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Department of Agriculture, Fisheries and Forestry

Approved arrangements general policies

Version 7.3

Approved Arrangements Program

Compliance and Enforcement Division

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Acknowledgement of Country

We acknowledge the Traditional Custodians of Australia and their continuing connection to land and sea, waters, environment and community. We pay our respects to the Traditional Custodians of the lands we live and work on, their culture, and their Elders past and present.

Version history

Date	Version	Amendments	Approved by
January 2010	1.0	First issue	Industry Arrangement Management Section
February 2011	2.0	Updated to include co-location	Industry Arrangement Management Section
July 2014	2.1	Rebranding and nonconformity of co-located networks amended	Approved Arrangements Section
January 2015	3.0	New template and amended review levels and audit rates	Approved Arrangements Section
June 2016	4.0	Updated references to the department and the Biosecurity Act 2015	Approved Arrangements Section
July 2016	5.0	Added disinsection	Approved Arrangements Section
February 2017	6.0	Updated: • disinsection (removed audit rates) • audit types Added: • corrective action requests issued outside audit • accreditation requirements	Approved Arrangements Section
May 2018	7.0	Updated appendix 2: • Brokers – monitoring and accessing compliance • Added accreditation for broker approved arrangement	Approved Arrangements Section
October 2018	7.1	Updated contact phone number for approved arrangements site enquiries	Approved Arrangements Section
February 2022	7.2	Updated: • web accessible template • suspension policy • audit rate policy	Approved Arrangements Section
November 2023	7.3	• Divided document into specific parts for (1) classes 1-14, (2) class 19 and (3) class 43.1 • Moved information from appendices in version 7.2 of the document into relevant parts 1, 2 and 3 of version 7.3 of the document Updated: • contact details and references for class 19 approved arrangements • content of audits section of part 1 classes 1-14 • terminology, replaced ‘nonconformity’ with ‘noncompliance’ Added: • key arrangement outcomes Removed: • corrective action request references from Part 1	Approved Arrangements Program

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Summary

This document details how the Department of Agriculture, Fisheries and Forestry will:

- assess and monitor compliance
- detect and report on noncompliance
- address noncompliance
- deal with requests and applications

for approved arrangements under Chapter 7 of the *Biosecurity Act 2015*.

The policies in this document are the basis on which the department ensures it is maintaining its obligation to the Australian public by appropriately regulating biosecurity concerns associated with an approved arrangement. The policies in this document have been developed to deliver effective risk-based compliance outcomes.

This document is divided into three parts:

- Part 1 – Class 1 to class 14 biosecurity activities
- Part 2 – Class 19 assessment and entry processing (AEP) activities

  (19.1: non commodity for containerised cargo clearance (NCCC) and 19.2: automatic entry processing for commodities (AEPCOMM) are collectively referred to as the class 19 AEP approved arrangements).
- Part 3 – Class 43.1 disinsection activities.

Introduction

In Australia, biosecurity is a shared responsibility between government, industry and individuals. Commitment to biosecurity is required from the three groups. The department entrusts biosecurity industry participants with the performance of specific biosecurity activities covered by an approved arrangement.

This responsibility places legislative obligations on the biosecurity industry participant approved to operate an approved arrangement. In turn, the department has an obligation to the Australian public to verify that the biosecurity industry participant is meeting their biosecurity responsibilities. The introduction of exotic pests and diseases to Australia could have exceptionally serious consequences for the Australian community, environment and economy.

1 Part 1

1.1 Scope - Class 1 to class 14 biosecurity activities

1.1.1 In scope

Part 1 applies to arrangements approved in accordance with Chapter 7 of the Biosecurity Act, to carry out specified biosecurity activities under classes 1 through 14.

1.1.2 Out of scope

Part 1 does not cover:

- the approved arrangement approval process
- prosecutions for offences against the Biosecurity Act
- determination of the fit and proper person status of applicants for an approved arrangement
- class 19.1 - non-commodity for containerised cargo clearance (see Part 2)
- class 19.2 - automatic entry processing for commodities (see Part 2)
- class 43.1 - disinsection (see Part 3).

1.2 Contacting the department

Any queries regarding application of Part 1 of this document, or its content should be directed to the contacts provided in Table 1.

If a biosecurity industry participant requests to make a change to their approved arrangement, such as:

- updates to contact persons or contact details, or
- addition of new site contacts

the request must be made by the approved arrangement's:

- manager, or
- site contact person associated with the approved arrangement.

Notices from the department to the biosecurity industry participant will be directed to the approved arrangement manager, with additional courtesy copies sent to the nominated approved arrangement site contact.

Queries concerning approved arrangements conditions and policy should be directed to the relevant area, as indicated in Table 1 below.

If your query or request is administrative, in regards to activities involving the physical handling of goods conducted at approved arrangement sites, please contact the Approved Arrangements Program.

If your query or request is audit related, please contact Audit and Assurance Branch.

If your query relates to both physical class (approved arrangement site) and class 19 assessment and entry processing (AEP) activities, or you are not sure, please contact Approved Arrangements Program.

Table 1 Contact details for approved arrangement enquiries

Type of enquiry	Area to contact	Phone	Email	Postal address	Hours of operation
Administrative	Approved Arrangements Program	1800 900 090	aa.canberra@aff.gov.au	Approved Arrangements Program Department of Agriculture, Fisheries and Forestry GPO Box 858 Canberra ACT 2601	8.30am – 4.30pm (Australian Eastern Standard Time)
Audit related	Audit and Assurance Branch	1800 900 090	auditservices@aff.gov.au	Audit and Assurance Branch Department of Agriculture, Fisheries and Forestry GPO Box 858 Canberra ACT 2601	9:00 am – 5:00pm (Australian Eastern Standard Time)

1.3 Definitions

Definitions can be found within the *Approved Arrangements Glossary*, on the department's website, or in the *Biosecurity Act 2015* (Chapter 1, Part 2). For words not defined in the glossary or the Act, definitions can be found in the most recent edition of the Macquarie Dictionary.

1.4 Approach to compliance and regulation

The department's approach to compliance management involves recognising biosecurity industry participant's behaviours and adjusting our compliance posture accordingly. The department applies a range of regulatory tools to manage compliance. Further information about these tools can be found in the *Compliance Policy* available on the department's website.

The department's approach to our regulatory responsibilities and regulatory practice principles can be found in the *Regulatory Practice Statement* available on the department's website.

1.5 Scope of an approved arrangement

A single approved arrangement typically involves biosecurity activities:

- under classes 1 through 14, and
- at a single physical site (noting that some approved arrangements involve activities not confined to a specific site).

1.6 Key arrangement outcomes

1.6.1 Key arrangement outcomes

Key arrangement outcomes (KAOs) are high level outcomes the biosecurity industry participant is responsible for meeting under an approved arrangement. Each class condition for an approved

arrangement is linked with a KAO. The KAOs are met by complying with the class conditions. Table 2 lists the KAOs for classes 1 – 14.

Table 2 List of KAOs for classes 1 – 14

KAO	Purpose
Containment	Goods subject to biosecurity control are contained in a way that prevents them, or any biosecurity risk material escaping into the environment.
Isolation	Goods subject to biosecurity control are isolated from other goods in a manner that prevents cross-contamination or cross-infestation.
Security	Controls are in place that prevent unauthorised access to goods subject to biosecurity control.
Identification	Goods subject to biosecurity control and areas in which biosecurity activities are carried out must be visually identifiable as such.
Traceability	Goods that are or were, subject to biosecurity control, are linked to records of the origin and movement of the goods and the biosecurity activities carried out in relation to the goods.
Hygiene	Approved arrangement sites are maintained in a state that minimises opportunity for, and susceptibility to pest, weed and disease establishment and/or infestation.
Movement	Goods subject to biosecurity control only move beyond the site in accordance with departmental conditions and any required departmental authorisation.
Release	Goods and their derivatives subject to biosecurity control are dealt with as such until they are formally released from biosecurity control, or they are exported or destroyed.
Awareness	People performing biosecurity activities involving goods subject to biosecurity control have the knowledge and capability to carry out those activities in accordance with the conditions of the approved arrangement.
Inspection	The site has the equipment, facilities and processes that enable inspection of goods subject to biosecurity control.
Treatment	The biosecurity industry participant has the processes and/or equipment and facilities to perform treatments of goods subject to biosecurity control in accordance with the conditions of the approved arrangement.
Arrangement compliance	The biosecurity industry participant is required to carry out biosecurity activities in accordance with the approved arrangement.
Notification	The department is advised of any event or circumstance for which it has specified that notification must be provided.
Supporting functions	Procedures, facilities and equipment are in place for the biosecurity activities carried out under the approved arrangement.

Table 2 lists the key arrangement outcomes for approved arrangement classes 1 – 14.

1.7 Fit and proper person assessment

The Biosecurity Act requires that the department consider whether an applicant seeking approval is a fit and proper person to hold an approved arrangement. Additionally, changes to the fit and proper person status of a biosecurity industry participant may be a relevant consideration in decisions to vary, suspend or revoke an approved arrangement. Consideration of whether the applicant or biosecurity industry participant is fit and proper to hold an approved arrangement is important because such a person is entrusted to manage biosecurity risk associated with their arrangement and not exploit this trust to circumvent biosecurity risk controls. The fit and proper person assessment includes consideration of associates of the applicant or biosecurity industry participant that are relevant to the operation of the approved arrangement.

An approved arrangement grants a concession and responsibility on persons that allows for them to do certain things the general public are not allowed to do. It is important that such persons are considered fit and proper to be able to conduct these activities and there is confidence that the person will operate within the scope of their approval and comply with conditions and requirements.

If the Director of Biosecurity determines that a person is not a fit and proper person, the Director may refuse to approve a proposed arrangement; or vary, suspend or revoke an approved arrangement. The regulations may prescribe other situations where the fit and proper person test may be applied.

Further information about the fit and proper person test can be found on the fit and proper test for approved arrangement applicants webpage.

1.7.1 Notifying change of fit and proper person-relevant circumstances

A biosecurity industry participant covered by an approved arrangement must notify the department in writing as soon as practicable and within 15 days of becoming aware of any change of circumstance (not previously notified to the department) concerning themselves or an associate, which may alter their fit and proper person status of the biosecurity industry participant.

1.8 Fees and charges

The department recovers the cost of the administration of approved arrangements through the imposition of application and fees and charges legislatively supported by the Biosecurity Charges Imposition (Customs) Regulation 2016 available on the *Federal Register of Legislation* website. The application of the regulations are explained in the department's *Charging Guidelines* and in further information is provided on the department's approved arrangement webpages.

1.9 Training accreditation for approved arrangements personnel

Class requirements include information about the type of biosecurity training accreditation needed for personnel carrying out activities under an approved arrangement.

To achieve biosecurity accreditation for most classes there are two options:

1) online accredited person training
2) in-house training.

Where a class requires specific accreditation (for example fumigation) this training must be completed in addition to biosecurity accreditation training.

1.9.1 Online accredited person training

Information about the online accredited person training can be found on the department's website.

1.9.2 In-house training

To be considered an accredited person, in-house training must be successfully completed. Records of participation must be provided when requested by the department.

Persons who complete in-house training accreditation are only considered accredited while employed by the biosecurity industry participant who delivered the training (it is not transferrable).

In-house training must include the following biosecurity topics:

- responsibilities of accredited persons
- management of biosecurity risk (containment, treatment, disposal)
- security and isolation
- hygiene
- inspections (for those classes undertaking inspections of containers)
- dunnage and waste disposal
- record keeping.

1.9.3 Reaccreditation

The department will advise biosecurity industry participants when reaccreditation training must be undertaken.

Reaccreditation may be required as a result of:

- changes to conditions
- serious or repeated noncompliance
- failed audit.

1.10 Monitoring and assessing compliance

1.10.1 Compliance monitoring strategy

The compliance monitoring strategy for biosecurity industry participants is risk based. This means that the department will focus its attention towards areas where there is an identified biosecurity risk or high probability of a biosecurity risk.

Noncompliance with departmental requirements poses a biosecurity risk. Therefore, biosecurity industry participants can expect less regulatory intervention when they are compliant and more regulatory intervention when noncompliance has been identified.

Under the Biosecurity Act, the department holds the power to monitor and audit the biosecurity industry participant against the requirements of their approved arrangement with or without prior notice.

1.10.2 Access for auditors, inspectors etc.

A biosecurity industry participant covered by an approved arrangement must provide access for Biosecurity Officers, Biosecurity Enforcement Officers, and any department approved auditor, to perform the functions and exercise the powers conferred on them by the Biosecurity Act or another law of the Commonwealth.

The biosecurity industry participant must provide a departmental auditor, or department approved auditor, with amenities and assistance as requested, and provide any required documents, records or

things relevant to the audit. Failure to provide access or assistance may result in regulatory action where compliance monitoring is unable to be performed.

Biosecurity Industry Participants are considered Persons Conducting a Business or Undertaking under the *Work, Health and Safety Act 2011* (WHS Act) and have a primary duty of care to ensure the health and safety of workers and others at their AA site, so far as is reasonably practical. Department of Agriculture, Fisheries and Forestry staff responsible for performing duties under the *Biosecurity Act 2015* (the Act) at AA sites have both rights and responsibilities in relation to their safety while performing their duties. Where safety issues negatively impact the department's ability to perform duties under the Act, grounds may exist for the application of sanctions against the arrangement.

1.10.3 Jurisdiction and enforcement

Whilst this policy deals primarily with arrangements under Chapter 7 of the Biosecurity Act, the department's portfolio legislation is broad. Therefore, where a suspected breach of legislation has been detected that falls outside of Chapter 7 of the Biosecurity Act, further departmental assessment and action may occur. Further monitoring, investigation and enforcement powers may be exercised under the *Regulatory Powers (Standard Provisions) Act 2014*.

The department may consider the suspension, revocation, variation or refusal of approval of an arrangement, as a result of the outcome of the departmental investigation. If serious noncompliant behaviour by a biosecurity industry participant comes to the attention of the department, further departmental assessment and action may occur, including civil or criminal sanctions, regardless of whether the noncompliance has been rectified. Further information can be found in the department's Compliance Policy available on the department's website.

1.10.4 Tools used to monitor and assess compliance

The department may monitor, assess and verify compliance through a range of tools including but not limited to audits and compliance and investigation monitoring visits at the biosecurity industry participant's premises or at any approved arrangement site where they may be performing an activity related to their approved arrangement. Further information can be found in the department's *Compliance Policy* available on the department's website.

1.11 Audit regime

A biosecurity industry participant may operate more than one approved arrangement site however audit outcomes and audit rates will be applied on a per site basis. Audit outcomes at any one approved arrangement site have no direct influence on audit rates at other approved arrangement sites belonging to the entity, even if co-located at the same physical address.

If noncompliance is detected, additional charges may be incurred for any management action required. This includes, but is not limited to, noncompliance notification, monitoring rectification of noncompliance, or providing any other direction necessary to manage biosecurity risks.

1.11.1 Audit types

Audits are a way by which the department monitors compliance with departmental requirements. Audits are a regulatory assessment of the biosecurity industry participant's ability to meet and maintain relevant approved arrangement conditions.

Table 3 below, lists the different types of audits for the classes of approved arrangements applicable to Part 1 and details when these audits are conducted.

Table 3 Audit types for approved arrangements

Type	Conducted…
Pre-approval	prior to: • approval of a new approved arrangement, or approved arrangement site • addition of a new approved arrangement class • approval of a variation to an existing approved arrangement.
Probation	following: • a failed audit • department-imposed suspension period • detection of a critical noncompliance • approval of a new approved arrangement • addition of a substantially different biosecurity activity • addition of a substantially different approved arrangement class; or • approval of a significant variation to an approved arrangement.
Regular	to monitor ongoing compliance of an approved arrangement. (May also be conducted to assess compliance prior to the end of a period of suspension).
Close out	when an approved arrangement site is revoked to ensure that associated biosecurity risk is managed appropriately. May be conducted on site or as a remote audit depending upon the specific situation.

Table 3 lists the audit types for approved arrangement.

Audits are charged at the prescribed fee-for-service rate in accordance with the departmental *Charging Guidelines*.

Regular and probation audits may be conducted with or without prior notification to the biosecurity industry participant as either announced or unannounced audits. Pre-approval audits will always be pre-arranged with the applicant.

Any noncompliance detected at audits will be managed in accordance with Section 1.12 Addressing noncompliance in Part 1 of this document.

1.11.2 Noncompliance classification

Table 4 Classification of noncompliance for approved arrangement sites

Type	Any…
Critical	• action, inaction or contravention of departmental requirements that results in the release or the imminent removal of goods subject to biosecurity control without prior written direction or approval from the department. • deliberate failure to comply with a departmental direction. Example: A biosecurity industry participant intentionally or accidently allows goods which are subject to biosecurity control to be removed from the approved arrangement site without approval from the department.
Major	• action, inaction or contravention of departmental requirements that results in a situation that may lead to the removal of goods subject to biosecurity control without prior written direction or approval from the department. • removal of goods subject to biosecurity control from the biosecurity area without prior written direction or approval from the department.

Type	Any…
	• action, inaction or contravention of departmental requirements that impedes the ability of departmental officers to effectively monitor and manage compliance with departmental requirements. • action, inaction or contravention of departmental requirements that results in cross-contamination between goods subject to biosecurity control and other goods, or the environment. Example 1: A biosecurity industry participant fails to secure goods which are subject to biosecurity control secure to prevent access and removal by unauthorised persons. Example 2: A biosecurity industry participant does not provide a safe working environment for biosecurity officers inspecting goods.
Minor	action, inaction or contravention of departmental requirements that results in a situation that may compromise the integrity of systems, processes or premises that are designed to manage and contain goods subject to biosecurity control. Example: A biosecurity industry participant fails to maintain records of Accredited Persons responsible for the handling of goods subject to biosecurity control.

Table 4 lists the classification of noncompliance for approved arrangement sites.

1.11.3 Audit results

Following each audit, the audit findings are documented, discussed at the audit exit meeting and provided to the biosecurity industry participant as a written audit report. The audit report includes details of evidence and associated findings of compliance and/or noncompliance. The audit result will be determined by the severity and total number of instances of noncompliance detected by the audit.

