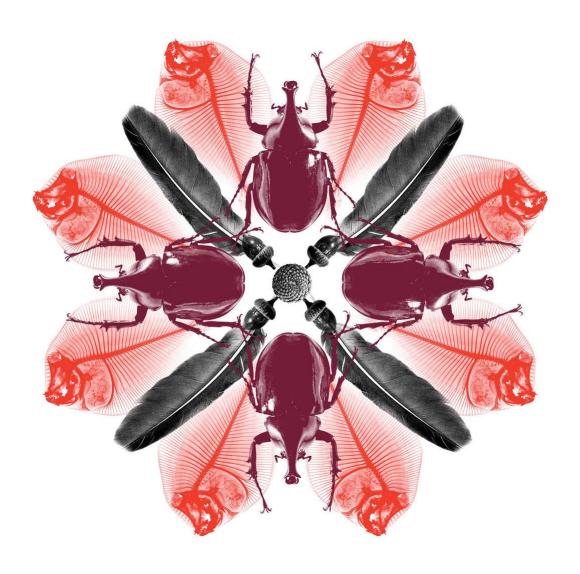


Approved Arrangement

for Biosecurity containment level 1 (BC1) informative text

First version1.0



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Department of Agriculture

Postal address GPO Box 858 Canberra ACT 2601 Switchboard 1800 900 090 Web www.agriculture.gov.au

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Version Control

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

Date	Version	Amendments	Approved by
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Part A - General information

1 Introduction

This document provides informative text that clarifies issues and also provides supplementary information to assist in interpreting the specific requirements for Biosecurity Containment level 1 (BC1).

The document 'Approved Arrangement (AA) Site Requirements for Biosecurity Containment Level 1 (BC1) Facilities' sets out the requirements that must be met by the Biosecurity Industry Participant (BIP) to ensure physical security around handling, risk and incident management, work practices, personnel, transport, biosecurity control, treatment and waste management.

The requirements are set out in 2 parts:

- Part 1 contains scope and generic requirements and applies to all BC1 facilities.
- Part 2 sets out the additional requirements for a certain type of facility. This is divided into 4 sections; Microbiological, Animal/Aquatic, Plant and Invertebrate.

The requirements for each of the facility type combinations are outlined below:

Requirements for approval as a BC1 Facility		
Facility Type	Parts and Sections Applicable	
5.11 Biosecurity Containment Level 1	Part 1 and Section 1 only of Part 2	
(BC1) Microbiological Facilities		
5.12 Biosecurity Containment Level 1	Part 1 and Section 2 only of Part 2	
(BC1) Animal and Aquatic Facilities		
5.14 Biosecurity Containment Level 1	Part 1 and Section 3 only of Part 2	
(BC1) Plant Facilities		
5.15 Biosecurity Containment Level 1	Part 1 and Section 4 only of Part 2	
(BC1) Invertebrate Facilities		

2 Further information

For more information on AA site requirements refer to http://www.agriculture.gov.au

3 Generic and BC1 facility classification and containment principles

The following table provides guidance on the facility type required for accommodating biosecurity goods (including organisms). The table includes details on:

- what level of containment a biosecurity good requires (i.e. examples of the types of goods requiring BC1 level of containment)
- the facility infrastructures and support services compromising a BC1 containment facility
- the generic actions which are permitted to occur within a BC1 facility.

The terms in the tables are used in the following way:

Facility Type – the facility classification based on the type of biosecurity goods accommodated. This classification is used to set out the requirements relating to the handling and containment of the applicable goods. The facility type includes microbiological, animal/aquatic, plant and invertebrate facilities where work such as research, analysis, or experimental activities occur. Activities may include, organism display and imported goods undergoing post arrival biosecurity control (the breeding and growing of plants, breeding and raising of animals). Within the table, the facility type is also defined and some general examples of the types of goods accommodated by each facility type.

Facility Infrastructure - type of area that can be used to provide containment of the goods and what structures and support services comprise the containment facility. A variety of containment facilities can be used, for example, larger animals can be held within a fenced enclosure while smaller animals may be housed in primary containment devices within a room. Plants may be in open fields or held within a permanent greenhouse structures. Facility infrastructure will include a containment facility which may or may not be within a building complex. Support facilities within a building complex may include, potting areas, instrument rooms, waste disposal areas and storage areas.

Activities - actions that are permitted with biosecurity goods within a particular facility type. For example, experimental activities with biosecurity goods, holding biosecurity goods for a specified period, or displaying biosecurity goods.

Goods – Imported items such as microorganisms, animals, plants, invertebrates and aquatic organisms.

Note: Assessments and the decision to direct an imported good to a containment facility is made in accordance with policy and on a case-by-case basis. In addition, the biosecurity risk will determine the type of structure and work practices required. Multiple classification approvals may be required. For example in vivo work with animals may require both microbiological and animal containment approvals.

