Text

Description automatically generated with medium confidence

Approved Arrangement

8.3 - autoclave

requirements

**Version 5.0**



© Commonwealth of Australia

**Ownership of intellectual property rights**

Unless otherwise noted, copyright (and any other intellectual property rights, if any) in this publication is owned by the Commonwealth of Australia (referred to as the Commonwealth).

**Creative Commons Licence**

All material in this publication is licensed under a Creative Commons Attribution 3.0 Australia Licence, save for content supplied by third parties, logos and the Commonwealth Coat of Arms.

Creative Commons Attribution 3.0 Australia Licence is a standard form licence agreement that allows you to copy, distribute, transmit and adapt this publication provided you attribute the work. A summary of the licence terms is available from creativecommons.org/licenses/by/3.0/au/deed.en. The full licence terms are available from creativecommons.org/licenses/by/3.0/au/legalcode.

This publication (and any material sourced from it) should be attributed as: Approved Arrangements section, 2016, Approved arrangement for autoclave requirements, (Approved arrangement for autoclave requirements - prepared for the Department of Agriculture, Water and the Environment), Canberra.

**Department of Agriculture, Water and the Evironment**

Postal address GPO Box 858

Canberra ACT 2601

Telephone 1800 900 090

Web [awe.gov.au](https://www.awe.gov.au/)

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

The Australian Government acting through the Department of Agriculture, Water and the Environment has exercised due care and skill in the preparation and compilation of the information and data in this publication. Notwithstanding, the department, its employees and advisers disclaim all liability, including liability for negligence, for any loss, damage, injury, expense or cost incurred by any person as a result of accessing, using or relying upon any of the information or data in this publication to the maximum extent permitted by law.

**Version control**

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

| Date | Version | Amendments | Approved by |
| --- | --- | --- | --- |
| 9 May 2011 | 1.0 | Revised document. | Co-regulation and Support Program |
| 30 Jun 2013 | 1.1 | Updated to reflect DAFF branding. | Industry Arrangements Reform Program |
| 8 Feb2016 | 2.0 | Updated template including nonconformity ratings. | Approved Arrangements section |
| 26 April 2016 | 3.0 | Updated 6.13, 4.3 and washaby criterion. | Approved Arrangements section |
| 16 Jun 2016 | 4.0 | Updated to new template, references to the department and the *Biosecurity Act 2015.* | Approved Arrangements section |
| October 2017 | 5.0 | * Updated template – accessibility * amalgamted requirements of class 10.1 * added   + storage requirements (table 10)   + using autoclave bags (table 11)   + site map requirement (table 13)   + general requirement 27 (table 14) * updated * security requirements (table 4) * biosecurity area (table 5) * general requirements 1, 4, 7, 14, 18 (table 14) * removed   + duplication with general requirements   + waste disposal | Approved Arrangements section |
| 1 December 2021 | 5.0 | Added biosecurity risk information to the purpose statement in Table 1 | Approved Arrangements section |

**Table of contents**

[Guide to using this document 5](#_Toc494870116)

[Definitions 5](#_Toc494870117)

[Other documents 5](#_Toc494870118)

[Nonconformity guide 5](#_Toc494870119)

[Approved arrangement requirements 6](#_Toc494870120)

[Table 1 Purpose 6](#_Toc494870121)

[Table 2 Scope 6](#_Toc494870122)

[Table 3 Site location 6](#_Toc494870123)

[Table 4 Security 6](#_Toc494870124)

[Table 5 Biosecurity area 7](#_Toc494870125)

[Table 6 Building and storage areas 7](#_Toc494870126)

[Table 7 Hygiene 8](#_Toc494870127)

[Table 8 Biosecurity cold storage facility 8](#_Toc494870128)

[Table 9A Wash bays 9](#_Toc494870129)

[Table 9B Wash bays (continued) 10](#_Toc494870130)

[Table 10 Requirements 11](#_Toc494870131)

[Table 11 Operations 11](#_Toc494870132)

[Table 12A Office and record requirements 12](#_Toc494870133)

[Table 12B Office and record requirements (continued) 13](#_Toc494870134)

[Table 13 Administration 13](#_Toc494870135)

[Table 14A General 14](#_Toc494870136)

[Table 14B General (continued) 15](#_Toc494870137)

[Table 14C General (continued) 16](#_Toc494870138)

# 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.

This document specifies the requirements to be met for the approval, operation and audit of this class of approved arrangement. 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 approved arrangements, regional contact details and copies of relevant approved arrangementsdocumentation is available on the department’s website: [awe.gov.au](https://www.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 *Approved Arrangements 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 approved arrangement.