The audit result is determined as either a pass or a fail using the compliance matrix in Table 5.

1.11.4 Compliance matrix

Table 5 Compliance matrix for approved arrangements

		Major noncompliance				Critical noncompliance
		0	**1**	**2**	**3 or more**	**1 or more**
Minor noncompliance	**0**	Pass	Pass	Pass	Fail	Fail
	1	Pass	Pass	Pass	Fail	Fail
	2	Pass	Pass	Pass	Fail	Fail
	3	Pass	Pass	Fail	Fail	Fail
	4	Pass	Fail	Fail	Fail	Fail
	5	Pass	Fail	Fail	Fail	Fail
	6	Pass	Fail	Fail	Fail	Fail
	7 or more	Fail	Fail	Fail	Fail	Fail

Table 5 shows the compliance matrix for approved arrangements.

One or more critical instances of noncompliance will result in a:

- failed audit (if detected at audit), and
- probation audit rate.

1.11.5 Audit rates

The frequency of audits is determined by the risk associated with the operation of the approved arrangement. Biosecurity industry participants that are newly approved or demonstrate poor compliance are audited more frequently than those which have a demonstrated history of good compliance.

Table 6 Audit rates for approved arrangements

Audit rate	Number of audits
Probationary	When subject to the probation rate, at least two probation audits will be conducted on any business day within the 180-day probation period.
Low	When on the low audit rate, at least one regular audit will be conducted on any business day within any 365-day period.

Table 6 lists the audit rates for approved arrangements.

1.11.6 Probationary audit rate

Where an approved arrangement has had a variation approved for the biosecurity activities carried out, it may be subjected to the probationary audit rate if the new biosecurity activity is significantly different to the biosecurity activities already being carried out.

Table 7 below, provides an example of some common classes of biosecurity activities which may be added to existing approved arrangements, and which will not usually result in the approved arrangement being placed on the probation audit rate (subject to a good history of compliance). The biosecurity industry participant will be advised if a probation audit rate will be applied to the varied arrangement.

Table 7 Addition of classes which will not usually result in a probation audit rate

Where the approved arrangement site currently includes class:	Addition of these classes will not usually result in a probation audit rate being applied:
1.1	4.1, 4.6
1.3	4.1, 4.6
2.1	2.2, 4.1, 4.6
2.2	4.1, 4.6
2.5	2.51, 2.52

Table 7 provides the addition of classes which will not usually result in a probation audit rate.

For newly approved or varied arrangements, the probationary audit rate is applied from the day of approval.

Where a biosecurity industry participant has failed an audit of their approved arrangement, they will be placed on the probationary audit rate, commencing from the date the biosecurity industry participant is notified of the failed audit.

For biosecurity industry participants who have demonstrated critical noncompliance, they will be placed on the probationary audit rate commencing from the date the biosecurity industry participant is notified of the critical noncompliance.

Biosecurity industry participants subject to probation due to being newly approved, or varied, must consecutively pass two probation audits in order to demonstrate their ability to successfully manage biosecurity risks associated with their approved arrangement. However, where no noncompliance is identified at the first probation audit, the department may waive the requirement for a second probation audit.

Biosecurity industry participants subject to the probationary audit rate due to demonstrating poor compliance (for example two failed audits, critical noncompliance) will always be subject to at least two probation audits in order to demonstrate their ability to successfully manage biosecurity risks associated with their approved arrangement site.

Biosecurity industry participants who demonstrate a satisfactory level of compliance during their probation period move to the low audit rate; they do not need to wait for the full 180-day period to elapse before being placed onto the low audit rate.

If the biosecurity industry participant fails any one of the probation audits, the 180-day period immediately restarts and continues until the biosecurity industry participant has passed two consecutive probation audits within 180 days.

If the biosecurity industry participant fails two probation audits within a probation period, the department may address the noncompliance through a range of responses (see 1.12 Addressing noncompliance) including but not limited to administrative actions and civil and criminal sanctions. If the department decides to allow the approved arrangement to continue, the department may vary the approved arrangement conditions, to ensure the associated biosecurity risks are being appropriately managed.

See Figure 1 Probation and audit process for individual approved arrangement sites.

1.11.7 Low audit rate

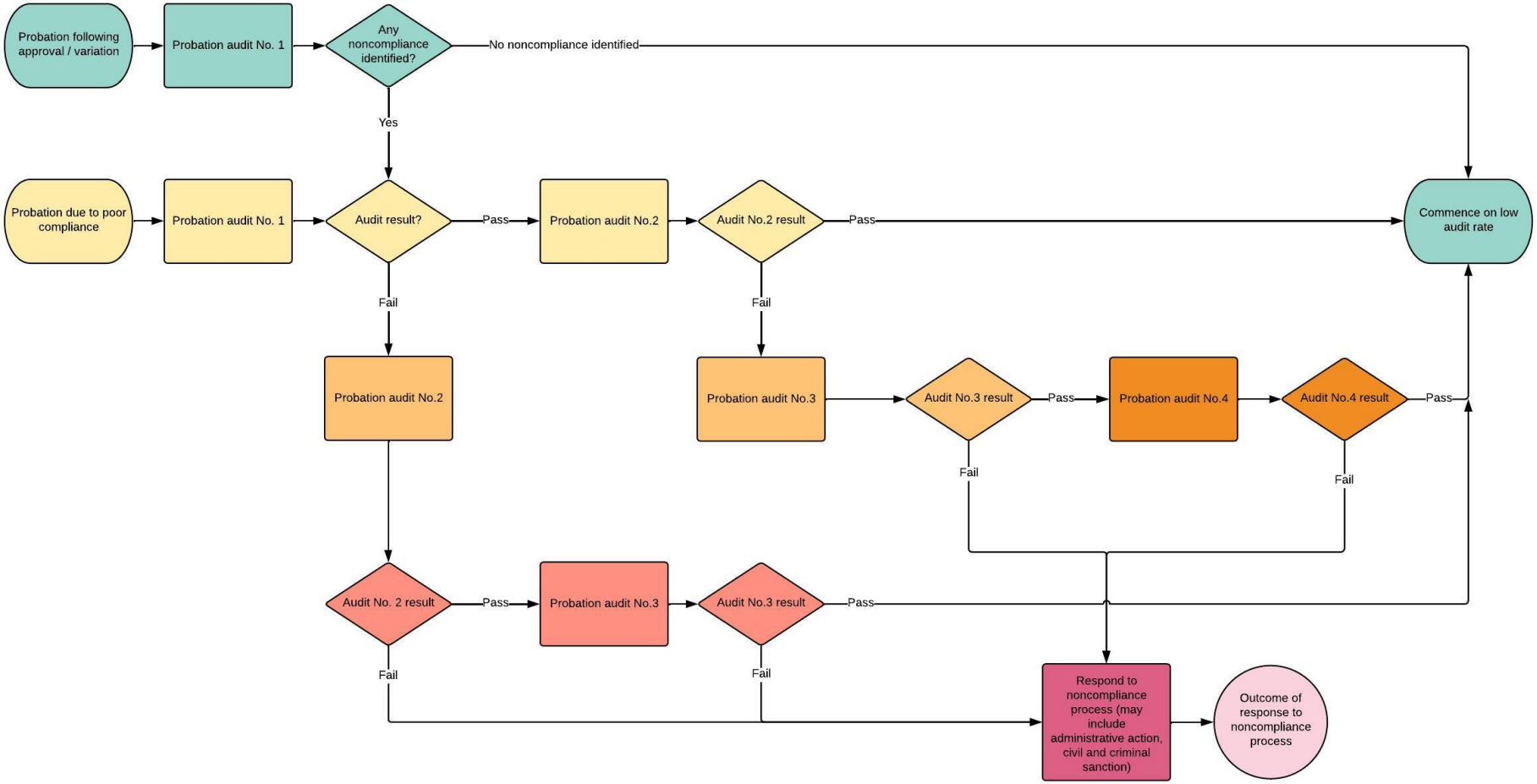
The low audit rate recognises and rewards the biosecurity industry participant's good history of compliance with departmental requirements by reducing the regulatory intervention. It is the lowest level of regulatory intervention for biosecurity industry participants.

This audit rate applies to biosecurity industry participants when they:

- have demonstrated a satisfactory level of compliance during a probation period
- have no noncompliance identified at their first probation audit (not applicable where probation is applied due to poor compliance history)
- continue to demonstrate a satisfactory level of compliance.

If the biosecurity industry participant fails an audit or a critical noncompliance is identified whilst at the low audit rate, the biosecurity industry participant will be placed on the probation audit rate.

Figure 1 Probation and audit process for individual approved arrangement sites



1.12 Addressing noncompliance

Approved arrangements are subject to a range of requirements in accordance with Chapter 7 of the Biosecurity Act. The biosecurity industry participant is required to comply with the conditions of their approved arrangement at all times. When the biosecurity industry participant fails to comply with the conditions to which their arrangement is subject, they are deemed to be noncompliant, and this noncompliance must be rectified. Failure to address noncompliance, or a history of poor compliance may result in a range of responses including but not limited to, administrative actions and civil and criminal sanctions. Further information on how the department addresses noncompliance can be found in the department's *Compliance Policy* available on the department's website.

1.12.1 Detection of noncompliance

Noncompliance can be detected in various ways, including but not limited to:

- audit
- surveillance
- compliance and investigation monitoring activities
- departmental officer visits to an approved arrangement site to review a previously identified noncompliance and, while there, noticing further noncompliance
- advice from a biosecurity officer performing inspections at an approved arrangement site
- biosecurity industry participant self-reporting noncompliance
- referral by a third party.

Where noncompliance is detected outside of an audit, the outcome may result in an increased audit rate, administrative action or civil or criminal sanctions.

1.12.2 Notification of noncompliance

Regardless of the method of detection, the department will notify the biosecurity industry participant of any noncompliance.

Where noncompliance is detected at audit, it will be brought to the attention of the biosecurity industry participant at the audit exit meeting. The audit report will contain details of identified instances of noncompliance, including classification of the noncompliance as per Table 4. A copy of the audit report will be provided at or after the completion of the audit.

Where a potential, but unconfirmed, critical noncompliance is detected at an audit the biosecurity industry participant will be notified at the audit exit meeting. Details will also be provided in the audit report provided after the audit.

Where noncompliance is detected outside of audit, it will be brought to the attention of the biosecurity industry participant in writing and will contain details of the detected noncompliance, including the classification of the noncompliance as per Table 4.

1.12.3 Addressing identified noncompliance

Written notification of noncompliance will specify a date by which the biosecurity industry participant is to submit evidence of addressing identified noncompliance. Following review, the

department will advise whether any further action is required. Depending on the severity of the noncompliance detected, the timeframe provided for addressing the noncompliance will vary. Once the noncompliance has been addressed, the biosecurity industry participant is to contact the department to report the action that has occurred.

Where a departmental officer needs to visit the biosecurity industry participant's approved arrangement site or witness performance of a specific activity at another location to review actions taken to rectify the noncompliance, the visit will be charged at the prescribed fee-for-service rate. Where the action taken to rectify the noncompliance can be reviewed by providing information to the department (such as photographs by email), this review will also be charged at the prescribed fee-for-service rate.

If the noncompliance has not been addressed to the department's satisfaction by the date specified in the written notification of noncompliance, the department may respond in a range of ways including, but not limited to, administrative actions and civil and criminal sanctions.

1.12.4 Impact on audit rate

The severity and number of noncompliance detected may impact on the audit rate, as per the compliance matrix. For example, an accumulation of noncompliance of various severity may result in a failed audit and therefore an increased audit rate.

Management of noncompliance may be charged at the prescribed fee-for-service rates in accordance with the departmental *Charging Guidelines*.

1.12.5 Administrative actions in response to noncompliance

If serious noncompliant behaviour by a biosecurity industry participant comes to the attention of the department through audit or any other way, the department may take administrative action, including but not limited to, suspension or revocation of the approved arrangement – see jurisdiction and enforcement.

Further information about the types of administrative actions the department may use in response to noncompliance can be found in the *Compliance Policy* available on the department's website.

1.13 Reviewable decisions

Certain decisions the department may make under the Biosecurity Act are reviewable decisions. If you are dissatisfied with a reviewable decision you may apply for review of that decision.

Each of the decisions which may be subject to review are set out under section 574 of the Biosecurity Act; see Table 8 which lists the reviewable decisions that are associated with the administration of approved arrangements.

When a reviewable decision has been made, the decision-maker will give written notice of the decision and the reason for that decision to the relevant person. Once the written reasons have been received, the relevant person may apply to the department for a review of that decision. The relevant person for each reviewable decision is indicated in Table 8. Information regarding the process for applying for a review will be provided in the notice of decision.

Table 8 Reviewable decisions under the Biosecurity Act

Reviewable decision to…	Provision under which the reviewable decision is made	Relevant person for the reviewable decision, is the…
refuse to approve a proposed arrangement	Subsection 406(1)	person who applied for the approval
refuse to approve a varied arrangement	Subsection 406(1) (as it applies because of subsection 412(3))	person who applied for the approval
approve a proposed arrangement subject to conditions	Subsection 406(3)	person who applied for the approval
vary the conditions of an approved arrangement	Subsection 413(1)(a)	biosecurity industry participant that is covered by the approved arrangement
require a biosecurity industry participant to vary an approved arrangement	Subsection 413(1)(b)	biosecurity industry participant that is covered by the approved arrangement
refuse to suspend a part of an approved arrangement	Subsection 417(4)	biosecurity industry participant that is covered by the approved arrangement
suspend an approved arrangement or a part of an approved arrangement	Subsection 418(1)	biosecurity industry participant that is covered by the approved arrangement
extend the period during which an approved arrangement or a part of an approved arrangement is suspended	Subsection 420(3)	biosecurity industry participant that is covered by the approved arrangement
revoke an approved arrangement	Subsection 423(1)	biosecurity industry participant that is covered by the approved arrangement

Table 8 lists reviewable decisions under the Biosecurity Act.

The general procedure to seek review of a decision is:

- the relevant person must lodge an application for review within 30 days after the day that the reviewable decision first came to the notice of the applicant—although the Director of Biosecurity may extend the 30-day period
- the application must be in writing and set out the reasons for the application
- when the application is received, the Director of Biosecurity must either review the decision personally or ensure that it is reviewed by an internal reviewer who was not involved in making the decision
- the Director of Biosecurity or the internal reviewer may affirm, vary or set aside the reviewable decision
- if the reviewable decision is set aside, the Director of Biosecurity or the internal reviewer may substitute another appropriate decision
- the decision on review takes effect on a day specified in the notice of decision, or if not specified, on the day the decision on review was made
- the person who made the decision must give the applicant written notice of the review decision

- a person who has received notice of the outcome of an internal review of a reviewable decision may make an application for further review by the Administrative Appeals Tribunal.

1.13.1 Exception

The only exception to the general procedure is where the decision maker was the Director of Biosecurity or the Director of Human Biosecurity. In that case the person may make an application for review directly to the Administrative Appeals Tribunal.

1.14 Suspension

An approved arrangement may be suspended subject to the conditions detailed in Chapter 7, Part 4 of the Biosecurity Act.

The administration of suspension of an approved arrangement may be charged at the prescribed fee-for-service rate in accordance with the departmental *Charging Guidelines*. The department may issue a biosecurity industry participant with directions to manage biosecurity risks where their approved arrangement has been suspended.

1.14.1 Suspension requested by a biosecurity industry participant

A biosecurity industry participant may request that the department suspend their approved arrangement, or part of an approved arrangement (for example when undertaking major building works, refurbishment, repair, or temporary closure).

A biosecurity industry participant can request the department to suspend their approved arrangement, in whole or part, by submitting a written request to the department. Further information is available on the department's website.

Where a valid request is made to suspend part of an approved arrangement the department will provide a written notice of decision within 30 days of when the request is received.

1.14.2 Suspension imposed by the department

The department may impose a suspension of an approved arrangement, or part of an approved arrangement, for reasons including, but not limited to:

- noncompliance with conditions of the arrangement
- noncompliance with requirements upon which approval of the arrangement was based
- the biosecurity industry participant no longer being a fit and proper person to hold an approved arrangement, as per section 530 of the Biosecurity Act
- a change to the level of biosecurity risk
- the biosecurity industry participant being liable for a cost-recovery charge which is overdue.

Typically, a written notice of intention to suspend will be provided prior to suspension, specifying the grounds for the suspension, and requesting the biosecurity industry participant to show cause as to why the approved arrangement should not be suspended. If the grounds for suspension are considered serious and urgent, the suspension may be immediate with no opportunity to show cause as to why the approved arrangement should not be suspended prior to the arrangement being suspended. A decision to suspend an approved arrangement is a reviewable decision.

If a decision is made to suspend an approved arrangement, or part of an approved arrangement, the biosecurity industry participant will be provided a notice specifying the period of suspension.

1.14.3 Audit requirements during suspension

Where the whole of an approved arrangement is suspended, regular audits will not be undertaken during the period of suspension. Note: The annual charge for approved arrangements will continue to be applied.

Where an approved arrangement is part suspended, for example where the approved arrangement includes multiple classes of activities but only one class is suspended, compliance monitoring is required for the activities not suspended. The audit rate will remain at the same rate as it was prior to suspension unless the suspension is due to noncompliance.

1.14.4 Varying the suspension period

The department may extend or shorten the period of suspension when, for example:

- the biosecurity industry participant is not fully compliant with their approved arrangement when the suspension period is due to end
- the biosecurity industry participant requests a change to the period of suspension.

1.14.5 Revoking a suspension

The department may revoke a suspension of an approved arrangement (or partly suspended approved arrangement) prior to the end of the suspension period, by written notice to the biosecurity industry participant.

If a biosecurity industry participant wishes to end their period of suspension prior to the end period specified in their notice of suspension, they should submit a written request to the relevant contact area – see contacting the department.