MICROBIOLOGICAL			
FACILITY TYPE *This definition covers all containment levels (BC1-4)	FACILITY INFRASTRUCTURE - BC1	TYPES OF GOODS AND ACTIVITIES - BC1	
Microbiological includes in vitro and in vivo work with organisms including protozoa and other parasites, fungi, archaea, bacteria, algae, viruses and viroids.	The whole building or any part of a building (could be a whole floor) used for scientific and related work, including research, testing or analysis. The laboratory facility may include areas such as:	Type of goods and activities may include: food products for in vitro analysis soil and water samples for destructive analysis sealed culture vessels biological materials used in vaccine research or 	
	 instrument rooms preparation rooms cool rooms controlled environment rooms plant growth cabinets. 	 manufacture. Tissue cultures (e.g. live plant material kept in sealed, sterile, rigid devices such as sealed flasks, capped tubes, or lidded containers) 	
	The facility could also include: • waste disposal rooms/areas • storage areas.	Note: Any handling of the plant material outside the tissue culture flask (e.g. for multiplication or analysis) is to occur in a Class 2 Biosafety Cabinet located within the BC1 facility.	
	In general, office areas should not form part of a containment laboratory.		

ANIMAL		
FACILITY TYPE *This definition covers all containment levels (BC1-4)	FACILITY INFRASTRUCTURE – BC1	TYPES OF GOODS AND ACTIVITIES – BC1
Animals include all animal species with backbones that are land based. This includes imported small laboratory animals such as mice, rats, rabbits, guinea pigs and/or other rodents, or large non-laboratory animals (non-imported animals) such as pigs, sheep, goats, deer, camels, cattle, horses. Other animals included are primates and some marsupials.	 Any area used to contain animals subject to biosecurity control including experimental, breeding or infected animals. The area may be: part of a building(Usually used for smaller animals such as rodents normally kept in cages or isolators. Cages or isolators for smaller animals may provide primary containment). the whole building a fenced enclosure for larger animals. The animal facility may include integrated or separated areas for: 	Activities at an animal facility may include: • approved in vivo studies with Australian animals (non-imported animals).
	 experimentation post mortem examination waste disposal etc. 	

AQUATIC ORGANISM		
FACILITY TYPE *This definition covers all containment levels (BC1-4)	FACILITY INFRASTRUCTURE – BC1	TYPES OF GOODS AND ACTIVITIES – BC1
Aquatic organisms include vertebrate or invertebrate animals which live most of their life in water. It also includes animals (amphibians) which move readily from water to land and vice versa. Aquatic animals include, annelids (e.g. aquatic segmented worms), cnidarians (e.g. jelly fish), echinoderms (e.g. starfish), monotreme (e.g. platypus), amphibians (e.g. frogs, toads, newts, salamanders, axolotl), fish (e.g. zebra fish), molluscs (e.g. snails), crustaceans (e.g. crab, shrimp, krill), other marine and freshwater animals such as otters.	Any area used to contain aquatic organisms to be biosecurity controlled. The BC1 aquatic facility may include: • a fenced enclosure containing a pool or pond where larger aquatic organisms may be contained • the whole building • part of a building where smaller species could be contained in tanks or aquaria • post mortem examination • waste disposal etc.	Type of goods and work classified Aquatic may include: • aquatic organism display (e.g. for crustaceans) • research and analysis of some low risk molluscs.

PLANT		
FACILITY TYPE *This definition covers all containment levels (BC1-4)	FACILITY INFRASTRUCTURE – BC1	TYPES OF GOODS AND ACTIVITIES – BC1
Plants include all plant species, both land based and aquatic.	Any part of a building, part of separate greenhouse infrastructures, or freestanding facilities used to contain plants and limit the spread of propagules, and the entry and escape of invertebrate vectors carrying infectious organisms. BC1 plant facilities may include:	 Type of goods and work classified Plant may include: imported plants (e.g. yuccas, dracaena, cacti, rose scion wood for budding onto domestic root stocks) held for a specific containment period for disease screening for the purposes of release.

INVERTEBRATE		
FACILITY TYPE *This definition covers all containment levels (BC1-4)	FACILITY STRUCTURE – BC1	TYPES OF GOODS AND ACTIVITIES – BC1
Invertebrates include all multi-cellular animal species without backbones that are primarily land based as adults. This includes Hexapods (insects, springtails etc.) Chelicerata (spiders, mites etc.), Myriapoda (Centipedes, millipedes etc) annelids (worms and leeches), some of the Platyhelminthes (flatworms), some Mematoda, (roundworms) and some molluscs (e.g. terrestrial gastropods).	Any part of a building used to contain invertebrates or organisms associated with invertebrates. Invertebrate facilities may include: • separate housing and unpack rooms • controlled environment rooms • an experimental area • waste disposal rooms/areas • exhibition displays.	Type of goods and work classified Invertebrate may include: • research and analysis of some low risk chelicerata and crustacean (horseshoe crab, Christmas Island crab) • low risk invertebrate display.
Invertebrate facilities will also usually hold semi aquatic snails.		