# 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 *Approved Arrangements General Policies*.

# Approved arrangement requirements

## Table 1 Purpose

| Requirements | Nonconformity guide |
| --- | --- |
| 1.1 Class 8.3 approved arrangement sites are utilised for autoclave treatment of biosecurity waste.  Autoclave treatment is specified as a department-approved treatment option for biosecurity waste in various other approved arrangement class condition documents. The biosecurity risks mitigated by autoclave vary according to the biosecurity waste material received at class 8.3 approved arrangement sites and includes various:   * plant pests and diseases (including weed seeds) associated with imported plants and imported goods that are made of or contain plant material * animal pests and diseases associated with imported animals and imported goods that are made of or contain animal material * aquatic animal diseases associated with imported aquatic animals and imported goods that are made of or contain aquatic animal material * contamination of soil or plant material in or on goods, packaging material or containers e.g., soil can contain seeds of exotic plants or weeds, plant diseases, and soil-borne animal diseases such as foot and mouth disease.   Information on biosecurity import conditions and biosecurity risks for imported goods, containers, other cargo and arriving vessels is available on the [department's website](https://www.awe.gov.au/biosecurity-trade/import/arrival/pests). | N/A |

## Table 2 Scope

| Requirements | Nonconformity guide |
| --- | --- |
| 2.1 The approved arrangement sites are not approved for any other biosecurity operations, except where the site has separate approval under another class. | N/A |

## Table 3 Site location

| Requirements | Nonconformity guide |
| --- | --- |
| 3.1 Approved arrangement sites must generally be located within the metropolitan area of a declared port that has a permanently based biosecurity officer. Applications are subject to approval by the Director of Biosecurity and will be considered on their individual merits with consideration being given to the biosecurity risk and serviceability associated with the location of each approved arrangement site. | N/A |

## Table 4 Security

| Requirements | Nonconformity guide |
| --- | --- |
| 4.1 Security measures must be in place that prevent access and removal of goods subject to biosecurity control by unauthorised persons. | Major |
| 4.2 Biosecurity areas must display a sign to effectively convey that status. | Minor or major |
| 4.3 Ingress and egress points, and areas where biosecurity waste are stored, handled, segregated or treated must display a biosecurity sign. These signs are to be:   * permanently affixed * professionally made * made to state: Biosecurity Area - Authorised Persons Only or Quarantine Area - Authorised Persons Only * on a yellow background, with black lettering minimum of 2.5 cm in height * secured on gates and/or doors and visible * provide an emergency contact number in case of spillage.   Note: Where new signs are being produced, they should use biosecurity not quarantine. | Minor |

## Table 5 Biosecurity area

| Requirements | Nonconformity guide |
| --- | --- |
| 5.1 The biosecurity areas must allow for biosecurity officers to easily inspect goods without work health and safety risks. | Major |
| 5.2 Biosecurity areas must be separate from other operations within the site. | Major |
| 5.3 The biosecurity storage area must be sufficiently isolated from the main thoroughfare and clearly defined by either a painted yellow line on the floor or a separate room. | Minor |
| 5.4 The biosecurity area must have an impervious floor, which is in good condition, and free of major cracks. | Major |
| 5.5 The biosecurity area floor must drain to a central/end floor drain into a solids trap that is connected directly sewer. | Major |
| 5.6 Where the site is not connected to sewer, liquid waste must be filtered (100 micron) before treatment by a department approved method prior to disposal. | Major |
| 5.7 Drains and tanks must be covered, and sewerage/drainage lines must be protected from physical damage. | Major |
| 5.8 Where biosecurity waste is to be stored prior to disposal it must be placed unde a rcover if the biosecurity area is not within a building. Biosecurity waste must be stored in such a manner as to ensure that the goods are stored a maximum of 2.5 m high. | Major |
| 5.9 Measures must be in place to prevent the loss of biosecurity waste (by wind, birds, vermin, feral animals etc.) at the time of unloading, treatment and or storage. | Major |
| 5.10 The site must have a designated biosecurity area to unload, store and segregate biosecurity waste. | Major |