1.14.6 Compliance level at ending of suspension period

The approved arrangement must be in full compliance at the end of the suspension period, regardless of whether it is partly or wholly suspended, and regardless of whether the suspension was voluntary or imposed by the department. If necessary, the suspension will be extended until the arrangement is fully compliant.

1.14.7 Ending a voluntary suspension

Where the approved arrangement was voluntarily suspended by the biosecurity industry participant, an audit may be required depending upon the reason for and duration of the suspension. For example, if the arrangement was suspended in order to carry out refurbishment of facilities or equipment an audit is likely to be required, or other evidence of compliance sought. In contrast, if the arrangement was voluntarily suspended due to unavailability of accredited staff, evidence of their return may be sufficient. The length of the period of suspension is also a consideration. The decision as to whether an audit is required, and the scope of the audit, will be at the discretion of the department. Where an audit is not required, other evidence demonstrating compliance may need to be provided prior to the end of the suspension period.

Following the ending of a voluntary period of suspension, if an audit is not required before the end of the suspension period, the audit rate resumes at the rate which was in place prior to the suspension, regardless of whether the arrangement was partially or wholly suspended.

If an audit is required prior to the end of the suspension period, any identified noncompliance will need to be addressed prior to the ending of the suspension period (which may necessitate extension of the suspension). Where the audit outcome is determined to be a 'fail' as Table 5. Compliance matrix for approved arrangements, a second audit is required. Where the outcome for the second audit is determined to be a 'fail' as per Table 5. Compliance matrix for approved arrangements, the department may take administrative action in response to the noncompliance. Where the outcome for the first or second audit is determined to be a 'pass' and noncompliance has been identified as per Table 5. Compliance matrix for approved arrangements, the noncompliance will need to be rectified prior to the end of the suspension period (which may need to be extended). Where the noncompliance has not been rectified prior to the end of the suspension period, the department may take administrative action.

A flowchart of the ending of suspension process is shown in Figure 2.

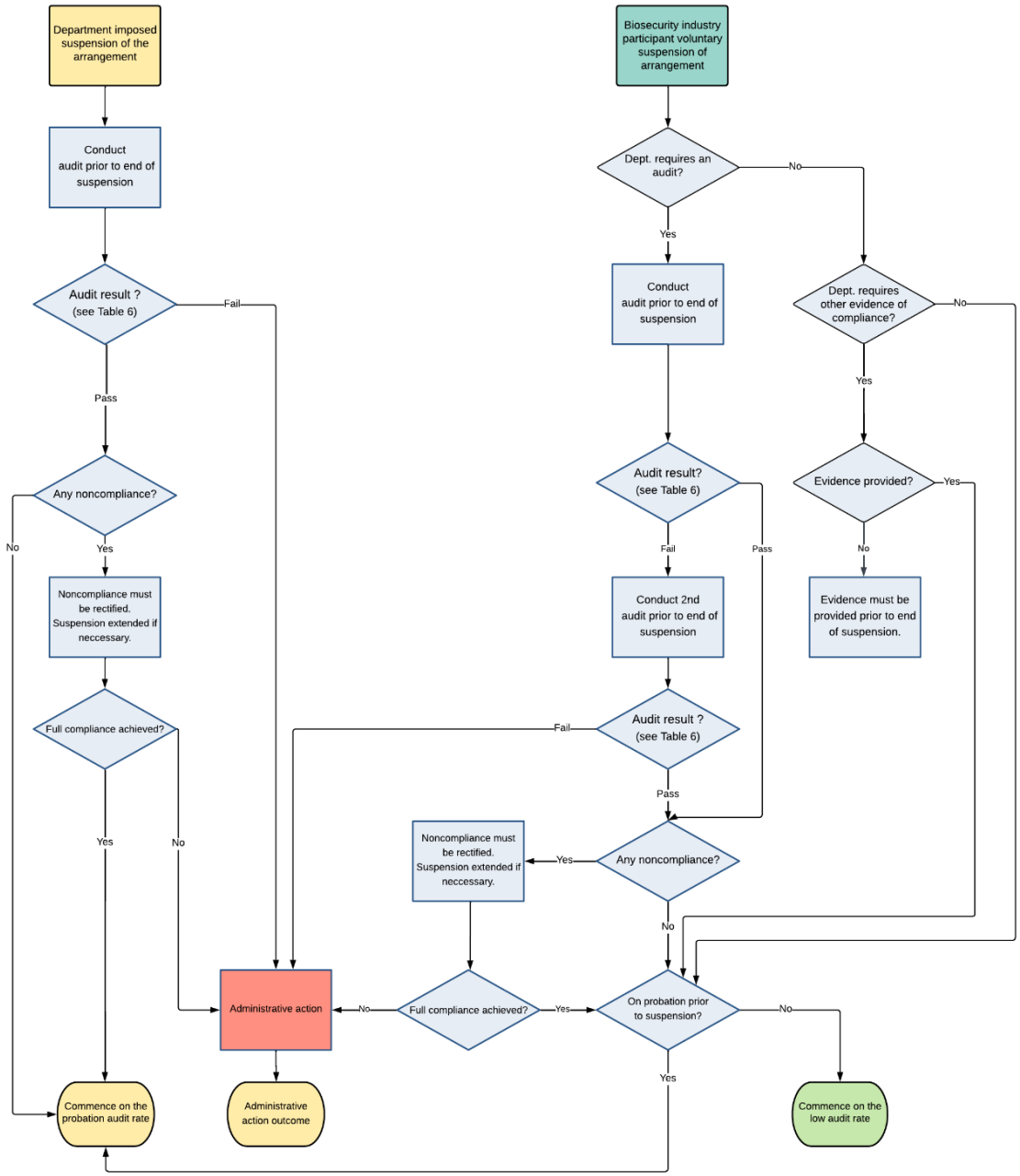
1.14.8 Ending of a department-imposed suspension

Where the approved arrangement was suspended by the department due to noncompliance, an audit will be carried out prior to the end of the suspension period to ensure compliance with conditions and requirements. Regardless of whether the arrangement was partially suspended or wholly suspended the audit scope will include all biosecurity activities covered by the arrangement. If the audit identifies noncompliance it will need to be rectified prior to the end of the suspension period (which may necessitate extension of the suspension).

If the audit outcome is determined to be a 'fail' as per Table 5 Compliance matrix for approved arrangements, the department may take administrative action. Where the audit outcome is determined to be a 'pass' and noncompliance has been identified as per Table 5. Compliance matrix for approved arrangements, the noncompliance will need to be rectified prior to the end of the suspension period (which may need to be extended) and the arrangement will then resume on the probation audit rate. Where the noncompliance has not been rectified prior to the end of the suspension period, the department may take administrative action.

Following any period of department-imposed suspension (part or whole), the arrangement will be placed on the probationary audit rate. The biosecurity industry participant must pass two consecutive probation audits to progress to the low audit rate.

Figure 2 Process for ending a period of suspension



1.15 Variation of an existing approved arrangement

An approved arrangement may be varied subject to the conditions detailed in Chapter 7, Part 3, of the Biosecurity Act. Administration of the variation of an approved arrangement may be charged at the prescribed fee-for-service rate in accordance with the departmental *Charging Guidelines*.

1.15.1 Variation requested by a biosecurity industry participant

Variations to approved arrangements are required where the conditions of an approved arrangement need to be changed. These changes may be of an administrative or operational nature. Usually, variations to approved arrangements are sought by a biosecurity industry participant but in some circumstances the department can impose variations. Some examples of where a variation is necessary include where a biosecurity industry participant wishes to vary the conditions of approval of an arrangement, including:

- propose an alternative means to meet departmental conditions
- seek exemption from certain approved arrangement conditions
- reduce the scope of activities covered by their approved arrangement

  or, vary the arrangement, including:

- add or remove an approved arrangement class.

The assessment of proposed variations to an approved arrangement entails consideration of:

- the effectiveness of the proposed variation in meeting the required biosecurity risk management outcome
- whether the proposed variation is capable of being effectively monitored for compliance by the department.

If a biosecurity industry participant wishes to vary their approved arrangement, they may apply by submitting a written application to the department. Further details are available on the department's website.

The applicant will be provided with a written notice of the outcome of their application. The variation must not be implemented until the department provides a written notice of decision to approve a varied arrangement.

Where the department decides there is an increase in biosecurity risk as a result of a variation the audit rate may change to the probation audit rate.

Depending on the complexity of the proposed variation, consideration of the application may take up to 90 days, and up to 120 days if the application requires scientific or technical advice to be sought.

The department may ask the biosecurity industry participant to provide further information to enable consideration of the application. If the department asks for further information the consideration time will be extended by the amount of time it takes for the biosecurity industry participant to provide the requested information. The department will specify the time period for providing further information.

1.15.2 Variation imposed by the department

The department may, by written notice, impose a variation or vary the conditions of an approved arrangement. This action may be taken if:

- the approved arrangement no longer meets the requirements on the basis of which approval was given; or
- the biosecurity industry participant is no longer a fit and proper person; or
- a condition of the approved arrangement has been contravened; or
- the level of biosecurity risk associated with the operation of the approved arrangement has changed; or
- a change needs to be made to the approved arrangement to correct a minor or technical error in the arrangement; or
- the arrangement needs to be varied for any other reason.

A variation notice will be provided specifying the varied conditions and date of effect.

Alternatively, the department may require the biosecurity industry participant to vary the arrangement. If the department requires the biosecurity industry participant to vary the arrangement, a notice will be provided which specifies the variation required and specifies the date by which the biosecurity industry participant must provide the varied arrangement to the department.

1.16 Revocation of an approved arrangement

An approved arrangement may be revoked subject to the conditions detailed in Chapter 7, Part 5, of the Biosecurity Act.

The administration of revocation of an approved arrangement may be charged at the prescribed fee-for-service rate in accordance with the departmental *Charging Guidelines*. The department may issue a biosecurity industry participant with directions to manage biosecurity risks where their approved arrangement has been revoked.

An audit may be conducted to ensure there are no goods subject to biosecurity control remaining at the site.

1.16.1 Revocation requested by a biosecurity industry participant

If a biosecurity industry participant wishes to have their approved arrangement revoked (cancelled), they must submit a request to the department.

A request for revocation must be made in writing and specify the proposed date of effect, which must not be fewer than 15 business days from the date the application is received. Further details are available on the department's website.

The department will provide a notice of revocation specifying the date of effect.

1.16.2 Revocation initiated by the department

The department may, by written notice, revoke an approved arrangement. This action may be taken if:

- the approved arrangement no longer meets the requirements on the basis of which approval was given; or
- the biosecurity industry participant is no longer a fit and proper person; or
- a condition of the approved arrangement has been contravened; or
- the level of biosecurity risk associated with the operation of the approved arrangement has changed; or
- the biosecurity industry participant is liable to pay a cost-recovery charge that is overdue, or
- the biosecurity industry participant is an associate of a:
  - person who has been refused approval of a proposed arrangement, or
  - biosecurity industry participant covered by an approved arrangement that has been revoked.

A written notice will be provided prior to revocation, specifying the grounds for the revocation, and requesting the biosecurity industry participant to show cause as to why the approved arrangement should not be revoked. If the grounds for revocation are considered serious and urgent, revocation may be applied without requesting the biosecurity industry participant to show cause as to why the approved arrangement should not be revoked.

If a decision is made to revoke an approved arrangement, or part of an approved arrangement, the biosecurity industry participant will be provided a notice stating that the approved arrangement has been revoked.

1.17 Transfer of an approved arrangement

An approved arrangement cannot generally be transferred to another person. An approved arrangement may only be transferred to another person if the biosecurity industry participant covered by the approved arrangement:

- dies; the approved arrangement may be transferred to the legal personal representative of the biosecurity industry participant
- is a body corporate in relation to which a receiver has been appointed; the approved arrangement may be transferred to the receiver
- is a body corporate of which an administrator has been appointed under section 436A, 436B or 436C of the *Corporations Act 2001*; the approved arrangement may be transferred to the administrator.

Further information in regard to the transfer of approved arrangements should be directed to the relevant contact area – see contacting the department.

1.18 Reportable biosecurity incidents

Certain incidents pose significant biosecurity risk if they occur. A biosecurity incident can be an act, omission or event. The reporting of biosecurity incidents will allow for biosecurity officers to efficiently manage biosecurity risks associated with an incident.

It is important that biosecurity incidents are reported as soon as practicable, to ensure that any biosecurity risks associated with the incident can be managed to an acceptable level and to limit the risk associated with any pest or disease entering, establishing or spreading into Australian territory. Biosecurity industry participants are required by law to report certain biosecurity incidents.

More information regarding biosecurity incidents, including events that must be reported and how to report the events, is available on the department's website.

1.19 Co-location of approved arrangement sites

The co-location policy provides for the option to link multiple approved arrangement sites at a common location. Co-location is often of particular benefit to biosecurity industry participants who operate multiple biosecurity containment approved arrangement sites in close proximity, such as in a university campus. Departmental assessment and approval of the approved arrangement sites that make up a co-located network is required. There are requirements for recordkeeping and the secure containment of goods being moved.

The assessment of containment facilities against approved arrangement class requirements requires individual assessment of each containment facility to a specific level and type, and individual registration of each containment facility as an approved arrangement site. The co-location of approved arrangement sites provides for the movement of goods subject to biosecurity control, such as research materials, between the approved arrangement sites within a co-located network.

Co-location is optional for approved arrangement sites. Approved arrangement sites in a co-located network must be operated by the same entity (same ABN).

1.19.1 Prerequisites for co-location

To be eligible for co-location, three mandatory criteria must be met.

1) Common approved arrangement manager

The approved arrangement manager nominated by your organisation as the person responsible for the management of biosecurity activities at the approved arrangement sites must be common across all co-located sites that make up the co-located network (see

Box 1).

2) Co-located approved arrangement sites must be located at the one physical address

To co-locate approved arrangement sites, they must be located within the boundary of a single property and not separated by a public road. For example, co-location of individual approved arrangement sites could be applied across a university campus, research centre, or pharmaceutical manufacturing facility. Co-location cannot be applied where facilities are separated by a public road.

Buildings that are separated by a public road are considered as a separate physical address (see Box 2)

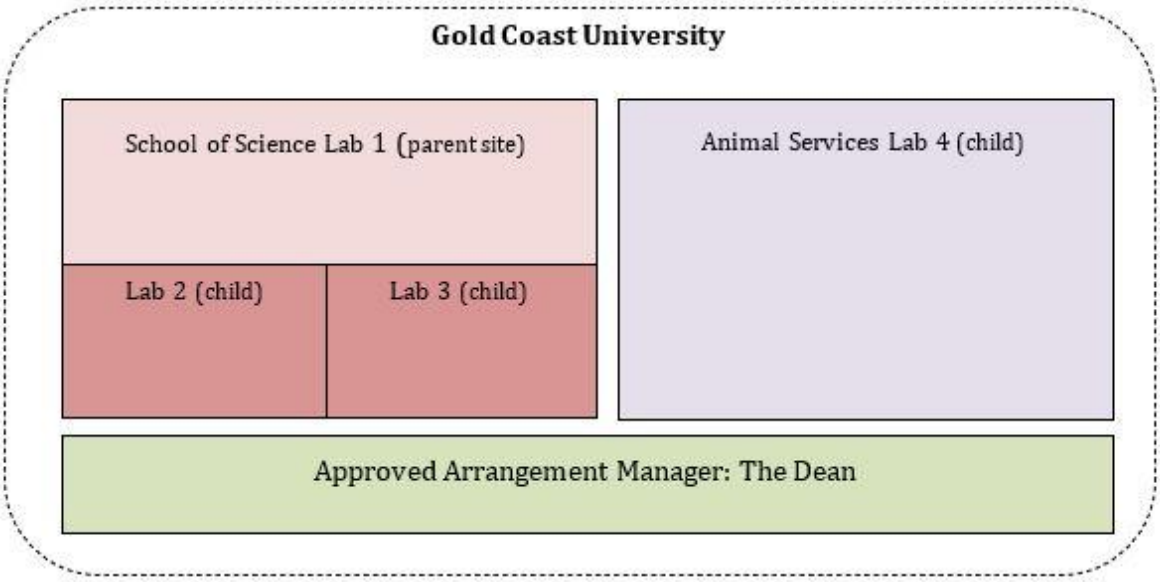
3) Approved arrangement sites are operated by the same entity

Co-located approved arrangement sites do not need to be grouped under a common approved arrangement, but they do need to be operated by the same entity.

Box 1 One university, one co-located network

- One parent approved arrangement site
- One approved arrangement manager
- Several approved arrangement sites comprise one co-located network of approved arrangement sites

Figure 3 Example of one university, one co-located network

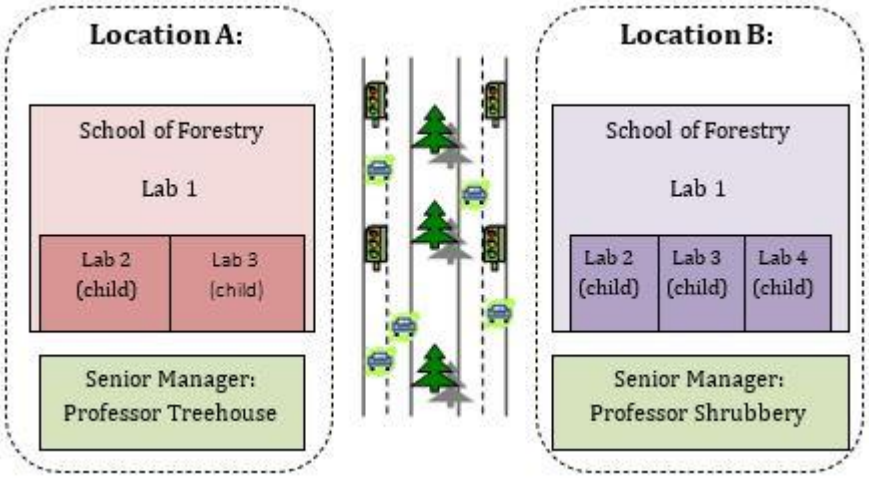


In Figure 3, the 'Dean' is the approved arrangement manager and is responsible for the biosecurity activities at both the School of Science and, Animal Services.