Part B - Supporting information

This part of the document provides supplementary information for meeting specific requirements.

1 AA site construction issues

1.1 Signage

Signs inform personnel that they are entering a restricted area, one that contains goods hazardous or dangerous to humans, animals, plants and/or the environment.

Signs may display the biological hazard symbol as shown in the Australian/New Zealand (AS/NZS) Standards or may be a specific biosecurity control sign.

Consideration should be given to signs being securely affixed, durable, prominently displayed and able to be clearly read by persons approaching the area at all times. Consideration may also be given for new signs to have black lettering on yellow background and contain the words 'Biosecurity control area – no unauthorised entry or removal of goods, penalties apply' or words to similar effect. The type and level of containment may also be displayed. Existing signs with 'Quarantine control area' do not need to be replaced.

1.2 Microbiological facilities construction – general

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

1.3 Animal facilities construction - general

Consideration should be given to the type of species to be contained when determining the fencing, housing and handling facilities required. To ensure facilities are constructed to prevent escape, consideration should be given to the use of electric or buried fencing. The facility needs to be secure against incursions by feral or predatory animals. Additional fencing directly containing the animals could be provided so that animals are effectively held within double fencing or housed animals are within a fenced compound, preventing contact with other animals, people or objects and the dispersal of biosecurity control material outside the animal enclosure. The biosecurity containment will need to take into account the animal's ability to throw or disperse items, including water splash. Perimeter fencing (the outer fence of double fencing) may include cattle grids.

State legislation and codes of practice for the keeping of animals should be referred to when determining the appropriate fencing and housing requirements.

1.4 Plant facilities construction - general

Plant facility structures can consist of a range of covering materials, examples include, glass, polycarbonates, flexible film plastics such as polythene or rigid screen material. However mesh gauze screen materials are not appropriate as they do not maintain shape, structure and form.

When designing and constructing plant platforms, consideration needs to be given to the material used. In addition to the material being impermeable, structural voids also need to be avoided. Where structural voids cannot be designed out of the platform, capping or sealing may be required, particularly, when using metal tubing. Another design option may be to ensure that any structural voids are accessible and cleanable.

1.5 Invertebrate facilities construction - general

Consideration may need to be given to the colour of work surfaces to aid in the detection of escaped invertebrates.

1.6 Wash facilities

Consideration will need to be given to the type of equipment to be washed and decontaminated, while small non-soiled equipment may potentially be cleaned in a large sink, vehicles will require durable, non-porous hardstand (e.g. concrete or asphalt).

The size and type of a wash facility will not only depend on the equipment and/or vehicles to be washed, but also the equipment being used to undertake cleaning and disinfection activities. Large vehicles or equipment will likely require larger facilities to ensure containment of splash and residue. The construction of the facility may also affect the size of the facility e.g. impervious splash walls of an applicable height on 3 sides with coving at wall to floor junctions can provide containment of splash and residue and thus potentially reduce wash facility size.

PPE in wash facilities may include waterproof footwear and protective clothing such as aprons or full rain equipment. The type of PPE to be used may be determined following a risk assessment.

1.7 Storage areas

Screened openings such as that applied to storage areas for liquid nitrogen dewars are not in conflict with fully enclosed requirements of storage areas.

The biosecurity containment storage unit may be within the biosecurity containment storage area.

2 Risk & incident management

2.1 Suspected or established presence of pest or disease

The Biosecurity Industry Participant (BIP) needs to be vigilant for disease or pests in or on imported goods subject to biosecurity control. Typically these may include viruses, parasitic disease, bacterial infection, fungal infection or mite infestation.

Where an exotic pest or disease is identified within the confines of the AA site, the department will assist in developing and establishing a pest or disease management plan to be used by the AA site to control and or eradicate the outbreak.

2.2 Immediate reporting to the department

Immediate reporting means, on the same day or where this is not possible the next business day when an incident occurs outside of normal business hours (Monday – Friday, 9.00am-5.00pm). Reportable incidents may include major spillage, presence of pest or disease, biosecurity consignment not received, animal dies or is euthanized.

Contact to the department can be made by either phone or email. Contact details for the department can be found on the department's website.

2.3 Animal escape or entry

The BIP will need to consider feral animal control measures and ensure continued secure containment of the relevant species. Measures which could assist include:

- a) implementing external fence perimeter monitoring for the site and biosecurity areas such as
 - checking every three months and after storms for any breaks or holes in the fence
 - ensuring any breach in the fence is repaired immediately
- b) having professional control programs.

