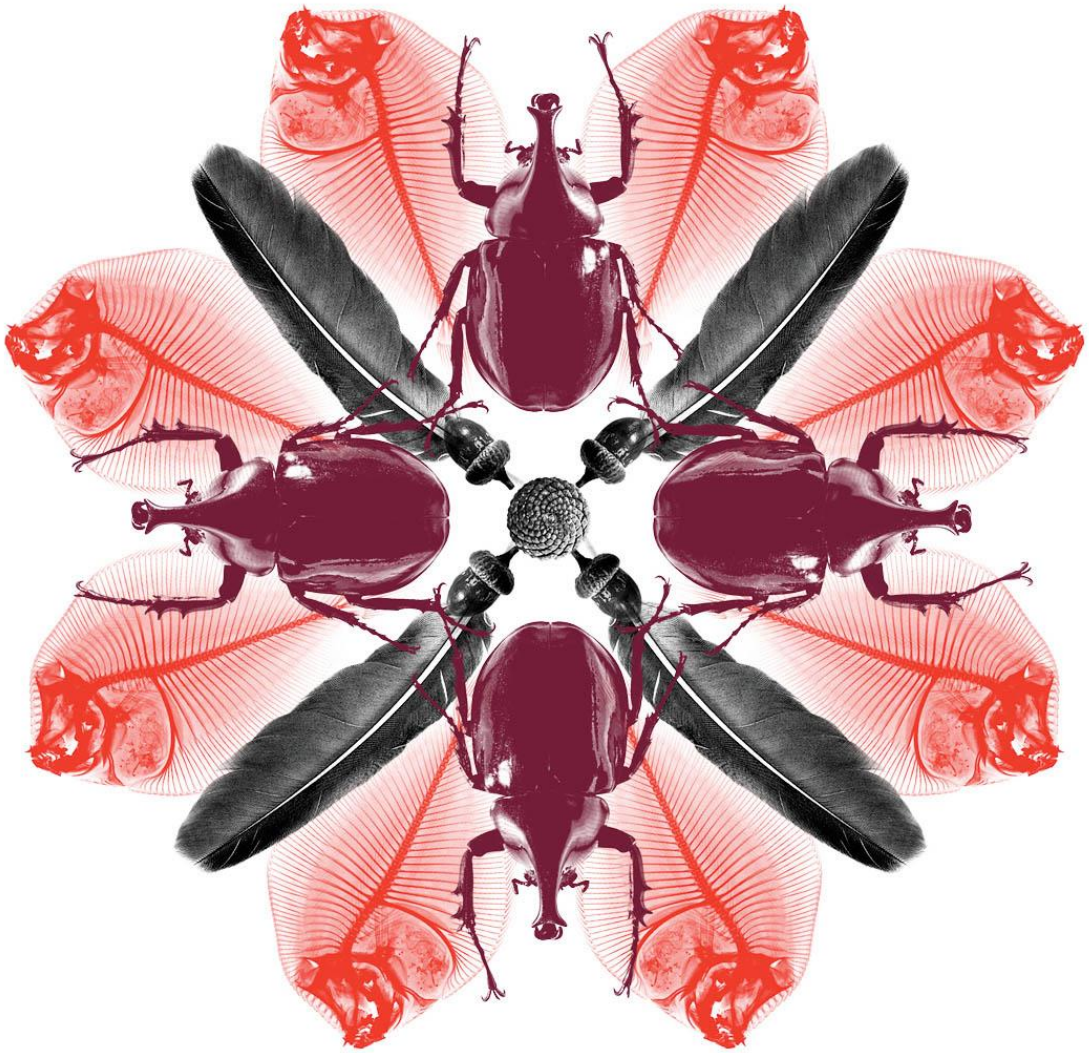
Approved Arrangements

For 5.4—Biosecurity containment level 4 (BC4)

Requirements—Version 3.1



Department of Agriculture and Water Resources

Postal address GPO Box 858

Canberra ACT 2601

Switchboard +61 2 6272 3933

Web agriculture.gov.au

Inquiries regarding the licence and any use of this document should be sent to: copyright@agriculture.gov.au.

Version control

Updates to this document will occur automatically on the department's website and the revision table below will list the amendments as they are approved.

Date	Version	Amendments	Approved by
5 Nov 2008	1.0	Revised document	Co-regulation and Support Program
30 Jun 2013	1.1	Updated to reflect DAFF branding	Industry Arrangements Reform Program
Mar 2015	1.2	Minor update in response to restructure	Approved Arrangements section
16 Jun 2016	2.0	Updated to new template, references to the department and the Biosecurity Act 2015	Approved Arrangements section
24 Jun 2016	3.0	Added Accredited Persons requirements	Approved Arrangements section
4 July 2016	3.1	Updated terminology and added another Accredited Persons requirement.	Approved Arrangements section

Contents

Guide to using this document

This document sets out the requirements that must be met before the relevant director will consider approval for the provision of biosecurity activities under section 406 of the *Biosecurity Act 2015*, otherwise known as an approved arrangement (AA).

This document specifies the requirements to be met for the approval, operation and audit of this class of AA. Compliance with the requirements will be assessed by audit.

In the event of any inconsistency between these requirements and any Import Permit condition, the Import Permit condition applies. If the applicant chooses to use automatic language translation services in connection with this document, it is done so at the applicant's risk.

Unless specified otherwise, any references to 'the department' or 'departmental' means the Department of Agriculture and Water Resources. Any references to contacting the department mean contacting your closest regional office.

Further information on AAs, regional contact details and copies of relevant AA documentation is available on the department's website.

Definitions

Definitions that are not contained within the Approved Arrangements Glossary can be found in the *Biosecurity Act 2015* or the most recent edition of the Macquarie Dictionary.

Other documents

The *AA General Policies* should be read in conjunction with these requirements. They will assist in understanding and complying with the obligations and requirements for the establishment and operation of an AA.

AA Requirements

1. Purpose

1.1 This document sets out the requirements that will achieve the structural and procedural requirements of an AA site class 5.4 under section 406 of the *Biosecurity Act 2015* (the Act).

1.2 As a condition of import, the department may impose post-entry biosecurity conditions that require certain products to be restricted for use within biosecurity facilities. The purpose of approval is to satisfy the department that the facility protects Australia's animal, plant and human health status. This is to ensure that post-entry biosecurity procedures are followed.

2. Scope

2.1 Class 5.4 sites: used for goods subject to biosecurity control that pose risks to animals, plants or humans if pests or diseases associated with them spread outside the AA site and with significant economic impact that would result to the people, the community or the environment.

2.2 The facility must meet the PC4 design and construction requirements as specified in Australian/New Zealand Standard TM 2243.3:2002 and 2982.1:1997. The applicable parts of these standards are outlined in this document.

2.3 BC level 4 or Physical Containment (PC) level 4 is the whole of the space approved by the department in accordance with the department's AA class 5.4 requirements.

2.4 A BC4 facility may incorporate non-work areas (access and supporting rooms and interconnecting corridors or common space areas) only where access to these areas is gained by swipe card or other similar controlled entry that prevents unauthorised access. Where access is not via a controlled entry, non-work areas may only be incorporated where access can only be gained via an anteroom. AA sites accessed by approved non-work areas must be BC4 or PC4 compliant. These facilities must be physically separate from offices used by containment facility personnel. Body showers, toilet cubicles and drinking water appliances may be included.

2.5 Class 5.4 sites are not approved for the distinctive needs of other biosecurity operations, except where the establishment has separate approval under another class. For example, a 5.4 facility is not automatically approved as a commercial fumigation facility. This would require separate class approval under class 4.6.

2.6 Note: a Biosecurity Industry Participant (BIP) may keep more than one kind of goods in the one facility, provided the applicable requirements for all those kinds of goods are met.

This kind of facility is appropriate for work with imported:

- micro-organisms
- approved plant material infected with pathogens subject to biosecurity control for in vitro and in vivo use
- infected fresh or frozen fruit and vegetable samples for in vitro use

- biological material for in vivo work in animals.

