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Version history

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

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<th>Approved by</th>
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<td>Jan 2010</td>
<td>1.0</td>
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<td>• corrective action requests issued outside audit</td>
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<td>• Accreditation requirements.</td>
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<td>May 2018</td>
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<td>• Updated appendix 2: Brokers – monitoring and assessing compliance.</td>
<td>Approved arrangements section</td>
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<td>• Added accreditation for broker approved arrangement.</td>
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<tr>
<td>October 2018</td>
<td>7.1</td>
<td>Updated contact phone number for approved arrangements site enquiries.</td>
<td>Approved arrangements section</td>
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Summary

This document details how the Department of Agriculture and Water Resources will:

- assess and monitor compliance
- detect and report on noncompliance
- address noncompliance
- apply administrative sanctions
- review and renew schedules
- deal with requests and applications

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

This policy document is 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. This policy has been developed to deliver effective risk-based compliance outcomes.

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 functions 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.

Contacting the department

Any queries regarding application of the General Policies or its content should be directed to the contacts shown below. 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.

Queries concerning approved arrangements requirements 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 Services.
- broker class activities, please contact the Broker Administration Team
- disinsection activities, please contact the Approved Arrangements section if it is relation to your agreement, or Travellers and Vessels for any operational inquiries.

If your query relates to both physical class (approved arrangement site) and broker class activities, or you are not sure, please contact Approved Arrangements.
Contact details for approved arrangement enquiries can be found below:

**Approved arrangement site enquiries**

Approved Arrangements  
Phone: +61 2 6272 2257  
**Hours of Operation:** 8.30am – 4.30pm (Australian Eastern Standard Time)  
Email: aa.canberra@agriculture.gov.au  
Postal address:
Approved Arrangements  
Department of Agriculture and Water Resources  
GPO Box 858  
Canberra ACT 2601

**Broker class enquiries**

Broker Administration  
Phone: 1800 900 090  
**Hours of Operation:** 8.30am – 4.30pm (Australian Eastern Standard Time)  
Email: broker.accreditation@agriculture.gov.au  
Postal address:
Broker Administration team  
Assessment, Policy and Projects  
Department of Agriculture and Water Resources  
GPO Box 858  
Canberra ACT 2601

**Disinsection class operational enquiries**

Conveyances and Ports Section  
Phone: +61 2 6272 4143  
**Hours of Operation:** 8.30am – 4.30pm (Australian Eastern Standard Time)  
Email: arrivals@agriculture.gov.au  
Postal address:
Travellers and Vessels  
Department of Agriculture and Water Resources  
GPO Box 858  
Canberra ACT 2601

**Disinsection class administration enquiries**

Approved Arrangements  
Phone: +61 2 6272 2257  
**Hours of Operation:** 8.30am – 4.30pm (Australian Eastern Standard Time)  
Email: aa.canberra@agriculture.gov.au  
Postal address:
Approved Arrangements  
Department of Agriculture and Water Resources  
GPO Box 858  
Canberra ACT 2601

**Scope**

**In Scope**  
This document applies to approved arrangements approved in accordance with Chapter 7 of the *Biosecurity Act 2015*, to carry out specified biosecurity activities.

**Out of Scope**  
This document does not apply to:  
- the approved arrangement approval process  
- prosecutions for offences against the *Biosecurity Act 2015*
• determination of the fit and proper person status of applicants for an approved arrangement.

Definitions
Definitions can be found within the approved arrangements glossary, on the department’s website, or in the Biosecurity Act 2015. For words not defined in the glossary or the Act, definitions can be found in the most recent edition of the Macquarie Dictionary.

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 Our approach to compliance webpage.