## Table 6 Building and storage areas

| Requirements | Nonconformity guide |
| --- | --- |
| 6.1 Buildings and structures must be maintained in a state of good repair and be weather-proof. Wall and floor junctions must be sealed. | Major |
| 6.2 Buildings and designated biosecurity areas (including storage and receival zones, chutes etc.), must be kept clean. Cargo and packaging residues, contaminants and spillages must be cleaned up and correctly disposed of as biosecurity waste without delay. | Major |

## Table 7 Hygiene

| Requirements | Nonconformity guide |
| --- | --- |
| 7.1 An effective pest control system must be in place to ensure that sites are managed in a way that effectively isolates goods subject to biosecurity control from environments in which pest and disease are likely to become established. As a minimum this will require the site to implement, and keep associated records of a periodic inspection regime and ensure knockdown spray (i.e. standard household aerosol insecticide spray) is kept onsite. In addition to details of the inspection regime and the onsite location of the knockdown spray, the pest control system may include:   * the use of insecticides, fumigation, rodenticides, periodic inspection, baits and/or traps * a site plan with numbered bait stations * if applicable, contract details.   Note: The operations of adjacent facilities must be considered when determining any additional pest control measures to be implemented. | Major |
| 7.2 Equipment used to handle biosecurity waste prior to treatment must be thoroughly cleaned and disinfected daily. If equipment is to be used for material other than biosecurity waste it must be cleaned and disinfected prior to such use. A department-approved disinfectant must be used. | Major |
| 7.3 Spillage of biosecurity waste must be immediately and thoroughly collected and the area of the spillage disinfected by a thorough application of a department-approved disinfectant. | Major |
| 7.4 Sufficient bins/containers of an appropriate size labelled: Biosecurity Waste, are to be provided for loose items, residues, spillages or material of biosecurity concern. Such bins/containers must have lids that remain closed and are to be emptied and, if required, disinfected in accordance with any provisions set by the department. | Major or critical |
| 7.5 Major spillage or loss of biosecurity waste is to be immediately reported to the department. A major spillage is classified as a spillage of biosecurity waste outside the confines of an approved arrangement site, which can be accessed by the general public, which cannot be readily cleaned up within fifteen minutes. | Major or critical |
| 7.6 Receptacles used in the storage of untreated biosecurity waste must be:   * thoroughly cleaned and disinfected prior to use with non-biosecurity waste. * washed in an approved wash bay at an approved arrangement site * cleaned with a department-approved disinfectant. | Major |
| 7.7 Sizing and shredding equipment used for biosecurity waste must be:   * thoroughly cleaned and disinfected prior to use for non-biosecurity waste * cleaned with a department-approved disinfectant. | Major |

## Table 8 Biosecurity cold storage facility

| Requirements | Nonconformity guide |
| --- | --- |
| Where there are biosecurity cold storage facilities at the approved arrangement site requirements 8.1 and 8.2 mustbe complied with. | N/A |
| 8.1 A system for adequately and accurately recording temperatures (e.g. thermograph) must be in place. These records must be available for inspection by a biosecurity officer upon request. | Major |
| 8.2 Cool rooms used for the storage of biosecurity waste must maintain a constant temperature of 4 degrees Celsius or below and biosecurity waste clearly marked. | Major |