This requirement is intended to apply to a wide range of different containment facilities. It is recognised that certain structural requirements, conditions and procedures apply to facilities with different functions. As such, approval as a type of class 5.4 will meet the requirements of a class 5.1 (excluding outdoor animal facilities), class 5.2 and 5.3 of the same type. For example, a class 5.4 microbiological facility will also meet all the requirements of a class 5.1, 5.2 and 5.3 microbiological facilities.

3. Requirements for approval

The applicant must provide the department with documentary evidence (certification) that the facility complies with:

3.1 The applicable design and construction standards of the Australian/New Zealand Standard TM (AS/NZS) 2982.1:1997 and 2243.3:2002 (the relevant sections of these standards are listed in this document).
Note: the minimum requirement for obtaining this evidence is to contract a department-approved 'third party' assessor. A list of department-approved third party assessors can be found on the department website.

3.2 An air leakage rate, at a differential pressure of 200 Pa, of no more than 120L/min (upon facility commissioning).

3.3 A transport plan detailing how the consignment will be taken from the port of arrival to the AA site must be submitted. When developing the plan ensure the following requirements are met:

- transport route is the most direct route between the two sites
- route taken is on sealed roads only.

4. Requirements to maintain approval

4.1 Any changes to the AA site should be carried out in a manner consistent with:

- the third party certification
- the AA requirements
- the conditions of approval
- any subsequent amendments or revisions to AS/NZS 2982.1:1997 and 2243.3:2002.

4.2 A change that significantly affects the overall containment system requires re-certification: this would include structural changes to 40per cent of the building. If a BIP has any doubt as to whether proposed changes to the physical structure of the AA site has any potential to reduce the level of biosecurity integrity, the department's approval must be obtained before the change is implemented.

4.3 The department must be notified in writing within 15 working days of any alterations to AA site management arrangements.

4.4 Additionally, a biosecurity officer may request that documented evidence be provided for compliance with the AS/NZS 2982.1:1997 and 2243.3:2002 when additions or modifications have been made to the facility.

4.5 Where structural changes have been made to the AA site, the department must be provided with a written statement describing the details of the alterations.

4.6 At all times after approval an air leakage rate of no more than 1200L/min should be maintained.

4.7 To ensure that the air leakage rate is no more that 1200L/min, air leakage testing must be undertaken every three years.

General requirements

This part outlines the general requirements that must be complied with by the BIP of any approval for a facility, irrespective of the type of facility and the containment level to which the facility is approved.

5. Hygiene and isolation

5.1 Biosecurity areas must be separate from other operations within the AA site. This can be achieved in a number of department-approved methods. Examples of how biosecurity area separation can be achieved include isolation from main thoroughfares with yellow lines, structural separation, a lockable room or building, a person-proof security fence, separate benches or similar structures. Examples of how storage separation can be achieved in a particular AA site class include cupboards, cool rooms, refrigerators, and freezers.

5.2 To achieve the necessary separation of work and goods, it may be necessary to have cool rooms, refrigerators, freezers or other storage units located outside the area where the work is undertaken. Where this is necessary, the AA site will need to have more than one biosecurity area.

5.3 This additional biosecurity storage area may be located outside the designated facility but must be within the one physical site. To be within one physical site the facility must be within the same common boundary as the approved storage area and must be approved under the one organisation or company.

5.4 Where material subject to biosecurity control is stored outside the designated AA site a transfer procedure (as per 11.1 point 3) must be in place to ensure the safe movement of goods subject to biosecurity control.

5.5 Biosecurity storage areas which are located outside the building that houses the facility must be a fully enclosable space contained within walls, doors, windows, floors and ceilings. Doors and windows must be lockable and secure.

5.6 For BC2 facility, the additional biosecurity area must be located within the building that houses the facility and where practical must be lockable. Movement procedures must be applied as per 11.1 point 3.

5.7 Where a biosecurity area is outside or separate to the area where the work is undertaken, the type of biosecurity area (such as refrigerator or freezer) must be stated on the scale drawing.

5.8 The separation of work and goods (such as separate outside storage areas) is not applicable to BC3 (BC3 facilities may only have the autoclave outside the immediate facility but within the building) or BC4 facilities which must operate as a closed entity.

5.9 The AA site must be managed to ensure that effective separation is maintained between cleared imported goods, domestic goods, imported goods awaiting release from biosecurity control, and, in the case of a department-approved dual import and export AA site, export goods.

5.10 Import Permit conditions and inspection procedures for some commodities may also apply in addition to these requirements.

5.11 Effective separation of all goods can be achieved by:

- an impervious physical barrier
- other department-approved methods.

Note: Effective separation will depend on the class of goods as the methods listed are not applicable to all AA classes. Examples of effective separation for some AA classes include, but are not limited to:

- sealed containers
- storage in separate rooms
- plywood, sheet metal or heavy gauge plastic sheeting that provides complete and unbroken physical separation between consignments
- double plastic wrap including a space separation between consignments of 1.2 metres
- remain consolidated within the shipping container.

The use of a method must be approved by the department and, should cross-contamination occur, the goods shall be treated as goods subject to biosecurity control.

5.12 The AA site must be managed in a way that ensures that all buildings and/or structures are maintained in a state of good repair.

5.13 An effective pest control system must be in place to ensure that facilities are managed in a way that effectively isolates goods subject to biosecurity control from environments in which pest and disease are likely to become established.

5.14 In addition to details of the inspection regime and the on-site location of the knock-down spray, this document may include:

- the use of insecticides, fumigation, rodenticides, periodic inspection, baits and/or traps
- a site plan with numbered bait stations
- contract details if applicable.

Note: The operations of adjacent facilities must be considered when determining any additional pest control measures to be implemented.

6. Biosecurity area

6.1 The biosecurity area must be of a size commensurate with the proposed quantity of goods being handled.

6.2 Biosecurity areas must be managed to allow biosecurity officers to conduct adequate inspections of goods in a timely and effective manner. This can occur by having:

- illumination to a sufficient level (within a building this will require a minimum 400 lux in storage areas and 600 lux in biosecurity inspection areas)
- goods accessible for inspection (this will require that goods be stored no more than 2.5 m high unless racks are used).

Note: ‘Accessible’ means goods must be able to be inspected as directed by a biosecurity officer. Generally, block stacking will not be regarded as being accessible.

7. Security

7.1 Biosecurity areas where goods subject to biosecurity control are stored or handled must display a biosecurity sign to assist in effectively managing the security of these goods. These signs are to be:

- secured on buildings, racks, fences, gates and/or doors and visible at all times
- permanently affixed
- of a professional standard
- made to state ‘Biosecurity Area – Authorised Persons Only, No Entry or Removal of Goods, Penalties Apply, (Biosecurity Act 2015)’ or 'Quarantine Area - Authorised Persons Only , No Entry or Removal of Goods, Penalties Apply, (Quarantine Act 1908)' or as directed for specific biosecurity operations
- on a yellow background, with black lettering.

Note 1: Cardboard and paper signs are not acceptable.
Note 2: Where new signs are being produced, they should use 'biosecurity’ not ‘quarantine’

7.2 Signs on external structures must be:

- a minimum 600 mm x 400 mm with lettering a minimum 25 mm height
- weatherproof and resistant to the elements

Signs within structures must be a minimum 295 mm x 210 mm with lettering a minimum 8 mm height.

7.3 The following procedures must be applied to manage the AA site in a way that effectively secures goods subject to biosecurity control from movement or interference by unauthorised persons:

- the department must be immediately informed of any incidents that could significantly compromise biosecurity security of the facility. This may include structural damage, electrical breakdowns, escapes or unauthorised entry and the removal of material subject to biosecurity control
- goods subject to biosecurity control must be stored in an area that is securely locked when unattended.

Note: Video surveillance, alarms or other security monitoring methods may also be used.

