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Department of Agriculture, Water and the Environment

Approved arrangement

5.2 – Biosecurity containment level 2 (BC2)

Informative text

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Department of Agriculture, Water and the Environment
GPO Box 858 Canberra ACT 2601
Telephone 1800 900 090
Web awe.gov.au

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Date	Version	Amendments	Approved by
18 Jan 2021	1.0	Final version	Caroline Gibson

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Part A – General Information

1 Introduction

This document provides informative text that clarifies issues and provides supplementary information to assist in interpreting the specific requirements for an Approved Arrangement (AA) at Biosecurity Containment Level 2 (BC2). This informative text is intended for guidance and for information purposes only. The information does not have mandatory status, though it may restate mandatory conditions from the approved arrangement site conditions document (nominated in paragraph 3 of this Section).

Where this document uses terminology such as "must", or "is required", it is normally restating or referencing conditions in the mandatory, approved arrangement site conditions document or other references such as transport regulations. However, this entire document is for information purposes only. The mandatory approved arrangement site conditions document and other regulatory requirements take precedence over the information provided in this document.

The approved arrangement site conditions document, '*Approved arrangement 5.2, biosecurity containment level 2, Conditions*' sets out the conditions that must be met by the biosecurity industry participant to ensure physical security around storage, handling, risk and incident management, work practices, personnel, transport, biosecurity treatments and waste management. The conditions are set out in multiple parts:

- Part 1 contains scope and generic conditions and applies to all BC2 approved arrangements.
- Parts 2 – 6 set out the additional conditions for a certain type classification. This is divided into five sections, Microbiological, Animal, Aquatic, Plant and Invertebrate.

The conditions applicable for each of the approved arrangement types are outlined below:

Conditions for approval as a BC2 approved arrangement site		
Class	**Type Classification**	**Parts Applicable**
5.2.1	Biosecurity Containment Level 2, Microbiological	Parts 1 and 2
5.2.2	Biosecurity Containment Level 2, Animal	Parts 1 and 3
5.2.3	Biosecurity Containment Level 2, Aquatic	Parts 1 and 4
5.2.4	Biosecurity Containment Level 2, Plant	Parts 1 and 5
5.2.5	Biosecurity Containment Level 2, Invertebrate	Parts 1 and 6

2 Further information

The "biosecurity industry participant" is defined in the legislation. Refer to the *Biosecurity Act, 2015*. For more information on approved arrangement site conditions and the department's general policies refer to: awe.gov.au.

3 Conditions, assessments and audits

The department's conditions, assessments and audits focus on containment, control and treatment measures for goods requiring biosecurity control. Regulatory conditions and the assessments, audits and advice from the department's personnel or its approved third-party assessors are for biosecurity control purposes only. These measures do not regulate or assess work health and safety (WH&S) measures or that of other authorities.

4 BC2 classification and containment principles

The following tables provide guidance on the type classification required for an approved arrangement site accommodating biosecurity goods (including organisms). The tables include:

- examples of the types of goods subject to biosecurity requiring level 2 (BC2) containment
- summaries of the containment and support infrastructure for a BC2 approved arrangement, and
- the generic actions which are typically permitted to occur within level 2 biosecurity containment.

Terms in the tables and in the regulatory conditions/informative text are used in the following way:

Approved Arrangement Site – the physical area where the biosecurity industry participant undertakes biosecurity activities covered by an Approved Arrangement. Biosecurity activities include work such as research and analysis.

Approved arrangement site boundary, or containment boundary – the outer enclosure that provides a physical barrier (for example a wall) for level 2 biosecurity containment. This physical enclosure wall is commonly termed the 'site boundary' or 'containment boundary'. It is the part of the BC2 infrastructure that delineates the boundary between an internal, level 2, biosecurity-controlled environment and an external environment that may be uncontrolled, or of a differing biosecurity control status. Note that the containment boundary is a specific component of the overall BC2 infrastructure.

Approved Arrangement (BC2) Infrastructure – the support facilities, equipment, services and systems that provide biosecurity level 2 containment at or around the approved arrangement site. A variety of biosecurity containment systems can be used. For example, animals may be housed or caged in primary containment rooms or contained in devices such as individually ventilated cages (IVCs) within a secondary containment room. Plants may be held within a permanent (primary containment) greenhouse or in plant growth chambers within a secondary containment room. The BC2 infrastructure may include one or more rooms and may include support facilities such as potting areas, equipment/instrument/imaging rooms, and waste storage and treatment rooms/areas. It will include the equipment, building services and systems that support the approved arrangement site.

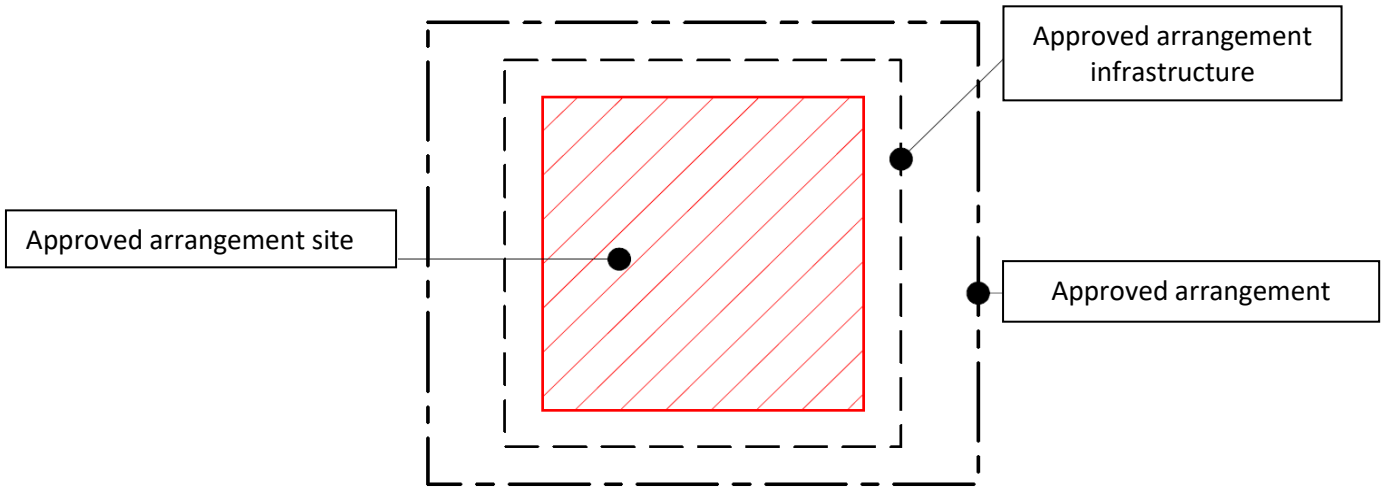


Figure 1. Illustration of Site Reference Terminology

Approved Arrangement- the area including the approved arrangement site, and approved arrangement (BC2) infrastructure. The approved arrangement will be a formal arrangement with the department for the

containment, handling, storage, treatment, disposal (including destruction and where applicable, approved release) and transport of goods subject to biosecurity control. Some infrastructure such as equipment/instrument rooms, waste storage and treatment areas may be separate from the approved arrangement site where work such as research and analysis occurs. The approved arrangement will include conditions for the approved arrangement (BC2) infrastructure (including the approved arrangement site), activities and goods subject to biosecurity control.

Type – the biosecurity containment classification, based on the type of biosecurity goods accommodated. The conditions for handling and containment of goods will depend on this classification. The type classification covers microbiological, animal, aquatic, plant and invertebrate approved arrangement sites where work such as research, analysis, or experimental activities occur. The work may also include the breeding and growing of plants, animals or invertebrates. General examples of the types of goods accommodated by each type of approved arrangement site are listed in the tables following.

Activities – actions that are permitted for handling and processing biosecurity goods within a particular type of approved arrangement site (for example, experimental activities with biosecurity goods or holding biosecurity goods for a specified control period).

''Goods" is defined in the legislation. Refer to the *Biosecurity Act, 2015*.

Note: Biosecurity assessments and the decision to direct an imported good to an approved arrangement site are made in accordance with departmental policy and on a case-by-case basis. Multiple classification approvals may be required. For example, in vivo work with animals may require both microbiological and animal containment approvals.

MICROBIOLOGICAL		
TYPE CLASSIFICATION ***This definition covers all containment levels (BC1-4)**	**BC2 INFRASTRUCTURE**	**TYPES OF GOODS and ACTIVITIES – BC2**
The microbiological type includes *in vitro* and *in vivo* work with organisms or cellular plant material including: • protozoa and other parasites • fungi, archaea, bacteria, algae, viruses and viroids • microscopic invertebrates with low mobility, such as many of the nematodes (for example, filariae) and trematodes (for example, Schistosoma Spp.).	The support facilities, equipment, services and systems that provide biosecurity level 2 containment at or around the approved arrangement site. The infrastructure may encompass a whole building or any part of a building (such as a whole floor) used for scientific and related work, including research, testing or analysis. The BC2 infrastructure may include areas such as: • equipment / instrument rooms • preparation rooms • cool rooms • controlled environment rooms • plant growth cabinets • waste treatment rooms/areas • storage areas. In general, office areas should not form part of a containment laboratory.	Microbiological approved arrangement sites may accommodate activities associated with microorganisms, animals or plant such as: • preparing samples for testing and analysis • parasitic work (for example, trematoda including shistosomes) for holding and in-vitro analysis • handling of animal material that is infected or specific pathogen free (SPF) • processing live plant material within primary containment devices. The type of goods and work classified as microbiological may include: a) soil and water samples for microbial or viral isolation b) cultures of microorganisms c) animal samples such as blood, tissues, and swabs (not for isolation of exotic pathogens) d) biological material for in vivo work in animals e) animal blood/tissue known or suspected to be infected with exotic pathogens (the containment level is assessed by the department on a case-by-case basis taking into account species, country of origin, and the pathogen/s concerned) f) tissue cultures (for example, live plant material kept in sealed tubes, petri dishes or similar sealed devices) g) plant growth in sealed cabinets or chambers, or h) handling positive controls such as infected plant material or plant pathogens.

ANIMAL		
TYPE CLASSIFICATION ***This definition covers all containment levels (BC1-4)**	**BC2 INFRASTRUCTURE**	**TYPES OF GOODS and ACTIVITIES – BC2**
The animal type includes all animal species with backbones that are terrestrial (land based). This includes small laboratory animals such as mice, rats, hamsters, guinea pigs and/or other rodents, rabbits, or large animals such as pigs, sheep, goats, deer, camels, cattle, horses. Other animals included are primates and some marsupials.	The support facilities, equipment, services and systems that provide biosecurity level 2 animal containment at or around the approved arrangement site. The infrastructure may encompass any suitable enclosure for containment of animals under biosecurity control, including experimental, breeding or infected animals. The BC2 approved arrangement site may be part of a building or a whole building. For smaller animals, filter cages or isolators normally provide primary containment with an enclosing room for secondary containment. For large animals, the room enclosure may provide primary containment. The BC2 infrastructure may include integrated or separated areas for: • equipment/instruments • experimentation • post-mortem, examination • waste treatment, storage, disposal.	Activities at an animal approved arrangement site may include: • *in vivo* work with animals • housing imported animals that may not be infected, but may harbour organisms and are required to be isolated and controlled, either for a period, or permanently • animal breeding (where approved). Note: When housing animals hosting microorganisms, the biosecurity level would be at least the containment level appropriate for the microorganism. Examples of BC2 goods include: • imported (including returning) animals held until eligible for release from biosecurity control • imported animals permanently held under biosecurity control • animals used in approved in vivo studies.

AQUATIC ORGANISMS		
TYPE CLASSIFICATION ***This definition covers all containment levels (BC1-4)**	**BC2 INFRASTRUCTURE**	**TYPES OF GOODS and ACTIVITIES – BC2**
Aquatic organisms include vertebrate or invertebrate animals which live most of their life in water. The classification also includes animals (amphibians) which move readily from water to land and vice versa, and marine, or freshwater organisms. Aquatic animals include annelids (for example, aquatic segmented worms), cnidarians (for example, jelly fish), echinoderms (for example, starfish), monotremes (for example, platypus), amphibians (for example, frogs, toads, newts, salamanders, axolotl), fish (for example, zebra fish), molluscs (for example, snails), crustaceans (for example, crab, shrimp, krill), other marine and freshwater animals such as otters.	The support facilities, equipment, services and systems that provide biosecurity level 2 aquatic animal containment at or around the approved arrangement site. The infrastructure may include primary containment (such as tanks) for separate housing and containment of aquatic organisms subject to biosecurity control. The BC2 approved arrangement site may be part of a building or a whole building. The aquatic BC2 infrastructure may include integrated or separated areas for: • equipment / instruments • experimentation • post-mortem examination • waste treatment, for example, storage, disposal.	The type of goods and work classified as aquatic may include: a) activities with small species such as zebra fish, snails, marine plankton, corals, starfish, jellyfish, or with larger animals such as crocodiles, alligators, sharks b) research on imported aquatic organisms infected with low to medium risk parasites/pathogens c) research with zebra fish involving live pathogens d) research involving isolating diseased aquatic organisms from healthy stock e) analysis of aquatic organisms. Aquatic organisms may be held within enclosures permanently or for specified biosecurity control periods. An aquatic approved arrangement site will also require a microbiological classification if the work proposed or undertaken involves culturing microorganisms, or *in vivo* work, or importing aquatic organisms infected with parasites.

PLANT		
TYPE CLASSIFICATION ***This definition covers all containment levels (BC1-4)**	**BC2 INFRASTRUCTURE**	**TYPES OF GOODS and ACTIVITIES – BC2**
Plants include all plant species, both terrestrial (land based) and aquatic.	The support facilities, equipment, services and systems that provide biosecurity level 2 plant containment at or around the approved arrangement site. The BC2 approved arrangement site may include part or all of a building or greenhouse structure used to contain plants and limit the spread of propagules, and the entry and escape of invertebrate vectors carrying infectious organisms. The BC2 approved arrangement site is commonly a permanent greenhouse structure clad in glass, polycarbonate or similar transparent or translucent material. Plant BC2 infrastructure may include plant growth cabinets, controlled environment chambers and integrated or separated areas for: • equipment / instruments • potting • waste treatment, storage, disposal A BC2 approved arrangement plant site (greenhouse) may be attached to a BC2 approved arrangement microbiology site (laboratory) where plants may be taken to undertake *in-vivo* work, and then returned to the approved arrangement plant site. Alternatively, plants may be accommodated in growth cabinets/chambers within a BC2 approved arrangement microbiology site (laboratory) that is suitably constructed for this purpose.	The type of goods and work classified plant may include: • *in vivo* work with plants • virus indexing • maintaining herbaceous and woody indicators for active virus testing • plant breeding A plant approved arrangement site will also require a microbiological classification if the work proposed or undertaken involves risk group 2 microorganisms or parasites. The microbiological classification will invoke additional conditions such as inward airflow. A plant approved arrangement site will also require an invertebrate classification if the work proposed or undertaken involves invertebrates.

INVERTEBRATE		
TYPE CLASSIFICATION ***This definition covers all containment levels (BC1-4)**	**BC2 INFRASTRUCTURE**	**TYPES OF GOODS and ACTIVITIES – BC2**
Invertebrates include all multi-cellular animal species without backbones that are primarily land based as adults. This includes hexapods (such as insects, springtails), chelicerata (such as spiders, mites), myriapoda (such as centipedes, millipedes), annelids (worms and leeches), some of the platyhelminthes (flatworms), some mematoda, (roundworms), culicoidea (mosquitoes, midges) and some molluscs (for example, terrestrial gastropods). Semi aquatic snails are usually classed as invertebrate type.	The support facilities, equipment, services and systems that provide biosecurity level 2 invertebrate containment at or around the approved arrangement site. The BC2 approved arrangement site may include any part or all of a building or greenhouse structures used to contain invertebrates or organisms associated with invertebrates. BC2 invertebrate infrastructure may include integrated or separated areas for: • unpacking • equipment / instruments • experimentation • plant growth • waste treatment, storage, and disposal. Normally invertebrates will be held in primary containment devices such as screened cages or isolators within a BC2 approved arrangement site providing secondary containment. Applications where the BC2 approved arrangement site provides primary containment for invertebrates are rare. The department has special conditions that apply for approval of any BC2 approved arrangement site as primary containment for invertebrates.	Type of goods and work classified invertebrate may include: a) invertebrate breeding and long term maintenance of colonies b) research and analysis of invertebrates and their interaction with hosts (plant animal or invertebrate), parasites or pathogens c) *in vivo* work such as infecting invertebrates with microorganisms (for example, fungi, bacteria or viruses) d) research on imported invertebrates infected with parasites (for example, terrestrial and semi-aquatic snails infected with shistosomes). An invertebrate approved arrangement site will also require a microbiological BC classification if the work proposed or undertaken involves culturing microorganisms, or *in vivo* work, or importing invertebrates infected with parasites. The microbiological classification will invoke additional conditions such as inward airflow. Similarly, if work in the invertebrate approved arrangement site includes live plants or animals a plant or animal type classification would also be required.

Part B – Supporting information

This part of the Informative Text document provides supplementary information for meeting specific BC2 conditions.

5 Assessment for an approved arrangement

Figure 2 following shows a typical assessment flowchart for an approved arrangement. The flowchart is intended as an informative overview of the department's normal approval sequence. It does not accurately detail the internal procedures within the department, which can, and may vary over time. It reflects a typical simplified approval process. The process may vary for a particular site application and may also be varied at the discretion of the department.

Assessment times for an approved arrangement are variable. However, initial consideration periods for applications are:

- 120 days, where there is a need for scientific or technical advice
- 90 days, in other cases.

Where the department requests further information, the timeframe is normally extended. Typically, this can add a further 60 days to the process.

6 Third party assessments

The department utilises approved third-party assessors (TPAs) for determining compliance with the construction related provisions of the BC2 conditions and higher-level approved arrangements. Third-party assessors are typically engineering and architectural professionals who have been assessed by the department as having the requisite skills to assess biosecurity containment facilities. A list of approved, third-party assessors, including contact details, is provided on the department's web site at awe.gov.au.

The applicant for an approved arrangement site must engage an approved third-party assessor to assess compliance with the construction related provisions of the '*Approved arrangement 5.2, biosecurity containment level 2, conditions*'. The department recommends engagement of a TPA at an early stage in the design/construction of an approved arrangement for biosecurity containment.

The TPA undertaking a compliance assessment cannot have any other role in a development project, as it will be considered a conflict of interest. It is permissible for an approved arrangement applicant to engage a TPA for design/construction advice or other project related purpose. However, a professional, undertaking project roles, cannot simultaneously act as the project compliance assessor. If a TPA is engaged for design/construction advice or other project related purposes, then a separate TPA must be engaged for the compliance assessment.

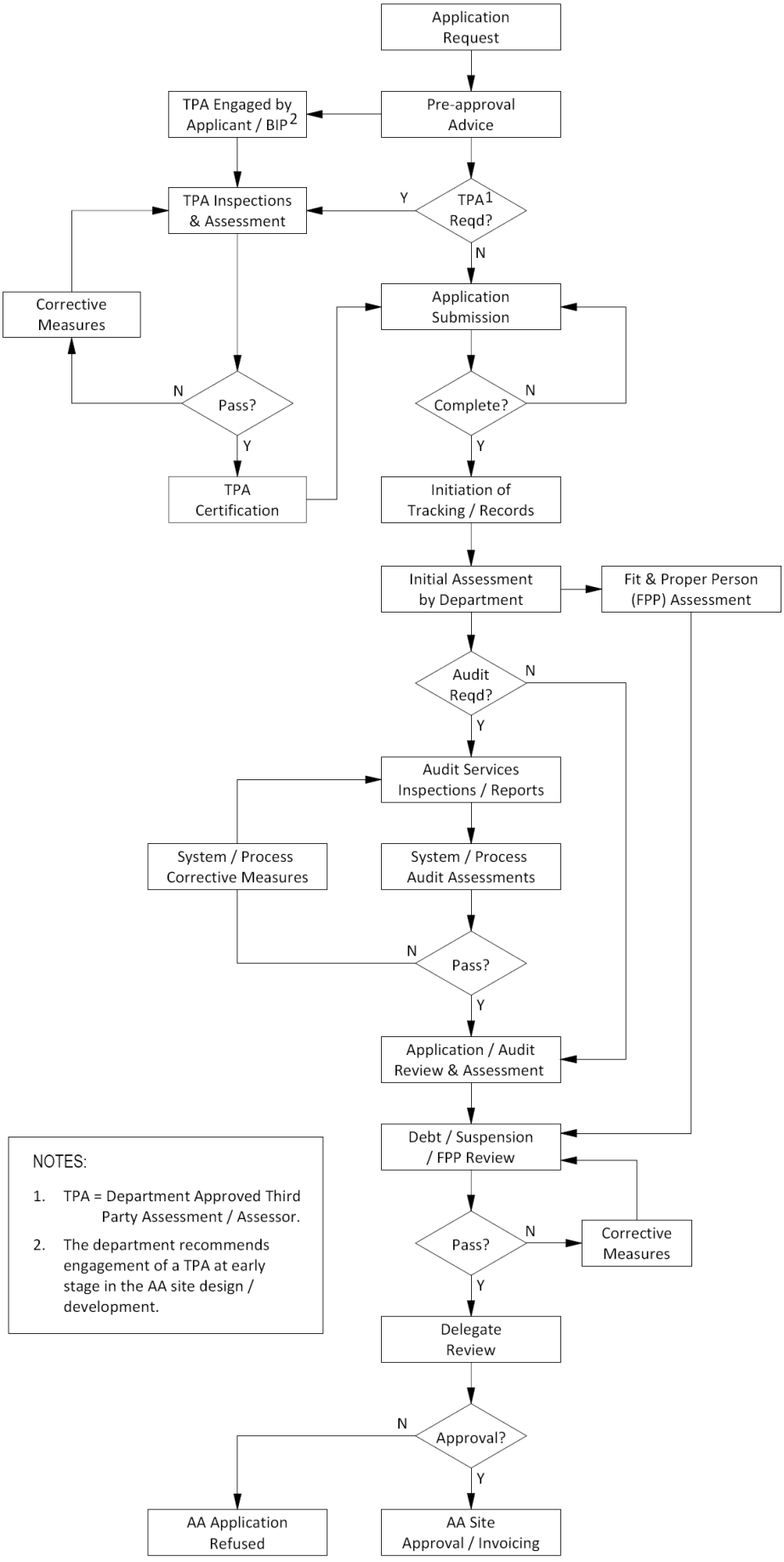


Figure 2. Overview Flowchart of AA Approval Process

The third-party assessor will review project documentation and undertake site inspections to determine construction compliance with the BC2 conditions. Normally a third party assessor will advise the applicant of elements having compliance issues so that these issues can be resolved and reinspected, as necessary.

Note: the department will not move forward with an approved arrangement application until it receives a certification from the third party assessor that facilities are compliant with the BC2 conditions. Therefore, all compliance issues must be resolved to the satisfaction of the third party assessor before an approved arrangement application can advance to the initial assessment stage shown in Figure 2.

The department also has its own internal auditors who will assess an approved arrangement application from the containment process and systems perspectives. The process/systems audits will normally follow receipt of a third-party assessor certification for the construction related features of the approved arrangement. Process/system audits will assess operational plans and procedures, such as containment protocols, biosecurity treatments, testing/verification methods, documentation, record keeping.

7 Import permit conditions

Import Permits may specify specific, supplementary or modified conditions for biosecurity control. The conditions in Import Permits take precedence over conflicting regulatory conditions. The legislation (*Biosecurity Act 2015*) has the highest order of precedence. However, the requirements of regulations and Import Permits will be consistent with the legislation.

8 Notification of site changes

The department requires notification, in writing, for significant approved arrangement site changes such as:

a) making alterations to, or works which can, or may alter the seal of, the containment boundary of the approved arrangement (BC2) site
b) assigning, transferring or relocating the biosecurity operations to another site, or
c) ceasing or significantly reducing or expanding the scale of biosecurity operations at the approved arrangement site.

When proposing to make alterations that affect the containment boundary, the biosecurity industry participant should consider whether it is necessary to invoke the suspension process as detailed in the department's *General Policies*.

It is difficult to define the limits of significant change that would require notification to the department. Minor site changes and minor works which do not alter or effect the seal of the containment boundary are permissible without notification. Changes to personnel responsible for controlling, directing, enforcing or monitoring people performing activities associated with the approved arrangement require notification. Other routine operational, organisational or administrative changes would not normally require notification, provided roles and responsibilities in relation to biosecurity control remain clear. Work on the containment systems such as:

a) replacing like for like items (single items not affecting the seal of the containment boundary) after damage or deterioration
b) repainting, resealing and other maintenance type activities, or
c) software updates and software maintenance

would not normally require notification to the department. Such activities could be notified, and explained at audit.

9 Personnel/staffing requirements

9.1 General competency

The competency of staff for an approved arrangement site is an issue of primary importance. Supervisory staff should have a sound understanding of biosecurity containment principles based on their professional qualifications or specific training in bioscience/biosecurity applications. Personnel who handle, process or manage goods subject to biosecurity must have the appropriate competency for their duties and an understanding of biosecurity risks and the general practice and specific procedures and protocols that they must follow to address such risks.

9.2 Training

Staff training measures should provide the level of competency required for personnel to carry out their duties in a manner that is fully consistent with the biosecurity conditions in place at the approved arrangement site. The operational practice should ensure that staff are suitably mentored and monitored during the initial phase of their employment until they are fully aware of the conditions to ensure biosecurity containment at the site.