## Table 9A Wash bays

| Requirements | Nonconformity guide |
| --- | --- |
| 9.1 Wash down areas must be located at the site for the cleaning of transport vehicles, biosecurity waste bins or compactors. The wash down area must be commensurate with the size of proposed cleaning handled by the site. | Critical |
| 9.2 The location and size of the wash bay must be clearly marked on the site plan. | Minor |
| 9.3 The wash bay must be constructed in accordance with the following:   * a concrete floor which is liquid impervious * a floor drain leading into a soil trap which is connected directly to municipal sewer or to another waste water disposal system approved by the department * any waste water storage, treatment and reticulation system must be enclosed. | Major |
| 9.4 Areas immediately adjacent to the wash bay should have an impermeable surface. If the area surrounding the wash pad has vegetation, the department will inspect for introduced weed species (at cost to the biosecurity industry participant). | Minor or major |
| 9.5 Waste water and residues from cleaning operations must be contained within the approved wash bay. | Major |
| 9.6 Waste water and residues from cleaning operations must only be discharged via the wash bay drain. | Major |
| 9.7 The wash bay must be washed down after cleaning operations each day. | Critical |
| 9.8 Waste water must be screened prior to discharge to municipal sewer or department approved treatment/holding tank.  For sites that do not have direct access to sewer for waste water discharge, waste water may be either:   * collected and transported off-site for discharge to sewer by a waste transport service operating under an appropriate approved arrangement with the department * collected and transported off-site for discharge to sewer by a non-department approved waste transport service. Where a non-department approved transport service is used, the transport and disposal of the waste water must be performed under department supervision. | Critical |
| 9.9 Soil residues from the wash bay soil trap or filter must be disposed of as biosecurity waste. | Major |
| 9.10 There must be adequate equipment available in order to carry out cleaning (steam/high pressure) and chemical disinfection spraying operations as directed by departmental officers. | Major |
| 9.11 Equipment (including footwear and protective clothing) used in the wash bay must be cleaned prior to removal from the wash bay. |  |
| 9.12 Trade water diversions from wash bays are approved for use under the following conditions:   * wash bays that install diversions that can be manually over ridden can wash items on the wash bays at any time as long as the wash water continues to be discharged to sewer * wash bays that have installed trade diversions that cannot be manually over ridden to discharge to sewer: washing of items cannot be conducted during periods of high rainfall that would see the water being discharged to stormwater * where trade diversions have been installed the wash bays shall be cleaned after every wash to ensure any residual material and water is discharged to sewer and not stormwater. | Major |

## Table 9B Wash bays (continued)

| Requirements | Nonconformity guide |
| --- | --- |
| 9.13 The wash bay must be washed down after cleaning operations each day. | Critical |
| 9.14 Waste water must be screened prior to discharge to municipal sewer or department approved treatment/holding tank.  For sites that do not have direct access to sewer for waste water discharge, waste water may be either:   * collected and transported off-site for discharge to sewer by a waste transport service operating under an appropriate approved arrangement with the department * collected and transported off-site for discharge to sewer by a non-department approved waste transport service. Where a non-department approved transport service is used, the transport and disposal of the waste water must be performed under department supervision. | Critical |
| 9.15 Wash bays must display a quarantine sign. These signs are to be:   * permanently affixed * professionally made * made to state 'Biosecurity Area - Authorised Persons Only' or 'Quarantine Area - Authorised Persons Only' * on a yellow background, with black lettering minimum of 2.5 cm in height * secured on the front of the wash pad walls and visible at all times.   Note: Where new signs are being produced, they should use biosecurity not quarantine. | Minor |
| Where recycling of waste water occurs within the wash bay at the site the following applies: | N/A |
| 9.16 A recycling waste water system must incorporate screening the liquid waste through a 100 micron filter prior to use in wash bay operations with imported goods. | Major |
| 9.17 During the recycling process, the biosecurity industry participant must, when operational, undertake weekly inspection for leaks from:   * pumps * valves * tanks (where applicable) * filter housing, pipes and connections where visible. | Major |
| 9.18 When leaks are detected they must be immediately repaired. | Major |
| 9.19 Waste filter media and detritus/refuse captured by filter media or screens must be treated as biosecurity waste. | Major |
| 9.20 Wash facilities must:   * be of a size commensurate with the vehicles or equipment being cleaned * be constructed of impermeable material and in a manner which ensures that all residues/sediment and splash from cleaning operations are contained and flow directly into holding tanks or a municipal sewage system or department approved system * have all sewage/drainage lines protected from physical damage.   Note: Where municipal sewage connection is not available and tanks are used, the tanks must be fully enclosed. | Major |
| 9.21 Soil traps must be installed in drains in locations where drainage inflow is likely to contain solids (e.g. detritus, refuse or other particulates). | Major |