The department’s approach to approved arrangements is based on the following principles:

<table>
<thead>
<tr>
<th>Principle</th>
<th>The department...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk based</td>
<td>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.</td>
</tr>
<tr>
<td>Consistency</td>
<td>seek to provide biosecurity industry participants with certainty about its actions by assessing, reporting, managing and administering fairly across comparable situations.</td>
</tr>
<tr>
<td>Proportionality</td>
<td>believes any administrative action should be in proportion to the level of potential biosecurity risk and the seriousness of the breach.</td>
</tr>
<tr>
<td>Transparency</td>
<td>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.</td>
</tr>
<tr>
<td>Timeliness</td>
<td>will strive for the resolution of noncompliance matters in a timely and appropriate manner.</td>
</tr>
<tr>
<td>Flexibility</td>
<td>will respond to changing situations, trends and technologies and review how it determines compliance.</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>will apply appropriate responses to achieve the most suitable outcomes.</td>
</tr>
<tr>
<td>Review</td>
<td>will, upon request, review decisions which are defined as reviewable decisions under Section 574 of the Biosecurity Act 2015.</td>
</tr>
</tbody>
</table>

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.

Scope of an approved arrangement
An approved arrangement can cover all of the biosecurity activities involving the physical handling of goods at one or more approved arrangement sites. An approved arrangement can also cover biosecurity activities that don’t involve the physical handling of goods, such as documentary assessment for goods subject to biosecurity control by accredited persons or performing disinsection treatments on aircraft. Both physical and non-physical biosecurity activities can be grouped together under the same approved arrangement.

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

- classes involving the physical handling of goods, there cannot be more than one approved arrangement per approved arrangement site
- broker approved arrangement classes, a Branch ID can only belong to a single approved arrangement.

**Fit and proper person assessment**

The *Biosecurity Act 2015* 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.

**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.

**Fees and levies**

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

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

The prescribed levies and fees are detailed in the department’s Charging guidelines.

Applicants for a new approved arrangement will be charged an application levy. This levy will not be applied where the entity making the application already holds a current approved arrangement under the *Biosecurity Act 2015*. 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 levy. The levy 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.

**Accreditation for non-broker approved arrangements**

Class requirements include information about the type of biosecurity accreditation needed to operate as 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 (e.g. fumigation) this training must be completed along with biosecurity accreditation training.

**Online accredited person training**

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

**In-house training**

To be considered an accredited person, in-house training must be successfully completed. Records of participation must be available 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

**Reaccreditation**

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

Reaccreditation may be required as a result of:

- changes to requirements
- critical noncompliance
- failed audit.
Accreditation for broker approved arrangements

To become an accredited person for the broker class approved arrangements the applicant must satisfy the following pre-requisites:

- be a licensed customs broker or self-reporting importer
- have obtained a certificate of attainment in the unit of competency TLIX5054 – Comply with biosecurity border clearance.

Continued biosecurity competency

In order to maintain accreditation for a broker approved arrangement, accredited persons must complete the continued biosecurity competency sessions stipulated by the department in a given continued biosecurity competency period.

Information regarding broker 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.

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 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 disinsection approved arrangements, monitoring activities may include the conduct of verification and efficacy testing of the disinsection treatment. Noncompliances identified during monitoring activity may serve as a trigger for an audit. Information gathered during monitoring activity may form part of the audit.

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 2015 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.

Jurisdiction and enforcement

Whilst this policy deals primarily with arrangements under Chapter 7 of the Biosecurity Act 2015, 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 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.

**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 delegate for the Director of Biosecurity (the delegate) 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 delegate 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 delegate will provide a written notice of their 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.

**Compliance monitoring**

For policy covering the compliance monitoring of:

- classes that involve the physical handling of goods subject to biosecurity control see Appendix 1.
- broker activities see Appendix 2.
- disinsection activities see Appendix 3.

**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 nonconformity 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 exists, a notice to rectify the noncompliance be issued in the form of a corrective action requests. The process for managing noncompliance remains the same as detailed in the ‘Noncompliance rectification’ section, in Appendix 1.

The compliance matrix, in Appendix 1, will be used to determine if 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.