8. Operating procedures

8.1 Biosecurity related spills include any spillage of goods subject to biosecurity control, waste or waste water. These spills must be disposed of in a manner as per the section on biosecurity waste.

8.2 Equipment used for the clean-up of biosecurity related spills must be provided. A list of broad-spectrum disinfectants can be found on the department’s website.

8.3 Any major spillage or loss of material subject to biosecurity control must be immediately reported to the department. Note: A major spillage is classified as a loss of material

subject to biosecurity control outside the confines of the AA site, that cannot be readily cleaned up within 15 minutes, or which may be accessed by the general public.

8.4 A procedure must be in place to ensure that the department is notified of any pest or disease infestation.

Administration and management

9. Record requirements

9.1 Recordkeeping procedures must provide the department with the confidence that the system has adequate controls and the necessary evidence to verify identifiable links to goods. This can be achieved by:

- electronic or manual records of all goods subject to biosecurity control imported through the AA site. This includes retaining originals or copies of Import Permits, biosecurity entries/directions or transfer approvals
- retaining records for a minimum period of 18 months after release from biosecurity control or disposal of the goods
- ensuring that records are available within 48 hours for inspection by the department.

Note*:* The department will continue to assess whether activities and arrangements have been implemented effectively and are meeting AA requirements. If records are unavailable during an inspection/audit, the department will return to the AA site within 48 hours to continue the assessment of documentation. This inspection will be charged at fee-for-service rates.

9.2 Records must be maintained of Accredited Persons.

10. Office and general AA site requirements

10.1 Office and general AA site requirements must provide the department with the confidence that applicable work health and safety standards have been met, this is achieved by:

- providing a first aid cabinet/kit which is fully stocked and meets the minimum commercial Australian Standard (AS2675-1983: Portable first aid kits for use by consumers)
- providing vehicle parking for visiting biosecurity officers (note: this may require Department of Agriculture and Water Resources identified parking or providing a parking permit)
- ensuring adequate security for any Department of Agriculture and Water Resources technical equipment left on the AA site
- providing access to and the availability of:
  - a desk, chair and a telephone with direct outside call access
  - toilet facilities
  - handwashing facilities and a hygienic means of drying hands
  - suitable arrangements to ensure amenities are clean.

Note: Additional mandatory requirements apply to AA site with permanent biosecurity officers.

10.2 The AA site must comply with all relevant safety codes and work health and safety legislation.

11. Administration

11.1 Administration and documentation requirements must provide the department with assurance that there are adequate controls. This must include:

- applications being accompanied by scale drawings (with dimensions and locations of biosecurity areas), identifying facilities for treatments, nearest main road and parking for biosecurity officers
- obtaining a departmental direction or prior written approval to move, accept, transfer or release any goods subject to biosecurity control from the approved facility to another approved facility that is not co-located
- where applicable, developing a transfer procedure for the safe movement of goods subject to biosecurity control between co-located facilities. This procedure must be provided at application, and at the request of a biosecurity officer.

11.2 When a direction, written approval or an applicable Import Permit to transfer goods subject to biosecurity control to an AA site that is not co-located has not been issued, apply in writing requesting authority. This will require details of the proposed suitable transport containers, the intended transport route and any other relevant information to support the case. The department may seek further information before making a decision

11.3 Control and security of the biosecurity area is the responsibility of the BIP. The BIP must ensure that there is an agreement with the department for training and/or electronic initiatives needed. Failure to comply with the approval requirements or any violation of the Act may result in the approval of the AA being withdrawn or suspended and legal action prompted.

11.4 The BIP must ensure that persons having physical access to goods subject to biosecurity control are aware that such items must only be handled by an Accredited Person or under the direct supervision of an Accredited Person.

11.5 Persons performing the function of an Accredited Person must have successfully completed the department's approved training to obtain and maintain Accredited Person status.

11.6 The BIP must notify the department in writing as soon as practicable within 15 working days of becoming aware of any change of status, not previously been notified to the department, of the BIP or their associates relevant to the operation of the AA in relation to any of the following matters:

- conviction of an offence or order to pay a pecuniary penalty under the *Biosecurity Act 2015, Quarantine Act 1908, Customs Act 1901*, the Criminal Code or the *Crimes Act 1914*
- debt to the to the Commonwealth that is more than 28 days overdue under the *Biosecurity Act 2015, Quarantine Act 1908, Customs Act 1901*, the Criminal Code or the *Crimes Act 1914*
- refusal, involuntary suspension, involuntary revocation/cancellation or involuntary variation of an Import Permit, quarantine approved premises, compliance agreement or AA under the *Quarantine Act 1908* or the *Biosecurity Act 2015*.

11.7 Biosecurity officers, biosecurity enforcement officers and department-approved auditors must be provided access to the AA site to perform the functions and exercise

the powers conferred on them by the Biosecurity Act or another law of the Commonwealth.

11.8 Departmental auditors or department-approved auditors must be provided with facilities and assistance as requested, as well as any required documents, records or things relevant to the audit.

11.9 The department must be notified of any Reportable Biosecurity Incident as soon as practicable, in accordance with the determination made by the Director of Biosecurity.

11.10 Department-approved auditors must be permitted to collect evidence of compliance and noncompliance with AA requirements through actions including the copying of documents and taking of photographs.

Specific requirements for BC5 approval

This section outlines the specific requirements that must be complied with for facilities to be approved to a specific facility type.

Note: These requirements are additional to the BC4 conditions, the requirements for approval, and the general requirements.

Microbiological QC4 facilities

12. Hygiene and isolation

12.1 Write-up areas may be approved as part of a BC4 facility. To be eligible for approval these areas must comply with BC4 requirements, be constructed such that horizontal surfaces are minimised (for example using minimal shelving), must not be used for generic office functions and should hold only essential reference materials (such as technical equipment manuals).

13. Waste disposal

13.1 Where applicable any biosecurity waste must be effectively contained and disposed of in a manner approved by the department and be detailed in a document outlining specific procedures for the disposal of any accumulated waste which may include a section on the:

- disposal of waste that is not subject to Import Permit conditions
- movement of waste within the AA site where an approved method is not available within the biosecurity area/facility.

13.2 Solid biosecurity waste must be bagged and placed in an unbreakable container with a secured lid for movement within the building to the approved disposal place.

13.3 Where waste cannot be disposed of immediately, there must be at a minimum the provision for:

- a separate storage device/area for the temporary holding of goods
- storage in lidded bins/containers of an appropriate size which are leak and pest-proof
- bins to be labelled 'Biosecurity Waste'
- double bagging of all waste.

13.4 Separate storage device/area must be approved by the department and be within the AA site to prevent loss, spillage or unauthorised access.

13.5 The department's approved methods of solid biosecurity waste disposal include incineration at a high temperature in a high efficiency incineration facility, deep burial or sterilisation by autoclaving.

13.6 Minimum autoclaving times after attainment of temperature for goods, residues or biosecurity waste shall be 121°C:

- (core temperature) for 15 minutes. Specify how the core temperature has been reached and detail how this temperature was recorded
- for 30 minutes where core temperature is not measured.

13.7 Biosecurity waste water must be disposed of by an approved municipal sewage system. An alarm must be provided to alert persons of any decontamination system malfunction.

13.8 The use of other waste disposal methods must be approved in writing by the department after demonstration of their efficacy to the satisfaction of the department. Such methods may require detailed scientific research.

14. Security

14.1 To assist in effectively managing the security of the AA site, a biosecurity sign be displayed on the entry door to the facility. Such signs are to include:

- requirements as stated in Part 6.1 above
- in addition, state 'microbiological containment – BC4 (or QC4) Facility'.
- the name and telephone number of the facility manager or other responsible person must be displayed near all access doors

Note: Where new signs are being produced, they should use BC not QC.

14.2 Access to the facility for cleaning, servicing of equipment and repairs must not occur until potentially contaminated surfaces have been disinfected with a department-approved broad-spectrum disinfectant.