## Table 10 Requirements

| Requirements | Nonconformity guide |
| --- | --- |
| 10.1 Waste coming into contact with untreated biosecurity waste must be handled and disposed of as biosecurity waste. | Critical |
| 10.2 Biosecurity waste must be kept refrigerated at 4° C or below where it is not being transferred into the control of another department approved waste contractor or disposed of by departmental approved method within:   * 21 days for non-perishable waste * 48 hours of perishable waste being generated. | Critical |
| 10.3 Biosecurity waste must not be stored for more than 90 days. | Major |
| 10.4 Records for each batch of stored biosecurity waste must also include length of time in storage and the temperature the waste was stored at. | Major |
| 10.5 Waste water that has been in contact with untreated biosecurity waste must be contained and treated prior to disposal. Disposal of untreated waste water to municipal sewerage systems is acceptable. | Critical |

## Table 11 Operations

| Requirements | Nonconformity guide |
| --- | --- |
| 11.1 Autoclave time and temperature recording equipment must be calibrated by a National Association of Testing Authorities (NATA) accredited testing organisation. | Critical |
| 11.2 Calibration and testing must be carried out at intervals not exceeding six months. | Critical |
| 11.3 The department must be contacted in any instance where the specified calibration and testing requirements cannot be met. | Critical |
| 11.4 Biological indicator tests are to be carried out at intervals not exceeding one month to confirm the effectiveness of the autoclaving procedure; and contacting the department in any instance where requirements described above cannot be met. | Major |
| 11.5 Airborne particles derived from shredding/grinding/ hammermill operations must be contained to eliminate escape into the environment. | Major |
| 11.6 The treatment parameters (including temperature and duration) of the autoclave must be automatically monitored and recorded. The date and time of treatment must also be recorded. | Critical |
| 11.7 The autoclave unit must be fitted with a temperature-measuring device that can:   * record time and temperatures parameters on a continuous basis * determine when the material subject to biosecurity control in the chamber has reached the target core temperature. | Critical |
| 11.8 Biosecurity waste must be a maximum of 50 mm in diameter prior to treatment to ensure it can be effectively treated under normal operating conditions. | Critical |
| 11.9 When autoclave bags are used and the good/waste subject to biosecurity control to be treated is not a liquid (i.e. dry), the bags must be either:   * opened prior to loading; * have water added; * slashed as loaded; or * each tied with a melting tie. | Major |
| 11.10 The autoclave must have a process (e.g. a mechanical alarm or procedure) that enables operators to determine when there has been a system failure during an autoclave process. | Critical |
| 11.11 Biosecurity waste is to be treated by autoclave at a minimum of 121 degrees Celcius (core temperature) for 15 minutes, or 121 degrees Celcius for 30 minutes where core temperature is not measured. | Critical |
| 11.12 Instances where the treatment process fails to achieve the minimum treatment parameters must be investigated and re–treatment of the biosecurity waste must be performed. The minimum parameters must be met before the waste can be released. | Major or critical |

## Table 12A Office and record requirements

| Requirements | Nonconformity guide |
| --- | --- |
| 12.1 Documented evidence of the satisfactory performance of equipment (e.g. a calibration equipment register including valid/current calibration certificates). | Major |
| 12.2 The biosecurity industry participant must   * provide a first aid cabinet/kit which is fully stocked and meets the minimum commercial Australian Standard (AS2675-1983: Portable first aid kits for use by consumers) * provide vehicle parking for visiting biosecurity officers (note: this may require department identified parking or providing a parking permit) * ensure adequate security for any departmental technical equipment left on the site * provide access and the availability of: * a desk, chair and a telephone with direct outside call access * toilet facilities * hand washing facilities and a hygienic means of drying hands * clean amenities. | Minor or major |
| 12.3 An autoclave biosecurity waste log sheet for each treatment cycle of biosecurity waste treated must be fully completed for every consignment of waste. The temperature reachedand the treatment time. | Major |
| 12.4 The autoclave biosecurity waste log sheet must include:   * delivery company – name * name and signature of receiver * date received. | Major |