Box 2 One university, two parent sites

- Two parent sites – Site A and Site B
- Site A and B are separated by a public road
- Approved arrangement manager for each location

Figure 4 Example of one university, two parent sites



In Figure 4, a public road runs between the two groups of labs. The two locations are therefore considered to be two separate physical locations. The university may choose to co-locate the laboratories at each location.

1.19.2 Movement of biosecurity goods between co-located sites

Co-located approved arrangement sites can move goods subject to biosecurity control between them without seeking a movement direction from the department. Goods subject to biosecurity control can only be moved to a co-located approved arrangement site with appropriate biosecurity risk management measures for the goods being moved. Requirements for the movement of goods subject to biosecurity between co-located approved arrangement sites can be found in the relevant approved arrangement class requirements.

1.19.3 Charges for co-located approved arrangement sites

Audits are applied on an individual approved arrangement site basis, so charges for audit activities are still applicable to each approved arrangement site within the co-located network as defined in the departmental *Charging Guidelines*. As the registration fee for approved arrangements is applied at the entity level, co-locating approved arrangement sites has no impact on the annual approved arrangement charge.

1.19.4 Application of General Policies

Each approved arrangement site that is part of a co-located network is subject to individual compliance measures. This means that any approved arrangement site that is part of a co-located network is treated as a separate, stand-alone approved arrangement site for the purposes of auditing, addressing noncompliance, and application of sanctions or actions for noncompliance.

1.20 Document review

Part 1 of this document is subject to regular review to ensure it continues to be relevant and effective.

The department reserves the right to assess and review the ongoing validity of Part 1 of this document at any time to ensure that the requirements continue to align with legislation, government policy and the relevant operating environment in meeting both departmental and industry needs.

1.21 Additional reference material

The following reference material contains information that relates to the application of Part 1 of this document, and is available on the department's website:

- glossary
- class conditions.

2 Part 2

2.1 Scope – Class 19 automatic entry processing (AEP) approved arrangements

2.1.1 In scope

Part 2 applies to arrangements approved in accordance with Chapter 7 of the Biosecurity Act, to carry out specified class 19 AEP biosecurity activities.

2.1.2 Out of scope

Part 2 does not apply to:

- the approved arrangement approval process
- prosecutions for offences against the Biosecurity Act
- determination of the fit and proper person status of applicants for an approved arrangement
- class 1 to 14 – specified biosecurity activities (see Part 1)
- class 43.1 - disinsection (see Part 3).

2.2 Contacting the department

Any queries regarding application of Part 2 of this document, or its content should be directed to the contacts provided in Table 9. If a biosecurity industry participant requests to make a change to their approved arrangement, such as:

- updates to contact persons or contact details
- addition of new site contacts
- applications for variation, suspension, cancellation, additional sites or classes,

the request must be made by the approved arrangements:

- manager, or
- site contact person associated with the approved arrangement.

Notices from the department to the biosecurity industry participant will be directed to the approved arrangement manager, with additional courtesy copies sent to the nominated approved arrangement site contact. Where contacts have not been updated by the BIP, an office bearer registered with the Australian Securities and Investment Corporation will be given the notice.

Queries concerning approved arrangements conditions and policy should be directed to the relevant area, as indicated below. If your query or request is in regard to:

- activities involving the physical handling of goods, conducted at approved arrangement sites, please contact Audit and Assurance Branch.
- class 19 assessment activities, please contact the Support team.

- updates to contact details, applications, variations, suspensions, and cancellations under the class 19 approved arrangement, please contact the AEP Arrangements team.

If your query relates to both physical class (approved arrangement site) and class 19 AEP approved arrangements, or you are not sure, please contact Approved Arrangements.

Table 9 Contact details for approved arrangements enquiries

Type of enquiry	Area to contact	Phone	Email	Postal address	Hours of operation
Approved arrangement	Approved Arrangements Program	1800 900 090	aa.canberra@aff.gov.au	Approved Arrangements Program Department of Agriculture, Fisheries and Forestry GPO Box 858 Canberra ACT 2601	8.30am – 4.30pm (Australian Eastern Standard Time)
Class 19 Automatic Entry Processing (AEP)	AEP Support team	1800 900 090	AEP.support@aff.gov.au	AEP Support Assessment Policy Department of Agriculture, Fisheries and Forestry GPO Box 858 Canberra ACT 2601	8.30am – 4.30pm (Australian Eastern Standard Time)
Class 19 Applications, variations, cancellations suspensions, updates to contact details	AEP Arrangements	1800 900 090	AEP.arrangements@aff.gov.au	AEP Arrangements Assessment Policy Department of Agriculture, Fisheries and Forestry GPO Box 858 Canberra ACT 2601	8.30 am –4.30pm (Australian Eastern Standard Time)

2.3 Definitions

Definitions can be found within the *Approved Arrangements Glossary*, on the department's website, or in the Biosecurity Act. For words not defined in the glossary or an Act, definitions can be found in the most recent edition of the Macquarie Dictionary.

2.4 Approach to compliance and regulation

Our approach to compliance management involves recognising regulated client behaviours and adjusting our compliance posture accordingly. The department applies a range of regulatory tools to manage compliance, from routine inspections and audits through to criminal prosecution. Further information can be found on the *Compliance Policy* webpage.

Table 10 Principles of the department's compliance management approach for approved arrangements

Principle	The department…
Risk based	believes that if biosecurity industry participants demonstrate a high level. of compliance with departmental requirements, they should expect to see reduced regulatory intervention. This allows the department to focus its resources on areas that pose greater biosecurity risks.

Principle	The department…
Consistency	seeks to provide biosecurity industry participants with certainty about its actions by assessing, reporting, managing and administering fairly across comparable situations.
Proportionality	believes any administrative action should be in proportion to the level of potential biosecurity risk and the seriousness of the breach.
Transparency	will deal with biosecurity industry participants in an open and transparent manner so that they will have a clear understanding of what is expected of them and what they can expect of the department.
Timeliness	will strive for the resolution of noncompliance matters in a timely and appropriate manner.
Flexibility	will respond to changing situations, trends and technologies and review how it determines compliance.
Effectiveness	will apply appropriate responses to achieve the most suitable outcomes.
Review	will, upon request, review decisions which are defined as reviewable decisions under Section 574 of the Biosecurity Act.

Table 10 provides the principles of the department's compliance management approach for approved arrangements.

By applying these principles, the department aims to ensure that biosecurity risk is managed, especially in addressing noncompliance, to prevent and deter noncompliant behaviour and to encourage greater compliance with departmental requirements.

2.5 Scope of a class 19 AEP approved arrangement

The class 19 AEP approved arrangement allows accredited persons to identify and manage biosecurity risk.

Multiple classes of biosecurity activities, in multiple locations, can be grouped under one or more approved arrangements as desired. For class 19 AEP approved arrangements, a Branch ID can only belong to a single class 19 arrangement.

2.6 Fit and proper person assessment

The Biosecurity Act requires that the department consider the fit and proper person status of an approved arrangement applicant prior to approval. Additionally, the fit and proper person status of a biosecurity industry participant is a relevant consideration in decisions to vary, suspend or revoke an approved arrangement. Consideration of whether the applicant or biosecurity industry participant is fit and proper to hold an approved arrangement is important because such a person might be involved in the importation of high-risk goods or be approved to undertake activities to manage their own biosecurity risk with oversight by the department. The fit and proper person assessment includes consideration of associates of the applicant or biosecurity industry participant that are relevant to the operation of the approved arrangement.

An approved arrangement grants a concession and responsibility on persons that allows for them to do certain things the general public are not allowed to do. It is important that such persons are considered fit and proper to be able to conduct these activities and there is confidence that the person will operate within the scope of their approval and comply with conditions and requirements.

If the Director of Biosecurity determines that a person is not a fit and proper person, the Director may refuse to approve a proposed arrangement; or vary, suspend or revoke an approved

arrangement. The regulations may prescribe other situations where the fit and proper person test may be applied.

Further information about the fit and proper person test can be found on the fit and proper test for approved arrangement applicants webpage.

2.6.1 Notifying change of fit and proper person-relevant circumstances

A biosecurity industry participant covered by an approved arrangement must notify the department in writing as soon as practicable and within 15 days of becoming aware of any change of circumstance (not previously notified to the department) which may alter their fit and proper person status of the biosecurity industry participant or their associates.

2.7 Fees and charges

The department applies fees and charges to recover the cost of the administration of approved arrangements. The charges associated with the operation of an approved arrangement include:

- an application charge
- an annual charge
- ongoing fees for service.

The prescribed fees and charges are detailed in the departmental *Charging Guidelines*.

Applicants for a new approved arrangement will be charged an application charge. This charge will not be applied where the entity making the application already holds a current approved arrangement under the Biosecurity Act. Assessment of the application will incur a prescribed fee-for-service charge which is time-based. Assessment may include both in-office and out-of-office activities, which are charged at different rates.

Each entity operating an approved arrangement will be charged an annual charge. The charge is applied once only, regardless of the number of approved arrangements that an entity holds.

Audit activities (both in-office and out-of-office) will be charged at the prescribed fee-for-service rate. Alternatively, a daily rate may be charged for audit activities, if the daily rate will be a lesser charge. Audit activities include, but are not limited to:

- pre-audit activities – undertaking preparation for the audit, organising the audit appointment, providing formal notification of the audit etc.
- issuing corrective action requests, monitoring rectification of identified noncompliance, or providing any other direction necessary to manage biosecurity risks
- post-audit activities – writing the audit report, assessing evidence for in-office corrective action requests management, updating records and databases etc.
- management of noncompliance.

The administration of changes to an approved arrangement, such as variation, suspension or revocation, may be charged at the prescribed fee for service rate.

2.8 Accreditation for approved arrangements covering class 19 activities

To become an accredited person for an approved arrangement carrying out class 19 activities, the applicant must satisfy the following pre-requisites:

- be a licensed nominee customs broker or self-reporting importer
- have obtained a certificate of attainment in the unit of competency TLIX0008 – Comply with biosecurity border clearance.

2.8.1 Continued biosecurity competency

In order to maintain accreditation for a class 19.1 – Non commodity for containerised cargo clearance (NCCC) or class 19.2 – Automatic entry processing for commodities (AEPCOMM) approved arrangements, accredited persons must complete the continued biosecurity competency sessions stipulated by the department in a given continued biosecurity competency period (1 April – 30 March).

Information regarding class 19 accreditation and continued biosecurity competency, including current continued biosecurity competency periods can be found on the training and accreditation for approved arrangements webpage on the department's website.

2.9 Monitoring and assessing compliance

The compliance monitoring strategy is risk based. This means that the department will focus its attention towards areas where there is an identified biosecurity risk or high probability of a biosecurity risk.

Noncompliance with departmental requirements poses a biosecurity risk. Therefore, biosecurity industry participants can expect less regulatory intervention when they are compliant and more regulatory intervention when noncompliance has been identified.

Under the Biosecurity Act, the department holds the power to monitor and audit the biosecurity industry participant against the requirements of their approved arrangement with or without prior notice.

Noncompliance identified during monitoring activity may serve as a trigger for an audit. Information gathered during monitoring activity may form part of the audit.

2.9.1 Access for auditors, inspectors etc.

A biosecurity industry participant covered by an approved arrangement must provide access for biosecurity officers, biosecurity enforcement officers, and any department approved auditor, to perform the functions and exercise the powers conferred to them by the Biosecurity Act or another law of the Commonwealth.

The biosecurity industry participant must provide a departmental auditor, or department approved auditor, with amenities and assistance as requested, and provide any required documents, records or things relevant to the audit.

2.9.2 Jurisdiction and enforcement

Whilst this policy deals primarily with arrangements under Chapter 7 of the Biosecurity Act, the department's portfolio legislation is broad. Therefore, where a suspected breach of legislation has been detected that falls outside of Chapter 7 of the Biosecurity Act, further departmental assessment and action may occur. Further monitoring, investigation and enforcement powers may be exercised under the *Regulatory Powers (Standard Provisions) Act 2014*.

The department may consider the suspension, revocation, or refusal of approval of an arrangement, as a result of the outcome of the departmental investigation. If serious noncompliant behaviour by a biosecurity industry participant comes to the attention of the department, further departmental assessment and action may occur, including civil or criminal prosecution.

2.9.3 Administrative action (show cause) process

If serious noncompliant behaviour by a biosecurity industry participant comes to the attention of the department through audit or any other way, the department may by written notice, request the biosecurity industry participant to show cause as to why their arrangement should not be suspended or revoked. The department will provide a notice which specifies the grounds upon which the department is considering suspension or revocation of the arrangement. The biosecurity industry participant will be requested to provide information and evidence to support their case, including any measures implemented to prevent a recurrence of the noncompliance.

The department may seek further information or advice before making a decision regarding the approved arrangement.

Whilst the biosecurity industry participant is subject to a show cause process, audits may be conducted, and the department may conduct other compliance monitoring activities to assess the biosecurity industry participant's ongoing compliance with departmental requirements.

Following consideration of the information provided by the biosecurity industry participant, the department will provide a written notice of its decision to either:

- take no action and continue the approval
- suspend the arrangement, in part or in whole, for a specified period
- vary the arrangement
- revoke the arrangement.

2.10 Monitoring and assessing compliance activities

2.10.1 Monitoring activities

The department will monitor biosecurity industry participants' compliance with the requirements of approved arrangements class 19.1 NCCC and 19.2 AEPCOMM. Collectively these arrangements are referred to as the class 19 AEP approved arrangements.

Ongoing compliance monitoring for the class 19 AEP approved arrangements will be primarily undertaken through document assessment verification at the approved arrangement branch level.

The department may also undertake other business assurance activities such as targeted assessments and audits to monitor compliance.

Further departmental assessment and action using powers under the *Regulatory Powers (Standard Provisions) Act 2014* may be exercised such as further monitoring, investigation and enforcement should a suspected breach of legislation be detected (see jurisdiction and enforcement).

Fees for service apply for activities in accordance with the departmental charging guidelines.

2.10.2 Document assessment verification

The two lodgement categories for document assessment verifications are:

- Category 1: import declarations lodged under class 19.1 NCCC approved arrangement where the accredited person has not entered a NCCC concern type to declare any non-commodity concerns.
- Category 2: import declarations lodged under class 19.1 NCCC or the class 19.2 AEPCOMM approved arrangement where the accredited person enters a NCCC concern type and/or AEP code in the system to generate an AIMS direction.

Where an import declaration is selected for document assessment verification, the department will direct the biosecurity industry participant to provide the documentation used to support the assessment.

The frequency of documentation assessment verification varies, depending on the category of lodgement and corresponding review level.

Verification rates are adjusted according to the results of the document assessment verification. Higher levels of compliance will result in lower verification rates. The verification rate for class 19.1 NCCC is applied independently from class 19.2 AEPCOMM (Figure 5 and Figure 6). Verification rates are applied separately to each individual commodity group within class 19.2 AEPCOMM. For further details see the document assessment verification - compliance action section.

The department may vary category 2 verification rates for class 19.2 AEPCOMM commodity groups if required and will advise biosecurity industry participants of these changes if they are implemented.

2.10.3 Document assessment - verification results

Document assessment verification results will be determined in accordance with class 19 requirements, the Minimum documentary and import declaration requirements policy, non-commodity information requirements policy and BICON requirements. Directions will be issued by the document assessment officer in accordance with the BICON onshore outcomes.

Details of noncompliance identified during document assessment verification activities will be reported to the biosecurity industry participant at the time of verification. Noncompliance will be classified in accordance with the classifications in Table 12.

2.10.4 Document assessment verification – noncompliance corrective actions

Where noncompliance is detected for class 19 approved arrangements through document assessment verification, written advice will be issued through a direction from the Agriculture Import Management System (AIMS) and sent to the email address listed in the Brokerage Branch ID in the ICS at the time of verification.

If a biosecurity industry participant reaches census review level a corrective action request will be issued in addition to the noncompliance advice.

When the department has assessed and is satisfied with the measures undertaken by the biosecurity industry participant to prevent ongoing noncompliance the corrective action request will be closed. The biosecurity industry participant will be placed at the probation review level. Where multiple corrective action requests have been issued to the biosecurity participant all of these must be closed before the review level is placed back on the probation review level.

Failure to action corrective action requests will result in the biosecurity industry participant being issued with a notice of intention as to why their approved arrangement should not be suspended or revoked.

2.10.5 Document assessment verification - compliance action

Where noncompliance is found for category 1 lodgements, the biosecurity industry participant will be subject to the changes in verification rate as shown in Figure 5.

Where noncompliance is found for category 2 lodgements, the biosecurity industry participant will be subject to the changes in verification rate as shown in Figure 6.