3 Management system

3.1 Identification of goods

A system would need to 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 which accurately identifies all goods subject to biosecurity control, will, and can, vary due to the type of goods. The size of containers and/or the type of goods should also be considered as labelling may not be possible. Such constraints will require another identification system to be implemented. Methods that could be used to identify goods subject to biosecurity control include:

- a) labelling goods in containers which also designates the volume or quantity of material
- b) a unique identifier such as bar coding or similar with reference to a logbook or other system
- c) growing a certain species of plants in designated and identified greenhouses
- d) labelling individual plant pots or containers in storage
- e) open field plants grown inside designated and clearly delineated areas such as using coloured pegs, markers or a partial enclosure
- f) having each animal identified by tattooing, microchip, ear tags, permanent branding or labels on cages/rooms of individually contained animals.

Labelling may need to be weather proof or resistant to cold temperatures to ensure identification of goods subject to biosecurity control is maintained.

4 Work practices

4.1 Specialised containment equipment

BIPs may deal with goods subject to biosecurity control in specialised containment equipment. This equipment may be located:

- outside the containment boundary where work, or manipulation is not undertaken on the goods subject to biosecurity control (e.g. computed tomography (CT) or magnetic resonance imaging (MRI) machines etc.)
- within the containment boundary where goods subject to biosecurity control are going to be manipulated within the equipment (e.g. anaerobic chamber).

5 AA site personnel

5.1 PPE contamination control

Where footbaths are used consideration will need to be given to contamination of the mats and solutions (containing a department approved disinfectant) in footbaths.

Changing will depend on usage and levels of contamination. To reduce footbath contamination, a separate bath using detergent within the water, next to the footbath, could be used. Such a footbath would be used only on entry to the facility and would not be subject to biosecurity control i.e. a department approved disinfectant would not be necessary. Additionally, stiff brushes to remove debris (e.g. dirt, manure, grass, leaves etc) or specially designed boot scrubbers could also be utilised. Out of direct sunlight, refers to placing the footbath where there is a barrier between the footbath and the sun (e.g. a glasshouse).

5.2 Security arrangements

Physical security measures may include a fence/gate/door that is lockable at all times when personnel are not present.

6 Transport of goods subject to biosecurity control

6.1 Movement of goods

The BIP can manage the movement of goods between:

- a) microbiological facilities (includes co-located and non co-located)
- b) co-located animal, aquatic, plant, and invertebrate facilities.

Department approval is required prior to the movement of live animals or live plants to non co-located facilities. BIPs will need to maintain records of the movements which will be audited by the department. This may be a phone log, file note, log book note, formal document or other such record.

Transportation may be between an AA site and another AA site (not of the same entity), between facilities (AA sites) of the same entity or between a facility and a linked storage unit. This transport includes surface transportation, including walking.

6.2 Movement to non co-located premises

A record of acceptance will be needed, confirming that the non co-located receiving facility is willing to accept the consignment and has received it intact. The record may be a phone log, file note, log book note, formal document or other such record.

6.3 Movement to co-located premises

Movement to co-located premises includes walking the goods subject to biosecurity control between sites (e.g. livestock such as sheep, cattle, goats (non-imported animals).

6.4 Transport regulations

The transport of goods subject to biosecurity control 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 (e.g. plants).

Documents such as Australian Standard (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. Other regulations such as the International Air Transportation Association (IATA), United Nations, Australia Post, Dangerous and prohibited Goods Packaging Guide etc. may also need to be consulted. It is the responsibility of the

sender to ensure compliance with all packaging and/or transport regulations not specifically detailed in department criteria or Import Permits.

7 Biosecurity treatments & waste management

7.1 Biosecurity treatments

The type of biosecurity control treatment that may be used will be determined by what item is being treated e.g. whether it is a good or waste subject to biosecurity control (could be microbiological, animal, aquatic, plant, invertebrate), equipment or a surface. The types of treatment include inactivation, disposal, and/or decontamination.

Examples of inactivation include dry or moist heat sterilization, gamma irradiation, alkaline hydrolysis, or other methods approved by the department.

Examples of disposal include high temperature incineration (to irreducible ash) at an incineration facility approved by the department, deep burial at department approved location, alkaline hydrolysis, or other methods approved by the department.

Examples of decontamination include disinfection using department approved disinfectant (refer to the department's website), or other methods approved by the department.

Goods/waste subject to biosecurity control and equipment may be treated by inactivation and disposal, and surfaces and equipment may be treated by decontamination. However BIPs will need to ensure the method of inactivation, disposal and decontamination used, is applicable and effective for the item being treated. Import Permit conditions may specify specific disposal requirements.

Further examples for the treatment of equipment include:

- a) disposing of specialised equipment (e.g. 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 (e.g. drenching or injecting guns, pruning tools)
- c) sterilisation or deep burial of, the detritus and / or animal / plant refuse contained in soil traps
- d) disposing of detritus and refuse from cleaning and decontamination of aquatic animal systems (freshwater and marine) such as traps/skimmers, and backwash water from the filtration system.

7.2 Biosecurity waste storage

Mechanisms to keep waste secure and protected from unauthorised access may include holding waste within a locked container and/or within a locked structure (e.g. building, fenced cage). Alternatives to having enclosed storage areas/collection points could be lockable biosecurity containers.

