



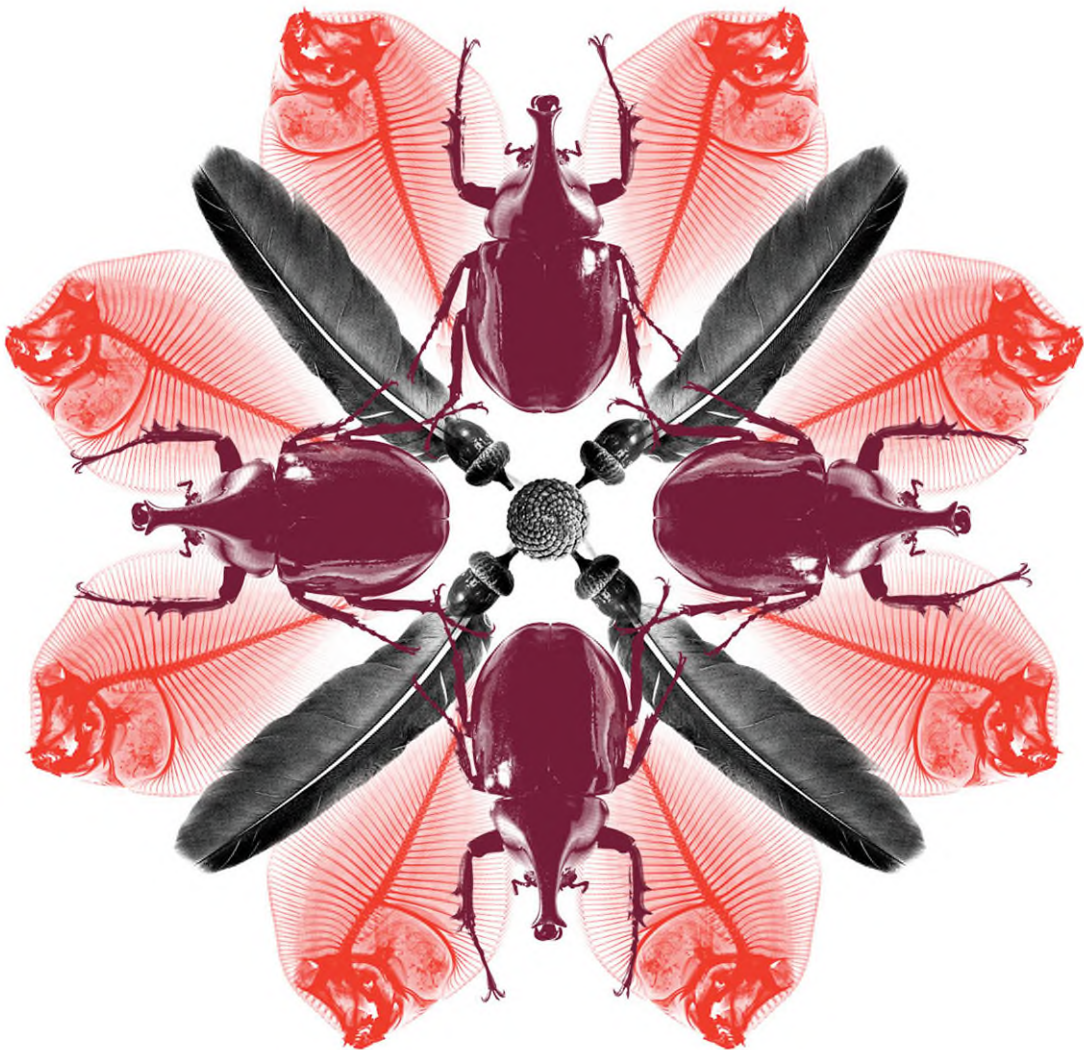
**Australian Government**  
**Department of Agriculture,  
Water and the Environment**

# **Approved Arrangement**

## **for 7.10 - Fertile poultry hatching eggs**

### **Requirements**

Version 5.0



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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.

<b>Date</b>	<b>Version</b>	<b>Amendments</b>	<b>Approved by</b>
9 May 2011	1.0	Revised document.	Co-regulation and Support Program
30 Jun 2013	1.1	Updated departmental branding.	Industry Arrangements Reform Program
Sept 2015	2.0	Updated departmental branding and template.	Approved Arrangements section
16 Jun 2016	3.0	Updated references to the department and the <i>Biosecurity Act 2015</i> .	Approved Arrangements section
21 Jun 2016	4.0	Updated HEPA filter requirements in 4.4 and post mortem Veterinary Officers in 8.7.	Approved Arrangements section
March 2018	5.0	Updated requirements following amendments to BICON and work instructions.	Horses, livestock and birds program
1 December 2021	5.0	Added biosecurity risk information to the purpose statement in Table 1	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, Water and the Environment. 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: [awe.gov.au](http://awe.gov.au).

## 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 requirement 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 requirements remains at the discretion of the Biosecurity Officer.

Nonconformity classifications are detailed in the *AA General Policies*.

## AA requirements

Requirements	Nonconformity guide	
<b>1. Purpose</b>		
<p>Class 7.10 approved arrangement sites are utilised to undertake post-arrival quarantine isolation, testing and treatment of fertile hatching eggs and birds including specific pathogen-free (SPF) sentinel birds subject to biosecurity control and as required by import permit conditions.</p> <p>Examples of biosecurity risks associated with live imported horses handled at a class 7.10 approved arrangement site include:</p> <ul style="list-style-type: none"> <li>• avian Influenza</li> <li>• Newcastle disease</li> <li>• infectious bursal disease</li> <li>• exotic Salmonella species infections</li> </ul> <p>Information on biosecurity import conditions and biosecurity risks for imported goods, containers, other cargo and arriving vessels is available on the <a href="#">department's website</a>.</p>		
<b>2. Scope</b>		
<p>Sites are not approved for any other biosecurity operations, except where the sites have separate approval under another class.</p> <p>New sites must comply with these requirements as published at the time. Refurbished sites must also comply with these requirements.</p>	<b>Major</b>	
<b>3. Site operations and location</b>		
<p>3.1</p> <p>Whilst the eggs/birds are subject to biosecurity control, the site must operate in order to isolate imported and sentinel birds from other avian species :</p> <ul style="list-style-type: none"> <li>• Option 1: using containment via HEPA filtration on supply and exhaust, generally equivalent to BC3 and specifically as described within these requirements.</li> </ul> <p style="padding-left: 20px;">OR</p> <ul style="list-style-type: none"> <li>• Option 2: using containment via HEPA filtration, as per option 1 for the first part of the biosecurity isolation period with deep bed filtration after approval to cease HEPA filtration has been given. Approval to cease HEPA filtration would normally be given after the second veterinary certificate has been received and assessed and all import conditions up to that date have been complied with. Option 2 may be applied in locations which are a minimum of 2.0 km from any commercial poultry facility boundaries and are a minimum of 400 m from any non-commercial poultry facilities.</li> </ul> <p><b>Note: If after approval, a commercial operator has production within 2km and/or it becomes known that non-commercial poultry is within 400 m, the AA site will need to operate as a BC3 for the entire period where birds are subject to biosecurity.</b></p>		<b>Critical</b>
<p>3.2</p>		<b>Major</b>

Requirements	Nonconformity guide
<p>The following information must be provided to support an application for approval of the site, together with any other additional information required by the Director of Biosecurity to be provided:</p> <ul style="list-style-type: none"> <li>• details of the land usage within 2 kilometres of the site boundary (including vacant and non-vacant land) when option 2 is utilised.</li> <li>• information on the susceptibility of the sites to flooding or storm surges and the precautions taken to address these risks.</li> <li>• This will require applicants to provide: <ul style="list-style-type: none"> <li>○ details about the likelihood and magnitude of flooding or storm surges</li> <li>○ the proximity of the sites to waterways.</li> </ul> </li> </ul>	
<b>4. Compliance</b>	
<p>4.1</p> <p>The approved AA site must contain a Biocontainment Unit (BU) generally equivalent to a BC3 facility as relevant to primary containment of avian species and more specifically as described within these requirements.</p> <p>The applicable design and construction standards are of the Australian/New Zealand Standard AS/NZS 2982.2010 and AS/NZS 2243.3:2010 or subsequent amendments. In this case the applicable standards are for animal PC3 facilities.</p> <p>The AA site must also contain biosecurity areas outside of the the BU that support it's function. These may include areas such as the effluent decontamination equipment and air conditioning/ventilation equipment.</p> <p>In addition to the Approved Arrangements (AA) requirements, the following must be complied with:</p> <ol style="list-style-type: none"> <li>a) the <i>Biosecurity Act 2015</i> and subordinate legislation;</li> <li>b) Import Permit conditions;</li> <li>c) directions given by the department;</li> <li>d) Import Conditions database.</li> </ol> <p>Where requirements in the standards conflict with the AA requirements, the AA requirements take precedence.</p>	<b>Major</b>
<p>4.2</p> <p>The biosecurity industry participant (BIP) must:</p> <ol style="list-style-type: none"> <li>a) ensure compliance with all relevant conditions and procedures carried out in relation to goods subject to biosecurity, at the approved site;</li> <li>b) ensure that its officers, employees, agents and contractors act consistently with, and ensure the proper performance of, the relevant conditions and the procedures in relation to the goods subject to biosecurity, at the approved place;</li> <li>c) assist the department with any investigation relating to compliance with the Act.</li> </ol> <p><b>Note: The biosecurity industry participant (BIP) is defined in the legislation.</b></p>	<b>Major</b>
<p>4.3</p>	<b>Major</b>

Requirements	Nonconformity guide
<p>The BIP must notify the department in writing as soon as practicable within 15 days of any change in:</p> <ul style="list-style-type: none"> <li>• Persons in positions responsible for controlling, directing, enforcing or monitoring people performing activities associated with the approved arrangement</li> <li>• BIP details, including: <ul style="list-style-type: none"> <li>○ entity name</li> <li>○ ABN or ACN</li> <li>○ postal address</li> <li>○ email address</li> <li>○ facsimile number</li> <li>○ telephone number.</li> </ul> </li> </ul>	
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<p>4.4</p> <p>Before use at an AA site, a BU must:</p> <ul style="list-style-type: none"> <li>• be inspected by an approved Third Party Assessor (TPA) against the 7.10 AA requirements;</li> <li>• submit the applicable TPA certification to the department;</li> <li>• have all containment features of the BU facility tested, commissioned and the results documented;</li> <li>• have a Department of Agriculture audit; and</li> <li>• receive an applicable Approved Arrangement (AA) site authorisation from the department.</li> <li>• Be constructed and sealed to be capable of supporting safe gaseous decontamination in the event of an outbreak of disease during the biosecurity period. Refer AS/NZS 2243.3 and specific performance requirements detailed within this document for performance leakage rates (ref. 9.30.5 and 9.30.6).</li> <li>• Construction and leakage performance must be certified by a person approved by the department, such as an approved TPA.</li> </ul>	<p><b>Critical</b></p>
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<p>4.5</p> <p>Containment features of the BU that must be tested, commissioned and reported, include:</p> <ol style="list-style-type: none"> <li>a) Containment envelope integrity (i.e. leakage rate);</li> <li>b) Liquid waste pipe integrity (pressure test);</li> <li>c) Functional systems such as door interlocks or indicators;</li> <li>d) Differential pressure control systems, alarms, instrumentation (including transient performance, fan failure and interlocks);</li> <li>e) Decontamination equipment and effluent treatment systems (e.g. steam or dry heat steriliser, fumigation chamber, digester, liquid waste heat treatment or approved chemical treatment);</li> <li>f) HEPA filter systems (including in-situ integrity testing).</li> </ol>	<p><b>Critical</b></p>
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<p>4.6</p>	<p><b>Major</b></p>