9.3 Testing and verification

Required testing and verification measures for containment such as cabinets, filters, biosecurity treatments should be undertaken by personnel having the training, competency and equipment necessary for reliable testing.

9.4 Departmental conditions

Personnel who have responsibilities for or perform tasks that may impact on goods subject to biosecurity control, need an understanding of the department's conditions related to their duties (for example, Import Permit conditions, directions, import conditions, database requirements). Note that the department has an accessible database for import conditions referred to as BICON (Biosecurity import conditions). This database is provided on the department's web site at: awe.gov.au.

10 Approved arrangement site construction

10.1 Signage

Signs need to inform personnel that they are entering a restricted area containing goods that are hazardous or dangerous to humans, animals, plants or the environment. Signs may display the biological hazard symbol as shown in Australian/New Zealand (AS/NZS) Standards or may be a specific biosecurity control sign. The level of containment is required to be displayed.

Signs should be securely affixed, durable, prominently displayed and legible to persons approaching the area, at all times. New signs should have black lettering on a yellow background and contain the words 'Biosecurity control area – no unauthorised entry or removal of goods, penalties apply' or words to similar effect. Existing signs with 'Quarantine control area' do not need to be replaced unless they have deteriorated.

It is desirable to have all rooms in an approved arrangement site identified in some rational manner such as via appropriate signage, coding, numbering. The room identification should be consistent with layout plans and other site documentation.

10.2 Display of other information

The approved arrangement site should have other information displayed as necessary to ensure operators and maintenance personnel are well informed to carry out their tasks. Information that may be displayed includes:

a) safety and operational instructions
b) limits and settings
c) designation of storage areas
d) location information or labelling for key elements (for example, PPE, spill kits, filters, backflow prevention)
e) as installed schematic diagrams of air handling services, liquid waste, vacuum, potable/non-potable water and power supply (as applicable).

10.3 Type classification

The required Type classification will be specified in the Import Permit for the goods. Note that multiple type classifications are possible. For example, an animal infected with an exotic bacterial agent will have to be contained in an approved arrangement site with both a Microbiological and Animal type classification. Where multiple type classifications apply, the mandatory conditions relevant to all applicable classifications must be met.

10.4 General BC2 construction

Structural joints should be avoided (or minimized, if unavoidable) in biosecurity containment.

A multi-level BC2 approved arrangement site may incorporate stairs. However, stairs create higher risks of accidents, particularly when transporting goods. This needs to be considered when planning a BC2 approved arrangement site. If stairs are incorporated in a BC2 approved arrangement site, the stairs and stairwell need to meet BC2 construction conditions. This means that surfaces must be impervious, smooth and cleanable. The stair and stairwell structure need a suitable design for cleanability, avoiding surfaces that are complex, remote or otherwise difficult to access.
Note: a multi-level atrium should not be part of a BC2 approved arrangement site because of the difficulties of accessing high-level surfaces for cleaning.

Service risers through a multi-level BC2 approved arrangement site should be avoided where practical. Where they must be accommodated, it is important to have suitable detailing so that they do not compromise BC2 containment. For example, the entire riser can be segregated from the approved arrangement site by sealed vertical cladding. Alternatively, the services can be individually sealed where they penetrate the approved arrangement site.

Where a passenger or goods lift operates through multiple floors accessing an approved arrangement site, it must be segregated from the approved arrangement site by at least a lobby or other non-controlled room or corridor at each access level. A lift door may not be an access door to a required airlock or anteroom. Note that a dumb waiter is regarded as a goods lift.

In general, the provision of toilets within an approved arrangement site is undesirable. However, the department recognises that some institutions, particularly those with large scale containment sites, find it necessary to provide this amenity for acceptable working conditions and/or operational efficiency.

If report writing areas form part of a biosecurity containment (BC2) approved arrangement site they should have minimal clutter (minimal shelving, holding only essential reference materials, documentation should not be stockpiled). These areas should be constructed and maintained to the same standard, as the remainder of the approved arrangement site.

Storage space and shelving within an approved arrangement site should be minimised to facilitate cleaning. Only essential equipment and reference documentation should be held in the approved arrangement site.

Internal fittings and furnishings require careful selection to ensure they are free of voids, crevices, rough or absorbent surfaces, or other details that are difficult to clean. Where windows are provided, fixed glazing is preferable to openable windows, even when the latter are sealed and locked. Simpler detailing normally makes fixed glazing easier to clean.

Where work rooms, storage, and support rooms, anteroom, or a corridor (preparation, treatment, report writing and storage) form part of an approved arrangement site, they would also need to meet BC2 construction conditions.

Floor furnishings that are resistant to commonly used cleaning agents include welded, chemical and solvent resistant vinyl (meeting ISO 10581) or an epoxy floor coating system over a stable and continuous floor surface.

Moveable or mobile work surfaces that are butted together and can be moved for cleaning, do not need to have the abutting joints sealed.

To ensure brick work or block work walls are smooth, cleanable and impermeable may require:

a) rendering or sheathing with plasterboard, or
b) filling and smoothing mortar joints, and surface sealing using paint.

A smooth acrylic paint finish is an acceptable finish for plasterboard walls in BC2 approved arrangement sites, other than for primary containment sites.

Fire sprinkler protection is permitted in BC2 approved arrangement sites. For invertebrate control, sprinkler heads will need to be sealed to the containment boundary. No special conditions for water control apply as the probability of water discharge from a sprinkler head (via fire or accident) is very low. Cages can be fitted to sprinkler heads where there is a heightened risk of physical damage.

Service pipes penetrating floors should be installed in coved plinths or have coved sleeves to avoid installation details that are difficult to clean and to prevent spilled liquids seeping into floors or lower building levels. An alternative approach is to penetrate flooring within a wall cavity and seal the pipe where it penetrates the wall surface. Exposed service piping and conduit/cabling should be spaced off walls to facilitate cleaning (25mm clearance is recommended).

Inline, cartridge type, medical vacuum filters of HEPA standard or 0.2 micron hydrophobic membrane filters can be used at vacuum points, or centrally, within a vacuum system.

An approved arrangement site needs provision for storage of clean and used personal protective equipment (PPE) such as eye and face protection, laboratory coats, coveralls, footwear, to suit the application. Clean and used personal protective equipment must be segregated. Storage for used personal protective equipment needs to be within the approved arrangement site, near the exit or just inside the inner door of any anteroom. Clean personal protective equipment may have segregated storage in a similar location, or may be stored in an anteroom, where applicable. Clean personal protective equipment must not be stored in any part of an approved arrangement site used as primary containment.

Note that clean PPE may also be stored directly outside the approved arrangement site. However, if it is not readily accessible to personnel entering the site, additional clean PPE should be stored for ready availability, as indicated above.

10.5 Invertebrate containment/exclusion

Animal, aquatic, plant and invertebrate containment requires screening of openings for invertebrate containment/exclusion. The maximum screen aperture is 250 microns (0.25mm). The preferred screening material for invertebrate control is fine, stainless steel, wire mesh. When proposing to use an alternative screen material, consideration should be given to the suitability of the screen material to be used.

Any material proposed for screening should have suitable:

1. mechanical strength under the airflow load
2. ability to remain undamaged with regular, vigorous cleaning
3. corrosion resistance, and
4. resistance to attack by insects from either inside or outside the approved arrangement site.

Applicable screened openings will include:

a) HVAC inlets and outlets
b) openable windows
c) permanent or openable air vents
d) any service or equipment vents that connect directly to the BC2 environment (for example, a drainage vent connected upstream of the liquid trap)
e) exhaust outlets from fume cupboards or hoods (where air is expelled outside the building)
f) exhaust outlet from a capture hood or fumigant exhaust for a biological safety cabinet.

For fume cupboards, outlet screening located at the rear of the working chamber is the preferred arrangement.

Where fine mesh screens cover openings handling contaminated airflow (for example, return air vents in primary containment animal rooms) it may be desirable to provide pre-filtration to avoid rapid blocking of screens by airborne contaminants.

Trapped drains to a municipal sewer do not need to be screened for invertebrate control. However, they may need screening, strainers or other suitable measures to protect drains from blockage (see Section 10.20 and Attachment A), or in lieu of having a liquid filled waste trap.

Note that the arrangement of waste liquid traps for BC2 invertebrate control in Animal, Aquatic, Plant and Invertebrate facilities, must seal the approved arrangement site. A liquid waste line that exits the approved arrangement site must have a liquid-filled trap upstream of any connection to a drainage main or other drain line that is not part of the approved arrangement site. The liquid seal on drainage traps must be permanently sustained. If traps are vulnerable to drying out, they require an effective, timer-based trap charging system to top up the traps with water from a suitable source. The other option is to have screened drains at the containment boundary

10.6 Standard of sealing

Approved arrangement sites do not require controlled air pressurisation. For some type classifications, an overall inward airflow is required. For BC2 approved arrangement sites that are not designed for invertebrate containment/exclusion, the site sealing should be to a superior quality, to conventional building standard. For microbiological approved arrangement sites, there should be no obvious, unsealed gaps or fissures in exposed wall or floor surfaces so that these are easy to clean and will not harbour contamination. It is not practical to seal tiled ceilings (permissible for microbiological type). These should be neatly fitted with no missing tiles or empty cut outs. In general, air infiltration into an approved arrangement site should be minimised, unless the site has (screened) vents to the exterior.

BC2 approved arrangement sites designed for containment or exclusion of invertebrates (animal, aquatic, plant and invertebrate types) need a higher standard of enclosure sealing that is consistent with the invertebrate screening aperture. In general, the whole BC2 approved arrangement site should not have unsealed gaps or crevices with width exceeding the applicable screen aperture. However, a reduction of sealing is permissible for access door seals. Refer to the mandatory conditions document for the gap limits for door seals.

Door 'seals to BC2 standard' should be selected and installed to contain, or exclude insects as indicated in the BC2 Conditions document.
Note: all doors for a BC2 approved arrangement site should be quality, close fitting doors, even when door seals are not a mandatory requirement.

Some BC2 approved arrangement sites are fitted with a large removable wall panel so that bulky equipment items can occasionally be moved in or out of the site. Limiting apertures to 250 microns around this type of feature is difficult. The feature should be avoided for applications requiring invertebrate containment/exclusion, if possible. Where it is necessary to provide such a feature, the panel will normally need some form of semi-permanent seal such as a breakable seal that is reconstructed when the panel is replaced. Similar issues may arise with the sealing of emergency exit doors, depending on the standard of sealing required (this is specified in the BC2 conditions document for varying situations). Additionally, maintenance access hatches may be installed in walls, however, they will need to be sealed, and retain seal when not being opened for temporary access to services.

10.7 False ceilings

Where an approved arrangement site has a false ceiling, the best construction practice is to isolate the ceiling space as part of the BC2 approved arrangement site or as a buffer zone above the approved arrangement site. For this purpose, perimeter walls of the BC2 approved arrangement site should rise through the ceiling plane to the underside of a slab or roof sheeting over the approved arrangement site. The use of a false ceiling space as a return air path is poor practice, though not precluded from approved arrangement sites. If this return air arrangement is employed, it is essential to physically segregate the BC2 ceiling space from non BC2 areas such as the ceiling space over an adjacent office area.

10.8 Shelving

Where shelving is necessary, open, fully inspectable and readily cleanable shelving systems are appropriate for containment applications. For adjustable shelving, systems that use slotted channel brackets with flanges clamped to the wall should be selected in preference to difficult to clean systems where the slotted bracket is clamped with the channel facing the wall.

10.9 Microbiological BC2 construction

Suspended tiled ceilings are permitted in microbiological BC2 approved arrangement sites but are not acceptable for other approved arrangement type classifications. A tiled ceiling is not permitted where a BC2 microbiological approved arrangement site (laboratory) is used as an anteroom to a plant approved arrangement site. Tiled ceilings must use tiles that do not shed particulates, do not absorb contaminants and are cleanable (for example, vinyl or mylar faced acoustic tiles or painted plasterboard tiles). Where there are absorbent cut edges on tiles they should not be exposed to the containment laboratory. They should be concealed by tee-bar flanges, such as escutcheon plates. If they are exposed to the laboratory, they should be sealed. A mild textured finish to ceilings is acceptable, provided the surface remains cleanable and the texture does not retain contamination when the surface is wiped with a cleaning cloth.

Where false ceilings are not employed, all exposed ceiling surfaces and exposed services must be cleanable. Where suspended ceilings do not fully cover the ceiling void, all surfaces and services beyond the vertical plane at the perimeter of the suspended ceiling are considered to be exposed. In general, a

planar ceiling (for tiled and untiled applications), without discontinuities, is desirable for cleaning purposes.

Internal fittings and fixtures, such as lights, air ducts and utility pipes should be selected and fitted to facilitate cleaning.

Plants may be held in growth cabinets or chambers within a microbiological approved arrangement site (laboratory). Plants must not be potted, cultivated, bred or raised in an open microbiology approved arrangement (laboratory) environment.

Animals cannot be held permanently in a BC2 microbiological approved arrangement. They may be temporarily accommodated for *in vivo* testing, but this must occur only for the duration of the test procedure. If animal accommodation or testing exceeds these limits, then the site must be approved for both microbiological and animal type classifications. In this case, all the mandatory conditions for an animal approved arrangement site must be met.

10.10 Animal BC2 construction

Consideration should be given to the animal species to be contained when determining the housing and caging facilities required. To prevent escape, it is preferable that animals are caged or housed in isolators within a BC2 approved arrangement site, wherever practical. Special measures may be needed where animals are skilled at escape from captivity. State legislation and codes of practice for the housing and welfare of animals should be referred to when determining appropriate animal accommodation.

For large animals, it is generally impractical to provide primary/secondary containment. Note that animal pens and open cages are not considered adequate to provide primary containment. The BC2 approved arrangement site commonly provides primary containment for large animals. Primary containment applications have additional conditions to address containment risks. For example, primary BC2 animal containment requires an anteroom.

10.11 Aquatic BC2 construction

Aquatic containment facilities commonly experience high humidity conditions and dampness. Surface finishes generally need to be impervious and resistant to deterioration from moisture.

Coved flooring may be used for tank bunding, provided it meets the retention volume requirements and has continuous sills at, or adjacent doorways, to contain liquid.

A method, or system must be in place to retain and if required decontaminate any spillage of fluid from a breakage, leakage, or overflow from a primary container. A range of fluid containment methods could be used, including:

a) approved arrangement site bunding, or
b) holding trays under storage containers, or
c) where incorporated an effluent decontamination system, or
d) a sump with an installed pump to remove the fluid

If the approved arrangement site has an effluent decontamination system (EDS) for retaining drainage from the site floors, and the floor is sloped sufficiently to retain the required volume within the approved arrangement site, then the EDS may be used as the secondary containment method.

Where floor wastes are not provided, consideration needs to be given to the volume of disinfectant used to decontaminate the retained spillage. Consideration may also need to be given to low level tundishes which may need to be protected, or sealed.

10.12 Plant BC2 construction

Any alternative cladding material (alternatives to glass, acrylic or polycarbonate sheeting) proposed for plant facilities will need impact resistance and resistance to deterioration from the elements, environmental and climatic events and attack by vermin and invertebrates. Glazing can be unreinforced glass of adequate thickness or reinforced glass such as wired or laminated glass.

The sealed outer door for plant BC2 approved arrangement sites refers to the outermost door of the plant containment site that is sealed to BC2 standard (see the conditions document for 'seals to BC2 standard').

Sticky traps for control and/or monitoring of insect pests should be located where they can be readily inspected.

When designing and constructing plant platforms, consideration needs to be given to the materials and frame sections used. The materials must be impermeable. In addition, voids that are impractical to clean, need to be eliminated. Where voids cannot be designed out of the platform, capping or sealing (for example, for metal tubing) will normally be required. An alternative design option is to ensure that any structural voids are accessible and cleanable (for example, by using channel or angle sections, as an alternative to hollow tubing).

To avoid cross contamination by water borne contaminants, platforms should not be placed directly above one another, unless the platforms are sealed and provided with catching trays.

10.13 Invertebrate BC2 construction

Invertebrates must be kept in primary containment devices unless specific departmental approval is obtained for primary containment of the invertebrates in the approved arrangement site. Primary containment applications for invertebrates are unlikely due to the need to have additional specific conditions in place. The department would require these additional specific conditions to be in place prior to approval of any BC2 approved arrangement site as primary containment for invertebrates.

Where practical, the colour of wall, ceiling and work surfaces should aid in the detection of escaped invertebrates.

Invertebrate applications require an acceptable method of preventing more than one anteroom door being opened at a time. Acceptable methods are:

a) interlocking doors
b) audible alarm system
c) indicator lights, or
d) viewing panels in doors (or equivalent, see Section 10.16).

Note: viewing panels are an acceptable control mechanism only where there is low personnel traffic (less than 5 transits per hour averaged over usage time) and where the sight lines allow personnel to readily view both anteroom doors and detect someone approaching a door from the opposite side.

An invertebrate approved arrangement site requires a full-length mirror so that personnel can examine themselves for any invertebrates attached to skin or clothing, just prior to exiting. Mirrors can be either located in the anteroom, or immediately prior to entering the anteroom before exiting the approved arrangement site.

10.14 Anterooms

Anterooms are required at BC2 level for:

a) plant approved arrangement sites
b) invertebrate approved arrangement sites, and
c) animal or aquatic approved arrangement sites that are primary containment (such as where animals are not housed in IVCs, filter cages, isolators, tanks).

For invertebrate, plant and aquatic approved arrangement sites, an invertebrate attractant and killing device is required in the anteroom.

An anteroom serving a BC2 area may not be used as a thoroughfare to non-controlled areas. It may be used for shared access to PC2 or other BC2 areas and, where approved by the department, to shared support facilities such as imaging or surgical facilities.

10.15 Self-closing doors

Access doors and anteroom (inner/outer) doors are required to be self-closing for the following BC2 situations:

a) a microbiological approved arrangement (laboratory) accommodating plants in growth cabinets or chambers
b) a microbiological approved arrangement (laboratory) used as an anteroom for a plant approved arrangement site, and
c) animal, aquatic, plant or invertebrate approved arrangement sites.

The maximum permissible closing time for self-closing doors for personnel access should be 10 seconds from the time of door release at 90^{o} opening. Self-closing doors used for animal or motorised plant (for example, forklift) access should have a maximum permissible closing time of 20 seconds from the time of door release at 90^{o} opening.

Note: these should be considered to be the outer time limits. Doors should close as quickly as practical for the application. Self-closers should not latch the doors open or automatically pause in the open position for longer than 5 seconds for personnel access doors or 10 seconds for doors used for animal or motorised plant access.

Where there is high traffic movement and the doors do not consistently close within the above time frames, a strip curtain, or air curtain should be installed at each self-closing door.

10.16 Access door viewing panels

Viewing panels, or equivalent, are required in access doors for animal, aquatic, plant and invertebrate approved arrangement sites. However, this requirement does not apply where approved arrangements sites need privacy or light control. The provision of viewing panels should allow personnel approaching a door to determine if someone is approaching from the opposite direction, or if another door to a common airlock is open. There are alternatives that can be equivalent to a viewing panel. These include:

a) full or partial door glazing
b) a viewing panel adjacent the door, or
c) a camera/display system.

Items (b) and (c) need to have suitable sight lines to provide equivalent performance to a door viewing panel.

10.17 Storage areas

An anteroom may be used for storage of clean and used/reusable clothing, footwear and PPE. Clean and used items must have segregated storage. Where the anteroom is used for storage of clean and used items, it is desirable to have a soft segregation of the anteroom into a clean zone encountered first on the entry path and a dirty zone encountered before entry to the BC2 room. This arrangement is illustrated in several of the options diagrams in Attachment B to this document.

Storage areas with screened ventilation openings are acceptable as fully enclosed storage areas. However, screening should be physically secure and to BC2 invertebrate screening requirements.

A biosecurity containment storage unit (for example, a lockable cabinet) may be within a BC2 approved arrangement site or within the building housing the BC2 approved arrangement site. Goods subject to biosecurity control must be stored in sealed packaging or containers.

Biosecurity treatment rooms are required to be within the same physical site as the BC2 approved arrangement site. However, the preference is to locate these rooms within the BC2 approved arrangement site or the building housing the BC2 approved arrangement site.

10.18 Clean rooms

In rare situations, a HEPA filtered clean room may need to be part of a BC2 microbiological approved arrangement site. If it is necessary to positively pressurise the clean room while maintaining air inflow to the BC2 approved arrangement site, an appropriately engineered system is required. Typically, the clean room can be sited internally in the BC2 approved arrangement site with buffer spaces around the clean room where an inflow is achieved.
Note: a clean room would not normally be required, or permitted, in animal, aquatic, plant or invertebrate approved arrangement sites.

The air inflow condition is intended to prevent airborne contaminants migrating from a BC2 approved arrangement site to non BC2 occupancies. Therefore adjacent buffer spaces may not be required around the clean room, where they are suitably constructed and sealed to prevent outflow across the boundary. For example they may not be required where the boundary separates the BC2 approved arrangement site from the building exterior, if the physical arrangement or construction prevents BC2 air from leaking into non BC2 interior spaces.

Note: if there is a false ceiling space above the clean room that is shared by BC2 and non BC2 occupancies, the following alternative approaches can be considered:

a) construct and seal the clean room enclosure so outflow across this ceiling boundary is prevented, or
b) create a separating buffer space in the false ceiling with a nett air inflow.

Note: the referenced buffer spaces are part of the BC2 approved arrangement site and are areas that effectively separate the positively pressurised BC2 clean room from non-BC2 interior spaces.

10.19 Vermin control

To prevent infestation by vermin, all gaps, cracks and holes in the BC2 infrastructure should be sealed.

Containment sites for animal, aquatic, plant and invertebrate types commonly attract vermin, so risk-based vermin control measures are required on access paths into the BC2 approved arrangement site. Risk-based measures should account for:

a) the exposure to vermin (for example, the location, adjacent environment, presence of vermin attractants such as food or waste facilities)

b) the vulnerability of the approved arrangement site to ingress by vermin (for example, barriers to ingress beyond the BC2 approved arrangement site, floor level), and
c) the likely vermin species (most prevalent species for the locale such as mice, rats, snakes, lizards, possums, bats, birds).

Vermin control measures that may be selectively applied include:

a) Rodent door jamb barriers (these should be at least 450mm high with the door opening inwards)
b) sticky mats
c) attractant traps
d) poison baits, and
e) repellent devices.

If a door jamb barrier is used, the trip hazard will need to be adequately addressed to avoid injury.

10.20 Drainage protection

Local authority and environmental regulations need to be considered when determining what material can be discharged to sewer and whether any form of pre-treatment (for example pH adjustment, cooling, straining) is required. From a biosecurity perspective, the important drainage considerations are:

a) drainage systems should have adequate integrity and be free from leakage
b) trapped drains (liquid sealed traps) need to remain permanently charged with liquid
c) drainage systems should be protected from blockage by removal of entrained solids and detritus, where present
d) material captured in strainers and traps should be conveniently removable and treatable by a department approved method (for example, steam sterilisation), preferably within the BC2 approved arrangement site. The need for reaching into deep cavities, scouring, scrubbing or special solids recovery equipment should be avoided, as far as practical
e) the capture mechanism for entrained material needs to be readily accessible for cleaning and suitable for decontamination using an approved disinfectant or heat treatment
f) where hypochlorite or sodium hydroxide treatment is applicable, waste liquid must be strained to remove particulates down to sub-millimetre level (a 100 micron aperture final strainer is required)
g) strainers, traps and other capture mechanisms should be designed for an acceptable service cycle and should not be prone to frequent blockage or overloading
h) arresting mechanisms, screens and traps need to be emptied and cleaned on a regular basis to prevent drains blocking or waste liquid overflowing onto floors.

For animal, plant and invertebrate BC2 approved arrangement sites, it should be assumed that floor and sink drains will need capture mechanisms for entrained solids and buoyant fibrous materials. The capture mechanism should be designed to prevent these materials blocking the drains. For other approved arrangement types, an application specific assessment should be undertaken to determine the need for, and function of, capture mechanisms.

If proprietary soil (silt) traps or other devices are adapted for biosecurity application, they need to be carefully selected to ensure they provide, or are adaptable to provide, the attributes listed above.

Strainer element apertures should be chosen to suit the application. An aperture size of 5mm is generally suitable, unless there are special application requirements (for example, for hypochlorite treatment) or local authority regulations, that require finer straining. Where fine aperture straining is necessary, it is desirable to have multiple strainers or screens of decreasing aperture in series and generous surface area for fine aperture screens. With fine aperture screens, the perimeter sealing must be reliable and effective so that fine particulates cannot bypass the screening. The width of perimeter gaps around fine mesh screen seals should not exceed the screen aperture size.

10.21 Ventilation

Some BC2 ventilation systems are not required to operate continuously. Where it is appropriate (for example, for a microbiology laboratory) a BC2 approved arrangement site ventilation system may be shut down when the containment area is unoccupied and goods subject to biosecurity control are suitably stored (to prevent controlled material being dispersed).

Note: the approved arrangement site ventilation system should not be shut down while there is ongoing processing or storage that may give rise to airborne fumes or contaminants in the approved arrangement site.

An inward airflow is required for approved arrangement sites of microbiological and animal type and not required for aquatic, plant and invertebrate types.
Note: that some facilities may have multiple type classifications. For example, a BC2 plant approved arrangement site that is primarily for research with laboratory functions, such as work on plant issues, tissue culture, crushing, microscopy would likely be classified as plant and microbiological type. In this circumstance, the approved arrangement site would require an inward airflow.

