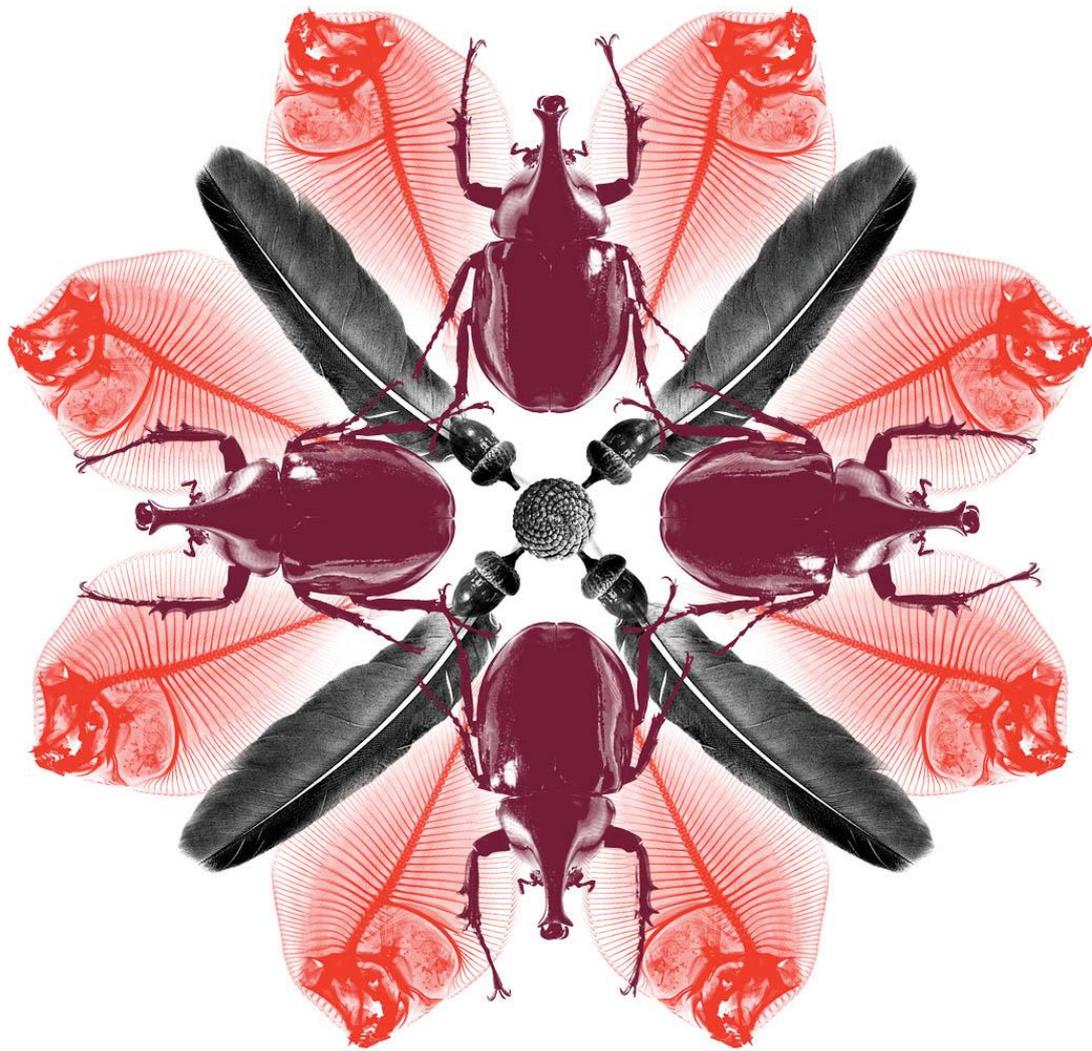


Approved Arrangements

For 7.4—Biosecurity insectary
containment level 4
Requirements—Version 3.0



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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.

Approved Arrangements: 7.4—Biosecurity insectary containment level 4

Date	Version	Amendments	Approved by
9 May 2011	1.0	Revised document.	Co-regulation and support program
30 June 2013	1.1	Updated to reflect DAFF branding.	Industry Arrangements Reform program
2 May 2016	2.0	Updated to reflect new departmental branding and template. Removed requirements for: written procedures and meeting 3rd party requirements.	Approved Arrangements section
16 June 2016	3.0	Updated references to the department and the <i>Biosecurity Act 2015</i>	Approved Arrangements Section

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Guide to using this document

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

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

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

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

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

Definitions

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

Other documents

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

Nonconformity guide

The nonconformity classification against each criterion is provided as a guide only. If more than one nonconformity is listed against a requirement, the actual nonconformity applied will correspond to the gravity of the issue. The nonconformity recorded against any requirement remains at the discretion of the biosecurity officer.

Nonconformity classifications are detailed in the AA General Policies.