15. Operational procedures

15.1 Containers holding goods subject to biosecurity control must be clearly labelled using standard scientific nomenclature. The labelling must enable clear reconciling of goods subject to biosecurity control with the following information:

- biosecurity entry number (where relevant)
- Import Permit number or the department's in vivo approval number and expiry dates
- importation date.

If the containers cannot be labelled with this information due to constraints, such as size, then a suitable identification system may be used such as referring to a logbook that contains the required information.

15.2 Equipment used or that has come into contact with goods subject to biosecurity control must be cleaned or rendered safe by an approved method. Department-approved methods include, but are not limited to:

- sterilisation
- incineration, as prescribed in Part 13: Waste disposal
- disinfection using the department's approved broad-spectrum disinfectant.

Equipment must be disinfected before being sent for repair or disposal and where appropriate, equipment may need to be disinfected at regular intervals.

15.3 Gloves shall be removed and hands thoroughly washed after handling goods subject to biosecurity control, working in a biological safety cabinet and before leaving the facility. Used gloves shall be discarded with the biosecurity waste.

15.4 To prevent cross-contamination while work is being undertaken there must be separation of biosecurity work from other work.

15.5 When working with goods subject to biosecurity control the following minimum requirements apply to clothing and other apparel:

- personnel must wear covering clothes
- closed footwear
- dirty clothing must be removed and laundered before re-use.

Note: The department must be provided with a written procedure of how protective clothing will be laundered.

15.6 If a separate culture room within the facility exists and is dedicated to this work, then complete protective clothing including overshoes and hats is required within this room. Dedicated apparel should be used in this culture room and not removed except for laundering or disposal.

15.7 To ensure the containment features of the facility are intact a document detailing annual inspection must be available to the department for audit purposes. The minimum requirements for this document include:

- an annual inspection report detailing findings
- the personnel who conducted the inspection.

Note*:* personnel include the holders of the approval, employees or the Biosafety Committee.

15.8 When not in use, containers of regulated articles must be stored securely in the biosecurity area (cool rooms, incubators, refrigerators, cupboards or similar structures).

15.9 A manual listing procedures and documents applicable to biosecurity, including emergency and maintenance procedures, must be available within the facility in a prominent position.

15.10 A negative pressure gradient shall be maintained that exists of 25 Pa in the anteroom and 50 Pa in the AA site facility relative to the pressure outside the facility. Additionally, the pressure inside the facility shall never fall below 25 Pa, relative to the pressure outside of the facility, when the door between the anteroom and the AA site facility is open.

15.11 Annual testing and certification by a qualified technician must include:

1) testing of the pressure differentials in accordance with AS 1807.10
2) integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7
3) checking that the control system is operating correctly and verifying alarms are set to operate when room differential air pressures depart from set points by more than 15 Pa for a period of greater than two minutes
4) the effectiveness of the effluent treatment and decontamination system.
5) Note: any failures of the effluent treatment system must be rectified and the system re-tested. Records must be retained.
6) A report of the testing in items 1) to 2) and of any maintenance conducted must be provided at the request of a biosecurity officer.

15.12 A manual listing procedures and documents applicable to biosecurity, including emergency and maintenance procedures must be available within the facility in a prominent position.

15.13 Where there are pressure steam sterilisers at the AA site the department must be provided with information concerning the calibration and certification of sterilisers and the efficacy of the treatment. The minimum requirements for sterilisers are that:

- relevant local regulations for pressure vessels are applied, including the timeframes for the regular certification of the steriliser
- steriliser cycles are calibrated. This can be achieved by the use of either:
  - thermocouples or resistance thermometers to ensure that the sterilisation temperature indicated has been achieved
  - chemical indicators which progressively change colour with the time exposed at the specified temperature
  - biological indicators such as spore strips
  - bacterial enzyme indicators used at regular intervals (for example, monthly)
  - other department-approved method.

15.14 The timing of the sterilisation stage of the cycle commences when the set temperature is recorded by the thermometer in the drain line.

15.15 Where indicators are used they must be placed in several positions in a load, including those least likely to attain sterilisation conditions.

15.16 The annual checking and certification of sterilisers or heat ovens must be carried out by a qualified technician.

15.17 Where a biological safety cabinet is integral to biosecurity functions, the minimum requirements for Biological Safety Cabinets are that:

- cabinets 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
- used filters be disposed of with biosecurity waste
- where class II cabinets are used they will need to pass the air barrier containment test in AS 1807.22.

15.18 The annual checking and certification of isolators must be carried out by a qualified technician.

15.19 Where there are flexible film isolators at the AA site the following applies:

- Isolators must operate at a pressure below that of the room in which they are located and inlet and exhaust systems must be HEPA filtered. Note: the annual checking and certification of isolators must be carried out by a qualified technician.

16. Administration and management

16.1 Records for each consignment of goods subject to biosecurity control must include:

- biosecurity entry number (where relevant)
- Import Permit number or departmental in vivo approval number for the regulated articles
- description of the regulated goods (using accurate scientific terminology)
- date of receipt of goods and country of origin
- location or part of facility where each item subject to biosecurity control is held, and the respective BC status
- records of any derivatives and additional cultures/material or substance grown from the original material subject to biosecurity control
- where applicable, quantities (for example, kg or litres) of goods received, destroyed and in storage
- date of completion of research
- details of any treatments
- method and date of disposal/destruction of goods subject to biosecurity control and any direct or indirect derivatives
- method and date of waste disposal/destruction
- the date of movement and the department's permission for any movement (including transfer certificates) of goods from the facility
- comprehensive details of any breaches of goods subject to biosecurity control from the facility.

16.2 A bi-annual summary of records, which includes the information in 16.1, must be provided at audit or at the request of a biosecurity officer.

16.3 A logbook (electronic or manual) recording steriliser load, temperature and duration of sterilisation cycle must be maintained.

16.4 Calibration specifications for equipment that has a bearing on the biosecurity status of the material (for example, autoclave); along with calibration records must be provided at audit and at the request of a biosecurity officer.

16.5 Drinking water, food and toilets shall only be located within designated areas of the biosecurity facility where goods are not handled, stored or treated and there is also no potential for harm to animals, plants, humans or the environment. A procedure must be in place which ensures gloves and garments are removed and hands are washed prior to drinking, eating or use of the toilet facilities.

Indoor animal BC4 facilities

The BIP of indoor animal containment approval must also meet the BC4 conditions and the requirements for approval, and the general requirements.

17. Isolation and hygiene

17.1 Adequate precautions should be taken to avoid cross contamination where post-mortem examinations are undertaken, this consists of providing a separate area for other activities such as animal production.

17.2 Secure housing/caging must be provided.

17.3 Write-up areas may be approved as part of a BC4 facility. To be eligible for approval, these areas must comply with BC4 requirements, be constructed such that horizontal surfaces are minimised (for example, using minimal shelving), must not be used for generic office functions and should hold only essential reference materials (such as technical equipment manuals).

18. Waste disposal

18.1 Department-approved methods of disposal of carcass subject to biosecurity control include incineration at a high temperature in a high efficiency incineration facility, deep burial, or sterilisation by autoclaving.

18.2 Minimum autoclaving times after attainment of temperature for goods, residues or biosecurity waste shall be either 121°C:

- (core temperature) for 15 minutes
- for 30 minutes where core temperature is not measured.

18.3 Department-approved methods of disposal of animal bedding subject to biosecurity control include incineration at a high temperature in a high efficiency incineration facility, deep burial, or sterilisation by autoclaving.

18.4 Biosecurity waste water must be disposed of by a department-approved method. Department-approved methods include disposal of waste water by an approved municipal sewage system. An alarm must be provided to alert persons of any decontamination system malfunction.

18.5 The use of other waste disposal methods must be approved in writing by the department after demonstration of their efficacy to the satisfaction of the department. Such methods may require detailed scientific research at the BIP's expense.

