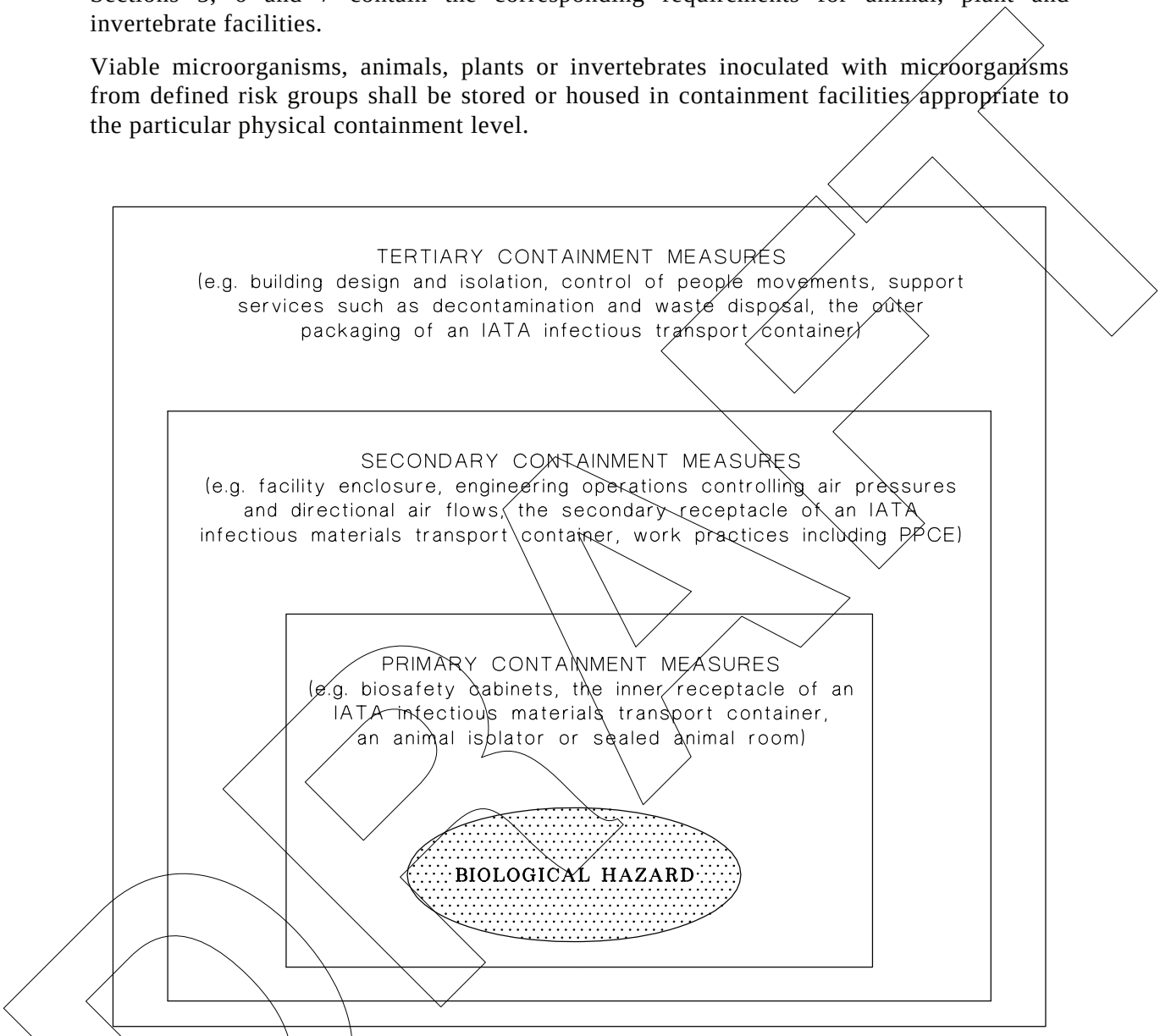


FIGURE 1 RELATIONSHIP BETWEEN CONTAINMENT MEASURES

4.2.2 Physical containment level 1 (PC1)

This level of facility with its practices and equipment is appropriate for student and undergraduate teaching laboratories. A Physical Containment Level 1 laboratory is suitable for work with microorganisms where the hazard levels are low, and where laboratory personnel can be adequately protected by standard laboratory practice. The organisms used are not known to cause disease in healthy humans or animals (i.e. organisms are in Risk Group 1). Work may be carried out on the open bench. Specimens that have been inactivated or fixed may be handled in a PC1 laboratory. Clause 4.4 provides requirements for a PC1 laboratory.

4.2.3 Physical containment level 2 (PC2)

This level of facility with its practices and equipment is applicable to clinical, diagnostic, industrial, teaching and other premises where work is carried out with microorganisms or material likely to contain microorganisms which may be present in the community, where the microorganism may be associated with animal or human disease of moderate severity, e.g. Risk Group 2 microorganisms. With good microbiological techniques, work with these agents 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. Clause 4.5 provides requirements for a PC2 laboratory.

4.2.4 Physical containment level 3 (PC3)

This level of facility with its practices and equipment is applicable to clinical, diagnostic and other premises where work is carried out with microorganisms or material likely to contain microorganisms where there is a risk of serious infection to humans or animals. Work with Risk Group 3 microorganisms shall be carried out in a PC3 laboratory.

A Physical Containment Level 3 laboratory provides safeguards such as an airlock and negative pressure to minimize the risk of infection to individuals, the community and the environment. Clause 4.6 provides requirements for a PC3 laboratory.

4.2.5 Physical containment level 4 (PC4)

This level of facility with its practices and equipment is applicable to work with dangerous microorganisms, including Risk Group 4 microorganisms that pose a high individual risk of life-threatening disease and may be readily spread to the community.

A Physical Containment Level 4 laboratory is a facility situated in a building separate from other laboratories or constructed as an isolated area within a building. The facility shall be maintained under negative pressure and include secondary barriers such as sealable openings into the laboratory, airlocks or liquid disinfection barriers, a clothing-change and shower room contiguous to the laboratory ventilation system, and exhaust air and liquid waste decontamination systems to prevent the escape of microorganisms to the environment. Clause 4.7 provides requirements for a PC4 laboratory.

4.3 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 shall be used to assist in ensuring all relevant requirements of the Standard are taken into account when conducting the assessment. A copy of the checklist and completed report shall be provided to the BC.

4.4 REQUIREMENTS FOR PC1 LABORATORIES

4.4.1 General

A Physical Containment Level 1 laboratory facility, which requires no containment equipment, is suitable for work with microorganisms in Risk Group 1.

4.4.2 Construction

Laboratory facilities shall be constructed in accordance with AS/NZS 2982.1 and the following requirements:

(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) Furniture shall be ergonomically suitable for use in the laboratory. The heights of laboratory stools and chairs shall be adjustable and commensurate with heights of the benches and safety cabinets. Seats shall be of smooth impervious material to facilitate cleaning.

(d) Washbasins with potable hot and cold water services shall be provided inside each laboratory room, near the exit.

NOTE: Potable water supply requirements are set out in AS/NZS 3500.

(e) Backflow prevention shall be provided for water supplies in the facility in accordance with Appendix D.

(f) Gas supplies in the facility shall comply with the backflow prevention and general requirements specified in Appendix D.

(g) Emergency showers and eyewash stations in accordance with AS/NZS 2982.1 shall be provided.

NOTES:

1 A full body shower should be provided within the same building as the laboratory.

2 In older laboratories which have not been built to comply with AS/NZS 2982.1, single-use packs of sterile eye irrigation fluids should be provided.

(h) Open spaces between and under benches, cabinets and equipment shall be accessible for cleaning.

(i) Fire control systems shall meet local, State, Territory or National regulations as appropriate.

NOTE: See also the requirements in AS/NZS 2243.1 concerning emergency alarm systems and associated operations.

(j) Alternative egress shall be provided in accordance with local building regulations.

(k) Facilities outside the laboratory shall be provided for storing outer garments and personal items as well as separate eating, drinking, food storage and rest areas.

(l) Laboratory clothing and storage and laundry services for such clothing shall be provided, along with adequate personal washing facilities inside the laboratory.

4.4.3 Personal protective clothing and equipment (PPCE)

PPCE worn and used in the laboratory shall comply with the requirements in AS/NZS 2243.1. See also Clause 9.2 for detailed information on PPCE.

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.

4.4.4 Work practices

Laboratory personnel shall observe the work practices in AS/NZS 2243.1 as well as the following (see also Clause 2.1.5):

(a) Do not bring food or drink for personal consumption into the laboratory or store it in laboratory refrigerators. Eating, drinking, smoking, shaving and the application of cosmetics shall be prohibited in laboratories.

NOTES:

1 This includes offices within the containment facility boundary.

2 Hands, pens and pencils, which can become contaminated from dirty surfaces, liquids and aerosols, should be kept away from the face.

(b) Long hair shall be tied back as it constitutes both a fire risk and a risk of contamination.

(c) Ensure all emergency and safety equipment is kept and maintained in accordance with the manufacturer's instructions. Ensure that all safety equipment remains readily accessible to the laboratory personnel at all times.

(d) Ensure that all work hazards are identified, assessed for their risk, and controls implemented where necessary.

(e) Identify hazardous work and ensure that appropriate backups are implemented if it is being carried out alone.

(f) Use measures, such as closed containers or secondary containment, when carrying materials. Always use safety carriers for transporting chemicals in glass or plastic containers with a capacity of 2 L or greater. Never carry containers of mutually reactive substances at the same time.

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

(h) Keep only the minimum required quantities of hazardous substances in the laboratory work area.

(i) 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.

(j) Wash skin areas which come in contact with chemicals, irrespective of concentration.

(k) Do not mouth pipette. Rules for the correct use of pipetting devices and syringes shall be followed. Blowing out residual volumes from pipettes creates aerosols; therefore it is preferable to use pipettes calibrated to deliver.

(l) Clearly identify and date cultures. Do not store cultures for long periods on the bench. Transfer them to a dedicated storage area, such as a refrigerator or part of a cold room.

(m) Take care to prevent the dissemination of 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.

(n) Because airborne fungal spores can spread in a similar manner to aerosols, Petri dish cultures of fungi shall be sealed with laboratory stretch film to prevent dispersal of spores which may be allergenic or contaminate other cultures.

NOTE: Where shedding of spores can occur, dedicated incubators should be allocated for specific use in fungal work.

(o) Handle diagnostic kits and control sera with care as the exclusion of all pathogens cannot be guaranteed.

(p) Take care to minimize the production of aerosols where work is carried out on the open bench. See also Clause 3.1.

(q) Take precautions to ensure that items such as reading and writing materials, telephones, keyboards, door handles, cupboards and fridges do not become contaminated, e.g. gloves removed and hands washed prior to use.

(r) Use self-adhesive labels.

(s) Clean up all spills immediately and decontaminate the area. (See Section 8.) Report significant spills and accidents immediately to the laboratory supervisor. A written record of accidents shall be prepared and maintained.

NOTES:

1 An example microbiological incident report form is in Appendix B.

2 A list of effective disinfectants is given in Appendix E.

(t) Decontaminate work benches at least daily and after each task is completed.

(u) Segregate specialized wastes (e.g. broken glassware, biological and radioactive substances) at point of discard and dispose of according to local regulations. (See also Section 12.)

NOTES:

1 Consideration should be given to decontamination of laboratory waste prior to disposal. If desired, decontamination may be performed with household bleach that has been appropriately diluted (see Table E1).

2 When disposing of imported biological materials, AQIS should be consulted for Australian situations. In New Zealand, Reference 1.3 should be consulted.

3 Formulations of household bleach usually contain about 4% *w/v* (40 000 p.p.m.) available chlorine.

(v) Remove laboratory gowns, store in facilities provided and wash hands and fingernails thoroughly before moving to areas outside the laboratory.

Personnel who wish to transfer material between institutions are advised to pay particular attention to the various statutory regulations regarding transport of biological materials which may be regarded as infectious (see Section 13).

4.5 REQUIREMENTS FOR PC2 LABORATORIES

4.5.1 General

A Physical Containment Level 2 facility is suitable for work with microorganisms in Risk Group 2 and incorporates all facilities (Clause 4.4.2), equipment (Clause 4.4.3) and practices (Clause 4.4.4) for Containment Level 1; however, additional conditions of access, safety equipment and staff training requirements apply.

A sign complying with Clause 10.1 containing the biological hazard symbol and the level of containment, together with any access restrictions shall be prominently displayed near each entrance to each individual laboratory.

NOTE: The signage for general infectious hazard is different from the signage for OGTR-certified laboratories, which is supplied by the OGTR (see also Clause 10.1).

4.5.2 Large PC2 areas

Institutions with large areas or whole floors designated as PC2 areas shall ensure that safety is maintained for both workers in the laboratory and visitors to the area. Some of the issues that need to be considered are measures for restricting public access to the PC2 area, including via lifts and stairs, preventing the use of laboratories as thoroughfares, ensuring office and long-term write-up areas are kept out of laboratories, keeping laboratory doors closed, prohibiting eating and drinking in the entire PC2 area and mandatory training programs for all staff working in these areas.

4.5.3 Laboratory facilities

Laboratory facilities shall be in accordance with Clause 4.4.2 and incorporate the following additional requirements:

(a) The ceilings, walls and floors 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.

NOTE: Non-particle shedding acoustic tiles that meet these requirements may be used for the ceiling.

(b) Internal fittings and fixtures, such as lights, air ducts and utility pipes shall be selected and fitted to minimize the horizontal surface area on which dust can settle.

(c) A dedicated hand basin with mixer taps of the hands-free operation type shall be provided for hand washing within each laboratory, near each exit.

(d) Suitable coat hooks for laboratory gowns shall be provided within the laboratory, adjacent to the laboratory access door.

(e) Facilities 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.

(f) Separate report writing and long-term write up areas shall be provided outside the laboratory.

(g) Water supplied to the laboratory shall be provided with back flow prevention in accordance with the requirements of AS/NZS 3500.

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

(i) A pressure steam sterilizer shall be available where steam sterilizing of infectious laboratory wastes is required. (See Clause 4.5.7(j).)

(j) Freezers, refrigerators or other storage units used for microorganisms located outside the designated laboratory shall be posted with the biological hazard symbol (see Figure F1 of Appendix F).

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.

(k) Containers shall be provided for collection, storage or disposal of infectious materials, clearly labelled disinfectants shall be available for decontamination purposes.

4.5.4 Laboratory ventilation

An inward flow of air shall be maintained by extracting room air. Recirculation is permitted but not into areas outside the PC2 facility.

NOTE: Mechanical ventilation should be provided to ensure the directional air flow is maintained.

A risk assessment shall 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.

4.5.5 Personal protective clothing and equipment

The protective equipment specified in Clause 4.4.3 shall be used. (See also Clause 9.2).

Gloves shall be worn when working with infectious materials, when working in a biological safety cabinet and when handling human blood and body fluids.

Specialized eye protection, e.g. goggles or visors, shall be used where appropriate to protect eyes from contaminated or dangerous materials, or from ultraviolet light.

4.5.6 Containment equipment

4.5.6.1 *Biological safety cabinets*

When it is intended that work with specimens containing microorganisms transmissible by the respiratory route or work producing a significant risk from aerosol production be conducted in the facility, a biological safety cabinet of Class I (see Clause 1.4.7.1) or Class II (see Clause 1.4.7.2) shall be provided (see also Clause 9.7).

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

4.5.6.2 *Cytotoxic drug safety cabinets*

When it is intended that work with materials containing prions be conducted in the facility, a laminar flow cytotoxic drug safety cabinet shall be provided (see also Clause 9.9).

Installation and use, including the decontamination of the safety cabinet shall be performed in accordance with the requirements of AS 2639.

4.5.6.3 *Centrifuges*

A centrifuge fitted with either sealed rotors or sealed buckets shall be used where large volumes or high concentrations of infectious material are used. (See also Clause 9.3.)

4.5.7 Work practices

In addition to the work practices described in Clause 4.4.4, the following work practices shall be observed:

(a) Access to the laboratory shall be limited to laboratory personnel and persons specified by the laboratory management. Laboratory doors shall be closed when work is in progress.

(b) Instruction and training in handling pathogens shall be provided to laboratory personnel with regular updates. See also Clause 2.1.4.

(c) Special care (see Department of Health and Ageing publication, *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting*) shall be taken in handling human blood, serum, other body fluids and substances that are visibly contaminated with blood, as these may contain viruses, such as hepatitis viruses or HIV. 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) Particular care shall be taken when using sharps such as syringes, needles and scalpels, as sharps injuries constitute a large portion of laboratory accidents (see also Reference 1.14). The use of syringes and needles shall be limited to parenteral injection and aspiration of fluids from laboratory animals and diaphragm-capped bottles. After use, all sharps shall be placed in a sharps container (see AS 4031) for disposal. Sharps containers shall be provided at each point of use. 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. Laboratory users shall be aware of the potential for glass equipment such as pipettes to become sharps during an accident.

NOTE: Such ‘potential’ sharps should be eliminated from laboratory procedures wherever practicable.

(e) All clinical specimens shall be regarded as potentially hazardous. Leaking containers shall be handled in a biological safety cabinet and the outside of the container disinfected (see Table E1). Where a replacement sample is readily obtained, the leaking specimen shall be decontaminated and discarded.

(f) For manipulations or Risk Group 2 microorganisms such as shaking, mixing, and ultrasonic disruption, 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.

(g) When working with specimens containing microorganisms transmissible by the respiratory route or when the work produces a significant risk from aerosol production, a biological safety cabinet of Class I or Class II shall be used (see also Clause 9.7).

(h) When working with materials containing prions, a laminar flow cytotoxic drug safety cabinet shall be used (see also Clause 9.9).

(i) Active sniffing of bacterial cultures for odours shall be discouraged.

(j) Any container of viable microorganisms shall be transported between laboratories or to pressure steam sterilizers within the building within a second unbreakable and closed container which can be readily decontaminated.

(k) Potentially contaminated re-usable glassware shall be disinfected or decontaminated prior to washing and re-use. This may be by chemical disinfection or thermal decontamination. 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) PPCE shall be removed in a predetermined appropriate order and hands washed thoroughly.

(n) Laboratory staff shall advise maintenance and service personnel of the special microbiological hazards in the laboratory. Potentially contaminated surfaces shall be disinfected before maintenance of equipment is conducted. All equipment shall be decontaminated prior to maintenance, service or removal from the area.

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

4.5.8 Standard Precautions

The Department of Health and Ageing has recommended adoption of the term ‘Standard Precautions’ as the basic risk minimization strategy for handling of human blood and body fluids, secretions and excretions (excluding sweat) and for contacting non-intact skin and mucous membranes. (See Department of Health and Ageing publication, *Infection control guidelines for the prevention of transmission of infectious disease in the health care setting.*) Standard Precautions are the work practices required for the basic level of infection control. They include the use of—

(a) good microbiological practices (e.g. aseptic techniques);

(b) good hygiene practices (particularly washing and drying hands before and after patient and specimen contact);

(c) protective barriers (including the wearing of gloves, gowns, plastic aprons, masks, eyeshields and goggles);

(d) waterproof and occlusive coverings over any break in skin integrity;

(e) appropriate procedures for the handling and disposal of contaminated wastes; and

(f) appropriate procedures for the handling and disposal of sharps.

The work practices described in Clause 4.5.7 meet the requirements of implementing Standard Precautions.

4.6 REQUIREMENTS FOR PC3 LABORATORIES

4.6.1 General

A Physical Containment Level 3 facility is suitable for work with pathogens in Risk Group 3 and incorporates all equipment and practices for Physical Containment Levels 1 (Clause 4.4) and 2 (Clause 4.5); 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.

4.6.2 Construction

In addition to construction requirements described for Physical Containment Levels 1 and 2, 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. The doors shall open outwards, be self-closing and the outer door lockable. Both doors shall be 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 or PPCE 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 size, removable panels to allow for entry and exit of large items of equipment should be considered. These should be readily resealed 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.

(b) Doors, apart from those to areas used for showering and changing, shall contain glass viewing panels to minimize entry and exit injuries. If viewing panels in doors do not allow adequate viewing of laboratory occupants, alternative observation arrangements, such as viewing panels in walls or electronic visual monitoring facilities (e.g. web cams or closed circuit television), shall be used.