## Table 12B Office and record requirements (continued)

| Requirements | Nonconformity guide |
| --- | --- |
| 12.5 The autoclave biosecurity waste log sheet must include biosecurity waste details:   * treatment site – name * treatment site – location * description * quantity * volume/weight * treatment - date * treatment time and duration * treatment temperature * core temperature of waste (if applicable) * if treatment fails, subsequent re-treatment details * reason * date and time * major spillage or loss: * reason * date and time * whether reported to the department * name * date and time * acknowledged by accredited person: * name and signature * date. | Major |
| 12.6 Records of the cleaning and disinfecting of the re-sizing and shredding equipment must be kept. Records to include:   * date of cleaning and disinfecting * name of department approved disinfectant used * name and signature of person who completed the cleaning and disinfecting of the sizing and shredding equipment | Major |
| 12.7 Records of the cleaning and disinfecting of the waste receptacles must be kept. Records to include:   * date of cleaning waste receptacles * name of department approved disinfectant used * name and signature of person cleaning waste receptacles. | Minor or Major |

## Table 13 Administration

| Requirements | Nonconformity guide |
| --- | --- |
| 13.1 Current site plans must be provided to the department. Site plans must be to scale and include biosecurity areas (storage, inspection, treatment/processing) and the location of parking for biosecurity officers. | Minor or major |
| 13.2 The department must be notified in writing, at least 15 working days prior to any modification to biosecurity areas where goods subject to biosecurity control are stored or treated/processed or otherwise dealt with. | Major |

## Table 14A General

| Requirements | Nonconformity guide |
| --- | --- |
| 14.1 Goods subject to biosecurity control must be maintained and processed at an approved arrangement site appropriate for the biosecurity risk associated with the goods. | Major or critical |
| 14.2 Goods subject to biosecurity control must be maintained and processed in accordance with the requirements of the relevant approved arrangement class. | Minor, major or critical |
| 14.3 Goods subject to biosecurity control must be maintained and processed in accordance with import conditions specified in the department's Biosecurity Import Conditions Database (BICON). | Minor, major or critical |
| 14.4 Goods subject to biosecurity control must be maintained and processed in accordance with an import permit (if applicable) . | Minor, major or critical |
| 14.5 Goods subject to biosecurity control must be maintained and processed in accordance with any other direction from the department. | Minor, major or critical |
| 14.6 Goods subject to biosecurity control must be maintained and processed in accordance with the *Biosecurity Act 2015* and subordinate legislation. | Major or critical |
| 14.7 Goods subject to biosecurity control must be kept physically separated from other goods (including during transport), to ensure negligible risk of cross contamination to:   * imported items that have been released from biosecurity control * domestic items * the Australian environment.   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. | Major or critical |
| 14.8 The standard of hygiene at the approved arrangement site must be appropriate for the nature of the goods subject to biosecurity control. | Major or critical |
| 14.9 Any equipment that has been used or brought in contact with imported items subject to biosecurity control, or which could have been potentially contaminated by the imported items, must not leave the biosecurity area until it has been processed (cleaned, disinfested, decontaminated) or disposed of in accordance with relevant approved arrangement requirements, import conditions and departmental directions. | Major or critical |
| 14.10 Goods subject to biosecurity control are not permitted to be moved outside an approved arrangement site except for the purpose of:   * moving directly and securely to another approved arrangement site, of the appropriate approved arrangement class, with prior written approval from the department * moving directly and securely to an approved arrangement 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 approved arrangement site * transport of biosecurity waste by a department approved waste transport company (operating under an approved arrangement for biosecurity waste transport).   If the items are being transported by a non-accredited Person (e.g. a truck driver), the forwarding biosecurity industry participant must ensure that this person is made aware of the conditions relating to the transport of the items. | Critical  Major |
| 14.11 Goods subject to biosecurity control are not permitted to leave the biosecurity area of an approved arrangement site, inadvertently or deliberately, without prior written direction or approval from the department. | Critical |