AA Requirements

Table 1 Scope

Requirements	Nonconformity guide
1.1 Sites utilised for goods subject to biosecurity control which pose significant risks to animals, plants or humans if the insect, pest or disease associated with them spreads outside the site and from which significant economic impact would result to the community or environment.	Not applicable
1.2 The facility must meet the PC4 design and construction requirements as specified in Australian/New Zealand Standard TM 2243.3:2002 and 2982.1:1997. The applicable parts of these standards are outlined in Part 3 of this document.	Not applicable
1.3 BIC level 4 or Physical Containment (PC) Level 4 is the whole of the space approved by the department in accordance with the department's class requirements for AA sites 7.4.	Not applicable
1.4 A BIC4 site may incorporate access and supporting rooms and interconnecting corridors or common space areas after entering through an airlock. It may compromise a number of like rooms such as interconnecting insectaries.	Not applicable
1.5 These sites must be physically separate from offices used by containment facility personnel and must include a body shower and inner and outer change room. Toilet cubicles and drinking water appliances may be included.	Not applicable
1.6 The site must be housed in a separate building or must form an isolated part of a building.1.7	Not applicable
1.7 Class 7.4 sites are not approved for the distinctive needs of other biosecurity operations, except where the site has separate approval under another class. Note: A Biosecurity Industry Participant (BIP) may keep more than one kind of goods in the one facility, provided the applicable requirements for all those kinds of goods are met.	Not applicable

Table 2 Requirements for approval

Requirements	Nonconformity guide
<p>2.1 The applicant must provide the department with documentary evidence (certification) that the site complies with:</p> <p>The applicable design and construction standards of the Australian/New Zealand Standard TM (AS/NZS) 2982.1:1997 and 2243.3:2002 (the relevant standards are listed in Part 3 of this document).</p> <p>The minimum requirement for obtaining this evidence is:</p> <ul style="list-style-type: none"> • by contracting a department approved 'third party' assessor • department-approved third party assessors can be found on the department's website. 	Critical
<p>2.2 An air leakage rate, at a differential pressure of 200 Pa, of no more than 120L/min (upon facility commissioning).</p>	Critical

Table 3 Requirements to maintain approval

Requirements	Nonconformity guide
<p>3.1 Any changes to the site should be carried out in a manner which preserves consistency with:</p> <ul style="list-style-type: none"> • the third party certification • conformation to the AA site requirements • compliance with the relevant design and construction standards in the Australian Building Code • the conditions of approval • continues to comply with any subsequent amendments or revisions to AS/NZS 2982.1:1997 and 2243.3:2002. <p>A change that significantly affects the overall containment system requires re-certification. This would include structural changes to 40 per cent of the building. If a BIP has any doubt as to whether a proposed change to the physical structure of the site, has any potential to reduce the level of biosecurity integrity, department approval must be obtained before the change is implemented.</p> <p>To ensure conformation to the AA site requirements, the department must be notified in writing:</p> <ul style="list-style-type: none"> • no less than 15 working days prior to any alterations to site operating arrangements (Standard Operating Procedures) • within 15 working days of any alterations to site management arrangements 	Major or critical
<p>3.2 At all times after approval an air leakage rate of no more than 1200L/min should be maintained.</p>	Critical
<p>3.3 Air leakage testing must be undertaken every three (3) years, to ensure the air leakage rate is no more than 1200L/min.</p>	Critical

Table 4 Hygiene and isolation

Requirements	Nonconformity guide
<p>4.1 The site must be managed to ensure that effective separation is maintained between cleared imported goods, domestic goods, imported goods awaiting biosecurity clearance, and export goods in the case of a department approved dual import and export site. BIP must also recognise that specific Import Permit conditions and inspection procedures for some commodities may apply in addition to these requirements.</p> <p>Where cross-contamination occurs, goods shall be treated as goods subject to biosecurity control.</p>	Major or critical
4.2 The site must be managed in a way that ensures that buildings and/or structures are maintained in a state of good repair.	Major
4.3 An effective pest control system must be in place to ensure that sites are managed in a way that effectively isolates goods subject to biosecurity control from environments in which pests and diseases are likely to become established.	Major
4.4 An insectary that has direct external access via an anteroom must have an effective vegetation suppression program in place. The program must ensure that open areas within 30 metres of the site are managed in a way that effectively isolates goods subject to biosecurity control from environments in which establishment could occur.	Major
4.5 Where a site is within 30 metres of a site boundary, the department may require additional measures to be implemented such as outdoor monitoring.	Major

Table 5 Biosecurity area

Requirements	Nonconformity guide
5.1 The biosecurity area must be of a size commensurate with the proposed quantity of goods being handled.	Major
5.2 Biosecurity areas must have illumination to a sufficient level. Within a building this will require a minimum 400 lux in storage areas and 600 lux in biosecurity inspection areas.	Minor