Requirements	Nonconformity guide
<p>To preserve the status of a BU at an AA site authorised for containment, the following items must be successfully tested and calibrated during the initial commissioning and thereafter, at the frequency specified:</p> <ol style="list-style-type: none"> <li>a) All decontamination equipment – at least annually;</li> <li>b) Containment envelope integrity (i.e. leakage rate) - at maximum three (3) yearly intervals.</li> </ol> <p>Testing, calibration and the acceptance criteria must conform to the requirements in this document.</p>	
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<p>4.7</p> <p>Approval will not be given before the department has conducted a physical site assessment of the AA site.</p> <p>Compliance with the requirements in paragraphs 4.7.1 to 4.7.3 below must be shown through, at a minimum:</p> <ul style="list-style-type: none"> <li>• the adoption of work procedures detailed in the site operations manual/standard operating procedures applicable to the handling of goods subject to biosecurity control, and</li> <li>• demonstration of structural compliance during the initial assessment of the site by the department.</li> </ul> <p>On application and to maintain AA site approval a site plan must be submitted to the department, and show:</p> <ol style="list-style-type: none"> <li>a) the overall dimensions of the site, buildings and structures, whether utilised for biosecurity operations or not;</li> <li>b) the location of biosecurity areas;</li> <li>c) the movement pathways of goods subject to biosecurity;</li> <li>d) road access into and within the AA site;</li> <li>e) parking designated for departmental officers.</li> </ol>	<b>Critical</b>
<p><b>Note: Designated parking areas may be allocated immediately prior to audit or inspection at the AA site.</b></p>	
<p>4.7.1</p> <ul style="list-style-type: none"> <li>• Biosecurity Officers must be granted access to the AA site at any time.</li> <li>• The department must be provided with details of the AA site’s nominated business hours.</li> <li>• Access to the AA site must be through property owned, rented or leased by the Biosecurity Industry Participant (BIP).</li> <li>• Access to the AA site must be via an all weather road.</li> </ul>	
<p>4.7.2</p> <p>The BU must be structurally and operationally separated from other operations and must not be used as an access point or thoroughfare to any other part of the sites. The nominated methods of achieving adequate separation must be detailed in the application for approval of the site.</p>	
<p>4.7.3</p>	

Requirements	Nonconformity guide
<p>The BU and other areas at the AA site must address relevant Australian and state human Work, Health and Safety (WHS) as well as animal welfare legislation and standards. Evidence of this must be provided at the time of application.</p>	
<p>4.8 Facilities</p>	
<p>4.8.1</p>	
<p>The BU must have facilities for veterinary examination of, and the collection of samples from, the animals subject to biosecurity control. This must include benches, lighting (600 lux for inspection/sampling area) water, sink, refrigeration for storing samples, chairs at the appropriate height for the work benches and sufficient storage for all required supplies.</p>	
<p>4.8.2</p>	
<p>The AA site must include equipment for the cleaning and disinfection of vehicles used for transporting fertile eggs.</p>	<p><b>Major</b></p>
<p>This equipment must include:</p>	
<p>a) a spill kit for containment of any solid/liquid contamination; b) disinfectant in sufficient quantities to disinfect the cargo area of the truck and any other equipment that may need disinfection;</p>	
<p>4.8.3</p>	
<p>Incubators and hatchers utilised for biosecurity operations must be located within the BU.</p>	
<p>4.9</p>	
<p>To ensure conformance to the AA site requirements, the BIP must ensure that the department's Horse, Livestock and Bird Imports Program in Canberra is notified in writing, at least 15 working days prior to any:</p>	
<ul style="list-style-type: none"> <li>• alterations to AA site's physical structure or operating arrangements (including the approved procedures) modification to, or closure of, the BU where goods subject to biosecurity control are stored or treated/processed or otherwise dealt with. Written approval from the Horse, Livestock and Bird Imports Program in Canberra must be obtained before any such changes are implemented.</li> </ul>	
<p><b>Note: it is the responsibility of the BIP to allow sufficient time for review by the Horse, Livestock and Bird Imports Program between application and when the alterations are required.</b></p>	<p><b>Major</b></p>
<ul style="list-style-type: none"> <li>• The BIP must notify the department in writing at least 15 working days prior to the applicant: <ul style="list-style-type: none"> <li>○ commencing any process of liquidation, winding up, dissolution or bankruptcy, any form of external administration, or scheme of arrangement</li> <li>○ proposing to assign, transfer, novate, cease or materially reduce business operations which include the procedures covered by the site approval.</li> </ul> </li> </ul>	

Requirements	Nonconformity guide
<p><b>Note: The department may require the submission of independent documented evidence confirming compliance with relevant parts of the AS/NZS 2982.2010 and 2243.3:2010 or subsequent amendments, when additions or modifications have been made to the AA site.</b></p>	
<p>The department must be notified in writing, prior to:</p>	
<p>a) making alterations to the physical structure of the AA site which affects the containment boundary (excluding minor works as follows);  b) assigning, transferring or relocating the biosecurity operations;  c) ceasing or materially reducing or expanding biosecurity operations;  d) entering into, or changing a sub-lease arrangement.</p>	
<p><b>Note: Approval may be required prior to implementing any of the above and the departments decommissioning requirements may need to be met.</b></p>	
<p><b>5. Work practices</b></p>	
<p>5.1</p>	
<p>The BIP must prevent any animal not included in the imported consignment or SPF sentinel birds from entering the BU.</p>	<p><b>Major</b></p>
<p>5.2</p>	
<p>While fertile eggs or birds are subject to biosecurity control, they must not leave the BU for any reason.</p>	<p><b>Major</b></p>
<p>5.3</p>	
<p>At all times, the AA site areas must remain clean and fit for their intended purpose at the time of approval and any subsequent approved changes.</p>	<p><b>Major</b></p>
<p>5.4</p>	
<p>Biosecurity buildings, feed storage areas and effluent and disposal areas must be built to reduce the likelihood of infestation with rodents or insects and to prevent access by wild birds. The method of achieving this must be detailed at the time of application for approval and must receive endorsement by the department. Periodic checks, at least monthly, by the Biosecurity Industry Participant (BIP) must be undertaken to ensure hygiene is maintained.</p>	<p><b>Major</b></p>
<p>5.5</p>	
<p>An effective pest control system must be in place to ensure that the site is managed in a way that effectively isolates goods subject to biosecurity control from areas where pests and diseases cannot be effectively controlled. As a minimum this will require the BIP to implement and keep associated records of a periodic inspection regime and ensure knockdown spray (i.e. standard household aerosol insecticide spray) is kept on-site. The BIP must demonstrate the inspection regime and the on-site location of the knockdown spray. This demonstration includes:</p>	<p><b>Minor</b></p>
<ul style="list-style-type: none"> <li>• how insecticides, fumigation, rodenticides, periodic inspection, baits and/or traps will be used and/or carried out;</li> <li>• a site plan with numbered bait stations, and</li> <li>• if applicable, contract details, for a pest control provider.</li> </ul>	

Requirements	Nonconformity guide
<b>Note: The operations of adjacent facilities must be considered when determining any additional pest control measures to be implemented.</b>	
<b>6. Ventilation</b>	
6.1  A ventilation system that establishes a negative pressure in the facility must be provided so that there is a directional airflow into the BU.	<b>Critical</b>
6.2  Within the BU, supply and exhaust ventilation terminals must be located to ensure a flow of incoming air from the vicinity of the entry door towards the highest risk work areas.	<b>Minor</b>
6.3  The BU must be maintained at an air pressure of at least 50 Pascals below the pressure of areas outside the BU containment barrier when both doors of the airlock are closed.	<b>Major</b>
6.4  When either airlock door is open the BU pressure must remain at least 25 Pascals below that of areas outside the BU containment barrier.	<b>Major</b>
6.5  The 0 Pa reference pressure must be measured to minimize the effects of fluctuations due to wind and other building ventilation systems.	<b>Minor</b>
6.6  The pressure differential must be achieved by use of an independent room exhaust fan located downstream of a HEPA filter and discharging to the outside atmosphere.  <b>Note: Depending on size the BU may require multiple supply and exhaust components such as fans and HEPA filters. In these situations, requirements apply to all such equipment.</b>	<b>Major</b>
6.7  Where a BU has supply air systems, the supply air and exhaust air systems must be interlocked to ensure inward airflow at all times.	<b>Major</b>
6.8  Differential pressures within the BU must be verified by testing.	<b>Major</b>
6.9  If exhaust flow is interrupted by fan failure, the supply must automatically shut down to prevent an adverse pressure gradient. A system alarm must register.	<b>Major</b>

Requirements	Nonconformity guide
6.10	
Doors must not open due to the normal pressure gradient in BU facilities or by transient adverse pressure gradients occurring during start up, shutdown, system failure, power failure, or due to any automatic security release related to emergency egress provisions.	<b>Major</b>
6.11	
Items of equipment, ducts and access panels to contained sections of the ventilation system must be marked with biohazard labels to minimize the risk of accidental containment breach.	<b>Minor</b>
6.12	
The BU must be constructed to prevent cracking or structural damage under the maximum positive or negative pressures generated by failure modes.	<b>Major</b>
6.13	
Transient pressure differential on start up must settle to a negative pressure within one minute.	<b>Minor</b>
6.14	
If air is recirculated, this must be achieved utilizing internally-mounted air conditioning equipment such that air does not leave the room.	<b>Major</b>
6.15	
Any internally-mounted equipment must be provided with removable panels as required to ensure accessibility for cleaning in order to support complete penetration of gas or vapour during room decontamination.	<b>Minor</b>
6.16	
Supply or replacement air must be filtered using a pre-filter of type 1 class A or class B complying with AS 1324.1 and having a minimum arrestance efficiency of 90% when tested in accordance with AS 1324.2 with test dust no. 4. These pre-filters must be located upstream of the supply HEPA filters.	<b>Major</b>
6.17	
There is no specific requirement for supply air ventilation rates. The recommendations in AS/NZS2982 and AS/NZS 2243.3 may be excessive for a production BU which is intended to be raising clean, uninfected animals.	
Supply ventilation rates must:	<b>Major</b>
<ul style="list-style-type: none"> <li>• be sufficient to maintain a safe working environment for operators and visitors</li> <li>• address animal welfare considerations</li> <li>• permit effective purging of air following a gaseous decontamination</li> </ul>	

Requirements	Nonconformity guide
<ul style="list-style-type: none"> <li>be sufficient to maintain negative pressure and biocontainment requirements of these requirements.</li> </ul>	
6.18	
<p>An exhaust air pre-filter of the same standard as the supply air pre-filter must be provided and mounted upstream of the HEPA filter.</p>	<b>Major</b>
<p><b>Note: Additional dander filters and roughing filters will normally be required for a BU.</b></p>	
6.19	
<p>All exhaust air must be filtered during the applicable biosecurity period nominated in clause 3.1, all air must be HEPA filtered prior to discharge to atmosphere. The HEPA filter must be installed, housed and maintained as specified in section 6.28: 'HEPA Filtration for Biosecurity'.</p>	<b>Major</b>
6.20	
<p>Differential pressure indication must be provided across each bank of HEPA filters. Pressures must be logged manually or automatically.</p>	<b>Major</b>
6.21	
<p>Pressure indication must be provided for each separate pressure controlled zone in the BU. Pressures must be recorded and logged manually or electronically.</p>	<b>Major</b>
6.22	
<p>Any differential pressure gauges or tubing that forms part of the facility pressure sensing and control equipment must be fitted with a 0.2 um hydrophobic membrane filter, (e.g. a miniature disk filter) located as close as possible to the BU containment barrier.</p>	<b>Major</b>
6.23	
<p>Membrane filters and tubing must be protected against mechanical damage.</p>	<b>Minor</b>
6.24	
<p>An emergency ventilation stop button must be provided outside the BU near to the exit.</p>	<b>Major</b>
6.25	
<p>The emergency stop button must operate independently of the main ventilation control and main BU pressure control system, such that emergency isolation of the ventilation can be implemented in event of central control system malfunction.</p>	<b>Major</b>