(c) 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.

(d) The laboratory and airlock shall be sealable to permit safe decontamination with gases.

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

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

(f) A pressure steam sterilizer for decontamination of laboratory wastes shall be contained in the laboratory, preferably located in the barrier wall of the PC3 facility but not situated in the airlock. If located in the barrier wall, the positioning shall ensure there is adequate access for loading and unloading of the steam sterilizer and the associated plant shall be accessible for maintenance from outside the facility.

NOTES:

1 Service and maintenance of the steam sterilizer should be achievable without requiring service personnel to enter the containment facility to the maximum extent that this is possible.

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.

(g) 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.

(h) Liquid effluents shall be discharged in a manner appropriate to the type of waste. The method of 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 local regulations.

(i) Where plant growth chambers form part of the PC3 facility, all openings shall be provided with screens in accordance with Clause 6.3.3(e).

(j) In addition to a normal telephone system, an independent back-up communication system shall be provided.

(k) Where human pathogens are not present and there is a risk to the health of workers through dehydration, due to circumstances such as heat stress, heavy work or long shifts in response to emergencies, drinking facilities may be provided in the facility if approved 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 washed prior to drinking.

4.6.3 Large PC3 facilities

Some institutions have large PC3 facilities consisting of several laboratories, animal rooms or a combination of these within the negative pressure area.

Additional safety structures that may be incorporated into the barrier wall include a dunk tank for removal of 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. Body showers and toilet facilities within the PC3 area may be included.

4.6.4 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 ventilation air that leaves the laboratory shall be treated as exhaust air in accordance with the requirements of this Clause.

Air may be recirculated within the 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.

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

Air supply and exhaust equipment shall be located to minimize the disturbance to the open faces of Class 1 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 adjacent rooms when both doors of the airlock are closed. When either door is open, the laboratory pressure shall remain at least 40 Pa below that of the adjacent rooms.

(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 6.10.1. An exhaust pre-filter of the same standard as the supply filter shall be provided, and mounted upstream of the HEPA filter.

(f) The HEPA filter shall be installed, housed and maintained as specified in Clause 9.10.2.

(g) A differential pressure gauge shall be mounted immediately outside the laboratory, adjacent to the entry point.

Any tubing that forms part of the laboratory pressure sensing and control equipment shall be fitted with a 0.22 μm hydrophobic membrane filter, (such as a miniature disk filter), located as close as possible to the laboratory room boundary. Filters and tubing shall be protected against mechanical damage.

An emergency ventilation stop button shall be provided outside the laboratory, adjacent to the differential pressure gauge.

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 failure.

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.

(h) 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 (g) 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.

(i) Exhaust air from Class III biological safety cabinets and flexible film isolators shall be discharged through the building exhaust system through a capture hood as described in AS/NZS 2647. It shall not be recirculated through the laboratory.

NOTE: 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.

4.6.5 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 labelled to minimize the risk of accidental exposure. The installation of services shall ensure proper access to equipment such as HEPA filters for maintenance and testing personnel and their equipment.

4.6.6 Personal protective clothing and equipment

In addition to the protective equipment specified in Clauses 4.4.3 and 4.5.5, appropriate respiratory protection equipment shall be made available (see also Clause 9.2).

4.6.7 Containment equipment

In addition to equipment specified for Physical Containment Level 2 (Clause 4.5.6), 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, flexible film isolators (see Clause 9.8) or Class III biological safety cabinets.

4.6.8 Work practices

In addition to work practices specified for Physical Containment Levels 1 (Clause 4.4.4) and 2 (Clause 4.5.7), the following practices shall be observed:

(a) 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 2.2.

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

(c) All 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.

(d) The laboratory door shall be locked when the room is unoccupied.

(e) All laboratory procedures with Risk Group 3 infective materials, shall be conducted in a biological safety cabinet of Class I, Class II or Class III or a flexible film isolator (see Clause 4.6.7).

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

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

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

NOTE: In most circumstances, the appropriate removal procedure is removing the gloves then washing the hands followed by removal of eye protection, gown and respiratory protection, taking care not to touch potentially contaminated parts of PPCE when doing so, then washing hands again.

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

(j) Outer clothing and personal effects shall be kept in storage facilities situated adjacent to the laboratory area and shall not be taken into the laboratory.

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

4.6.9 Health monitoring

When working with human pathogens, each person working in the laboratory 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 personnel working in the laboratory, and stored for future reference. (See also Clause 2.2.3.)

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

4.7 REQUIREMENTS FOR PC4 LABORATORIES

4.7.1 General

A Physical Containment Level 4 facility is suitable for work with pathogens in Risk Group 4 and incorporates all equipment and practices for Physical Containment Levels 1, 2 and 3 (Clauses 4.4, 4.5 and 4.6 apart from Item 4.6.2(k)); however, additional requirements on conditions of access and egress, safety equipment and staff training apply.

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.

4.7.2 Construction

In addition to the design features and facilities specified for Physical Containment Levels 1, 2 and 3, the following facilities shall be provided:

(a) The laboratory 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.

NOTE: Recommendations on acceptable room airtightness are given in Appendix H.

(b) An outer and inner change room, separated by a walk-through double-door shower airlock, 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 entry or similar, is preferred as a means of entry.

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

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.

The four doors of each entry/exit path shall either be self-closing or 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 Privacy for changing and showering may require door access features and interlocks or alarms additional to the above biocontainment requirements.

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

(c) Walls, floors and ceilings of the facility shall be constructed in such a manner as to form a sealed internal shell which facilitates easy fumigation. The internal surfaces of the shell shall be resistant to liquids and chemicals used in the laboratory 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.

(d) A double-ended pressure steam sterilizer (autoclave) 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 outer wall. The sterilizer shall comply with the requirements of Clause 9.6.

(e) 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.

(f) 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.

(g) An observation window, or suitable alternative monitoring facilities, shall be installed so that laboratory occupants can be observed from outside the laboratory.

(h) Prior to disposal, all laboratory effluents, including those from the shower facility, shall be decontaminated by either heat or chemical treatment.

(i) All services of the completed facility shall be tested, commissioned and the results documented, before use. An operating manual shall be prepared and adopted.

(j) 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, biosafety cabinets, room access and shower controls.

(k) A facility shall be available for the quarantine, isolation and medical care of personnel with illnesses potentially, or known to be, laboratory associated.

If provided, positive pressure suit areas shall comply with the requirements in Clause 4.7.8.

4.7.3 Laboratory ventilation

The laboratory 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. 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 4.6.4(g).

(b) Both supply and exhaust air shall be filtered through HEPA filters as specified in Clause 9.10.1. The HEPA filters shall be installed and housed as specified in Clause 9.10.2. Prefilters to both the supply and exhaust HEPA filters shall be provided as specified in Clause 4.6.4 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 flexible film isolators and 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.

4.7.4 Personal protective clothing and equipment

The protective clothing and equipment specified in Clause 4.7.6(d) shall be used. In addition, in certain laboratories a positive pressure suit may be required (see Clause 4.7.8).

4.7.5 Containment equipment

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

(a) A Class II biological safety cabinet (see Clause 4.7.6(g)).

(b) A flexible film isolator under negative pressure (see Clause 9.8) or a Class III biological safety cabinet.

4.7.6 Work practices

In addition to the work practices specified for Physical Containment Levels 1 (Clause 4.4.4), 2 (Clause 4.5.7) and 3 (Clause 4.6.8), the following practices shall be observed:

(a) All staff shall be trained in the specific working aspects of the laboratory, including the containment and clean-up of infectious spills, and shall use the safety equipment provided. Staff shall receive specific training, with written instructions and information in the handling of the relevant pathogens.

(b) Staff shall be supervised by senior scientists who are trained and experienced in working with the relevant pathogens. A facility operations manual shall be prepared.

(c) 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.

(d) All street clothing, including underwear, shall be removed and retained in the outer clothing change room. Complete laboratory clothing, including shoes, shall be provided by the organization and shall be used by all personnel entering the facility. When leaving the facility, personnel shall remove their laboratory clothing and store or discard it in the inner change room before showering.

(e) Personnel entering or leaving the laboratory shall indicate, either manually or electronically, the time of each exit and entry.

(f) Supplies, materials and specimens shall only be brought into the facility through the change and shower rooms, the double-doored pressure steam sterilizer, the fumigation chamber, the airlock or the dunk tank.

(g) All procedures within the facility involving agents assigned to Risk Group 4 shall be conducted in negative pressure flexible film isolators, Class III biological safety cabinets, or alternatively Class II biological safety cabinets used in conjunction with one-piece positive pressure personnel suits ventilated by a life-support system.

(h) 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 in the laboratory for use only when there is no alternative, such as for parenteral injection, phlebotomy or aspiration of fluids from laboratory animals and diaphragm bottles.

NOTE: Plasticware should be substituted for glassware whenever possible.

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

(j) Biological materials to be removed, in a viable or intact state, from flexible film isolators or from the maximum 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. The secondary container shall be removed from the facility through the disinfectant dunk tank, fumigation chamber or an airlock designed for this purpose. No other materials shall be removed from the maximum containment 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 flexible film isolator or a maximum containment 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.

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

(l) 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.

(m) 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.

4.7.7 Health monitoring

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. See also Clause 4.7.2(k).

4.7.8 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 that includes an alarm and emergency back-up breathing air system.

In addition to the facilities specified in Clauses 4.7.2 and 4.7.3, the following requirements apply to the suit area:

(a) Entry shall be via an airlock fitted with a personal body shower 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) An air supply for connection to the positive pressure suit shall be provided in the anteroom.

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

(d) An automatically-starting emergency power source shall be provided. Essential control equipment shall monitor and re-establish room pressure conditions during operation on emergency power. Sufficient uninterruptible power shall be provide to ensure this occurs.

(e) 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.

(f) 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.

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

In addition to the work practices in Clause 4.7.6, the following work practices apply:

(i) Upon entering the airlock, the person shall have a personal body shower before proceeding to the anteroom and donning a positive pressure suit prior to entering the second airlock.

(ii) 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. The suit and clothing shall be removed in the anteroom and a full body shower shall be taken in the shower airlock.

SECTION 5 ANIMALS AND ANIMAL CONTAINMENT FACILITIES

5.1 REQUIREMENT FOR CONTAINMENT FACILITIES FOR ANIMALS

Separate areas should be considered for animal housing, experiments, post-mortem examinations, disposal of wastes and associated maintenance. Infected, non-infected and quarantined animals shall be separately housed, and precautions taken to prevent cross-infection. Even uninoculated animals may harbour organisms dangerous to humans.

As a general principle, the biological and physical containment recommended for working with infectious agents *in vivo* and *in vitro* are comparable. Infected animals shall be handled by procedures that protect staff and the environment. In Animal PC3 and Animal PC4 facilities, infected animals shall be contained in primary containment devices, such as ventilated cages fitted with exhaust HEPA filters, a biosafety cabinet, or alternatively, the animal room can be the primary containment device.

When housing animals in which microbiological agents are to be used, the physical containment levels for work with microbiological agents involving animals shall follow the animal containment levels PC1, PC2, PC3 or PC4 as appropriate for the pathogen. Requirements for Animal PC1, Animal PC2 and Animal PC3 containment facilities are set out in Clauses 5.9, 5.10 and 5.11.

NOTE: Animal facilities associated with animal PC4 containment require special additional considerations, and specialized advice should be sought on these.

Laboratory animal facilities are an extension of the laboratory and may be integral to, and inseparable from, the laboratory.

The animal containment facilities shall comply with the *Australian code of practice for the care and use of animals for scientific purposes* (Reference 1.15).

In Australia, animals exposed to exotic organisms shall be housed in containment facilities that meet the requirements of AQIS, animals exposed to genetically modified organisms shall be housed in accordance with OGTR requirements and disposal of such animals shall be in accordance with the relevant regulations.

In New Zealand, animals exposed to exotic or genetically modified organisms shall be housed in containment facilities approved by MAF in accordance with MAF Regulatory Authority Standard 154.03.03 (Reference 1.16) and disposed of in accordance with regulations.

5.2 TRAINING

Training staff in animal handling is the best method of preventing injury, both to staff members and to animals. Work procedures specified in Section 4 shall also be adopted in animal containment facilities (see Reference 1.15).

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

Staff shall be competent in inoculation procedures designed to prevent self-inoculation and to minimize aerosol formation. Penetration of organisms through the skin, particularly from self-inoculation during post-mortem examinations and from contact with ecto-parasites, is a real risk when handling or inoculating animals.

5.3 PERSONAL PROTECTIVE CLOTHING AND EQUIPMENT (PPCE)

PPCE appropriate for the work being carried out shall be worn. Personal clothing shall be covered by a laboratory coat or gown as a minimum. Overalls should be considered. Closed footwear shall be worn, preferably separate shoes or boots that remain within the animal containment facility. Gloves shall be worn at all times.

Protective clothing shall be removed before leaving the animal containment facility. Dirty clothing shall be laundered within the establishment or by a commercial laundry and not taken home. See also Clause 5.10.3(b) and Clause 5.11.3(c) for PC2 and PC3 requirements respectively.

It is recommended that respiratory protection is worn to prevent the development of laboratory animal allergies (see Clause 5.7). Usually P1 particulate respirators are adequate but advice from an occupational hygienist or similar should be sought.

5.4 DISSECTION AND POST-MORTEM EXAMINATIONS

Post-mortem examinations shall be carried out under physical containment conditions equivalent to the Risk Group of the microorganism present.

Dissection tables shall be of impervious, washable material. Gloves, aprons (preferably disposable) and eye protection should be worn. Respiratory protection shall be used if there is a danger of infection by the respiratory route. Spillage trays and containers for used instruments shall be used. Procedures shall be followed to avoid cuts with the instruments used.

5.5 DECONTAMINATION AND WASTE DISPOSAL

Animal containment facilities should have decontamination facilities within their own areas. All used instruments and containers shall be decontaminated before cleaning. Infectious small animal bedding and cage wastes shall be rendered safe prior to disposal or reuse as described in Clause 12.2. Infected carcasses should preferably be autoclaved, incinerated or treated in an alkali digestor (or the equivalent). Any special precautions that are needed, such as decay of radioisotopes, shall be taken.

5.6 TRANSPORT OF ANIMALS AND ANIMAL TISSUES

Where it is necessary to transport animals or animal tissues from the containment facility to the laboratory or another facility, the appropriate precautions shall be determined. Animals and animal tissues shall not be moved to an animal facility of a lower level of containment, e.g. from PC3 to PC2.

5.7 LABORATORY ANIMAL ALLERGIES

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 1.17.) To reduce the incidence of these conditions, adequate ventilation (with increased numbers of air changes per hour) should be ensured and local exhaust systems provided where necessary. In addition, animal handlers, technical and scientific staff should take appropriate precautions to prevent the development of these conditions.

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

5.8 DESIGN OF ANIMAL CONTAINMENT FACILITIES

Facilities for laboratory and experimental animals shall be physically separated from other activities such as animal production and animal quarantine areas.

Animals under experiment may be either small laboratory animals (e.g. mice, rabbits) or large domestic animals (e.g. pigs, sheep, 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.

Cages and racks for small animals shall be demountable and able to be sterilized. In use, they shall be labelled to indicate the identity and date of any *inocula* given.

All internal areas shall be protected to prevent infestation by vermin. All areas should be regularly cleaned.

5.9 REQUIREMENTS FOR ANIMAL PC1 CONTAINMENT FACILITIES

5.9.1 General

An Animal PC1 containment facility is suitable for work with pathogens in Risk Group 1 and uninfected animals. Good work practices rather than specific microbiological containment procedures are required.

5.9.2 Facilities

Secure animal facilities have been developed by using the measures adopted for disease control programs by animal health authorities. PC1 animal facilities shall comply with the following:

(a) Facilities and arrangements for animal husbandry and management shall be consistent with good animal welfare practices and in accordance with the *Australian Code of Practice for the care and use of animals for scientific purposes.*

(b) All fencing, housing and handling facilities shall be of a construction suitable for the secure containment of the relevant species. The fencing shall be secure against escape or incursions by feral, predatory or infectious animals.

NOTE: Electric fencing and buried fencing should be used where appropriate.

(c) Secure perimeter fencing, additional to fences or housing directly containing the animals, shall be provided so that animals are effectively held within double fencing or housed animals are within a fenced compound.

(d) Suitable handling and restraint facilities shall be enclosed within the secure perimeter fence.

(e) Other provisions such as subdivision fencing shall meet requirements for animal husbandry and welfare purposes.

(f) Entry to the facility shall be restricted to authorized personnel and staff.

(g) Backflow prevention shall be provided for water supplies in the facility in accordance with Appendix D.

(h) Gas supplies in the facility shall comply with the backflow prevention and general requirements specified in Appendix D.

5.9.3 Work practices

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

(a) All gates shall be locked when animals are not under direct supervision.

(b) 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.

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

(d) Animals shall be prevented from escaping, with reasonable contingencies in place for accidents such as during handling.

(e) Animals shall be properly identified (e.g. by tattooing, microchip or permanent branding) and accounting procedures shall be established.

5.10 REQUIREMENTS FOR ANIMAL PC2 CONTAINMENT FACILITIES

5.10.1 General

An Animal PC2 containment facility is suitable for work with pathogens in Risk Group 2 and incorporates all the requirements of an Animal PC1 containment facility with additional requirements of construction, access, safety equipment and staff training.

5.10.2 Construction

The animal containment facility shall incorporate the following features:

(a) The animal containment facility shall be constructed with impermeable and easily cleaned surfaces.

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

(b) Drainage existing in the floor shall always contain water or disinfectant in the trap.

(c) Each room of the facility shall be posted with a sign identifying the containment level of the animal containment facility and emergency contacts.

(d) 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 containment facility.

(e) Windows in the animal containment facility shall be closed and sealed.

(f) Doors to animal containment facilities shall open inwards to minimize the possibility of any animals escaping and be self-closing.

(g) An inward flow of air shall be maintained by extracting room air or other comparable air handling system. Recirculation is permitted but not into areas outside the PC2 facility.

NOTE: Mechanical ventilation should be provided to ensure the directional air flow is maintained.

(h) Any openings in the walls, roof or ceiling, such as windows, 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 stainless steel or a suitable material with regards to its mechanical strength under the airflow load, its ability to remain undamaged with the regular vigorous cleanings needed to remove dust, plant fibre, its corrosion resistance and its 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 thrip.

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.

(i) Each animal facility shall be equipped with a handwash basin complete with hands-free mixing taps near each exit.

NOTES:

1 A full body shower should be provided within the same building as the animal facility.

2 Where a handwash basin is not provided in individual animal rooms, consideration should be given to the provision of a hands-free dispenser providing appropriate disinfectant hand rub to reduce cross-contamination risk. See Reference 1.18.

(j) A separate area within the animal containment facility shall be provided for reference documents and papers. Report writing and long-term write up shall occur outside the facility.

NOTE: Worksheets may be used on the bench.

(k) The water supply to each animal facility shall be provided with backflow prevention in accordance with the requirements of AS/NZS 3500.

(l) 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 provide in the facility if approved 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 washed prior to drinking.

5.10.3 Work practices

In addition to the work practices for Animal PC1 containment facilities, work practices for Animal PC2 facilities shall be as follows:

(a) Only authorized persons shall enter the animal containment facility.

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.

(b) Animals or animal tissues transported into the animal containment facility shall be suitably enclosed. Live animals shall be transported in a manner that will prevent escape.

(c) Protective clothing, gloves and footwear shall be worn.

NOTES:

1 It is recommended that such clothing not be worn in other areas.

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

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

(e) Animals shall be constrained during experimental handling.

(f) Eating, drinking, smoking and the storage of food or drink for human use shall not be permitted in animal containment facilities.

(g) 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.

(h) Care shall be taken in the use of syringes, needles and other sharps. Sharps containers shall be provided at each point of use.

NOTE: Sharps use should be eliminated wherever possible.

(i) Any container of viable microorganisms being transported out of the animal containment facility to another facility or to the pressure steam sterilizer shall be carried in a second unbreakable and closed container that shall be surface decontaminated before removal.

NOTE: This includes animals that may be infected with microorganisms.

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

(k) Personnel shall wash their hands after handling cultures and animals and before leaving the animal containment facility.