2.10.6 Other compliance action

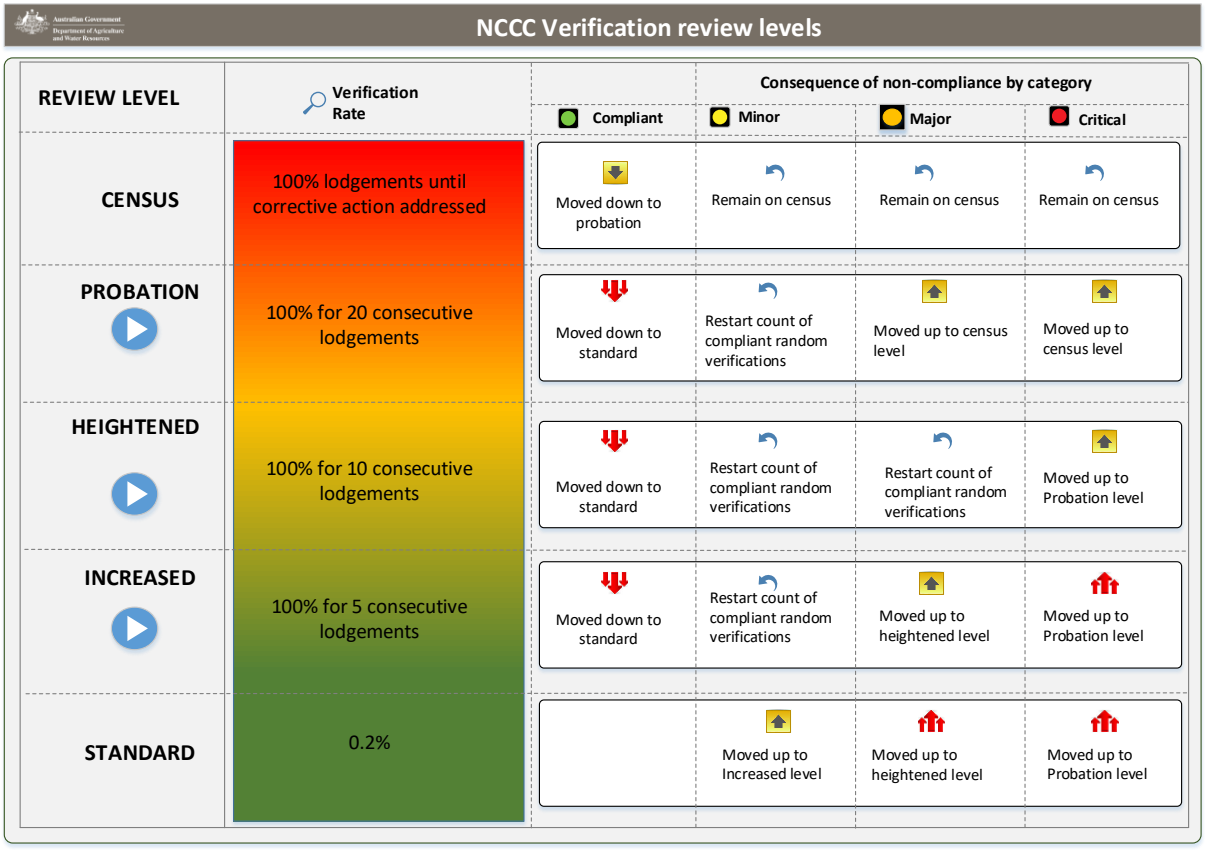
If a biosecurity industry participant's review level increases to census for any category 1 or category 2 lodgement, the department will manage the noncompliant behaviour in accordance with the seriousness and biosecurity risk posed by the actions undertaken by the biosecurity industry participant or their associates.

The actions may include an audit or the issuing of a notice of intention to suspended or revoke.

If serious noncompliant behaviour by a biosecurity industry participant and/or associates comes to the attention of the department, further departmental assessment and action may occur, including civil or criminal prosecution.

In addition, the department may take additional noncompliance action where there are multiple failures across different arrangements that are assessed by the department resulting in a change in the biosecurity risk associated with the operation of the arrangement and/or failure of conditions associated with the arrangement. This includes investigating and taking action against individual associates (accredited persons) of the biosecurity industry participant, in accordance with the noncompliance—failure to comply with accredited persons' responsibilities found in the training and accreditation for approved arrangements classes 19.1 and 19.2 document.

Figure 5 Verification rates for category 1 lodgements

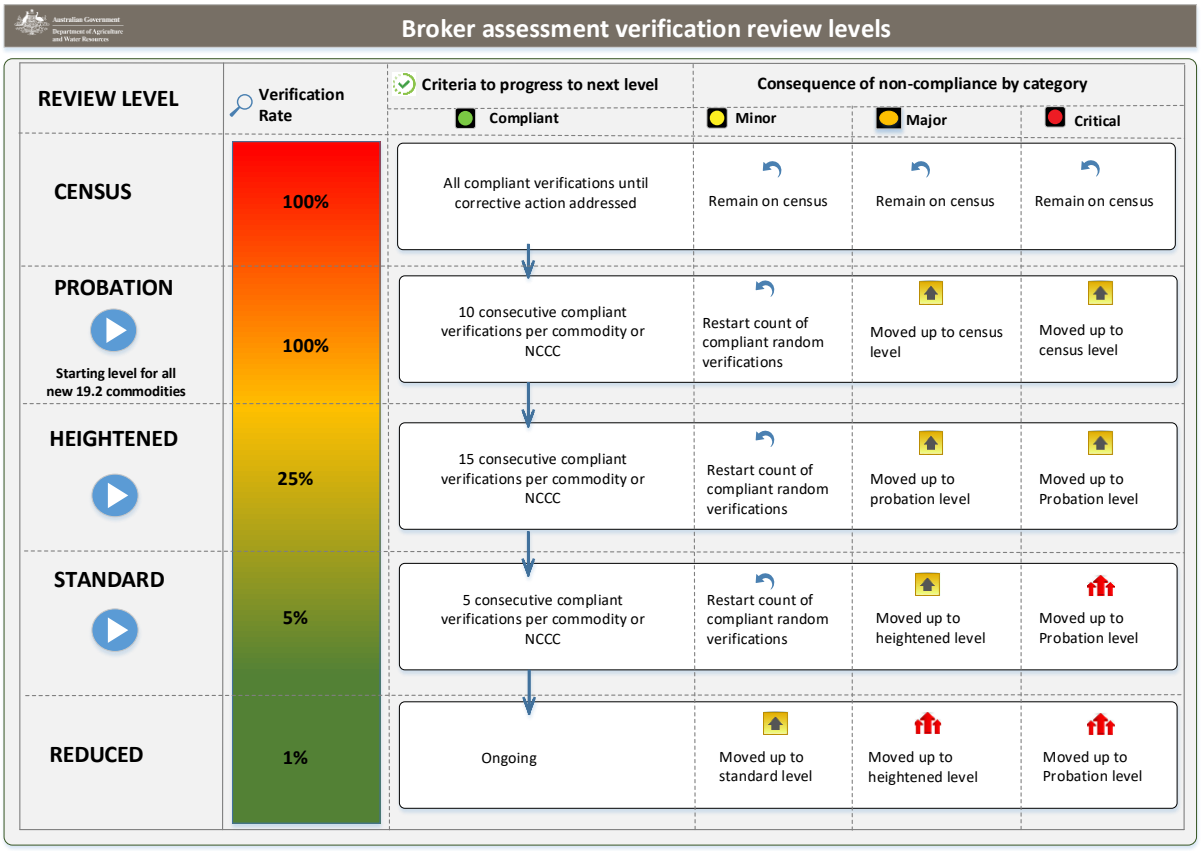


Newly approved class 19.1 NCCC approved arrangements will commence at standard review level.

A detection of a critical noncompliance will result in the biosecurity industry participant being placed on the probation review level regardless of review level the biosecurity industry participant is on. Any detection of major or critical noncompliance found while on the probation review level will result in being placed at the census review level.

Where a biosecurity industry participant is placed on the census review level, the department will issue a corrective action request. The department must be satisfied with the proposed measures to rectify the corrective action requests before the biosecurity industry participant will be placed on the probation review level.

Figure 6 Verification rates for category 2 lodgements



Newly approved class 19.2 AEPCOMM approved arrangements will start on the probation review level for all commodity groups covered by the arrangement.

A detection of a critical noncompliance will result in the biosecurity industry participant being placed on the probation review level regardless of review level the biosecurity industry participant is on. Any detection of major or critical noncompliance found while on the probation review level will result in being placed at the census review level.

Where a biosecurity industry participant is placed on the census review level, the department will issue a corrective action request. The department must be satisfied with the proposed measures to rectify the corrective action requests before the biosecurity industry participant will be placed on the probation review level.

2.10.7 Noncompliance found outside document assessment verification

Where noncompliance against class 19.1 NCCC or class 19.2 AEPCOMM is found outside of document assessment verification, the noncompliance will be managed in accordance with the document assessment verification—compliance action section.

2.10.8 Audits

Class 19 audits are used to ensure that the biosecurity industry participant:

- is compliant with the requirements under their approved arrangement

- has accredited persons that have undergone the relevant training and are up to date with their continued biosecurity competency.

Where an audit is required, the biosecurity industry participant will be notified by the department.

2.10.9 Audit results

Audit results will be determined through the use of the Noncompliance table - class 19 approved arrangement audits, that can be found in Table 11. For information on noncompliance classification, see Table 12.

The biosecurity industry participant will be provided with an audit report following completion of the audit activity. The audit report will include a pass or fail audit result and evidence of compliance or noncompliance.

The severity of noncompliance will be determined in accordance with the noncompliance classifications.

The biosecurity industry participant is responsible for taking action on any matter that requires corrective actions.

2.10.10 Noncompliance

Major and minor noncompliance will be recorded in the audit report. The department may issue noncompliance notifications for individual instances of major and/or minor noncompliance if specific corrective action is required by the biosecurity industry participant.

Critical noncompliance will be documented on a corrective action request.

2.10.11 Noncompliance and compliance action

Where a biosecurity industry participant fails an audit, they will be issued with a notice of intention to suspended or revoke. The biosecurity industry participant will be placed on review level Census for category 1 (Figure 5) and category 2 (Figure 6) lodgements.

Table 11 Noncompliance table—class 19 approved arrangement audits

Number of minor noncompliance	Number of major noncompliance				Number of critical noncompliance
	0	1	2	3 or more	1 or more
0	Pass	Pass	Pass	Fail	Fail
1	Pass	Pass	Pass	Fail	Fail
2	Pass	Pass	Fail	Fail	Fail
3	Pass	Pass	Fail	Fail	Fail
4	Pass	Fail	Fail	Fail	Fail
5 or more	Fail	Fail	Fail	Fail	Fail

Table 11 provides the noncompliance table for class 19 approved arrangement audits.

Three or more instances of major noncompliance will result in a failed audit.

Five or more instances of minor noncompliance will result in a failed audit.

Combinations of minor and major noncompliance will result in a failed audit in accordance with the Noncompliance table – class 19 approved arrangement audits, in Table 11.

2.10.12 Noncompliance classification

Table 12 Classification of noncompliance for class 19 approved arrangements

Type of noncompliance	Noncompliance could be any…
Critical	Action, inaction or contravention of requirements which has led to goods being assessed for release or released from biosecurity control without the required biosecurity intervention. Deliberate failure to comply with a departmental direction. Example: Accredited person assesses documents and releases a consignment under AEPCOMM without the mandatory documents required as per the BICON requirements.
Major	Action, inaction or contravention of requirements which has led to the requirements not being met for a consignment, but the goods are being sent for further biosecurity intervention (that is, inspection of commodity/non commodity).
Minor	Administrative errors that do not impact biosecurity integrity. Example 1: Accredited person accepting an old packing declaration that still contains the Prohibited Packing statement. Example 2: Accredited person fails to enter an AQIS entity identifier number in ICS, but the treatment provider is approved.

Table 12 lists the classification of noncompliance for class 19 approved arrangements.

For a full list of compliance classifications against each requirement, see the compliance classifications for broker class approved arrangements Compliance classifications for class 19 approved arrangements - DAFF (agriculture.gov.au).

2.10.13 Appealing noncompliance action reviews

Where a biosecurity industry participant believes the result of a document assessment verification was incorrect and has supporting evidence that the documents initially presented met relevant BICON import conditions, requirements and policies, the biosecurity industry participant may request a reassessment.

The department relies on the documents initially presented in the Cargo Online Lodgement System (COLS) for document assessment verification. The biosecurity industry participant is responsible for ensuring documents required to assess the consignment are presented and correct at the time of lodgement.

If a biosecurity industry participant chooses to appeal noncompliance action, they will remain under the increased review level until a finding has been reached or the review level has been passed—whichever happens first.

Where the reassessment upholds the original assessment, fees for service will be applied as per the departmental *Charging Guidelines*.

2.11 Reviewable decisions

Certain decisions the department may make under the Biosecurity Act are reviewable decisions. If you are dissatisfied with a reviewable decision you may apply for review of that decision.

Each of the decisions which may be subject to review are set out under section 574 of the Biosecurity Act; see Table 13 which lists the reviewable decisions that are associated with the administration of approved arrangements.

When a reviewable decision has been made, the decision-maker will give written notice of the decision and the reason for that decision to the relevant person. Once the written reasons have been received, the relevant person may apply to the department for a review of that decision. The relevant person for each reviewable decision is indicated in Table 13. Information regarding the process for applying for a review will be provided in the notice of decision.

Table 13 Reviewable decisions under the Biosecurity Act

Reviewable decision to…	Provision under which the reviewable decision is made	Relevant person for the reviewable decision, is the…
refuse to approve a proposed arrangement	Subsection 406(1)	person who applied for the approval
refuse to approve a varied arrangement	Subsection 406(1) (as it applies because of subsection 412(3))	person who applied for the approval
approve a proposed arrangement subject to conditions	Subsection 406(3)	person who applied for the approval
vary the conditions of an approved arrangement	Paragraph 413(1)(a)	biosecurity industry participant that is covered by the approved arrangement
require a biosecurity industry participant to vary an approved arrangement	Paragraph 413(1)(b)	biosecurity industry participant that is covered by the approved arrangement
refuse to suspend a part of an approved arrangement	Subsection 417(4)	biosecurity industry participant that is covered by the approved arrangement
suspend an approved arrangement or a part of an approved arrangement	Subsection 418(1)	biosecurity industry participant that is covered by the approved arrangement
extend the period during which an approved arrangement or a part of an approved arrangement is suspended	Subsection 420(3)	biosecurity industry participant that is covered by the approved arrangement
revoke an approved arrangement	Subsection 423(1)	biosecurity industry participant that is covered by the approved arrangement

Table 13 lists the reviewable decisions under the Biosecurity Act.

The general procedure to seek review of a decision is:

- the relevant person must lodge an application for review within 30 days after the day that the reviewable decision first came to the notice of the applicant—although the Director of Biosecurity may extend the 30-day period
- the application must be in writing and set out the reasons for the application
- when the application is received the Director of Biosecurity must either review the decision personally or ensure that it is reviewed by an internal reviewer who was not involved in making the decision

- the Director of Biosecurity or the internal reviewer may affirm, vary or set aside the reviewable decision
- if the reviewable decision is set aside the Director of Biosecurity or the internal reviewer may substitute another appropriate decision
- the decision on review takes effect on a day specified in the notice of decision, or if not specified, on the day the decision on review was made
- the person who made the decision must give the applicant written notice of the review decision
- a person who has received notice of the outcome of an internal review of a reviewable decision may make an application for further review by the Administrative Appeals Tribunal.

2.11.1 Exception

The only exception to the general procedure is where the decision maker was the Director of Biosecurity or the Director of Human Biosecurity. In that case the person may make an application for review directly to the Administrative Appeals Tribunal.

2.12 Suspension

An approved arrangement may be suspended subject to the conditions detailed in Chapter 7, Part 4 of the Biosecurity Act.

The administration of suspension of an approved arrangement may be charged at the prescribed fee-for-service rate in accordance with the departmental *Charging Guidelines*.

2.12.1 Suspension requested by a biosecurity industry participant

A biosecurity industry participant may request that the department suspend their approved arrangement, or part of an approved arrangement (for example when undertaking major building works, refurbishment, repair, or temporary closure).

A biosecurity industry participant can request the department to suspend their approved arrangement, in whole or part, by submitting a written request to the relevant contact area – see contacting the department. The period of suspension cannot extend beyond the period of approval.

The request for suspension must:

- be in writing
- specify whether a whole or part suspension is requested
- specify a proposed start time, which must be no fewer than 15 working days from the day the department receives the request
- specify the duration of the proposed suspension (for example, by specifying an end date)
- for part suspension, detail the biosecurity activities that the biosecurity industry participant will not be authorised to carry out during the suspension period
- for part suspension, explain how biosecurity risks associated with goods, premises or other things that the biosecurity industry participant is authorised to deal with will be managed during the suspension period.

Where a request is made to suspend part of an approved arrangement the department will provide a written notice of decision within 30 days of when the request is received.

2.12.2 Suspension imposed by the department

The department may impose a suspension of an approved arrangement, or part of an approved arrangement, for reasons including, but not limited to:

- noncompliance with conditions of the arrangement
- noncompliance with requirements upon which approval of the arrangement was based
- the biosecurity industry participant no longer being a fit and proper person to hold an approved arrangement, as per section 530 of the Biosecurity Act
- a change to the level of biosecurity risk
- the biosecurity industry participant being liable for a cost-recovery charge which is overdue.

Typically, a written notice of intention to suspend will be provided prior to suspension, specifying the grounds for the suspension, and requesting the biosecurity industry participant to show cause as to why the approved arrangement should not be suspended. If the grounds for suspension are considered serious and urgent, the suspension may be immediate with no opportunity to show cause as to why the approved arrangement should not be suspended prior to the arrangement being suspended. A decision to suspend an approved arrangement is a reviewable decision.

If a decision is made to suspend an approved arrangement, or part of an approved arrangement, the biosecurity industry participant will be provided a notice specifying the period of suspension.

2.12.3 Audit requirements during suspension

Where the whole of an approved arrangement is suspended, regular audits will not be undertaken during the period of suspension. Note: The annual charge for approved arrangements will continue to be applied.

Where an approved arrangement is part suspended (for example where the approved arrangement includes multiple classes of activities but only one class is suspended) compliance monitoring is required for the activities not suspended. The audit rate will remain at the same rate as it was prior to suspension unless the suspension is due to noncompliance.

2.12.4 Varying the suspension period

The department may extend or shorten the period of suspension when, for example:

- the biosecurity industry participant is not fully compliant with their approved arrangement when the suspension period is due to end
- an audit required to assess compliance is not completed before the end of the suspension period
- the biosecurity industry participant requests a change to the period of suspension.

2.12.5 Revoking a suspension

The department may revoke a suspension of an approved arrangement (or partly suspended approved arrangement) prior to the end of the suspension period, by written notice to the biosecurity industry participant.

If a biosecurity industry participant wishes to end their period of suspension prior to the end period specified in their notice of suspension, they should submit a written request to the relevant contact area – see contacting the department.

2.12.6 Compliance level at ending of suspension

The approved arrangement must be in full compliance at the end of the suspension period, regardless of whether it is partly or wholly suspended, and regardless of whether the suspension was voluntary or imposed by the department. If necessary, the suspension will be extended until the arrangement is fully compliant.