18.6 Where a facility performs a primary containment function and animal holding areas/pens/cages are plumbed to floor drains, these drains must be fitted with traps to ensure that all solids (such as bedding, faecal matter) are collected during research and at times of pen/cage washing and disinfection. Waste solids collected from drains must be treated by an approved method.

18.7 The department's approved methods of solid biosecurity waste disposal include incineration at a high temperature in a high efficiency incineration facility, deep burial, or sterilisation by autoclaving.

18.8 Where the facility has floor drains, the drain traps should always be filled with water and a suitable approved broad spectrum disinfectant, and be secure against entry by pests.

19. Security

19.1 A nominated personnel employed by the AA site is responsible for gate, door or animal enclosure keys. The name, designation/position title and contact details of this person must be supplied with the application form and when a change in the nominated staff member occurs.

19.2 To assist in effectively managing the security of the AA site, a biosecurity sign be displayed on the entry door to the facility. Such signs are to include:

- requirements as stated in Part 6.1 above
- the statement: 'indoor animal containment – BC4 (or QC4) Facility'.

The name and telephone number of the facility manager or other responsible person must be displayed near access doors

Note: Where new signs are being produced, they should use 'BC' not 'QC'.

19.3 Access to the facility for cleaning, servicing of equipment and repairs must not occur until potentially contaminated surfaces have been disinfected with an approved broad-spectrum disinfectant.

20. Operational procedures

20.1 Arrangements must be in place for animals undergoing in vivo trials involving imported biologicals that ensures daily checking. A written record must be kept of daily checks.

20.2 Identification must be possible for animals subject to biosecurity control, for example by microchip, tattooing, permanent branding or through a cage labelling system.

20.3 Where applicable, cages and racks must be labelled to indicate the identity and date of any inocula given.

20.4 Where it is necessary to transport animals (alive or dead) from the AA site, in addition to the requirements in Part 11: Administration, procedures must include details on pens/cages used for transport and the decontamination of these with a department-approved broad-spectrum disinfectant.

20.5 Unexpected animal mortalities or incidence of disease must be reported to the department immediately and investigated. The department must be kept up to date on the progress of the investigation and must be provided a report at the conclusion of the investigation.

20.6 When working with goods subject to biosecurity control the following minimum requirements apply to clothing and other apparel:

- personnel must wear covering clothes
- closed footwear
- dirty clothing must be removed and laundered before re-use.

20.7 Prior to entering the facility and in the anteroom, or where applicable, inner change room, the following minimum requirements apply to clothing and other apparel, personnel must:

- put on overshoes
- wear covering clothes and a hat.

20.8 Additionally, these garments must be:

- removed on leaving the facility and kept in the anteroom between uses
- laundered at appropriate intervals
- where disposable protective clothing is used it must be disposed of in the manner described in the waste disposal section of this document.

20.9 Where the facility has floor drains, the drain traps should always be filled with water and a suitable approved broad spectrum disinfectant, and be secure against entry by pests.

20.10 A negative pressure gradient shall be maintained that exists of 25 Pa in the anteroom and 50 Pa in the AA site relative to the pressure outside the facility. Additionally, the pressure inside the facility shall never fall below 25 Pa, relative to the pressure outside of the facility, when the door between the anteroom and the AA site is open.

20.11 Annual testing and certification by a qualified technician must include:

1) testing of the pressure differentials in accordance with AS 1807.10
2) tntegrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7
3) checking that the control system is operating correctly and verifying alarms are set to operate when room differential air pressures depart from set points by more than 15 Pa for a period of greater than 2 minutes
4) the effectiveness of the effluent treatment and decontamination system

   Note: Any failures of the effluent treatment system must be rectified and the system re-tested. Records must be retained.

5) a report of the testing in items i) to iv) and of any maintenance conducted must be provided at the request of a biosecurity officer.

20.12 A manual listing procedures and documents applicable to biosecurity, including emergency and maintenance procedures must be available within the facility in a prominent position.

20.13 Where there are pressure steam sterilisers at the AA site, the department must be provided with information concerning the calibration and certification of sterilisers and the efficacy of the treatment. The minimum requirements for sterilisers are that:

- relevant local regulations for pressure vessels be applied, including the timeframes for the regular certification of the steriliser
- steriliser cycles be calibrated. This can be achieved by the use of either:
  - thermocouples or resistance thermometers to ensure that the sterilisation temperature indicated has been achieved
  - chemical indicators which progressively change colour with the time exposed at the specified temperature
  - biological indicators such as spore strips
  - enzyme indicators used at regular intervals (for example, monthly)
  - other department-approved methods.

20.14 The timing of the sterilisation stage of the cycle commences when the set temperature is recorded by the thermometer in the drain line.

20.15 Where indicators are used they must be placed in several positions in a load, including those least likely to attain sterilisation conditions.

21. Administration and management

21.1 Records for each consignment of goods subject to biosecurity control must include:

- date of receipt of goods and country of origin
- Import Permit number, in vivo approval number or transfer approval
- location or part of facility where each item subject to biosecurity control is held
- date of completion of research
- details of any treatments
- method and date of disposal/destruction of goods subject to biosecurity control (if applicable) and any direct or indirect derivatives
- the date of movement and the department's permission for any movement (including transfer certificates) of goods from the facility
- comprehensive details of any breaches of goods subject to biosecurity control from the facility.

21.2 A record must be maintained of an up to date inventory of the animals present and a chronological record of procedures performed, including details of post mortem results.

21.3 Drinking water, food and toilets shall only be located within designated areas of the biosecurity facility where goods are not handled, stored or treated and there is also no potential for harm to animals, plants, humans or the environment. A procedure must be in place which ensures gloves and garments are removed and hands are washed prior to drinking, eating or use of the toilet facilities.

Plant laboratory containment—level 4 (BC4) facilities

22. Hygiene and isolation

22.1 Write-up areas may be approved as part of a BC4 facility. To be eligible for approval, these areas must comply with BC4 requirements, be constructed such that horizontal surfaces are minimised (for example, minimal shelving), must not be used for generic office functions and should hold only essential reference materials (such as technical equipment manuals).

23. Waste disposal

23.1 Where applicable any biosecurity waste must be effectively contained and disposed of in a manner approved by the department and be detailed in a document outlining specific procedures for the disposal of any accumulated waste, this may include a section on:

- the disposal of waste that is not subject to Import Permit conditions
- waste transportation (where the waste has not been rendered safe at the AA site) by an approved transporter or under the department's supervision
- the movement of waste within the AA site where an approved method is not available within the biosecurity area/facility.

23.2 Solid biosecurity wastes must be bagged and placed in an unbreakable container with a secured lid for movement within the building to the approved disposal place.

23.3 Where waste cannot be disposed of immediately, there must be as a minimum the provision for:

- a separate storage device/area for the temporary holding of goods
- storage in lidded bins/containers of an appropriate size which are leak and pest proof
- bins to be labelled 'Biosecurity Waste'
- double bagging of all waste.

23.4 Separate storage device/area must be approved by the department and be within the AA site to prevent loss, spillage or unauthorised access.

23.5 The department's approved methods of solid biosecurity waste disposal include incineration at a high temperature in a high efficiency incineration facility, deep burial, or sterilisation by autoclaving.

23.6 Minimum autoclaving times after attainment of temperature for goods, residues or biosecurity waste shall be either 121°C:

- (core temperature) for 15 minutes. Specify how the core temperature has been reached and detail how this temperature was recorded.
- for 30 minutes where core temperature is not measured.

23.7 Biosecurity waste water must be disposed of by an approved municipal sewage system. An alarm must be provided to alert persons of any decontamination system malfunction.

23.8 The use of other waste disposal methods must be approved in writing by the department after demonstration of their efficacy to the satisfaction of the department. Such methods may require detailed scientific research.

24. Security

24.1 To assist in effectively managing the security of the AA site, a biosecurity sign be displayed on the entry door to the facility. Such signs are to include:

- requirements as stated in Part 6.1 above
- the statement: 'plant containment – BC4 (or QC4) Facility'.