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

Where conditions/import permits allow, waste may be stored for the duration of the biosecurity control period, and then released as general waste if the goods are released from biosecurity control.

7.3 Biosecurity waste disposal

Department approved methods of liquid waste disposal include:

- a) a municipal sewage system, or
- b) hypochlorite treatment for plant and animal facilities, or
- c) slow sand filtration for plant facilities.

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

BC1 animal waste may be disposed of within the bounds of the AA site:

- a) pending release of the consignment for imported animals
- b) following 30 days from collection for animals undergoing in-vivo studies. This includes the use of solid material as an organic fertiliser, subsoil application, or the irrigating of the liquid on pastures.

7.4 Biosecurity waste treatment

Waste may be treated in another part of the entity where there are procedures for the 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.

8 Alternative Treatments - where sewer is not available

8.1 Plant & animal liquids - hypochlorite treatment

8.1.1 Construction

Where a hypochlorite treatment system is proposed, the following should be considered:

- a) a two tank system, consisting of a liquid waste storage tank and treatment tank (assists in ensuring activities such as plant irrigation can continue)
- b) an automatic dosing pump
- c) mechanical agitation. This could occur by either using a mixer or pump which recirculates the water through the tank
- d) structures, such as bunding that prevents the spillage of raw or partially treated liquid waste from, for example, leaking seals or while replacing seals on pumps, changing filters, cleaning screens or tank or pipe failure.

8.1.2 Treatment

Hypochlorite can be used in either liquid or granular form i.e. sodium hypochlorite (liquid form such as bleach) or calcium hypochlorite (usually granular). The BIP should be aware that:

- a) calcium hypochlorite will have less effect on pH, as opposed to sodium hypochlorite which will likely raise pH
- b) calcium hypochlorite is more likely to maintain its strength, as opposed to sodium hypochlorite which is less stable
- c) calcium hypochlorite has greater available chlorine than sodium hypochlorite.

To ensure that hypochlorite has been added correctly, and to monitor the correct concentration of free chlorine, testing the solution for chlorine content is necessary. This can be undertaken using a swimming pool test kit, which is widely available and are an easy and convenient way to assess chlorine concentration. BIPs need to be aware that the necessary concentration for the initial test considerably exceeds the ranges shown in a test kit

(measuring a maximum 5parts per million (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 (i.e. 50) to give the true concentration of chlorine.

To assist in ensuring that concentrations of hypochlorite, initially added, are appropriate, load profiling can be used. Load profiling would involve determining the approximate hypochlorite concentration required to be added to the treatment tank to achieve a consistent 200 ppm (minimum) taking into account the type of circulation activity. The amount of hypochlorite needed to be added, is likely to be well above the 200 ppm required at the initial test. The use of load profiling to assist in ensuring that initial concentration is correct will reduce the need to add further hypochlorite and undertake retest to ensure the concentration is at least 200 ppm.

Once treated the BIP may discharge liquid waste water to any location in line with other regulatory authorities.

8.2 Alternative slow sand filtration (SSF) treatment - plants

When proposing to construct a slow sand filtration system, consideration needs to be given to the volume of waste water to be treated as this will determine the size of the filter surface area required. The construction of any system needs to consider the need for periodical shut down for cleaning and/or repairs.

8.2.1 Construction

A slow sand filter can be constructed in a tank with non-reactive surfaces such as plastic or fibreglass lined galvanised tanks, poly or concrete tanks. Incorporating a pump from the overflow tank or from the filter water reservoir will assist in ensuring that the water layer is maintained at a constant depth. This is particularly important as the filter should never stand with an exposed dry top layer. The slow sand filtration process involves maintaining the top 50 to 100 millimetres(mm).

The filter bed can consist of a uniform fine particle sand mixture or alternative media such as granulated rockwool. To assist in monitoring filter head loss an open clear pipe fixed to the exterior of the filter can be used. When the flow rate slows (as indicated by head loss) the water layer above the sand bed can be drained and the particulate matter, silt etc. that was slowing the water flow scraped off. The top layer of sand should also be removed (20mm) as it will contain some suspended organic matter and silt. In a granulated rockwool filter, some settling may occur over time and cleaning may also involve the need to top up with more rockwool.

The installation of two filter beds should be considered to ensure that liquid waste can be passed through one filter, whilst the other is being cleaned.

A slow sand filtration system should also include a drainage system. This could consist of:

- 1) 3 graded gravel layers, 2-8mm, 8-16mm, 16-32mm when using sand, or a geo-textile fabric and one graded gravel layer can be used when using granulated rockwool
- 2) connecting perforated drainage pipes across the base.