## Table 14B General (continued)

| Requirements | Nonconformity guide |
| --- | --- |
| 14.12 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 area where the items subject to biosecurity control are being handled and must be able to:   * visually verify for themselves that the items are being handled in accordance with the department's requirements * communicate immediately and effectively with the persons being supervised. | Major |
| 14.13 Persons performing the function of an accredited person must have successfully completed accreditation training. | Major |
| 14.14 Records must be maintained of accredited persons. | Minor |
| 14.15 Goods subject to biosecurity control must be clearly and visibly identified as being under biosecurity control to persons who can physically access the goods or the containers holding the goods. The measures taken must ensure that persons having physical access to goods subject to biosecurity control can differentiate between goods subject to biosecurity control and goods that are not subject to biosecurity control. | Major |
| 14.16 The biosecurity industry participant must ensure records are kept for a minimum of 18 months for goods subject to biosecurity control at the approved arrangement site. | Minor or major |
| 14.17  The biosecurity industry participant must ensure goods subject to biosecurity control are traceable in terms of (where applicable):   * declaration/entry number * import permit number * Air Waybill or Bill of Lading number * date of receipt * country of origin * processing (including inspection, treatment, testing) details * movement details * release from biosecurity control * disposal details * storage location * accredited person responsible for the items. | * Major * Major * Minor * Major * Major * Major * Major * Major * Major * Major * Major |
| 14.18 The biosecurity industry participant 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. | **Major** |
| 14.19 A contingency plan must be in place to manage unexpected events that threaten to compromise biosecurity integrity of the approved arrangement site. Unexpected events include:   * appearance of pests or symptoms of disease * structural damage (due to storms etc.) * unauthorised removal of goods subject to biosecurity control * spillages of goods subject to biosecurity control * sudden unavailability of an accredited person. | * Major * Major * Major * Major * Minor |

## Table 14C General (continued)

| Requirements | Nonconformity guide |
| --- | --- |
| 14.20 Ceasing or transferring operations - the department must be informed, in writing, at least 15 working days prior to intended:   * closure of a current approved arrangement site * relocation of the business, including the approved arrangement class function * ceasing of operation as an approved arrangement site.   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 approved arrangement site with prior approval from the department. The biosecurity industry participant will be liable for associated costs. | Major  Critical |
| 14.21 If there is any doubt as to whether goods:   * are subject to biosecurity control * remain subject to biosecurity control * become subject to biosecurity control   then the goods must be handled in accordance with requirements for goods subject to biosecurity control. | Major |
| 14.22 The biosecurity industry participant 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 biosecurity industry participant or their associates relevant to the operation of the AA in relation to any of the following matters:   * conviction of an offence or order to pay a pecuniary penalty under the *Biosecurity Act 2015, Quarantine Act 1908, Customs Act 1901, the Criminal Code or the Crimes Act 1914* * debt to the Commonwealth that is more than 28 days overdue under the *Biosecurity Act 2015, Quarantine Act 1908, Customs Act 1901, the Criminal Code or the Crimes Act 1914* * refusal, involuntary suspension, involuntary revocation/cancelation or involuntary variation of an import permit, quarantine approved premises, compliance agreement or approved arrangement under the *Quarantine Act 1908* or the *Biosecurity Act 2015*. | Critical |
| 14.23 Departmental officers and department approved auditors, must be provided access to the approved arrangement site to perform the functions and exercise the powers conferred on them by the Biosecurity Act or another law of the Commonwealth. | Critical |
| 14.24 Departmental officers or department approved auditors, must be provided with facilities and assistance as requested, and any required documents, records or things relevant to the audit. | Major or critical |
| 14.25 The department must be notified of any reportable biosecurity incident as soon as practicable, in accordance with the determination made by the Director of Biosecurity. | Critical |
| 14.26 Department approved auditors must be permitted to collect evidence of compliance and noncompliance with approved arrangement requirements through actions including the copying of documents and taking of photographs. | Major or critical |
| 14.27 The biosecurity industry participant must notify the department in writing as soon as practicable within 15 days of any change in:   * persons in positions responsible for controlling, directing, enforcing or monitoring people performing activities associated with the approved arrangement * biosecurity industry participant details, including: * entity name * ABN or ACN * postal address * email address * facsimile number * telephone number. | Major or critical |