The name and telephone number of the facility manager or other responsible person must be displayed near access doors.
Note: Where new signs are being produced, they should use 'BC' not 'QC'.

25. Operational procedures

25.1 To ensure the containment features of the facility are intact a document detailing annual inspection must be available to the department for audit purposes. The minimum requirements for this document include:

- an annual inspection report detailing findings
- the personnel who conducted the inspection.

Note*:* Personnel include the BIP, employees or the Biosafety committee.

25.2 Documentary evidence that screens, filters and similar equipment is cleaned according to the frequency and procedures specified by the manufacturer, must be provided to the department. This includes the manufacturer's frequency plan and procedures and the recording of the date that the cleaning occurred.

25.3 Unexpected incidences of pest or disease must be reported to the department immediately.

25.4 When working with goods subject to biosecurity control the following minimum requirements apply to clothing and other apparel:

- personnel must wear covering clothes
- closed footwear
- dirty clothing must be removed and laundered before re-use.

25.5 A means of washing hands after handling animals subject to biosecurity control must be available.

25.6 Where the facility has floor drains, the drain traps should always be filled with water and a suitable approved broad spectrum disinfectant.

25.7 A manual listing procedures and documents applicable to biosecurity control, including emergency and maintenance procedures must be available within the facility in a prominent position.

25.8 A negative pressure gradient shall be maintained that exists of 25 Pa in the anteroom and 50 Pa in the AA site relative to the pressure outside the facility. Additionally, the pressure inside the facility shall never fall below 25 Pa, relative to the pressure outside of the facility, when the door between the anteroom and the AA site is open.

25.9 Annual testing and certification by a qualified technician must include:

1) testing of the pressure differentials in accordance with AS 1807.10
2) integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7
3) checking that the control system is operating correctly and verifying alarms are set to operate when room differential air pressures depart from set points by more than 15 Pa for a period of greater than 2 minutes
4) the effectiveness of the effluent treatment and decontamination system
5) Note: Any failures of the effluent treatment system must be rectified and the system re-tested. Records must be retained.
6) A report of the testing in items 1) to 4) and of any maintenance conducted must be provided at the request of a biosecurity officer.

25.10 A manual listing procedures and documents applicable to biosecurity control, including emergency and maintenance procedures must be available within the facility in a prominent position.

25.11 Where there are pressure steam sterilisers at the AA site the following minimum requirements applies for sterilisers are that:

- relevant local regulations for pressure vessels are applied, including the timeframes for the regular certification of the steriliser
- steriliser cycles are calibrated. This can be achieved by the use of either:
  - thermocouples or resistance thermometers to ensure that the sterilisation temperature indicated has been achieved
  - chemical indicators which progressively change colour with the time exposed at the specified temperature
  - biological indicators such as spore strips
  - enzyme indicators be used at regular intervals (for example, monthly)
  - other approved methods.

25.12 The timing of the sterilisation stage of the cycle commences when the set temperature is recorded by the thermometer in the drain line.

25.13 Where indicators are used they must be placed in several positions in a load, including those least likely to attain sterilization conditions.

25.14 The annual checking and certification of sterilisers or heat ovens must be carried out by a qualified technician.

25.15 Where a biological safety cabinet is integral to biosecurity functions, the following minimum requirements for biological safety cabinets are that:

- cabinets 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
- used filters be disposed of with biosecurity waste
- where class II cabinets are used they will need to pass the air barrier containment test in AS 1807.22.

Note: The annual checking and certification of cabinets must be carried out by a qualified technician.

26. Administration and management

26.1 Records for each consignment of goods subject to biosecurity control must include:

- date of receipt of goods and country of origin
- Import Permit number, in vivo approval number or transfer approval
- plant material type (where applicable include scientific name)
- location or part of facility where each item subject to biosecurity control is held
- date of completion of research
- details of any treatments
- method and date of disposal/destruction of goods subject to biosecurity control (if applicable) and any direct or indirect derivatives
- the date of movement and the department's permission for any movement (including transfer certificates) of goods from the facility
- comprehensive details of any breaches of goods subject to biosecurity control from the facility.

26.2 A record must be maintained of an up to date inventory of the plant material present and a chronological record of procedures performed.

26.3 A logbook (electronic or manual) recording steriliser load, temperature and duration of sterilisation cycle must be maintained.

26.4 Drinking water, food and toilets shall only be located within designated areas of the biosecurity facility where goods are not handled, stored or treated and there is also no potential for harm to animals, plants, humans or the environment. A procedure must be in place which ensures gloves and garments are removed and hands are washed prior to drinking, eating or use of the toilet facilities.

Applicable Australian/New Zealand Standards

This part outlines the specific standards that an approved third party assessor will certify. The applicable parts of the standards must be complied with for facilities to be approved to a specific facility type.

Where reference is made to an Australian/New Zealand Standard (or clause in an Australian/New Zealand Standard) in the requirements against which a facility is to be certified, that referenced standard (or clause) must also be met.

Note: These requirements are additional the BC4 conditions and the requirements for approval, the general requirements, and the specific requirements for BC4 approval of a particular facility type.

Australian/New Zealand Standard—Laboratory design and construction part 1: general requirements (AS/NZS 2982.1:1997)

The structural parts of this standard (AS/NZS 2982.1:1997) are applicable to BC4.

Specific standards

27. Microbiological BC4 facilities

These standards from AS/NZS 2982.1:1997 are the minimum for work with microbiological goods at the BC4 level.

27.1 Section 2: General laboratory design and construction requirements (excluding 2.2, 2.6, 2.7 (a) (vi) and (vii) and 2.7 (c), 2.9, 2.11, 2.12 and 2.13).
Section 3: Reticulated services (excluding 3.7.3).
Section 4: Electrical services (excluding 4.2 and 4.3 paragraph 1).
Section 5: Ventilation and air quality (excluding 5.1, 5.2 paragraph 2, 5.3, 5.5.1, 5.5.3, 5.6 (b) last sentence only and 5.7).
Section 6: Health and safety requirements (excluding 6.1, 6.4, 6.5 and 6.6).

27.2 In substitution for 6.2 (safety showers), the following clause will be applied:
Clean up provisions are required which may be:

- fixed appliances (such as showers and eyewash stations)
- single use apparatus (such as disinfectant swabs, squeeze bottles).

Note: Where safety showers and eyewash facilities are installed they must comply with the requirements of 6.2.
The approach to clean up provisions must be unobstructed.

27.3 In substitution for 6.3 (handwashing facilities) the following clause will be applied:
Work areas where goods subject to biosecurity control are handled must contain either a hand wash basin fitted with hands free taps, or some other means of decontaminating hands.
Alternatives to wash basins include:

- dispensers fitted with approved antiseptic solutions, are considered suitable, provided the dispensers can be operated without using the hands
- a sink of hands-free operation.

Section 8: Biological laboratories (only 8.3).
Appendix B: Additional requirements for microbiological facilities (excluding B1, B2, B3, B4 (a), (c), (d), (e), B5 (d) (e), (g), (h) and B6 (c) and (l)).

27.4 Where a basin is provided for washing hands an antiseptic hand wash dispenser must be supplied.

28. Indoor animal BC4 facilities

These standards from AS/NZS 2982.1:1997 are the minimum for work with indoor animal goods at the BC4 level.

28.1 Section 2: General laboratory construction requirements (excluding 2.2, 2.6, 2.7 (a) (vi) and (vii) & 2.7 (c); 2.9, 2.10, 2.11, 2.12 and 2.13).
Section 3: Reticulated services (excluding 3.7.3).
Section 4: Electrical services (excluding 4.2 and 4.3 paragraph 1).
Section 5: Ventilation and air quality (excluding 5.1, 5.2 paragraph 2, 5.3, 5.5.1, 5.5.3, 5.6 (b) last sentence only and 5.7).
Section 6: Health and safety requirements (excluding 6.1, 6.4, 6.5 and 6.6).