8.2.2 SSF cleaning and replacement

To ensure the SSF continues to provide clean water the BIP will need to implement arrangements for filter cleaning. These arrangements would need to include:

a) closing the inlet valve

- b) 24 hours later closing the outlet valve
- c) removing the top 20 30mm of filter media
- d) following filter start up steps as detailed in requirements.

The BIP should consider replacing the filter when the filter media reaches the minimum thickness of 1metre. This would include:

- a) removing the residual filter media down to the gravel bed
- b) refilling the filter bed to maximum level with clean media
- c) following the SSF start up steps as detailed in requirements.

8.3 Demonstration of efficacy for alternative liquid waste methodology

The BIP will need to provide information containing the efficacy of any alternative liquid waste treatment. Such information may include the name of the treatment, how the treatment works and evidence (e.g. trial tests) the treatment is effective against the relevant pest/disease.

9 Dry & moist heat sterilisation

9.1 Logging time and temperature

Where autoclaves do not have thermocouple ports, logging of time and temperature may be undertaken using wireless data loggers. Alternatively, an operator may use a bacterial enzyme indicator.

9.2 Autoclave bags

When using autoclave bags BIPs will need to consider how 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 for inactivation.

9.3 Biological validation

Biological validation of steriliser cycles can be achieved by using commonly used biological indicators such as those detailed below.

Process	Species	Incubation temperature
Steam under pressure	Geobacillus Stearothermophilus	56 degrees Celsius
		Rapid enzyme BI (60°C)
Dry heat	Bacillus Atrophaeus	37 degrees Celsius
Sub-atmospheric	Geobacillus Stearothermophilus	56 degrees Celsius
steam		

9.4 Load profiling - sterilisation

In lieu of the individual steriliser cycle validation, the BIP may undertake load profiling to develop effective validation processes for generic or particular loads.

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

When developing and ensuring load profiling is effective, BIPs need to consider the 'validated state' of the steriliser arising from the following factors; the mechanical state of the steriliser, the sterilisation process programmed into the machine, type and size of goods and any packaging, loading of the steriliser, and other factors such as cleaning of materials, which can have an effect on the reliability of the overall decontamination process.

Load profiling is an intensive exercise involving planning, evaluation of test methods and systems, and the collection and assessment of data when performing the load profiling tests. This process requires repeated physical and biological testing and considerable record keeping. Different loads will require the establishment of new load profiles. The establishment of this approach is more rigorous than routine monitoring activities.

9.5 Content of load

Consideration may need to be given to the liquids being sterilised i.e. salt water will require the steriliser to be constructed of appropriate material to prevent corrosion.

10 Animal husbandry & management

10.1 Bedding replenishment

Any cleaning regime for an animal enclosure, implemented by the BIP will need to address the removal and replacement of animal bedding when this is used.

10.2 Periodic monitoring of facilities

BIPs should consider the periodic monitoring of facilities to ascertain when cracks and crevices in facilities appear. Any cracks and crevices should then be sealed to prevent them from harbouring pests.

11 Horticultural & Agricultural Practice

11.1 Observation methods

The BIP will need to provide a record detailing the observation method used i.e. the technique used to monitor pest and disease.

11.2 General practice

Segregation can be achieved for example by providing different work benches.

12 Terminology used in BC1 requirements

Term or acronym	Explanation
Adjacent	Adjoining each other with the same common side touching or abutting.
	The process of verifying and making adjustments (where
	necessary) to ensure operation within specified tolerance:
	1. verification – ascertaining measurement is within specified tolerance
	2. calibration – adjustments to measurement to bring within
Calibration	specified tolerance, only where the measurement is outside of
	specified tolerance (calibration is not required where
	measurement is within specified tolerance)
	3. re-verification – ascertaining adjustments to measurement is
	within specified tolerance.
	Able to remove contaminants ensuring preservation to the
Cleanable	original state or condition and free of contaminating matter. May
Cleanable	be by brushing, wiping or washing.
	A group of animals under a single in- vivo approval regardless of
Cohort	inoculation date.
	Substances, usually liquids, powders, sprays, or granules, that are
	used to remove dirt, dust and stains from surfaces and avoid the
Common cleaning agents	spreading of dirt and contaminants. Common types are acid,
	alkaline or neutral. Examples include bleach and vinegar.
	A system (includes both structural requirements and procedural
Containment	practices) for confining biosecurity goods within a defined space.
	The barrier, border, or the limits of an approved defined space
	where goods are handled or dealt with. For example, the fence
Containment boundary	containing the BC1 animals, or the room containing the biological
Containing Countain,	safety cabinet and where work is undertaken on biosecurity
	goods.
December of the second	Means a procedure that eliminates or reduces microorganisms to
Decontamination	a safe level.
	A shortcoming, or failing which may affect containment such as
Defects	the loss of seal on a cold room, major cracks in the floor, walls,
	fences or transport containers.
Birry College College	A substance made with or produced from the original goods
Direct or indirect derivatives	subject to quarantine.
Diameter diameter (f)	The destruction of the goods subject to biosecurity control at the
Disposal (or to dispose of)	AA site or another department approved facility.
Door jamb	The surrounding case (usually timber or metal) in which the door
Door jamb	opens and closes. Each door jamb has sides and a header.
	Fully enclosed within walls, doors, floors and roof. The facility ma
Enclosed BC1 facilities	or may not have ceilings, windows, and/or screened openings.
	Such facilities have floors that are impermeable to liquids.
	Enclosed plant biosecurity control facilities include greenhouses
	constructed from glass, polycarbonate, flexible film plastics such
Enclosed BC1 plant and	as polythene (polyhouses/igloos/tunnel houses) and approved
animal facilities	screen. Enclosed animal facilities include animal houses which
	may be an enclosed shed, a room, or facilities may be constructed