Table 6 Security

Requirements	Nonconformity guide
6.1 Security measures must be in place that prevent access and removal of biosecurity goods by unauthorised persons.	Major or critical
<p>6.2 Biosecurity areas where goods subject to biosecurity control are stored or handled must display biosecurity signage to assist with effectively managing the security of these goods. These signs are to be:</p> <ul style="list-style-type: none"> • secured on a buildings, racks, fences, gates and doors and be visible at all times • permanently affixed • professionally made • made to state 'Biosecurity Area – No Unauthorised Entry or Removal of Goods, Penalties Apply, (<i>Biosecurity Act 2015</i>)', or 'Quarantine Area – No Unauthorised Entry or Removal of Goods, Penalties Apply, (<i>Quarantine Act 1908</i>)' or as directed for specific biosecurity operations • on a yellow background, with black lettering. <p>Note 1: Cardboard and paper signs are not acceptable. Note 2: Where new signs are being produced, they should use 'biosecurity' not 'quarantine'.</p>	Minor
<p>6.3 Signs on external structures must be:</p> <ul style="list-style-type: none"> • a minimum 600 mm x 400 mm with lettering a minimum 25 mm height • weatherproof and resistant to the elements. <p>Signs within structures must be a minimum 295 mm x 210 mm with lettering a minimum 8 mm height (example attached).</p>	Minor
6.4 The department must be immediately informed of any incidents which could significantly compromise the biosecurity integrity of the site. This may include structural damage, electrical breakdowns, escapes or unauthorised entry and the removal of material subject to biosecurity control.	Major or critical
<p>6.5 To assist in effectively managing the security of the site the following must be applied:</p> <ul style="list-style-type: none"> • a logbook must be kept, recording visitor names, their company and the time and date of visits • the name and telephone number of the site manager or other responsible person must be displayed near access doors • a biosecurity sign be displayed on the entry door to the site. Such signs are to include requirements as stated in 3.3 (b), and in addition, state 'Insectary Containment – BIC4 (or QIC4) Facility'. <p>Note: Where new signs are being produced, they should use 'BIC' not 'QIC'.</p>	Minor
6.6 Where maintenance is required within the site, these personnel must follow the same procedural and security routines as site staff.	Major

Table 7A Operating procedures

Requirements	Nonconformity guide
<p>7.1 For goods subject to biosecurity control the following minimum requirements apply:</p> <ul style="list-style-type: none"> the site holder must be in possession of a relevant biosecurity control order prior to movement of the goods and must comply with directions specified. if the status of a consignment is unknown the goods must be considered subject to biosecurity control. 	Major or critical
7.2 The department must be notified of any pest or disease infestation.	Major or critical
<p>7.3 Exotic specimen containers must be clearly labelled and cross referenced to a central logbook of insect stocks kept in the site.</p> <p>Note: Specimens should be housed in secure primary containers. This will require the containers to be labelled with the common and scientific name.</p>	Major
<p>7.4 Packages of insects must be handled in a manner that ensures no egress of insects.</p> <p>Note: This will require packages to be only opened within the containment facility and the package to be then decontaminated.</p>	Major or critical
7.5 Personnel must leave the site through the clothing, change and shower rooms, except in cases of emergency where alternative exits may be used.	Major or critical
<p>7.6 Standard precautions and work practices are required when working with goods subject to biosecurity control. This will require street clothing, including underwear, to be removed and retained in the outer clothing change room. Complete protective clothing, including shoes must be used by personnel entering the site. When leaving the site, personnel must remove their protective clothing and store or discard it in the inner change room before showering.</p> <p>Protective clothing must be laundered at appropriate intervals. Dirty clothing must be removed and laundered before re-use. Where disposable protective clothing is used it must be disposed of in the manner described in the waste disposal section of this document.</p>	Major
<p>7.7 Each person leaving the biosecurity area must ensure that there are no insects attached to any part of the clothing or body. To achieve this requirement work practices must include:</p> <ul style="list-style-type: none"> the use of a full length mirror and a vacuum device garments being removed or retained in the anteroom or site prior to washing or disposal, garments must be sealed in bags and steam sterilised. 	Major
7.8 Personnel entering or leaving the site must indicate, either manually or electronically, the time of each entry and exit.	Minor

Table 7B Operating procedures (continued)

Requirements	Nonconformity guide
<p>7.9 Equipment used or that has come into contact with goods subject to biosecurity control must be cleaned or rendered safe by a department approved method. Department approved methods include, but are not limited to:</p> <ul style="list-style-type: none"> • sterilisation • incineration, as prescribed under the waste disposal section of this document. • disinfection using a department approved broad-spectrum disinfectant. 	Minor or major
<p>7.10 Equipment must be disinfected before being sent for repair or disposal and where appropriate, equipment may need to be disinfected at regular intervals.</p>	Minor or major
<p>7.11 The site must be fumigated after each series of experiments.</p>	Major
<p>7.12 Any plants used during experiments must be located over watertight trays which drain directly to the drainage system. Plants, soil and soil substitutes used in experiments must be pressure steam sterilised prior to removal from the site.</p>	Major or critical
<p>7.13 Traps fitted to outlets to arrest the passage of material of biosecurity concern must be serviced at regular intervals. Waste and other material caught in traps must be treated as per waste disposal requirements of this document.</p>	Major or critical
<p>7.14 A negative pressure gradient shall be maintained that exists of 25 Pa in the anteroom and 50 Pa in the AA site relative to the pressure outside the site. Additionally, the pressure inside the site must never fall below 25 Pa, relative to the pressure outside of the site, when the door between the anteroom and the AA site is open.</p>	Critical
<p>7.15 Annual testing and certification by a qualified technician must include:</p> <ul style="list-style-type: none"> • testing of the pressure differentials in accordance with AS 1807.10 • integrity testing of installed HEPA filters in accordance with AS 1807.6 or 1807.7 • checking that the control system is operating correctly and verifying alarms are set to operate when room differential air pressures depart from set points by more than 15 Pa for a period of greater than 2 minutes • the effectiveness of the effluent treatment and decontamination system Note: Any failures of the effluent treatment system must be rectified and the system re-tested. Records must be retained • a report of the testing in items i) to iv) and of any maintenance conducted must be provided at the request of a biosecurity officer. 	Critical