Requirements	Nonconformity guide
6.26	<b>Major</b>
An emergency alarm must be provided within the BU to indicate a loss of negative pressure. Alarms must be either audible or visible taking into account animal welfare considerations. Alarms must ensure that operators inside the BU are immediately made aware of a loss of pressure.	
6.27	<b>Major</b>
The BU ventilation system must be equipped with isolation valves to facilitate isolation and gaseous decontamination of the BU. The BU ventilation system must be equipped with isolation valves or suitable sealing arrangements to facilitate isolation and gaseous decontamination of the BU, the HEPA filter housings and filters, and of any exhaust duct between the BU, up to and including the exhaust HEPA filter housings..	
6.28 HEPA Filtration for Biosecurity	<b>Major</b>
Supply and exhaust air must be filtered. Where:	
Option 1 is applied to operating arrangements, supply and exhaust must pass through HEPA filters.	
Option 2 is applied to operating arrangements, supply and exhaust must pass through HEPA filters until the supervising Veterinary Officer has given approval to cease the HEPA filtration during the isolation period. Following approval to cease HEPA filtration, dust filters for supply air, panel and deep bed dust filters at exhaust outlets must be fitted to remove feathers, dander and dust.	
For Option 2, HEPA filters are only required for the first part of the post arrival biosecurity isolation period. Contact the Horse, Livestock and Bird Imports Program and the supervising Veterinary Officer for approval to cease HEPA filtration during the isolation period. Refer to section 3.1.	
6.28.1	<b>Major</b>
HEPA Filters must meet all the requirements of AS 4260 with a minimum performance of Grade 2.	
6.28.2	
Filter seals must not support microbiological growth.	
6.28.3	
HEPA filters for a BU must be mounted in gastight housing(s) located as close as practical to the BU operational spaces.	<b>Major</b>
6.28.4	
Where applicable, interconnecting ductwork between the BU and HEPA filter housings must be of gastight construction.	
6.28.5	

Requirements	Nonconformity guide
<p>HEPA filter housings must be designed to facilitate,</p> <ol style="list-style-type: none"> <li>inspection and replacement of HEPA filters without personal injury or filter damage</li> <li>in-situ integrity testing of the HEPA filter; and</li> <li>gaseous decontamination of HEPA filters and their enclosures.</li> </ol> <p>Note: If there is contamination in the bird flock, the whole facility is decontaminated, including the HEPA filter housings</p> <p>If there has not been contamination, then the whole bird flock is released and there is presumed to be no contamination; the whole facility is opened up. In this case, the rooms, roughing filters, exhaust duct, HEPA filter housings and HEPA filters are not contaminated.</p> <p>If the department considers that there is any contamination present, then the most likely place for this to be concentrated (i.e. in the largest burden of particles), is the roughing filters back in the rooms.</p>	
<p>6.28.6</p> <p>HEPA filter housings must incorporate the following features:</p> <ol style="list-style-type: none"> <li>gastight construction (with sealed access doors for filter maintenance and integrity testing);</li> <li>gastight inlet/outlet isolating capability for gaseous decontamination of exhaust HEPA filters so that they can be decontaminated independently of the main BU spaces;</li> <li>for supply HEPA filters, these may be provided in separate housings similar to exhaust HEPA filter housings, or may be of room terminal type with isolation capability on upstream connection side;</li> <li>secure filter element clamping and mounting tracks for damage free handling;</li> <li>upstream and downstream valved ports for gaseous decontamination for housings which are not terminally mounted to the room. Terminally mounted supply HEPA filter housings must have upstream valved ports;</li> <li>upstream and downstream valved pressure tapplings for monitoring filter pressure drop (gauge tubing to the contaminated side of the filter housing must be fitted with a 0.2 um filter, e.g. a miniature disk filter);</li> <li>differential pressure indication with indications marking loaded filter status;</li> <li>a facility to introduce a test airflow and aerosol to establish the integrity of the filter element and its mounting.</li> </ol>	
<p>6.29</p> <p>Installed HEPA filters must be tested in-situ for filter / seal / housing integrity using a Cold DOP or equivalent test method. The testing must provide assurance that the installed filter efficiency is not inferior to 99.99% for 0.3 micron particulates.</p> <p>Annual testing and certification by a qualified technician must include:</p> <ul style="list-style-type: none"> <li>testing of the pressure differentials in accordance with AS 1807.10 or subsequent amendments</li> </ul>	<p><b>Major</b></p>



Requirements	Nonconformity guide
<ul style="list-style-type: none"> <li>integrity testing of all installed HEPA filters in accordance with AS 1807.6 or AS 1807.7 or subsequent amendments</li> <li>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.</li> </ul> <p><b>Note: any failures of the system/s must be rectified and the system/s re-tested. Records must be retained.</b></p> <p>A report of the testing of items in this section and of any maintenance conducted must be provided at the request of a Biosecurity Officer.</p>	
6.30	
<p>Class III isolators, including flexible film isolators, must operate at a more negative pressure to the room in which they are located.</p> <p>Inlet systems must be HEPA filtered.</p> <p>Exhaust systems must be HEPA filtered with at least two HEPA filters in series; one at the isolator boundary and a second exhaust HEPA filter between the isolator boundary and the external environment.</p> <p>The annual checking and certification of isolators must be carried out by a qualified technician</p>	Major
6.31	
<p>During operations under Option 2 after release from HEPA filtration, the BU must be maintained such that there is a net inflow of air creating a negatively pressured environment</p>	Major
6.32	
<p>An outer and inner change room, separated by a shower airlock with interlocking, self closing doors, must be provided for personnel entering and leaving the facility.</p>	Major
6.33	
<p>The outer door of the facility must be lockable.</p> <p><b>Note: The outer shower door forms the BU containment boundary.</b></p>	Major
6.34	
<p>An entry and exit 'traffic light' alarm system or door interlock control system must be provided to prevent the simultaneous opening of the doors on each side of the showers.</p>	Major

Requirements	Nonconformity guide
<p>6.35</p> <p>A minimum 3 minute timer must be provided for the shower.</p>	<p><b>Minor</b></p>
<p>6.36</p> <p>Showers must have wash liquid, or soap.</p>	<p><b>Major</b></p>
<p>6.37</p> <p>Towels used for drying after showering must be laundered on site.</p>	<p><b>Minor</b></p>
<b>7. Personnel decontamination</b>	
<p>7.1</p> <p>All items of clothing and jewellery, watches, band-aids or wound dressings must have been removed prior to entering the BU. Eye glasses may enter/exit via the dunk tank followed by rinsing with clean water or via the shower after being thoroughly cleaned and disinfected with alcohol wipes.</p>	<p><b>Major</b></p>
<p>7.2</p> <p>All personnel must enter and leave the BU through the clothing change and shower airlock.</p> <p><b>Note: Emergency exits may be used if safety would be compromised.</b></p>	<p><b>Major</b></p>
<p>7.3</p> <p>When entering the BU, personnel must:</p> <ol style="list-style-type: none"> <li>a) remove all street clothing, including underwear in the outer clothing change room.</li> <li>b) ensure that the shower door seal is in place and inflated prior to having a full body shower, for a minimum of three minutes.</li> <li>c) not exit the shower until the seal is fully deflated.</li> </ol>	<p><b>Major</b></p>
<p>7.4</p> <p>On entering the inner change room, personnel must dress in dedicated facility clothing and enclosed footwear.</p>	<p><b>Minor</b></p>
<p>7.5</p> <p>The facility clothing and enclosed footwear must remain in the facility until completion of the quarantine isolation period.</p>	<p><b>Major</b></p>
<p>7.6</p> <p>When leaving the BU, personnel must:</p> <ol style="list-style-type: none"> <li>a) remove all facility clothing including footwear, and store or discard it in the inner clothing change room.</li> <li>b) ensure that the shower door seal is in place and inflated prior to having a full body shower, for a minimum of three minutes.</li> <li>c) not exit the shower until the seal is fully deflated.</li> </ol>	<p><b>Major</b></p>

Requirements	Nonconformity guide
<b>Note: On entering the outer change room, personnel can dress in street clothing and footwear.</b>	
7.7  Towels used within the inner clothing change room must remain within the BU containment boundary until the birds have been released from biosecurity control, unless they are decontaminated in a steam steriliser.	<b>Major</b>
7.8  Any disposable clothing worn in the BU must be treated as biosecurity waste and dealt with in accordance with the section on waste.	<b>Major</b>
<b>8. Personal Equipment</b>	
8.1  Personal equipment that is brought into the BU must remain within the BU until the supervising departmental Veterinary Officer has given written authorisation for the removal of the equipment. Generally, the supervising Veterinary Officer will only authorise the removal of equipment from the BU after birds have been released from biosecurity control.  In some limited cases, the supervising Veterinary Officer will provide written authorisation for the removal of personal equipment from the BU before the birds are released from biosecurity control, providing it is cleaned and disinfected before removal.	<b>Major</b>
<b>9. Building construction and maintenance</b>	
9.1  The BU must be fully enclosed within walls (with or without non-openable windows or transparent sections), doors, floors and roof or ceilings. Where there are windows in the BC3 facility, they must be permanently closed and sealed.	<b>Critical</b>
9.2  The BU access doors must be secured at all times, restricting access to authorized persons only.	<b>Major</b>
9.3  The floors and/or floor furnishings of the BU and support rooms containing potentially contaminated, materials, equipment or liquid (e.g. BU storage tanks) must be:  a) smooth; b) impermeable to liquids; c) cleanable; and d) resistant to proposed cleaning agents.	<b>Major</b>
9.4  The walls of the facility must be,	<b>Major</b>

Requirements	Nonconformity guide
a) smooth; b) cleanable; and c) resistant to proposed cleaning agents.	
9.5  The ceilings of the facility must be,  a) smooth; b) impermeable to liquids; c) cleanable; and d) resistant to proposed cleaning agents.  <b>Note: Tiled ceilings do not meet this requirement.</b>	<b>Major</b>
9.6  Entry and exit to the BU must be via an airlock that must include a shower.	<b>Major</b>
9.7  The BU containment barrier must be at the outer door of the shower airlock.	<b>Major</b>
9.8  Provisions for the storage of personnel protective equipment (PPE), clothing, shoes, towels and bath floor mats must be provided in appropriate locations. If it is proposed to use any PPE multiple times, the storage facilities must be arranged such that each item of used PPE does not come into contact with other items.	<b>Minor</b>
9.9  Doors, apart from those to areas used for showering and changing, must contain viewing panels.	<b>Minor</b>
9.10  All access doors to the facility airlock and any change rooms must be self-closing.	<b>Major</b>
9.11  Provision for dedicated facility footwear (for primary containment room) is required.	<b>Minor</b>
9.12  Shower airlock doors in the BU, must be pneumatically sealed on both sides of the shower. Any alternative to this requirement must be approved by the department prior to construction.	<b>Major</b>
9.13  Any emergency egress provision must include an airlock. The outer door must be sealed using pneumatic inflatable seals or an alternative approved by the	<b>Major</b>

Requirements	Nonconformity guide
department. The inner and outer doors of the air-lock must be interlocked. A manual override to disengage the interlock and deflate the outer door for unimpeded escape can be provided in case of door control system failure.	
9.14	
Strainers must be installed in drains in locations where drainage inflow is likely to contain solids (e.g. detritus, aquatic refuse or other particulates).	<b>Major</b>
9.15	
Decontamination chambers, pass through ports, dunk tanks and steam sterilisers must not compromise BU security, biosecurity, or seal integrity. Doors must be interlocked to ensure internal spaces cannot be exposed to areas outside of the BU until the spaces have been decontaminated successfully.	<b>Major</b>
9.16	
On any airlock, there must be a method of preventing more than one airlock door being opened at any one time.	<b>Major</b>
9.17	
The shower airlock must not be used for any work nor contain any equipment, PPE or washing facilities, apart from the shower.	<b>Major</b>
9.18	
Biosecurity facilities must be designed, constructed and maintained to reduce infestation by vermin. Refer to section 5.4.	<b>Major</b>
9.19	
A double-ended, barrier wall steam steriliser (not in the airlock) must be installed through the barrier of the BU.	<b>Major</b>
9.20	
The barrier wall steam steriliser must have an airtight seal to the containment boundary.	<b>Major</b>
9.21	
Barrier wall steam sterilisers must incorporate:	
<ul style="list-style-type: none"> <li>a) automatic interlocking of the inner door with the outer door , ensuring that both door cannot be opened simultaneously,</li> <li>b) sterile membrane filtering or heat treatment of all displaced or evacuated air, steam and liquid,</li> <li>c) protection of pressure sensing instrument tubing by filters that can be steam sterilised,</li> <li>d) the ability to decontaminate by steam or chemical all potentially contaminated pipework,</li> </ul>	<b>Major</b>