**Reviewable decisions**

Certain decisions the department may make under the *Biosecurity Act 2015* 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 2015*; see table 1 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 the below table. Information regarding the process for applying for a review will be provided in the notice of decision.

Decisions that are subject to review under the *Biosecurity Act 2015* are shown in the table below.

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

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 (AAT).

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 AAT.

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

The administration of suspension of an approved arrangement may be charged at the prescribed fee-for-service rate in accordance with the department’s Charging guidelines.

Suspension requested by a biosecurity industry participant
A biosecurity industry participant may request for the suspension of an approved arrangement, or part of an approved arrangement, by applying to the department.

At the time of full suspension of an approved arrangement site there must be nil goods subject to biosecurity onsite (including waste). Any outstanding corrective action requests will be cancelled. The period of suspension cannot be such that the end date exceeds the period of approval.

If a biosecurity industry participant wishes to suspend 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 suspension must:
• be in writing
• specify whether 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
• detail the biosecurity activities that the biosecurity industry participant will not be authorised to carry out during the period in which only part of the arrangement is suspended
• 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.
The department will provide a written notice of decision within 30 days of when the request is received.

**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 departmental requirements
- the biosecurity industry participant no longer being a fit and proper person to hold an approved arrangement, as per S530 of the Act
- a change to the level of biosecurity risk
- the biosecurity industry participant being liable for an outstanding cost-recovery charge which is overdue.

A written notice 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, suspension may be applied without requesting the biosecurity industry participant to show cause as to why the approved arrangement should not be suspended.

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.

**Audit requirements during suspension**

Where an approved arrangement is suspended in full, audits will not be undertaken during the period of suspension.

Where an approved arrangement is part suspended (e.g. one class of approval where the approved arrangement has multiple classes approved, or one approved arrangement site where the approved arrangement is comprised of multiple approved arrangement sites) compliance monitoring is required for the activities not suspended. The audit rate will remain at the same rate as it was prior to suspension. The audit rate may be increased to a higher rate following the ending of a suspension period.

**Revocation of suspension**

Following a period of suspension the arrangement may be reinstated subject to the approval of the department.

An audit will be conducted prior to reinstatement. The arrangement will only be reinstated where there is no noncompliance for the scope of the arrangement that was subject to suspension.

A biosecurity industry participant has two options for audits prior to the reinstatement of their activities/requirements: approved arrangement sites that have been subject to part suspension, may elect for a full scope pre-approval audit. This option may hold appeal where the approved arrangement site will shortly be due for their regular scheduled audit.

**Option 1 – partial audit**

Selection of this option will not alter the timing for the next scheduled audit (except where they fail the audit).

- Pre-approval audit (prior to revocation of suspension) scope is confined only to the suspended activities/requirements.
- Noncompliance must be rectified prior to reinstatement.
- The due date for the next full scope audit will not be altered by the timing of the part scope pre-approval audit.
Note: If any noncompliance is detected outside the audit scope it will not impede reinstatement (but will require rectification). Noncompliance detected outside the audit scope may affect the audit outcome. The audit outcome will be determined using the normal pass/fail matrix (e.g. three majors = fail).

Option 2 – full audit
Selection of this option will result in an adjustment to the timing for annual audit activities (providing the audit result is a pass).
- The audit scope includes approved biosecurity activities.
- The only noncompliance required to be rectified prior to reinstatement are those associated with the suspended activities/requirements.
- Any identified noncompliance that does not relate to the activities/requirements which were subject to suspension will not impede reinstatement, but they will have to be rectified according to the standard process for dealing with noncompliance.
- The due date for the next full scope audit will be established from the audit result (e.g. due in 12 months if the audit is a pass and the biosecurity industry participant is on the lowest rate).

Where an approved arrangement site is reinstated following any period of voluntary or imposed whole suspension, it recommences at the probationary audit rate. The biosecurity industry participant must pass two consecutive audits to progress to the low audit rate regardless of the previous audit rate.