28.2 In substitution for 6.2 (safety showers), the following clause will be applied:
Clean up provisions are required which may be:

- fixed appliances (such as showers and eyewash stations)
- single use apparatus (such as disinfectant swabs, squeeze bottles).

Note: Where safety showers and eyewash facilities are installed they must comply with the requirements of 6.2.
The approach to clean up provisions must be unobstructed.

28.3 In substitution for 6.3 (hand washing facilities) the following clause will be applied:
Work areas where goods subject to biosecurity control are handled must contain either a hand wash basin fitted with hands free taps, or some other means of decontaminating hands.
Alternatives to wash basins include:

- dispensers fitted with approved antiseptic solutions, are considered suitable, provided the dispensers can be operated without using the hands
- a sink of hands-free operation.

Section 8: Biological laboratories (only 8.6.8, 8.6.10 and 8.6.11).
Appendix C: Additional requirements for animal accommodation (excluding C1, C2 (a), (c) and C3 (a), (b), (c), (d), (e) and (g)).

28.4 Where a basin is provided for washing hands an antiseptic hand wash dispenser be provided.

29. Plant laboratory BC4 facilities

These standards from AS/NZS 2982.1:1997 are the minimum for work with plant goods at the BC4 level.

29.1 Section 2: General laboratory design and construction requirements (excluding 2.2, 2.6, 2.7 (a) (vi) and (vii) & 2.7 (c), 2.9, 2.11, 2.12 and 2.13).
Section 3: Reticulated services (excluding 3.7.3).
Section 4: Electrical services (excluding 4.2 and 4.3 paragraph 1).
Section 5: Ventilation and air quality (excluding 5.1, 5.2 paragraph 2, 5.3, 5.5.1, 5.5.3, 5.6 (b) last sentence only and 5.7).
Section 6: Health and safety requirements (excluding 6.1, 6.4, 6.5 and 6.6).

29.2 In substitution for 6.2 (safety showers), the following clause will be applied:
Clean up provisions are required which may be:

- fixed appliances (such as showers and eyewash stations)
- single use apparatus (such as disinfectant swabs, squeeze bottles).

Note: Where safety showers and eyewash facilities are installed they must comply with the requirements of 6.2.
The approach to all clean up provisions must be unobstructed.

29.3 In substitution for 6.3 (handwashing facilities) the following clause will be applied:
Work areas where goods subject to biosecurity control are handled must contain a hand wash basin fit.
Handwash basins must be located inside the laboratory, near to the exit serviced with hot and cold potable water. Potable water requirements must be met in accordance with AS 3500.
Alternatives to wash basins include:

- dispensers fitted with approved antiseptic solutions, provided the dispensers can be operated without using the hands
- a sink of hands-free operation.

Section 8: Biological laboratories (only 8.3).

29.4 Where a basin is provided for washing hands an antiseptic hand wash dispenser must be supplied.

Australian/New Zealand Standard—Safety in laboratories part 3: microbiological aspects and containment facilities (AS/NZS 2243.3:2002)

The following parts of this standard (AS/NZS 2243.3:2002) are applicable to BC Level 4.

Specific standards

30. Microbiological BC4 facilities

30.1 The following standards from AS/NZS 2243.3:2002 are the minimum for work with microbiological goods at the BC4 level.
Section 4.7: Physical Containment Level 1 (PC1) requirements (only 4.7.2 (d) applies).
Section 4.8: Physical Containment Level 2 (PC2) requirements (only 4.8.3 (b)).

30.2 Large HVAC heat exchangers (e.g. chilled beams and some other natural or forced convectors) located within containment occupancies may be vulnerable to contamination, if they are not protected by efficient air filters. The likely contamination and implications for containment should be carefully assessed where such devices are proposed or are used.
Section 4.9: Physical Containment Level 3 (PC3) requirements (only 4.9.2 (a) – excluding the requirements for doors to open outwards, and be self-closing.
The requirement for doors to open outwards will be assessed as flexible depending on the context of the facility and rooms within. 4.9.2 (b), (c) and 4.9.3 (a), (b), (c), (d), (e), (f) and (i)).

30.3 In Substitution for 4.9.3 (g) the following clause will be applied:
Each separate room within a facility must have:

- a room pressure gauge that can be viewed by personnel prior to entering the facility
- an audible alarm.

Notes:

- The room pressure gauge must measure the differential pressure relative to the 'adjacent rooms' external to the facility. The reference pressure should be taken from 'adjacent rooms', normally the access space not the ceiling space. The adjacent space should not be subject to significant variations in ambient static pressure due to external influences such as ambient winds, ventilation equipment, fans, or any other equipment that could give rise to pressure fluctuations.
- The number of gauges required to safely monitor facility pressures will depend on the number of rooms, the number of independent supply and exhaust systems, and layout.

30.4 In substitution for 4.10.2 (j) the following clauses will be applied:

1) The facility must have an automatically-starting emergency power source to ensure continuing operation of the ventilation system, room access and shower controls.
2) Sufficient uninterruptible power must be provided for essential equipment such as biological safety cabinets.

Notes:

- The emergency power source would need to be designed to enable an automatic changeover as soon as practicable. Any such system would need to ensure emergency lighting and communication systems are reactivated within the shortest practical timeframe.
- An uninterruptible power supply (UPS) must be provided for biosafety cabinets to ensure seamless supply is maintained.

When a suit area is provided within the facility, the following standards must be met in addition to all other requirements listed only 4.10.8 (a), (b), (c) and (d).

31. Indoor animal BC4 facilities

31.1 The following standards from AS/NZS 2243.3:2002 are the minimum for work with indoor animal goods at the BC4 level.
Section 4.7: PC1 requirements (only 4.7.2 (c) & (d). applies)
Section 4.8: PC2 requirements (only 4.8.3 (b)).

31.2 Large HVAC heat exchangers (for example, chilled beams and some other natural or forced convectors) located within containment occupancies may be vulnerable to contamination if they are not protected by efficient air filters. The likely contamination and implications for containment should be carefully assessed where such devices are proposed or used.
Section 4.9: PC3 requirements (only 4.9.2 (a) – excluding the requirement for doors to open outwards, and be self-closing. The requirement for doors to open outwards will be assessed as flexible depending on the context of the facility and rooms within. 4.9.2 (b), (c) and 4.9.3 (a), (b), (c), (d), (e), (f) and (i))

31.3 In substitution for 4.9.3 (g) the following clause will be applied:
Each separate room within a facility must have:

- a room pressure gauge that can be viewed by personnel prior to entering the facility
- an audible alarm.

Notes:

- The room pressure gauge must measure the differential pressure relative to the adjacent rooms external to the facility. The reference pressure should be taken from adjacent rooms, normally the access space not the ceiling space. The adjacent space should not be subject to significant variations in ambient static pressure due to external influences such as ambient winds, ventilation equipment, fans, or any other equipment that could give rise to pressure fluctuations.
- The number of gauges required to safely monitor facility pressures will depend on the number of rooms, the number of independent supply and exhaust systems, and layout.
- The audible alarm is to indicate loss of negative room pressure in excess of 2 minutes.
- Where practicable other air conditioning control switches and exhaust fan speed set point control should also be located adjacent to the gauges.
- The HEPA filter gauge can also be mounted with the room gauges.

- If there is a closable door between two rooms they are separate.

Section 4.10: PC4 requirements (only 4.10.2 (a), (b), (c), (d), (e), 4.10.3 (a), (b), (c), (d)).

31.4 In substitution for 4.10.2 (j) the following clauses will be applied:

1) The facility must have an automatically-starting emergency power source to ensure continuing operation of the ventilation system, room access and shower controls.

2) Sufficient uninterruptible power must be provided for essential equipment such as biological safety cabinets.

Notes:

- The emergency power source would need to be designed to enable an automatic changeover as soon as practicable. Any such system would need to ensure emergency lighting and communication systems are reactivated within the shortest practical timeframe.
- An uninterruptible power supply (UPS) must be provided for biosafety cabinets to ensure seamless supply is maintained.