(l) Potentially contaminated re-usable glassware shall be disinfected or decontaminated prior to washing and reuse. This may be by chemical disinfection or thermal decontamination. For chemical disinfection, pipettes shall be placed vertically in an appropriate disinfectant solution, tip-first and fully immersed, to minimize 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.

(m) Microbiological wastes, animal bedding, small animal cages and animal carcasses shall be rendered safe before disposal in accordance with Clause 12.2.

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

5.11 REQUIREMENTS FOR ANIMAL PC3 CONTAINMENT FACILITIES

5.11.1 General

An Animal PC3 containment facility is suitable for work with pathogens in Risk Group 3 and incorporates all equipment and practices for Animal PC1 containment (Clause 5.9) and Animal PC2 containment (Clause 5.10); however, additional requirements for construction, conditions of access, safety equipment and staff training apply.

When hazardous disease agents are being used for small animals, primary containment measures such as biosafety cabinets or individually ventilated isolators fitted with HEPA exhaust filters should be used wherever practicable.

Where primary animal containment measures cannot be used, due to the nature of the work or the size of the animals, the facility forms the primary containment measure. Where the facility forms the primary containment measure, a full body shower shall be provided within the facility and staff shall wear PPCE appropriate to the risk of the hazardous disease agents that may be present. The facility shall include provisions to change animal cages, bedding, feed and water without compromising microbiological containment.

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.

5.11.2 Construction

Similar requirements to those applying to Animal PC1 and Animal PC2 containment facilities also apply to Animal PC3 facilities. The following additional requirements shall be provided:

(a) The Animal PC3 facility shall be isolated from other non-PC3 areas by an airlock having two doors in series, each fitted with automatic closers. The outer door shall be lockable.

Where the facility forms the primary containment measure, an outer and inner change room, separated by a shower airlock shall be provided. Suitable warning devices or

interlocks shall be provided to minimize the risk of both shower doors being open simultaneously. The outer shower door shall form the limit of PC3 containment for decontamination purposes.

NOTE: The airlock is provided to ensure the maintenance of the negative pressure within the Animal PC3 facility and prevent any airflow between the Animal PC3 facility and areas external to the facility. It should not be used for any work, nor should it contain any equipment, washing facilities or PPCE worn in the PC3 facility.

(b) The Animal PC3 facility shall not be accessible to unauthorized persons or open on to a public thoroughfare.

(c) The PC3 area shall be maintained at a minimum negative pressure of 50 Pa when both doors are closed, and 40 Pa when one door is open. The negative pressure shall be achieved by means of an independent room exhaust discharging to open air through a pre-filter and HEPA exhaust filter. The exhaust air shall be discharged in such a manner that it is dispersed away from occupied buildings and outside air intakes.

(d) A differential pressure gauge incorporating a magnetically coupled indicating mechanism and a sealed differential pressure diaphragm shall be provided within the laboratory to indicate negative pressure in the room.

NOTES:

1 Other airconditioning control switches and the exhaust fan speed setpoint control should be located adjacent to the gauge.

2 An audible alarm to indicate loss of room pressure control should be provided.

3 A Magnehelic gauge meets the gauge requirements.

(e) The replacement air shall be drawn into the room through a filtered aperture, the size of which can be adjusted and set to achieve the room negative pressure. The replacement air filter shall be of Type 1 Class A or Class B 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. The filter shall not be mounted in the door.

(f) The exhaust filter shall be a HEPA type as specified in Clause 9.10.1. The HEPA filter shall be installed, housed and maintained as specified in Clause 9.10.2. All pre-filters shall be of medium grade having a minimum efficiency to arrest 95% of all particles above 5 μm To prolong the life of the exhaust filters against rapid clogging by animal hair and feed dust, or in the case of poultry, skin danders and feather down, a roughing filter should be used preceding the main filter. This will allow filter changing procedures in which one filter is always interposed between the room and outside atmosphere.

NOTE: 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.

(g) The facility shall be constructed so that the finishes on walls, floors, ceilings and benches are impervious and easily cleanable.

(h) The facility shall contain a pressure steam sterilizer, preferably located in the barrier wall of the PC3 facility but not situated in the air lock. See also Clause 9.6.1.

(i) Provision shall be made for decontamination of the Animal PC3 facility. Where gaseous formaldehyde decontamination is used, the formaldehyde shall be effectively neutralized or removed so that the discharge to the atmosphere does not contain contaminants in excess of levels specified by the appropriate regulatory authority.

(j) In addition to a normal telephone system, an independent back-up communication system shall be provided.

5.11.3 Work practices

In addition to requirements for Animal PC1 and Animal PC2 containment (see Clauses 5.9 and 5.10), the following work practices shall apply:

(a) The Animal PC3 facility shall be inspected at least annually by the BC to ensure that its containment requirements comply with Clause 5.11.2 Items (a) and (c) to (f) by reviewing records including HEPA filter integrity test reports and room pressure readings.

(b) All staff shall have specific training in handling Risk Group 3 organisms and in the use of safety equipment and operation of the facility.

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

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

(d) Protective clothing shall be removed before leaving the animal facility. Dirty clothing shall be decontaminated, preferably in a pressure steam sterilizer, before being laundered.

(e) Where the animal facility forms the primary containment measure, a full body shower shall be taken upon exiting the facility.

(f) All equipment used in the Animal PC3 facility shall be decontaminated prior to maintenance, service or removal.

(g) Live animals infected with Risk Group 3 microorganisms shall not leave the facility.

(h) Microbiological wastes, animal excrement, liquid effluents, animal bedding, small animal cages and animal carcasses shall be rendered safe, preferably by decontamination in a pressure steam sterilizer, before disposal 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.

(i) If the animal facility does not form the primary containment measure, all animal handling procedures with Risk Group 3 infective materials shall be done either in a Class I or II biological safety cabinet (or the equivalent).

(j) Outer clothing and personal effects shall be kept in storage facilities outside to the animal containment facility and shall not be taken into the facility.

(k) The facility door shall be locked when the room is unoccupied.

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

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

5.11.4 Health monitoring

When working with human pathogens, a baseline serum sample should be obtained from personnel working in the facility, and stored for future reference. (See also Clause 2.2.3.).

Consideration should be given to the immunization of staff in accordance with Clause 2.2.4.

SECTION 6 PLANT CONTAINMENT FACILITIES

6.1 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 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 PC2, Plant PC3, and Plant PC4 containment standards include the prevention of the escape of plants and seeds and limiting the entry and escape of invertebrate vectors.

For housing of plants in Australia, reference should be made to AQIS and OGTR guidelines and regulations for exotic plant species and genetically modified plant species respectively.

In New Zealand, exotic or genetically modified plant species shall be housed in containment facilities approved by MAF in accordance with MAF Regulatory Authority Standard 155.04.09 (Reference 1.19).

This Section sets out requirements for four levels of plant physical containment (Plant PC) facilities for containing plants infected with nominated microorganisms. The appropriate location, construction requirements and work practices are shown in Clause 6.2 for Plant PC1 facilities, while Clauses 6.3, 6.4 and 6.5 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.

6.2 REQUIREMENTS FOR PLANT PC1 CONTAINMENT FACILITIES

6.2.1 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 Risk Group 1. Plant PC1 facilities provide the most basic containment and include structures comprising greenhouses, screen houses and flexible film plastic structures. Plant PC 1 facilities are suitable for use with plants infected with common plant microorganisms that are endemic and widely dispersed.

NOTE: Plant PC 1 facilities are not suitable for plants that have been genetically modified.

6.2.2 Location

Plant PC1 facilities have no special location requirements.

6.2.3 Construction

The following minimum features shall be incorporated in Plant PC1 containment facilities:

(a) Durable floor, walls, ceiling and roof 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 surfaces shall be cleanable in accordance with the requirements for research and maintenance of plants in good health.

(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 shall be provided for water supplies in the facility in accordance with Appendix D.

(e) Gas supplies in the facility shall comply with the backflow prevention and general requirements specified in Appendix D.

6.2.4 Work practices

No special procedures are required apart from those that are consistent with good agricultural or horticultural practice, including pest and disease control management.

6.3 REQUIREMENTS FOR PLANT PC2 CONTAINMENT FACILITIES

6.3.1 General

The following standard of plant containment facilities and work practices (Plant PC2) is regarded as a suitable minimum for work with plants infected with plant microorganisms in Risk Group 2. Plant PC2 facilities incorporate all the appropriate requirements of Plant PC1 containment facilities as well as those of Clauses 6.3.2, 6.3.3 and 6.3.4.

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. Plant PC2 facilities are suitable for use with plants infected with endemic plant microorganisms with limited distribution or exotic plant microorganisms that pose only a minor hazard to plants and have limited natural ability to be transmitted outside the facility without a suitable vector.

NOTE: In Australia, this is the minimum level of plant physical containment required for working with genetically modified plant species.

6.3.2 Location

The Plant PC2 facility should have a buffer zone of at least 10 m free of primary or alternative hosts that may be susceptible to infection from the plant microorganisms being used in the containment facility.

The potential impact of severe environmental events such as flood, fire, earthquake and high winds should be considered when selecting sites for Plant PC2 facilities.

6.3.3 Construction

In addition to the construction requirements specified in Plant PC1, a Plant PC2 facility shall incorporate the following features:

(a) The Plant PC2 facility shall have a durable, washable and impermeable floor.

(b) Transparent sections of the walls and roof covering shall be made out of glass, polycarbonate or similar suitable rigid material which resists deterioration from the elements and resists attack by invertebrates such as insects and arthropods. Joins between structural components shall be sealed. Screen material and flexible film plastics such as polythene shall not be used as the primary construction covering.

(c) The Plant PC2 facility shall have an anteroom for entry and exit. The anteroom shall be fitted with a 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. Outer doors shall include locks and handles. A self-closing device shall be fitted on each outer door. Suitable coat hooks for gowns shall be provided within the work area, adjacent to the anteroom access door.

(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 stainless steel, or suitable material with regards to its mechanical strength under the airflow load, its ability to remain undamaged with the regular vigorous cleaning needed to remove dust, plant fibre, its corrosion resistance and its 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 thrip.

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

(f) The drainage exits shall conform to local municipal standards with all wastewater draining to a municipality 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.

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

(h) A dedicated hand basin of the hands-free operation type shall be provided for hand washing within each plant containment facility, near the exit.

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

(i) Entrances to the containment facility shall be posted with a sign identifying the containment level of the plant physical containment facility and emergency contacts.

6.3.4 Personal protective clothing and equipment

Personnel shall wear gowns in the facility and these garments shall be removed on leaving the facility and kept in the facility between uses. They shall be laundered at appropriate intervals.

Measures shall be taken to ensure no plant or microbial 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.

6.3.5 Work practices

In addition to the work practices for Plant PC1, the following shall apply:

(a) 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.

(b) All doors to the plant containment facility shall be locked for the duration of the work, except for those periods when personnel are actually working inside it.

(c) Personnel shall decontaminate their hands on entering and leaving the facility using the hand basin provided.

(d) Only persons authorized by the BC shall enter the plant containment facility. All such persons shall be trained to follow normal facility routines as well as these operating procedures, including entry and exit procedures.

(e) Operations that can generate allergens or toxins shall be performed in a Class II biological safety cabinet as specified for Laboratory Physical Containment Level 2 (PC2) containment (see Clause 4.5.6.1).

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

(g) Plants shall be raised off the floor on non-absorptive benches to minimize disease contamination.

(h) The facility shall have an effective insect and rodent control program in place. 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, plants should be sprayed regularly with an appropriate insecticide.

(i) Living plants or tissues shall not be taken from the Plant Physical Containment facility except to an equivalent containment laboratory. Transport of Plant PC2 materials shall comply with Section 13.

NOTE: AQIS and OGTR have additional requirements when transporting quarantinable and genetically modified material.

(j) Waste plants, tissues, soil, soil substitutes and planting pots shall be collected in a sealed insect-proof container and treated to render the plant microorganism non-viable. Pruning equipment shall be disinfected prior to removal from the facility. Dead or unwanted plant material and spilled growing medium shall be cleaned up immediately followed by disinfection of affected areas.

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

6.4 REQUIREMENTS FOR PLANT PC3 CONTAINMENT FACILITIES

6.4.1 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 Risk Group 3. Plant PC3 facilities shall incorporate all the appropriate requirements of Plant PC1 and Plant PC2 containment as well as those of Clauses 6.4.2, 6.4.3 and 6.4.4.

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.

6.4.2 Location

Where located in areas that suffer from extreme climatic events (e.g. storms or cyclones), the design of the facility shall take these factors into account to minimize the risk of damage. Plant 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).

Plant PC3 facilities shall not be located in areas that are geologically unstable and prone to earthquakes or land slippage (see AS 1170.4).

6.4.3 Construction

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

(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. If ordinary glass is used, a physical screen shall be fitted to protect against hailstones. Additional protection shall be provided where required to protect against extreme climatic events (see Clause 6.4.2).

(b) Joins between any structural components shall be sealed and mechanically strong and durable to prevent failure due to expansion and contraction, chemical degradation or UV radiation.

(c) The facility shall have an airlock for entry and exit, with both doors fitted with self-closing devices. The airlock shall allow materials, equipment and trolleys to pass through, ensuring one door can be closed at all times. Both doors shall be fitted with seals to limit air leakage and entry/egress of invertebrates when closed. The 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, 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.

NOTES:

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

4 The airlock takes the place of the anteroom required for Plant PC2 facilities.

(d) Doors, apart from those to areas used for showering and changing, shall contain glass viewing panels to minimize entry and exit injuries. If viewing panels in doors do not allow adequate viewing of laboratory occupants, alternative observation arrangements, such as viewing panels in walls or electronic visual monitoring facilities (e.g. webcams or closed circuit television), shall be used.

(e) 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.

(f) The laboratory and airlock shall be sealable to permit safe decontamination with gases.

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

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

(h) A dedicated hand basin with mixer taps of the hands-free operation type shall be provided for hand washing within each plant containment facility, near the exit to the airlock.

(i) 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.

(j) A pressure steam sterilizer for decontamination of plant facility wastes shall be provided in the laboratory, preferably located in the barrier wall of the Plant PC3 facility but not located in the airlock.

If located in the barrier wall, the positioning shall ensure there is adequate access for loading and unloading of the steam sterilizer and the associated plant shall be accessible for maintenance from outside the facility.

NOTES:

1 Service and maintenance of the steam sterilizer should be achievable without requiring service personnel to enter the containment facility to the maximum extent that this is possible.

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.

(k) A liquid waste treatment system shall be provided to treat all liquid waste to minimize the risk of escape of viable plant material and microorganisms. The treatment methodology shall undergo a risk analysis to ensure that escape will be minimized effectively.

NOTE: Potential treatment methods include—

(i) direct connection to a municipal sewerage system;

(ii) heat treatment;

(iii) chemical treatment; and

(iv) steam sterilization.

(l) Where propagules (such as seeds, pollen, or invertebrate life stages) could potentially survive extended immersion under water, liquid waste outlets shall be fitted with strainers of adequately fine gauge to prevent escape.

(m) The drainage exits shall conform to local municipal standards. The floor of the facility shall be designed such that all waste water is collected and drained appropriately.

(n) 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).

(o) In addition to a normal telephone system, an independent back-up communication system shall be provided.

NOTE: An intercom or telephone system should be provided to allow voice communication beyond the containment zone to reduce traffic into and out of the facility. An information transfer system for recording and transferring data outside the containment zone should be available (e.g. fax or computer).

(p) 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 if approved 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 washed prior to drinking.

6.4.4 Plant facility ventilation

A ventilation system that establishes a negative pressure in the plant facility shall be provided so that there is a directional airflow into the working area. Where plant 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 shall be structurally designed to take account of the operation under negative pressures.

Air may be recirculated within the facility. Any air that leaves the facility shall be treated in an identical manner to exhaust air by HEPA filters mounted in separately accessible gas tight housings.

NOTE: Room-mounted split airconditioning units can be readily gaseously decontaminated concurrently with a room decontamination. These units should be located with care to avoid airflows that can affect the operation of Class II biological safety cabinets.

The plant facility ventilation shall incorporate the following features:

(a) The plant facility shall be maintained at an air pressure of at least 50 Pa below the pressure of adjacent rooms when both doors of the airlock are closed. When either door is open, the PC3 pressure shall remain at least 40 Pa below that of the adjacent rooms.

(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 9.10.1. An exhaust pre-filter of the same standard as the supply filter shall be provided, and mounted upstream of the HEPA filter.

(f) The HEPA filter shall be installed, housed and maintained as specified in Clause 9.10.2.

(g) A differential pressure gauge incorporating a magnetically coupled indicating mechanism and a sealed differential pressure diaphragm shall be provided within the plant facility to indicate negative pressure in the room. Other air conditioning control switches and the exhaust fan speed setpoint control shall be located adjacent to the gauge. The control system shall be provided with an audible alarm to indicate loss of negative room pressure.

NOTE: A Magnehelic gauge meets the gauge requirements.

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

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

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

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

(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.

6.4.5 Work practices

In addition to work practices specified for Plant PC1 and Plant PC2 Physical Containment, the following work practices shall apply:

(a) The facility shall be inspected at least every six months to ensure that its containment features are intact. Screens, filters and similar equipment shall be cleaned or replaced in accordance with manufacturer's specified procedures.

(b) Plants entering the facility shall be treated prior to entry to destroy or remove unwanted invertebrates.

(c) Packages of plant microorganisms shall be opened only within the containment facility as appropriate. Packaging material shall be decontaminated as soon as possible.

(d) Appropriate signage indicating the nature of the plant microorganisms present in the facility and any special entry requirements shall be posted on the outer entry door.

(e) Personnel shall put on overshoes or dedicated footwear and step into the footbath on entry and exit. Personnel shall wear disposable gloves and full coverage protective clothing (e.g. boiler suit, hair covering). These garments shall be removed on leaving the Plant PC3 facility and placed into sealed containers within the facility prior to decontamination. Personnel shall wash their hands and face prior to exiting the containment facility.

(f) 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. 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.

(g) All liquid wastes shall be treated in a manner deemed to minimize the risk of escape of viable plant material and microorganisms. See Clause 6.4.3(k).

(h) Dedicated cleaning equipment (e.g. brooms, mops, rubbish bins) shall be kept within the facility. Personnel entering the facility for cleaning, servicing of equipment, repairs or other activities shall be appropriately trained and authorized by the BC.

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

6.5 REQUIREMENTS FOR PLANT PC4 CONTAINMENT FACILITIES

6.5.1 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 Risk Group 4. Plant PC4 facilities incorporate all the appropriate requirements of Plant PC1, Plant PC2 and Plant PC3 containment as well as those of Clauses 6.5.2, 6.5.3 and 6.5.4.

Plant PC4 facilities include permanent greenhouse structures with inward directional airflow to prevent microorganism escape. Containment of microorganisms is achieved using strict work practices and highly specialized physical infrastructure design. 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.

6.5.2 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.

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 shall be lockable.

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 either be self-closing or 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 A security card access procedure, with additional numerical pad entry or similar, is preferred as a means of entry.

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

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

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

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

(d) 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.

(e) A double-ended pressure steam sterilizer shall be provided to decontaminate materials from the facility and from the 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 9.6.

(f) A pass-through dunk tank, fumigation 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 shall be treated by a method that renders plant microorganisms non-viable prior to leaving the containment facility. Disposal after treatment shall be in accordance with local municipality requirements, including any necessary post-treatment to render the effluent safe.

(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, biosafety cabinets, room access and shower controls.

6.5.3 Plant facility ventilation

The plant facility ventilation system 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. 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 4.6.4(g).

(b) Both supply and exhaust air shall be filtered through HEPA filters as specified in Clause 9.10.1. The HEPA filters shall be installed and housed as specified in Clause 9.10.2. Prefilters to both the supply and exhaust HEPA filters shall be provided as specified in Clause 4.6.4 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 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.

6.5.4 Work practices

In addition to work practices specified for Plant PC1, Plant PC2 and Plant PC3, the following work practices shall apply:

(a) The plant facility management shall establish policies and written procedures whereby only persons who have been trained and have been assessed as competent shall enter the facility. A person with responsibility for the overall operation of the facility shall be identified.

(b) The facility shall have a high level of physical security with restricted access. A log shall be kept of all personnel and visitors entering the facility. Personnel shall check

the pressure monitoring device before entering the containment zone to verify correct functioning.