Where reinstated after a period of part suspension, the audit rate continues at the current rate (provided the pre-approval audit result is a pass).

If the biosecurity industry participant fails two audits following reinstatement whilst at the probation audit rate, a show cause process will be initiated.

A flowchart of the reinstatement process is shown in Appendix 4.

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

**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 delegate 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.

**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.

**Revocation of an approved arrangement**

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

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

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

**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.

**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.
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](#).

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 risk incidents is available on the [department’s website](#).

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 (e.g. directions for movement, treatment, export, destruction etc.) 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).
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.

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 entities that operate biosecurity containment facilities. Co-located approved arrangement sites are able to 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 features for the goods being moved. 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.

Although co-location can be undertaken for all classes of approved arrangement sites, it is of particular relevance to biosecurity industry participants that operate multiple containment facility approved arrangement sites in close proximity, such as in a university campus. 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).

Note: Approved arrangement sites do not need to be grouped under a common approved arrangement to be co-located.

For additional information about co-location see Appendix 5 – Co-location of approved arrangement sites.

Document review
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 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.

**Additional reference material**

The following reference material contains information that relates to the application of this document, they are available on the departments website:

- glossary
- class requirements.
Appendix 1: Physical handling of goods subject to biosecurity control – monitoring and assessing compliance

An approved arrangement may cover activities at multiple approved arrangement sites. Audits and responses to noncompliance, will be applied on a per approved arrangement site basis. Audit outcomes at any one approved arrangement site has no influence on audit rates at other approved arrangement sites belonging to the same approved arrangement.

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.

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 requirements.

The following table lists different types of audits and details when they are conducted:

<table>
<thead>
<tr>
<th>Type</th>
<th>Conducted…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-approval</td>
<td>prior to:</td>
</tr>
<tr>
<td></td>
<td>• approval of a new approved arrangement, or approved arrangement site; or</td>
</tr>
<tr>
<td></td>
<td>• addition of a new approved arrangement class; or</td>
</tr>
<tr>
<td></td>
<td>• approval of a variation to an existing approved arrangement</td>
</tr>
<tr>
<td></td>
<td>• revocation of a suspension of approval (part or whole), to ascertain whether suspension can be lifted.</td>
</tr>
<tr>
<td>Probation</td>
<td>following:</td>
</tr>
<tr>
<td></td>
<td>• approval of a new approved arrangement, or approved arrangement site; or</td>
</tr>
<tr>
<td></td>
<td>• addition of a new approved arrangement class; or</td>
</tr>
<tr>
<td></td>
<td>• revocation of suspension of approval; or</td>
</tr>
<tr>
<td></td>
<td>• approval of a variation to an approved arrangement; or</td>
</tr>
<tr>
<td></td>
<td>• a failed audit or detection of a critical nonconformity.</td>
</tr>
<tr>
<td>Scheduled</td>
<td>An audit scheduled at the low audit rate to monitor ongoing compliance of an Approved Arrangement site.</td>
</tr>
</tbody>
</table>

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

The above audit types may be conducted with or without prior notification to the biosecurity industry participant as either announced or unannounced audits.

Any noncompliance detected at audits will be managed in accordance with the Approved arrangement sites - addressing noncompliance section of this document.
Noncompliance classification

The classification of noncompliance for approved arrangement sites is shown below.

<table>
<thead>
<tr>
<th>Type</th>
<th>Any 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.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>• deliberate failure to comply with a departmental direction.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>Major</td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• removal of goods subject to biosecurity control from the biosecurity area without prior written direction or approval from the department.</td>
</tr>
<tr>
<td></td>
<td>• action, inaction or contravention of departmental requirements that impedes the ability of departmental officers to effectively monitor and manage compliance with departmental requirements.</td>
</tr>
<tr>
<td></td>
<td>• action, inaction or contravention of departmental requirements that results in cross-contamination between goods subject to biosecurity control and other goods, or the environment.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Example 2: A biosecurity industry participant does not provide a safe working environment for Biosecurity Officers inspecting goods.</td>
</tr>
<tr>
<td>Minor</td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Example: A biosecurity industry participant fails to maintain records of Accredited Persons responsible for the handling of goods subject to biosecurity control.</td>
</tr>
</tbody>
</table>

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.