Access points to ventilation air filters or filter plenums should have signage informing maintenance personnel of any potential biohazard due to accumulated particulates. Where the accumulation of particulate material on ventilation filters is likely to have a significant component of goods subject to biosecurity or hazardous material or where there may be gross contamination of filters (for example, in primary animal containment applications), filtration should occur before air leaves the BC2 approved arrangement site.

The use of a false ceiling space (for example, above ceiling tiles) as an un-ducted ventilation air path should be avoided. This practice can give rise to long term build-up of contaminated dusts in the ceiling space. The dust will be disturbed if ceiling tiles are removed.

Locating heat transfer equipment such as air handlers, fan coil units, split air conditioner components, chilled beams, condensing units, within a BC2 approved arrangement site, is undesirable. These items are difficult to clean and undesirably increase the need for service personnel to access a BC2 approved arrangement site. However, the location of forced draft coolers within BC2 cool and cold rooms is an accepted practice, which ensures optimum functionality.
Note: air filters are required for finned HVAC heat exchangers (excluding forced draft coolers for cool/cold rooms) located within BC2 facilities. Forced draft coolers should have coarse fin spacing so that they can be flushed for cleaning and disinfection.

10.22 Fabric ducting

Permeable fabric ducting is permissible for BC2 air distribution applications. The entire surface of the fabric should be permeable, in order to inhibit dust or contaminants from settling on the fabric.
Note: this does not preclude nozzles in the ducting, provided there is sufficient flow through the fabric to inhibit dust settlement.

The fabric should be located wholly within the BC2 approved arrangement site and should be removable for cleaning or decontamination. If the ducting becomes soiled or is visually contaminated it should be washed or wiped down with a department approved disinfectant within the BC2 approved arrangement site, and re-erected, or decontaminated and washed outside the BC2 approved arrangement site, then returned and re-erected. The duct manufacturer should be consulted for applicable cleaning methods.

Before disposal, the ducting must be treated by a department approved method (for example, steam sterilisation or chemical decontamination and washing).

10.23 Screening for animal cage/bottle treatment areas

Note: this section (10.23) describes the provisions that apply where used animal cages/bottles are treated separately from their contents. If the container and contents are collectively treated by a department approved method (e.g. heat treatment), they are no longer goods subject to biosecurity control. This section outlines the constraints that apply where contents are decanted from used animal cages/bottles and the containers are separately washed.

A used cage/bottle knock out/decanting area must be within the BC2 approved arrangement site and must have 250-micron maximum aperture, invertebrate screening over ventilation and vent openings, including openable windows. Used bottles should have their contents decanted to sewer drainage. Used bedding may be bagged or binned in the decanting areas and transferred for treatment or disposal by a department approved method.

Any bedding transfer system (for example, a vacuum or gravity transfer duct to a waste receptacle) must fully screen the bedding material from access by vermin or invertebrates. Used bedding can be transferred via a sealed transfer duct and sealed connection to a receptacle bin or bag. Alternatively, the collecting bin or bag can be housed in an enclosure screened to 250-microns aperture (a sealed transfer duct would then run from a screened decanting room to a bin or bag in a screened waste enclosure).

A cage/bottle washing area may be located within the BC2 approved arrangement site, or in a separate room within the same building as the BC2 approved arrangement site. It is preferable that the cage/bottle washroom be within or directly connected to the BC2 approved arrangement site. The cage washing area requires screening over ventilation and vent openings for invertebrate control.

Cage and bottle washer exhaust ducts do not require screening, as these screens would quickly block. However, these exhausts will need to be fitted with an automated mechanism to close the exhaust duct to access by vermin or invertebrates, when the washer is not in use.

If the animal room provides primary containment, used cage/bottle treatment must be performed in separate room/s not accommodating animals.

There are no constraints on clean cage/clean bottle filling as the goods are not subject to biosecurity control. This process may be undertaken within a BC2 approved arrangement site or outside the approved arrangement site.

10.24 Siting of containment cabinets

The containment protection provided by cabinets can be adversely affected by poor siting. Strong air currents can disrupt the airflow with open fronted cabinets and significantly reduce protection, increasing biosecurity risk. It is therefore very important to avoid siting cabinets in thoroughfares, in line with a doorway, or close to an air supply diffuser.

The siting of cabinets should be considered prior to installation, with consideration given to the location of doors, windows, fume cupboards, other cabinets, other approved arrangement site furniture, or equipment that may generate draughts, ventilation grilles, and diffusers, or other air moving equipment. The siting process should involve an assessment of all environmental and working conditions, undertaken to identify any draught, or air circulations that may interfere with cabinet performance. A thorough assessment is necessary and needs to consider all aspects affecting cabinet performance.

10.25 Performance testing for containment cabinets

Containment cabinets include any BSC or cytotoxic cabinet that is part of the BC2 infrastructure. Also included is any fume cupboard that is part of the BC2 infrastructure and is used with material subject to

biosecurity control. Fume cupboards that are not used with material subject to biosecurity control are not included in this classification.

Performance testing for containment cabinets is required:

a) on site prior to initial use
b) after a significant mechanical or electrical repair
c) after relocation of the cabinet
d) after HEPA filter replacement, and
e) at least every 12 months.

The performance testing comprises (as applicable)

a) filter installation integrity (BSC Class I, II, cytotoxic)
b) inward air velocity (BSC Class I, fume cupboard)
c) air velocity and uniformity in works zone (BSC Class II and cytotoxic)
d) containment at the aperture (BSC Class II and cytotoxic)
e) work zone Integrity (BSC Class II and cytotoxic)
f) alarm system function (BSC Class I, II, cytotoxic, fume cupboard).

Inward air (face) velocity testing for Class I biosafety cabinets, fume cupboards, aperture containment testing for Class II biosafety cabinets, and cytotoxic cabinets, should be undertaken with the associated room air handler running to verify that room airflow does not disrupt airflow through the aperture or sash opening.

Containment cabinets should have current test certificates to confirm that the critical functions have been successfully tested within the previous 12-month period.
Notes:

1. a test certificate by a NATA accredited or otherwise competent operator will normally be accepted as evidence of the above testing.
2. retesting is required after a 'significant' mechanical or electrical repair. This would typically be a repair to any problem likely to disrupt the cabinet airflow.

Aerosol challenge methods such as Cold DOP or equivalent (for example, durasyn 164) are acceptable for on-site integrity testing of HEPA filter installations.

The testing of the integrity of air barriers (work zone integrity) may be alternatively determined by the KI Discus test (potassium iodide) method. Overseas made cabinets may need to be tested using the KI Discus test.

Measuring instrumentation for testing containment cabinets must be calibrated.

10.26 Fume cupboards

Fume cupboards are containment devices for chemical hazards, flammability hazards and, occasionally, radioactive hazards. Fume cupboards may be used for these hazards in a BC2 approved arrangement site. Fume cupboards may be exhausted to atmosphere or recirculating type, as suited to the application.

Normally fume cupboards should not be used for handling microorganisms or other material subject to biosecurity control. Biological safety cabinets are the appropriate protection for biohazards. However, in rare cases where biosecurity goods are accompanied by corrosive, flammable, toxic or radioactive products, it may be necessary to use a fume cupboard in lieu of a biological safety cabinet. Before using a fume cupboard for a biosecurity application, consider whether the associated corrosive, toxic, flammability or radioactive risk can be handled by a conventional or special purpose biological safety cabinet. For example, it may be practical to use a class 1 biological safety cabinet with an additional

adsorbent filter or with a discharge to atmosphere via a capture hood, if non-biological contaminants such as solvent vapours are present at very low concentrations.
Note: the BC2 conditions for fume cupboards only apply to fume cupboards used for handling goods subject to biosecurity control. They do not apply to fume cupboards that are part of the BC2 infrastructure but are not used for handling goods subject to biosecurity control. However, for applications requiring invertebrate containment, all fume cupboards must have invertebrate screening, regardless of usage.

Where a fume cupboard is used for handling goods subject to biosecurity control in a BC2 approved arrangement site, the fume cupboard exhaust must discharge to atmosphere and be fitted with an effective scrubber for attenuating contaminants subject to biosecurity control. Normally the fume cupboard manufacturer's standard scrubber unit will be acceptable.

10.27 Decontamination of containment cabinets

Containment cabinets used with goods subject to biosecurity control require decontamination before annual recertification, filter change, maintenance work or relocation. Suitable decontamination methods are as follows:

a) a biological safety cabinet or cytotoxic cabinet requires gaseous decontamination
b) a cabinet used with cytotoxic material requires an initial treatment to deactivate/remove cytotoxic material before gaseous decontamination
c) a fume cupboard requires work zone cleaning and disinfection with a department approved disinfectant or, alternatively, gaseous decontamination
d) a fume cupboard scrubber should be decontaminated by circulating a department approved disinfectant solution for the chemical manufacturers contact period.

Note: gaseous decontamination is an acceptable method to decontaminate a fume cupboard. However, it may be difficult to seal the fume cupboard chamber adequately for safe decontamination.

Where a cabinet decontamination must be repeated due to inadequate efficacy, the decontamination technique should be carefully assessed to help determine the reason for failure. For example, check that the correct amount of chemical was used and that it was not reduced by leakage from the cabinet or sealing membranes during the decontamination process.

10.28 Service reticulation

Reduced pressure zone backflow prevention devices (RPZD) for water services should be located outside the BC2 containment boundary for ease of inspection by maintenance personnel.

Disposal systems (for example, pipes, tanks and pumps) that are resistant to damage from reticulated wastewater include:

a) polyvinyl chloride polymer (PVC) or high-density polyethylene (HDPE) for pipes, and
b) fibreglass reinforced plastic for tank construction.

11 Risk and incident management

11.1 Health testing of rodents

Imported animals need an initial health check and/or general examination within 24 hours of arrival at an approved arrangement site. Imported rodents will be directed to BC2 or higher rated animal containment approved arrangement sites, and generally be tested for infection or contamination by organisms (for example, Hanta virus) that are a biosecurity risk. Normally, cleared rodents will be released from biosecurity control, unless they are exposed to goods subject to biosecurity control for research or testing purposes. The specific requirements will be specified in rodent Import Permits.

11.2 Suspected or established presence of pest or disease

The biosecurity industry participant needs to be vigilant for disease or pests in or on imported goods subject to biosecurity control. Typically, these circumstances may involve a viral, bacterial or fungal infection, parasitic disease or mite infestation.

The biosecurity industry participant is required to notify the department if the circumstances suggest that the biosecurity goods have an infection or contamination by an organism that is a biosecurity risk. The indicators for this may be arrested growth, physical deterioration, sickness or death that is unexpected or unexplained. Results from testing or post-mortem examination may also lead to this conclusion.

Where an exotic pest or disease (not an approved import) is identified within the confines of an approved arrangement site, the department will assist in developing and establishing a pest or disease management plan to be used by the biosecurity industry participant to control and or eradicate the outbreak.

11.3 Immediate reporting to the department

Immediate reporting means on the same day or on the next business day when an incident occurs outside of normal business hours (Monday – Friday, 9.00am – 5.00pm). Reportable incidents typically include major spillage, presence of pest or disease, biosecurity consignment not received, an animal unexpectedly dying or needing to be euthanized or testing/post-mortem results raising biosecurity issues.

Contact with the department should be made by either phone or email. Contact details for the department can be found on the department's website, awe.gov.au.
Note: an unexpected animal death does not include animals that are euthanized as part of a research program or the normal mortality rate in a large cohort of animals or organisms. Mortality rates can vary with species, however, biosecurity industry participants should be aware of what these rates generally are for the species being held, and subject to biosecurity control. Where mortality rates fall outside the generally expected rate for the species, or there is an unexpected death, an investigation should occur and the department notified.

11.4 Animal escape or entry

Contingency plans to prevent animal escape during handling should be in place. Specialised equipment such as a tranquiliser gun or restraint may be required. Special precautions may be needed to prevent the escape of small invertebrates, particularly flying and other highly mobile invertebrates.

11.5 Invertebrate vegetation suppression programs

An invertebrate approved arrangement site that has direct external access via its anteroom must have an effective vegetation suppression program in place. The program must ensure that open areas within 30 metres of the approved arrangement site are managed in a way that effectively isolates organisms subject to biosecurity control from environments in which their establishment could occur. The biosecurity industry participant should develop a document outlining the control measures, and have it available to the department for audit purposes. This document would include:

a) the use of weedicides, fumigation
b) periodic inspection and
c) if applicable, contract details.

An effective vegetation suppression program would require the eradication of vegetation which could potentially be host to the insects being held within the site. Where an approved arrangement site is

within 30 metres of a property boundary, the department may require additional measures to be implemented such as outdoor monitoring.

12 Management/work practices

12.1 Identification of goods

A system should be in place to ensure that staff who have access to goods subject to biosecurity control are aware of the methods and process used to identify those goods, giving these staff the ability to differentiate between goods subject to biosecurity control and those not subject to biosecurity control.

Methods to establish and maintain an up-to-date system to accurately identify all goods subject to biosecurity control can vary with the type of goods. The size of containers and/or the type of goods should also be considered when developing an appropriate identification system. Labelling may not be possible. Such constraints will require an alternative identification system to be implemented. Methods that can be used to identify, goods subject to biosecurity control include:

a) labelling goods in containers (also designating the volume of material)
b) providing a unique goods identifier such as barcoding or similar with reference to a logbook, database or other suitable reference system
c) growing a certain species of plants in designated and identified greenhouses
d) labelling individual plant pots or containers in storage
e) growing plants in designated and clearly delineated areas or enclosures
f) identifying animals by tattooing, microchip, ear tags, permanent branding or labels on cages/rooms of individually contained animals.

Labelling may need to be waterproof or resistant to cold temperatures (for cold storage) to ensure the identification of goods subject to biosecurity control is maintained.

Where possible goods need to be labelled in a manner that identifies them as being subject to biosecurity control. However, labelling can include any system which enables traceability of the goods subject to biosecurity.

12.2 Segregation of goods

Segregation of goods is an important practice for maintaining biosecurity control and for limiting cross contamination in approved arrangement sites. Clean clothing, equipment and PPE must be segregated from used or reusable items. Contaminated and non-contaminated goods and wastes must be segregated. Waste is also commonly segregated (for example, into liquid and solid waste) for treatment purposes.

It is desirable, where practical, to keep clean goods in sealed containers before usage and to ensure that contaminated goods are stored in primary containment or sealed containers when not under examination, or otherwise in use.

In general, a containment cabinet or other primary containment approved arrangement site or equipment must not be used simultaneously with goods subject to biosecurity control and goods not subject to biosecurity control, unless the relevant goods not subject to biosecurity control are subsequently treated as goods subject to biosecurity control. However, this requirement does not apply to a BC2 microbiology approved arrangement site (laboratory) were goods subject to biosecurity control may be segregated using dedicated work areas, provided this method is effective for segregation. Note, however, that the desirable practice is for all goods subject to biosecurity control goods in a BC2 microbiology approved arrangement site (laboratory) to be processed within a class I or class II biosafety cabinet or other primary containment. Processing goods subject to biosecurity on an

exposed bench is acceptable only where there is very low risk of any material subject to biosecurity control being dispersed beyond the work area.

12.3 Segregation of invertebrates of the same species

There are particular risks where goods subject to biosecurity control are held in proximity to domestic invertebrates of the same species. This situation increases the risk of cross contamination or cross breeding between invertebrate colonies. In addition, if an invertebrate is found outside the approved arrangement site, it can be difficult to identify which colony the invertebrate has escaped from.

A BC2 approved arrangement site for invertebrates subject to biosecurity control cannot be located in a building accommodating domestic invertebrates of the same species unless:

a) the domestic invertebrates are treated as the same (or higher level) of goods subject to biosecurity control, or
b) the department has assessed the segregating arrangement and provided its written approval.

Before approving such an arrangement, the department will need to be satisfied that the relevant invertebrate colonies have adequate physical separation and suitable segregating procedures/protocols can be implemented and maintained. In addition, there would need to be measures in place to separately attract and capture escapees from each invertebrate colony. These measures would need to assure the department that the origin of any escaped invertebrate would be readily identifiable.

12.4 Cleaning

It is desirable to keep an approved arrangement site as clean as practical, in order to control contaminant dispersion. The practical standard of cleanliness will depend on the application. However, there should be routine cleaning and immediate clean-up of any accidental or gross contamination.

Cleaning methods should confine material and minimise contaminant dispersion and dust creation. Floor cleaning methods specified for microbiological approved arrangement sites (wet mopping, dry mopping with a dust retaining mop, or vacuuming with HEPA filtered vacuum cleaner) are commonly suitable for facilities where goods are confined in isolators, ventilated cages and tanks. Hosing out floors should be avoided, where feasible, as this cleaning method will disperse contaminants unless it is carefully applied to suitable primary containment sites (those with suitable drainage and floor bunding).

12.5 Removal of goods subject to biosecurity control from containment

In general, goods subject to biosecurity control must be handled within the approved arrangement site. However, there are circumstances where goods can be temporarily or permanently removed for relocation, release, treatment or processing. For example:

a) goods (excluding rodents not cleared) can be transported to a co-located BC2 approved arrangement site (with applicable type classification) without specific departmental approval
b) microbiological, animal, aquatic, plant and invertebrate goods may be approved for transport to a non co-located BC2 approved arrangement site with the department's written approval
c) goods can be removed for treatment (inactivation, disposal or destruction) by a department approved method
d) goods can be removed on expiry of a temporary biosecurity control period
e) goods can be temporarily removed under controlled conditions for specialised processing or examination using specialised equipment. The period of removal should not exceed that necessary for processing or examination. A limit of 8 hours applies for examining or processing a biosecurity good other than an animal. A maximum limit of 72 hours applies for long duration processing such as a surgical procedure on an animal and recovery for transport.

Typical circumstances in which goods may be removed temporarily under item (e) above, include:

a) goods (such as microscopic slides or samples) may be removed for examination by specialised microscopy equipment such as an electron microscope
b) goods (such as animals) may be temporarily removed for specialised examination such as computed tomography (CT) scans, magnetic resonance imaging (MRI)
c) Goods (such as animals) may be removed to a specialised facility for processing such as a surgical procedure and post-operative recovery.

Note: rodents cannot be removed from their initial containment until cleared by initial health checks for agents having a biosecurity risk (for example, for Hanta virus).

Suitable controls must be in place to minimise risks to biosecurity control when undertaking procedures or processing goods outside the BC2 approved arrangement site. Ideally, the goods should be in primary containment when examined outside the approved arrangement site. Where this is not practical, it is necessary to institute other control measures. For example:

a) a biosecurity sample should be fixed or mounted so that it will not be dispersed during examination. The exposure time outside primary containment needs to be minimised. Surfaces contacted by the sample should be decontaminated after processing
b) an animal may be caged for transfer to a CT or MRI scanning facility. It will be necessary to keep the animal segregated from animals not subject to biosecurity control and ensure that the animal cannot escape. It will be necessary to restrain, sedate or anaesthetise the animal when it is released from the cage for imaging. In addition, surfaces exposed to the animal will require decontamination after imaging using an approved disinfectant.
c) goods subject to biosecurity control should have appropriate supervision and tracking when they are outside the approved arrangement site. Personnel handling the goods should be aware of their biosecurity status and the constraints that need to be imposed.
d) for a surgical, or similar, procedure the animal should be sedated or anesthetised before removal from caging and restrained, as necessary. After surgery, the animal should be monitored and returned to its cage or primary containment as soon as practical. The surgical site should be decontaminated and surgical waste treated as biosecurity waste.

If biosecurity industry participants encounter applications other than the above and are unsure if procedures or measures are equivalent to the above, they should contact the department for advice.

12.6 Deactivation of cytotoxic contamination

The recommended procedure for the deactivation of cytotoxic contamination, prior to gaseous decontamination of a cytotoxic cabinet, is as follows. (The procedure assumes that the cabinet has been exposed to both cytotoxic and goods subject to biosecurity control):

a) ensure the cytotoxic cabinet is operating
b) working from top to bottom inactivate cytotoxic surface contamination using a suitable inactivating solution (If there is no particular inactivation solution for the cytotoxic contamination, use a hot solution of 1:20, by volume, alkaline detergent followed by sterile water)
c) lift the air intake grille, place it on the cabinet work floor and inactivate both sides
d) remove the intake grille from the cabinet to a suitable sink or drain tray. Swab both sides of the intake grille with disinfectant and drain
e) deactivate and dry the surfaces of the work floor and any attached supports (avoid wetting the HEPA filter during this or any subsequent stage)
f) remove the work floor from the cabinet to a suitable sink or drain tray. Swab all surfaces with disinfectant and drain
g) repeat I and (f) above for any separate work floor supports

h) if liquid has collected in the sump, absorb it with cloths and pads. Deactivate the sump and wipe dry
i) rinse and dry components removed from the cabinet and reassemble into the cabinet in reverse order to disassembly
j) swab the sink or drain tray with disinfectant, rinse off and run waste liquid to sewer
k) bag all deactivation/cleaning waste
l) decontaminate the cleaning waste by saturation with disinfectant or another department approved method
m) if the waste may contain viable cytotoxic material, it must be disposed of as cytotoxic waste.

Following the above procedure, de-energise the cabinet, seal up and decontaminate the cabinet by gaseous decontamination. Use a department approved disinfectant for all disinfection stages listed above.

12.7 Sealing and safe removal of cytotoxic contaminated sump filter

The recommended procedure for sealing and safe removal of a contaminated sump HEPA filter from a cytotoxic cabinet is as follows. (The procedure assumes that the cabinet has been exposed to cytotoxic and goods are subject to biosecurity control):

a) deactivate the cabinet cytotoxic contamination and fumigate the cabinet in accordance with the procedure in the foregoing clause (the intake grille, work floor and supports should remain disassembled from the cabinet during the gaseous decontamination procedure)
b) energise the cytotoxic cabinet
c) remove and bag the prefilter as cytotoxic waste (after gaseous decontamination, the filters no longer require handling or treatment as biosecurity waste)
d) clean the return lip of the sump
e) apply a foundation bead of sealant around the inside of the sump HEPA filter
f) spray the sump HEPA filter with a spray-on adhesive to trap hazardous material on the filter
g) turn off the cytotoxic cabinet
h) fit a specially made sealing plate of suitable, impervious material over the filter face
i) seal the edges of the sealing plate in such a way that all contaminated surfaces of the gasket and filter casing are effectively covered and allow the sealant to cure
j) remove the sump HEPA filter from the cabinet
k) seal the filter in a suitable plastic bag
l) place the bagged prefilter, HEPA filter and cleaning waste in a carton and seal again in plastic
m) label the carton ‘Caution: Cytotoxic Waste – Dispose by High Temperature Incineration Only’.

12.8 Growth conditions for plant release

It is important that plants grown for release from biosecurity control, have growth conditions that will apply natural climatic stresses. Natural climatic stresses for plants include environmental factors such as heat and cold. Growth of plants in artificial conditions, without natural stresses, may inhibit disease expression. Plants grown in glasshouses will normally experience natural climatic stresses. Where plants are grown in more controlled conditions, in growth chambers or cabinets, the programmed conditions must simulate natural growth or growth in a glasshouse with plants exposed to natural climatic stresses. If the conditions are not specified by the department, suitable programmed growth conditions should be developed and documented by the biosecurity industry participant.

12.9 Release of preserved plant material from biosecurity control

Plant material visually free of pest contamination or disease symptoms may be preserved by a department approved method that will enable release from biosecurity control.

12.10 Plant potting

There are no constraints on the preparation of plant pots using pots and potting media (soil, potting mix) that are not subject to biosecurity control (including goods that have been rendered goods not subject to biosecurity control following approved biosecurity treatment such as steam sterilisation).
Imported plants subject to biosecurity control may be initially potted in pots prepared from non-controlled goods in a dedicated potting area that is separate from the BC2 approved arrangement site (but within the same physical site as the approved arrangement site). However, this area cannot be used for re-potting plants transferred from the BC2 approved arrangement site. It cannot be used for potting with used pots or potting media from the BC2 approved arrangement site, unless they are treated by a department approved method before reuse.

Where pots, or potting media from a BC2 approved arrangement site are reused without prior biosecurity treatment, or where plants subject to biosecurity control are re-potted, the potting must be undertaken:

a) within a growth chamber in a BC2 approved arrangement site
b) in a plant BC2 approved arrangement site
c) in the head house forming an anteroom to a plant BC2 approved arrangement site, or
d) in a Class I or Class ll biological safety cabinet in a BC2 approved arrangement site.

Note: it is not acceptable to undertake potting up within a small anteroom which is part of a plant BC2 approved arrangement site, for reasons of contamination control. However, where the anteroom is a generously sized head house, potting up within the head house is acceptable. In this situation, the anteroom/head house should be zoned into a clean and dirty zone and the potting area located in the dirty zone to minimise the likelihood of clean items such as clothing, PPE being contaminated by the potting operations (See Attachment B).

12.11 Aquatic practices

To enable efficiencies, biosecurity industry participants may have tanks of marine fish containing different species from the same consignment. However, tanks and consignments of freshwater fish must contain only a single species.

Approval of requests for ongoing prophylactic or therapeutic treatment(s) will be considered by the department on a case-by-case basis. The assessment is needed to ensure that potential disease agents are not inadvertently masked. Biosecurity industry participants should be aware that approval of prophylactic or therapeutic treatments may also result in an extension to the biosecurity control period.

12.12 Maintenance activities

Maintenance activities for an approved arrangement site should be monitored and controlled to ensure that containment protocols are not breached. Maintenance personnel who are not specifically trained for support of biosecurity containment infrastructure should be accompanied by trained biosecurity personnel to monitor maintenance activity.