(c) All street clothing, including underwear, shall be removed and retained in the outer clothing change room. Complete facility clothing, including shoes, shall be provided by the organization and shall be used by all personnel entering the facility. When leaving the facility, personnel shall remove their facility clothing and store or discard it in the inner change room before showering.

(d) All liquid wastes shall drain to collecting tanks. Liquid waste and plant and arthropod material shall be decontaminated to destroy microorganisms prior to disposal.

(e) Work surfaces and floors shall be decontaminated regularly and immediately after spillages.

SECTION 7 INVERTEBRATE CONTAINMENT FACILITIES

7.1 GENERAL

Invertebrates may pose a significant hazard to humans, animals, the environment, agriculture and forestry. Invertebrates classified into 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 nature of the invertebrate itself, any pathogens that it may be carrying, and its potential to act as a vector for human, animal or plant pathogens. Any or all of these factors need to be considered to assess the impact on personnel and the environment.

Hazards associated with invertebrate facilities include escape of invertebrates and escape of pathogens using vectors other than the invertebrates themselves. Compliance with microbiological, plant and animal Sections of this Standard shall be included where applicable.

For housing of invertebrates in Australia, reference should be made to AQIS and OGTR guidelines and regulations for exotic invertebrate species and genetically modified invertebrate species respectively. In New Zealand, reference should be made to MAF Regulatory Authority Standard 155.04.09 (Reference 1.19).

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 7.2 for minimum level Invertebrate PC1 facilities, while Clauses 7.3, 7.4 and 7.5 cover Invertebrate PC2, Invertebrate PC3 and Invertebrate PC4 facilities respectively.

7.2 REQUIREMENTS FOR INVERTEBRATE PC1 CONTAINMENT FACILITIES

7.2.1 General

The following standard of invertebrate physical containment (Invertebrate PC1) facilities and work practices is regarded as a suitable minimum for work with invertebrates in Risk Group 1. Invertebrate PC 1 facilities are suitable for use with invertebrates that are endemic and widely dispersed.

NOTE: Invertebrate PC1 facilities are not suitable for invertebrates that have been genetically modified. Invertebrate PC1 facilities are not generally suitable for imported species unless they are known to exhibit no pesticide resistance and do not harbour any exotic parasites.

7.2.2 Location

Invertebrate PCI facilities have no special location requirements.

7.2.3 Construction

The Invertebrate PC1 containment facility shall incorporate the following minimum features:

(a) The floor, walls, ceiling and roof shall be durable, suitable for the invertebrate species and appropriate for the local climate.

(b) All surfaces shall be cleanable in accordance with the requirements for research and maintenance of invertebrates in good health.

(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 shall be provided for water supplies in the facility in accordance with Appendix D.

(e) Gas supplies in the facility shall comply with the backflow prevention and general requirements specified in Appendix D.

7.2.4 Work practices

Mobile invertebrates shall be contained in cages or equivalent suitable containers.

Appropriate pest and disease control management procedures shall be implemented.

7.3 REQUIREMENTS FOR INVERTEBRATE PC2 CONTAINMENT FACILITIES

7.3.1 General

The following standard of invertebrate containment facilities and work practices is regarded as a suitable minimum for work with invertebrates in Risk Group 2. Invertebrate PC2 facilities incorporate all appropriate requirements of Invertebrate PC1 containment facilities as well as those of Clauses 7.3.2, 7.3.3 and 7.3.4.

Invertebrate PC2 facilities include permanent 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.

NOTE: In Australia, this is the minimum level of invertebrate physical containment requirement for working with generically modified Invertebrate species.

7.3.2 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 PC4 facility should have a buffer zone of at least 10 m free of primary or alternative hosts that may be susceptible to infection from microorganisms potentially being carried by the Invertebrates being used in the containment facility.

7.3.3 Construction

In addition to the construction requirements specified for Invertebrate PC1, an Invertebrate PC2 facility shall incorporate the following features:

(a) The facility shall have a durable and washable 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. Joins between structural components shall be sealed.

(c) The facility shall have an anteroom for entry and exit. The anteroom shall be fitted with a 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. Outer doors shall include locks and handles. A self-closing device shall be fitted on each outer door. Suitable coat hooks for gowns shall be provided within the anteroom.

(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 stainless steel, or suitable material with regards to its mechanical strength under the airflow load, its ability to remain undamaged with the regular vigorous cleaning needed to remove dust, plant

fibre, its corrosion resistance and its 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 municipal standards with all wastewater draining to a municipality 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.

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

(h) A dedicated hand basin of the hands-free operation type shall be provided for hand washing within each invertebrate containment facility, near the exit.

NOTE: Where a PC2 laboratory is directly connected to the invertebrate physical containment facility, the hand basin may be in the laboratory.

(i) Entrances to the containment facility shall be posted with a sign identifying the type of invertebrate physical containment facility and emergency contacts.

7.3.4 Personal protective clothing and equipment

Personnel shall wear gowns in the facility and these garments shall be removed on leaving the facility and kept in the facility between uses. They shall be laundered at appropriate intervals.

Measures shall be taken to ensure no invertebrate or microbial 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.

7.3.5 Work practices

In addition to work practices specified for Invertebrate PC1, the following work practices shall apply:

(a) Packages of invertebrates shall be opened only within the containment facility as appropriate. Packaging material shall be decontaminated as soon as possible.

(b) 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.

(c) All doors to the facility shall be locked for the duration of the work, except for those periods when personnel are actually working inside it.

(d) 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 apparel, 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.

(e) Personnel shall decontaminate their hands on entering and leaving the facility using the hand basin provided.

(f) Only persons authorized by the BC shall enter the invertebrate containment facility. All such persons shall be trained to follow normal facility routines as well as these work practices, including entry and exit procedures.

(g) Operations that may generate allergens or toxins shall be performed in a Class II BSC as specified for laboratory PC2 facilities (see Clause 4.5.6.1).

(h) Application of pesticides shall be performed utilizing appropriate PPCE.

(i) 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.

(j) Living invertebrates or tissues shall not be taken from the facility except to an equivalent containment laboratory. Transport of Invertebrate PC2 materials shall comply with Section 13.

NOTE: AQIS and OGTR have additional requirements when transporting quarantinable and genetically modified material.

(k) Dead invertebrates, host plants and plant tissues, soil, soil substitutes and planting pots shall be collected in a sealed insect-proof container and treated to render any microorganisms that have colonised the material non-viable. Pruning equipment shall be disinfected prior to removal from the facility. Dead or unwanted invertebrate material and spilled growing medium shall be cleaned up immediately followed by disinfection of affected areas.

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

7.4 REQUIREMENTS FOR INVERTEBRATE PC3 CONTAINMENT FACILITIES

7.4.1 General

The following standard of invertebrate physical containment facilities and work practices (Invertebrate PC3) is regarded as a suitable minimum for work with invertebrates in Risk Group 3. Invertebrate PC3 facilities incorporate all the appropriate requirements of Invertebrate PC1 and Invertebrate PC2 containment as well as those of Clauses 7.4.2, 7.4.3 and 7.4.4.

Invertebrate PC3 facilities include permanent structures with sealed windows [A1) 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.

7.4.2 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).

Invertebrate PC3 facilities shall not be located in areas that are geologically unstable and prone to earthquakes or land slippage (see AS 1170.4).

7.4.3 Construction

In addition to the construction requirements specified for Invertebrate PC1 and Invertebrate PC2 facilities, an Invertebrate PC3 facility shall incorporate the following features:

(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. If ordinary glass is used, a physical screen shall be fitted to protect against hailstones. Additional protection shall be provided where required to protect against extreme climatic events (see Clause 7.4.2).

(b) Joins between any structural components shall be sealed and mechanically strong and durable to prevent failure due to expansion and contraction, chemical degradation or UV radiation.

(c) In addition to the anteroom (see Clause 7.3.3(c)), the facility shall have an airlock for entry and exit, with both doors fitted with self-closing devices. The airlock shall allow materials, equipment and trolleys to pass through, ensuring one door can be closed at all times. Both doors shall be fitted with seals to limit air leakage.

NOTE: If the invertebrate containment facility connects via its anteroom to another containment facility of the same level, an airlock is not required between the two containment facilities.

(d) The anteroom shall also be fitted with provisions, such as—

(i) drop down door seals fined 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;

(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; and

(iv) a full height mirror and vacuum device for removal of invertebrates from personnel.

(e) The invertebrate containment facility shall be provided with a footbath containing a suitable disinfectant.

NOTE: The preferred location of this footbath is immediately inside the work area.

(f) Doors, apart from those to areas used for showering and changing, shall contain glass viewing panels to minimize entry and exit injuries. If viewing panels in doors do not allow adequate viewing of laboratory occupants, alternative observation arrangements, such as viewing panels in walls or electronic visual monitoring facilities (e.g. webcams or closed circuit television), shall be used.

(g) 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.

(h) The laboratory and airlock shall be sealable to permit safe decontamination with gases.

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

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

(j) A dedicated hand basin with mixer taps of the hands-free operation type shall be provided for hand washing within each invertebrate containment facility, near the exit to the anteroom.

(k) Water supply to the containment facility shall be fitted with backflow prevention in accordance with the requirements of AS/NZS 3500.

(l) Supporting equipment (such as ventilation equipment, pumps and irrigation equipment, heating and cooling equipment, plant shading devices) 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.

(m) A pressure steam sterilizer for decontamination of invertebrate facility wastes shall be provided in the laboratory, preferably located in the barrier wall of the Invertebrate PC3 facility but not located in the airlock.

If located in the barrier wall, the positioning shall ensure there is adequate access for loading and unloading of the steam sterilizer and the associated plant shall be accessible for maintenance from outside the facility.

NOTES:

1 Service and maintenance of the steam sterilizer should be achievable without requiring service personnel to enter the containment facility to the maximum extent that this is possible.

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.

(n) A liquid waste treatment system shall be provided to treat all liquid waste to minimize the risk of escape of invertebrates and microorganisms. The treatment methodology shall undergo a risk analysis to ensure that escape will be minimized effectively.

NOTE: Potential treatment methods include—

(a) direct connection to a municipal sewerage system;

(b) heat treatment;

(c) chemical treatment; and

(d) steam sterilization.

(o) In situations where local waste treatment of liquids is not proposed, and where invertebrates could potentially survive extended immersion under water, liquid waste outlets shall be fitted with strainers of adequately fine gauge to prevent escape.

(p) The drainage exits shall conform to local municipal standards. The floor of the facility shall be designed such that all waste water is collected and drained appropriately.

(q) 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).

(r) In addition to a normal telephone system, an independent back-up communication system shall be provided.

NOTE: An intercom or telephone system should be provided to allow voice communication beyond the containment zone to reduce traffic into and out of the facility. An information transfer system for recording and transferring data outside the containment zone should be available (e.g. fax or computer).

7.4.4 Invertebrate facility ventilation

A ventilation system that establishes a negative pressure in the invertebrate facility shall be provided so that there is a directional airflow into the working area. Where invertebrate 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 shall be structurally designed to take account of the operation under negative pressures.

Air may be recirculated within the facility. Any air that leaves the facility shall be treated in an identical manner to exhaust air by HEPA filters mounted in separately accessible gas tight housings.

NOTE: Room-mounted split airconditioning units can be readily gaseously decontaminated concurrently with a room decontamination. These units should be located with care to avoid air flows that can affect the operation of Class II biological safety cabinets.

The invertebrate facility ventilation shall incorporate the following features:

(a) The invertebrate facility shall be maintained at an air pressure of at least 50 Pa below the pressure of adjacent rooms when both doors of the airlock are closed. When either door is open, the PC3 area pressure shall remain at least 40 Pa below that of the adjacent rooms.

(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 9.10.1. An exhaust pre-filter of the same standard as the supply filter shall be provided, and mounted upstream of the HEPA filter.

(f) The HEPA filter shall be installed, housed and maintained as specified in Clause 9.10.2.

(g) A differential pressure gauge incorporating a magnetically coupled indicating mechanism and a sealed differential pressure diaphragm shall be provided within the invertebrate facility to indicate negative pressure in the room. Other air conditioning control switches and the exhaust fan speed setpoint control shall be located adjacent to the gauge. The control system shall be provided with an audible alarm to indicate loss of negative room pressure.

NOTE: A Magnehelic gauge meets the gauge requirements.

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

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

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

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

(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.

7.4.5 Work practices

In addition to work practices specified for Invertebrate PC1 and Invertebrate PC2 facilities, the following work practices shall apply:

(a) The facility shall be visually inspected at least every six months to ensure that its containment features are intact. Screens, filters and similar equipment shall be cleaned or replaced in accordance with manufacturers specified procedures.

(b) 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.

(c) Personnel shall put on overshoes or dedicated footwear and step into the footbath on entry and exit. Personnel shall wear disposable gloves and full coverage protective clothing (e.g. boiler suit, hair covering). These garments shall be removed on leaving the Invertebrate PC3 facility and placed into sealed containers within the facility prior to decontamination. Personnel shall wash their hands and face prior to exiting the containment zone.

(d) 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.

(e) Support materials such as soil and plants transported into the facility shall be treated prior to entry to destroy or remove unwanted contaminants.

(f) All solid waste including plant material, pots, soil and soil substitutes shall be collected and treated to render invertebrates and any associated microorganisms or pathogens non viable (e.g. sterilization). Wastes shall not be allowed to accumulate and shall not be stored outside the facility.

(g) All liquid wastes shall be treated in a manner deemed to minimize the risk of escape of invertebrates and microorganisms. See Clause 7.4.3 (h).

(h) Dedicated cleaning equipment (e.g. brooms, mops, rubbish bins) shall be kept within the facility. Personnel entering the facility for cleaning, servicing of equipment, repairs or other activities shall be appropriately trained and authorized by the BC.

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

7.5 REQUIREMENTS FOR INVERTEBRATE PC4 CONTAINMENT FACILITIES

7.5.1 General

The following standard of invertebrate physical containment facilities and work practices (Invertebrate PC4) is regarded as a suitable minimum for work with invertebrates in Risk Group 4. Invertebrate PC4 facilities incorporate all the appropriate requirements of Invertebrate PC1, Invertebrate PC2 and Invertebrate PC3 containment as well as those of Clauses 7.5.2, 7.5.3 and 7.5.4.

Invertebrate PC4 facilities include permanent structures with inward directional airflow to prevent the escape of invertebrates. Containment is achieved using strict operational procedures and highly specialized physical infrastructure design.

NOTE: The design of an Invertebrate PC4 facility is complex and those planning its construction should seek specialized advice.

7.5.2 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 to facilitate periodic integrity testing.

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.

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 be self-closing or 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 A security card access procedure, with additional numerical pad entry or similar, is preferred as a means of entry.

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

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

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

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

6 The inner change room may provide the functions of the anteroom as set out in Clause 7.4.3(d).

(d) 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.

(e) A double-ended pressure steam sterilizer shall be provided to decontaminate materials out of the facility and out of the 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.

(f) The sterilizer shall comply with the requirements of Clause 9.6.

(g) A pass-through dunk tank, fumigation 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.

(h) All drains in the facility and anteroom shall empty into collecting tanks and shall be treated by a method that renders microorganisms non-viable prior to leaving the containment facility. Disposal after treatment shall be in accordance with local municipality requirements, including any necessary post-treatment to render the effluent safe.

(i) 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.

(j) 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.

7.5.3 Invertebrate facility ventilation

The invertebrate facility ventilation system 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. 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 4.6.4(g).

(b) Both supply and exhaust air shall be filtered through HEPA filters as specified in Clause 9.10.1. The HEPA filters shall be installed and housed as specified in Clause 9.10.2. Prefilters to both the supply and exhaust HEPA filters shall be provided as specified in Clause 4.6.4 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 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.

7.5.4 Work practices

In addition to work practices specified for Invertebrate PC1, Invertebrate PC2 and Invertebrate PC3 containment, the following work practices shall apply:

(a) The invertebrate facility management shall establish policies and written procedures whereby only persons who have been trained and have been assessed as competent shall enter the facility. A person with responsibility for the overall operation of the facility shall be identified.

(b) The facility shall have a high level of physical security with restricted access. A log shall be kept of all personnel and visitors entering the facility. Personnel shall check the pressure monitoring device before entering the containment zone to verify correct functioning.

(c) All street clothing, including underwear, shall be removed and retained in the outer clothing change room. Complete facility clothing, including shoes, shall be provided by the organization and shall be used by all personnel entering the facility. When

leaving the facility, personnel shall remove their facility clothing and store or discard it in the inner change room before showering.

(d) All liquid wastes shall drain to collecting tanks. Liquid waste and plant and invertebrate material shall be decontaminated to destroy microorganisms prior to disposal.

Work surfaces and floors shall be decontaminated regularly and immediately after spillages.

SECTION 8 LABORATORY SPILLS

8.1 GENERAL

The response for an accidental spillage of biohazardous material in the laboratory (hereafter referred to in this Section as 'spills') will depend upon an assessment of the hazard (risk group) of the material and the volume. Possible consequences of the spill such as reduced staff safety, environmental pollution and cross-contamination shall be included in the assessment. The response to spills is categorized into spills inside a BSC and spills outside a BSC; the latter type is further categorized into low risk and high risk spills. All spills in PC3 and PC4 laboratories external to BSCs or similar containment devices shall be considered as high risk spills.

In spills external to BSCs, low risk infectious material that is spilled without generating significant aerosol should be cleaned up with a paper towel soaked with an effective chemical disinfectant. A spill external to a BSC of a large volume of high risk infectious material with the generation of aerosols will require clean-up personnel to wear protective clothing and respiratory protection.

Procedures shall be implemented for the following:

(a) The handling of staff whose skin, mucous membranes or both have been exposed to a spill of high risk infectious material, particularly in PC3 and PC4 laboratories.

(b) The treatment/evacuation of injured personnel, with consideration given to the avoidance of inhalation of aerosols by emergency personnel.

8.2 PLANNING

8.2.1 General

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

(a) ensuring staff are competent in the correct response to accidents, 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 clean-up group to select the correct approach for the particular circumstances.

A spills clean-up team should be employed for cleaning up of high risk spills. This team shall have training in the correct response procedure for the various containment levels of laboratories in the institution, i.e. PC2 to PC4) and the risk groups of the microorganisms handled.

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

8.2.2 Emergency facilities 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 will be exacerbated by the lack of drains underneath most emergency showers.

With large volume or high risk 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. Any contaminated PPCE is left behind.

Eyewash stations or hand-held drench hoses in the laboratories can be used when there is contamination of the eyes/face/mucous membranes with infectious material or chemicals, as waste will 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.

8.2.3 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 logo.

(b) Suitable disinfectant supplies.

NOTE: Appendix E lists suitable disinfectants.

(c) Absorbent materials.

(d) Protective clothing including spare gowns, gloves and respiratory protection equipment.

(e) Appropriate waste containers.

(f) Spare clothing for contaminated personnel.

8.3 SPILLS INSIDE BIOLOGICAL SAFETY CABINETS

Droplet-size spills or those up to 1 mL may be treated easily by wiping or flooding with a suitable disinfectant solution. If a larger spill or breakage occurs, more extensive treatment may be needed.

Spills inside a biological safety cabinet are generally considered of a lower risk 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. The suggested procedure 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 over the spill. Alternatively, proprietary absorbent materials that release hypochlorite may be used. Allow approximately 10 min to effect disinfection.

NOTE: Appendix E 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 (or remove for sterilization) 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.

8.4 SPILLS OUTSIDE BIOLOGICAL SAFETY CABINETS

8.4.1 General

Spills outside biological safety cabinets may be of varying degrees of complexity, ranging from spills within laboratories 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 laboratories 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 in the laboratory, it shall be assumed that an aerosol has been generated.

All staff members shall learn the basic procedure for the control of laboratory spills. Disinfection procedures for spills of infectious material shall contain the contamination in the affected area. Spills in confined areas, especially cold-rooms, require special considerations e.g. the air-conditioning system and air flow direction. General spills, such as from liquid cultures or culture plates, shall be treated with a suitable disinfectant.

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.

8.4.2 Assessment of risk

The response to an accidental spill of biohazardous material in the laboratory will depend upon the following:

(a) The risk group of the microorganism.