2.12.7 Ending a voluntary suspension

Where the approved arrangement was voluntarily suspended by the biosecurity industry participant, an audit may be required depending upon the reason for and duration of the suspension. For example, if the arrangement was suspended in order to carry out refurbishment of facilities or equipment an audit is likely to be required, or other evidence of compliance sought. In contrast, if the arrangement was voluntarily suspended due to unavailability of accredited staff, evidence of their return may be sufficient. The length of the period of suspension is also a consideration. The decision as to whether an audit is required, and the scope of the audit, will be at the discretion of the department. Where an audit is not required, other evidence demonstrating compliance may need to be provided prior to the end of the suspension period.

Following the ending of a voluntary period of suspension, if an audit is not required before the end of the suspension period, the audit rate resumes at the rate which was in place prior to the suspension, regardless of whether the arrangement was partially or wholly suspended.

If an audit is required prior to the end of the suspension period, any identified noncompliance will need to be addressed prior to the ending of the suspension period (which may necessitate extension of the suspension). Where the audit outcome is determined to be a ‘fail’ as per Table 11. Noncompliance table—class 19 approved arrangement audits, a second audit is required. Where the outcome for the second audit is determined to be a ‘fail’ as per Table 11 Noncompliance table—class 19 approved arrangement audits, the biosecurity industry participant may be asked to show cause as to why their arrangement should not be further suspended or revoked. Where the outcome for the first or second audit is determined to be a ‘pass’ and noncompliance has been identified as per Table 11 Noncompliance table—class 19 approved arrangement audits, the noncompliance will need to be rectified prior to the end of the suspension period (which may need to be extended). Where the noncompliance has not been rectified prior to the end of the suspension period, the biosecurity industry participant may be asked to show cause as to why their arrangement should not be further suspended or revoked.

A flowchart of the ending of suspension process is shown in Figure 7.

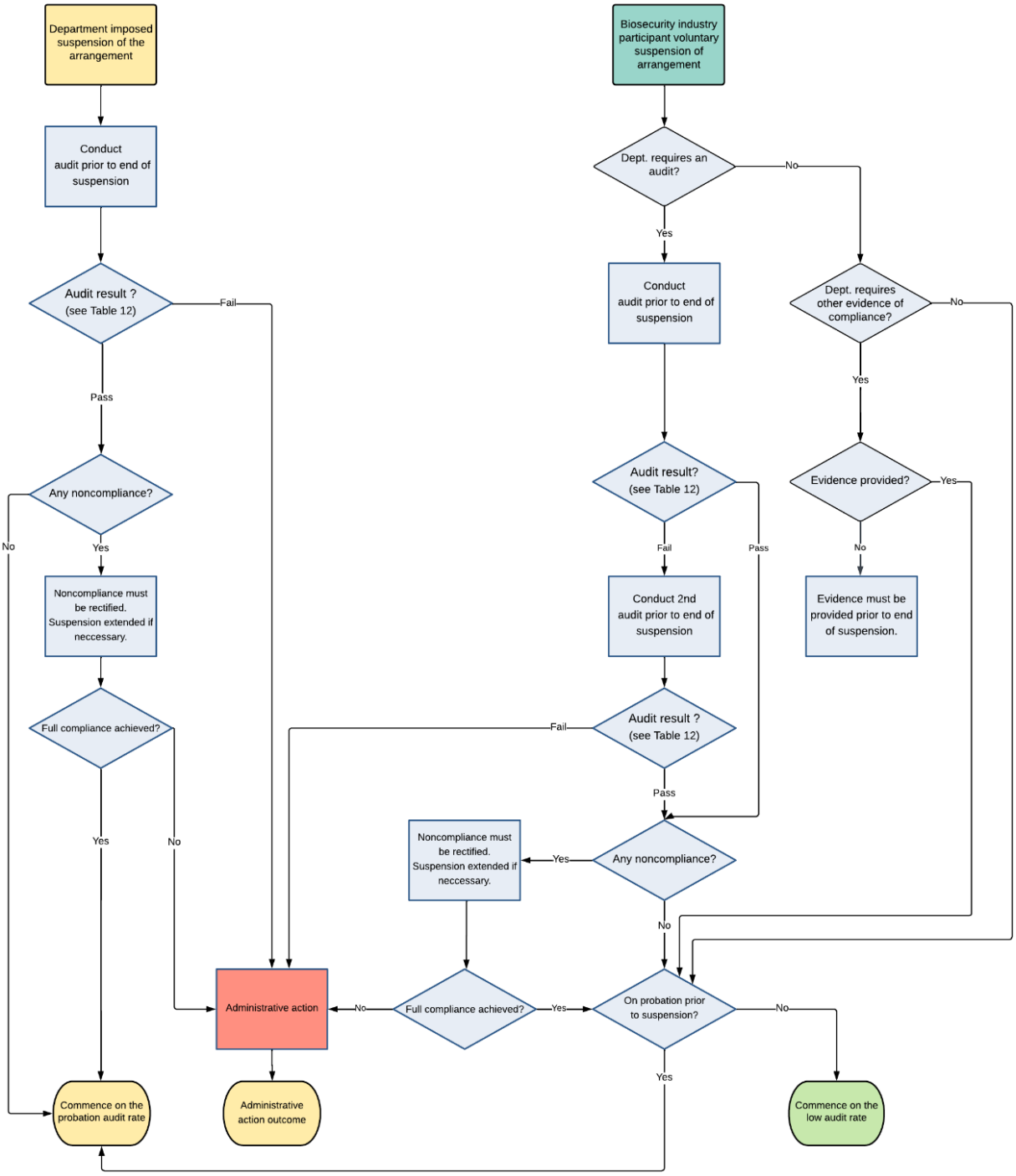
2.12.8 Ending of a department-imposed suspension

Where the approved arrangement was suspended by the department due to noncompliance, an audit will be carried out prior to the end of the suspension period to ensure compliance with conditions and requirements. Regardless of whether the arrangement was partially suspended or wholly suspended the audit scope will include all biosecurity activities covered by the arrangement. If the audit identifies noncompliance it will need to be rectified prior to the end of the suspension period (which may necessitate extension of the suspension).

If the audit outcome is determined to be a 'fail' as per Table 11 Noncompliance table—class 19 approved arrangement audits, the biosecurity industry participant may be asked to show cause as to why their arrangement should not be further suspended or revoked. Where the audit outcome is determined to be a 'pass' and noncompliance has been identified as per Table 11 Noncompliance table—class 19 approved arrangement audits, the noncompliance will need to be rectified prior to the end of the suspension period (which may need to be extended) and the arrangement will then resume on the probation audit rate. Where the noncompliance has not been rectified prior to the end of the suspension period, the biosecurity industry participant may be asked to show cause as to why their arrangement should not be further suspended or revoked.

Following any period of department-imposed suspension (part or whole), the arrangement will be placed on the probationary audit rate. The biosecurity industry participant must pass two consecutive probation audits to progress to the low audit rate.

Figure 7 Process for ending a period of suspension



2.13 Variation of an existing approved arrangement

An approved arrangement may be varied subject to the conditions detailed in Chapter 7, Part 3, of the Biosecurity Act. Administration of the variation of an approved arrangement may be charged at the prescribed fee-for-service rate in accordance with the departmental *Charging Guidelines*.

2.13.1 Variation requested by a biosecurity industry participant

Variations to approved arrangements are required where the conditions of an approved arrangement need to be changed. These changes may be of an administrative or operational nature. Usually, variations to approved arrangements are sought by a biosecurity industry participant but in some circumstances the department can impose variations. Some examples of where a variation is necessary include where a biosecurity industry participant wishes to vary the conditions of approval of an arrangement, including:

- propose an alternative means to meet departmental requirements
- seek exemption from certain approved arrangement requirements
- reduce the scope of activities covered by their approved arrangement

or vary the arrangement, including:

- add or remove an approved arrangement site or Branch ID from an approved arrangement
- move an approved arrangement site or Branch ID from one approved arrangement to another approved arrangement
- add or remove an approved arrangement class.

The assessment of proposed variations to approved arrangement requirements entails consideration of:

- the effectiveness of the proposed variation in meeting the required biosecurity risk management outcome
- whether the proposed variation is capable of being effectively monitored for compliance by the department.

Reasons for seeking approval of a varied arrangement could include the biosecurity industry participant:

- seeking to implement an alternative solution for meeting the outcome of an approved arrangement requirement, which is not currently provided for by the requirement
- believing an approved arrangement requirement should not be applied, or should be altered, as it is not appropriate to the scope of activities performed by the biosecurity industry participant.

If a biosecurity industry participant wishes to vary their approved arrangement, they may apply to the department by submitting a written application to the relevant contact area – see contacting the department.

The application for variation must include the:

- applicant's name and contact details

- biosecurity activities to be carried out by the applicant
- proposed places where the biosecurity activities are to be carried out
- details of the proposed variations to the approved arrangement.

The applicant will be provided with a written notice of the outcome of their application. The variation must not be implemented until the department provides a written notice of decision to approve a varied arrangement.

Where the department decides there is an increase in biosecurity risk as a result of a variation the audit rate may change to the probation audit rate.

Depending on the complexity of the proposed variation, consideration of the application may take up to 90 days, and up to 120 days if the application requires scientific or technical advice to be sought.

The department may ask the biosecurity industry participant to provide further information to enable consideration of the application. If the department asks for further information the consideration time will be extended by the amount of time it takes for the biosecurity industry participant to provide the requested information. The department will specify the time period for providing further information.

2.13.2 Variation imposed by the department

The department may, by written notice, impose a variation to an approved arrangement or vary the conditions of an approved arrangement. This action may be taken if:

- the approved arrangement no longer meets the requirements on the basis of which approval was given; or
- the biosecurity industry participant is no longer a fit and proper person; or
- a condition of the approved arrangement has been contravened; or
- the level of biosecurity risk associated with the operation of the approved arrangement has changed; or
- a change needs to be made to the approved arrangement to correct a minor or technical error in the arrangement; or
- the arrangement needs to be varied for any other reason.

A variation notice will be provided specifying the varied conditions and date of effect. Alternatively, the department may require the biosecurity industry participant to vary the arrangement. If the department requires the biosecurity industry participant to vary the arrangement, a notice will be provided which specifies the variation required and specifies the date by which the biosecurity industry participant must provide the varied arrangement to the department.

2.14 Revocation of an approved arrangement

An approved arrangement may be revoked subject to the conditions detailed in Chapter 7, Part 5, of the Biosecurity Act.

The administration of revocation of an approved arrangement may be charged at the prescribed fee-for-service rate in accordance with the departmental *Charging Guidelines*.

An audit may be conducted to ensure that any relevant biosecurity risk is appropriately managed.

2.14.1 Revocation requested by a biosecurity industry participant

If a biosecurity industry participant wishes to have their approved arrangement revoked (cancelled), they may apply to the department.

An application for revocation must be made in writing and specify the proposed date of effect, which must not be less than 15 business days from the date the application is received. An application for revocation of an approved arrangement should be made to the relevant contact area – see contacting the department.

The department will provide a notice of revocation specifying the date of effect.

2.14.2 Revocation by the department

The department may, by written notice, revoke an approved arrangement. This action may be taken if:

- the approved arrangement no longer meets the requirements on the basis of which approval was given; or
- the biosecurity industry participant is no longer a fit and proper person; or
- a condition of the approved arrangement has been contravened; or
- the level of biosecurity risk associated with the operation of the approved arrangement has changed; or
- the biosecurity industry participant is liable to pay a cost-recovery charge that is overdue, or
- the biosecurity industry participant is an associate of a:
  - person who has been refused approval of a proposed arrangement, or
  - biosecurity industry participant covered by an approved arrangement that has been revoked.

A written notice will be provided prior to revocation, specifying the grounds for the revocation, and requesting the biosecurity industry participant to show cause as to why the approved arrangement should not be revoked. If the grounds for revocation are considered serious and urgent, revocation may be applied without requesting the biosecurity industry participant to show cause as to why the approved arrangement should not be revoked.

If a decision is made to revoke an approved arrangement, or part of an approved arrangement, the biosecurity industry participant will be provided a notice stating that the approved arrangement has been revoked.

2.15 Transfer of an approved arrangement

An approved arrangement cannot generally be transferred to another person. An approved arrangement may only be transferred to another person if the biosecurity industry participant covered by the approved arrangement:

- dies, the approved arrangement may be transferred to the legal personal representative of the biosecurity industry participant
- is a body corporate in relation to which a receiver has been appointed, the approved arrangement may be transferred to the receiver
- is a body corporate of which an administrator has been appointed under section 436A, 436B or 436C of the *Corporations Act 2001*, the approved arrangement may be transferred to the administrator.

Further information in regard to the transfer of approved arrangements should be directed to the relevant contact area – see contacting the department.

2.16 Reportable biosecurity incidents

Certain incidents pose significant biosecurity risk if they occur. A biosecurity incident can be an act, omission or event. The reporting of biosecurity incidents will allow for biosecurity officers to efficiently manage biosecurity risks associated with an incident.

It is important that biosecurity incidents are reported as soon as practicable, to ensure that any biosecurity risks associated with the incident can be managed to an acceptable level and to limit the risk associated with any pest or disease entering, establishing or spreading into Australian territory.

More information regarding biosecurity incidents is available on the department's website.

2.16.1 Events that are reportable biosecurity incidents in relation to relevant goods

Events relating to prohibited goods, conditionally non prohibited goods or suspended goods

Each of the following events is a reportable biosecurity incident in relation to relevant goods that are prohibited goods, conditionally non prohibited goods or suspended goods. The goods:

- are in a container, a conveyance or other premises and are not as described on a manifest or an import permit relating to the goods
- are in a container, a conveyance or other premises that is damaged and the goods are no longer secure
- have been lost or stolen
- have been destroyed in circumstances other than in compliance with a direction given by a biosecurity officer.

Events relating to conditionally non prohibited goods

A change to the intended use of relevant goods that are conditionally non prohibited goods is a reportable biosecurity incident in relation to the goods.

Events relating to goods generally
Each of the following events is a reportable biosecurity incident in relation to any relevant goods:

- the goods or any container holding the goods, or the conveyance or other premises in which the goods are being held, have been, or are likely to have been, exposed to contamination, infestation or infection from prohibited goods, conditionally non prohibited goods or suspended goods
- the goods are infested with a live pest (for example, an insect, invertebrate or other animal)
- biosecurity measures (such as directions for movement, treatment, export, and destruction) that have been required to be taken in relation to the goods, have not been taken (including because it was not possible for the biosecurity measures to be taken in relation to the goods).

2.16.2 Requirements for reporting reportable biosecurity incidents

Information that must be included in a report

The following information must be included in a report of a reportable biosecurity incident:

- details of the goods
- the location of the goods
- a description of the incident
- if known, when and where the incident occurred
- when the person making the report became aware of the incident
- whether the goods have been moved since the incident occurred
- the name and contact details of the person making the report; and any other person who may have information about the incident
- details of any steps taken to manage the incident.

How a report must be made
A report of a reportable biosecurity incident must be made orally or in writing. If:

- a report is made orally, and
- the Director of Biosecurity, or a biosecurity officer, asks the person who made the report to also provide the report in writing within a specified period, the report must also be made in writing within the period specified in the request.

2.17 Document review

Part 2 of this document is subject to regular review to ensure it continues to be relevant and effective.

The department reserves the right to assess and review the ongoing validity of Part 2 of this document at any time to ensure that the requirements continue to align with legislation, government policy and the relevant operating environment in meeting both departmental and industry needs.

2.18 Additional reference material

The following reference material contains information that relates to the application of Part 2 of this document, and is available on the department's website:

- glossary
- class requirements.

3 Part 3

3.1 Scope – Class 43.1 disinsection activities

3.1.1 In Scope

Part 3 applies to approved arrangements for disinsection activities (class 43.1) approved under Chapter 7 of the Biosecurity Act.

3.1.2 Out of Scope

Part 3 does not apply to:

- the approved arrangement approval process
- prosecutions for offences against the Biosecurity Act
- determination of the fit and proper person status of applicants for an approved arrangement
- class 1 to class 14 – specified biosecurity activities (see Part 1)
- class 19.1 – non-commodity for containerised cargo clearance (see Part 2)
- class 19.2 – automatic entry processing for commodities (see Part 2).

3.2 Contacting the department

Any queries regarding application of Part 3 of this document, or its content should be directed to the contacts provided in Table 14. If a biosecurity industry participant requests to make a change to their approved arrangement, such as:

- updates to contact persons or contact details
- addition of new site contacts
- applications for variation, suspension, or revocation

  the request must be made by the approved arrangement:

  - manager, or
  - site contact person.

Notices from the department to the biosecurity industry participant will be directed to the approved arrangement manager, with additional courtesy copies sent to the nominated approved arrangement site contact.

Queries concerning approved arrangements conditions and policy should be directed to the relevant area, as indicated below. If your query or request is in regard to:

- activities involving the physical handling of goods, conducted at approved arrangement sites, please contact Audit Operations.
- disinsection activities, please contact Approved Arrangements if it is relation to your agreement, or Conveyance Policy Section for any operational enquiries.

Table 14 Contact details for approved arrangements enquiries

Type of enquiry	Area to contact	Phone	Email	Postal address	Hours of operation
Disinsection class operational enquiries	Conveyances Policy Section	+61 2 6272 5772	arrivals@aff.gov.au	Conveyances Policy Section Department of Agriculture, Fisheries and Forestry GPO Box 858 Canberra ACT 2601	8.30am – 4.30pm (Australian Eastern Standard Time)
Approved arrangement	Approved Arrangements Program	1800 900 090	aa.canberra@aff.gov.au	Approved Arrangements Program Department of Agriculture, Fisheries and Forestry GPO Box 858 Canberra ACT 2601	8.30am – 4.30pm (Australian Eastern Standard Time)

3.3 Definitions

Definitions can be found within the *Approved Arrangements Glossary*, on the department's website, or in the Biosecurity Act. For words not defined in the glossary or an Act, definitions can be found in the most recent edition of the Macquarie Dictionary.