	T .
Equipment	An item, apparatus or device used to handle, facilitate or work with goods subject to biosecurity control.
Filter media	That portion of a filtration system that provides the liquid-solid separation, 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 that is a structure permeable to liquids and gases.
Flexible plastic greenhouse	A greenhouse structure in which the enclosing surface is polythene/polyethylene. For example, tunnel, igloo, poly house.
Footbath station	The identified location (e.g. at the entry of the facility) where the footbath, stiff brush to remove mud, and clear instructions outlining procedures and minimum contact times are placed. The area may also include a separate bath of detergent for precleaning.
	A substantially or partially enclosed work station that is designed to: a) prevent the spread of fumes
Fume cabinets	b) exhaust fumes providing dilution or filtrationc) reduce the risk to associated appliances.For biosecurity control purposes this includes fume cabinets, fume cupboards and fume hoods. They may be ducted and/or recirculating.
Glass/polycarbonate greenhouses	A greenhouse structure in which the enclosing surface is glass or polycarbonate. Both materials resist deterioration from the elements.
Hands-free decontamination station	The identified location (e.g. at the entry of the facility) where a dedicated hands free basin or alternative method of decontaminating hands are placed. The hand basin or alternative means of decontaminating hands must be operated using a sensor, or any part of the body except the hands (e.g. elbows, feet). Alternatives to hand basins include: a) dispensers fitted with approved antiseptic solutions b) a sink of hands free operation.
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.
In vitro	Studies taking place in a test tube or other laboratory equipment.
In vivo	Studies in which the effects of various biological entities are tested on whole, living organisms usually animals including humans, and plants as opposed to a partial or dead organism, or those done in vitro.
Lawn A stretch of grass-covered land, especially one closely mo	
Major spillage	A loss of goods/waste/material 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.

Microorganisms	A microscopic living organism, which may be a single cell or
	multicellular. Include protozoa and other parasites, fungi, archaea,
	bacteria, algae, viruses and viroids.
One physical site address	The facility is within the same common boundary as the approved
	storage area and must be approved under the one organisation or
On an his assemble as a stand	company.
Open biosecurity control	The designated area within an AA site where goods that are
area	subject to biosecurity control are exposed to the elements. Refers to microorganisms, animals, plants, invertebrates and
Organism	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.
Plant material	Any part of a plant subject to biosecurity control (e.g. tissues,
	root, stem, leaf etc.).
Post arrival biosecurity	The period of time between importation of the goods and their
control (PABC) period	release from biosecurity control.
	A transmissible pathogenic agent which has proteinaceous
Prion	particles that lack nucleic acids. Diseases caused include Bovine
	Spongiform Encephalopathy and Scrapie.
	Biosecurity containment storage area/unit is where goods/waste
	subject to biosecurity control are kept, where no work is
Biosecurity containment	undertaken with goods/waste subject to biosecurity control, and
storage area/unit	which may be located outside the containment boundary.
	Examples of containment area/unit include freezers, refrigerators, cool rooms etc.
Biosecurity containment	Activities undertaken with goods subject to biosecurity control
work	including, manipulation, growing and breeding of goods.
WOIK	Any material that has come in contact with biosecurity controlled
Biosecurity material	goods/waste (e.g. bedding, faecal matter, animal toys, leaf litter,
Diosecutity material	packaging etc).
	A loss of goods/waste/material subject to biosecurity control
Biosecurity spill	outside the confines of the facility.
Descrid	A document stating results achieved and/or providing evidence of
Record	activities performed.
Screen/shade house	Structures which are covered in insect screening material or a
	layer of knitted, woven, or punched opaque material that is
	constructed in such a way that sunlight, air and moisture can pass
	only through the spaces between the strands of the material and
	is able to maintain shape, structure and form.
Sealed primary containment	The constraints immediately surrounding the goods, such as
device Slow sand filtration (SSF) Smooth	sealed flask, capped test tube, lidded container or other
	receptacle.
	Slow sand filters are used in water purification for treating raw
	water to produce a potable product. A uniform, even surface free of tissues, gaps and with seams
	which are flush to the remaining surface.
Soil trap	A filtration mechanism designed to trap and hold solids such as
	detritus, animal/plant refuse or other particulates.
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.
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Support areas	A common area that may either be within or outside the containment boundary but still within the same physical site as the AA site, with equipment used for goods subject to biosecurity control. Examples include imaging, potting up, goods receival and steam sterilisation treatment 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	Includes the processes (e.g. information and security requirements at the facility of origin and receipt) involved with the physical movement of quarantine goods from one premises/location to another approved premises/location.
Unauthorised access	Restricting the ability for persons not authorised/employed by the BIP to enter areas containing goods/waste subject to biosecurity control.
Waste	Goods subject to biosecurity or biosecurity material that: (a) is proposed to be disposed of; or (b) is disposed of; or , in relation to a good, means waste associated with the product after it is disposed of. For the purposes of containment, waste can be divided into liquid and solid waste.
Liquid waste	 All contaminated or potentially contaminated liquids for disposal in enclosed facilities and imported water being dealt with in both enclosed and open facilities. This may include, at BC1: Microbiological facilities; culture media, buffers and wash water from the cleaning of glassware (e.g. petri dishes, pasteur pipettes, beakers etc.), equipment (e.g. pestle and mortar, spatula, laboratory mills, testing and measuring devices such as pH Meter, analysers etc.) and containers which have been used to store or transport goods subject to biosecurity control. Animal facilities; wash water from the cleaning of crates, cages, and transport vehicles where the animal is transported in a container which enables external air circulation. It includes wash water from enclosed (animal housing) animal facility cleaning, and fresh water arriving with animals. Aquatic facilities; liquid from aquatic storage tanks in equipment rooms, liquid from aquatic environments such as pools, ponds, 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 (e.g. nets, diagnostic or monitoring equipment). Plant Facilities; waste water from plant irrigation activities in enclosed (greenhouses) facilities, and the cleaning of pruning or other equipment within these facilities. Invertebrate facilities; culture media, water held or used in containers with invertebrates and wash water from the cleaning of cages or isolators. Excludes waste water from: the cleaning of animal troughs