When a suit area is provided within the facility, the following standards must be met in addition to all other requirements listed only 4.10.8 (a), (b), (c) and (d).
Section 10: Animals and animal containment facilities (only 10.8.1 (b) associated notes only, (f), 10.9.2 (b), (c) – excluding the third paragraph and the associated note, and the requirement for automatic closers if another system such as alarms is fitted, and (d)).

32. Plant laboratory BC4 facilities

32.1 The following standards from AS/NZS 2243.3:2002 are the minimum for work with plant goods at the BC4 level.
Section 4.7: PC1 requirements (only 4.7.2 (d) applies).
Section 4.8: PC2requirements (only 4.8.3 (b)).

32.2 Large HVAC heat exchangers (e.g. chilled beams and some other natural or forced convectors) located within containment occupancies may be vulnerable to contamination, if they are not protected by efficient air filters. The likely contamination and implications for containment should be carefully assessed where such devices are proposed or are used.
Section 4.9: PC3 requirements (only 4.9.2 (a) – excluding the requirements for doors to open outwards, and be self-closing. The requirement for doors to open outwards will be assessed as flexible depending on the context of the facility and rooms within. 4.9.2 (b), (c) and 4.9.3 (a), (b), (c), (d), (e), (f) and (i)).

32.3 In substitution for 4.9.3 (g) the following clause will be applied. Each separate room within a facility must have:

- A room pressure gauge that can be viewed by personnel prior to entering the facility
- an audible alarm.

Notes:

- The room pressure gauge must measure the differential pressure relative to the adjacent rooms external to the facility. The reference pressure should be taken from adjacent rooms, normally the access space not the ceiling space. The adjacent space should not be subject to

significant variations in ambient static pressure due to external influences such as ambient winds, ventilation equipment, fans, or any other equipment that could give rise to pressure fluctuations.

- The number of gauges required to safely monitor facility pressures will depend on the number of rooms, the number of independent supply and exhaust systems, and layout.
- The audible alarm is to indicate loss of negative room pressure in excess of 2 minutes.
- Where practicable other air-conditioning control switches and exhaust fan speed set point control should also be located adjacent to the gauges.
- The HEPA filter gauge can also be mounted with the room gauges.
- If there is a closable door between two rooms they are separate.

Section 4.10: PC4 requirements (only 4.10.2 (a), (b), (c), (d), (e), and 4.10.3 (a), (b), (c), (d)).

32.4 In substitution for 4.10.2 (j) the following clauses will be applied:

1) The facility must have an automatically-starting emergency power source to ensure continuing operation of the ventilation system, room access and shower controls.
2) Sufficient uninterruptible power must be provided for essential equipment such as biological safety cabinets.

Notes:

- The emergency power source would need to be designed to enable an automatic changeover as soon as practicable. Any such system would need to ensure emergency lighting and communication systems are reactivated within the shortest practical timeframe.
- An uninterruptible power supply (UPS) must be provided for biosafety cabinets to ensure seamless supply is maintained.
- When a suit area is provided within the facility, the following standards must be met in addition to all other requirements listed only 4.10.8 (a), (b), (c) and (d).

Additional requirements

33. Specific requirements for biosecurity containment—level 4 (BC4) microbiological, animal and plant facilities

33.1 A facility must be constructed so that each room within achieves upon commissioning an air leakage rate, at a differential pressure of 200 Pa, of no more than 120L/min. An air leakage test must be provided for new or refurbished facilities.
Note: A small ante-room/airlock of less than 10 m2 floor area may be added with the adjacent room for the purpose of this requirement.

33.2 Where drinking fountains are provided they must be of hands-free operation and be within a designated area where goods are not handled, stored or treated

33.3 Write-up areas may be approved as part of a BC4 facility. To be eligible for approval, these areas must comply with BC4 requirements, be constructed such that

horizontal surfaces are minimised (for example, using minimal shelving), must not be used for generic office functions and should hold only essential reference materials (such as technical equipment manuals).

34. HEPA filters

34.1 HEPA filters must 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 must also be of gastight (seam welded stainless steel) construction.

34.2 The design of the filter housing must 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 services.
Note: housings should 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 ceilings should be avoided.

34.3 To enable testing and gaseous decontamination filter housings should incorporate the following features:

- sealed access doors for filter maintenance and integrity testing
- gastight isolating valves on the air inlet and outlet ducts
- secure filter element clamping and mounting tracks
- upstream and downstream valved ports
- upstream and downstream valved pressure tappings to permit monitoring of the filter air flow pressure drop
- a differential pressure gauge incorporating a magnetically coupled indicating mechanism and a sealed differential pressure diaphragm
- a facility to introduce a test airflow and cold generated aerosol to establish the integrity of the filter element and its mounting.

35. Waste service piping

35.1 Waste piping must be installed such that the length of horizontal piping is minimised. The pipe path should have the maximum practical fall (preferably vertical). The pipe should be routed via plant rooms and accessible building risers. The route should avoid ceiling spaces and occupied areas unless this is impractical.

35.2 Piping must be conservatively selected to suit the fluid flow and pressure applicable. The pipe material should resist degradation from exposure to waste products or likely cleaning and disinfection agents.
Note: Fully welded 316l stainless steel piping of 1.0 mm thickness is recommended. Single skin piping is considered satisfactory.

35.3 Piping must be physically protected where exposed to mechanical damage.

35.4 Piping must be labelled ‘Biosecurity Containment Pipework – Do not disturb’ throughout its length. Biohazard warning symbols should also be provided at regular intervals.

35.5 Piping should be capable of being visually inspected throughout its length. Double skin pipe construction is recommended in any locations where visual inspection is unable to be undertaken. However, this contingency should be avoided where practical.

35.6 A filtration system is required for removal of solids prior to liquid waste entering the holding tank. The filtration system must be capable of being removed for cleaning and decontamination. Solids removed from waste water are deemed to be biosecurity waste and must be treated as such. Steam sterilisation is recommended.
Note: The efficacy of the waste treatment system in sterilising particulate matter should be considered when determining the filtration system screen size to be utilised for solids removal.

35.7 The floor of the waste treatment plant room must be fully bunded to a volume that ensures retention of all waste in the event of a holding tank failure at full capacity. The bunded space should drain to a sealed sump. A submersible sump pump must be provided along with flexible hosing to discharge the spillage after chemical disinfection
Note: Consideration should be given to the provision of a safety shower and eyewash station within the plant room.

35.8 A 'continuous flow alarm' is desirable for water services connected to appliances draining to the treatment system.
Note: A suitable timer can warn users where water flow to a single appliance exceeds a reasonable period of time.

35.9 Vents to the waste system must be fitted with sterile filters. Filters must be carefully selected to ensure that sufficient air is passed to ensure traps are not compromised. 0.2 micron hydrophobic membrane filters are recommended. These must be capable of being decontaminated, preferably by steam sterilisation.

35.10 Where toilets are installed, it is recommended that these are urine-only systems. Where urine-only toilets are installed a 'Lady-San' or similar disposal station for small quantities of toilet paper and other minor solids should be supplied. Solid waste collected from disposal stations must be treated as biosecurity waste.

36. Specific requirements for biosecurity containment—level 4 (BC4) animal and plant facilities

36.1 Any openings in the walls, ceiling or roof, such as vents, drainage outlets and air conditioning or ventilation inlets and outlets, must be screened at the containment boundary with fine mesh screens having an aperture size small enough to prevent entry or egress of insects.
Screens must be of suitable material to withstand the air flow load (to remain undamaged following cleaning) and be resistant to attack by insects or corrosion.
Note: An aperture size small enough to prevent entry or egress of insects will require a maximum aperture size of 0.25 mm or 250 microns (um).

36.2 The size of insects to which plants and animals subject to biosecurity control held within the facility are potential hosts must also be considered when determining the appropriate screen size.