Requirements	Nonconformity guide
e) sealed bonnet pressure relief valves, preceded with bursting discs, and monitoring of the interspace for pressure rise.	
9.22	
A measure must be in place to enable BU personnel working with goods subject to biosecurity to be observed from outside the BU.	<b>Major</b>
9.23	
The BU must have two independent communication systems, with	
<ul style="list-style-type: none"> <li>a) one being two-way between personnel within and outside the BU, and the other,</li> <li>b) allowing a person within the BU to attract the attention of personnel outside the BU.</li> </ul>	<b>Major</b>
9.24	
Exposed surfaces and services within the BU enclosure, internal change room and shower airlock must be impervious, smooth and cleanable. Refer also to 9.3, 9.4 and 9.5.	<b>Major</b>
9.25	
Valve and control equipment must be located outside the containment boundary.	<b>Major</b>
9.26	
Structural joints should not form part of the BU containment barrier. Where unavoidable, they must:	
<ul style="list-style-type: none"> <li>a) be impermeable;</li> <li>b) be smooth;</li> <li>c) be permanently sealed to a high standard; and</li> <li>d) where exposed, resist deterioration from proposed cleaning agents and ultraviolet radiation.</li> </ul>	<b>Major</b>
9.27	
Enclosed facilities must be constructed in a manner that allows cleaning and, if required, decontamination. Floors and walls must be impermeable to liquids. Where there are openings in floors, the seal around these openings must prevent the penetration of liquids into the floor substrate.	<b>Major</b>
9.28	
All areas within the BU including storage, corridor and support areas (e.g. imaging areas and storage space with / without shelving) must meet BU requirements.	<b>Major</b>
9.29 Internal fixtures and furnishings	
9.29.1	<b>Major</b>

Requirements	Nonconformity guide
Fittings and furnishings within the BU (e.g. ceiling lights, utility pipes etc) must be impervious, smooth and cleanable.	
9.29.2	
Work surfaces must:	
<ul style="list-style-type: none"> <li>a) be cleanable;</li> <li>b) be smooth;</li> <li>c) be finished with a material that is impermeable to liquids;</li> <li>d) be scratch-resistant; and</li> <li>e) have all joints (including joints to other surfaces) sealed.</li> </ul>	
<b>Note: Impermeable to liquids includes the underside of bench tops and openings cut in benches for items such as cable penetrations, sinks etc.</b>	
9.29.3	
Where sharps are utilised, the BU must have containers for the collection of sharp items as per AS 4031.	
9.29.4	
Cabinetry framing, shelving, and cupboard doors must be:	
<ul style="list-style-type: none"> <li>a) cleanable;</li> <li>b) smooth;</li> <li>c) finished with a material that is impermeable to liquids.</li> </ul>	
9.29.5	
Where cabinetry or fittings are wall mounted, they must have a perimeter seal to the adjoining wall.	
9.29.6	
Under-bench cupboards must be supported off the floor e.g. on wheels, plinths, legs, glides or brackets.	
9.29.7	
Where the BU has walk-in cool rooms, these must have condensing units and other contamination prone components located outside the containment enclosure.	
9.30 Decontamination	
9.30.1	
The ventilation system must be equipped with isolation valves to facilitate isolation and gaseous decontamination of the containment facility.	<b>Major</b>
9.30.2	
The facility must be constructed to contain aerosols or gases.	

Requirements	Nonconformity guide
<p>9.30.3</p> <p>Facility design and construction must exclude inaccessible spaces.</p> <p><b>Note: Electrical and pipe ducting, or air conditioning equipment located within the BU must have removable covers, joinery units with fully accessible voids or cable ducting with removable covers.</b></p>	
<p>9.30.4</p> <p>All facility penetrations must be sealed gas tight.</p>	
<p>9.30.5</p> <p>A new or refurbished BU (less than 12 months since construction or refurbishment), must have an air leakage rate not exceeding 120 litres per minute at 200 Pascals differential test pressure.</p>	
<p>9.30.6</p> <p>Containment facilities with more than 12 months service as a BU, or equivalent, must have an air leakage rate not exceeding 1,200 litres per minute at 200 Pascals differential test pressure. Refer AS/NZS 2243.3 appendix H6 for additional safety precautions recommended for facilities with leakage performance between 120 lpm and 1,200 lpm.</p>	
<p>9.30.7</p> <p>If a large BU is subdivided into individual compartments for undertaking leakage testing, then each tested compartment must have the capability to be sealed and individually gaseous decontaminated. The leakage requirements nominated above apply to each separate decontamination-capable zone.</p>	
<p>9.30.8</p> <p>Subsequent leakage testing must be:</p> <ol style="list-style-type: none"> <li>witnessed and accepted by a department approved assessor; or</li> <li>undertaken and reported by competent personnel and the test process /report accepted by a department approved assessor.</li> </ol>	
<hr/> <p>9.31 Reticulated Services</p>	
<p>9.31.1</p> <p>The following services must be clearly and permanently labelled or identified, at accessible and visible locations, over their complete length:</p> <ol style="list-style-type: none"> <li>potable and non-potable water piping;</li> <li>liquid waste piping systems.</li> </ol>	<p><b>Major</b></p>
<p>9.31.2</p> <p>Valves (e.g. RPZ devices) and control equipment must be located outside the containment boundary.</p>	



Requirements	Nonconformity guide
<p>9.31.3</p> <p>Liquid waste pipe systems must:</p> <ol style="list-style-type: none"> <li>incorporate service isolation valves for isolating and decontaminating all BU waste reticulated within the building; and</li> <li>have the isolating valves easily accessible.</li> </ol>	
<p>9.31.4</p> <p>Vacuum systems serving the BU must:</p> <ol style="list-style-type: none"> <li>incorporate liquid interceptor vessels traps including a safe means of isolating and adding a suitable liquid decontaminant within the BU, and</li> <li>have 0.2 micron membrane filters provided to each vacuum point within the BU.</li> <li>The vacuum pump shall be fitted with a a 0.2um grade filter.</li> <li>Discharge from the vacuum system shall be outside away from building openings and HVAC outside air intakes</li> </ol>	
<p>9.31.5</p> <p>In-line filters must be accessible for replacement without breaching containment.</p>	
<p>9.31.6</p> <p>Disposal systems (e.g. pipes, tanks and pumps) must be constructed of materials that are resistant to damage from the reticulated waste.</p>	
<p>9.31.7</p> <p>Backflow prevention devices in accordance with AS/NZS 3500 must be installed in individual water lines supplying:</p> <ol style="list-style-type: none"> <li>personnel and emergency showers, hand wash sinks and eye wash stations;</li> <li>laboratory and process sinks (separate protection required for each room serving as primary containment);</li> <li>outlets in BSCs (separate protection required for each room); and</li> <li>outlets for animal drinking water (separate protection required for each room serving as primary containment).</li> </ol>	
<hr/>	
<p>9.32 Access to Services</p>	
<p>9.32.1</p> <p>Access to any BU equipment in voids surrounding the immediate perimeter of the BU and to the ventilation equipment that serves the BU must be restricted to authorised persons.</p>	<b>Major</b>
<p>9.32.2</p> <p>Items of equipment, ducts and access panels in sections of the ventilation system forming part of the containment barrier must be marked with biohazard labels.</p>	
<p>9.32.3</p>	

Requirements	Nonconformity guide
There must be access to equipment such as HEPA filters for maintenance and testing personnel and their equipment.	
9.33 Buildings, structures and plant equipment must be maintained in a state of good repair. Regular maintenance checks and servicing must be conducted according to the manufacturer's recommendations or as agreed with the department.	<b>Critical</b>
9.34 Biosecurity buildings must be constructed with impervious surfaces on floors, walls and ceilings. Wall and floor junctions must be sealed, or some other measure must be in place to ensure that they can be effectively cleaned and disinfected and do not allow leakage of air beyond the required limits.	<b>Major</b>
9.35 Biosecurity buildings and equipment (e.g. HEPA filter housings and ductwork) must be constructed such that they can be sealed to enable decontamination using formaldehyde gas or an approved alternative.	<b>Critical</b>
9.36 Access to potentially contaminated parts of a BU or its equipment for cleaning, servicing of equipment and repairs must not occur until potentially contaminated surfaces have been disinfected with an approved broad-spectrum disinfectant.	<b>Major</b>
9.37 All equipment, facilities and building testing, checks and maintenance must be carried out according to the manufacturer's recommendations and as approved by the department in the AA site's standard operating procedures. Records of these checks, testing and maintenance must be kept for a minimum of 12 months and must be made available to the department upon request.	<b>Major</b>
<b>10. Signage and security</b>	
10.1 A sign showing the level of containment (i.e. BC3/PC3) must be prominently displayed at each entry to the BU when goods subject to biosecurity control are held, stored, handled or grown. Biosecurity signs around the BU and storage areas must: <ul style="list-style-type: none"> <li>• be securely affixed</li> <li>• be durable</li> <li>• be prominently displayed and able to be clearly read by persons approaching the area at all times</li> </ul> <b>Note: Where new signs are being produced, they should use biosecurity not quarantine.</b>	<b>Minor</b>
10.2	<b>Major</b>

Requirements	Nonconformity guide
<p>The site must at all times operate in a manner that prevents fertile eggs, birds, clean feed, bedding, samples, tissues, waste consumables, containers or other goods and equipment subject to biosecurity control from:</p> <ul style="list-style-type: none"> <li>being moved and/or interfered with by persons other than those specifically authorised to do so by the supervising department Veterinary Officer being moved into or out of the BU, other than in accordance with written permission from the department (which includes the approved procedures).</li> </ul>	
<p>10.3</p> <p>Access to the BU must be limited to persons on the access list compiled by the manager and approved by the supervising Department Veterinary Officer. Site employees at all times must accompany visitors to the BU including Biosecurity Officers.</p>	<p><b>Major</b></p>
<p>10.4</p> <p>The site must implement 24 hour security arrangements to effectively secure goods subject to biosecurity control from movement or interference by unauthorised persons. The proposed security arrangements must be detailed at the time of application for approval and receive endorsement by the department. This may include the use of video surveillance. Alarms or other security monitoring methods may also be used.</p> <p>Where practical, services for the BU facility must be located outside the containment boundary. Supporting equipment (ventilation equipment, pumps and other equipment, heating and cooling equipment, shading devices) must be located outside the containment facility, wherever practical, to minimize the requirements for repair and maintenance inside the facility.</p> <p><b>Note: The need for service personnel to enter the containment facility should be minimised.</b></p>	<p><b>Major</b></p>
<p>10.5</p> <p>The site must at all times operate in a manner that controls access to the site, and controls access to the BU, including (at a minimum):</p> <ul style="list-style-type: none"> <li>ensuring all employees authorised to enter the BU unaccompanied, are accredited by completing the online training course Approved Arrangements for Accredited Persons (Classes 1 to 8) on the website Guardian—online training by the Australian Industry Working Group on Biosecurity, or are accompanied by an employee who has completed this training</li> <li>keeping an access register with the names of each person authorised to enter the BU</li> <li>ensuring the access register with the list of persons authorised to enter the BU is approved by a department Veterinary Officer recording the name of each person who enters the BU, when they enter the BU and when they exit the BU and their reason for entering.</li> </ul>	<p><b>Major</b></p>
<p>10.6</p> <p>The department's Horses, Livestock and Birds Program and the supervising Department Veterinary Officer must be notified immediately of any incidents that could compromise the security, including biosecurity, of the site. This</p>	<p><b>Critical</b></p>