13 Approved arrangement site personnel

13.1 Contamination control

Smoking, shaving and the application of cosmetics are prohibited in an approved arrangement site.
Eating and drinking are normally prohibited in an approved arrangement site. However, eating and drinking within large-scale facilities may be accepted where:

a) it is essential for acceptable operational efficiency and staff amenity, and
b) infrastructure and systems to fully segregate these activities from goods subject to biosecurity control and adequately control biosecurity risks are in place.

A hands-free decontamination station should include:

a) a basin with hands-free taps and hands-free dispenser for hand wash liquid or soap, or
b) a hands-free dispenser fitted, where applicable with department approved hand sanitiser (a volatile antiseptic solution or gel).

Note: hands-free taps require a convenient foot, elbow or sensor operating mechanism. If they use levers for elbow operation, the levers should be the typical length of surgeon's taps. Short levers that are inconvenient to operate with elbows do not qualify as hands-free.

Acceptable hand wash liquids include chlorhexidine and ethanol-based cleansers. Refer to listing on the department's website at: awe.gov.au.

Used paper towels from drying hands after decontamination maybe disposed of as general domestic (non-controlled) waste.

Where there are service or plant spaces above or adjacent equipment (for example, condensing units above a cool room/freezer) the biosecurity industry participant will need to ensure the regular cleaning of such spaces. It is preferable for plant items to be located outside the BC2 approved arrangement site, where practical.

13.2 Footbaths and disinfectant mats

Footbaths and disinfectant mats cannot assure a complete decontamination of footwear. However, testing has shown that they can achieve a significant reduction in the biological contamination carried on footwear, if they are correctly applied and maintained. The important factors are:

a) adhering dirt, debris, organic material, should be cleaned off footwear, before immersion in the disinfectant bath, or stepping on the mat
b) the disinfectant type and concentration should be carefully selected to maximise efficacy (the disinfectant action must be strong to compensate for what is a relatively short contact time)
c) the soles of footwear should be properly immersed and scoured over the sponge, mat or fingers in the base of a disinfectant bath
d) the disinfectant contact time be as per manufacturer's recommendations
e) the disinfectant mat, or bath and components should be regularly cleaned and the disinfectant replenished before the system loses efficacy.

As the procedure for foot bath usage is an important determinant of its efficacy, it is important to have usage instruction prominently displayed adjacent to the footbath. A typical usage instruction would be as follows:

a) use the [stiff brush or other device] to remove adhering material from footwear
b) step into the disinfectant bath and immerse the whole tread of footwear
c) scour footwear on the [mat or rubber fingers] within the bath to ensure effective contact
d) Maintain disinfectant contact for at least [the contact time] before stepping out of the bath.

The contact time for disinfection should be determined by objective criteria such as published test literature, or the disinfectant manufacturer's recommendation.

The rate of contamination of the footbath/mat and disinfectant solution needs to be considered. Changing frequency will depend on usage and levels of contamination. Disinfectant manufacturer's test strips can be used to measure solution strength in footbaths (and in other decontamination equipment such as dunk tanks).

It's important that footwear be as clean as practical before immersion in disinfectant. A stiff brush or specially designed boot scrubber maybe necessary for cleaning footwear. To reduce footbath contamination, a separate bath using a water/detergent solution, next to the footbath, may be used. If trolleys are used, the length of footbath should be sufficient to ensure that the entire rolling surface of the wheel or tire is decontaminated.

Disinfection mats or sponges need to be cleaned on a regular basis. If the mat is heavily contaminated, footwear may not be effectively disinfected. For example, leaf litter on the mat surface can impede disinfectant contact with a shoe sole. In addition, the power of the disinfectant decreases, when it contacts organic material. The desirable frequency of mat cleaning depends on the situation. Cleaning may be necessary multiple times each week.

Tacky, or sticky type mats are generally not as effective for contamination control with variable efficacy. These type of mats could be a useful adjunct to other foot decontamination methods but should not be considered to be an effective biosecurity control prevention method.

There are a variety of automated or semi-automated footwear decontaminations systems that employ disinfectant sprays and other cleaning/decontamination mechanisms. These can be substituted for footbaths or disinfectant mats where the biosecurity industry participant can demonstrate that their efficacy is equivalent to, or superior to, conventional immersion systems. These systems should be applied and maintained in accordance with the manufacturer's instructions.

13.3 Managing cross contamination

Cross contamination management measures are important for biosecurity control. The management regime should include prevention measures and contingency plans should cross contamination occur. Cross contamination issues may arise, for example, with animal accommodation, shared equipment, shared instrumentation, handling, transport, feeding.

Animals not of equivalent biosecurity or health status should not be intermingled or exposed to each other. Storage and animal accommodation may need to be cleaned and decontaminated before restocking with biosecurity goods of differing consignments or status.

Note: the class of biological safety cabinet can affect the level of protection from cross contamination. A class I biological safety cabinet provides no protection to the product, and its working chamber is therefore more exposed to cross contamination, than the chamber of a class II or class III biological safety cabinet.

14 Transport of goods subject to biosecurity control

14.1 Movement of goods

The transportation of goods subject to biosecurity control may be between an approved arrangement site and another approved arrangement site (not of the same entity), between approved arrangement sites of the same entity or between an approved arrangement site, and a storage/support unit.

The biosecurity industry participant may manage the following movement of goods subject to biosecurity control (excluding rodents) without reference to the department:

a) movement between a BC2 approved arrangement site and BC2 storage
b) movement from a BC2 approved arrangement site or BC2 storage, for up to 72 hours, to a support area (such as for surgical procedures, veterinary treatment, scanning/imaging)

c) movement of microbiological goods such as samples and swabs between co-located BC2 microbiological approved arrangement sites (laboratories)
d) movement of oocytes between co-located aquatic and microbiological approved arrangement sites of the same, lower (5.1.1/5.1.2), or higher containment level, and
e) movement between co-located BC2 approved arrangement sites of the same type (animal, aquatic, plant or invertebrate).

Department approval is required prior to the movement of all goods subject to biosecurity control (includes live animals, live aquatic organisms, live plants, or live invertebrates, and all goods classed microbiological) to a non-co-located approved arrangement site. Approval may be obtained via an Import Permit, or transfer permit/direction. The biosecurity industry participants will need to maintain movement records for auditing by the department. The records may be a phone log, file notes, logbook notes, electronic data entry, formal record document or other approved format.

Except for items (b and d) in the above listing, the biosecurity industry participant must ensure that:

a) goods subject to biosecurity control are not moved to a lower containment level than indicated on the Import Permit, and
b) the receiving site is the same approved arrangement type as the sending site.

For any transportation of biosecurity goods, consideration needs to be given to the likely exposure of goods to physical damage and these risks need to be addressed.

Note: C64 containers (referenced in the mandatory conditions) are rigid lockable containers which are transported in enclosed trucks within a mobile, rubber sealed and plastic walled cupboard, titled a 'transporter'.

14.2 Movement of live animals

Live animals are a challenging class of goods to transport as they cannot be sealed in containers like most other goods subject to biosecurity control. In addition, they may require food, water and bedding for longer journeys. The primary objective, in transporting animals, is to prevent animals escaping and avoid any direct or indirect physical contact of animal(s) subject to biosecurity control with animal(s) not subject to biosecurity control. Indirect physical contact occurs when an animal not subject to biosecurity control is exposed to contamination from an animal subject to biosecurity control by an indirect mode such as:

a) exposure to untreated surfaces that have been in contact with, or in proximity to, the animal subject to biosecurity control
b) exposure to equipment, instruments, surgical item that have not been suitably decontaminated after use with the controlled animal
c) exposure to waste products or body fluids from the controlled animal
d) Ingestion of food or water also used by the controlled animal.

Ideally, animals should be transported in suitable, secure primary containment devices. Typically, these might be isolators, IVCs, secured filter cages, boxes with ventilation opening covered with fine mesh, fabric or filter media, tanks. It will be more practical to transport larger animals in conventional cages or other restraints that are secure but not effective primary containment. This is permissible at BC2 level. However, animals subject to biosecurity control need to be kept segregated from animals not subject to biosecurity control or animals of different biosecurity status such as different cohort. Therefore, if animals are not in effective primary containment, their transport vessel must fully enclose the animal and not be shared with animals not subject to biosecurity control or animals of a different biosecurity cohort.

Containers, food, water and bedding exposed to transported animals and any animal waste will need to be treated as goods subject to biosecurity control. Where animals are outside the approved arrangement site and not held in suitable primary containment, surfaces that may be contaminated by contact or proximity to the animals, must be cleaned and decontaminated with a department approved disinfectant after holding, transport, procedures. For example, it will be necessary to clean and decontaminate the transport vessel at the destination point if animals are transported in unsealed cages or equivalent restraints.

14.3 Movement of live invertebrates

Suitable precautions to prevent escape need to be taken when transporting live invertebrates, subject to biosecurity control particularly small flying invertebrates such as mosquitos. These invertebrates can escape from small openings in caging or packaging and their escape can be difficult to detect. When invertebrates are transported outside a BC2 approved arrangement site, they are required to be in suitable primary and secondary containment, even for short journeys within an approved arrangement.

14.4 Movement to non co-located approved arrangement site

A record of acceptance will be needed, confirming that the non co-located receiving site is willing to accept the consignment and has received it intact. The record may be a phone log, file note, logbook note, electronic data entry, formal record document or other, approved format.

14.5 Movement to co-located approved arrangement site

Movement to co-located sites includes walking the goods subject to biosecurity between sites.

14.6 Transport regulations

The transport of goods subject to biosecurity is covered by a range of regulations relating to movement by air, rail and road. Different packaging and transport arrangements apply depending on whether the materials are infectious substances, biological products or exempt substances (for example, plants).

Documents such as Australian Standards AS 4834 *Packaging for surface transport of biological material* and AS/NZS 2243.3 2010, Section 13 will need to be consulted if biological material is being transported.

Note that for Category B (infectious substances) and C biological material (low probability of causing disease), AS 4834 requires:

a) good quality, strong packaging to resist shocks and transport loadings and prevent loss of contents
b) Three component packaging (leak proof primary receptacle, leak proof secondary packaging and a solid, strong, durable and securely closed outer container)
c) absorbent material in secondary packaging for liquids (sufficient to absorb the contents of the primary receptacle)
d) for multiple primary receptacles, individual wrapping and separation to prevent contact, or, securing together
e) durable and legible marking (including consignor and consignee contact name, organisation, address and emergency telephone numbers)
f) documentation (transporter documentation must be accessible without opening the package).

The following forms of packaging are not permitted:

a) a liquid nitrogen dry shipper must not be used as secondary packaging
b) an unsupported polystyrene container (for example, esky) must not be used as outer packaging.

Note: packaging for air cargo transport must comply with International Air Transportation Association (IATA) requirements. These requirements are similar to the above. However, they include additional requirements such as:

a) outer package volume/weight limits (4 litres for liquids, 4 kg for solids)
b) primary receptacle pressure/temperature rating for liquids (95 kPa in range -40ºC to + 55ºC)
c) sift proof primary receptacle and secondary packaging requirements for solid substances
d) packaging to withstand a 1.2 metre drop test with no leakage
e) special marking (for example, "Biological Substance, Category B", diamond symbol with UN substance code, shipper's details, consignee details, incident reporting details, damage/leakage inspection requirements).

The requirements for air transport on passenger aircraft are more restrictive and include volume/weight limits of 50 mL/50 gm. Refer to International Civil Aviation Organisation (ICAO) requirements.

Publications such as the Australia Post *Dangerous and Prohibited Goods Packaging Guide* will need to be consulted for postal delivery.

Note: the listings above are simplified, informative only, summaries of surface and air transport requirements for BC2 biological material. The applicable source documents should be consulted for the detailed requirements applicable to each consignment. It is the responsibility of the sender to ensure compliance with all packaging and/or transport regulations not specifically detailed in department conditions or Import Permits.

15 Biosecurity treatments

15.1 General

Processes for inactivation, disposal (including destruction) or decontamination of goods subject to biosecurity control (including waste) are referred to as biosecurity treatments or biosecurity control treatments. The biosecurity control treatment that may be used will be largely determined by the item being treated (for example, whether it is a good or waste material, solid or liquid, of microbiological, animal, aquatic, plant, invertebrate type, an equipment item or a surface).

Examples of inactivation methods include approved heat treatments such as dry and moist heat sterilisation and gamma irradiation. A large range of goods and waste material may be inactivated by these methods. Moist heat sterilisation in a pressure steam steriliser is a particularly common and reliable method of inactivation. Refer to Section 17 of this document for the department's conditions for dry and moist heat sterilisation. The generic irradiation rate for inactivation of animal/microbiological goods is 50 kGy. Import permits may specify other rates for particular goods.

Examples of disposal/destruction include deep burial at a department approved location, high temperature incineration (to irreducible ash) at an incineration site approved by the department and alkaline hydrolysis. For BC2 effluent (excluding, for example, imported water or larvae contaminated water which requires hypochlorite treatment), disposal to a town sewer is an approved disposal method.

Examples of decontamination include gaseous decontamination and disinfection using a department approved disinfectant (refer to the department's website at awe.gov.au. Surfaces and equipment (including filters) and some porous materials (including cleaning cloths) may be treated by approved decontamination methods. Gaseous decontamination is a common decontamination method applicable to containment cabinets and air filters.

The biosecurity industry participants will need to ensure the treatment method used, is applicable and effective for the item being treated. Import Permit conditions may specify specific treatment or disposal requirements.

Examples of targeted treatments include:

a) disposing of specialised equipment (for example, broken glassware, syringe needles, biological substances) in containers designated for that particular type of waste, which may then be decontaminated off site
b) decontaminating equipment (for example, drenching or injecting guns, pruning tools) using an approved disinfectant and washing
c) pressure steam sterilisation or deep burial disposal of detritus and/or animal/plant refuse contained in soil traps or aquatic animal systems (freshwater and marine) such as traps/skimmers
d) disposal to sewer of backwash water from aquatic filtration systems (with pre-treatment by hypochlorite for imported or potentially larvae contaminated water).

Waste may be decontaminated in another part of the approved arrangement where there are suitable procedures for its secure transport and disposal. In addition, safety equipment and spill kits (to be used in cases of waste spillage) should be maintained at the waste storage and/or collection point.

Where a remote, pressure steam steriliser is used for BC2 decontamination, it should be located as close to the BC2 approved arrangement site as practical.

15.2 Validation using indicators

Biological indicators are commonly used for validation of biosecurity control treatments and routine process verification. They are suitable for use in dry and moist steriliser cycles, gaseous decontamination and some other methods of decontamination.

Process	Indicator Species	Incubation Temperature
Steam under pressure	*Geobacillus stearothermophilus*	56 °C Rapid enzyme BI (60°C)
Sub-atmospheric steam	*Geobacillus stearothermophilus*	56 °C
Gaseous decontamination	*Geobacillus stearothermophilus*	56 °C
Dry heat	*Bacillus atrophaeus*	37 °C

Common biological indicators are detailed above. The biological indicator is incubated at the required temperature after exposure to the decontamination process. The efficacy of the process is assessed by determining if the indicator microorganism is sufficiently viable to grow in a culture medium.

Where suitable for the control treatment, bacterial enzyme or chemical indicators may be used as an alternative to biological indicators. These indicators need to be used and assessed in accordance with the manufacturer's instructions.

15.3 Process failure

A control treatment must be repeated, if any embedded treatment indicator fails to validate the process (for example, a gaseous decontamination). In this event, the biosecurity industry participants should assess the treatment process and determine the likely reason or reasons for the failure. For example, check (as applicable) the cleaning/pre-treatment, temperature profile, amount/ activity of chemical used, loading, confinement, environmental conditions. Check that the correct indicator is used.

15.4 Disposal after treatment

After appropriate and successful biosecurity treatments, goods or waste no longer require biosecurity control. Suitably treated waste may be disposed of as general waste.

16 Gaseous decontamination

16.1 Application

Gaseous decontamination is a common method for decontamination of containment cabinets and filters at BC2 level. It may also be used for decontamination of equipment in chambers or for decontamination of a large enclosure (for example, an animal room). However, large scale gaseous decontamination is uncommon at BC2 level.

16.2 Gaseous decontaminants

There are a large number of gaseous decontaminants or fumigants used for various agricultural, medical, industrial and domestic applications. A small number of gaseous decontaminants are suitable for BC2 applications. These include:

a) formaldehyde
b) vaporised Hydrogen Peroxide (VHP)
c) Chlorine Dioxide.

16.3 Gaseous decontamination of containment cabinets

A containment cabinet should be cleaned and decontaminated:

a) prior to filter removal
b) prior to performance testing (see Section 10.24)
c) when there is a significant change in use or risk of accumulated biological contamination
d) before a cabinet is relocated
e) after a serious spill or similar contamination incident within the cabinet, and
f) prior to decommissioning or replacement.

16.4 Gaseous decontamination process

A basic gaseous decontamination process comprises several stages, for example:

a) the enclosure is cleaned and internal covers and any access panels are opened to facilitate decontaminant gas penetration
b) the enclosure ventilation plant is de-energised
c) the enclosure boundary is sealed airtight (or as close to airtight, as practical, for example, by taping plastic membranes over openings)
d) the enclosure temperature and relative humidity are adjusted to, or maintained within, acceptable limits
e) gaseous decontaminant is released or injected into the sealed enclosure to provide a target airborne concentration
f) the sealed enclosure is held for a set contact period while decontaminant gas disperses and kills organisms and microorganisms
g) decontaminant gas is then purged from the space by controlled ventilation (Class II biological safety cabinets are normally fitted with an adjacent ventilation exhaust spigot for this purpose).

Formaldehyde decontamination may require an additional stage for neutralisation of adsorbed gas and polymer removal.

All of the gaseous decontamination processes require specific, written process protocols for safety and efficacy. Facilities should be locked and warning notices posted while gaseous decontamination is in progress.

For efficacy, it is normally necessary to fumigate within specific ranges of room temperature and relative humidity (RH) and with these conditions held stable and within prescribed limits. Elevated RH is required for the efficacy of some fumigants. Elevated RH softens the walls of microorganisms and allows the decontaminating agent to penetrate and inactivate the target. Elevated temperature will improve the rate of diffusion of fumigant gas and avoid condensation. The minimum recommended temperature for fumigation is dependent on the choice of fumigant. A relatively stable temperature is desirable in order to stabilise RH.

The concentration of gaseous decontaminant needs to be maintained at, or slightly above, the limits for reliable decontamination over the entire contact time. After gaseous decontaminant is released it will diffuse through the enclosure. Some physical sorption (absorption and adsorption) of the gaseous decontaminant will occur over time causing a decline in decontaminant concentration. The extent of physical sorption of decontaminant can affect the required initial concentration. The amount of gaseous decontaminant dispersed must be sufficient both to satisfy the total sorption during treatment and also to leave enough free decontaminant gas to kill the target microorganisms.

Recommended minimum concentrations, contact times and limiting environmental conditions for gaseous decontaminants vary across published literature. Typical target parameters are tabulated below.

Gaseous decontaminant	Application	Concentration in Air	Contact Time (hrs)	Room Environmental Limits
Formaldehyde	BSCs, Canisters	20 mg/litre 16,000 ppm	6	70% - 85%RH 21°C – 40°C
	Large enclosure	7.4 mg/litre 6,000 ppm	24	70% - 85%RH 21°C – 40°C
Hydrogen Peroxide Vapour	BSCs, Canisters	1 mg/litre 800 ppm	2	Initially 30% - 50% RH 10°C – 40°C
	Large enclosure	0.3 mg/litre 250 ppm	7	Initially 40% - 60% RH 10°C – 40°C
Chlorine Dioxide	BSCs, Canisters	2 mg/litre 1600 ppm	1	65% - 80%RH 15°C – 40°C
	BSCs, Canisters	1 mg/litre 800 ppm	2	65% - 80%RH 15°C – 40°C
	Large enclosure	0.5 mg/litre 400 ppm	5	65% - 80%RH 15°C – 40°C

ppm: parts per million by weight

Notes to Table:

1. Mixtures of formaldehyde or chlorine dioxide gas in air, can be explosive. However, this risk prevails at much higher decontaminant gas concentrations than tabulated above.
2. The use of an excessive concentration of formaldehyde gas can result in polymer deposition that may cause filter blockage and be difficult to remove from surfaces.
3. For biosecurity applications, hydrogen peroxide vapour is applied as a ‘dry’ process, where the concentration and enclosure conditions ensure that the vapour does not condense on surfaces.
4. RH reduction may be applied before the start of a hydrogen peroxide gaseous decontamination process because additional moisture is evolved over the exposure interval by the decomposition of hydrogen peroxide into water and oxygen. This progressively elevates the enclosure RH. However, it should not rise to a level where condensation will occur.

Note: from the foregoing table, that higher decontaminant gas concentrations can be used to reduce contact time. As microorganisms vary in their resistance to destruction by physical and chemical means, the biosecurity industry participant may need to undertake testing to determine an appropriate and reliable method of gaseous decontamination, gas concentration and contact time for a particular application. Validated concentration and time parameters should normally be used in lieu of the general parameters in the foregoing table.

To ensure a gaseous decontamination process is effective, it will need to:

a) employ an effective gaseous decontaminant
b) confine the decontaminant to the target volume
c) maintain target volume conditions (temperature, humidity) in the range required for efficacy of the decontaminant gas
d) ensure the decontaminant gas penetrates throughout the target volume to maintain near uniform gas concentration
e) maintain a target concentration of fumigant gas for a duration sufficient for reliable decontamination.

Forced circulation may be required where decontaminant gas diffusion is restricted.

16.5 Ensuring efficacy

The efficacy of a gaseous decontamination process needs to be verified by either:

a) the use and monitoring of suitably placed (biological or bacterial enzyme) indicators for each gaseous decontamination process or alternatively
b) by using a profiled gaseous decontamination process reproducing a standardised methodology that has been pre-tested, verified and documented.

When a gaseous decontamination process is replicated exactly in accordance with a validated profile [item (b) above], biological indicators are not required for each implementation of the process.

For large scale gaseous decontaminations (for example, for rooms) that are infrequent, it will normally be appropriate to use method (a) above. For more frequent, small scale gaseous decontaminations (for example, for containment cabinets), method (b) will likely be more cost effective.

16.6 Placement of indicators

For validating gaseous decontamination procedures, (biological or bacterial enzyme) indicators should be dispersed throughout the approved arrangement site, or cabinet. They should be placed in representative positions and positions that are likely the most difficult for the decontaminant gas to diffuse or penetrate into.

For containment cabinets, the following indicator positions are required for process profiling test work:

a) on the work floor (Class l, ll biological safety cabinet, cytotoxic cabinet, fume cupboard)
b) in the sump (Class ll biological safety cabinet and cytotoxic cabinet)
c) on the rear wall of the work zone (Class l, II, biological safety cabinet, cytotoxic cabinet, fume cupboard)
d) on the downstream guard of the HEPA filter (Class l, ll biological safety cabinet and cytotoxic cabinet) and
e) below the pre-filter screen (Class l biological safety cabinet).

A positive control (unexposed) indicator must be used as part of the verification. The control indicator must be from the same batch as the test indicators used in the decontamination process.

For containment cabinets, the following indicator positions are required for individual (non-profiled) process validation:

a) on the rear wall of the work zone (Class l, II biological safety cabinet, cytotoxic cabinet, fume cupboard)
b) on the downstream guard of the exhaust HEPA filter (Class l, ll biological safety cabinet and cytotoxic cabinet).

17 Dry and moist heat sterilisation

17.1 Criteria for acceptable efficacy

The most common form of moist heat sterilisation applied at BC2 level is pressure steam sterilisation. The department's minimum requirements for acceptable efficacy for this treatment are:

a) 15 minutes at 121 ^{o}C, or
b) 3 minutes at 134 ^{o}C.

Note: the time and temperature listed above are the minimum. The minimum temperature must be achieved throughout the load for the minimum cycle time.

Where dry heat sterilisation is a suitable inactivation method, the acceptable time/temperature requirements will normally be specified in the Import Permit for goods. These parameters are quite variable and dependent on the heat susceptibility of the goods and other factors.

17.2 Temperature sensor calibration

Annual sensor calibrations are required for all forms of heat sterilisation (including alkaline hydrolysis and hot water immersion treatment) to ensure that required sterilising or inactivating temperatures are met. Where calibration errors are identified, the biosecurity industry participant should:

a) adjust display instrumentation to read within acceptable error limits, and
b) either adjust control sensors to read within acceptable error limits, or
c) otherwise correct for errors (for example, by programming calibration or set-point offsets in controllers).

The biosecurity industry participant should record calibration adjustments or corrections.

17.3 Heat steriliser validation

The efficacy of dry and moist heat sterilisation processes is dependent on reliably achieving the required minimum sterilising temperature for the required minimum holding time in each process cycle. The penetration of steam or heat into the load is critical to ensuring all parts of the load are subjected to the minimum sterilisation conditions. For steam sterilisation, effective air removal is critical, as air pockets will inhibit heat and moisture penetration. The loading configuration is also critical for air removal and heat and moisture penetration. Personnel who operate sterilisers need to be trained to prepare loads in a manner that facilitates air removal and steam and heat penetration.

The department requires that each heat sterilisation cycle be validated using sensor recording instrumentation, indicators, or load profiling. In the two former cases, sensors or indicators must validate the process for the part of the load where heat or moisture penetration is most restricted (normally referenced as the coolest and densest parts of the load). Logs or indicators for each sterilisation cycle should be examined to confirm efficacy, then results should be recorded and archived to provide traceability.

An acceptable alternative to individual cycle validation is to set up a standardised and verified loading and processing regime referred to as load profiling.

17.4 Load profiling – heat sterilisation

In lieu of the individual steriliser cycle validation, the biosecurity industry participant may undertake load profiling to develop and implement effective validation processes for generic loads.