(b) The host range of the microorganism.

(c) The likely transmission mechanism.

(d) The volume of spill.

The safety of yourself and others in the vicinity should be considered.

8.4.3 Spills of low risk

Material of low risk that is spilled with minimal aerosol generation should be cleaned up in the following manner:

(a) Put on appropriate protective clothing such as gloves and gowns.

(b) Place absorbent material wetted with suitable disinfectant over the spill. Alternatively, proprietary absorbent materials which release hypochlorite may be used. Allow approximately 10 min to effect disinfection. Remove any sharp objects with forceps and discard as contaminated sharps.

(c) Use the same disinfectant solution to wipe over the area likely to have been contaminated.

(d) Carefully mop up the spill and disinfection solution, and transfer all contaminated materials for disposal.

(e) Remove protective clothing and wash hands.

8.4.4 Spills of high risk

8.4.4.1 *General*

A spill of high risk will require clean-up personnel wearing protective clothing and may require respiratory protection. When the spill occurs, the area shall be immediately evacuated 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.

8.4.4.2 *Spills of high risk in PC2 laboratories*

The clean-up procedure shall be as follows:

(a) If safe to do so, contain the source of the spill. Take measures to avoid breathing the aerosol, warn others in the room and all leave the room immediately.

(b) Remove the laboratory gown and any other garment suspected of being contaminated, and place in a biohazard bag for subsequent decontamination.

(c) If it is suspected that shoes are contaminated, remove and place in a separate biohazard bag.

(d) If contamination is superficial, wash affected areas and put on a clean laboratory gown. If spilled material has soaked through clothing, take a complete body shower in a regular, i.e. not an emergency, shower wherever possible. Use an eyewash station if the eyes have been exposed.

(e) Close the door and place a biohazard sign with ‘DO NOT ENTER’ on the door.

(f) Warn others to keep out of the area of the spill.

(g) Notify the area supervisor of the spill.

(h) Stay out of the spill area for at least 30 min.

NOTE: Consideration should be given to isolation of recirculating ventilation systems.

(i) 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 8.2.)

(j) Before entering the area of the spill, put on appropriate protective clothing and equipment, such as gowns, gloves, boots, eye and respiratory protection.

(k) Determine the extent of contamination.

(l) Place absorbent material, such as paper towels, wetted with disinfectant, over the spill. Allow at least 10 min to effect disinfection.

NOTE: Appendix E provides a list of disinfectants.

(m) 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 disposal.

(n) Use the same disinfectant solution to wipe over surrounding areas likely to have been contaminated with aerosols.

(o) Ensure that each member of the clean-up team decontaminates boots, discards gloves and discards or decontaminates respirator and clothing.

(p) Complete an incident report form.

8.4.4.3 *Spills of high risk in PC3 laboratories*

The clean-up procedure shall 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. Take measures to avoid breathing the aerosol, warn others in the room and all prepare to leave the room immediately.

(c) Remove the laboratory gown and any other garment suspected of being contaminated, and place in a biohazard bag for subsequent decontamination.

(d) If it is suspected that shoes are contaminated, remove and place in a separate biohazard bag.

(e) If contamination is superficial, remove PPCE, wash hands and leave the PC3 facility via the airlock. If spilled material has soaked through clothing, and there is a shower in the laboratory, take a full body shower. If there is no shower in the laboratory, put on emergency clothing, leave the laboratory and take a complete body shower in a regular, i.e. not an emergency, shower.

(f) Place a biohazard sign with 'DO NOT ENTER' on the outer door of the airlock.

(g) Discuss the nature of the spill with the clean-up team, who need to be familiar with PC3 entry and exit procedures and satisfy any health requirements, such as vaccinations. Check all necessary equipment is available. (See Clause 8.2.)

NOTE: The 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.

(h) Leave the ventilation system on and stay out of the spill area for at least 30 min.

(i) Before entering the PC3 area via the airlock, put on appropriate protective clothing and equipment, such as gowns, gloves, boots, eye and respiratory protection (see Clause 8.2). This emergency clothing and equipment shall remain inside the PC3 area.

(j) Determine the extent of contamination.

(k) Place absorbent material, such as paper towels, wetted with disinfectant, over the spill. Allow at least 10 min to effect disinfection.

NOTE: Appendix E provides a list of disinfectants.

(l) 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 disposal.

(m) Use the same disinfectant solution to wipe over surrounding areas likely to have been contaminated with aerosols.

(n) Discard all clothing and PPCE for decontamination or autoclaving before leaving the PC3 facility. If a shower is present in the laboratory, shower before leaving the facility. If there is no shower in the laboratory, put on emergency clothing, exit via the airlock and take a regular, i.e. not an emergency, shower.

(o) Complete an incident report form.

8.4.4.4 *Spills of high risk in PC4 laboratories*

The clean-up procedure shall be as follows:

(a) If safe to do so, contain the source of the spill. Take measures to avoid breathing the aerosol and warn others in the room.

(b) Discuss the nature of the spill with the clean-up team, who need to be familiar with PC4 entry and exit procedures and have any required precautions such as vaccinations. Check all necessary equipment is available. (See Clause 8.2.)

(c) Put on appropriate protective clothing and equipment, such as gowns, gloves, boots, eye and respiratory protection (see Clause 8.2). This emergency clothing and equipment shall remain inside the PC4 area.

(d) Determine the extent of contamination.

(e) Place absorbent material, such as paper towels, wetted with disinfectant, over the spill. Allow at least 10 min to effect disinfection.

NOTE: Appendix E provides a list of disinfectants.

(f) 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 disposal.

(g) Use the same disinfectant solution to wipe over surrounding areas likely to have been contaminated with aerosols.

(h) Discard all clothing and PPCE for decontamination or autoclaving before showering out of the PC4 facility.

(i) Complete incident report form.

8.5 CENTRIFUGE SPILLS

Where a spill or leak is detected within a centrifuge, the procedure will depend upon the risk of the agent involved (see Clause 8.1) as well as the construction of the equipment. The clean-up procedure should be as follows:

(a) *Centrifuges with sealed rotors or buckets that can withstand high temperatures* Thermally decontaminate intact at 121°C for a minimum of 4 min.

(b) *Centrifuges with non-sealed rotors and centrifuges not able to withstand high temperatures* Where breakage or spillage is observed, allow 30 min for aerosols to settle. Place the rotor or bucket in an appropriate non-corrosive disinfectant solution (see Appendix E). 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 9 GENERAL PRECAUTIONS AND SPECIAL EQUIPMENT

9.1 GENERAL PRECAUTIONS

9.1.1 Hazardous substances

Many media components, chemicals and reagents used in the microbiological laboratory are hazardous to health. For some substances, specific risks, including chemical carcinogenicity or teratogenicity, have not been fully characterized. Consideration should be given to safe work practices including the use of fume cupboards that comply with AS/NZS 2243.8, recirculating fume cabinets that comply with AS/NZS 2243.9, and of appropriate personal protective equipment such as gloves, safety glasses and respirators, as required.

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

9.1.2 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, disinfected at regular intervals and before being sent for repair or disposal.

9.1.3 Discard containers

Containers should be decontaminated before their contents are either discarded or they are washed for re-use. Lids or covers should be loosened or vented before placing the containers in a steam sterilizer (see Clause 9.6.3).

9.1.4 Bunsen burners

Bunsen burners should be installed with flexible tubing, impermeable to the gas used, and secured by clips at both the burner and the gascock. Bunsen burners should be extinguished when not in use, should not be sited near flammable solvents and should not be used in biological safety cabinets.

9.1.5 Disposable syringes and needles

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

9.2 PERSONAL PROTECTIVE CLOTHING AND EQUIPMENT (PPCE)

9.2.1 General

Personal protective clothing and equipment may act as a barrier to minimize the risk of exposure to aerosols, splashes and accidental inoculation. The clothing and equipment selected is dependent on the nature of the work performed. Protective clothing shall be worn when working in the laboratory. Before leaving the laboratory, PPCE shall be removed and hands washed. Detailed information on the use of PPCE is available in AS/NZS 2243.1.

9.2.2 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.

9.2.3 Footwear

Closed footwear shall be worn, i.e. footwear that covers the toes and heels. Where specific safety footwear is required for a particular hazard, it shall be selected in accordance with AS/NZS 2210.

9.2.4 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.

9.2.5 Respiratory protection

Microbiological work should be planned to limit the reliance on respiratory protective equipment (RPE). Most work with microorganisms transmissible by the respiratory route is conducted in containment equipment such as BSC. 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 selection of respiratory protective equipment therefore depends upon a variety of factors.

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. AS/NZS 1715 should be consulted for information on types of RPE, types of filters and the selection of appropriate RPE for a particular situation. AS/NZS 1715 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.

NOTE: The lack of exposure standards for microorganisms means that the concept of minimum protection factors, as described in AS/NZS 1715, cannot be applied.

Air-purifying RPE is available with interchangeable filters for protection against gases, vapours, particulates and microorganisms. Very little exposure data is available to show the efficacy of different types of filters against specific microorganisms. RPE employing a HEPA filter (P3 filter) provides the best respiratory protection against microorganisms where filters are used. However, other types of filters such as P1 and P2 can be effective if protection against the aerosol itself is adequate to prevent infection. 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.

Supplied air RPE can also be powered or non-powered. The supplied air can be at atmospheric pressure or as a compressed breathing gas. Supplied air RPE provides full personal respiratory protection, if used correctly.

Face masks designed for use in health care, such as those covered by AS 4381, do not meet the requirements for RPE specified in AS/NZS 1715.

Advice shall be sought from a suitably qualified person, e.g. an occupational hygienist, to assist in selection of the correct type of RPE. To achieve optimal protection, RPE should be individually fitted and tested.

9.2.6 Gloves

Contamination of hands may occur when laboratory procedures are performed. Hands are also vulnerable to ‘sharps’ injuries. Disposable latex 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 thoroughly washed. 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.

9.3 CENTRIFUGES

9.3.1 General

The use of centrifuges can present a hazard to operators, to other laboratory staff, to experimental work and to the environment. Tube breakage, bucket breakage or rotor failure can cause ejection and scattering of infectious material; therefore sealed-bucket or sealed-rotor centrifuges should be used. When selecting a centrifuge, preference should be given to models with minimal vibration and noise. Light-weight rotors should be considered.

NOTE: The size and weight of loaded centrifuge components should be considered to ensure they do not present manual handling hazards.

Centrifuges with vacuum pumps 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.

Centrifuges shall not be placed 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.

Reusable centrifuge tubes, buckets and rotors used for centrifuging infectious materials shall be capable of withstanding repeated decontamination in a pressure steam sterilizer at 121°C without deterioration. If the life of any seals is shortened by repeated sterilizing, a note shall be appended to the centrifuge instruction manual to emphasize the limitation. Centrifuge tubes and buckets shall be inspected before use, and units showing damage shall be discarded. Tubes and buckets with caps or lids that can be securely sealed shall be used when centrifuging infectious material or potentially infectious material. Loaded tubes together with buckets if used, shall be carefully balanced before centrifuging.

NOTE: For the management of centrifuge spills, see Clause 8.5.

Centrifuge bowls shall be cleaned regularly and decontaminated with an appropriate disinfectant solution at regular intervals and before servicing.

Rotors and buckets shall be inspected for damage, cracking or corrosion regularly and discarded if there is significant damage in line with the manufacturer’s recommendations. Rotors and buckets shall be decontaminated with appropriate disinfectant on a regular basis and before servicing.

NOTE: Some disinfectants can damage the materials out of which some rotors and buckets are constructed.

Logbooks shall be kept for medium and high speed centrifuges to ensure timely maintenance and safety inspections of the rotors.

9.3.2 Sealed-bucket and sealed-rotor centrifuges

The lid of the rotor or the swing-out bucket shall be impact-resistant, preferably transparent and the seal on the rotor/bucket shall be visually distinguishable from its seating. It shall be possible to remove the rotor or buckets from the centrifuge without breaking the seal.

9.3.3 Other centrifuges

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 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 high speed centrifuges, the tubes shall be loaded, and the tubes and rotors unloaded, in a biological safety cabinet.

(c) Centrifuge bowls shall be disinfected following contamination such as when tubes break or leak during centrifuging (see Clause 8.5).

(d) 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.

9.3.4 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. (See Section 4.)

9.4 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 Clause 4.2). 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).

9.5 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 and 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 nitrogen gas. Only approved vessels shall be used for the storage and transport of liquid nitrogen.

(e) 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. Liquid nitrogen shall not be stored in unventilated rooms such as cold rooms.

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

9.6 PRESSURE STEAM STERILIZERS

9.6.1 General

Pressure steam sterilizers are used in laboratories both for sterilization of media and equipment required for the culture of microorganisms, and for sterilization 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 local 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.

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.

9.6.2 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.

9.6.3 Downward displacement 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. 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 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.

9.6.4 Pre-vacuum (porous load) sterilization

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 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 in the chamber exhaust line to protect the liquid in the vacuum pump from contaminated aerosols and periodically maintained.

9.6.5 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.

NOTE: Refer to Clause 3.7 and Note 1 to Table 3.4 for recommended sterilizing times for Creutzfeldt-Jakob and other prions.

9.6.6 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 certified by a recognized certification body, e.g. the National Association of Testing Authorities (NATA). 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 9.1 lists commonly-used biological indicators and has been based on information in Reference 1.20.

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.

9.6.7 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.

9.6.8 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 9.1

COMMONLY-USED BIOLOGICAL INDICATORS

Process	Species	Incubation temperature
Steam under pressure	*Geobacillus stearothermophilus*	56°C Rapid enzyme B1 (60°C)
Dry heat	*Bacillus subtilis* var *niger*	37°C
Ethylene oxide	*Bacillus subtilis* var *niger*	37°C
Subatmospheric steam and formaldehyde	*Geobacillus stearothermophilus*	56°C

9.7 BIOLOGICAL SAFETY CABINETS

Two classes of biological safety cabinets are in common use, Class I and Class II, see Clause 1.4.5.

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 laboratory. 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 laboratory 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 laboratory 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 disinfectant 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 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. The presentation is available from the publications list on the Victorian Infectious Diseases Reference Laboratory web site, www.vidrl.org.au. The video 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.

9.8 FLEXIBLE FILM ISOLATORS

A flexible film isolator 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 laboratory animals.

NOTES:

1 The isolator envelope is constructed of plastic film which is flexible, puncture and tear-resistant and optically clear and attached to a rigid supporting frame.

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

3 Isolators 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.

9.9 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.

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.

9.10 HEPA FILTERS

9.10.1 Specification

HEPA filters for containment facilities shall be either—

(a) Type 1, Class A filters as specified in AS 1324.1 with metal separators and elastomeric compression seals, which meet all requirements of AS 4260 with a minimum performance of Grade 2; or

(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.

9.10.2 Installation and maintenance

HEPA filters for containment facilities shall be mounted in gastight housing(s) located as close as possible to the containment facility to minimize the length of potentially contaminated ductwork. The interconnecting ductwork between the containment room and the HEPA filter housing shall also be of gastight construction.

The design of the filter housing shall facilitate the testing of the integrity of the HEPA filter element and mounting, and the periodic gaseous decontamination of the filter element and associated mounting surfaces independently of the gaseous decontamination of the facility.

Housings shall be placed in fully accessible locations 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 incorporating a magnetically coupled indicating mechanism and a sealed differential pressure diaphragm.

NOTE: A Magnehelic type gauge complies with this requirement.

(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 10 WORK AREAS

10.1 WARNING SIGNS

The following warning signs shall be prominently displayed external to and near the entrance to each laboratory involved in the handling of hazardous microorganisms:

(a) A sign containing the biological hazard warning symbol and the level of containment of the laboratory. For general microbiological laboratories, the sign shall comply with the requirements in Paragraph F2 of Appendix F. For gene technology laboratories, these signs are supplied by the OGTR.

NOTE: Details of the biological hazard symbol are also described in Appendix F.

(b) Radiation and other warning symbols, if appropriate to the laboratory.

10.2 SEGREGATION OF SPECIAL AREAS

Where the functions are required, separate areas shall be provided for the following:

(a) Preparation of media.

(b) Collection of specimens from patients, if relevant.

(c) Receipt of samples.

(d) Holding of materials awaiting sterilization.

(e) Sterilization.

(f) Storage of sterile articles.

(g) Essential write-up and essential laboratory clerical work.

Procedures for collecting specimens from patients shall be closely controlled (see Department of Health and Ageing, *Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting*). Appropriate sterile equipment shall be provided, and used, to ensure the safety of the patient and of the laboratory staff.

10.3 ANIMAL AREAS

Animal containment facilities shall be segregated from laboratories and shall contain separate areas for infected animals, for non-infected animals and for post-mortem examinations (see Section 5).

SECTION 11 LABORATORY CLEANING

11.1 GENERAL

The laboratory's physical containment level shall be considered when setting out laboratory cleaning arrangements and services. Dedicated cleaning equipment shall be provided for PC3 and PC4 laboratories. Such equipment shall be stored within the containment facility.

Clean surroundings facilitate clean work. Laboratory 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

The laboratory supervisor shall issue special instructions (particularly to cleaning contractors) necessary for the cleaning of microbiological laboratories. 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. Only laboratory staff shall handle infectious materials.

11.3 BENCHES AND WORK SURFACES

Workbenches shall be kept tidy and free of materials not being used. Benches and work surfaces shall be cleared at the end of each working day and then disinfected. Under-bench cupboards, where used, should be mobile or suspended to facilitate cleaning of under-bench areas.

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 are better stored in closed cupboards.

11.5 FLOOR CLEANING

The time of the day allocated for floor cleaning shall be specified. General floor cleaning shall 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 a microbiological laboratory.

(d) *Sweeping* Brooms shall not be used, as they produce airborne dust that can increase contamination of work in the laboratory.

SECTION 12 WASTE DISPOSAL

NOTE: See also AS/NZS 3816 and NZS 4304.

12.1 COLLECTION

Laboratory wastes shall be collected in segregated containers, clearly identified according to the following categories:

(a) *Non-infectious material* Waste paper, plastics, and paper products shall be collected in a single layer plastic bag.

(b) *Sharps* These include syringes with needles, broken glass, scalpel blades and shall be collected in a rigid, puncture-proof container (see AS 4031).

(c) *Infectious material* Sample remains, used Petri dishes, culture bottles, disposable equipment, used gloves, biological tissue, fluids, infected animal carcasses and bedding shall be collected in a robust plastic bag displaying the biohazard symbol, which can be decontaminated in a pressure steam sterilizer and is retained in a solid tray, or a solid-based container with a non-sealing lid.

NOTES:

1 Special precautions are required for large volumes of liquid waste.

2 After decontamination, bags with the biohazard symbol may be repackaged into unmarked bags for disposal.

(d) *Co-mingled material* The disposal of co-mingled waste, such as infectious and radioactive waste, or infectious and chemical wastes shall be conducted in a manner that addresses both hazards.

(e) *Radioactive infectious material* Collect solid waste into robust plastic containers, labelled with isotope and date, within a secondary solid container. Collect liquid waste into container for disinfection.

NOTE: See also AS/NZS 2243.1 for other types of waste.

12.2 TREATMENT AND DISPOSAL OF WASTES

All unwanted wastes containing live microorganisms shall be—

(a) decontaminated by pressure steam sterilization;

(b) treated by a chemical disinfectant;

(c) incinerated in a high temperature, high efficiency EPA-approved (Australia) or regional council-approved (New Zealand) incineration facility; or

(d) disposed by any other process approved by the relevant regulatory authority.

When incineration is used, adequate containment shall be provided for transport of infectious waste from the laboratory to the incinerator.

After decontamination or chemical treatment, waste shall be disposed of in accordance with relevant authority requirements.

NOTE: EPA-approved incineration for cytotoxic drugs exceeds the requirements for microbial destruction (see also Reference 1.21).

The following points shall be observed:

(i) All waste involving genetically modified organisms shall be disposed of in accordance with the requirements of the relevant regulatory authority.

(ii) Ensure that wastes that melt during steam sterilization do not block sterilizer drain holes.

(iii) Only validated steam sterilizer cycles (see Clauses 9.6.5 and 9.6.6) shall be used.

(iv) Chemical wastes shall be disposed of in accordance with AS/NZS 2243.2 and Government requirements where applicable.