3.4 Approach to compliance and regulation

Our approach to compliance management involves recognising regulated client behaviours and adjusting our compliance posture accordingly. The department applies a range of regulatory tools to manage compliance, from routine inspections and audits through to criminal prosecution. Further information can be found on the *Compliance Policy* webpage.

Table 15 Principles of the department's compliance management approach for approved arrangements

Principle	The department…
Risk based	believes that if biosecurity industry participants demonstrate a high level of compliance with departmental requirements, they should expect to see reduced regulatory intervention. This allows the department to focus its resources on areas that pose greater biosecurity risks.
Consistency	seeks to provide biosecurity industry participants with certainty about its actions by assessing, reporting, managing and administering fairly across comparable situations.
Proportionality	believes any administrative action should be in proportion to the level of potential biosecurity risk and the seriousness of the breach.
Transparency	will deal with biosecurity industry participants in an open and transparent manner so that they will have a clear understanding of what is expected of them and what they can expect of the department.
Timeliness	will strive for the resolution of noncompliance matters in a timely and appropriate manner.
Flexibility	will respond to changing situations, trends and technologies and review how it determines compliance.
Effectiveness	will apply appropriate responses to achieve the most suitable outcomes.
Review	will, upon request, review decisions which are defined as reviewable decisions under Section 574 of the Biosecurity Act.

Table 15 lists the principles of the department's compliance management approach for approved arrangements.

The department's approach to compliance management of approved arrangements is based on these principles.

By applying these principles, the department aims to ensure that biosecurity risk is managed, especially in addressing noncompliance, to prevent and deter noncompliant behaviour and to encourage greater compliance with departmental requirements.

3.5 Scope of an approved arrangement

An approved arrangement can cover biosecurity activities that do not involve the physical handling of goods, such as performing disinsection treatments on aircraft.

Multiple classes of activities, in multiple locations, can be grouped under one or more approved arrangements as desired.

3.6 Fit and proper person assessment

The Biosecurity Act requires that the department consider the fit and proper person status of an approved arrangement applicant prior to approval. Additionally, the fit and proper person status of a biosecurity industry participant is a relevant consideration in decisions to vary, suspend or revoke an approved arrangement. Consideration of whether the applicant or biosecurity industry participant is fit and proper to hold an approved arrangement is important because such a person might be involved in the importation of high-risk goods or be approved to undertake activities to manage their own biosecurity risk with oversight by the department. The fit and proper person assessment includes consideration of associates of the applicant or biosecurity industry participant that are relevant to the operation of the approved arrangement.

An approved arrangement grants a concession and responsibility on persons that allows for them to do certain things the general public are not allowed to do. It is important that such persons are considered fit and proper to be able to conduct these activities and there is confidence that the person will operate within the scope of their approval and comply with conditions and requirements.

If the Director of Biosecurity determines that a person is not a fit and proper person, the Director may refuse to approve a proposed arrangement; or vary, suspend or revoke an approved arrangement. The regulations may prescribe other situations where the fit and proper person test may be applied.

Further information about the fit and proper person test can be found on the fit and proper test for approved arrangement applicants webpage.

3.6.1 Notifying change of fit and proper person-relevant circumstances

A biosecurity industry participant covered by an approved arrangement must notify the department in writing as soon as practicable and within 15 days of becoming aware of any change of circumstance (not previously notified to the department) which may alter their fit and proper person status of the biosecurity industry participant or their associates.

3.7 Fees and charges

The department applies fees and charges to recover the cost of the administration of approved arrangements. The charges associated with the operation of an approved arrangement include:

- an application charge
- an annual charge
- ongoing fees for service.

The prescribed fees and charges are detailed in the departmental *Charging Guidelines*.

Applicants for a new approved arrangement will be charged an application charge. This charge will not be applied where the entity making the application already holds a current approved arrangement under the Biosecurity Act. Assessment of the application will incur a prescribed fee-for-service charge which is time-based. Assessment may include both in-office and out-of-office activities, which are charged at different rates.

Each entity operating an approved arrangement will be charged an annual charge. The charge is applied once only, regardless of the number of approved arrangements that an entity holds.

Audit activities (both in-office and out-of-office) will be charged at the prescribed fee-for-service rate. Alternatively, a daily rate may be charged for audit activities, if the daily rate will be a lesser charge. Audit activities include, but are not limited to:

- pre-audit activities – undertaking preparation for the audit, organising the audit appointment, providing formal notification of the audit etc.
- issuing corrective action requests, monitoring rectification of identified noncompliance, or providing any other direction necessary to manage biosecurity risks
- post-audit activities – writing the audit report, assessing evidence for in-office corrective action requests management, updating records and databases etc.
- management of noncompliance.

The administration of changes to an approved arrangement, such as variation, suspension or revocation, may be charged at the prescribed fee for service rate.

3.8 Monitoring and assessing compliance

The compliance monitoring strategy is risk based. This means that the department will focus its attention towards areas where there is an identified biosecurity risk or high probability of a biosecurity risk.

Noncompliance with departmental requirements poses a biosecurity risk. Therefore, biosecurity industry participants can expect less regulatory intervention when they are compliant and more regulatory intervention when noncompliance has been identified.

Under the Biosecurity Act, the department holds the power to monitor and audit the biosecurity industry participant against the requirements of their approved arrangement with or without prior notice.

For approved arrangements covering disinsection activities (class 43.1), monitoring activities may include the conduct of verification and efficacy testing of the disinsection treatment. Noncompliance

identified during monitoring activity may serve as a trigger for an audit. Information gathered during monitoring activity may form part of the audit.

3.8.1 Access for auditors, inspectors etc.

A biosecurity industry participant covered by an approved arrangement must provide access for biosecurity officers, biosecurity enforcement officers, and any department-approved auditor, to perform the functions and exercise the powers conferred to them by the Biosecurity Act or another law of the Commonwealth.

The biosecurity industry participant must provide a departmental auditor, or department-approved auditor, with amenities and assistance as requested, and provide any required documents, records or things relevant to the audit.

3.8.2 Jurisdiction and enforcement

Whilst this policy deals primarily with arrangements under Chapter 7 of the Biosecurity Act, the department's portfolio legislation is broad. Therefore, where a suspected breach of legislation has been detected that falls outside of Chapter 7 of the Biosecurity Act, further departmental assessment and action may occur. Further monitoring, investigation and enforcement powers may be exercised under the *Regulatory Powers (Standard Provisions) Act 2014*.

The department may consider the suspension, revocation, or refusal of approval of an arrangement, as a result of the outcome of the departmental investigation. If serious noncompliant behaviour by a biosecurity industry participant comes to the attention of the department, further departmental assessment and action may occur, including civil or criminal prosecution.

3.8.3 Administrative review (show cause) process

If serious noncompliant behaviour by a biosecurity industry participant comes to the attention of the department through audit or any other way, the department may by written notice, request the biosecurity industry participant to show cause as to why their arrangement should not be suspended or revoked. The department will provide a notice which specifies the grounds upon which the department is considering suspension or revocation of the arrangement. The biosecurity industry participant will be requested to provide information and evidence to support their case, including any measures implemented to prevent a recurrence of the noncompliance.

The department may seek further information or advice before making a decision regarding the approved arrangement.

Whilst the biosecurity industry participant is subject to a show cause process, audits may be conducted, and the department may conduct other compliance monitoring activities to assess the biosecurity industry participant's ongoing compliance with departmental requirements.

Following consideration of the information provided by the biosecurity industry participant, the department will provide a written notice of its decision to either:

- take no action and continue the approval
- suspend the arrangement, in part or in whole, for a specified period
- vary the arrangement

- revoke the arrangement.

3.9 Disinsection monitoring and assessing compliance

Biosecurity officers may conduct audits. Audits may be conducted at, but not limited to, the biosecurity industry participant's sites, aircraft, or at the site of a third party. Audits are charged at the prescribed fee-for-service rate in accordance with the departmental *Charging Guidelines*.

If noncompliance is detected, additional charges may be incurred for any management action required. This includes, but is not limited to, issuing corrective action requests, monitoring rectification of noncompliance, or providing any other direction necessary to manage biosecurity risks.

If serious noncompliant behaviour by a biosecurity industry participant, and/or associates, comes to the attention of the department, further departmental assessment and action may occur, including civil or criminal prosecution.

Audits may be announced or unannounced. Biosecurity officers may audit relevant records, observe the process occurring and conduct verification and efficacy testing of the disinsection treatment.

3.9.1 Noncompliance classification

Noncompliance detected under this approved arrangement are classified into three levels.

Table 16 Classification of noncompliance for disinsection

Type	Description
Critical	• A deviation (or multiple deviations) from departmental requirements that will almost certainly compromise the effectiveness and/or integrity of this approved arrangement in such a way that immediate corrective action/regulatory investigation is required by the department.
Major	• A deviation (or multiple deviations) from departmental requirements that may compromise the overall effectiveness and/or integrity of this approved arrangement.
Minor	• A deviation from departmental requirements which does not, by itself, compromise the overall effectiveness and/or integrity of this approved arrangement.

Table 16 provides the classification of noncompliance for disinsection.

3.9.2 Audit results

Following each audit, the audit findings are documented and provided to the biosecurity industry participant as a written audit report. The audit report includes the audit result (pass or fail), details of evidence and associated findings of compliance and/or noncompliance. The audit result will be determined by the number and classification of each noncompliance detected during the audit.

On completion of an audit the biosecurity officer will assess the result, as pass or fail, on the basis of the number and classification of each noncompliance detected during the audit as outlined in the audit result matrix.

Table 17 below, details the audit result matrix.

Table 17 Audit result matrix for disinsection

		Major noncompliance				Critical noncompliance
		0	**1**	**2**	**3 or more**	**1**
Minor noncompliance	**0**	Pass	Pass	Fail	Immediate suspension of AA	
	1	Pass	Pass	Fail		
	2	Pass	Pass	Fail		
	3	Pass	Fail	Fail		
	4 or more	Fail	Fail	Fail		

Table 17 provides the audit result matrix for disinsection.

3.9.3 Critical noncompliance

Critical noncompliance may be detected in a number of ways including, but not limited to:

- audit
- surveillance
- referral by a third party
- self-reported.

Self-reported critical noncompliance will be managed by the department on a case-by-case basis. Regardless of the method of detection, the department will provide written notification of any confirmed critical noncompliance to the biosecurity industry participant. A critical noncompliance may result in either a:

- critical corrective action requests; or
- show cause process; and
- probation audit rate.

3.9.4 Addressing noncompliance

Approved arrangements are subject to a range of requirements in accordance with Chapter 7 of the Biosecurity Act. The biosecurity industry participant is required to comply with the requirements at all times. When the biosecurity industry participant fails to meet the requirements for approval, they are deemed to be noncompliant, and this noncompliance must be rectified. Failure to address noncompliance, or a history of poor compliance may result in suspension or revocation of the approved arrangement.

3.9.5 Detection of noncompliance

Noncompliance can be detected in a number of ways and is not limited to only audit and surveillance activities.

3.9.6 Notification of noncompliance

Regardless of the method of detection, the department will notify the biosecurity industry participant of any noncompliance.

Where any noncompliance is detected at audit, they will be brought to the attention of the biosecurity industry participant at the audit exit meeting. A corrective action request will be issued if the noncompliance is rated as a minor, major, or critical. The audit report will contain details of the noncompliance found. A copy of the audit report will be provided at or after the completion of the audit.

Where a potential, but unconfirmed, critical noncompliance is detected at an audit the biosecurity industry participant will be verbally notified at the audit exit meeting. Details will also be provided in the audit report provided after the audit.

3.9.7 Noncompliance rectification

Corrective action requests will specify a date by which the noncompliance must be rectified. Depending on the classification of noncompliance detected, the rectification timeframe will vary. Once the corrective action requests have been rectified, the biosecurity industry participant is to contact the department to report the rectification and organise for the corrective action requests to be finalised.

Where a departmental officer needs to visit the biosecurity industry participant or witness performance of a specific activity at another location to determine if the noncompliance has been satisfactorily rectified, the visit will be charged at the prescribed fee-for-service rate. Where the corrective action requests can be assessed by providing other evidence to the department (such as photographs) this assessment will also be charged at a fee-for-service rate.

For potential noncompliance, the department, in conjunction with the biosecurity industry participant, will first attempt to contain and manage any immediate biosecurity risk posed by the noncompliance.

Rectification measures may vary and will be determined on a case-by-case basis.

If the noncompliance in the corrective action request has not been rectified by the deadline for rectification, a new corrective action request will be issued. If three successive corrective action requests are issued for the same noncompliance, and the noncompliance has not been rectified, the biosecurity industry participant may be requested to show cause as to why their approved arrangement should not be suspended or revoked.

3.9.8 Suspension

Suspension of the approved arrangement may occur where either:

- three or more major noncompliance are detected at an audit
- one or more critical noncompliance is detected at an audit.

3.9.9 Revocation of suspension

When an approved arrangement is suspended, the biosecurity industry participant must undergo a pre-approval audit (prior to revocation of suspension) in order to establish compliance. If the biosecurity industry participant passes a pre-approval audit, the approved arrangement will be reinstated. On re-instatement, the biosecurity industry participant will be subject to the probationary audit rate.

If the biosecurity industry participant fails a pre-approval audit the approved arrangement will remain suspended. The biosecurity industry participant will show cause, in writing, as to why its approved arrangement should not be revoked. The biosecurity industry participant must include evidence or details of the methods to be used to prevent a recurrence of noncompliance, as well as any other relevant information. The department may seek further information before making a decision whether to re-instate, continue to suspend or to cancel the approved arrangement.

3.9.10 Cancellation

If the approved arrangement is suspended three or more times, the approved arrangement will be cancelled and the biosecurity industry participant will be required to undertake an alternative approved disinsection process in accordance with the *Schedule of Aircraft Disinsection Procedures for Flights into Australia and New Zealand*.

3.9.11 Surveillance

The department may conduct surveillance visits at the biosecurity industry participant's premises or at any approved arrangement site where they may be performing an activity related to their approved arrangement.

3.10 Noncompliance detected outside of an audit

Where noncompliance is detected outside of an audit, the outcome may result in an increased audit rate or show cause process. Noncompliance detected outside of an audit will be recorded as a non-audit event and do not count towards the next audit result.

Noncompliance detected outside of an audit may be identified in a number of ways including:

- departmental officer visits an approved arrangement site to close out a previously identified noncompliance and, while there, notices further noncompliance.
- advice from a biosecurity officer performing inspections at an approved arrangement site.
- biosecurity industry participant self-reports noncompliance.
- referral by a third party.

If the department identifies noncompliance, a notice to rectify the noncompliance may be issued in the form of a corrective action request. The process for managing noncompliance remains the same as detailed in the noncompliance rectification section.

The audit result matrix for disinsection (Table 17) will be used to determine if the count and severity of instances of identified noncompliance constitutes an audit pass or audit fail outcome.

Where the outcome is determined to be a:

- pass – no additional action is required
- fail – the approved arrangement site audit rate will change to the probationary audit rate.

The date of commencement of the probationary audit rate is the date the fail outcome is determined.

3.11 Reviewable decisions

Certain decisions the department may make under the Biosecurity Act are reviewable decisions. If you are dissatisfied with a reviewable decision you may apply for review of that decision.

Each of the decisions which may be subject to review are set out under section 574 of the Biosecurity Act; see Table 18 which lists the reviewable decisions that are associated with the administration of approved arrangements.

When a reviewable decision has been made, the decision-maker will give written notice of the decision and the reason for that decision to the relevant person. Once the written reasons have been received, the relevant person may apply to the department for a review of that decision. The relevant person for each reviewable decision is indicated in Table 18. Information regarding the process for applying for a review will be provided in the notice of decision.

Table 18 Reviewable decisions under the Biosecurity Act

Reviewable decision to…	Provision under which the reviewable decision is made	Relevant person for the reviewable decision, the…
refuse to approve a proposed arrangement	Subsection 406(1)	person who applied for the approval
refuse to approve a varied arrangement	Subsection 406(1) (as it applies because of subsection 412(3))	person who applied for the approval
approve a proposed arrangement subject to conditions	Subsection 406(3)	person who applied for the approval
vary the conditions of an approved arrangement	Subsection 413(1)(a)	biosecurity industry participant that is covered by the approved arrangement
require a biosecurity industry participant to vary an approved arrangement	Subsection 413(1)(b)	biosecurity industry participant that is covered by the approved arrangement
refuse to suspend a part of an approved arrangement	Subsection 417(4)	biosecurity industry participant that is covered by the approved arrangement
suspend an approved arrangement or a part of an approved arrangement	Subsection 418(1)	biosecurity industry participant that is covered by the approved arrangement
extend the period during which an approved arrangement or a part of an approved arrangement is suspended	Subsection 420(3)	biosecurity industry participant that is covered by the approved arrangement
revoke an approved arrangement	Subsection 423(1)	biosecurity industry participant that is covered by the approved arrangement

Table 18 shows the decisions that are reviewable under the Biosecurity Act.

The general procedure to seek review of a decision is:

- the relevant person must lodge an application for review within 30 days after the day that the reviewable decision first came to the notice of the applicant—although the Director of Biosecurity may extend the 30-day period
- the application must be in writing and set out the reasons for the application

- when the application is received the Director of Biosecurity must either review the decision personally or ensure that it is reviewed by an internal reviewer who was not involved in making the decision
- the Director of Biosecurity or the internal reviewer may affirm, vary or set aside the reviewable decision
- if the reviewable decision is set aside the Director of Biosecurity or the internal reviewer may substitute another appropriate decision
- the decision on review takes effect on a day specified in the notice of decision, or if not specified, on the day the decision on review was made
- the person who made the decision must give the applicant written notice of the review decision
- a person who has received notice of the outcome of an internal review of a reviewable decision may make an application for further review by the Administrative Appeals Tribunal.

3.11.1 Exception

The only exception to the general procedure is where the decision maker was the Director of Biosecurity or the Director of Human Biosecurity. In that case the person may make an application for review directly to the Administrative Appeals Tribunal.

3.12 Suspension

An approved arrangement may be suspended subject to the conditions detailed in Chapter 7, Part 4 of the Biosecurity Act.