Load profiling is establishing and validating a standard heat sterilising methodology and complementary loading arrangement that can be reused subsequently without a detailed recording of loading configuration, detailed logging of temperature probes, or use of lethality indicators.

Load profiling principles are applicable to validating any method of sterilisation. The information required for operation and load profiling can be obtained by site measurement of individual sterilisers, from persons conducting steriliser performance qualification tests and from regular maintenance and monitoring activities undertaken by biosecurity industry participants.

When developing effective load profiles, biosecurity industry participants need to assess and define all the variable factors that contribute to a validated profile. These include the set-up of the steriliser, the sterilisation process programmed into the machine, the type and size of goods and any packaging, the loading arrangement and other factors (such as cleanliness of materials) that affect the efficacy of the process.

Load profiling is an intensive exercise involving planning, profile development, testing, data collection, assessment of collected data, validation and documentation of validated profiles and procedures. New load profiles will be required where there are changes in the loads that need to be sterilised. Development of load profiles requires testing that is more rigorous than the routine monitoring activities used for individual verification of non-profiled loads. The development process requires repeated physical and biological testing and considerable record keeping.

For load profiling tests, steriliser efficacy can be assessed using either physical parameters (time/ temperature) or lethality indicators. In the former case, the sterilisation conditions are assessed by spatial sampling with temperature sensors. In the latter case, bacterial enzyme, biological or chemical indicators are used for spatial assessment of lethality. Typically, assessments are undertaken in six positions in a load, including the coolest part of the chamber (commonly near the drain point for moist heat treatment), and the densest part of the load.

A steriliser load profiling validation trial will typically include:

a) developing a suitable, standard loading configuration for each generic load
b) determining the process and conditions required for sterilising each generic load by assessing aspects such as the type of goods, pre-cleaning of goods, or equipment, packaging, packing of the steriliser and any other factors affecting sterilisation efficacy
c) verifying that the intended sterilisation conditions are being achieved throughout the load using either physical parameters or lethality indicators.

The load profiled cycle is validated via multiple (at least three) successful trials using results from the chosen physical or biological monitoring method.

17.5 Corrosive loads

Consideration may need to be given to the corrosive or destructive effects of goods being sterilised (for example, routine salt water loads will require a steriliser to be constructed of appropriate material to prevent corrosion).

Note: it is desirable to bag biosecurity waste that may corrode sterilisers. A common example of such waste is disinfectant saturated paper towels and cloths.

17.6 Autoclave bags

When using autoclave bags, biosecurity industry participants will need to consider how steam penetration can be achieved. This may require the addition of a small amount of water to the bag to assist in reaching the correct temperature and moisture level for inactivation.

17.7 Repair of leakage

Internal or external leakage from any heat sterilising equipment compromises biosecurity. When a leak is detected (for example, weeping past a liquid discharge valve seal) it should be immediately repaired.

17.8 Vent filters

Vent filters for sterilisers are required to be replaced within the manufacturer's recommended replacement interval. Any filters in service beyond 12 months are required to be tested at 12 months (maximum) intervals. There are a variety of filter integrity tests including, aerosol challenge, bubble point, diffusion test, forward flow test, pressure hold test. The verification test method should be selected to suit the type of vent filter utilised. A test certificate will need to be provided to confirm filter integrity.

18 High temperature alkaline hydrolysis

18.1 General

High temperature alkaline hydrolysis is a long duration process where heat, moisture and alkaline chemistry are used in an aggressive treatment that decomposes organic material such as large animal carcases. A large animal carcass is difficult to sterilise using conventional wet heat sterilisation, because of the difficulty in achieving reliable heat penetration. The alkaline hydrolysis process eliminates this issue by decomposing the carcass to expose all tissues to heat, moisture and the alkaline agent. Note that, normally, a large animal carcass would be dismembered before alkaline hydrolysis to accelerate decomposition.

18.2 Ensuring efficacy

The alkaline hydrolysis process requires individual process monitoring unless a validated load profile is used. The cycle parameters to be monitored are process temperature, pressure, pH and duration.

Biological, bacterial enzyme or chemical indicators can be used, in theory, for assessing the efficacy of an alkaline hydrolysis cycle. However, the indicator will likely be deactivated before a load (for example, a carcass) is fully decomposed. Unless indicators are sealed deep into the largest masses of tissue, they will provide an unreliable indication of efficacy. A more reliable indicator of efficacy is to observe the product at the end of the alkaline hydrolysis cycle and assess whether it is fully decomposed, as intended. Samples from the processed load can be cultured to assess whether any microorganisms have survived the process.

19 Hot water treatment for plant material

19.1 Hot water immersion

Hot water immersion is an acceptable (alternative) treatment for inactivation of seeds and other plant material at BC2 level. The treatment requires full immersion of goods subject to biosecurity control in initially clean, potable water, maintained at a suitable, elevated temperature. The required temperature and duration of immersion will vary with the heat/moisture susceptibility of the goods.

Normally the minimum temperature and duration will be given in the Import Permit for the plant material. If not, the required temperature/duration can be obtained from the BICON database or by contacting the department.

Important factors for hot water immersion treatment are as follows:

a) the equipment must provide accurate temperature / time control with temperature sensors / gauges calibrated at least every 12 months
b) the plant material must remain immersed over the inactivation cycle
c) the immersion water bath / tank must have a closed lid to avoid water / vapour loss or dispersion of material subject to biosecurity control
d) the water temperature must not drop more than 1^{o}C below the required inactivation temperature throughout the cycle
e) the temperature / time cycle must be monitored, reviewed and recorded for verification purposes
f) the water must be discarded (to sewer after cooling) or disinfected after processing a consignment as a precaution against recontamination or cross contamination.

20 Waste management

20.1 Biosecurity waste storage

Mechanisms to keep waste secure and protected from unauthorised access may include holding waste within a building or within a locked container. Waste can be held in sealed bins (or in sealed bags in wheelie bins) in a secure cage or enclosure. Waste may also be held in a secure temporary holding area when an approved waste contractor is used.

Liquid waste may be collected in disposable (plastic) containers, reusable (glass, plastic, metal) containers that can stand the appropriate treatment, or purpose-built containers for retaining or treating liquid effluent.

Note: there are limits for the duration of storage of most waste materials. The storage limits for different types or classes of waste can vary, and depends on the good/waste subject to biosecurity control. These limits may be specified in the class conditions document, department directions, or in Import Permits. In addition, waste is usually required to be moved to cold storage after storage duration limits that vary according to the nature of the waste. Animal carcasses require cold storage as soon as practical after death, where soil would be non-perishable allowing storage for an extended period. Refer to the mandatory conditions for the duration limits applicable for waste storage.

20.2 Biosecurity liquid waste disposal

All untreated liquid waste and liquid waste from disinfection (chemical decontamination) and hot water immersion treatments are required to be discharged into a municipal sewer. Liquid waste from other approved waste treatments (for example, steam or heat sterilisers, digesters) may be discharged into the sewer or disposed of by other means, largely at the biosecurity industry participant's discretion. However, the disposal must be in accordance with applicable waste regulations. In addition, the recycling of treated waste is not permitted without specific departmental approval.

Wash water from cleaning animal housing must be discharged to sewer or collected in containers that can withstand a department approved treatment.

Where a BC2 approved arrangement site does not have access to a municipal sewer, waste liquid may be treated by other department approved methods such as heat treatment (steam sterilisation, batch or continuous flow heat treatment). In this situation, the department may also approve an alternative treatment such as hypochlorite treatment with a specified (non-sewer) disposal method.

The use of alternative (non-sewer) liquid waste treatment and disposal methods must be approved in writing by the department after demonstration of treatment efficacy to the satisfaction of the department. Such methods may require detailed research and/or testing at the biosecurity industry participant's expense.

20.3 Treatment of imported water

Imported water is water that originates from overseas and is not part of an acceptable manufactured product. It would typically be imported as an environment for imported aquatic animals or as drinking water for imported animals. It may also be imported on its own (for example, for research on water borne organisms, water contents or quality). Imported water requires a department approved treatment. The approved treatments include:

a) pressure steam sterilisation (steam steriliser)
b) heat sterilisation (batch or continuous flow)
c) hypochlorite treatment with disposal to sewer.

20.4 Hypochlorite treatment

Hypochlorite pre-treatment is required for disinfection of imported water before disposal to sewer. This is also an approved treatment and disposal method for water that is contaminated or potentially contaminated by culicidae (mosquito) larvae, requiring biosecurity control. Hypochlorite disinfection and a specified (non-sewer) disposal method may also be approved as an alternative treatment for waste water from BC2 facilities that do not have access to a municipal sewer.

Hypochlorite can be used in either liquid or granular form, that is, as sodium hypochlorite (liquid form such as bleach) or calcium hypochlorite (usually granular).

Notes:

1. calcium hypochlorite will have less effect on pH, as opposed to sodium hypochlorite which will likely raise pH
2. calcium hypochlorite is more likely to maintain its strength, as opposed to sodium hypochlorite which is less stable
3. calcium hypochlorite has greater available chlorine than sodium hypochlorite.

Testing the treated solution for chlorine content and monitoring the concentration of free chlorine is necessary. The testing must verify that hypochlorite has been dispersed correctly and the solution strength is adequate to maintain the minimum free chlorine required. Testing can be undertaken using a swimming pool test kit. These kits are widely available and provide an easy and convenient way to assess chlorine concentration.
Note: the concentration necessary for hypochlorite decontamination considerably exceeds the range available in a pool test kit (usually measuring a maximum 5 ppm). Therefore, test samples will need to be diluted 50:1 with distilled water or rainwater. The measured concentration should then be multiplied by the dilution factor (50) to give the true concentration of chlorine.

Where the bio burden in imported water consignments is reasonably consistent, process profiling can be used to ensure that the concentration of free chlorine is at or above the target values for the various stages of the treatment process. Process profiling would involve determining the initial hypochlorite concentration required to provide a 200 ppm (minimum) free chlorine level after agitation, taking into account the type of circulation activity. The amount of hypochlorite needed will initially produce a free chlorine concentration well above 200 ppm, as free chlorine will be consumed as the process proceeds. The use of process profiling to establish a suitable initial concentration will reduce the need to add further hypochlorite and undertake retesting to ensure the free chlorine concentration is at least 200 ppm after agitation is completed.

20.5 Sodium hydroxide treatment (animal accommodation)

Sodium hydroxide decontamination and a specified (non-sewer) disposal method may be approved by the department as an alternative treatment for effluent water from BC2 animal approved arrangement sites that do not have access to a municipal sewer.
The procedure for this treatment is given in the BC2 conditions document.

Note: this is a cold hydrolysis process that does not decompose animal tissues in the manner that occurs with high temperature, alkaline hydrolysis. Like hypochlorite treatment, it provides contact decontamination. It is therefore necessary to sieve solids exceeding 100 microns from the liquid effluent before treatment. The removed solids need to be treated by an approved treatment such as heat treatment, deep burial.

The sodium hydroxide decontamination process can be profiled in a similar manner to the hypochlorite process provided the worst case, effluent bio burden is catered for.

21 Animal husbandry and management

21.1 Handling and support facilities

Animal handling and support facilities (for example, for holding, imaging, microscopic examination, treatment, surgery) cannot be used simultaneously for animals subject to biosecurity control and for animals not subject to biosecurity control. After usage with animals subject to biosecurity control, facilities or equipment areas that may have been contaminated, must be decontaminated, before reusing the apparatus with animals not subject to biosecurity control.

21.2 Bedding replenishment

The cleaning regime for an animal approved arrangement site will include the removal of soiled animal bedding and replacement with clean bedding at suitable intervals. The replacement interval will be dependent on the rate of bedding contamination. It may be influenced by factors such as the stocking density, status of animals and the evolution of pollutants such as ammonia gas. Soiled bedding must be decontaminated by a department approved method.

21.3 Dissection and post-mortem

Where a post-mortem is required, and cannot be conducted within 12 hours, the animal may be stored for no more than 3 days in a manner that prevents general decay and enzyme breakdown. This would require the animal to be stored at a temperature not exceeding 5^{o}C.

Tissues fixed in the specified volumes/weights and using the chemicals approved by the department to inactivate the goods, may be removed from biosecurity control.

22 Horticultural and agricultural practice

22.1 General practice

Segregation of goods can be achieved, for example, by providing different work benches to avoid contact between biosecurity goods.

Training records and personnel records and other documents can be used to assist in demonstrating, at audit, that personnel have the applicable competency. Such documentation, including any assessment process can further assist in providing supporting evidence to the department, when determining competency.

22.2 Observation method

The biosecurity industry participant will need to provide a record detailing the observation method or technique used to monitor for pests and disease. The observation method should include enough detail to determine the method used, for example, the monitoring process, would include the observation sample, such as number of plants randomly inspected, incidence and severity (for example low, moderate, high), plant reaction if pest and/or disease present. It would also include the methodology used to determine the observation method.

23 Decommissioning/decontaminating BC2 infrastructure

23.1 General considerations

The need to decommission BC2 infrastructure may arise in a number of situations, including:

a) suspending or ceasing operations
b) relocating or restructuring operations or
c) redeveloping or refurbishing containment infrastructure.

Before BC2 infrastructure is decommissioned on a permanent or prolonged basis, the biosecurity industry participant has a responsibility to:

a) notify the department as early as practical and at least 15 days before any planned decommissioning.
b) remove or treat all applicable goods subject to biosecurity control (including waste) and
c) decontaminate the infrastructure to eliminate ongoing biosecurity risks.

BC2 infrastructure may also be decontaminated following a consignment of goods subject to biosecurity control, and then the approved arrangement site used for other goods, prior to being reused with biosecurity goods. The decontamination process, as detailed in table 9, of the conditions document applies to decontaminating the site for temporary use with other goods.

23.2 Removal or treatment of goods subject to biosecurity control

Goods subject to biosecurity control can be removed by exporting or transferring goods to other approved arrangement sites of suitable type and the same or higher biosecurity containment level. Alternatively, goods can be treated by a department approved biosecurity treatment (inactivation, decontamination, disposal or destruction) to destroy or render goods as non-controlled status.

23.3 Eliminating ongoing biosecurity risks

The first stage in eliminating ongoing biosecurity risks is to systematically assess the exposure to contamination of all components of the BC2 infrastructure including building components, fittings, furnishings, services and equipment. After identifying components exposed to contamination, the biosecurity industry participant will need to develop treatment proposals to eliminate ongoing risks.

Decontamination proposals will need to conform to the applicable BC2 conditions. However, while it is practical to define basic treatments to be applied, this may not capture all of the detailed measures needed to eliminate ongoing risk. It is the biosecurity industry participant's responsibility to develop and apply practical and effective decontamination measures.

Note: in some instances it will be necessary to dismantle infrastructure or equipment to provide effective cleaning and decontamination. There will also be instances where economics will favour destruction or deep burial of components over inactivation or decontamination treatments.

23.4 Close-out inspection/s and audit

The department's audit services group will undertake close-out inspection/s and audit for decommissioned BC2 approved arrangements and infrastructure. The biosecurity industry participant will need to provide complete records of assessments and treatments in order to satisfy the auditors that any ongoing biosecurity risks are sufficiently low to close-out the decommissioning.

24 Abbreviations and Terminology

24.1 Abbreviations

Abbreviation	Description
AA	Approved Arrangement
AAG	Audit Assurance Group (department's auditing group)
AIMS	AQIS Import Management System
AS	Australian Standard
AS/NZS	Australian and New Zealand Standard
BC2	Biosecurity Containment Level 2
BICON	Biosecurity Import Conditions (the department's accessible database for import conditions)
BIP	Biosecurity Industry Participant
BSC	Biological Safety Cabinet
CT	Computed Tomography
DOP	Dioctyl Phthalate (Liquid for HEPA filter test aerosol)
EPA	Environmental Protection Agency
^{o}C	Degrees Celsius (temperature)
HEPA	High Efficiency Particulate Air (filter)
HVAC	Heating Ventilation and Air Conditioning
IATA	International Air Transport Association
IVC	Individually Ventilated Cage
ISO	International Standards Organisation
KAO	Key Arrangement Outcome
kPa	Kilo Pascal (pressure unit)
kGy	Kilo Gray (irradiation unit)
kW	Kilo Watt (unit for power or heat transfer rate)
MIMS	Mineral Insulated Metal Sheathed (electrical cables)
MRI	Magnetic Resonance Imaging
NATA	National Association of Testing Authorities
NCG	Non Conformity Guide
Pa	Pascal (pressure unit)
PC2	Physical Containment Level 2
pH	Scale 0 - 14 measuring how acidic or alkaline a substance is (pH 7 is neutral, acidic < 7, alkaline > 7)
PMS	Process Management System
PPE	Personal Protective Equipment
ppm	Parts per million

Abbreviation	Description
PVC	Poly Vinyl Chloride
RH	Relative Humidity
RPZD	Reduced Pressure Zone Device (plumbing backflow preventer)
SOP	Standard Operating Procedure
SPF	Specific Pathogen Free
TPA	Third Party Assessor
UN	United Nations

24.2 Terminology used in BC2 conditions

In general, the following table does not include terminology listed in the department's Generic Glossary. Refer to the department's website for the Generic Glossary.

Term or acronym	Explanation
Adjacent	Adjoining each other with the same common side touching or abutting.
Airlock	A separate fully enclosed space with separate access doors designed to segregate adjacent enclosures/sites.
Anteroom	A separate, enclosed space used for access to and egress from an approved arrangement site, and can have specific containment functions such as storage of PPE.
Approved Arrangement	Defined in the legislation. See *Biosecurity Act 2015*.
Approved Arrangement site	Defined in the Approved Arrangements Glossary. See *department*'s website**.**
Approved arrangement site boundary or **containment boundary**	Defined in the Approved Arrangements Glossary. See also Part A4, *BC2 classification and containment principles*.
BICON	Biosecurity Import Conditions (the departments accessible database for import conditions)
Biosecurity area	Any part of an approved arrangement site, or the entire approved arrangement site, including an associated airlock or anteroom. The biosecurity area may include, or exclude storage and treatment areas.
Biosecurity containment storage area/unit	Biosecurity containment storage area/unit is where goods/waste subject to biosecurity control are kept and where no work is undertaken with goods/waste subject to biosecurity control. The area/unit may be located outside the containment boundary. Examples of storage area/unit include freezers, refrigerators, cool rooms.
Biosecurity containment work	Activities undertaken with goods subject to biosecurity including, testing, manipulation, growing and breeding of goods.
BC2 Infrastructure	The support facilities, equipment, services and systems that provide biosecurity level 2 containment at or around the approved arrangement site. See Part A4, *BC2 classification and containment principles.*
Biosecurity industry participant	Defined in the legislation. See *Biosecurity Act 2015*.
Biosecurity treatment	A department approved method of inactivation, decontamination or disposal/destruction of equipment, surfaces, or of goods subject to biosecurity control. The approved treatment method will vary with the type of good being processed and may be specified in the Import Permit for the goods.
Calibration	The process of verifying and making adjustments (where necessary) to ensure measurement accuracy is within a specified tolerance: 1. verification – ascertaining measurement is within specified tolerance 2. calibration – adjustments to measurement to bring within specified tolerance, only where the measurement is outside of

Term or acronym	Explanation
	specified tolerance (calibration is not required where measurement is within specified tolerance) 3. re-verification – ascertaining adjustments to measurement is within specified tolerance.
Cleanable	Able to remove contaminants ensuring preservation to the original state or condition and free of contaminating matter (may be by brushing, wiping or washing).
Cohort	A group of animals under a single in-vivo approval regardless of inoculation date.
Co-located	Defined in the Approved Arrangements Glossary.
Commissioning and testing	A process whereby equipment or systems are set into operation, adjusted for correct operation and assessed by suitable trial operations to verify correct operation.
Common cleaning agents	Substances, usually liquids, powders, sprays, or granules, that are used to remove dirt, dust and stains from surfaces and avoid the spreading of dirt and contaminants. Common types are acid, alkaline or neutral. Examples include solutions of detergent, alcohol, bleach and vinegar.
Compliant corridor	One that meets the BC2 conditions (services cleanable, smooth, joints sealed.)
Containment	A system (includes both infrastructure requirements and procedural practices) for confining biosecurity goods within a defined space.
Containment cabinet	A biological safety cabinet or cytotoxic drug safety cabinet that is part of the BC2 infrastructure. Also includes a fume cupboard that is part of the BC2 infrastructure and is used with goods subject to biosecurity control.
Containment device	Includes containment cabinets, other primary containment devices, controlled environment chambers, IVC racks within the approved arrangement site
Culicidae	The mosquito family incorporating almost 3,600 species. A small number of species are subject to biosecurity control. However, the non-expert will not readily discriminate them from species not subject to biosecurity control.
Decontamination	A procedure that eliminates or reduces microorganisms to a safe level.
Defect	A shortcoming or failing which may affect containment such as the loss of seal on a cold room, major cracks in the floor or walls of an approved arrangement site, leaking transport containers, leakage from treatment equipment.
Direct or indirect derivatives	A substance made with or produced from the original goods subject to biosecurity control.
Disinfection	Specialised cleansing technique with a department approved agent that kills or destroys microorganisms.
Disposal (or to dispose of)	An approved elimination process that includes the destruction of the goods subject to biosecurity control by high temperature incineration or alkaline hydrolysis and measures such as deep burial at a department approved site. It also includes discharge of waste liquid (and hypochlorite treated, imported or larvae contaminated water) to sewer at BC2 level.

Term or acronym	Explanation
Door jamb	The surrounding case (usually timber or metal) in which the door opens and closes. Each door jamb has sides and a header.
Dry heat sterilisation	Sterilisation by heating in the absence of moisture. This process requires a much higher temperature and/or exposure time than a moist heat sterilisation process of similar efficacy.
Equipment	An item, apparatus or device used to handle, facilitate or work with goods subject to biosecurity control.
Essential Personnel	Persons required to enter the approved arrangement site to remove affected personnel, and/or contain the incident.
Facility, or facilities	A place, or piece(s) of equipment provided for a particular purpose, or to serve a specific function, that is outside, or not necessarily part of the approved arrangement site.
Filter media	That portion of a filtration system that provides particulate separation from a liquid or gas, such as close-woven textiles or metal screens, papers, nonwoven fabrics, granular beds, or porous media. The filter media may be a natural or synthetic material or a manufactured article. Filter media have a porous structure permeable to liquids and gases.
Footbath	Disinfectant filled immersion tray/container for decontamination of footwear. It should include a stiff brush to remove mud, a mat for scouring footwear and clear instructions outlining procedures and minimum contact time. It may also include a separate bath of detergent for pre-cleaning footwear.
Fume cupboard	An enclosed workstation, exhaust ventilated and having a face opening with movable, transparent sash. It is designed to: a) accommodate small scale testing and processing of hazardous materials b) physically contain and prevent the spread of toxic, corrosive or noxious airborne contaminants such as gases, fumes and particulates and c) exhaust fumes providing dilution, scrubbing or filtration before safe discharge. A fume cupboard may be ducted to atmosphere or recirculate through a special filter for contaminant absorption. Only the former type may be used goods subject to biosecurity control, in special circumstances.
Fume hood	This terminology is normally applied to an exhaust ventilated device for capturing airborne contaminants with a lower standard of enclosure than a fume cupboard. Typically, the hood will have an inverted bath form or some special form for the application. Fume hoods generally have lower containment and capture efficiency than a fume cupboard. They are normally applied for removal of heat and for vapour or particulate removal in industrial or commercial processing. Note: They are generally unsuitable for containment of goods subject to biosecurity control.

Term or acronym	Explanation
Goods	Defined in the legislation. See *Biosecurity Act 2015*.
Greenhouse	An enclosed structure in which the major enclosing surface is transparent or translucent glass, acrylic or polycarbonate sheeting or another suitable, department approved material that must resist deterioration from the elements.
Hands-free decontamination station	Hand basin or alternative means of decontaminating hands. Must be operated using a sensor, or any part of the body except the hands (for example, arm, elbow, foot). Notes: 1. To qualify as hands-free, the device must be easy to operate without using hands. Stiff, short lever taps will not qualify. 2. At BC2 level, alternatives to a hands-free, hand basin include: a) a hands-free dispenser fitted with an approved, volatile antiseptic solution or b) a laboratory sink of hands-free operation.
HEPA (filter)	High efficiency particulate air (filter). The designation for a sub-micron air filter with particulate arrestance efficiency of at least 99.99% for 0.3 micron particulates.
Hot water immersion	An approved treatment for inactivation of seeds or plant material at BC2 level. It requires full immersion of goods subject to biosecurity control in hot water with a temperature and duration of processing that assures efficacy.
Imported water	Water sourced from outside Australia (for example, water hosting aquatic organisms, drinking water with imported animals).
Inactivation	Any department approved method that: a) destroys the ability of the goods/organism to replicate, or b) makes the goods/organism inactive/unable to function, by destroying and/or altering the goods/organism.
Individually ventilated cage (IVC)	A cage that provides separation between individual animals, including the separation of air.
Major spillage	A loss of goods/waste/subject to biosecurity control outside the confines of the facility, which cannot be readily cleaned up within 15 minutes, or which may be accessed by the general public.
Microfiltration	Filtration process where contaminated fluid is passed through a membrane with sufficiently fine pore size, to separate microorganisms and/or suspended particles from the process liquid.
Microorganisms	A microscopic living organism, which may be a single cell or multi-cellular. Includes protozoa and other parasites, fungi, archaea, bacteria, algae, viruses and viroids.
Moist heat sterilisation	Sterilisation by heating in the presence of moisture, either by steam heating or by heating a target that has a suitable moisture content. Moist heat sterilisation requires pressurisation, where the exposure temperature is above 100 degrees Celsius.
Organism	Refers to microorganisms, animals, plants, invertebrates and aquatic organisms.
Personal protective equipment (PPE)	Any devices or equipment, including clothing, designed to be worn or held by a person on its own, or as part of a system, to protect against one or more biosecurity control risks or other hazards.