(v) In Australia, radioactive wastes 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 wastes 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 (Reference 1.22).

(vi) Containers of sharps shall be rendered non-infectious.

NOTE: General uncontaminated laboratory wastes may be disposed of in the same manner as household waste.

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 (Reference 1.23), which are adopted by 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.

Unpacking procedures and precautions shall be consistent with the type of package being unpacked.

If infectious waste is to be removed from a laboratory, 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* (Reference 1.24).

(b) The Australia Post, *Dangerous and Prohibited Goods Packaging Guide* (Reference 1.25).

(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 1.26).

(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 (Reference 1.23).

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.

13.3 IMPORTATION REGULATIONS

For Australia, quarantine permission to import any biological material shall be obtained as set out in Clause 2.3.1. In addition, there are restrictions on the movement of imported biological materials within Australia. For information on these restrictions, the Chief Quarantine Officer (Animals) at the Department of Agriculture, in each state, or Department of Agriculture, Fisheries and Forestry in the Australian Capital Territory, should be contacted. In New Zealand, a permit to import biological material shall be obtained in accordance with Clause 2.3.2.

NOTE: If compliance with the Hazardous Substances and New Organisms Act 1996 (NZ) is required, import approval will need to be obtained from ERMA prior to seeking the MAF permit.

13.4 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.

13.5 CLASSIFICATION AND PACKAGING

13.5.1 General

Clauses 13.5.2 to 13.5.5 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.

13.5.2 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)	Highly pathogenic avian influenza 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)	*Mycobaterium tuberculosis* (cultures only)
Coxiella burnetti (cultures only)	Omsk haemorrhagic fever virus
Crimean-Congo haemorrhagic fever virus	Nipah virus
Dengue virus (cultures only)	*Poliovirus* (cultures only)
Eastern equine encephalitis virus (cultures only)	Rabies virus (cultures only)
Escherichia coli, verotoxigenic (cultures only)	*Ricksettsia prowazekii* (cultures only)
Ebola virus	*Ricksettsia ricksettsii* (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 I* (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)
Human immunodeficiency 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.

13.5.3 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.

13.5.4 Genetically modified microorganisms and organisms

Genetically modified microorganisms shall be transported according to the regulations published by the OGTR or ERMA, as appropriate.

13.5.5 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.

13.6 TRANSPORT OF INFECTED ANIMALS

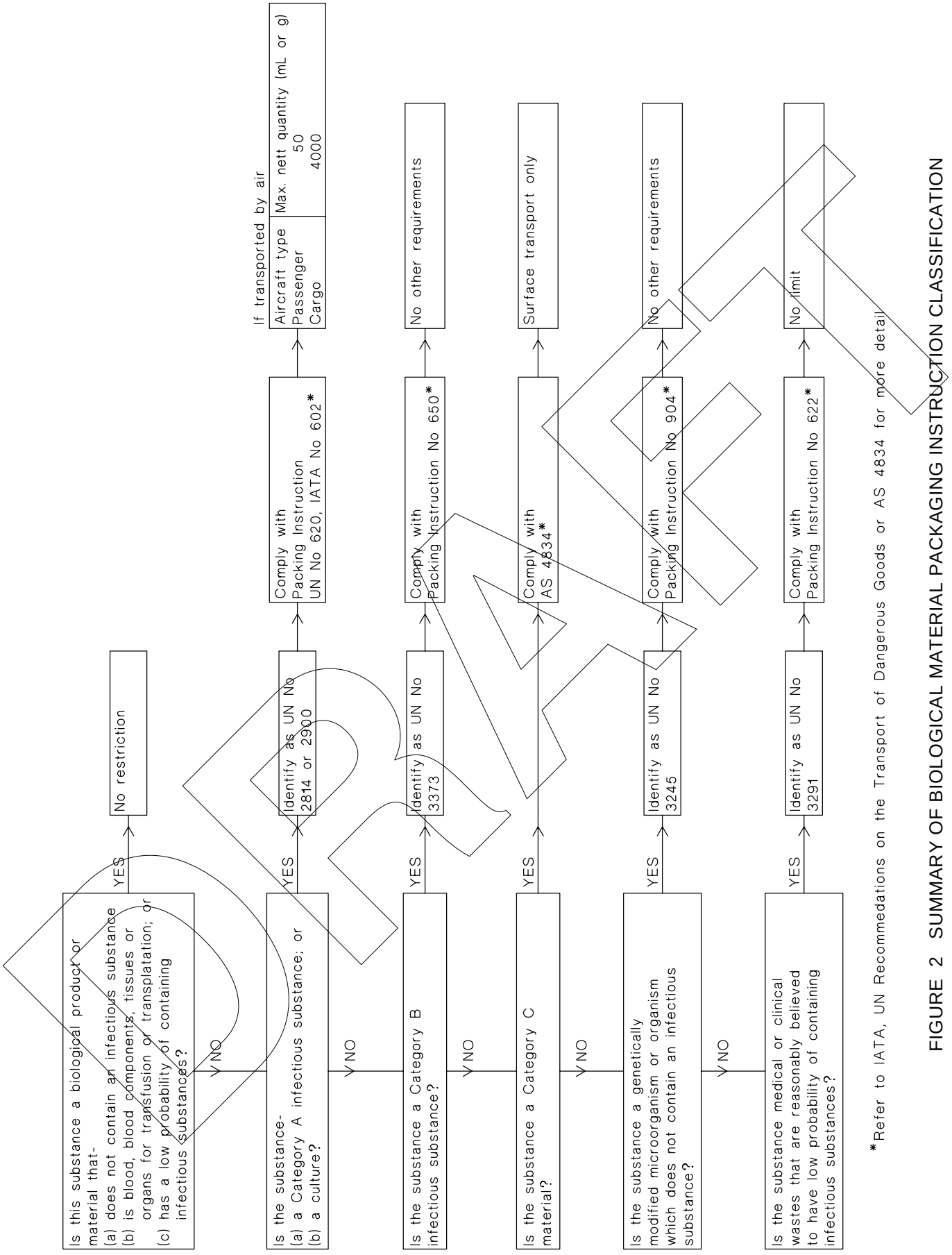
A live animal that has been intentionally infected and is known or suspected to contain an infectious substance shall not be transported by air unless the infectious substance contained cannot be consigned by any other means. Infected animals may only be transported under terms and conditions approved by the competent authority.

Unless an infectious substance cannot be consigned by any other means, it shall not be transported in a live animal.

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.

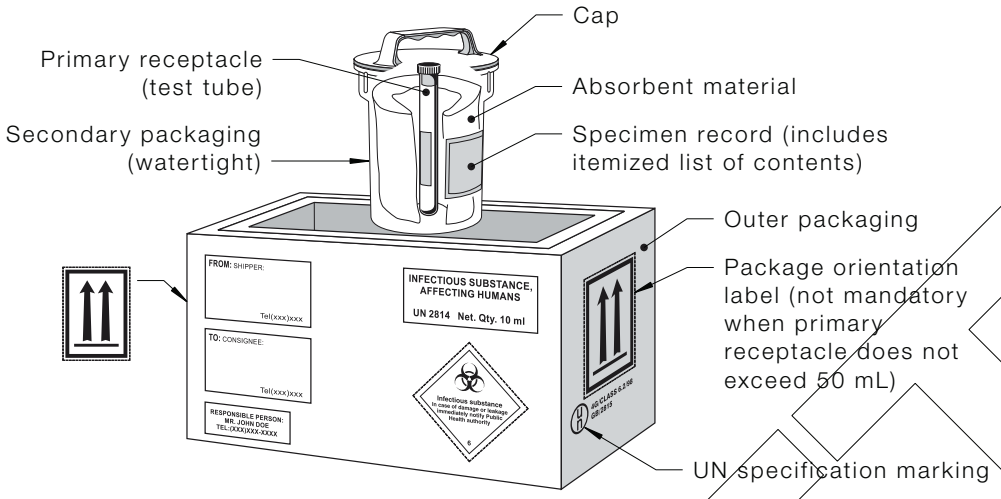
13.7 DOCUMENTATION

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.

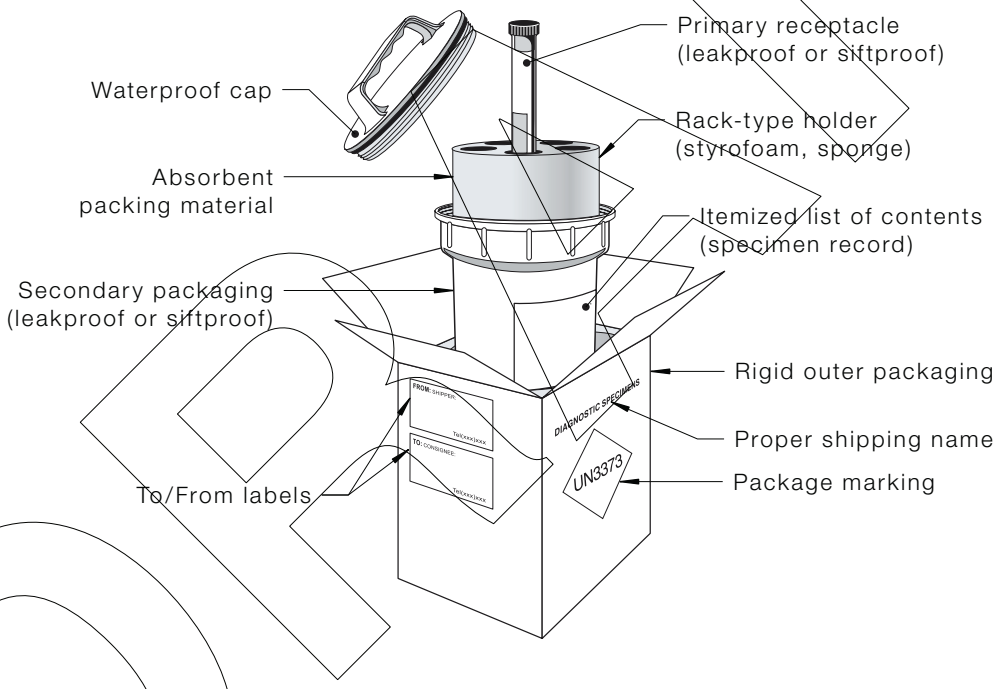


*Refer to IATA, UN Recommedations on the Transport of Dangerous Goods or AS 4834 for more detail

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

REFERENCES 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

1170 Minimum design loads on structures (known as the SAA Loading Code)
1170.4 Part 4: Earthquake loads

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

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

1885 Measurement of occupational health and safety performance (Series)

2243 Safety in laboratories
2243.4 Part 4: Ionizing radiations

2252 Biological safety cabinets
2252.1 Part 1: Biological safety cabinets (Class 1) for personnel and environment protection
2252.2 Part 2: Laminar flow biological safety cabinets (Class II) for personnel, environment and product protection

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

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

4381 Single-use face masks for use in health care

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

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

1336 Recommended practices for occupational eye protection

1337 Eye protectors for industrial applications

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

ISO
3864 Safety colours and safety signs

NZS
4304 Management of healthcare waste

5433 Transport of dangerous goods on land

Advisory Committee on Novel Genetic Techniques
New Zealand code of practice for small-scale genetic manipulation research

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

AUSTRALIAN BUILDING CODES BOARD
Building Code of Australia

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 (New Zealand Ministry of Agriculture and Forestry)

*In course of preparation

154.03.02 Containment facilities for microorganisms
154.03.03 Containment facilities for vertebrate laboratory animals
155.04.09 Containment facilities for new organisms (including genetically modified organisms) of plant species

OGTR (Office of the Gene Technology Regulator, Australia)
Guidelines for the certification of facilities/Physical containment requirements

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

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

New Zealand Hazardous Substances and New Organisms Act 1996
New Zealand Hazardous Substances and New Organisms (Low-risk genetic modification) Regulations, 2003
New Zealand Hazardous Substances and New Organisms Amendment Act 2003

NTAC (National Tuberculosis Advisory Committee)
Guidelines for Australian Mycobacteriology Laboratories. (published in *Communicable Diseases Intelligence*; vol 30: p. 116 – 128)

A3 REFERENCES

The following publications are referred to in this Standard:

1.1 Hazardous Substances and New Organisms Act 1996. Wellington, New Zealand.

1.2 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.

1.3 MINISTRY OF AGRICULTURE AND FORESTRY. MAF Regulatory Authority Standard 154.03.02 *Containment facilities for microorganisms.* Wellington, NZ, 2002.

1.4 Hazardous Substances and New Organisms (Low-risk genetic modification) Regulations 2003. Wellington, New Zealand.

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1.6 MINISTRY OF AGRICULTURE AND FORESTRY. *Transitional facilities for biological products*. MAF Regulatory Authority Standard 154.02.17. Wellington, NZ, 1998.

1.7 US DEPARTMENT OF HEALTH AND HUMAN SERVICES. *Biosafety in microbiological and biomedical laboratories*. 4th ed. Washington D.C.: US Government Printing Office, 1999.

1.8 UK ADVISORY COMMITTEE ON DANGEROUS PATHOGENS. *Categorization of biological agents according to hazard and categories of containment.* 4th ed. London: HSE Books, 1995.

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

1.10 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).

1.11 ASHDOWN, L.R. Melioidosis and safety in the clinical laboratory. *Journal of Hospital Infection*. 1992; vol. 21: p.301-6.

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

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

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

1.15 NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL. *Australian code of practice for the care and use of animals for scientific purposes*. 6th ed. Canberra: Australian Government Publishing Service, 1997. (Available from web site at www.health.gov.au/nhmrc/publications/titles.htm)

1.16 MINISTRY OF AGRICULTURE AND FORESTRY. MAF Regulatory Authority Standard 154.03.03. Containment facilities for vertebrate laboratory animals. Wellington, New Zealand. 2002.

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

1.18 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.

1.19 MINISTRY OF AGRICULTURE AND FORESTRY. MAF Regulatory Authority Standard. 155.04.09. *Containment facilities for new organisms (including genetically modified organisms) of plant species*. Wellington, New Zealand. 2003.

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

1.21 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.

1.22 NATIONAL RADIATION LABORATORY. *Code of safe practice for the use of unsealed radioactive materials*. Christchurch, New Zealand 1996.

1.23 UNITED NATIONS. *Recommendations on the Transport of Dangerous Goods*. Model Regulations. 13th ed. Geneva: United Nations.

1.24 INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA). *Dangerous Goods Regulations*. Montreal: IATA Dangerous Goods Board, 2001 (updated annually).

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

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

1.27 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.

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1.29 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.

1.30 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.

1.31 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.

1.32 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.

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

1.34 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.

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.

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

2.5 FLEMING, D.O., RICHARDSON, J.H., TULIS, J.J., and VESLEY, D. (eds.). Laboratory safety: *Principles and practices*. 2nd ed. Washington D.C.: American Society for Microbiology, 1995.

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

2.7 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.

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

2.9 NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL. *Guidelines for laboratory personnel working with carcinogenic or highly toxic chemicals*. Canberra: Australian Government Publishing Service, 1990.

2.10 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.

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

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

2.13 RICHMOND, J.Y. (ed.). *Anthology of Biosafety. I. Perspectives on laboratory design*. American Biological Safety Association, 1999.

2.14 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.

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

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

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2.18 OFFICE OF THE GENE TECHNOLOGY REGULATOR. *Handbook on the Regulation of Gene Technology in Australia*. Canberra: Office of the Gene Technology Regulator, 2001.

2.19 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.

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

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

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

2.23 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 you saw happen

7. SUPERVISOR:

   Name: Signature: Date:

8. FOLLOW UP PREVENTATIVE ACTION:

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 1, 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;

(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 strains. These can be supplied free of charge on application to the National Polio Reference Laboratory, Victorian Infectious Diseases Reference Laboratory, North Melbourne, Victoria or Environmental Science and Research, New Zealand. Further information on the eradication and containment of wild polioviruses is available from the website www.vidrl.org.au or www.surv.esr.cri.nz/virology/virology.php.

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

* 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.

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 in for the PC2/polio laboratory. Major facility requirements are described in Clause 4.6.2. 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

WATER AND GAS SUPPLIES TO CONTAINMENT FACILITIES

(Normative)

D1 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.

D2 WATER SUPPLIES

D2.1 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 D1:

(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 boundary 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.

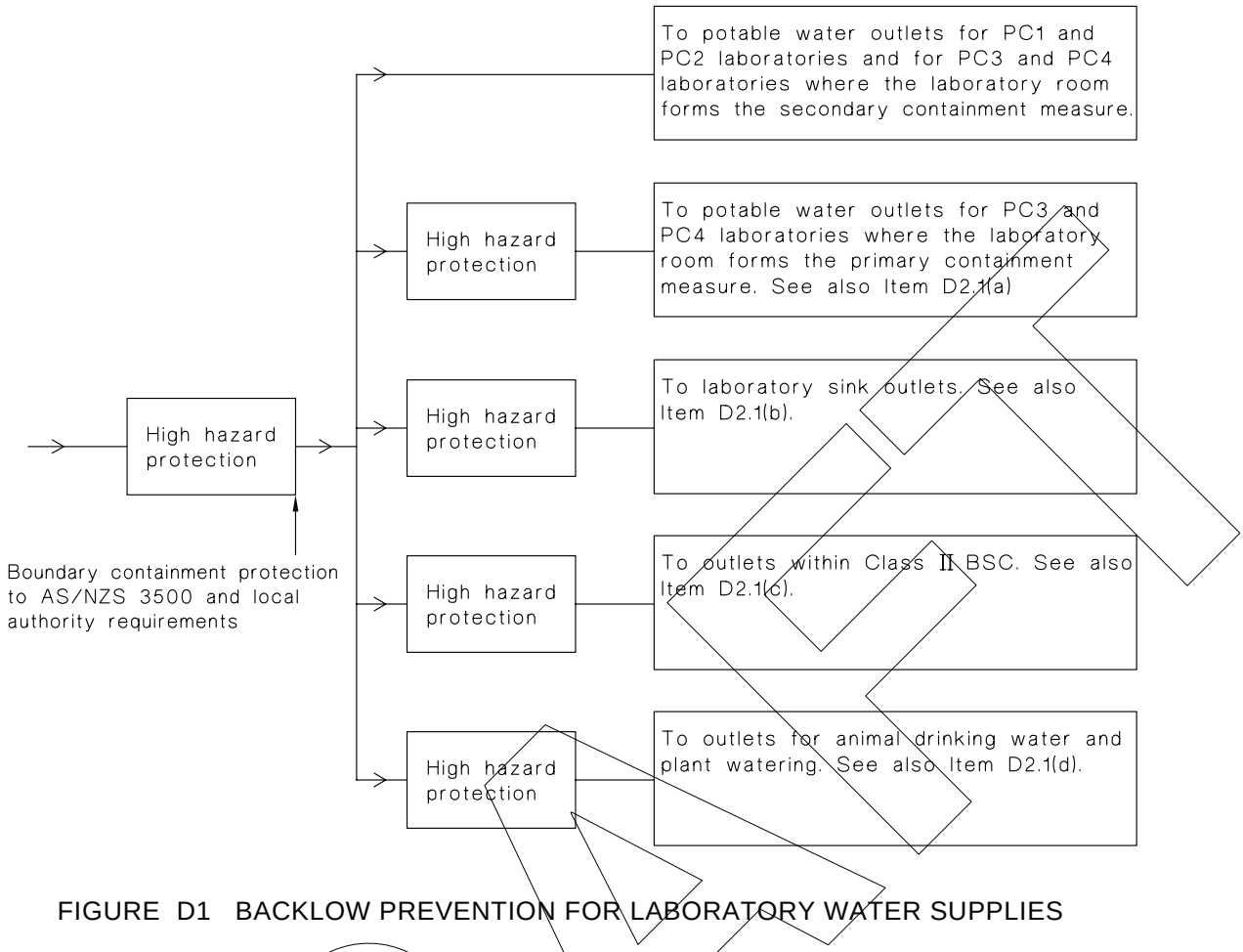


FIGURE D1 BACKLOW PREVENTION FOR LABORATORY WATER SUPPLIES

D2.2 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 D2(a).

(b) Reverse flow protection including alarms shall be provided. See Figure D2(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.