Requirements	Nonconformity guide
includes structural damage, unauthorised entry to the site, removal from the site of fertile poultry eggs and birds subject to biosecurity control, removal or leakage of any biosecurity waste or equipment, or any breach, or suspected breach, of the approved procedures or these conditions.	
<b>11. Biosecurity treatment and waste management</b>	
<p>11.1</p> <p>Biosecurity waste must be effectively contained/treated and disposed of in a manner approved by the department. A document outlining specific procedures for the holding or treatment and disposal of biosecurity waste must be included in the AA site's standard operating procedures and must receive endorsement from the department.</p>	
<p>11.1.1</p> <p>Effective containment/treatment of solid biosecurity waste includes:</p> <ul style="list-style-type: none"> <li>• double bagging and storage in the freezer inside the BU until the consignment has been released from biosecurity control; or</li> <li>• double bagging and autoclaving (steam sterilising) prior to disposal</li> <li>• incinerating at a high temperature in a high efficiency incineration facility approved by the department.</li> </ul>	
<p>11.1.2</p> <p>Waste subject to biosecurity control must be segregated from other waste.</p>	
<p>11.1.3</p> <p>All biosecurity waste or waste potentially contaminated with goods subject to biosecurity control (both liquid and solid), must be decontaminated by a department approved method.</p>	<b>Major</b>
<p><b>Note:</b></p> <ol style="list-style-type: none"> <li>1. <b>Heat treatment within approved parameters is a department approved treatment.</b></li> <li>2. <b>Import Permit conditions may specify specific disposal requirements.</b></li> </ol>	
<p>11.1.4</p> <p>The BIP must use one of the following department approved methods of inactivation, decontamination and/or disposal:</p> <ol style="list-style-type: none"> <li>a) dry or moist heat sterilization;</li> <li>b) high temperature incineration (to irreducible ash);</li> <li>c) disinfection using department approved disinfectant;</li> <li>d) high temperature alkaline hydrolysis;</li> <li>e) batch or continuous flow heat treatment (for liquid waste);</li> <li>f) other methods approved by the department.</li> </ol> <p><b>Note: The Import Permit may specify treatment requirements.</b></p>	
<p>11.1.5</p>	

Requirements	Nonconformity guide
<p>The BIP must use a department approved method for the decontamination of contaminated or potentially contaminated surfaces (e.g. work surfaces).</p> <p><b>Note: The Import Permit may specify treatment requirements.</b></p>	
<p>11.2 Equipment handling</p> <p>11.2.1</p> <p>The BIP must decontaminate any equipment that has potentially been exposed to contaminated biosecurity material, by a department approved method prior to carrying out any maintenance, service or before being removed from the BU.</p> <p><b>Note: Removal from the facility will not normally be allowed during biosecurity isolation of the birds and will require the departments approval.</b></p> <p>11.2.2</p> <p>Animal waste (feathers; remains of birds following post-mortems or animal bedding) is biosecurity waste and must be treated as detailed in 11.1.</p> <p>Where animal holding areas/pens/cages are plumbed to floor drains, these drains must be fitted with strainers to ensure that all solids (e.g. bedding, faecal matter) are collected. Waste solids collected from drains must be treated as detailed in 11.1.</p>	<p><b>Critical</b></p>
<p>11.3</p> <p>Liquid waste must be disposed of by screening through a 250 micron mesh screen followed by:</p> <ul style="list-style-type: none"> <li>• approved heat/chemical treatment followed by release to a municipal sewer or</li> <li>• storage in a department approved treatment/holding tank followed by treatment by an approved method or holding for the duration of the applicable biosecurity period.</li> </ul> <p>11.3.1</p> <p>All waste filter media and detritus/refuse captured by filter media or screens must be treated as biosecurity waste and must be thermally decontaminated or stored until the birds are released from biosecurity control. Refer 13.11 for recording requirements.</p> <p>11.3.2</p> <p>The following requirements apply to the chemical treatment of biosecurity liquid waste:</p> <ul style="list-style-type: none"> <li>• Liquid waste must be filtered to remove solids and mixed uniformly with hypochlorite.</li> <li>• For a period not less than 60 minutes free chlorine must remain above 200ppm and the pH of the water must remain below 7.0.</li> </ul> <p>An example protocol that would achieve this outcome is:</p> <ol style="list-style-type: none"> <li>1. Liquid waste must pass through a 250 micron screen prior to hypochlorite treatment (solids are collected and steam sterilised)</li> </ol>	<p><b>Major</b></p>

Requirements	Nonconformity guide
<p>2. From the commencement of step 3. to the conclusion of step 5., appropriate monitoring (either continuous or at regular intervals), must occur to ensure:</p> <p>a) The pH of the liquid waste remains below 7.</p> <p>b) The concentration of the hypochlorite is greater than or equal to 200ppm (200mg/L).</p> <p><i>Processes must be in place to correct pH or free chlorine concentrations found to be outside the required ranges and treatment time to ensure that the liquid waste is treated at the required pH and chlorine level for at least 60 minutes.</i></p> <p>3. Following filtration, liquid waste must pass to a tank/retention vessel where sufficient hypochlorite must be added to achieve a concentration of at least 200 ppm.</p> <p>4. Following addition of hypochlorite, liquid waste must be agitated for at least 10 minutes to ensure thorough mixing of hypochlorite.</p> <p>5. Following agitation, liquid waste must be retained for a period of not less than 60 minutes.</p> <p>6. During the 60 minute period the pH and chlorine concentration must be monitored. The concentration must be adjusted and the 60 minute period must be re-started if the parameters are measured outside of the requirements.</p> <p>7. Following the 60 minute retention period, the liquid waste can be discharged in accordance with jurisdictional environmental requirements.</p> <ul style="list-style-type: none"> <li>• Sodium hypochlorite is an example of a chemical that may be used for chlorine treatment for biosecurity liquid waste.</li> </ul>	

Chemicals must be used by the sooner of: an expiry time frame as specified by the manufacturer, or within two years of the manufacture date.

#### 11.4

For liquid waste being treated at the site during quarantine isolation, procedures and records must include the following:

- collection and securing of waste
- treatment being applied
- treatment application regime including:
  - date and times of treatment and testing
  - pH measurements
  - pH adjustment if required (initial and final pH)
  - amount of hypochlorite added
  - concentration of free chlorine in treatment tank after agitation
  - amount of additional hypochlorite added (where required)
  - concentration of free chlorine in treatment tank after further agitation (when additional hypochlorite added)
  - concentration of free chlorine at conclusion of 1 hour treatment and time treatment completed
  - date of manufacture of hypochlorite
  - date of expiry of hypochlorite.

**Major**

Requirements	Nonconformity guide
<p>11.5</p> <p>Liquid waste treatment facilities/tanks must be constructed in a way to:</p> <ul style="list-style-type: none"> <li>• restrict access to pipes, plant and equipment to suitably qualified and trained persons</li> <li>• ensure containment of liquid waste using a sealed system from the BU collection points until discharge at the end of the successful treatment cycle.</li> <li>• exclude exposure to untreated liquid waste prior to and during treatment</li> <li>• ensure untreated liquid waste is not released</li> <li>• enable consistent agitation</li> <li>• enable holding for at least one hour during treatment.</li> </ul> <p>When leaks are detected they must be immediately repaired.</p> <p>Work Health and Safety procedures must address the risk of working with acid/alkali (low/high pH) chemicals, chlorine compounds and liquid waste.</p>	<b>Major</b>
11.6 Liquid Waste Treatment Plant room	
<p>11.6.1</p> <p>The floors and/or floor furnishings of the liquid waste treatment room must be:</p> <ol style="list-style-type: none"> <li>a) smooth;</li> <li>b) impermeable to liquids;</li> <li>c) cleanable; and</li> <li>d) resistant to common cleaning agents.</li> </ol>	
<p>11.6.2</p> <p>The walls of the liquid waste treatment room must be smooth, cleanable and resistant to common cleaning agents.</p>	
<p>11.6.3</p> <p>The ceilings of the liquid waste treatment room must be:</p> <ol style="list-style-type: none"> <li>a) smooth</li> <li>b) impermeable to liquids</li> <li>c) cleanable; and</li> <li>d) resistant to common cleaning agents.</li> </ol>	<b>Major</b>
<b>Note: Tiled ceilings are not permitted.</b>	
<p>11.6.4</p> <p>The floor of the liquid waste treatment room must be bunded to the largest potential spill volume. This volume can include multiple tanks where interconnecting pipes could result in a combined spill event.</p>	
<p>11.6.5</p> <p>The bunded space within the liquid waste treatment room must drain to a sealed sump.</p>	
<p>11.6.6</p> <p>The sealed sump must enable manual discharge of the spillage after chemical disinfection.</p>	

Requirements	Nonconformity guide
<p>11.6.7</p> <p>A mechanism must be in place to prevent a water fixture overloading the liquid waste treatment system.</p>	
<p>11.6.8</p> <p>Air must be exhausted from the liquid waste treatment room to outside atmosphere. Exhaust ducts within buildings must be treated as “local exhaust” and must be installed in accordance with the requirements of AS/NZS 2982.</p>	
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<p>11.7 Liquid Waste Treatment Facilities</p>	
<p>11.7.1</p> <p>The waste disposal system (e.g. pipes, tanks and pumps) must be constructed of materials that are compatible with the liquid waste and with the liquid waste treatment chemicals.</p>	
<p>11.7.2</p> <p>The liquid waste treatment pipe and vent system must be capable of being decontaminated using a suitable chemical (e.g. sodium hydroxide). Isolation valves, fillpoints and venting paths must be provided to ensure air pockets can be eliminated and that the procedure can be carried out safely and can maintain biosecurity.</p>	
<p>11.7.3</p> <p>Pipe systems must not contain pockets, voids or spaces which may not be exposed to chemical treatment during a decontamination procedure.</p>	
<p>11.7.4</p> <p>Pipe material must be impact resistant and piping must be physically protected where exposed to mechanical damage.</p>	
<p>11.7.5</p> <p>All vents connected to the waste system tanks and pipes must be fitted with 0.2um hydrophobic membrane filters that can be decontaminated in situ by steam sterilisation, chemical decontamination or an equivalent department approved method.</p>	<p><b>Major</b></p>
<p>11.7.6</p> <p>When first commissioned and after modification, the pipe system must be pressure integrity tested at static pressure (i.e. Where the waste and vent system is filled for liquid decontamination), plus 100 kPa. The waste and vent systems may be segregated for this test if desired. If this method is adopted, isolation valves between wastes and vents must be permanently installed.</p>	
<p>11.7.7</p> <p>Pipe construction must be double skin in locations where visual inspection cannot be undertaken. Annular spaces of double-skin pipe segments must drain to visible locations so that leaks can be monitored.</p>	
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<p>11.8 Biosecurity treatments</p>	
<p>11.8.1</p>	<p><b>Major</b></p>



Requirements	Nonconformity guide
<p>Waste subject to biosecurity control must be treated by a department approved method before release from biosecurity control.</p> <p>11.8.3</p> <p>The BIP must use a department approved method for the decontamination of contaminated or potentially contaminated surfaces (e.g. work surfaces).</p> <p><b>Note: The Import Permit may specify treatment requirements.</b></p>	
<p>11.9 Contaminated or potentially contaminated liquid waste treatment</p> <p>11.9.1</p> <p>Liquid waste must be treated before disposal. Treatment may include:</p> <ol style="list-style-type: none"> <li>steam sterilisation;</li> <li>batch heat treatment;</li> <li>continuous flow heat treatment;</li> <li>chemical treatment utilising the procedure described herein; or</li> <li>a department approved method.</li> </ol> <p>After treatment, liquid waste must be discharged into sewer unless another discharge arrangement is specifically approved by the department.</p> <p>11.9.2</p> <p>Where batch heat treatment is undertaken for liquid waste decontamination the minimum holding time after attainment of holding temperature must be 30 minutes at 121°C.</p> <p><b>Note: Liquid waste which is heat treated by this batch method is permitted to contain solids.</b></p> <p>11.9.3</p> <p>For continuous flow and chemical heat treatment, all liquid waste must be screened through a 250 micron filter prior to decontamination.</p> <p>11.9.4</p> <p>Where continuous flow heat treatment is undertaken for liquid waste decontamination, the minimum holding time after attainment of holding temperature must comply with one of the following schedules:</p> <ol style="list-style-type: none"> <li>4 minutes at 133°C; or</li> <li>3 minutes at 134°C; or</li> <li>2 minutes at 136°C.</li> </ol> <p><b>Note: liquid waste which is heat treated by this continuous flow method must not contain any solids greater than 250 microns in size.</b></p> <p>11.9.5</p> <p>An effluent waste treatment process must contain and treat any solid material captured within the system, or a filtration / strainer system must be provided for removal of solids prior to liquid waste entering the equipment.</p> <p>11.9.6</p> <p>Where a filtration system is installed, it must be capable of being decontaminated,</p> <ol style="list-style-type: none"> <li>without releasing potentially contaminated biosecurity material; and</li> <li>prior to removal and disposal or cleaning of the element.</li> </ol> <p>11.9.7</p>	<p><b>Major</b></p>