Term or acronym	Explanation
Physical site	An area, a structure, or a group of structures, or an area within a location (often bounded by roads, or defined by land tenure) where something was, is, or will be located.
Plant material	Any part of a plant subject to biosecurity control (for example, tissues, root, stem, leaf).
Post arrival biosecurity control (PABC) period or **Biosecurity control period**	The required period of time between importation of the goods and their release from biosecurity control.
Prion	A transmissible pathogenic agent which has proteinaceous particles that lack nucleic acids. Diseases caused include Bovine Spongiform Encephalopathy and Scrapie.
Profiling (load or **process)**	'Load profiling' or 'process profiling' denote a pre-test regime that validates a standardised biosecurity treatment so that the treatment can be applied without individual process validation, provided it is implemented in accordance with the standardised conditions validated by pre-testing. 'Load profiling' is normally used in reference to steam sterilising. 'Process profiling' is normally used for other biosecurity treatments such as gaseous fumigation, liquid heat treatment. Both terms have a common meaning. Note: Dummy loads can be used to establish profile parameters.
Record	A document stating results achieved and/or providing evidence of activities performed.
Sealed primary containment device	The constraints immediately surrounding the goods, such as sealed flask, capped test tube, lidded container or other receptacle. The constraints must prevent the passage of organisms and or goods out of the device to the surrounding environment.
Smooth	A uniform, even surface free of fissures, gaps and with seams that are flush to the remaining surface.
Soil trap	A settling tank designed to separate and hold soil, sand or other particulates and detritus entrained in liquid waste. It commonly includes a removable strainer element for solids separation. Also called a silt trap.
Specialised containment equipment	Any device that is used with goods subject to biosecurity control. This includes containment cabinets, processing vessels, centrifuges, vacuum systems and imaging devices.
Sterilisation	A validated process that eliminates, kills, deactivates and renders free from viable organisms.
Structural void/joints	A space in the containment boundary/building or a gap/hole in tubular steel that occurs in the construction of plant platforms.
Support room/areas	A common room/area that may either be within or outside the containment boundary but still within the same physical site as the approved arrangement site, with equipment used for goods subject to biosecurity control. Examples include imaging and goods receival areas.
Tampering or damage	Refers to the accidental or deliberate altering or damaging of a package or container in a manner that potentially allows access to the goods subject to biosecurity control.
Transport	The process (including, for example, information and security requirements) involved with the physical movement of goods subject to biosecurity control from one location to another location.

Term or acronym	Explanation
Trapped drain	A drain trap (for example P-trap, U-bend) designed to retain a small amount of water each time a plumbing device (tap or sink draining) is used. This water standing in the bottom of the curved portion of the trap seals the drain.
Type Classification	Biosecurity containment classification based on the type of biosecurity goods accommodated. The type classification covers microbiological, animal, aquatic, plant and invertebrate approved arrangement sites
Unauthorised access	Access by persons not authorised/employed by the biosecurity industry participant to enter areas containing goods/waste subject to biosecurity control.
Waste – Biosecurity waste	Biosecurity waste is goods subject to biosecurity control (including materials, organisms and derivatives) that require disposal. For the purposes of containment, waste can be divided into liquid and solid waste.
Waste - Liquid biosecurity waste	Liquid biosecurity waste is contaminated or potentially contaminated (goods subject to biosecurity control) liquids for disposal. This may include, at BC2 level: • Microbiological laboratories: culture media, buffers and wash water from the cleaning of glassware (for example, petri dishes, pasteur pipettes, beakers), equipment (for example, pestle and mortar, spatula, laboratory mills, testing and measuring devices such as pH meter, analysers) and containers which have been used to store or transport goods subject to biosecurity control. • Animal biosecurity containment: wash water from the cleaning of crates, cages. It includes wash water from animal housing, animal facility cleaning, and fresh water arriving with animals. • Aquatic biosecurity containment: liquid from aquatic storage tanks in equipment rooms, liquid from aquatic environments such as tanks or aquaria. It also includes the liquid from cleaning aquatic animal systems (freshwater and marine), such as traps/skimmers, and backwash water from the filtration system and liquid from the cleaning of any equipment (for example, nets, diagnostic or monitoring equipment). • Plant biosecurity containment: waste water from plant irrigation activities in greenhouses, and the cleaning of pruning or other equipment within these greenhouses. • Invertebrate biosecurity containment: culture media, water held or used in containers with invertebrates and wash water from the cleaning of cages or isolators. Liquid waste may also include water from internal flooding, as the result of: a) container leak or breakage b) a burst pipe, damaged appliance, fixture or fitting, or c) an appliance, fixture or fitting being accidently left on.

Term or acronym	Explanation
Waste – Liquid biosecurity waste treatment	A liquid biosecurity waste treatment is a department approved method for inactivation, disposal or decontamination of liquid waste. At BC2 level, disposal of liquid waste to a town sewer is an approved disposal method. However, some liquid waste such as imported, or larvae contaminated water requires hypochlorite pre-treatment before disposal to sewer. Other approved liquid waste treatments include batch or continuous flow heat treatment and pressure steam sterilisation. Liquid waste from BC2 containment can be inactivated or decontaminated outside the BC2 approved arrangement site. However, all such waste must be contained until treatment. Where no town sewer is available for liquid waste disposal, the department may approve hypochlorite decontamination and non-sewer disposal, on a case by case basis, after demonstration of treatment efficacy to the satisfaction of the department.
Waste - Solid biosecurity waste	Solid biosecurity waste is contaminated or potentially contaminated solid material subject to biosecurity control, for disposal, after or as part of an approved treatment. This may include: • BC2 microbiological laboratories: cultures, organism or goods subject to biosecurity control (for example soil), by-product, derivative, used petri dishes, sharps, damaged or broken containment equipment for disposal, gloves and other disposable PPE (when used). • BC2 animal containment: animal carcasses, inoculation equipment, drenching or injecting gun, thermometer cleaning/wiping, gloves and other disposable PPE. It also includes animal waste for example, faecal material, vomit, hair and bedding. • BC2 aquatic containment: aquatic organism carcasses, faecal and other goods subject to biosecurity control removed from aquatic storage tanks or from other aquatic environments such as tanks or aquaria. It also includes the solid material which can be removed from aquatic animal systems such as traps/skimmers and filtration systems, containment structures in which aquatic organisms are held, and damaged or broken equipment such as nets. • BC2 plant containment: plants and plant material (for example, rejected plants, pruning's, roots), any diseased material subject to biosecurity control, and material used for packaging, such as crates and liners. It also includes potting mix, soil or detritus removed from soil traps and damaged or broken equipment for disposal from greenhouses. • BC2 invertebrate containment: invertebrates, host and/or environmental materials subject to biosecurity control (for example, plants or their parts), containment structures in which the invertebrates are held, damaged or broken equipment, gloves and other disposable PPE (when used).

Term or acronym	Explanation
	• Sharps which are segregated into their own category. Sharps include syringes with needles, broken glass, scalpel blades and glass pasteur pipettes.
Waste - Solid biosecurity waste treatment	A solid biosecurity waste treatment is an approved biosecurity treatment for inactivation or disposal of solid waste. The most common treatment methods for BC2 solid waste are dry or moist heat treatment. Less common are deep burial and incineration.
Waste - Perishable waste	Waste that is liable to rot or decay. Examples include fruit, vegetables, other non-shelf stable food products and animal tissue.
Waste - Non-perishable waste	Waste that is not liable to rot or decay. Examples include drenching or injecting gun and used petri dishes.
Work shift	The set period of time in a 24 hour period, during which personnel perform their duties with goods subject to biosecurity control.
Work surfaces	Any flat surface where goods subject to biosecurity control are handled, dealt with and/or manipulated. Examples include bench tops, work benches. For BC2, this includes any exposed bench surfaces, such as cut-outs, ends and the underside.
Write-up area	Designated areas within the approved arrangement site that are used for result write-up. These areas must meet the standards applicable to the biosecurity containment level of the approved arrangement site.

ATTACHMENT A

Mesh screen requirements

Mesh screens are required for invertebrate, animal, aquatic, and plant containment. The mesh screens must be installed in all ventilation openings and other air paths through an approved arrangement site, unless otherwise stated in the mandatory conditions.

If liquid waste points are liquid-trapped, they do not require mesh screens for invertebrate control. However, if the liquid waste point is exposed to non-liquid contaminants (for example, fibre, particulates, solids, gel) then a suitable arresting and capture mechanism must be provided to avoid blocking of the drain. This capture mechanism may incorporate a mesh screen, sieve, strainer, trap or other device, as appropriate for the material that needs to be arrested. The aperture of screens, sieves and strainers should be selected to suit the application. In the absence of specific application data, an aperture size of 5mm (5000 micron) could be utilised for liquid waste points.

It is preferable that solids capture mechanisms for liquid waste are located and accessible within the BC2 approved arrangement site. Ideally, material should be removed from capture mechanisms and treated within the approved arrangement site. It is permissible to locate capture mechanisms externally to the approved arrangement site. However, this requires either provision to decontaminate captured material in situ, or a suitable process for removing, packaging and treating captured material at the approved arrangement.

If a chemical treatment (such hypochlorite or sodium hydroxide decontamination) is utilised, then the liquid inflow to this process needs to be sieved through a 100 micron aperture screen before treatment in order to guarantee the efficacy of the chemical decontamination.

The table following provides a summary of the various screening requirements needed for ventilation and waste points for alternative BC2 applications.

Note:
Material sieved from liquid wastes needs to be subsequently treated as solid waste by a department approved method such as heat sterilisation.

Summary Table – Mesh Screens for BC2 Containment Applications

LEGEND

N/R Screen not normally required. Provision is discretionary.

Ms Mesh or other screen commonly required for sieving entrained solids at drain point (screen aperture to suit application-maximum 5mm). Not required where liquid effluent is uncontaminated by solids or particulates (Note 4).

100, 250 Mesh screen required, of given aperture size in microns (Note 5).

BC2 application	Type Classification	Ventilation Openings	Hand Basin Drains (Note 2)	Sink Drain (Note 2)	Shower Drain (Notes 2-6)	Open Floor Waste/Tundish (Notes 2-6)	Sealed Floor Waste (Note 8)
BC2 approved arrangement site with drainage connected to a municipal sewer.	Micro	N/R	N/R	N/R	N/R	N/R	N/R
	Animal	250	Ms	Ms	Ms	Ms	Ms
	Aquatic	250	Ms	Ms	Ms	Ms	Ms
	Plant	250	Ms	Ms	Ms	Ms	Ms
	Invertebrate	250	Ms	Ms	Ms	Ms	Ms
Animal cage preparation area (Note 1).	Animal	250	N/R	Ms	Ms	Ms	Ms
BC2 approved arrangement site using chemical waste treatment such as hypochlorite or sodium hydroxide (Note 7).	Micro	N/R	100	100	100	100	100
	Animal	250	100	100	100	100	100
	Aquatic	250	100	100	100	100	100
	Plant	250	100	100	100	100	100
	Invertebrate	250	100	100	100	100	100

Notes:

1. See section 10.23 of this document.
2. Liquid traps are required for all basins, sinks, shower drains, tundishes and floor wastes.
3. Soil traps are required for any drainage points likely to intake soil, silt or sand (for example, animal, plant and potting wastes).
4. Screening or an alternative suitable capture mechanism is required for drains exposed to fibrous, low density and non-settling contaminants such plant refuse, bedding, animal fibre. The screening may be incorporated as part of a soil trap.
5. Screens require adequate surface area (to avoid frequent cleaning, blockage) and perimeter seals to at least the same straining standard as the required screen aperture.
6. Effluent screening should be located and arranged to provide convenient and secure access for removal and treatment (for example, steam sterilisation) of strained materials. Normally, soil traps and effluent screening need to be accessible from within the BC2 approved arrangement site.
7. A chemical treatment requires sieving liquid waste for solids down to 100 microns for effective decontamination. The tabulated drain screening applies to drains flowing to the chemical treatment.
8. Sealed floor waste would be opened only for drainage of liquid waste after the BC2 approved arrangement site is decommissioned and decontaminated. It would be resealed before the return to service.

ATTACHMENT B

Containment Options Diagrams

Description

This attachment provides illustrations of compliant, level 2, biosecurity containment approved arrangement sites that are typical for a range of type classifications and applications. The illustrations are conceptual and in simplified, diagrammatic form. They illustrate typical layouts for various applications. They are generally not unique solutions. Various combinations and permutations of the BC2 conditions can result in alternative arrangements or layouts that would be compliant.

The features illustrated in the options diagrams are typical for the applications. They do not illustrate every element required for a particular application. Refer to the mandatory conditions document for the full listing of conditions for particular type classifications. The diagrams are not to any scale.

Segregated Storage

The diagrams show multiple stores for segregated PPE, waste, materials and equipment. Storage requirements are application specific and the numbers of containers required are not accurately reflected in the simplified diagrams. Containment applications typically require a multitude of storage facilities for segregation of goods. Clean clothing, equipment and PPE must be segregated from used or reusable items. Contaminated and non-contaminated goods and wastes must be segregated. Waste is also segregated (for example, into liquid and solid waste) for treatment purposes. The diagrams show segregated paper towel storage (for hand drying after decontamination), as these items may be treated as domestic, not biosecurity, waste.

In general, clean items should be stored adjacent the biosecurity containment approved arrangement site entrance. This would be in an anteroom, if provided, or just outside the approved arrangement site entrance. Used or contaminated items should be stored in the dirty zone of zoned anterooms or within the BC2 rooms.

Illustrations

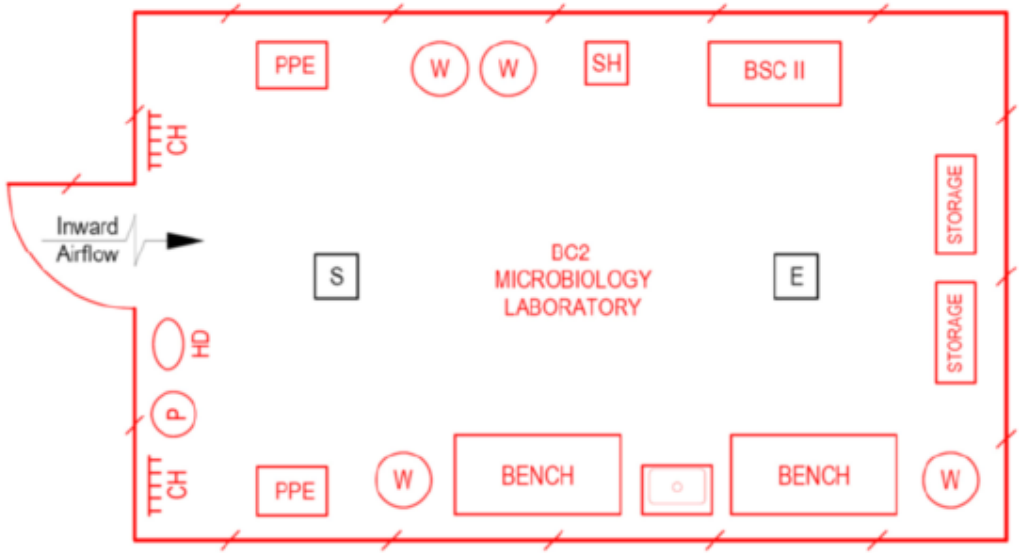
The containment options illustrated are as follows:

Option	Type	Description
1	Microbiological	Microbiological Laboratory
2		Microbiological Laboratory with Limited Plant Accommodation
3		Microbiological Laboratory with Plants in Environmental Chamber
4	Animal	Small Animal Secondary Containment
5		Small Animal Primary Containment
6		Large Animal Primary Containment
7	Aquatic	Aquatic Organism Secondary Containment
8	Plant	Plant Site using Plant Cabinets/Chambers with Potting Area
9		Plant Greenhouse with Exposed Plants and Potting Area
10		Plant Greenhouse with multiple BC2 or BC2/PC2 Sites/Enclosures
11		Plant Greenhouse with multiple Sites at Varying Containment Levels
12	Plant / Invertebrate	Plant or Invertebrate Site with Provision for Large Scale Processing such as Soil Sterilisation
13	Invertebrate	Invertebrate Site Connected to BC2 Microbiology Laboratory
14		Biosecurity Site for Invertebrates with Plant Hosts

BC2 Option 1: Microbiological Laboratory

LEGEND

- BC2 Site Boundary
- HD — Hand Decontamination Station
- CH — Segregated Clean/Used Laboratory Coat Hooks
- PPE — Segregated Storage Clean/Reused PPE
- STORAGE — Segregated General Storage Clean/Soiled Reuse Items
- Laboratory Sink
- W — Segregated Waste Container
- P — Paper Towel Container
- SH — Sharps Container
- BENCH — Laboratory Work Bench
- BSC II — Biological Safety Cabinet Class II
- S — Supply Air Fitting
- E — Exhaust Air Fitting



KEY FEATURES:

1. Compliant microbiology laboratory with hand decontamination station and coat hooks near the exit.
2. All working material to be sealed in primary containment devices and not exposed in the laboratory when not in use (for example, seeds, milled product not to remain in open containers or exposed on bench surfaces).
3. Work areas to be decontaminated whenever changing work (for example with different samples) and on, at least, a daily basis.
4. Doors should be sealed to prevent entry of vermin that may be attracted to the material subject to biosecurity control and held in the laboratory.
5. Material subject / not subject to biosecurity control (including waste) must be appropriately segregated and held in clearly labelled containers.

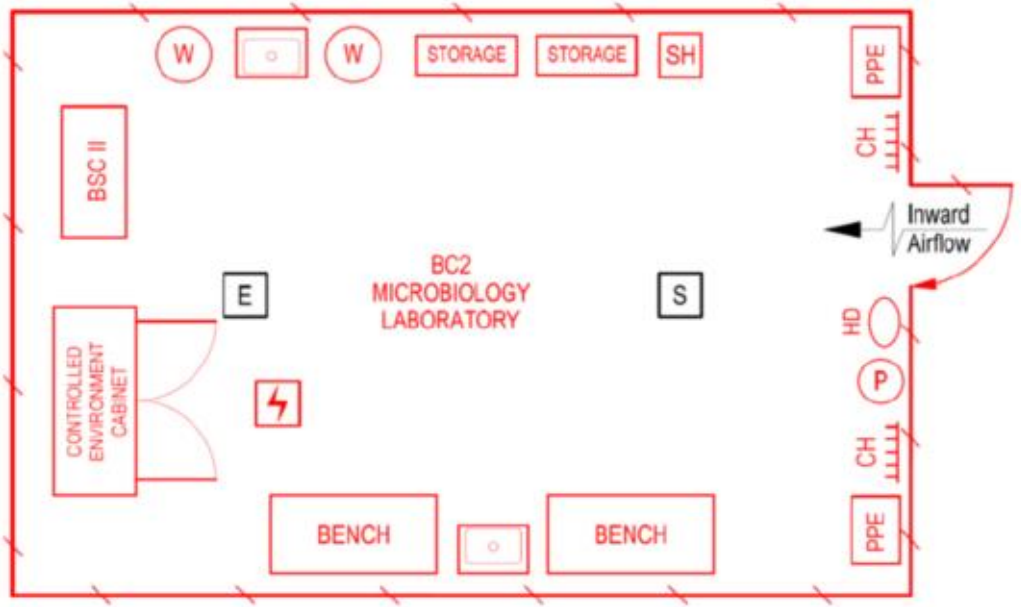
ACTIVITY CONSTRAINTS:

1. A BC2 microbiology laboratory is suitable for activities with plants that do not involve the growing of live plants exposed to the laboratory. Such activities include,
   - seed examination or analysis where seeds are not germinated;
   - seed milling with appropriate air circulation rate and filtration of return / exhaust air;
   - plant tissue examination and testing for diagnostic purposes;
   - early stage plant and tissue growth procedures where live plant material is kept in sealed tubes, petri dishes or similar sealed devices.
2. Inspection and (in vivo) work on live plant material may take place provided the work area is cleaned routinely and after completion of work.
3. Animals may not be held in a microbiological laboratory other than on a temporary basis for the duration of in vivo testing.
4. Any work that could aerosolise biosecurity controlled material must be undertaken in a Class II biosafety cabinet.

BC2 Option 2: Microbiological Laboratory with Limited Plant Accomodation and Activities

LEGEND

- BC2 Site Boundary
- HD — Hand Decontamination Station
- CH — Segregated Clean/Used Laboratory Coat Hooks
- PPE — Segregated Storage Clean/Reused PPE
- STORAGE — Segregated General Storage Clean/Soiled Reuse Items
- BSC II — Biological Safety Cabinet Class II
- Clean Up Sink
- W — Segregated Waste Container
- P — Paper Towel Container
- Invertebrate Attractant & Killing Device
- Self Closing Door
- S — Supply Air Fitting
- E — Exhaust Air Fitting



KEY FEATURES:

1. Compliant microbiology laboratory with hand decontamination station and coat hooks near the exit.
2. Plants are held within a growth cabinet that has sealed doors and openings fully screened with 250 micon aperture mesh. With this arrangement, it is not necessary to screen openings in the microbiology laboratory.
3. All works sealed in primary containment devices and not exposed in the laboratory when not in use (for example, seeds, milled product do not remain in open containers or exposed on bench surfaces).
4. Work areas are decontaminated whenever changing work (for example with different samples) and on, at least, a daily basis.
5. An invertebrate attractant and killing device is installed in the microbiology laboratory.
6. The laboratory access door is self closing and is sealed to prevent the entry of vermin.

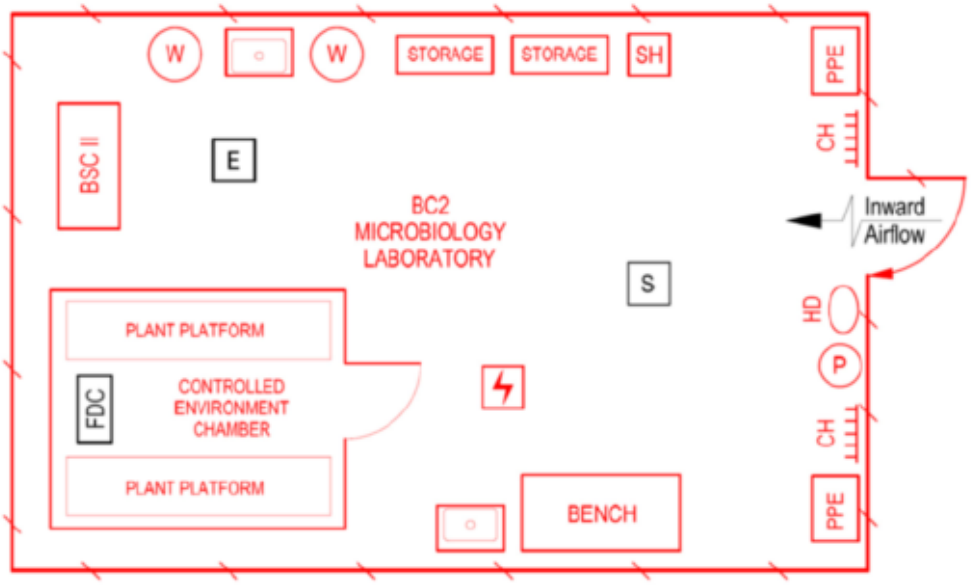
ACTIVITY CONSTRAINTS:

1. A BC2 microbiology laboratory is suitable for activities with plants that do not involve the growing of live plants exposed to the laboratory. Such activities include,
   - seed examination or analysis where seeds are not germinated;
   - seed milling with appropriate air circulation rate and filtration of return / exhaust air;
   - plant tissue examination and testing for diagnostic purposes;
   - early stage plant and tissue growth procedures where live plant material is kept in sealed tubes, petri dishes or similar sealed devices.
2. Inspection and (in vivo) work on live plant material may take place provided the work area is cleaned routinely and after completion of work.
3. Potting up in the open laboratory is not permitted. It must be in primary containment if it is undertaken within the laboratory.
4. Any work that could aerosolise biosecurity controlled material must be undertaken in a Class II biosafety cabinet.
5. Material subject / not subject to biosecurity control (including waste) must be appropriately segregated and held in clearly labelled containers.

BC2 Option 3: Microbiological Laboratory with Controlled Environment Chamber holding Plants

LEGEND

- BC2 Site Boundary
- HD — Hand Decontamination Station
- CH — Segregated Clean/Used Laboratory Coat Hooks
- PPE — Segregated Storage Clean/Reused PPE
- STORAGE — Segregated General Storage Clean/Soiled Reuse Items
- BSC II — Biological Safety Cabinet Class II
- Clean Up Sink
- W — Segregated Waste Container
- P — Paper Towel Container
- Invertebrate Attractant & Killing Device
- Self Closing Door
- S — Supply Air Fitting
- E — Exhaust Air Fitting
- FDC — Forced Draft Cooler



KEY FEATURES:

1. Compliant microbiology laboratory with hand decontamination station and coat hooks near the exit.
2. Plants are held within a controlled environment chamber (or alternatively, plant growth cabinets). The controlled environment chamber (or each growth cabinet) including its door, is screened and sealed to a maximum 250 microns aperture. With this arrangement, it is not necessary to screen openings in the microbiology laboratory.
3. Biosecurity goods are sealed in primary containment devices and not exposed in the laboratory when not in use (for example, seeds, milled product do not remain in open containers or exposed on bench surfaces).
4. Work areas are decontaminated whenever changing work (for example with different samples) and on, at least, a daily basis.
5. An invertebrate attractant and killing device is installed in the microbiology laboratory.
6. The controlled environment room enclosure is accessible so that the sealing and screening can be maintained.
7. The condensing unit for the forced draft cooler is located outside the microbiological laboratory to improve cleanability and minimise sites that can harbour invertebrates.
8. The laboratory door is self closing and sealed to prevent the entry of vermin.