The audit result is determined as either a pass or a fail using the following compliance matrix.
Compliance matrix

The following table shows how an audit result is determined from the number and type of noncompliance identified.

<table>
<thead>
<tr>
<th>Minor non-conformity</th>
<th>Major non-conformity</th>
<th>Critical non-conformity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Pass</td>
<td>Pass</td>
</tr>
<tr>
<td>1</td>
<td>Pass</td>
<td>Pass</td>
</tr>
<tr>
<td>2</td>
<td>Pass</td>
<td>Fail</td>
</tr>
<tr>
<td>3</td>
<td>Pass</td>
<td>Fail</td>
</tr>
<tr>
<td>4</td>
<td>Fail</td>
<td>Fail</td>
</tr>
<tr>
<td>5</td>
<td>Fail</td>
<td>Fail</td>
</tr>
<tr>
<td>6</td>
<td>Fail</td>
<td>Fail</td>
</tr>
<tr>
<td>7 or more</td>
<td>Fail</td>
<td>Fail</td>
</tr>
</tbody>
</table>

One or more critical noncompliance will result in a failed audit (if detected at audit). Three or more major noncompliance will result in a:
- failed audit (if detected at audit), and
- probation audit rate.

Seven or more minor noncompliance will result in a:
- failed audit (if detected at audit), and
- probation audit rate.

Audit rates

The two audit rates that apply to approved arrangements are:

<table>
<thead>
<tr>
<th>Audit rate</th>
<th>Number of audits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probationary</td>
<td>Two audits within 180 days</td>
</tr>
<tr>
<td>Low</td>
<td>One audit within 365 days</td>
</tr>
</tbody>
</table>

Probationary audit rate

Applies to:
- newly-approved approved arrangement sites, or approved arrangement sites that have been reinstated following full, or partial, suspension (includes existing approved arrangement sites with a newly-approved approved arrangement class)
- approved arrangement sites that have a change in biosecurity activity or new classes approved where required
- approved arrangement sites that have failed a scheduled audit
- approved arrangement sites that have had their audit rate increased due to noncompliance detected outside of an audit and/or a critical nonconformity.

Note: Where the approved arrangement has been subject to an administrative change which has resulted in a new arrangement number (e.g. new ABN or change of entity name) the audit rate for individual approved arrangement sites will remain unchanged.

The probationary audit rate commences from the day of approval for new approved arrangement sites (or the day of re-instatement following a period of suspension).

For approved arrangement sites that have failed an audit, the probationary audit rate commences from the date of the failed audit.
For critical noncompliance, the probationary audit rate commences from the date a critical nonconformity is confirmed.

Approved arrangement sites on the probationary audit rate must consecutively pass two probation audits in order to demonstrate their ability to successfully manage biosecurity risks associated with their approved arrangement site. If the approved arrangement site fails any one of the probation audits, the six month period immediately restarts and continues until the approved arrangement site has passed two consecutive probation audits within six months.

Approved arrangement sites that have passed two consecutive probation audits automatically move to the low audit rate and do not need to wait for the full six-month period before being placed onto the low audit rate.

If the approved arrangement site fails two probation audits, the biosecurity industry participant may be requested to show cause as to why their approved arrangement site should not be suspended or revoked (or if the approved arrangement site is part of a multi-site approved arrangement, part suspension applied, or variation of the approved arrangement so as to effect revocation of the approved arrangement site).