Table 8 Pressure steam sterilisers

Requirements	Nonconformity guide
8.1 Sterilisers must be located within the site where the work subject to biosecurity control is being undertaken.	Critical
<p>8.2 The BIP must provide the department with information concerning the calibration and certification of sterilisers, and the efficacy of treatment. The minimum requirements for sterilisers are that:</p> <ul style="list-style-type: none"> • relevant local regulations for pressure vessels be applied, including the timeframes for the regular certification of the steriliser. • steriliser cycles be calibrated. This can be achieved by the use of: <ul style="list-style-type: none"> - thermocouples or resistance thermometers to ensure that the sterilisation temperature indicated has been achieved - chemical indicators which progressively change colour with the time exposed at the specified temperature - biological indicators such as spore strips - enzyme indicators be used at regular intervals (for example, monthly) - other department-approved methods. <p>Note: The timing of the sterilisation stage of the cycle commences when the set temperature is recorded by the thermometer in the drain line.</p> <p>Where indicators are used they must be placed in several positions in a load, including those least likely to attain sterilisation conditions.</p>	Critical
<p>8.3 The annual checking and certification of sterilisers or heat ovens must be carried out by a qualified technician.</p> <p>Note: Where an autoclave is found to be defective, the autoclave must be clearly marked to show that it is defective and must not be used for biosecurity waste or equipment until the defect has been corrected.</p>	Major

Table 9 Waste disposal

Requirements	Nonconformity guide
9.1 Where applicable any biosecurity waste must be effectively contained and disposed of in a manner approved by the department.	Major or critical
9.2 Where waste cannot be disposed of immediately, there must be as a minimum the provision for: <ul style="list-style-type: none"> • a separate storage device/area for the temporary holding of goods • storage in lidded bins/containers of an appropriate size which are leak and pest proof • bins to be labelled 'Biosecurity Waste' • double bagging of waste. 	Major
9.3 Department-approved methods of solid biosecurity waste disposal include incineration at a high temperature in a high efficiency EPA approved incineration facility or sterilisation by autoclaving. Minimum autoclaving times after attainment of temperature for goods, residues or biosecurity waste shall be 121 degrees Celsius: <ul style="list-style-type: none"> • (core temperature) for 15 minutes, or • for 30 minutes where core temperature is not measured. Where the 15 minute autoclaving time is used, the BIP must specify how the core temperature has been reached and detail how this temperature was recorded.	Critical
9.4 Biosecurity waste water must be disposed of by a department approved method. Measures must be incorporated to minimise the disposal of viable biosecurity material (such as eggs, larvae, fungal or other) via the waste water system. <p>Note: This will require a system to be in place which decontaminates effluent from the biosecurity/work area, inner change room and shower before being discharged. An alarm must be provided to alert persons of any decontamination system malfunction. The use of a waste water disposal method must be approved in writing by the department and may require demonstration of their efficacy to the satisfaction of the department. Such methods may require detailed scientific research at the AA holder's expense.</p>	Major or critical

Table 10A Record requirements

Requirements	Nonconformity guide
<p>10.1 Recordkeeping procedures must provide the department with the confidence that the system has adequate controls and the necessary evidence to verify identifiable links to goods.</p> <p>This can be achieved by:</p> <ul style="list-style-type: none"> • electronic or manual records of goods subject to biosecurity control imported through the site (this includes retaining originals or copies of Import Permits, biosecurity entries/directions or transfer approvals) • retaining records for a minimum period of 18 months after biosecurity clearance or disposal of the goods • ensuring that records are available within 48 hours for inspection by the department. <p>Note: The department will continue to assess whether activities and arrangements have been implemented effectively, and are achieving requirements. If records are unavailable during an audit, the department will return to the AA site within 48 hours to continue the assessment of documentation.</p>	Minor or major
<p>10.2 Where goods are handled for a third party, BIP must have an arrangement in place which ensures that departmental directions and permit conditions are communicated to both parties.</p>	Major
<p>10.3 A record detailing replacement dates for insecticide strips/pads on biosecurity bins.</p>	Minor

Table 10B Record requirements (continued)