The administration of suspension of an approved arrangement may be charged at the prescribed fee-for-service rate in accordance with the departmental *Charging Guidelines*.

3.12.1 Suspension requested by a biosecurity industry participant

A biosecurity industry participant may request that the department suspend their approved arrangement, or part of an approved arrangement (for example when undertaking major building works, refurbishment, repair, or temporary closure).

A biosecurity industry participant can request the department to suspend their approved arrangement, in whole or part. The period of suspension cannot extend beyond the period of approval.

The request for suspension must:

- be in writing
- specify whether a whole or part suspension is requested
- specify a proposed start time, which must be no fewer than 15 working days from the day the department receives the request
- specify the duration of the proposed suspension (for example, by specifying an end date)
- for part suspension, detail the biosecurity activities that the biosecurity industry participant will not be authorised to carry out during the suspension period

- for part suspension, explain how biosecurity risks associated with goods, premises or other things that the biosecurity industry participant is authorised to deal with will be managed during the suspension period.

Where a request is made to suspend part of an approved arrangement the department will provide a written notice of decision within 30 days of when the request is received. Further information is available on the department's website.

3.12.2 Suspension imposed by the department

The department may impose a suspension of an approved arrangement, or part of an approved arrangement, for reasons including, but not limited to:

- noncompliance with conditions of the arrangement
- noncompliance with requirements upon which approval of the arrangement was based
- the biosecurity industry participant no longer being a fit and proper person to hold an approved arrangement, as per section 530 of the Biosecurity Act
- a change to the level of biosecurity risk
- the biosecurity industry participant being liable for a cost-recovery charge which is overdue.

Typically, a written notice of intention to suspend will be provided prior to suspension, specifying the grounds for the suspension, and requesting the biosecurity industry participant to show cause as to why the approved arrangement should not be suspended. If the grounds for suspension are considered serious and urgent, the suspension may be immediate with no opportunity to show cause as to why the approved arrangement should not be suspended prior to the arrangement being suspended. A decision to suspend an approved arrangement is a reviewable decision.

If a decision is made to suspend an approved arrangement, or part of an approved arrangement, the biosecurity industry participant will be provided a notice specifying the period of suspension.

3.12.3 Audit requirements during suspension

Where the whole of an approved arrangement is suspended, regular audits will not be undertaken during the period of suspension. Note: The annual charge for approved arrangements will continue to be applied.

Where an approved arrangement is part suspended (for example where the approved arrangement includes multiple classes of activities but only one class is suspended) compliance monitoring is required for the activities not suspended. The audit rate will remain at the same rate as it was prior to suspension unless the suspension is due to noncompliance.

3.12.4 Varying the suspension period

The department may extend or shorten the period of suspension when, for example:

- the biosecurity industry participant is not fully compliant with their approved arrangement when the suspension period is due to end
- an audit required to assess compliance is not completed before the end of the suspension period

- the biosecurity industry participant requests a change to the period of suspension.

3.12.5 Revoking a suspension

The department may revoke a suspension of an approved arrangement (or partly suspended approved arrangement) prior to the end of the suspension period, by written notice to the biosecurity industry participant.

If a biosecurity industry participant wishes to end their period of suspension prior to the end period specified in their notice of suspension, they should submit a written request to the relevant contact area. Further information is available on the department's website.

3.12.6 Compliance level at ending of suspension

The approved arrangement must be in full compliance at the end of the suspension period, regardless of whether it is partly or wholly suspended, and regardless of whether the suspension was voluntary or imposed by the department. If necessary, the suspension will be extended until the arrangement is fully compliant.

3.12.7 Ending a voluntary suspension

Where the approved arrangement was voluntarily suspended by the biosecurity industry participant, an audit may be required to be carried out depending upon the reason for and duration of the suspension. For example, if the arrangement was suspended in order to carry out refurbishment of facilities or equipment an audit is likely to be required, or other evidence of compliance sought. In contrast, if the arrangement was voluntarily suspended due to unavailability of accredited staff, evidence of their return may be sufficient. The length of the period of suspension is also a consideration. The decision as to whether an audit is required, and the scope of the audit, will be at the discretion of the department. Where an audit is not required, other evidence demonstrating compliance may need to be provided prior to the end of the suspension period.

Following the ending of a voluntary period of suspension, if an audit is not required before the end of the suspension period, the audit rate resumes at the rate which was in place prior to the suspension, regardless of whether the arrangement was partially or wholly suspended.

If an audit is required prior to the end of the suspension period, any identified noncompliance will need to be addressed prior to the ending of the suspension period (which may necessitate extension of the suspension). Where the audit outcome is determined to be a ‘fail’ as per Table 17, a second audit is required. Where the outcome for the second audit is determined to be a ‘fail’ as per Table 17, the biosecurity industry participant may be asked to show cause as to why their arrangement should not be further suspended or revoked. Where the outcome for the first or second audit is determined to be a ‘pass’ and noncompliance has been identified as per Table 17, the noncompliance will need to be rectified prior to the end of the suspension period (which may need to be extended). Where the noncompliance has not been rectified prior to the end of the suspension period, the biosecurity industry participant may be asked to show cause as to why their arrangement should not be further suspended or revoked.

A flowchart of the ending of suspension process is shown in Figure 8.

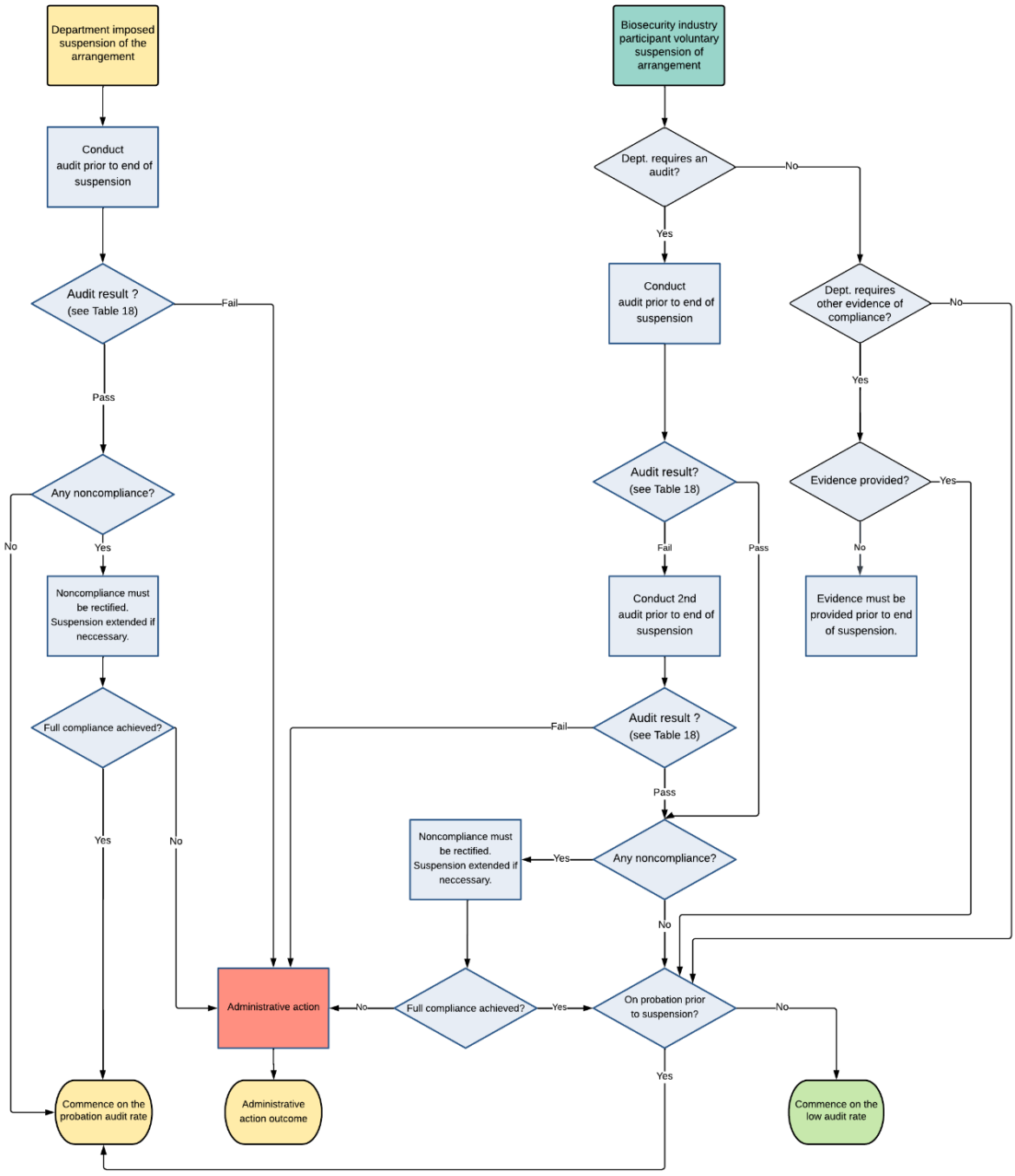
3.12.8 Ending of a department-imposed suspension

Where the approved arrangement was suspended by the department due to noncompliance, an audit will be carried out prior to the end of the suspension period to ensure compliance with conditions and requirements. Regardless of whether the arrangement was partially suspended or wholly suspended the audit scope will include all biosecurity activities covered by the arrangement. If the audit identifies noncompliance it will need to be rectified prior to the end of the suspension period (which may necessitate extension of the suspension).

If the audit outcome is determined to be a 'fail' as per Table 17, the biosecurity industry participant may be asked to show cause as to why their arrangement should not be further suspended or revoked. Where the audit outcome is determined to be a 'pass' and noncompliance has been identified as per Table 17, the noncompliance will need to be rectified prior to the end of the suspension period (which may need to be extended) and the arrangement will then resume on the probation audit rate. Where the noncompliance has not been rectified prior to the end of the suspension period, the biosecurity industry participant may be asked to show cause as to why their arrangement should not be further suspended or revoked.

Following any period of department-imposed suspension (part or whole), the arrangement will be placed on the probationary audit rate. The biosecurity industry participant must pass two consecutive probation audits to progress to the low audit rate.

Figure 8 Process for ending a period of suspension



3.13 Variation of an existing approved arrangement

An approved arrangement may be varied subject to the conditions detailed in Chapter 7, Part 3, of the Biosecurity Act. Administration of the variation of an approved arrangement may be charged at the prescribed fee-for-service rate in accordance with the departmental *Charging Guidelines*.

3.13.1 Variation requested by a biosecurity industry participant

Variations to approved arrangements are required where the conditions of an approved arrangement need to be changed. These changes may be of an administrative or operational nature. Usually, variations to approved arrangements are sought by a biosecurity industry participant but in some circumstances the department can impose variations. Some examples of where a variation is necessary include where a biosecurity industry participant wishes to vary the conditions of approval of an arrangement, including:

- propose an alternative means to meet departmental requirements
- seek exemption from certain approved arrangement requirements
- reduce the scope of activities covered by their approved arrangement.

The assessment of proposed variations to approved arrangement requirements entails consideration of:

- the effectiveness of the proposed variation in meeting the required biosecurity risk management outcome
- whether the proposed variation is capable of being effectively monitored for compliance by the department.

If a biosecurity industry participant wishes to vary their approved arrangement, they may apply by submitting a written application to the department. Further information is available on the department's website.

The applicant will be provided with a written notice of the outcome of their application. The variation must not be implemented until the department provides a written notice of decision to approve a varied arrangement.

Where the department decides there is an increase in biosecurity risk as a result of a variation the audit rate may change to the probation audit rate.

Depending on the complexity of the proposed variation, consideration of the application may take up to 90 days, and up to 120 days if the application requires scientific or technical advice to be sought.

The department may ask the biosecurity industry participant to provide further information to enable consideration of the application. If the department asks for further information the consideration time will be extended by the amount of time it takes for the biosecurity industry participant to provide the requested information. The department will specify the time period for providing further information.

3.13.2 Variation imposed by the department

The department may, by written notice, impose a variation to an approved arrangement or vary the conditions of an approved arrangement. This action may be taken if:

- the approved arrangement no longer meets the requirements on the basis of which approval was given; or
- the biosecurity industry participant is no longer a fit and proper person; or
- a condition of the approved arrangement has been contravened; or
- the level of biosecurity risk associated with the operation of the approved arrangement has changed; or
- a change needs to be made to the approved arrangement to correct a minor or technical error in the arrangement; or
- the arrangement needs to be varied for any other reason.

A variation notice will be provided specifying the varied conditions and date of effect. Alternatively, the department may require the biosecurity industry participant to vary the arrangement. If the department requires the biosecurity industry participant to vary the arrangement, a notice will be provided which specifies the variation required and specifies the date by which the biosecurity industry participant must provide the varied arrangement to the department.

3.14 Revocation of an approved arrangement

An approved arrangement may be revoked subject to the conditions detailed in Chapter 7, Part 5, of the Biosecurity Act.

The administration of revocation of an approved arrangement may be charged at the prescribed fee-for-service rate in accordance with the departmental *Charging Guidelines*.

An audit may be conducted to ensure there are no goods subject to biosecurity control remaining at the site.

3.14.1 Revocation requested by a biosecurity industry participant

If a biosecurity industry participant wishes to have their approved arrangement revoked (cancelled), they may apply to the department.

An application for revocation must be made in writing and specify the proposed date of effect, which must not be less than 15 business days from the date the application is received. Further information is available on the department's website.

The department will provide a notice of revocation specifying the date of effect.

3.14.2 Revocation by the department

The department may, by written notice, revoke an approved arrangement. This action may be taken if:

- the approved arrangement no longer meets the requirements on the basis of which approval was given; or

- the biosecurity industry participant is no longer a fit and proper person; or
- a condition of the approved arrangement has been contravened; or
- the level of biosecurity risk associated with the operation of the approved arrangement has changed; or
- the biosecurity industry participant is liable to pay a cost-recovery charge that is overdue, or
- the biosecurity industry participant is an associate of a:
  - person who has been refused approval of a proposed arrangement, or
  - biosecurity industry participant covered by an approved arrangement that has been revoked.

A written notice will be provided prior to revocation, specifying the grounds for the revocation, and requesting the biosecurity industry participant to show cause as to why the approved arrangement should not be revoked. If the grounds for revocation are considered serious and urgent, revocation may be applied without requesting the biosecurity industry participant to show cause as to why the approved arrangement should not be revoked.

If a decision is made to revoke an approved arrangement, or part of an approved arrangement, the biosecurity industry participant will be provided a notice stating that the approved arrangement has been revoked.

3.15 Transfer of an approved arrangement

An approved arrangement cannot generally be transferred to another person. An approved arrangement may only be transferred to another person if the biosecurity industry participant covered by the approved arrangement:

- dies, the approved arrangement may be transferred to the legal personal representative of the biosecurity industry participant
- is a body corporate in relation to which a receiver has been appointed, the approved arrangement may be transferred to the receiver
- is a body corporate of which an administrator has been appointed under section 436A, 436B or 436C of the *Corporations Act 2001*, the approved arrangement may be transferred to the administrator.

Further information in regard to the transfer of approved arrangements should be directed to the relevant contact area – see contacting the department.

3.16 Reportable biosecurity incidents

Certain incidents pose significant biosecurity risk if they occur. A biosecurity incident can be an act, omission or event. The reporting of biosecurity incidents will allow for biosecurity officers to efficiently manage biosecurity risks associated with an incident.

It is important that biosecurity incidents are reported as soon as practicable, to ensure that any biosecurity risks associated with the incident can be managed to an acceptable level and to limit the risk associated with any pest or disease entering, establishing or spreading into Australian territory.

More information regarding biosecurity incidents is available on the department's website.

3.16.1 Events that are reportable biosecurity incidents in relation to relevant goods

Events relating to prohibited goods, conditionally non prohibited goods or suspended goods

Each of the following events is a reportable biosecurity incident in relation to relevant goods that are prohibited goods, conditionally non prohibited goods or suspended goods. The goods:

- are in a container, a conveyance or other premises and are not as described on a manifest or an import permit relating to the goods
- are in a container, a conveyance or other premises that is damaged and the goods are no longer secure
- have been lost or stolen
- have been destroyed in circumstances other than in compliance with a direction given by a biosecurity officer.

Events relating to conditionally non prohibited goods

A change to the intended use of relevant goods that are conditionally non prohibited goods is a reportable biosecurity incident in relation to the goods.

Events relating to goods generally

Each of the following events is a reportable biosecurity incident in relation to any relevant goods:

- the goods or any container holding the goods, or the conveyance or other premises in which the goods are being held, have been, or are likely to have been, exposed to contamination, infestation or infection from prohibited goods, conditionally non prohibited goods or suspended goods
- the goods are infested with a live pest (for example, an insect, invertebrate or other animal)
- biosecurity measures (such as directions for movement, treatment, export, and destruction) that have been required to be taken in relation to the goods, have not been taken (including because it was not possible for the biosecurity measures to be taken in relation to the goods).

3.16.2 Requirements for reporting reportable biosecurity incidents

Information that must be included in a report

The following information must be included in a report of a reportable biosecurity incident:

- details of the goods
- the location of the goods
- a description of the incident
- if known, when and where the incident occurred
- when the person making the report became aware of the incident
- whether the goods have been moved since the incident occurred

- the name and contact details of the person making the report; and any other person who may have information about the incident
- details of any steps taken to manage the incident.

How a report must be made
A report of a reportable biosecurity incident must be made orally or in writing. If:

- a report is made orally, and
- the Director of Biosecurity, or a biosecurity officer, asks the person who made the report to also provide the report in writing within a specified period, the report must also be made in writing within the period specified in the request.

3.17 Document review

Part 3 of this document is subject to regular review to ensure it continues to be relevant and effective.

The department reserves the right to assess and review the ongoing validity of Part 3 of this document at any time to ensure that the requirements continue to align with legislation, government policy and the relevant operating environment in meeting both departmental and industry needs.

3.18 Additional reference material

The following reference material contains information that relates to the application of Part 3 of this document, and is available on the department's website:

- glossary
- class requirements.