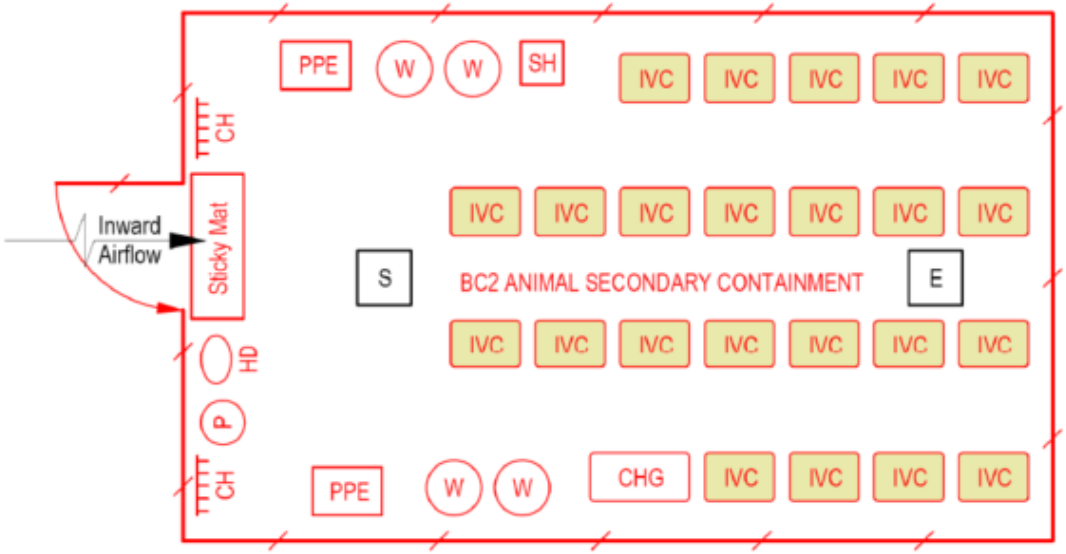
ACTIVITY CONSTRAINTS:

1. A BC2 microbiology laboratory is suitable for activities with plants that do not involve the growing of live plants exposed to the laboratory (See the activity listing for the foregoing Options 1 and 2).
2. Inspection and (in vivo) work on live plant material may take place provided the work area is cleaned routinely and after completion of work. Plant material must not be left exposed in the microbiological laboratory after the completion of a relevant procedure or inspection.
3. Potting up must be undertaken in the controlled environment room, in the biological safety cabinet or in a compliant potting up area external to the microbiological laboratory. It must not occur within the microbiological laboratory.
4. Any work that could aerosolise biosecurity controlled material must be undertaken in a Class II biosafety cabinet.
5. Material subject / not subject to biosecurity control (including waste) must be appropriately segregated and held in clearly labelled containers.

BC2 Option 4: Small Animal Secondary Containment

LEGEND

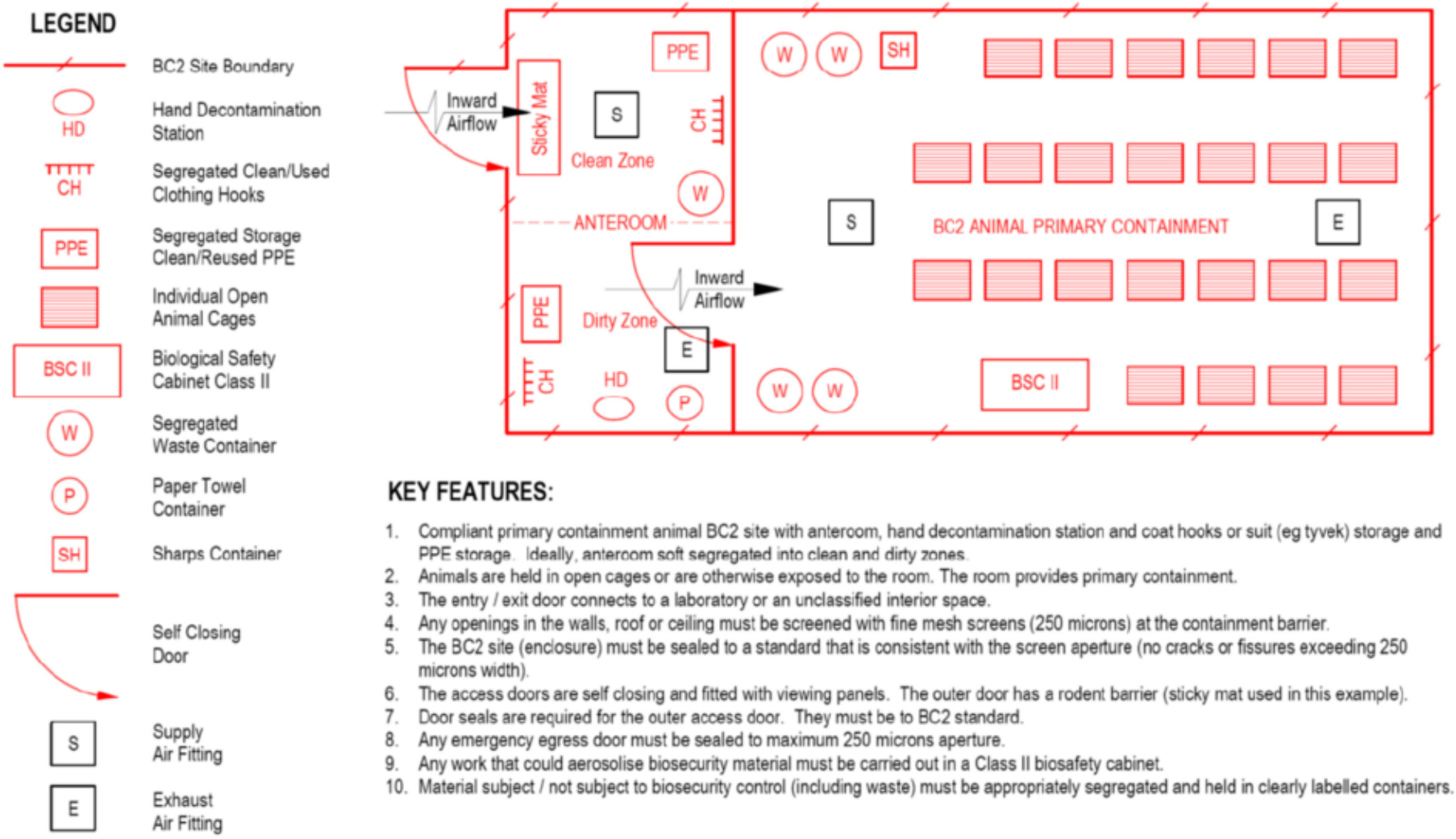
- BC2 Site Boundary
- HD — Hand Decontamination Station
- CH — Segregated Clean/Used Clothing Hooks
- PPE — Segregated Storage Clean/Reused PPE
- IVC — Individually Ventilated Cage (IVC)
- CHG — Animal Change Station
- W — Segregated Waste Container
- P — Paper Towel Container
- SH — Sharps Container
- Self Closing Door
- S — Supply Air Fitting
- E — Exhaust Air Fitting



KEY FEATURES:

1. Compliant secondary containment animal BC2 site with hand decontamination station and coat hooks near the exit.
2. Animals are held in IVCs or similar primary containment. A change station is used to provide primary containment for bedding changes and other procedures. The room provides secondary containment.
3. The entry / exit door connects to a laboratory or an unclassified interior space.
4. Any openings in the walls, roof or ceiling must be screened with fine mesh screens (250 microns) at the containment barrier.
5. The BC2 site (enclosure) must be sealed to a standard that is consistent with the screen aperture (no cracks or fissures exceeding 250 microns width).
6. The access door is self closing and fitted with a viewing panel and sticky mat, rodent barrier.
7. Door seals are required for the entry / exit. They must be to BC2 standard.
8. Any emergency egress door must have seals to BC2 standard if it opens to an interior space with controlled access. It must be sealed to maximum 250 microns aperture if it opens to an exterior space or space with uncontrolled access.
9. Any work that could aerosolise biosecurity material must be carried out in a Class II biosafety cabinet.
10. Material subject / not subject to biosecurity control (including waste) must be appropriately segregated and held in clearly labelled containers.

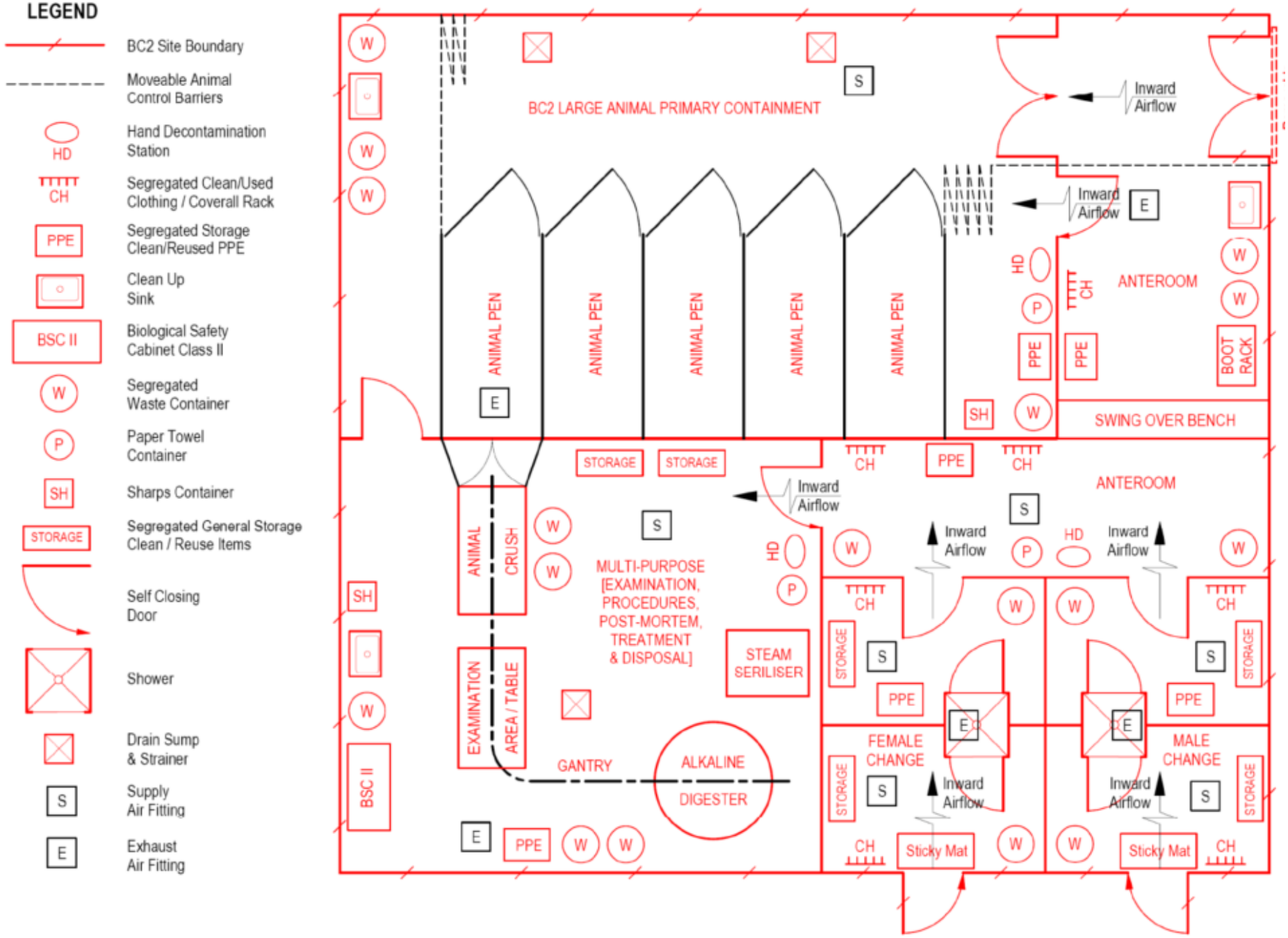
BC2 Option 5: Small Animal Primary Containment



KEY FEATURES:

1. Compliant primary containment animal BC2 site with anteroom, hand decontamination station and coat hooks or suit (eg tyvek) storage and PPE storage. Ideally, anteroom soft segregated into clean and dirty zones.
2. Animals are held in open cages or are otherwise exposed to the room. The room provides primary containment.
3. The entry / exit door connects to a laboratory or an unclassified interior space.
4. Any openings in the walls, roof or ceiling must be screened with fine mesh screens (250 microns) at the containment barrier.
5. The BC2 site (enclosure) must be sealed to a standard that is consistent with the screen aperture (no cracks or fissures exceeding 250 microns width).
6. The access doors are self closing and fitted with viewing panels. The outer door has a rodent barrier (sticky mat used in this example).
7. Door seals are required for the outer access door. They must be to BC2 standard.
8. Any emergency egress door must be sealed to maximum 250 microns aperture.
9. Any work that could aerosolise biosecurity material must be carried out in a Class II biosafety cabinet.
10. Material subject / not subject to biosecurity control (including waste) must be appropriately segregated and held in clearly labelled containers.

BC2 Option 6: Large Animal Primary Containment



APPLICATION CONDITIONS:

1. A large animal enclosure will likely be exposed to gross contamination when it provides primary containment. The infrastructure and operational protocols need to confine contamination to the primary containment rooms and prevent its dispersion beyond the BC2 biosecurity area and particularly into clean change rooms.
2. Careful consideration should be given to the type of work undertaken and the likely mechanisms and routes for transfer of contamination. All material subject to biosecurity control (including equipment, PPE, clothing, waste etc) needs to be appropriately segregated from uncontaminated goods by suitable handling, storage and treatment protocols. This will likely require significant provision for segegated storage containers and related infrastructure.
3. Meeting operational requirements will be facilitated by routine cleaning procedures and soft zoning into clean and dirty zones in the anterooms and other areas, where suitable.
4. Animal carcasses and tissues must be treated by department approved methods. Liquid and waterborne waste (including fully decomposed digester waste, after cooling / pH adjustment) may be disposed of to sewer.
5. Waste treatment may occur outside the containment facility if BC2 conditions for transport and handling are met.

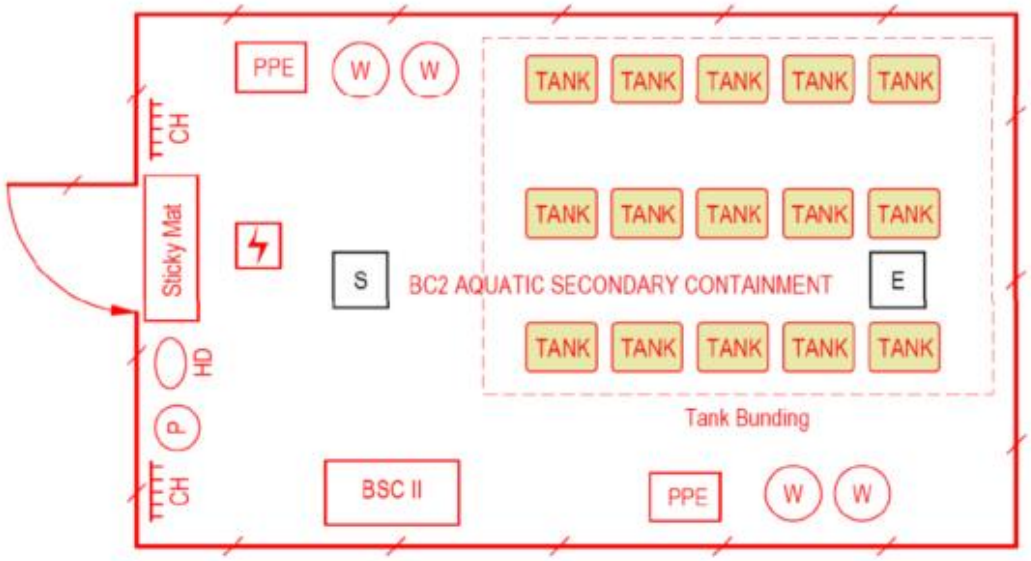
KEY FEATURES:

1. A large animal, primary containment BC2 site with anteroom, hand decontamination stations, segregated PPE, segregated apron / clothing / coverall hooks.
2. Personnel change rooms with shower facilities are provided as the anteroom entry / exit. The change rooms have clothing storage, towels etc and may be used for storage of clean PPE, aprons, coveralls etc.
3. It is preferable if the outer doors connect to internal spaces (that may be laboratory spaces or unclassified). However, outer doors for animal or change room access may be external doors.
4. The change rooms are treated as part of the anteroom in the illustration. The containment boundary runs through the outer change room walls and doors. This avoids the need to seal shower doors so that domestic type shower construction is suitable. The containment boundary could alternatively run through the change room outer shower doors and shower partition walls. However, this would require special outer shower doors sealed to BC2 standard.
5. The outer change room doors are self closing and sealed to BC2 conditions. They each have a sticky mat rodent barrier. The change room doors have no viewing ports. However, suitable mechanisms (for example, sensors and indicator lights) indicate if change rooms are occupied.
6. The outer animal entry door is sealed to BC2 requirements. It is lockable and should be unlocked only during animal entry / exit or for materials or equipment transfer. It is fitted with a 450 mm high, door jamb type, rodent barrier that is removable for animal entry.
7. Openings in the walls, roof or ceiling are sealed with 250 micron mesh for invertebrate control. The BC2 site (enclosure excluding access doors) is sealed to a standard consistent with the screen aperture with no openings, cracks or fissures exceeding 250 microns width.
8. Any emergency egress door (not shown) will be sealed to 250 microns.
9. Materials subject / not subject to biosecurity control (including waste) are collected and stored in appropriately segregated storage. Containers are clearly labelled to designate the contents.
10. Any work work with microorganisms transmissible by the respiratory route or work that could aersolise biosecurity material will be undertaken in a Class II biosafety cabinet.

BC2 Option 7: Aquatic Organism Secondary Containment

LEGEND

- BC2 Site Boundary
- HD — Hand Decontamination Station
- CH — Segregated Clean/Used Clothing Hooks
- PPE — Segregated Storage Clean/Reused PPE
- TANK — Primary Containment Tank
- BSC II — Biological Safety Cabinet Class II
- W — Segregated Waste Container
- P — Paper Towel Container
- Invertebrate Attractant & Killing Device
- Self Closing Door
- S — Supply Air Fitting
- E — Exhaust Air Fitting



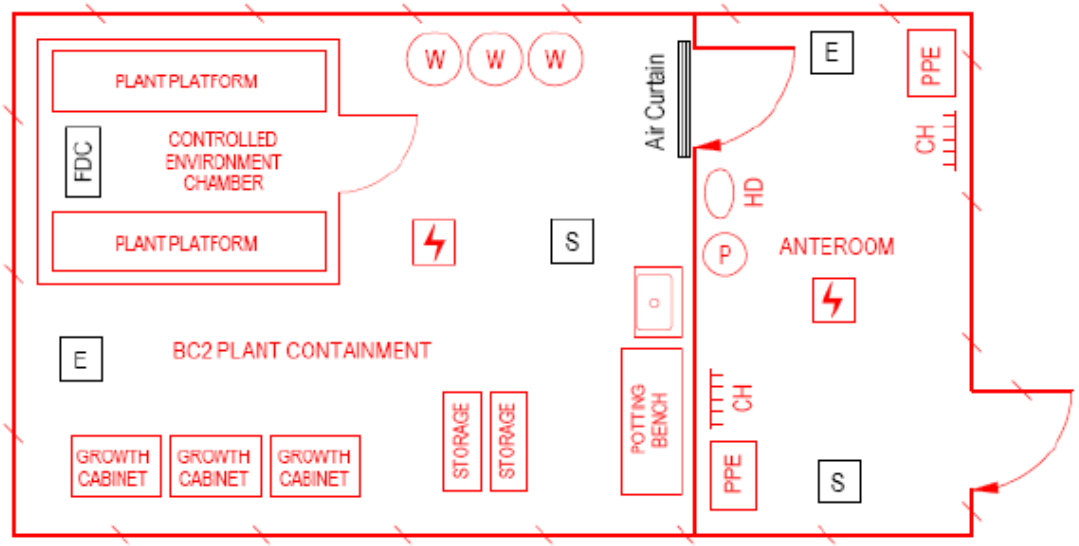
KEY FEATURES:

1. Compliant secondary containment aquatic BC2 site with hand decontamination station and coat hooks near the exit.
2. Aquatic organisms are held in tanks or similar primary containment. The room provides secondary containment.
3. The entry / exit door connects to a laboratory or an unclassified interior space.
4. Any openings in the walls, roof or ceiling must be screened with fine mesh screens (250 microns) at the containment barrier.
5. The BC2 site (enclosure) must be sealed to a standard that is consistent with the screen aperture (no cracks or fissures exceeding 250 microns width).
6. The access door is self closing and fitted with a viewing panel and sticky mat, rodent barrier.
7. Door seals are required for the entry / exit. They must be to BC2 standard.
8. Any emergency egress door must have seals to BC2 standard if it opens to an interior space with controlled access. It must be sealed to maximum 250 microns aperture if it opens to an exterior space or space with uncontrolled access.
9. Any work that could aerosolise biosecurity material must be carried out in a Class II biosafety cabinet.
10. Material subject / not subject to biosecurity control (including waste) must be appropriately segregated and held in clearly labelled containers.
11. Tanks are lidded and have 750mm (minimum) access ways where their capacity exceeds 1000 litres.
12. Water supplies to tanks have appropriate backflow prevention and filtration.
13. Tanks are bunded to capture at least 130% of the largest connected storage capacity.

BC2 Option 8: Plant Containment using Plant Cabinets / Chambers with Potting Area

LEGEND

- BC2 Site Boundary
- HD — Hand Decontamination Station
- CH — Segregated Clean/Used Clothing Hooks
- PPE — Segregated Storage Clean/Reused PPE
- STORAGE — Segregated General Storage Clean/Soiled Reuse Items
- W — Segregated Waste Container
- P — Paper Towel Container
- Clean Up Sink
- Invertebrate Attractant & Killing Device
- Self Closing Door
- S — Supply Air Fitting
- E — Exhaust Air Fitting
- FDC — Forced Draft Cooler



KEY FEATURES:

1. Compliant plant BC2 site with anteroom, hand decontamination station, coat hooks, PPE storage and invertebrate attractant and killing device. Hand decontamination can be in the BC2 room near the exit or in the anteroom, as shown.
2. An anteroom is needed for this application because of the exposed potting activities. If plants and activities were all in primary containment, the BC2 room would be secondary containment and could form the anteroom.
3. The outer anteroom door connects to a laboratory, unclassified space or the building exterior.
4. Any openings in the walls, roof or ceiling of the plant containment must be screened with fine mesh (250 microns) at the containment boundary.
5. The plant BC2 site (enclosure) must be sealed to a standard that is consistent with the screen aperture (no cracks or fissures exceeding 250 microns width).
6. The growth cabinets and controlled environment chamber do not need special screening or seals as the screened containment room provides invertebrate control.
7. The anteroom doors are self closing and the outer door is fitted with seals to BC2 standard. Each door is glazed or fitted with a viewing panel.
8. Any emergency egress door from the plant containment must be sealed to maximum 250 microns aperture.
9. Personnel fit / remove overshoes in the anteroom on entry to / exit from, the facility. An alternative to this measure would be to a footbath or usage of dedicated footware that remains in the plant containment room or anteroom.
10. An air curtain at the containment room exit to the anteroom is desirable for flying or leaping invertebrates.
11. Material subject / not subject to biosecurity control (including waste) must be appropriately segregated and held in clearly labelled storage.

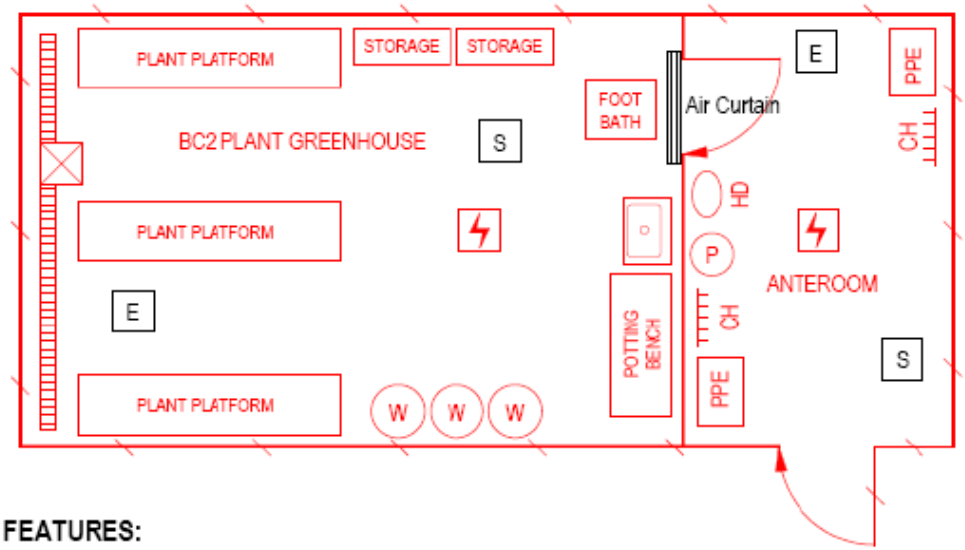
ACTIVITY CONSTRAINTS

1. Live plants may remain exposed within the containment enclosure and potting up may be undertaken within the enclosure.
2. Any work which aerosolises biosecurity material should be undertaken in a Class II biosafety cabinet, where practical. If it is not practical, the work must be undertaken with suitable PPE to control the biosecurity material.