Requirements	Nonconformity guide
<p>10.4 Records for each consignment of goods subject to biosecurity control must include:</p> <ul style="list-style-type: none"> • biosecurity entry number (where relevant) • Import Permit number • date of receipt of goods and country of origin • specimen type (including scientific name) • number of specimens imported • comprehensive details of any inclusions (e.g. parasites imported with the specimens) • details of any host material that may have been included with the imported goods/specimens • details about the destruction of the transport packaging (usually required within 24 hours of arrival at the AA site according to the Import Permit) • location or part of site where each item subject to biosecurity control is held • comprehensive details of rearing, genetic crosses or generational breeding (where applicable) • date of completion of research • details of any treatments • method and date of goods disposal/destruction (if applicable) • the date and department permission for any movement (including transfer certificates) of goods from the site • comprehensive details of any breaches of goods subject to biosecurity control from the site. • documentary evidence that screens, filters, and similar equipment have been cleaned in accordance with the manufacturer's specified frequency and procedures. 	Major or critical
<p>10.5 Calibration specifications for equipment that has a bearing on the biosecurity status of the material (e.g. autoclave), along with calibration records must be provided at audit and at the request of a biosecurity officer.</p>	Minor or major
<p>10.6 A bi-annual summary of records, which includes the information under section 10.4 of this document must be provided at audit or at the request of a biosecurity officer.</p>	Minor or major
<p>10.7 A logbook (electronic or manual) recording steriliser load, temperature and duration of sterilisation cycle must be maintained.</p>	Minor or major

Table 11 Office and general site requirements

Requirements	Nonconformity guide
<p>11.1 Office and general site requirements must provide the department with the confidence that applicable work health and safety standards have been met, this is achieved by:</p> <ul style="list-style-type: none"> • providing a first aid cabinet/kit which is fully stocked and meets the minimum commercial Australian Standard (AS2675-1983: Portable first aid kits for use by consumers) • providing vehicle parking for visiting biosecurity officers (note: this may require department identified parking or providing a parking permit) • ensuring adequate security for any of the department's technical equipment left on the site • providing access and the availability of: <ul style="list-style-type: none"> - a desk, chair and a telephone with direct outside call access - toilet facilities - hand washing facilities and a hygienic means of drying hands - suitable arrangements to ensure amenities are clean. <p>Note: Additional mandatory requirements apply to AA sites with permanent biosecurity officers.</p>	Minor
<p>11.2 The site must comply with relevant safety codes and work health and safety legislation.</p>	Minor
<p>11.3 Design principles and minimisation strategies apply to ensure segregation of drinking water, food and toilet facilities. At a minimum this will require:</p> <ul style="list-style-type: none"> • drinking water, food and toilets only being located within designated areas of the biosecurity site where goods are not handled, stored or treated • personnel must ensure that there is no potential for the transmission of harm to humans, animals, plants or the environment. <p>Note: Minimisation strategies to prevent transmission may include the use of work practices and procedures. This could include the removal of gloves and garments and the washing of hands prior to drinking, eating or use of toilet facilities.</p>	Minor

Table 12 Administration

Requirements	Nonconformity guide
<p>12.1 Administration and documentation requirements must provide the department with the assurance that there are adequate controls. This must include:</p> <ul style="list-style-type: none"> • applications being accompanied by scale drawings (with dimensions and locations of biosecurity areas), identifying facilities for treatments, nearest main road and parking for biosecurity officers • obtaining a departmental direction or prior written approval to move, accept, transfer or release any goods subject to biosecurity control from the approved AA site to another department approved site that is not co-located. 	Major or critical
<p>12.2 The nominated manager will need to apply in writing requesting authority to transfer goods subject to biosecurity control to an AA site not co-located when a direction, written approval or an applicable Import Permit has not been issued. This will require details of proposed suitable transport containers if applicable, the intended transport route and any other relevant information to support the case. The department may seek further information before making a decision.</p>	

Table 13 Australian/New Zealand standard—laboratory design and construction part 1: general requirements (AS/NZS 2982.1:1997)