Requirements	Nonconformity guide
<p>Solids, sludge and particulates captured from liquid waste by filters or strainers must be decontaminated by a department approved method.</p> <p>11.9.8</p> <p>In locations where a municipal sewer is unavailable, the department must approve, in writing, an alternative liquid waste disposal methodology.</p>	
<p>11.10</p> <p>Liquid waste decontamination (batch &amp; continuous flow) - validation</p> <p>11.10.1</p> <p>Liquid waste treatment systems must be validated during commissioning and annually, thereafter, in conjunction with the major, annual services on the liquid waste decontamination system. The validation process must include:</p> <ul style="list-style-type: none"> <li>a) NATA Temperature sensor calibrations for thermal based systems;</li> <li>b) chemical concentration measuring instruments for chemical based systems;</li> <li>c) Flow rate verification for continuous flow systems;</li> <li>d) Verification of holding time, temperature, and concentration as applicable;</li> <li>e) Demonstration that controls and fail safe mechanisms are in place to prevent discharge of potentially contaminated biosecurity material in event of equipment failure or malfunction;</li> <li>f) Verifying process controls and fail safe systems function as per the manufacturer's specification;</li> <li>g) Leakage testing for internal or external leakage;</li> <li>h) methodologies to decontaminate components of the treatment systems and pipes for maintenance; and</li> <li>i) methodologies to manage equipment or pipe failure without loss of biosecurity integrity.</li> </ul>	
<p>11.10.2</p> <p>To ensure accurate measurement of physical parameters, liquid waste heat treatment equipment must:</p> <ul style="list-style-type: none"> <li>a) Have temperature sensors calibrated (to the temperature being used) using measuring equipment that has a current certificate of calibration issued by a body with third-party (e.g. NATA) accreditation for conducting such calibrations;</li> <li>b) Have actual treatment holding temperature verified with -0%, +10% of the design temperature by the above calibration;</li> <li>c) Have effluent flow verified within +0%, -10% of design flow rate for continuous flow systems.</li> </ul>	<p><b>Major</b></p>
<p><b>Note:</b></p> <ol style="list-style-type: none"> <li>1. <b>Design temperature and design flow rate must be chosen to meet the department's minimum temperature and holding time for decontamination.</b></li> <li>2. <b>Refer to the BC3 Informative Text for information on methods of flow verification.</b></li> </ol>	
<p>11.10.3</p> <p>Potentially contaminated sections of liquid waste treatment systems must be tested for leakage by:</p> <ul style="list-style-type: none"> <li>a) static pressurisation to the normal working pressure plus a suitable safety margin recommended by the manufacturer, or</li> </ul>	

Requirements	Nonconformity guide
b) an equal method approved by the department.	
<p>11.11 Monitoring liquid waste treatment</p> <p>11.11.1</p> <p>During the treatment of contaminated or potentially contaminated biosecurity liquids, the BIP must undertake daily visual inspection for leaks from:</p> <p>a) pumps; b) valves; c) tanks; and d) filter housing, pipes and connections.</p> <p>11.11.2</p> <p>When leaks are detected they must be immediately repaired, logged and reported to the department.</p> <p>11.11.3</p> <p>All discarded waste filter media and material captured by filter media or screens must be treated as biosecurity waste.</p>	<b>Major</b>
11.12 Dry and moist heat sterilisation - validation	
<p>11.12.1</p> <p>Steriliser cycles must be validated by demonstrating that:</p> <p>a) physical parameters have been met for each load cycle (i.e. the department approved time and temperature has been reached in both the coolest part of the chamber and the potentially coolest part of the load); and b) biological lethality parameters have been demonstrated under testing at monthly intervals (This item requires the assessment of biological indicators that have been placed in several positions in a load, including the coolest part of the chamber (drain point for moist heat treatment), the potentially coolest part of the load and adjacent to each temperature sensor; c) or, alternatively, validated load profiling must be used.</p> <p>11.12.2</p> <p>To ensure accurate measuring of physical parameters, sterilisers must:</p> <p>a) Have temperature gauges or sensors and equipment (e.g. thermocouples) calibrated (to the temperature being used) using measuring equipment that has a current certificate of calibration issued by a body with third-party (e.g. NATA) accreditation for conducting such calibrations. b) Have calibration performed at least every 12 months.</p>	<b>Major</b>
<p>11.12.3</p> <p>To ensure that the department approved temperature is met when undertaking dry or moist heat sterilisation, the BIP must compensate for the estimated uncertainty and any calibration error.</p>	
<p>11.12.4</p> <p>For every sterilising cycle, the BIP must:</p> <p>a) log time and temperature details at one minute intervals or less, or b) use bacterial enzyme indicators in both the coolest part of the steriliser and the densest part of the load.</p>	
<b>Note:</b>	

Requirements	Nonconformity guide
<p><b>1. For load profiled cycles the recorded temperature must be the reference temperature for which the profile was validated;</b></p> <p><b>2. For other cycles the recorded temperature must be the lowest reading from probes in the coolest part of the chamber and the densest part of the load.</b></p>	
<p>11.13 Moist heat sterilisation – loading</p> <p>11.13.1</p> <p>Pressure moist heat sterilisation loading must ensure that:</p> <p>a) small articles such as test tubes or bottles are packed in open mesh baskets/similar containers or in autoclave bags;</p> <p>b) screw caps on containers are loosened; and</p> <p>c) empty containers are placed on their sides in the chamber.</p> <p>11.13.2</p> <p>When autoclave bags are used and the goods/waste to be treated is not liquid (i.e. dry), the bags must be either:</p> <p>a) opened prior to loading;</p> <p>b) have water added;</p> <p>c) be slashed as loaded; or</p> <p>d) tied with melting ties.</p> <p>11.13.3</p> <p>A steriliser cycle with pre-vacuum stage for air removal, must be used for porous loads such as clothing.</p> <p>11.13.4</p> <p>For all moist heat sterilisation cycles to be considered complete and acceptable the minimum continuous holding times after attainment of temperature (set point when using physical parameters at the coldest part of the load) must be:</p> <p>a) 15 minutes at 121 degrees Celsius and 103 kPa, or</p> <p>b) 3 minutes at 134 degrees Celsius and 203 kPa.</p> <p>11.13.5</p> <p>Pressure steam steriliser vent filters must be replaced as recommended by the filter manufacturer based on the number of cycles, with a minimum time interval of 12 months and disposed of as biosecurity waste.</p>	<b>Major</b>
<p>11.14 Dry heat sterilisation - loading</p> <p>11.14.1</p> <p>Dry heat sterilisation loading for goods/waste subject to biosecurity control must ensure that:</p> <p>a) Loads are arranged to allow uninterrupted airflow.</p> <p>b) Any containers used enable heat conductivity.</p>	<b>Major</b>
<p>11.15 Dry and moist heat sterilisation – using physical parameters for the logging of temperature cycles</p> <p>11.15.1</p> <p>The BIP must ensure effective sterilisation by, commencing the sterilisation stage when the set point temperature is recorded by the sensor (e.g. thermocouple, resistance temperature detector) in:</p>	<b>Major</b>

Requirements	Nonconformity guide
<p>a) both the coolest part of the chamber (normally the drain point) and the densest part of load for moist heat sterilisation; or</p> <p>b) the densest part of the load for dry heat sterilisation.</p>	
<p>11.16 Steriliser load profiling</p> <p>11.16.1</p> <p>Steriliser load profiling validation must include:</p> <p>a) Determining the process and conditions required for sterilising each generic load (this requires consideration of every aspect of goods/waste subject to biosecurity processing, including the type of goods, cleaning, packaging, packing of the steriliser and any other factor affecting sterilisation efficacy).</p> <p>b) Verifying that the intended sterilisation conditions are being achieved throughout the load in the standard loading configuration to be used (this requires spatial sampling with temperature sensors, e.g. thermocouples placed in the corners and middle of the steriliser and in the drain line).</p> <p>c) Validating the generic cycle using results from the chosen physical and biological monitoring methods.</p> <p>d) Demonstrating, by undertaking a minimum of 3 trials that the intended sterilisation conditions will be consistently achieved during repeated operation of the steriliser.</p> <p>11.16.2</p> <p>Revalidation of load profiling must be undertaken when there are any changes in parameters or equipment.</p>	<b>Major</b>

## 12. Work practices and animal husbandry

### 12.1

The BIP, at the time of application for approval, must provide a site operations manual/standard operating procedure that is approved by the Horse, Livestock and Bird Imports Program and meets current import permit and biosecurity risk management requirements. This document must detail biosecurity operations that will be undertaken at the site and accurately and comprehensively detail procedures that will be followed by accredited and other persons working with goods subject to biosecurity control and maintaining associated records. The site manual must include details of at least the following:

- work procedures for vermin and rodent control measures within the site
- standard format for records including:
  - daily bird health records (including all testing, monitoring and treatments)
  - visitor records
  - cleaning and disinfection records
  - waste and treatment records
  - daily compliance reports
- work procedures for visitors to the site, including ensuring adequate decontamination occurs prior to leaving the BU
- work procedures for receiving fertile eggs subject to biosecurity control into the BU.
- work procedures for daily monitoring of the health of birds on the site

**Critical**

Requirements	Nonconformity guide
<ul style="list-style-type: none"> <li>• work procedures addressing attendance of any essential external service providers (<b>Note: That the department will not approve the entry of non-essential service providers while fertile eggs/birds subject to biosecurity control are being held at the site</b>)</li> <li>• work procedures for cleaning and disinfection of the BU and equipment used in the BU</li> <li>• work procedures for hygiene, dedicated or disposable clothing and footwear</li> <li>• work procedures for releasing birds from the site at the end of biosecurity isolation period</li> <li>• work procedures for emergency situations such as fires</li> <li>• work procedures outlining requirements for reporting: <ul style="list-style-type: none"> <li>○ daily compliance report submission</li> <li>○ disease detection/suspicion</li> <li>○ breaches of any conditions of the site approval or noncompliance with the procedures set out in the site operations manual/standard operating procedure, or the Import Permit conditions</li> </ul> </li> <li>• work procedures for waste (other than liquid) storage, treatment and removal</li> <li>• work procedures for liquid waste collection, screen cleanout, storage, treatment and removal</li> <li>• procedures for training staff and (where relevant) private personnel, and authorising their entry to the site and any particular biosecurity areas or other areas of the site.</li> <li>• procedures for collection, packaging, decontamination of packaging, and despatch of veterinary samples</li> <li>• work procedures for managing the site in a way that prevents fertile eggs/birds subject to biosecurity control being moved, and/or being interfered with, by unauthorised persons. These procedures may include: <ul style="list-style-type: none"> <li>○ ensuring visitors to the BU are accompanied or supervised by an authorised person at all times</li> <li>○ locking the BU when unattended</li> </ul> </li> <li>• work procedures for controlling access to the site, and separate controls for the BU. These procedures may include: <ul style="list-style-type: none"> <li>○ registers of people authorised to access the site and visitors</li> <li>○ procedures for nightly lock-down where applicable.</li> </ul> </li> </ul>	
<p>12.2</p> <p>The approved procedures must be followed at the site at all times.</p>	<p><b>Major</b></p>
<p>12.3</p> <p>The Biosecurity Industry Participant (BIP) must ensure that a copy of the approved procedures are made available to the department upon request. Approval of the procedures will be subject to review/renewal by the department Veterinary Officer or the Horse, Livestock and Bird Imports Program at</p>	<p><b>Major</b></p>