BC2 Option 9: Plant Greenhouse with Exposed Plants and Potting Area

LEGEND

- BC2 Site Boundary
- HD — Hand Decontamination Station
- CH — Segregated Clean/Used Clothing Hooks
- PPE — Segregated Storage Clean/Reused PPE
- STORAGE — Segregated General Storage Clean/Soiled Reuse Items
- W — Segregated Waste Container
- P — Paper Towel Container
- Clean Up Sink
- Invertebrate Attractant & Killing Device
- Drain Sump & Strainer
- Gutter Drain feeding Sump
- Self Closing Door
- S — Supply Air Fitting
- E — Exhaust Air Fitting



KEY FEATURES:

1. Compliant plant BC2 site with anteroom, hand decontamination station, coat hooks, PPE storage and invertebrate attractant and killing device. Hand decontamination can be in the BC2 room near the exit or in the anteroom, as shown.
2. The outer anteroom door connects to a laboratory, unclassified space or the building exterior.
3. Any openings in the walls, roof or ceiling of the plant containment must be screened with fine mesh (250 microns) at the containment boundary.
4. The plant BC2 site (enclosure) must be sealed to a standard that is consistent with the screen aperture (no cracks or fissures exceeding 250 microns width).
5. The anteroom doors are self closing and the outer door is fitted with seals to BC2 standard. Each door is glazed or fitted with a viewing panel.
6. Any emergency egress door from the plant containment must be sealed to maximum 250 microns aperture.
7. A footbath is provided to reduce the bioburden on footware when exiting the facility. An alternative to this measure would be to use removable overshoes or dedicated footware that remains in the greenhouse.
8. Material subject / not subject to biosecurity control (including waste) must be appropriately segregated and held in clearly labelled storage.

ACTIVITY CONSTRAINTS

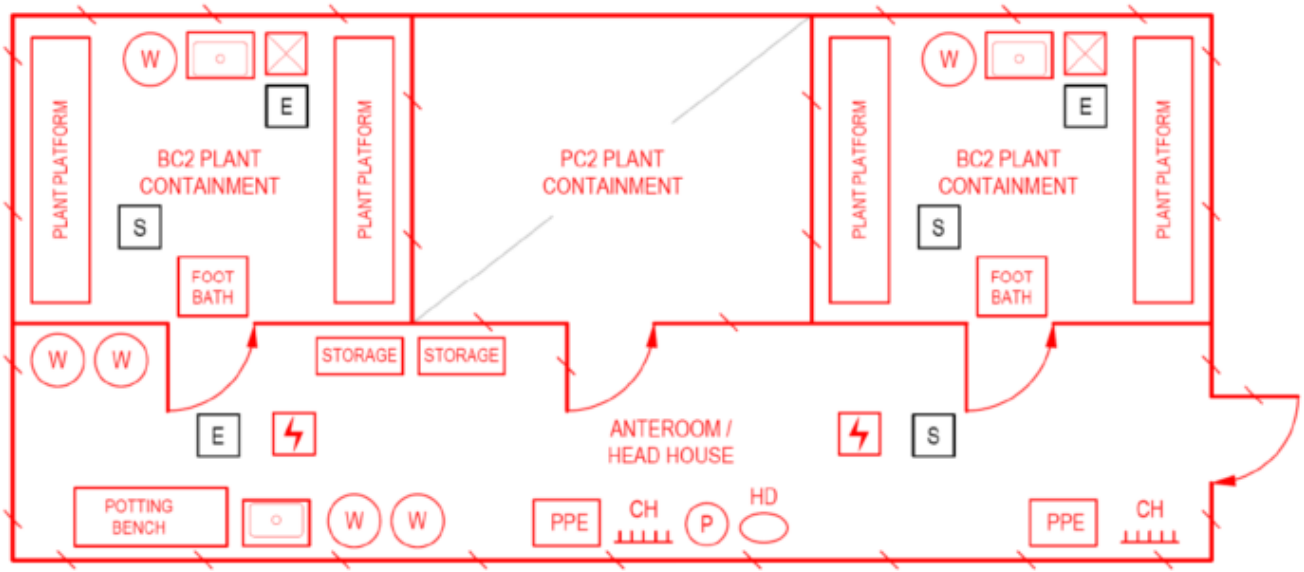
1. Live plants may remain exposed within the greenhouse and potting up may be undertaken within the greenhouse.
2. Any work which aerosolises biosecurity material should be undertaken in a Class II biosafety cabinet, where this is practical. If it is not practical, the work must be undertaken with suitable PPE to control the biosecurity material.

Note regarding robotic infrastructure with automated track style plant platforms:
Any area exposed to the track system must be regarded as part of the live plant environment. Both the greenhouse area and support spaces that are linked by the track system must therefore comply with BC2 plant containment conditions. If segregated (for example, by a wall that the the track system traverses), the greenhouse area and support areas may share a common anteroom. The system layout and hardware arrangement must provide access for routine and effective cleaning and decontamination of mechanisms and plant containers.

BC2 Option 10: Plant Greenhouse with multiple BC2 or BC2/PC2 Sites.

LEGEND

- BC2 Site Boundary
- HD — Hand Decontamination Station
- CH — Segregated Clean/Used Coat Hooks
- PPE — Segregated Storage Clean/Reused PPE
- STORAGE — Segregated General Storage Clean/Soiled Reuse Items
- W — Segregated Waste Container
- P — Paper Towel Container
- Clean Up Sink
- Invertebrate Attractant & Killing Device
- Drain Sump & Strainer
- Self Closing Door
- S — Supply Air Fitting
- E — Exhaust Air Fitting



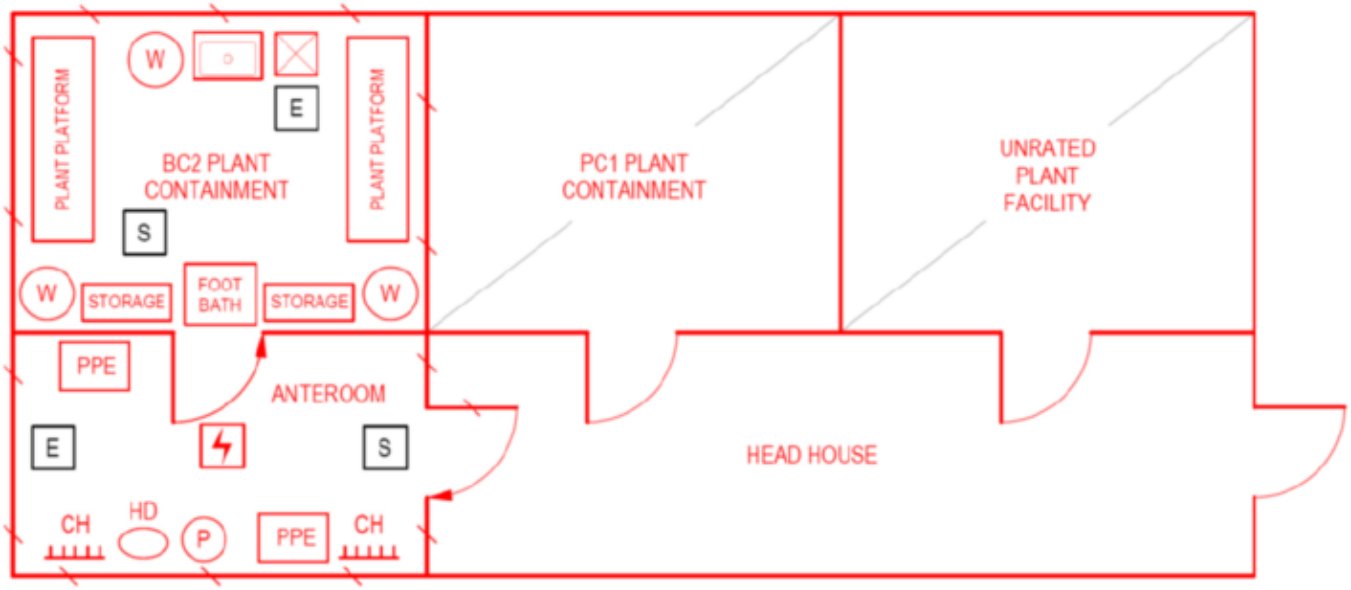
KEY FEATURES:

1. This application has several BC2 plant greenhouse rooms with a shared anteroom or head house. Both BC2 and PC2 plant containment may share the common anteroom or head house. If the shared room is a head house, it must comply with BC2 plant anteroom conditions.
2. A hand decontamination station, coat hooks, PPE storage and invertebrate attractant / killing device are located in the anteroom / head house.
3. Additional hand decontamination and dedicated PPE can be provided adjacent the exit from individual plant containment rooms where cross contamination is of concern.
4. The shared anteroom / head house is sufficiently large so that it can be soft segregated (zoned) into a clean zone (near the entry) and dirty zone (remote from the entry). The dirty zone can accommodate potting up activities for the plant facilities. The head house can accommodate additional functions such as plant support space, waste storage, storage of tools and equipment (including decontamination equipment).
5. The outer anteroom / head house door connects to a laboratory, unclassified space or the building exterior.
6. Openings in the walls, roof or ceiling of the plant containment must be screened with fine mesh screens (250 microns) at the containment boundary.
7. The BC2 site (enclosure) must be sealed to a standard that is consistent with the screen aperture (no cracks or fissures exceeding 250 microns width).
8. All the anteroom / head house doors are self closing and the outer door is fitted with seals to BC2 standard. The doors are either glazed or fitted with a viewing panel.
9. Any emergency egress door from the plant containment must be sealed to maximum 250 microns aperture.
10. Personnel traverse a footbath when entering or exiting an individual plantcontainment room. If cross contamination is not of concern, personnel may fit / remove shoe covers in the anteroom / headhouse or use dedicated footware that remains in the anteroom / head house dirty zone.
11. Material subject / not subject to biosecurity control (including waste) must be appropriately segregated and held in clearly labelled storage.

BC2 Option 11: Plant Greenhouse with multiple Rooms at Varying Containment Levels.

LEGEND

- BC2 Site Boundary
- HD — Hand Decontamination Station
- CH — Segregated Clean/Used Clothing Hooks
- PPE — Segregated Storage Clean/Reused PPE
- STORAGE — Segregated General Storage Clean/Soiled Reuse Items
- W — Segregated Waste Container
- P — Paper Towel Container
- Clean Up Sink
- Invertebrate Attractant & Killing Device
- Drain Sump & Strainer
- Self Closing Door
- S — Supply Air Fitting
- E — Exhaust Air Fitting



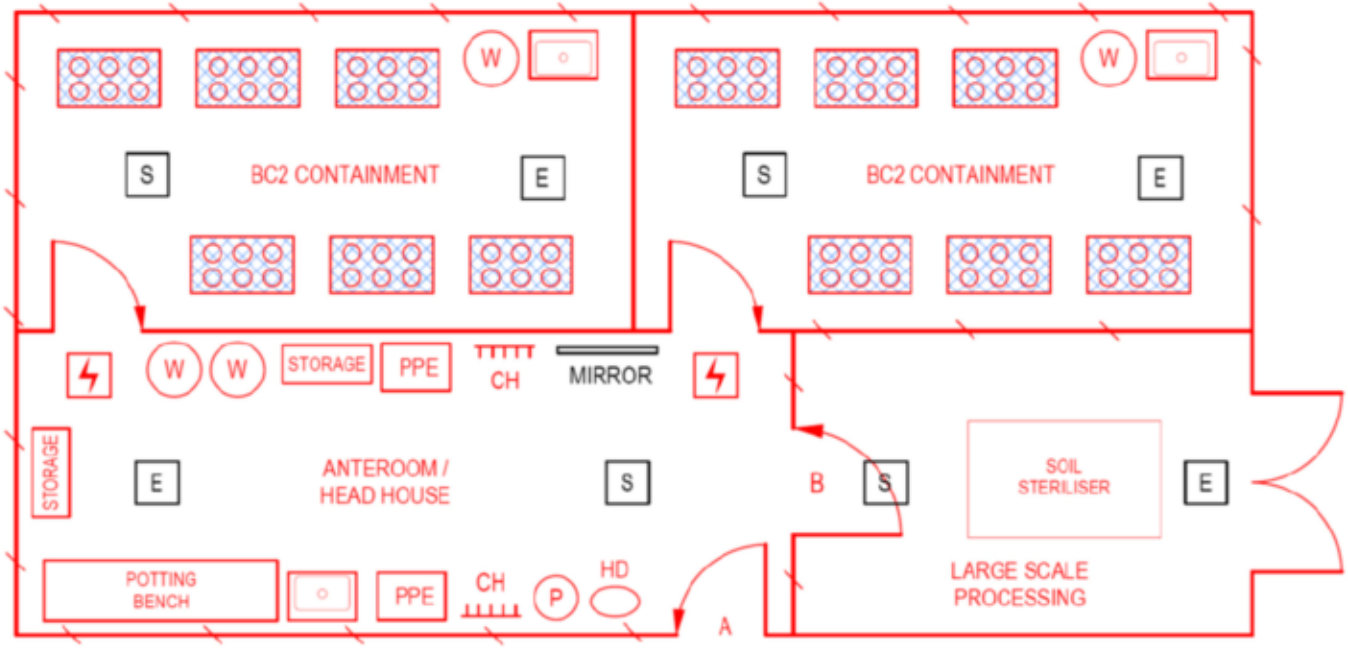
KEY FEATURES:

1. The BC2 plant containment requires a dedicated anteroom as the other rooms sharing the head house are not of equivalent containment level.
2. A hand decontamination station, coat hooks, PPE storage and invertebrate attractant and killing device are located in the anteroom.
3. Any openings in the walls, roof or ceiling of the BC2 site (enclosure) must be screened with fine mesh screens (250 microns) at the containment boundary.
4. The BC2 site (enclosure) must be sealed to a standard that is consistent with the screen aperture (no cracks or fissures exceeding 250 microns width).
5. The anteroom doors are self closing and the outer door is fitted with seals to BC2 standard. The doors are either glazed or fitted with a viewing panel.
6. Any emergency egress door from the plant containment must be sealed to maximum 250 microns aperture.
7. Personnel traverse a footbath when entering or exiting the plant BC2 site. Alternatively, personnel could fit / remove shoe covers in the anteroom or use dedicated footware that remains in the anteroom or BC2 plant containment.
8. Material subject / not subject to biosecurity control (including waste) must be appropiately segregated and held in clearly labelled storage.

BC2 Option 12: Plant or Invertebrate Site with Provision for Large Scale Processing such as Soil Sterilisation

LEGEND

- BC2 Site Boundary
- HD — Hand Decontamination Station
- CH — Segregated Clean/Used Coat Hooks
- PPE — Segregated Storage Clean/Reused PPE
- STORAGE — Segregated General Storage Clean/Soiled Reuse Items
- W — Segregated Waste Container
- P — Paper Towel Container
- Clean Up Sink
- Invertebrate Attractant & Killing Device
- Primary Invertebrate / Host Plant Containment
- Self Closing Door
- S — Supply Air Fitting
- E — Exhaust Air Fitting



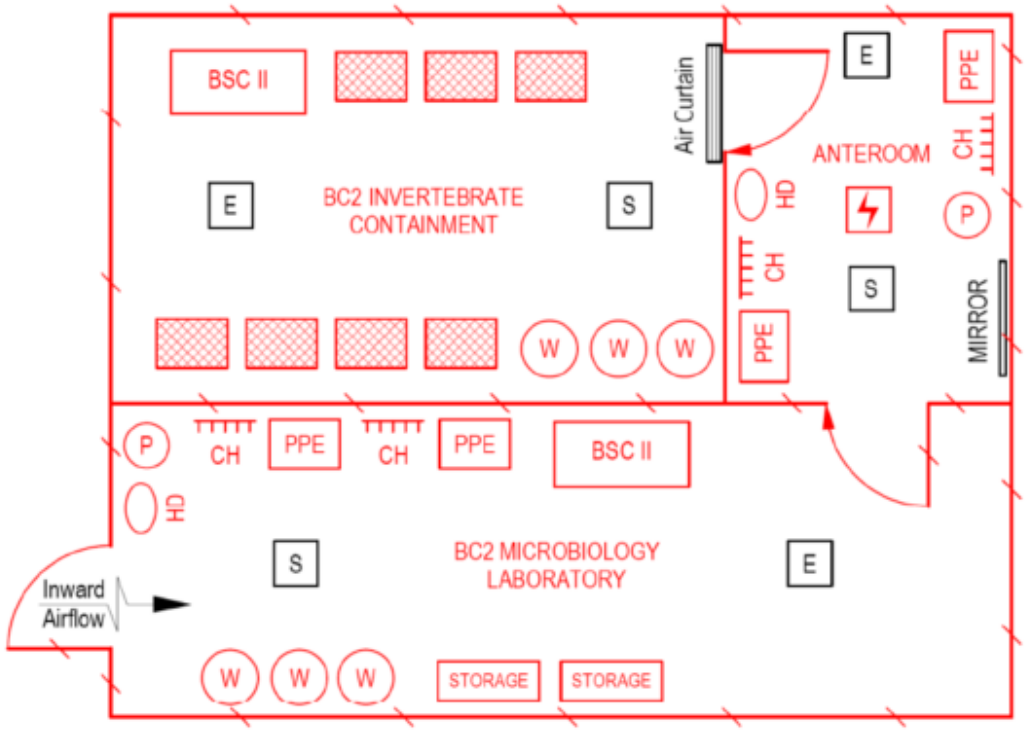
KEY FEATURES:

1. The major feature illustrated for this application is a large scale processing room for treatments such as soil sterilisation, fumigation etc. The external twin leaf door (which is difficult to seal) and the processing equipment, make this room unsuitable for use as an anteroom. For this reason, the processing room is sited directly on the exterior of a head house / anteroom.
2. The application could be either Plant or Invertebrate so elements appropriate to either or both alternatives are illustrated.
3. For invertebrate application, the invertebrates would be accommodated in primary containment (with or without plants). The containment rooms would provide secondary containment.
4. For plant applications, the containment rooms could provide primary or secondary plant containment.
5. A hand decontamination station, coat hooks, PPE storage and invertebrate attractant / killing devices are located in the anteroom / head house.
6. The shared anteroom / head house is sufficiently large so that it can be soft segregated (zoned) into a clean zone and dirty zone. The dirty zone can accommodate potting up activities. The head house can accommodate additional functions such as plant support space, waste storage, storage of tools and equipment (including decontamination equipment).
7. Openings in the walls, roof or ceiling of the BC2 site (enclosure) must be screened with fine mesh screens (250 microns) at the containment barrier. The BC2 site (enclosure) must be sealed to a standard that is consistent with the screen aperture.
8. All anteroom / head house doors are self closing and the outer doors (A & B) are fitted with seals to BC2 standard. If door (B) needs to be oversized for material transfer, it should remain a single leaf door so that seals to BC2 standard can be accommodated.

BC2 Option 13: Invertebrate Containment connected to BC2 Microbiology Laboratory

LEGEND

- BC2 Site Boundary
- HD — Hand Decontamination Station
- CH — Segregated Clean/Used Clothing Hooks
- PPE — Segregated Storage Clean/Reused PPE
- STORAGE — Segregated General Storage Clean/Soiled Reuse Items
- Invertebrate Primary Containment
- BSC II — Biological Safety Cabinet Class II
- W — Segregated Waste Container
- P — Paper Towel Container
- Invertebrate Attractant & Killing Device
- Self Closing Door
- S — Supply Air Fitting
- E — Exhaust Air Fitting



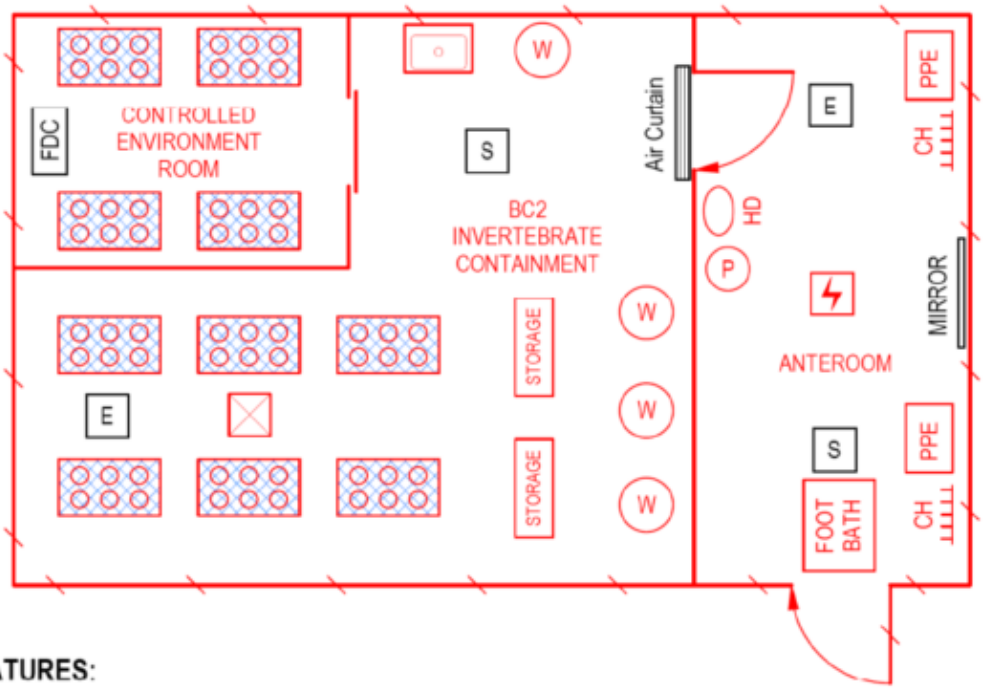
KEY FEATURES:

1. Compliant invertebrate BC2 site with anteroom, hand decontamination station, coat hooks, PPE storage, invertebrate attractant and killing device and mirror for personnel to examine themselves for any carried invertebrates. The microbiology laboratory cannot be used as an anteroom for this facility type.
2. Invertebrates are held in primary containment such as fine mesh cages, glass tanks etc. The room provides secondary containment. The entry / exit door connects to a BC2 microbiology laboratory.
3. Any openings in the walls, roof or ceiling of the invertebrate BC2 site (enclosure) must be screened with fine mesh screens (250 microns) at the containment boundary.
4. The invertebrate BC2 site (enclosure) must be sealed to a standard that is consistent with the screen aperture (no cracks or fissures exceeding 250 microns width).
5. The anteroom doors are self closing and fitted with viewing panels.
6. The door accessing the anteroom from the microbiology laboratory is fitted with seals to BC2 standard.
7. Any emergency egress door from the invertebrate containment must be sealed to maximum 250 microns aperture.
8. An air curtain at the containment room exit to the anteroom is desirable for flying or leaping invertebrates.
9. Any work that could aerosolise biosecurity material must be carried out in a Class II biosafety cabinet.
10. Material subject / not subject to biosecurity control (including waste) must be appropriately segregated and held in clearly labelled storage.

BC2 Option 14: Containment for Invertebrates with Plant Hosts

LEGEND

- BC2 Site Boundary
- HD — Hand Decontamination Station
- CH — Segregated Clean/Used Clothing Hooks
- PPE — Segregated Storage Clean/Reused PPE
- STORAGE — Segregated General Storage Clean/Soiled Reuse Items
- Primary Invertebrate / Host Plant Containment
- Clean Up Sink
- W — Segregated Waste Container
- P — Paper Towel Container
- Drain Sump & Strainer
- Invertebrate Attractant & Killing Device
- Self Closing Door
- S — Supply Air Fitting
- E — Exhaust Air Fitting
- FDC — Forced Draft Cooler



KEY FEATURES:

1. Compliant invertebrate BC2 site with anteroom, hand decontamination station, coat hooks, PPE storage, invertebrate attractant and killing device, footbath and mirror for personnel to examine themselves for any carried invertebrates.
2. Invertebrates and plant hosts are held in primary containment such as fine mesh cages, screened cabinets etc. The room provides secondary containment.
3. All surface within the BC2 site must be readily inspectable for escaped invertebrates. This will influence the number, location and detailing of storage units, equipment, fittings etc.
4. Any openings in the walls, roof or ceiling of the invertebrate BC2 site (enclosure) must be screened with fine mesh screens (250 microns) at the containment boundary.
5. The internal forced draft cooler (and other equipment) can be enclosed in 250 micron mesh to avoid it harbouring escaped invertebrates (non mandatory).
6. The invertebrate BC2 site (enclosure) must be sealed to a standard that is consistent with the screen aperture (no cracks or fissures exceeding 250 microns width).
7. The outer anteroom door has with seals to BC2 standard. The anteroom doors are self closing and fitted with viewing panels. They have a mechanism (eg interlock, traffic lights, viewing panels) to avoid simultaneous opening.
8. Any emergency egress door from the invertebrate containment must be sealed to a maximum 250 microns aperture.
9. An air curtain at the containment room exit to the anteroom is desirable for flying or leaping invertebrates.
10. Any work that could aerosolise biosecurity material must be carried out in a Class II biosafety cabinet.
11. Material subject / not subject to biosecurity control (including waste) must be appropriately segregated and held in clearly labelled storage.