	open housing and handling facilities
	hand basins or hand washing
	 plant irrigation activities at open greenhouses and open field and the cleaning of all equipment within these facilities.
Liquid waste treatment	Liquid waste at BC1 facilities may be disposed through the sewerage system, treated by an approved method or in some circumstances stored pending successful completion of any PAQ period. All liquid waste from low risk BC1 and medium risk BC2 containment facilities can be treated outside the facility. However, all such waste must be contained until treatment. Wash water from enclosed (animal housing) facility cleaning must be direct to sewer or collected in containers that can withstand an approved treatment. Wash water from open housing and handling facilities may be dispersed over open ground within the biosecurity containment boundary.
Solid waste	All contaminated or potentially contaminated solid biosecurity controlled materials for treatments, may include: • at BC1 Microbiological Facilities; culture, organism or good subject to biosecurity control, by-product, derivative, used petri dishes, cultures, sharps, damaged or broken containment equipment for disposal, gloves and other disposable PPE (when used). • at BC1 Animal Facilities; animal carcasses, inoculation equipment, drenching or injecting gun, thermometer cleaning/wiping, gloves and other disposable PPE. It also includes containment structures in which animals are held indoors and animal waste e.g. faecal material, vomit, hair and bedding. • at BC1 Aquatic Facilities; aquatic organism carcasses, faecal and other biosecurity controlled material removed from aquatic storage tanks or from other aquatic environments such as pools, ponds, 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 etc. • at BC1 Plant Facilities; plants and plant material from open and closed facilities (e.g. rejected plants, pruning), any diseased biosecurity controlled material, 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 enclosed (greenhouse) facilities. • at BC1 Invertebrate Facilities; invertebrates, host and/or environmental biosecurity controlled materials (e.g. plants or their parts), containment structures in which the invertebrates are held, damaged or broken equipment, gloves and other disposable PPE (when used).

	 sharps which are segregated into their own category. Sharps include syringes with needles, broken glass, scalpel blades and glass pasteur pipettes.
Solid waste treatment	All equipment at microbiological, animal, aquatic, invertebrate and enclosed plant facilities at the BC1 level may be decontaminated then disposed. Solid waste at BC1 animal and plant facilities may be stored, with department approval and then released as general waste pending successful completion of any PAQ period.
Perishable waste	Waste that is liable to rot or decay. Examples include fresh fruit/vegetables and other non-shelf stable food products.
Non-perishable waste	Waste that is not liable to rot or decay. Examples include drenching or injecting gun and used petri dishes.
Work surfaces	Any flat surface where goods subject to biosecurity control are handled, dealt with and/or manipulated etc. Examples include bench tops, work benches. For: BC1 this includes the top and edge of the surface. BC2 this includes any exposed bench surfaces, such as cutouts, ends and the underside.
Write up area	Designated areas within the containment barrier that are used for result write-up. These areas must meet BC standards.