Requirements	Nonconformity guide
verification audits and when deficiencies are noted or changes to biosecurity risk management measures are required.	
<p>12.4</p> <p>Compliance with the approved procedures, these AA site requirements and other import requirements must be reviewed at least annually. Audit inspection and review will occur prior to each consignment if deemed necessary by the department Veterinary Officer or Director of the Horse, Livestock and Bird imports program. Non-compliance with these requirements may result in the revocation of an import permit and/or suspension of the AA site's approval.</p>	<b>Major</b>
<p>12.5</p> <p>A transport plan, detailing how the consignment will be taken from the port of arrival to the AA site must be submitted. The transport plan must include:</p> <ul style="list-style-type: none"> <li>• the most direct route between the two sites</li> <li>• use of all weather roads or as approved by the department</li> <li>• in the event of an incident or accident during transport, the importer must submit a contingency plan. The contingency plan must: <ul style="list-style-type: none"> <li>○ include reference to the road transport authority, police, fire, and ambulance</li> <li>○ clearly outline how biosecurity will be maintained</li> <li>○ include procedures for the clean-up of any contaminated site/s, prevention of access by animals and non-essential personnel, and decontamination of any personnel that may be exposed to egg material or other biosecurity risk material.</li> </ul> </li> </ul>	<b>Minor</b>
<p>12.6</p> <p>Procedures must be developed by the BIP and approved by the department, for the effective decontamination and, where necessary, disposal of potentially contaminated or known to be contaminated refuse such as faeces, litter and liquid effluent as per the section on biosecurity waste. Approved procedures must be followed at all times.</p>	<b>Critical</b>
<p>12.7</p> <p>Procedures approved by the department must be in place to ensure:</p> <ul style="list-style-type: none"> <li>• inward air flow</li> <li>• capture of dander and dust as close as practicable to where it is generated</li> <li>• filtration of all supply and exhaust air.</li> </ul> <p>These procedures must be operational at all times.</p>	<b>Critical</b>
<p>12.8</p> <p>Procedures approved by the department, must be in place to ensure the safe ingress and egress of personnel and material including decontamination prior to removal or exit from the BU. For example, showers, dunk tank decontamination chamber and autoclave. Unless personnel are entering or exiting, doors must remain closed and sealed. These procedures must be followed at all times.</p>	<b>Critical</b>
<p>12.9</p>	<b>Major</b>

Requirements	Nonconformity guide
<p>Procedures (including identification and approval of sites) approved by the department, must be in place for the safe disposal of birds and associated waste should there be an outbreak of one of the prescribed diseases.</p>	
<p>12.10</p> <p>Procedures must be in place and approved by the department, to ensure records are kept of any poultry medication stored or used on the site. Permission must be obtained from the Director of Animal and Plant Biosecurity (via the Horse, Livestock and Bird Imports Program) prior to any medication being used on the birds subject to biosecurity control.</p>	<b>Critical</b>
<p>12.11</p> <p>Procedures must be in place and approved by the department, to ensure any sampling and post-mortems are carried out by a department Veterinary Officer or under the supervision of a department Veterinary Officer by a private/industry/importer veterinarian or trained personnel.</p>	<b>Critical</b>
<p>12.12</p> <p>Procedures must be in place and approved by the department, to approve and control the movement of staff operating the site including procedures to ensure that staff will have no other contact with poultry or other birds during prescribed times. Anyone entering the BU must declare that they have not had any contact with other poultry or birds at least 48 hours prior to the visit and will not have any contact with poultry or birds for a minimum period of 120 hours after the visit.</p>	<b>Critical</b>
<p>12.13</p> <p>Procedures must be in place and approved by the department, to facilitate the department's supervision of the site and consignment, including agreement on the level of that supervision as well as the department's inspection of each consignment and/or (if necessary) supervising destruction of the consignment. This is the biosecurity performance procedure. As a minimum, the Biosecurity Officers/Veterinarians must be invited with 14 days notice to be present to oversee the following activities:</p> <ul style="list-style-type: none"> <li>• arrival of egg consignment at port of entry and dispatch to the private biosecurity AA site</li> <li>• autoclaving and disposal or storage of imported egg packaging materials within the BU of the AA site</li> <li>• disinfection of the transport vehicle and any materials that have been in contact with the imported consignment, with a disinfectant approved by the department</li> <li>• collection of samples from pipped embryos and mortalities or culls due to illness during the first 10 days following hatch or as required by the department</li> <li>• collection of sera from sentinel chicks and cloacal swabs from the imported flock at six weeks of age</li> <li>• dispatch of samples to AAHL or approved government laboratories</li> <li>• any follow-up biosecurity/testing procedures arising from laboratory results or any decision by the Director of Biosecurity</li> </ul>	<b>Critical</b>



Requirements	Nonconformity guide
<ul style="list-style-type: none"> <li>inspection of the imported flock within 72 hours prior to release from biosecurity control</li> <li>post-mortem and sampling of birds.</li> </ul>	
12.14	
<p>Procedures must be established by the BIP, approved by the department and followed by the BIP, to ensure the department is notified immediately if any of the following occurs:</p>	
<ul style="list-style-type: none"> <li>clinical disease</li> <li>mortalities out of the normal range</li> <li>breakdown in exhaust air filtration system or air flow direction reversal</li> <li>breaks in procedures which could potentially impact on biosecurity integrity.</li> </ul>	<b>Critical</b>
12.15	
<p>As a minimum the consignment must successfully pass tests for diseases specified in the import conditions. Random departmental inspections during the period of biosecurity, including inspection of records may occur at any time, including at:</p>	
<ul style="list-style-type: none"> <li>eggs set</li> <li>chicks hatched</li> <li>chicks placed in pens</li> <li>random documentation checks by the department may occur to inspect records for: <ul style="list-style-type: none"> <li>detailed daily mortality records and culling records including reasons for culling</li> <li>bird selection and culling criteria</li> <li>treatments and medications</li> <li>daily visual observations of flock health and vigour.</li> </ul> </li> </ul>	<b>Critical</b>
12.16	
<p>Procedures must be in place and approved by the department, to ensure proper husbandry and management of the hatching eggs and birds.</p>	<b>Major</b>
12.17	
<p>The applicant must pay the fees for service imposed under the department's fees determination in relation to the site by the due date shown on an invoice issued.</p>	<b>Major</b>
12.18	
<p>The BIP must ensure that all requirements including Import Permit conditions that apply to fertile eggs and birds subject to biosecurity control, are complied with while at the site.</p>	<b>Critical</b>
12.19	
<p>Procedures must be in place and approved by the department, to ensure:</p>	
<ul style="list-style-type: none"> <li>the thorough clean out and safe disposal of refuse at the end of the all in/all out biosecurity program.</li> <li>documentation of general procedures for waste disposal</li> </ul>	<b>Major</b>

Requirements	Nonconformity guide
<ul style="list-style-type: none"> <li>preparation of specific work instructions for individual tasks.</li> </ul> <p>The company must comply with procedures and requirements detailed in import permits and the AA site class 7.10 requirements for Fertile poultry hatching eggs, the procedures approved by the department and the birds must meet all import requirements in order for the birds to be released from biosecurity control.</p> <p>The company must comply with directions issued by Biosecurity Officers.</p>	
<b>13. Information Management</b>	
13.1 AA Site Documentation	
13.1.1	
<p>The BIP must retain a complete record of premises approval documentation, including:</p> <ol style="list-style-type: none"> <li>Third Party Assessor (TPA) certification,</li> <li>test documentation for containment features of the facility,</li> <li>Department of Agriculture audit report.</li> </ol>	
13.1.2	
<p>Test documentation for containment features of the BC3 facility [preceding clause, item (b)] must include the original and most recent:</p> <ol style="list-style-type: none"> <li>Containment envelope integrity test record;</li> <li>HEPA filter integrity test record;</li> <li>Pressure test record for effluent waste piping (as applicable);</li> <li>BSC, cytotoxic cabinet and fume cupboard (as applicable) test records;</li> <li>Verification test records for decontamination and waste treatment systems; and</li> <li>Decontamination load profiling records (as applicable).</li> </ol>	<b>Major</b>
13.1.3	
<p>The BIP must retain records of recurrent testing and calibrations necessary to maintain the approval of the AA site.</p>	
13.2 Records	
13.2.1	
<p>Records must be retained for all goods subject to biosecurity control for a minimum of 24 months from the date of being treated, or released.</p>	
13.2.2	
<p>All records must be made available to the department, within two business days, upon request.</p>	<b>Major</b>
13.2.3	
<p>The BIP must maintain records of all activities related to biosecurity control, including records of:</p> <ul style="list-style-type: none"> <li>biosecurity directions/orders and forms</li> <li>Import Permit number</li> <li>description of the goods subject to biosecurity control</li> </ul>	

Requirements	Nonconformity guide
<ul style="list-style-type: none"> <li>• date of receipt of goods and country of origin</li> <li>• dates of leaving of the fertile eggs</li> <li>• owner/importer name and address</li> <li>• name and address of any private or company veterinarians involved with the consignment</li> <li>• veterinary treatments administered including type of treatment and date administered</li> <li>• veterinary inspection records</li> <li>• Import permit</li> <li>• detailed daily mortality and culling records</li> <li>• post mortem of mortalities (which must be conducted by a veterinarian) and results.</li> <li>• Building records</li> <li>• laboratory testing results</li> <li>• Method and date of waste disposal and/or treatment</li> <li>• BU and equipment cleaning regime</li> <li>• Maintenance checks, servicing and certification.</li> </ul>	
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13.3 Treatment records	
13.3.1 treatment records – dry or moist heat	
13.3.1.1	
The BIP must provide records of:	
<ul style="list-style-type: none"> <li>a) traceability information of the contents of each load for goods subject to biosecurity control via permits, directions etc;</li> <li>b) any processing problems/malfunctions, times and durations of malfunctions, a description of the malfunction and the corrective action taken;</li> <li>c) dates of the above.</li> </ul>	
13.3.1.2	
For dry or moist heat sterilisers, the BIP must provide records of:	
<ul style="list-style-type: none"> <li>a) cycle monitoring, including temperature and duration;</li> <li>b) biological monitoring.</li> </ul>	<b>Critical</b>
<b>Note: Records of monitoring includes the sensor / indicator positions within the load, temperature and the result of monitoring.</b>	
13.3.1.3	
For dry or moist heat sterilisers the BIP must provide a certificate of calibration for the instrumentation (minimum temperature gauge or temperature sensor calibration) of each steriliser.	
13.3.1.4	
Where load profiling validation is used for sterilisers, the BIP must, in addition, provide records of investigations leading to specifications or sterilisation conditions to be used for each validated load. This must include a validation report detailing:	

Requirements	Nonconformity guide
<p>a) equipment used e.g. specific type of steriliser (make and model), data logger and probes including model and calibration certificate numbers;</p> <p>b) time and temperature of each probe throughout the test process;</p> <p>c) type of load validated and how the load was packed;</p> <p>d) cycle description e.g. time, temperature, downward displacement, pre-vacuum etc;</p> <p>e) test results e.g. time target temperature was reached, sterilisation end time, time sterilisation temperature achieved for, and minimum temperature during the cycle;</p> <p>f) the date the validation test was performed.</p>	
13.3.2 Liquid waste records	
Liquid waste treatment records must include details of all treatment parameters listed at 11.4.	
<hr/> 13.4	
Records provided to the department must be accurate and must not contain false or misleading information.	<b>Major</b>
<hr/> 13.5 Health monitoring and post mortem	
13.5.1	
Daily health / monitoring records must be maintained for all birds subject to biosecurity control, they must include:	
<p>a) number and types of eggs brought in and associated documentation</p> <p>b) numbers and types of birds hatched and culled</p> <p>c) daily mortality records</p> <p>d) post-mortem results of mortalities and culls</p> <p>e) bird selection and culling criteria</p> <p>f) treatments and medications</p> <p>g) daily visual observations of flock health and vigour.</p>	
13.5.2	
Animal health records must be updated immediately following any health examination, treatment or procedure.	<b>Major</b>
13.5.3	
A post mortem examination report must include:	
<p>a) date of examination;</p> <p>b) AA site;</p> <p>c) veterinary officer who supervised/undertook the examination;</p> <p>d) animal identification;</p> <p>e) results/finding of external and internal examinations;</p> <p>f) pathology/chemical/specimen results;</p> <p>g) findings or opinion as to cause of death.</p>	
<hr/> 13.6	
Records must include the date the record was made, who made the record, the signature (or electronic equivalent) of the person who made the record and, where necessary, the signature of the person who reviewed the record. They must be made in a manner that prevents them being subsequently altered.	<b>Major</b>