Standards from AS/NZS 2982.1:1997	Nonconformity guide
13.1 AS/NZS Section 2: General laboratory design and construction requirements (excluding 2.1, 2.2, 2.6 2.7 (a) (vi) and (vii) & 2.7 (c), 2.9, 2.10, 2.11, 2.12 and 2.13). Note: 2.4 walls and 2.5 ceilings – must be from material that resists attack from insects. 2.5 ceilings - excludes the use of false (suspended tiled) ceilings.	Consult AA where a NC is detected
13.2 Joints between structural components must be sealed.	Consult AA where a NC is detected
13.3 AS/NZS Section 3: Reticulated services (excluding 3.7.3).	Consult AA where a NC is detected
13.4 AS/NZS Section 4: Electrical services (excluding 4.2 and 4.3 paragraph 1).	Consult AA where a NC is detected
13.5 AS/NZS Section 5: Ventilation and air quality (excluding 5.1, 5.2, 5.3, 5.5.1, 5.5.3, 5.6 (b) last sentence only, and 5.7).	Consult AA where a NC is detected
13.6 AS/NZS Section 6: Health and safety requirements (excluding 6.1, 6.4, 6.5 and 6.6). In substitution for 6.2 (safety showers), the following clause will be applied: Clean up provisions are may include: <ul style="list-style-type: none"> • fixed appliances (such as showers and eyewash stations) • single use apparatus (such as disinfectant swabs, squeeze bottles). Note: Where safety showers and eyewash facilities are installed they must comply with the requirements of 6.2.	Consult AA where a NC is detected
13.7 The approach to clean up provisions must be unobstructed.	Consult AA where a NC is detected
13.8 In substitution for 6.3 (hand washing facilities) the following clause will be applied: Work areas where goods subject to biosecurity control are handled must contain either a wash basin fitted with hands-free tap(s), or some other means of decontaminating hands.	Consult AA where a NC is detected
13.9 Hand wash basins must be located inside the laboratory, near to the exit and serviced with hot and cold potable water. Potable water requirements must be met in accordance with AS 3500. Note: Alternatives to wash basins, include: <ul style="list-style-type: none"> • dispensers fitted with approved antiseptic solutions, provided the dispensers can be operated without using the hands, or • a sink of hands-free operation. 	Consult AA where a NC is detected
13.10 Where a basin is provided for washing hands an antiseptic hand wash dispenser be supplied.	Consult AA where a NC is detected

Standards from AS/NZS 2982.1:1997 are the minimum for work with insectary goods at the BIC4 level.

Table 14 Australian/New Zealand Standard—safety in laboratories part 3: microbiological aspects and containment facilities (AS/NZS 2243.3:2002)

Standards from AS/NZS 2243.3:2002	Nonconformity guide
14.1 AS/NZS Section 4.7: Physical Containment Level 1 (PC1) requirements (only 4.7.2 (d) applies where applicable).	Consult AA where a NC is detected
14.2 AS/NZS Section 4.8: Physical Containment Level 2 (PC2) requirements (only 4.8.3 (b)).	Consult AA where a NC is detected
14.3 AS/NZS Section 4.9: Physical Containment Level 3 (PC3) requirements (only 4.9.2 (a) – first sentence, (c) and 4.9.3 (a), (b), (c), (d), (e) and (f)).	Consult AA where a NC is detected
<p>14.4 In substitution for 4.9.3 (g) the following clause will be applied:</p> <p>Each separate room within a site must have:</p> <ul style="list-style-type: none"> • a room pressure gauge that can be viewed by personnel prior to entering the site, and • an audible alarm. <p>Notes:</p> <ul style="list-style-type: none"> • The room pressure gauge must measure the pressure relative to a common ambient reference pressure in the area outside but immediately surrounding the site. The adjacent area should not be subject to significant variations in pressure due to influences such as ambient wind direction and/or fluctuations, ventilation equipment, fans, or any other equipment that could cause pressure fluctuations. • The number of gauges required to safely monitor site pressures will depend on the number of rooms, the number of independent supply and exhaust systems, and layout. • The audible alarm is to indicate loss of negative room pressure in excess of two (2) minutes. • Where practicable, other air conditioning control switches and exhaust fan speed set point control must be located in close proximity (readily accessible to personnel before entering the site) or be located adjacent to the gauges. • The HEPA filter gauge can also be mounted with the room gauges. • If there is a closable door between two rooms they are separate 	Consult AA where a NC is detected
14.5 AS/NZS Section 4.10: Physical Containment Level 4 (PC4) requirements (only 4.10.2 (d), (e), 4.10.3 (a) – excluding the last sentence, and (b)).	Consult AA where a NC is detected
<p>In substitution for 4.10.2 (j) the following clauses will be applied:</p> <p>The site must have an automatically-starting emergency power source to ensure continuing operation of the ventilation system, room access and shower controls.</p> <p>Notes: The emergency power source would need to be designed to enable an automatic changeover as soon as practicable. Any such system would need to ensure emergency lighting and communication systems are reactivated within the shortest practical timeframe.</p>	Consult AA where a NC is detected

Standards from AS/NZS 2243.3:2002 are the minimum for work with insectary goods at the BC4 level.

Table 15A Specific department requirements for insectary containment—level 4 (BIC4) facilities

Requirements	Nonconformity guide
15.1 The site must be housed in a separate building or form an isolated part of a building. Full access to exterior surfaces of the structure and service penetrations must be provided to facilitate periodic integrity testing.	Consult AA where a NC is detected
15.2 Entry and exit to the site must be via a double door system (airlock) and include an anteroom. Note: The airlock may also operate as the anteroom. Where this is applied, the airlock must have no direct source of natural/artificial light.	Consult AA where a NC is detected
15.3 Where the site is freestanding, it must have an anteroom and an airlock for entry and exit. The airlock must be of a suitable size to allow materials, equipment and trolleys to pass through with one door closed at all times. This will require the site to be physically separated from other areas including offices used by site personnel and not accessible by the general public. A timer should be provided to permit personnel to shower for a defined period as part of the exit procedure.	Consult AA where a NC is detected
15.4 The airlock/anteroom and biosecurity work areas must have mechanisms in place to deter vermin and control specimens that may escape from their primary containers. Measures which can be used to prevent specimens escaping include: <ul style="list-style-type: none"> • self-closing devices on doors • seals on the side and top edges of doors • drop down door seals (fitted to both inner and outer doors of the airlock) • sticky pest strip (in the airlock) • insect traps (including the electric type) • darkened room • air curtains. Note: The insect trap used in the anteroom should be of the type effective for the species being contained.	Consult AA where a NC is detected
15.5 The anteroom must be provided with a vacuum device to remove insects from persons leaving the site.	Consult AA where a NC is detected
15.6 Doors should open inwards. This requirement will be assessed as flexible depending on the context of the site and the rooms within.	Consult AA where a NC is detected
15.7 There must be a method of preventing more than one door being opened at any one time. This can be achieved by: <ul style="list-style-type: none"> • interlocking doors • alarms and/or lights. 	Consult AA where a NC is detected