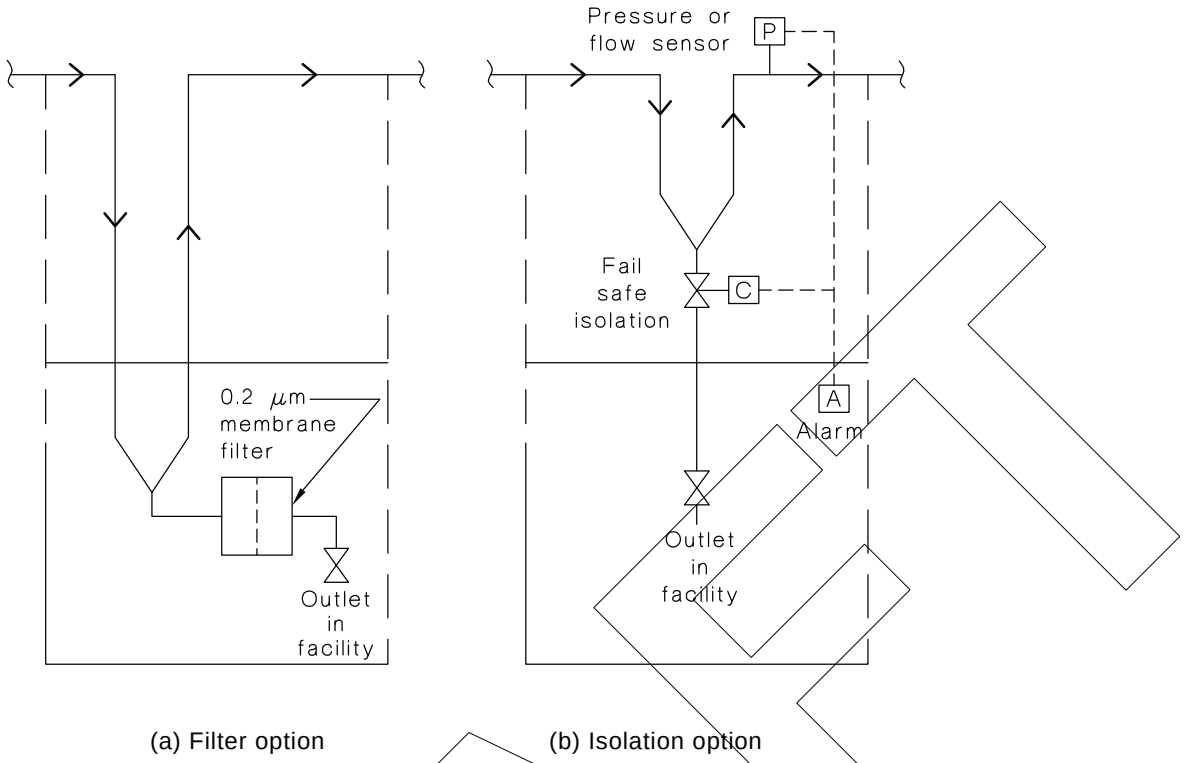


FIGURE D2 BACKFLOW PREVENTION FOR LOOPED SERVICE OUTLETS

D3 GAS SERVICES

D3.1 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.

D3.2 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 D3:

(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 D3.1(c).

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

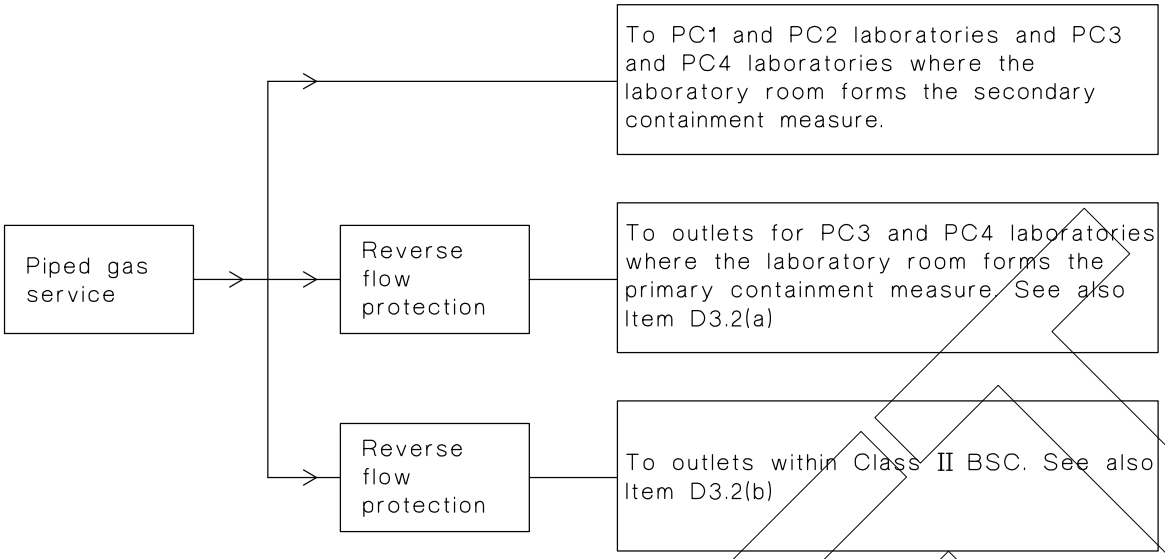


FIGURE D3 BACKFLOW PREVENTION FOR GAS SERVICES

APPENDIX E

CHEMICAL DISINFECTANTS

(Informative)

E1 INTRODUCTION

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. Where time permits, heat-labile materials and equipment may be sterilized by gaseous chemicals such as ethylene oxide or by ionizing radiation.

E2 SUSCEPTIBILITY OF MICROORGANISMS

Microorganisms vary in their susceptibility to chemical disinfectants. Lipid-containing viruses and the vegetative forms of most bacteria are relatively susceptible. Fungi, acid-fast bacteria (*Mycobacterium* spp.) and non-lipid-containing viruses are less susceptible while bacterial spores are resistant to the action of many chemical disinfectants. The agents of scrapie, Creutzfeldt-Jakob disease and other prions are extremely resistant to chemical disinfection (see Clause 3.7 and Note 1 to Table 3.4).

E3 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.

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.

E4 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.

E5 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 E1 to E3 should be consulted for assistance when selecting disinfectants. Table E1 provides recommended applications for chemical disinfectants in microbiological laboratories. Table E2 provides recommendations for the disinfection levels to be used in relation to the listed types of microorganisms. Table E3 provides examples of disinfectants of different disinfection levels.

E6 PROPERTIES OF COMMONLY-USED DISINFECTANTS

E6.1 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 1.27).

Commercially available chlorine solutions vary in the concentration of available chlorine they contain. For example, some solutions contain 4% 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.

E6.2 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.

E6.3 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 1.28) and is currently under review. 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 1.29 and, for BSC, AS/NZS 2647 should be consulted.

E6.4 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. For example, after instruments are placed in glutaraldehyde disinfectant, the gloved hands should be rinsed under running water before the lid is replaced on the container; when the instruments are removed from the disinfectant, any excess glutaraldehyde should be drained back into the container. The tap used for rinsing the instruments under running water should be located as close as practicable to the disinfectant container. Rinsing under running tap water is preferable to rinsing in containers of still water because traces of glutaraldehyde are retained in the latter. However, these traces are not sufficient to prevent contamination of the water by *Pseudomonas aeruginosa* or other potentially pathogenic bacteria. For some purposes, water sterilized by heat or bacteria-retentive filters is used for final rinsing.

E6.5 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.

E6.6 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 1.30 and 1.31). It is corrosive to metalware and damaging to fabrics but less so than is sodium hypochlorite of equivalent activity.

E6.7 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.

E6.8 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.

E6.9 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.

E6.10 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.

E6.11 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 1.32). 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.

E6.12 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.

E6.13 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 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.

NOTE: References 1.33 and 1.34 provide further information on OPA.

E7 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 E1

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	Synthetic phenolics*
Biological safety cabinet (BSC) work surfaces	Synthetic phenolics* after bacteriological work *or* Iodophor* *or* other disinfectant according to the pathogen being handled	For BSC with capture hoods, glutaraldehyde† (with cabinet fan operating) —swabbed (see AS/NZS 2647)
BSC before servicing or testing	Formaldehyde vapour (see Paragraph E6.3)	
Centrifuge rotor or sealable bucket after leakage or breakage	Disinfection not the preferred method. Pressure steam sterilizing at 121°C for 15 min recommended	Glutaraldehyde† for 10 min *or* synthetic phenolics* for bacterial spills for 10 min
Centrifuge bowl after leakage or breakage	Glutaraldehyde† for 10 min (swabbed twice within the 10 min period then wiped with water)	Synthetic phenolics* for bacterial spills for 10 min
Discard containers (pipette jars)	Chlorine disinfectant at 2 000–2 500 p.p.m. (0.2–0.25%), freshly prepared and changed daily	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 *or* glutaraldehyde† then water
Gnotobiotic animal isolators	Peracetic acid at 2% *v/v* conc—swabbed	
Hand disinfection	Chlorhexidine (0.5–4% *w/v*) in alcoholic formulations for 2 min	Isopropyl (60–70% *v/v*) or ethyl alcohol (80% *v/v*) with emollients or Povidone-iodine (0.75–1% av I) for 2 min
Hygienic handwash	Chlorhexidine (4% *w/v*) in detergent formulation (or alcoholic formulations) for 15 s	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%) for 10 min‡ (active against hepatitis viruses and HIV)	Glutaraldehyde† for 10 min
Spills of bacterial cultures	Synthetic phenolics* (unaffected by organic load) for 10 min	High concentration chlorine disinfectant at 5000-10 000 p.p.m. (0.5 – 1%)‡ *or* Iodophor* for 10 min

* Dilute according to manufacturer's instructions.

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

‡ Freshly prepared.

TABLE E2

RECOMMENDED DISINFECTION LEVEL FOR TYPES OF MICROORGANISMS

Disinfection level	Bacteria			Fungi*	Viruses	
	Vegetative	Tubercle bacillus	Spores		Lipid and medium size	Non-lipid and small size
High	+	+	+	+	+	+
Intermediate	+	+	–	+	+	+
Low	+	–	–	+	+	–

* Includes non-pigmented spores, but not necessarily chlamydospores and pigmented spores

NOTE: Plus signs indicate that a microbiocidal effect can be expected when the disinfectants are properly employed at their normal use concentrations.

TABLE E3

DISINFECTION LEVELS OF COMMON DISINFECTANTS

State	Name	Disinfection level
Gas	Ethylene oxide	High
Gas	Formaldehyde	High
Liquid	Peracetic acid	High
Liquid	Aldehydes	High
Liquid	Stabilized hydrogen peroxide	High to intermediate
Liquid	Alcohol	Intermediate
Liquid	Iodophor	Intermediate
Liquid	Iodine-alcohol	Intermediate

APPENDIX F

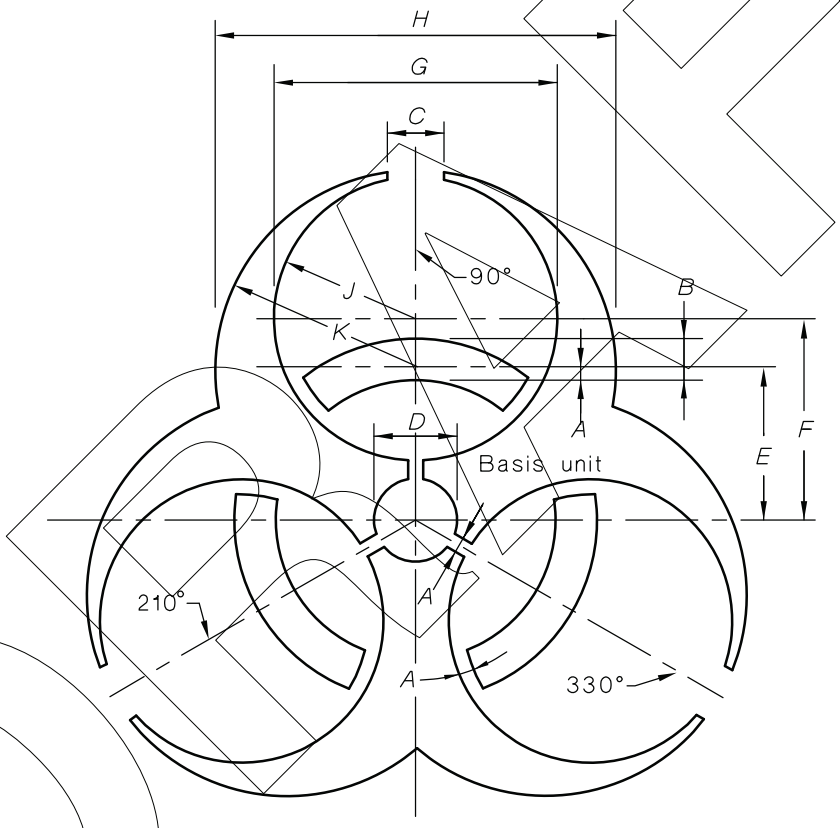
BIOLOGICAL HAZARD SIGNS

(Normative)

F1 BIOLOGICAL HAZARD SYMBOL

The biological hazard symbol shown in Figure F1 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 F1 BIOLOGICAL HAZARD SYMBOL

F2 GENERAL MICROBIOLOGICAL LABORATORY SIGN

The sign for general microbiological laboratories shall be in the format shown in Figure F2, i.e. it shall show the biological hazard symbol shown in Figure F1 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.

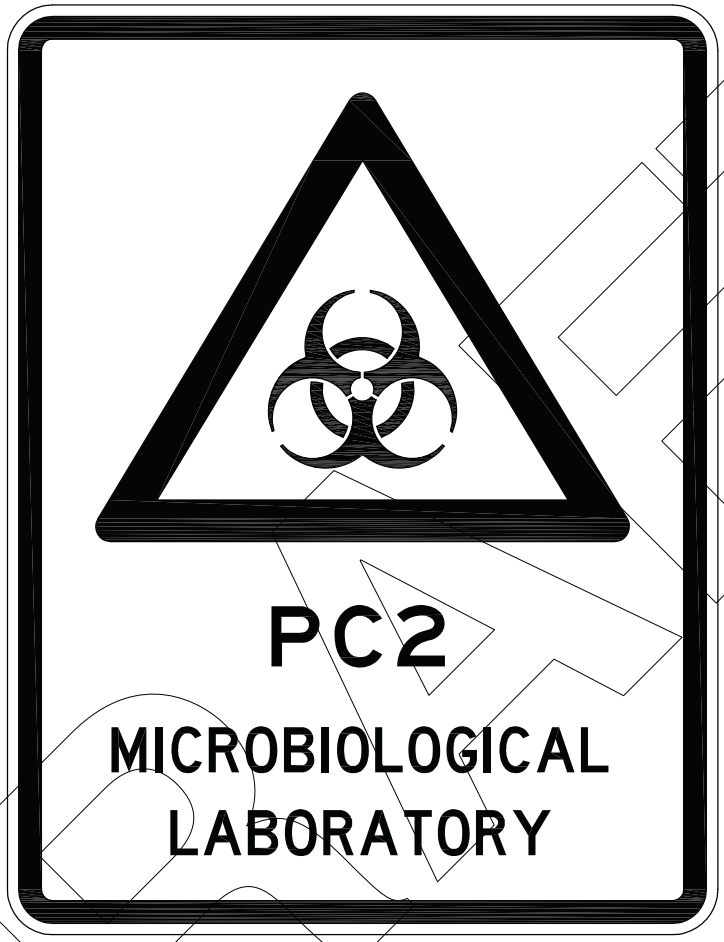


FIGURE F2 LAYOUT FOR GENERAL MICROBIOLOGICAL LABORATORY WARNING SIGN (EXAMPLE FOR PC2 LABORATORY)

APPENDIX G

EXAMPLES OF RECOMMENDED LAYOUTS FOR PC3 AND PC4 FACILITIES

(Informative)

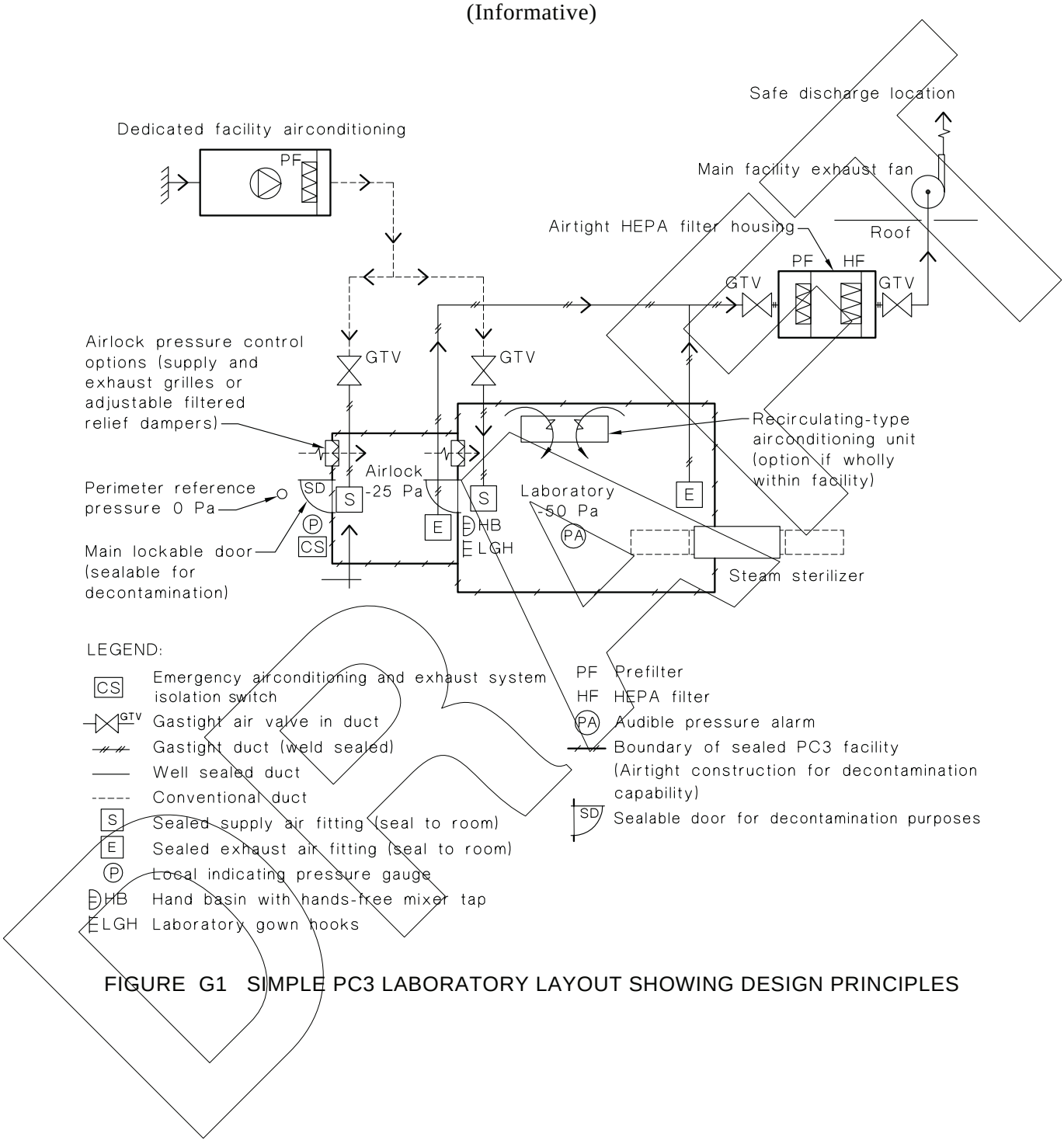
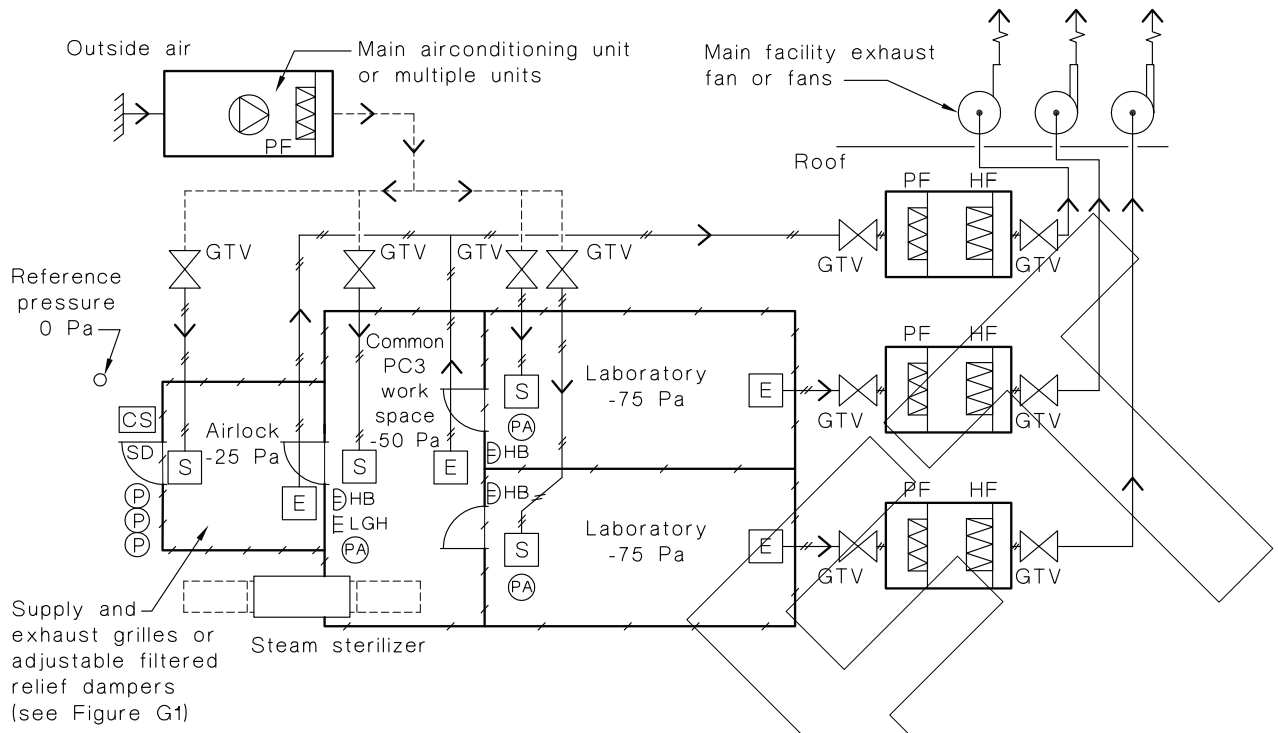