Requirements	Nonconformity guide
<p>13.7</p> <p>Records detailing the vermin and rodent control measures within the site must be maintained.</p>	<p><b>Minor</b></p>
<p>13.8</p> <p>Records detailing cleaning and disinfection of personnel, equipment and buildings/facilities must be maintained and must include at least the following:</p> <ul style="list-style-type: none"> <li>• date of cleaning/disinfection</li> <li>• process and chemicals used</li> <li>• name of person who performed the treatment.</li> </ul>	<p><b>Major</b></p>
<p>13.9</p> <p>Records detailing examinations of the external perimeter fence of the site and each BU must be maintained.</p>	<p><b>Minor</b></p>
<p>13.10</p> <p>Records detailing entry/exit of personnel to and from the BU at all times when eggs or birds are subject to Biosecurity control.</p>	<p><b>Major</b></p>
<p>13.11</p> <p>Where there is storage of biosecurity waste for longer than 21 consecutive days, records must include:</p> <ol style="list-style-type: none"> <li>a) monitoring (e.g. time and temperature) of the cold room;</li> <li>b) duration of storage (i.e. start date of quarantine isolation of the eggs/birds and out (date of release from biosecurity control OR date of autoclaving and removal from the facility));</li> <li>c) the nature/type.</li> </ol>	<p><b>Minor</b></p>
<p>13.12</p> <p>Functional / Integrity Test Records</p> <p>A BIP must preserve an annual report verifying the functional testing of pressure differential systems and integrity testing of HEPA filters. The report must record any faults discovered and any maintenance or corrective measures undertaken.</p>	<p><b>Major</b></p>
<p><b>14. Office and general site requirements</b></p>	
<p>14.1</p> <p>The site must be equipped with an emergency power supply to ensure operation of essential services in the case of a power outage. Essential services include: computer and ventilation system, power to building management system to ensure negative pressure is maintained. This may be in the form of a Uninterrupted Power Supply (UPS) or a generator back up system.</p> <p>Essential services for logging and recovery of biosecurity, such as ventilation control systems, must be connected to an appropriate UPS.</p>	<p><b>Critical</b></p>
<p>14.2</p> <p>Where re-usable covering garments such as overalls and gowns are used in Biosecurity operations, the BU must be equipped with laundry facilities for cleaning of those items.</p>	<p><b>Critical</b></p>

Requirements	Nonconformity guide
<p>14.3</p> <p>The site must have refrigeration facilities inside the BU and outside for use as required. In particular, for storage of samples, dead birds and any requirements for transport of samples (sample transport media).</p>	<p><b>Major</b></p>
<p>14.4</p> <p>Health and safety must be maintained at the AA site so that Biosecurity Officers can safely perform their duties.</p>	<p><b>Major</b></p>
<p>14.5</p> <p>Directions given by Biosecurity Officers at the site must be complied with.</p>	<p><b>Major</b></p>
<p>14.6 AA site Access</p> <p>14.6.1</p> <p>Biosecurity Officers must be granted access to the AA site at any time.</p> <p>14.6.2</p> <p>The department must be provided with details of the AA site's nominated business hours.</p> <p>14.6.3</p> <p>Access to the AA site must be through property owned, rented or leased by the BIP.</p> <p>14.6.4</p> <p>Access to the AA site must be via an all weather road.</p>	<p><b>Major</b></p>
<b>15. General</b>	
<p>15.1</p> <p>In addition to the AA site requirements, the following must be complied with:</p> <p>a) the <i>Biosecurity Act 2015</i> and subordinate legislation;</p> <p>b) Import Permit conditions;</p> <p>c) directions given by the department;</p> <p>Biosecurity Import Conditions database.</p> <p>The Biosecurity Industry Participant (BIP) must:</p> <p>a) ensure compliance with all relevant conditions and procedures carried out in relation to goods subject to biosecurity control at the approved site;</p> <p>b) ensure that its officers, employees, agents and contractors act consistently with, and ensure the proper performance of, the relevant conditions and the procedures in relation to the goods subject to biosecurity control at the approved site;</p> <p>c) assist the department with any investigation relating to compliance with the Act.</p>	<p><b>Major</b></p>
<p>15.2</p> <p>Goods subject to biosecurity control must be kept physically separated from other goods (including during transport), to minimise the potential for cross-contamination with the following:</p> <ul style="list-style-type: none"> <li>• imported items that have been released from biosecurity control</li> </ul>	<p><b>Major</b></p>

Requirements	Nonconformity guide
<ul style="list-style-type: none"> <li>• domestic items</li> <li>• the Australian environment.</li> </ul> <p><b>Note: Isolation can be achieved through the use of distance or physical barriers. The amount of distance or type of physical barrier required will depend on the nature of the goods subject to biosecurity control.</b></p>	
<p>15.3</p> <p>The standard of hygiene at the AA site must be appropriate for the nature of the goods subject to biosecurity control.</p>	<b>Major</b>
<p>15.4</p> <p>Goods subject to biosecurity control are not permitted to be moved outside an AA site except for the purpose of:</p> <ul style="list-style-type: none"> <li>• moving directly and securely to another AA site, of the appropriate AA class, with prior written approval from the department</li> <li>• moving directly and securely to an AA site of the same class (or of the same class but a higher biosecurity containment level sub-class) that is co-located with the original AA site</li> <li>• transport of biosecurity waste by a department approved waste transport company (operating under an AA for biosecurity waste transport).</li> </ul> <p>If the items are being transported by a non-Accredited Person (e.g. a truck driver), the forwarding BIP must ensure that this person is made aware of the conditions relating to the transport of the items. Supervision by a biosecurity officer may be required.</p>	<b>Critical</b>
<p>15.5</p> <p>Goods subject to biosecurity control are not permitted to leave the BU of an AA site, inadvertently or deliberately, without prior written direction or approval from the department.</p>	<b>Critical</b>
<p>15.6</p> <p>All personnel who have responsibilities for, or perform tasks that may impact on goods subject to biosecurity control, must be able to demonstrate an understanding of department requirements (e.g. Import Permit conditions, directions, Import Conditions database requirements).</p> <p>An Accredited Person must personally conduct or directly supervise activities involving physical contact with, or handling of items, subject to biosecurity control. Directly supervise means that the Accredited Person must be present in the BU where the items subject to biosecurity control are being handled and must be able to:</p> <ul style="list-style-type: none"> <li>• visually verify for themselves that the items are being handled in accordance with the department's requirements</li> <li>• communicate immediately and effectively with the persons being supervised.</li> </ul>	<b>Major</b>
<p>15.7</p> <p>Persons performing the function of an Accredited Person must have successfully completed the department's approved training to obtain and maintain Accredited Person status.</p>	<b>Major</b>

Requirements	Nonconformity guide
<p>15.8</p> <p>Records must be maintained of Accredited Persons.</p>	<p><b>Minor</b></p>
<p>15.9</p> <p>Ensure goods subject to biosecurity control are traceable in terms of (where applicable):</p> <ul style="list-style-type: none"> <li>• declaration/entry number</li> <li>• import Permit number</li> <li>• Air Waybill or Bill of Lading number</li> <li>• date of receipt</li> <li>• processing (including inspection, treatment, testing) details</li> <li>• release from Biosecurity Control</li> <li>• disposal details</li> <li>• storage location</li> <li>• Accredited Person responsible for the items.</li> </ul>	<p><b>Major</b></p>
<p>15.10</p> <p>The BIP must ensure that persons having physical access to goods subject to biosecurity control are aware that such items must only be handled by an Accredited Person or under the direct supervision of an Accredited Person.</p>	<p><b>Major</b></p>
<p>15.11</p> <p>The BIP must undertake incident control actions and contact the department when there is:</p> <ol style="list-style-type: none"> <li>a) a major spillage of goods/waste subject to biosecurity control outside the containment facility (Any major spillage or loss of goods/waste subject to biosecurity control must be immediately reported to the department. All spilled/unrecoverable goods/waste subject to biosecurity control must be treated by a department approved method).</li> <li>b) suspected or established presence of pest or disease (This will require the BIP to immediately contact the department).</li> <li>c) unauthorised removal, loss or release of goods, waste or equipment subject to biosecurity control.</li> </ol> <p>The BIP is required to,</p> <ol style="list-style-type: none"> <li>1. Contact the department within 48 hours of the unauthorised removal, loss or release of equipment subject to biosecurity control.</li> <li>2. Contact the department Immediately for other incidents, including unauthorised loss or release of goods or waste subject to biosecurity control.</li> </ol>	<p><b>Major</b></p>
<p><b>Note: Unrecoverable goods/waste subject to biosecurity control is that which can no longer be used for its intended purpose.</b></p>	
<p>15.12</p> <p>A contingency plan must be in place to manage unexpected events that threaten to compromise biosecurity integrity of the AA site. Unexpected events include:</p>	<ul style="list-style-type: none"> <li>• <b>Major</b></li> </ul>



Requirements	Nonconformity guide
<ul style="list-style-type: none"> <li>• appearance of pests or symptoms of disease</li> <li>• structural damage (due to storms etc.)</li> <li>• unauthorised removal of goods subject to biosecurity control</li> <li>• spillages of goods subject to biosecurity control</li> <li>• mechanical breakdown/malfunction/loss of power</li> <li>• sudden unavailability of an Accredited Person.</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Major</b></li> <li>• <b>Major</b></li> <li>• <b>Major</b></li> <li>• <b>Major</b></li> <li>• <b>Major</b></li> </ul>
<p>15.13</p> <p>Ceasing or transferring operations - the department must be informed, in writing, at least 15 working days prior to intended:</p> <ul style="list-style-type: none"> <li>• closure of a current AA site</li> <li>• relocation of the business, including the AA class function</li> <li>• ceasing of operation as an AA site.</li> </ul> <p>Any goods subject to biosecurity control that remain at the AA site must be treated or destroyed in accordance with a department approved method or transferred to another AA site with prior approval from the department. The BIP will be liable for associated costs.</p> <p>Also refer to section 5.2.</p>	<p><b>Minor</b></p>
<p>15.14</p> <p>If there is any doubt as to whether goods:</p> <ul style="list-style-type: none"> <li>• are subject to biosecurity control</li> <li>• remain subject to biosecurity control</li> <li>• become subject to biosecurity control</li> </ul> <p>then the goods must be handled in accordance with requirements for goods subject to biosecurity control.</p>	<p><b>Major</b></p>
<p>15.15</p> <p>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"> <li>• conviction of an offence or order to pay a pecuniary penalty under the <i>Biosecurity Act 2015, Quarantine Act 1908, Customs Act 1901, the Criminal Code or the Crimes Act 1914</i></li> <li>• debt to the Commonwealth that is more than 28 days overdue under the <i>Biosecurity Act 2015, Quarantine Act 1908, Customs Act 1901, the Criminal Code or the Crimes Act 1914</i></li> <li>• 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>.</li> </ul>	<p><b>Critical</b></p>
<p>15.16</p> <p>Biosecurity Officers, Biosecurity Enforcement Officers and department approved auditors, must be provided access to the AA site to perform the functions and</p>	<p><b>Critical</b></p>

Requirements	Nonconformity guide
exercise the powers conferred on them by the Biosecurity Act or another law of the Commonwealth.	
15.17	
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.	<b>Major</b>
15.18	
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.	<b>Critical</b>
15.19	
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.	<b>Critical</b>