Table 15B Specific department requirements for insectary containment—level 4 (BIC4) facilities (continued)

Requirements	Nonconformity guide
15.8 Transparent sections (such as site windows) must be permanently sealed and not able to be opened.	Consult AA where a NC is detected
15.9 Any transparent section must be either made of impact-resistant material or have some form of protection. Note: Suitable impact resistance material includes double glazing or reinforced glass (such as laminated with 3M film). Protection could include the fitting of a mesh screen. Any mesh screen will need to be of sufficient strength to withstand the impact of hailstones or rocks.	Consult AA where a NC is detected
15.10 Any openings in the walls, ceiling or roof, such as vents, drainage outlets and air conditioning or ventilation inlets and outlets, must be screened at the containment boundary, with fine mesh screens having an aperture size small enough to prevent entry or egress of insects. Screens must be of suitable material to withstand the air flow load, to remain undamaged following cleaning and be resistance to attack by insects or corrosion. Note: An aperture size small enough to prevent entry or egress of insects will require a maximum aperture size of 0.10 mm or 100 microns (um). The species and size of insect to be held in the site should be taken into account when determining the appropriate screen aperture size. Reticulated supply services such as laboratory gases, hot and cold water supply, purified water loops are not required to be secured.	Consult AA where a NC is detected
15.11 Penetrations, including pipes, cables, power outlets, lights and other service penetrations must be sealed. Note: Where lights are fitted to ceilings or other site surfaces, any light fitting penetrations must be sealed in such a way that during normal operation, maintenance or replacement of lamps the seal remains effective in preventing the ingress and/or egress of insects or other pests.	Consult AA where a NC is detected
15.12 Walls and ceilings must be white or pale in colour.	Consult AA where a NC is detected
15.13 Where possible, supporting apparatus (such as pumps, irrigation, heating, cooling and ventilation equipment, plant shading devices, steam steriliser maintenance components) are to be located outside the site. Note: The provision of a gaseous decontamination chamber should be considered where it is necessary to remove items that cannot be steam sterilised.	Consult AA where a NC is detected

Table 15C Specific department requirements for insectary containment—level 4 (BIC4) facilities (continued)

Requirements	Nonconformity guide
<p>15.14 An insectary should be constructed so that upon commissioning, it achieves an air leakage rate, at a differential pressure of 200 Pa, of no more than 120L/min. An air leakage test must be provided for new or refurbished facilities.</p> <p>Note: A small ante-room/airlock of less than ten (10) m² floor area may be added with the adjacent room for the purpose of this requirement.</p>	Consult AA where a NC is detected

Table 16 HEPA filters

Requirements	Nonconformity guide
<p>16.1 HEPA filters must be mounted in gas tight housings located as close as possible to the containment facility to minimize the length of potentially contaminated ductwork. The interconnecting ductwork between the containment room and the HEPA filter housing must also be of gastight (seam welded stainless steel) construction.</p>	Consult AA where a NC is detected
<p>16.2 The design of the filter housing must facilitate the testing of the integrity of the HEPA filter element and mounting, and the periodic gaseous decontamination of the filter element and associated mounting services.</p> <p>Note: Housings should be placed in fully accessible locations with clear access to facilitate filter integrity testing, physical handling of filter elements and operation of isolating valves. Installations in false ceilings should be avoided.</p>	Consult AA where a NC is detected
<p>16.3 To enable testing and gaseous decontamination filter housings should incorporate the following features:</p> <ul style="list-style-type: none"> • sealed access doors for filter maintenance and integrity testing • gastight isolating valves on the air inlet and outlet ducts • secure filter element clamping and mounting tracks • upstream and downstream valved ports • upstream and downstream valved pressure tappings to permit monitoring of the filter air flow pressure drop • a differential pressure gauge incorporating a magnetically coupled indicating mechanism and a sealed differential pressure diaphragm • a facility to introduce a test airflow and cold generated aerosol to establish the integrity of the filter element and its mounting. 	Consult AA where a NC is detected