FIGURE G1 SIMPLE PC3 LABORATORY LAYOUT SHOWING DESIGN PRINCIPLES



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
- 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 G2 ADDITIONAL FEATURES FOR A MULTIPLE ROOM PC3 FACILITY

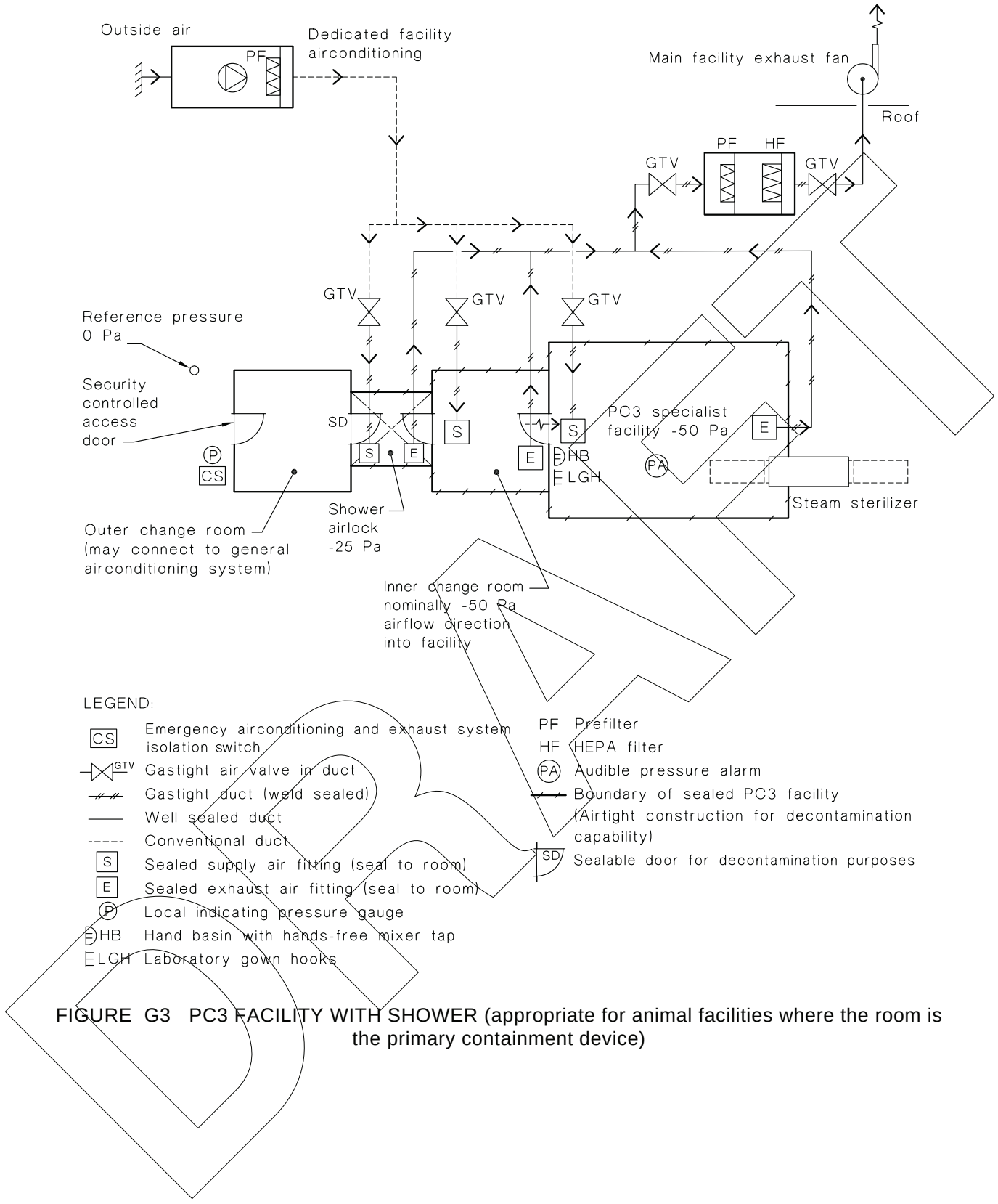


FIGURE G3 PC3 FACILITY WITH SHOWER (appropriate for animal facilities where the room is the primary containment device)

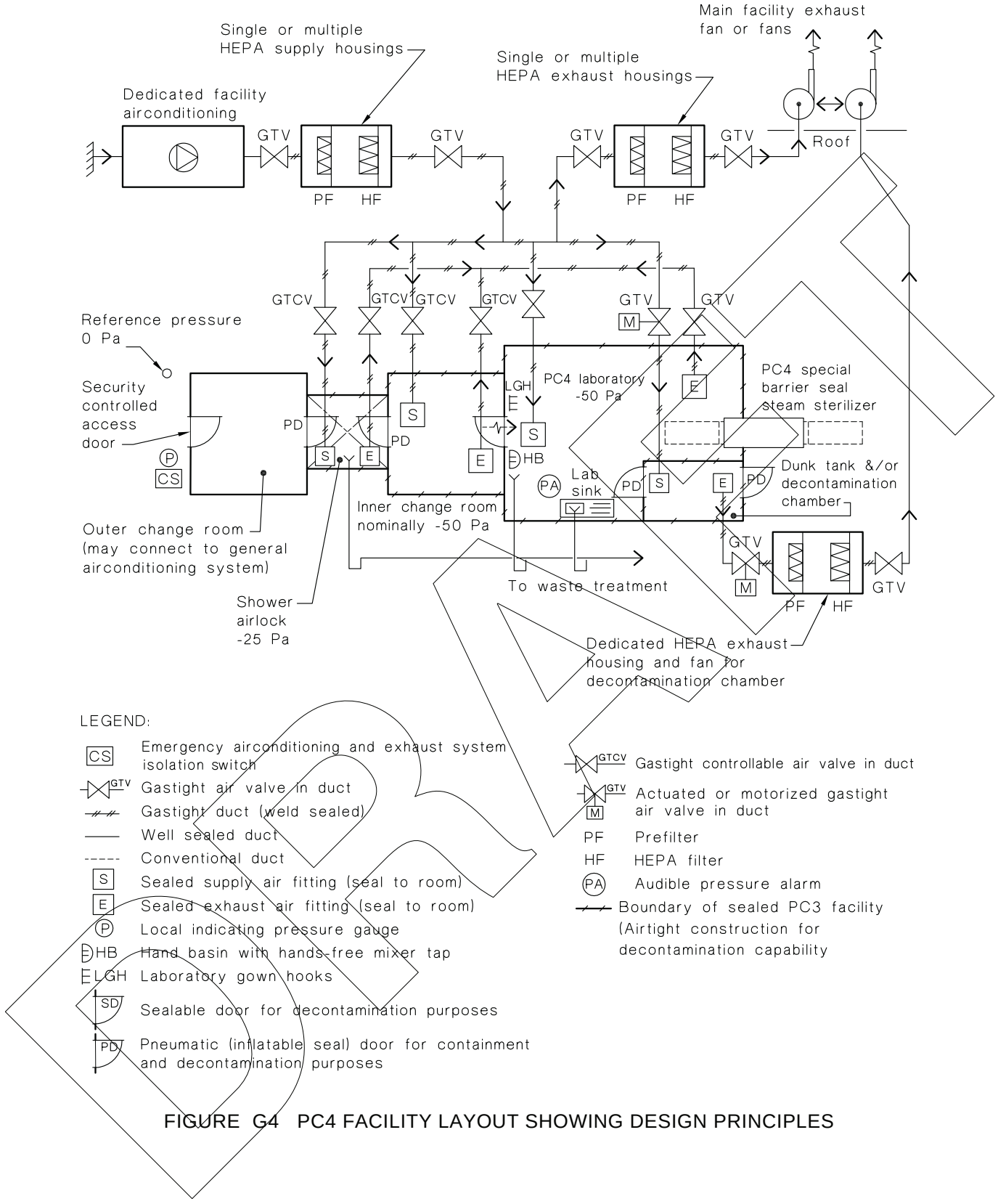


FIGURE G4 PC4 FACILITY LAYOUT SHOWING DESIGN PRINCIPLES

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

The following facilities have a requirement for containment of aerosols and of gases used in decontamination:

(a) PC3 and PC4 laboratories.

(b) PC3 and PC4 animal containment facilities.

(c) PC4 plant containment facilities.

(d) PC4 invertebrate containment facilities.

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.

(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.

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 pathogen 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 15 h 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 pathogen aerosols 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.

It is recommended that facilities be re-tested periodically to ensure that the appropriate leakage rate has been maintained during normal use of the laboratory. Facilities should be retested

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

whenever any modifications take place that could affect the integrity of the seal. As an absolute minimum, facilities should be re-tested 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 E6.3 of Appendix E and Reference 1.29 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.

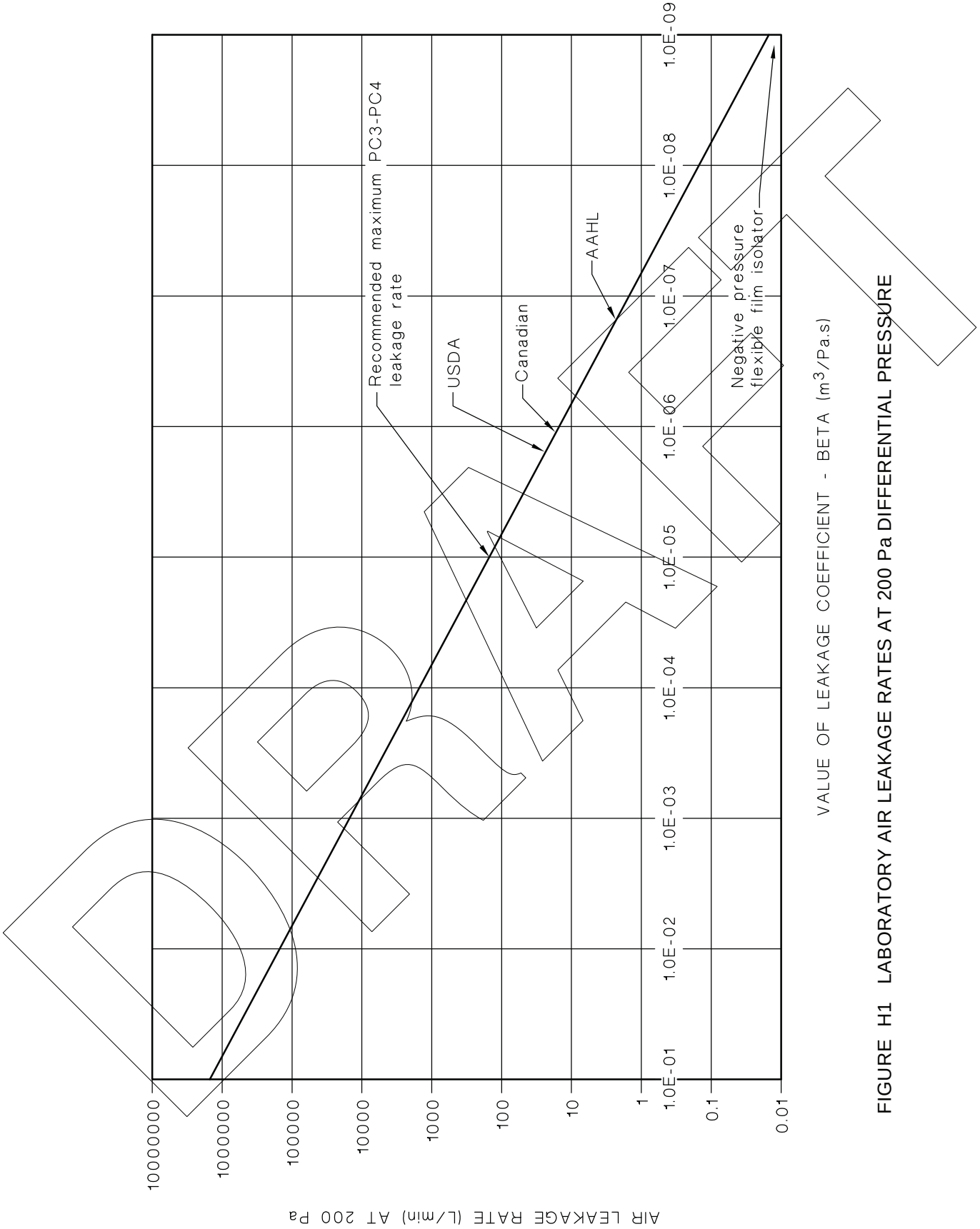


FIGURE H1 LABORATORY AIR LEAKAGE RATES AT 200 Pa DIFFERENTIAL PRESSURE

*** END OF DRAFT ***

PREPARATION OF JOINT AUSTRALIAN/NEW ZEALAND STANDARDS

Joint Australian/New Zealand Standards are prepared by a consensus process involving representatives nominated by organizations in both countries drawn from all major interests associated with the subject. Australian/New Zealand Standards may be derived from existing industry Standards, from established international Standards and practices or may be developed within a Standards Australia, Standards New Zealand or joint technical committee.

During the development process, Australian/New Zealand Standards are made available in draft form at all sales offices and through affiliated overseas bodies in order that all interests concerned with the application of a proposed Standard are given the opportunity to submit views on the requirements to be included.

The following interests are represented on the committee responsible for this draft Australian/ New Zealand Standard:

Australian Industry Group

Australian Institute of Occupational Hygienists

CSIRO

Department of Labour New Zealand

Department of Primary Industries (Victoria)

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

National Measurement Institute (Australia)

New Zealand Chemical Industry Council

New Zealand Microbiological Society

RMIT University

Royal Australian Chemical Institute

Victorian WorkCover Authority

WorkCover New South Wales

Additional interests participating in preparation of Standard:

Australasian Plant Pathology Society

Australian National University

Australian Quarantine and Inspection Service

Australian Society for Microbiology

Biosafety Consultant

Containment consultants

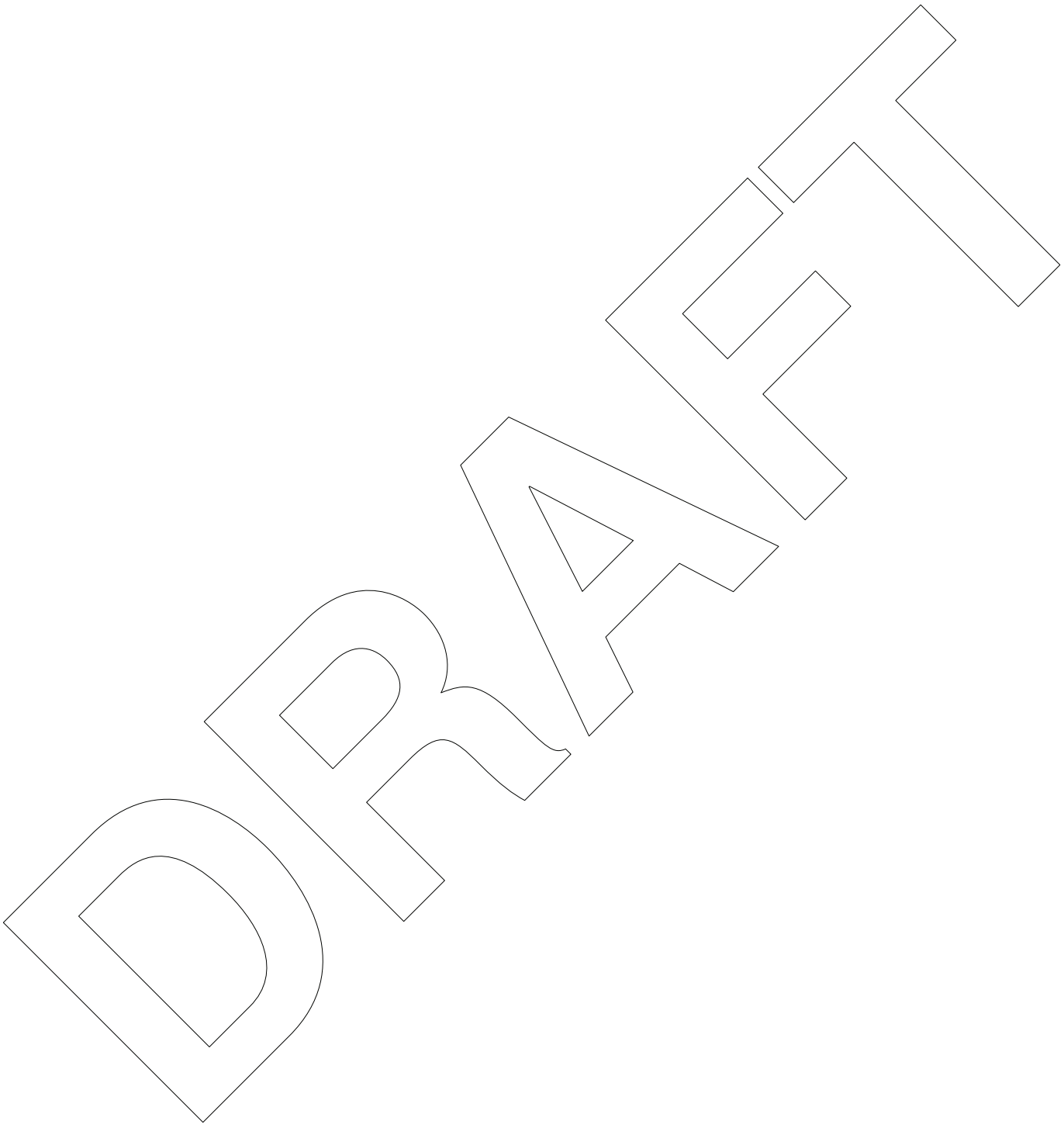
CSIRO, Division of Livestock Industries

Microbiologists

Office of The Gene Technology Regulator

Sterilizing Research Advisory Council of Australia (Vic.)

Victorian Infectious Diseases Reference Laboratory



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