Table 17A Waste service piping

Requirements	Nonconformity guide
17.1 Waste piping must be installed such that the length of horizontal piping is minimised. The pipe path should have the maximum practical fall (preferably vertical). The pipe should be routed via plant rooms and accessible building risers. The route should avoid ceiling spaces and occupied areas unless this is impractical.	Consult AA where a NC is detected
17.2 Piping must be conservatively selected to suit the fluid flow and pressure applicable. The pipe material should resist degradation from exposure to waste products or likely cleaning and disinfection agents. Note: Fully welded 316l stainless steel piping of 1.0 mm thickness is recommended. Single skin piping is considered satisfactory.	Consult AA where a NC is detected
17.3 Piping must be physically protected where exposed to mechanical damage.	Consult AA where a NC is detected
17.4 Piping must be labelled 'Biosecurity (or Quarantine) Containment Pipework – Do not disturb' throughout its length. Biohazard warning symbols should also be provided at regular intervals. Note: Where new signs are being produced, they should use biosecurity not quarantine.	Consult AA where a NC is detected
17.5 Piping should be capable of being visually inspected throughout its length. Double skin pipe construction is recommended in any locations where visual inspection is unable to be undertaken. However this contingency should be avoided, where practical.	Consult AA where a NC is detected
17.6 A filtration system is required for removal of solids prior to liquid waste entering the holding tank. The filtration system must be capable of being removed for cleaning and decontamination. Solids removed from waste water are deemed to be biosecurity waste and must be treated as such. Steam sterilisation is recommended. Note: The efficacy of the waste treatment system in sterilising particulate matter should be considered when determining the filtration system screen size to be utilised for solids removal.	Consult AA where a NC is detected
17.7 The floor of the waste treatment plant room must be fully bunded to a volume that ensures retention of waste in the event of a holding tank failure at full capacity. The bunded space should drain to a sealed sump. A submersible sump pump must be provided, along with flexible hosing to discharge the spillage after chemical disinfection. Note: Consideration should be given to the provision of a safety shower and eyewash station within the plant room.	Consult AA where a NC is detected
17.8 A 'continuous flow alarm' is desirable for water services connected to appliances draining to the treatment system. Note: A suitable timer can warn users where water flow to a single appliance exceeds a reasonable period of time.	Consult AA where a NC is detected

Table 17B Waste service piping (continued)

Requirements	Nonconformity guide
<p>17.9 Vents to the waste system must be fitted with sterile filters.</p> <p>Note: Filters must be carefully selected to ensure that sufficient air is passed to ensure traps are not compromised. 0.2 micron hydrophobic membrane filters are recommended. These must be capable of being decontaminated, preferably by steam sterilisation.</p>	<p>Consult AA where a NC is detected</p>
<p>17.10 Where toilets are installed, it is recommended that these are urine only systems. Where urine only toilets are installed, a 'Lady-San' or similar disposal station for small quantities of toilet paper and other minor solids should be supplied. Solid waste collected from disposal stations must be treated as biosecurity waste.</p>	<p>Consult AA where a NC is detected</p>

Table 18 General

Requirements	Nonconformity guide
18.1 Where drinking fountains are provided they must be of a hands-free operation and be within a designated area where goods are not handled, stored or treated.	Consult AA where a NC is detected
18.2 Write-up areas may be approved as part of the site. To be eligible for approval, these areas must be constructed such that horizontal surfaces are minimised (for example, with minimal shelving), must not be used for generic office functions and should hold only essential reference materials (such as technical equipment manuals).	Consult AA where a NC is detected
<p>18.3 The BIP must notify the department in writing as soon as practicable within 15 working days of becoming aware of any change of status, not previously been notified to the department, of the BIP or their associates relevant to the operation of the AA in relation to any of the following matters:</p> <ul style="list-style-type: none"> • conviction of an offence or order to pay a pecuniary penalty under the <i>Biosecurity Act 2015</i>, <i>Quarantine Act 1908</i>, <i>Customs Act 1901</i>, the Criminal Code or the <i>Crimes Act 1914</i> • debt to the Commonwealth that is more than 28 days overdue under the <i>Biosecurity Act 2015</i>, <i>Quarantine Act 1908</i>, <i>Customs Act 1901</i>, the Criminal Code or the <i>Crimes Act 1914</i> • refusal, involuntary suspension, involuntary revocation/cancellation or involuntary variation of an Import Permit, quarantine approved premises, compliance agreement or AA under the <i>Quarantine Act 1908</i> or the <i>Biosecurity Act 2015</i>. 	Critical
18.4 Biosecurity officers, biosecurity enforcement officers and department-approved auditors must be provided access to the AA site to perform the functions and exercise the powers conferred on them by the Biosecurity Act or another law of the Commonwealth	Critical
18.5 Departmental auditors or department-approved auditors must be provided with facilities and assistance as requested, and any required documents, records or things relevant to the audit.	Major or critical
18.6 The department must be notified of any Reportable Biosecurity Incident as soon as practicable, in accordance with the determination made by the Director of Biosecurity.	Critical
18.7 Department-approved auditors must be permitted to collect evidence of compliance and noncompliance with AA requirements through actions including the copying of documents and taking of photographs.	Major or critical