If the delegate decides to allow the approved arrangement site to continue, the approved arrangement site will recommence at the probation audit rate and will again need to pass two consecutive audits to be placed onto the low audit rate.

See Figure 1 below for the probation and audit process for individual approved arrangement sites.

**Low audit rate**

The low audit rate recognises and rewards the biosecurity industry participant’s 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 that:

- have passed two consecutive probation audits
- continue to pass their scheduled audits at the low audit rate.

If the biosecurity industry participant fails an audit or a critical nonconformity is identified whilst at the low audit rate, the biosecurity industry participant automatically moves to the probation audit rate.

**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.
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 nonconformity to the biosecurity industry participant. A critical nonconformity may result in either a:

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

Addressing noncompliance

Approved arrangements are subject to a range of requirements in accordance with Chapter 7 of the 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


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**Figure 1: Probation and audit process for individual approved arrangement sites**

- Newly endorsed or reinstated AA
- Failed Audit
- Critical Non Conformity
- Suspended AA is reinstated

Preapproval audit is passed; AA Operator commences elevated audit rate

1. **Probation audit 1**
   - Audit passed
   - 180 days timeframe for Elevated audit rate restarts
   - Audit failed

2. **Probation audit 2 or 3**
   - Audit passed
   - Audit failed

3. **Probation audit 3 or 4**
   - Audit passed
   - Audit failed

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- Low audit rate commenced

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Show cause process

Delegate to assess suitability for continuing agreement
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.

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

**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. A corrective action requests will be issued if the noncompliance is rated as a minor, major, or critical. The audit report will contain details of identified instances of noncompliance. 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.

**Noncompliance rectification**
Corrective action requests will specify a date by which noncompliance must be rectified. Depending on the classification of noncompliance detected, the rectification timeframe will vary. Once the corrective action requests has 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’s approved arrangement site 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 compliance, the department, in conjunction with the biosecurity industry participant, will first attempt to contain and manage any immediate biosecurity risk posed by the nonconformity.

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

If the noncompliance detailed in the corrective action requests has not been rectified by the deadline for rectification, a new corrective action requests will be issued. If three successive corrective action requests are issued for the same instance of 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.

**Impact on audit rate**
The type and number of instances of noncompliance detected may impact on the audit rate, as per the compliance matrix. For example an accumulation of instances of noncompliance of various classifications (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 Charging Guidelines.
Appendix 2: Brokers – monitoring and assessing compliance

Monitoring activities

The department will monitor biosecurity industry participant’s compliance with the requirements of approved arrangement class 19.1: Non commodity for containerised cargo clearance (NCCC) and 19.2: Automatic entry processing for commodities (AEPCOMM). Collectively these arrangements are referred to as the broker class approved arrangements.

Ongoing compliance monitoring for the broker class approved arrangements will be primarily delivered through document assessment verification at the brokerage approved arrangement branch level.

The department will 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 department’s Charging guidelines.

Document assessment verification

The two lodgement categories for document assessment verifications are:

- **Category 1**: includes import declarations lodged under class 19.1 where the accredited person declares nil non-commodity concerns
- **Category 2**: includes import declarations lodged under class 19.1 where the accredited person declares non-commodity concerns (accredited person answers no to Gen-dec Question 7 or Question 9) or lodges an import declaration for goods under class 19.2.

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 is applied independently from class 19.2 (}
Figure  and Figure ). Verification rates are applied separately to each individual commodity group within class 19.2. For further details see the Document assessment verification - compliance action section.

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

**Document assessment - verification results**

Document assessment verification results will be determined in accordance with broker class 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 .

**Document assessment verification – noncompliance corrective actions**

Where noncompliance is detected for broker class 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 for the Brokerage Branch ID nominated in the Integrated Cargo System (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 biosecurity industry participant will be placed at the probation review level.

Failure to action a 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.

**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
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.

**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 suspend 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 broker approved arrangements (class 19.1 and class 19.2)* document.
Newly approved broker class 19.1 arrangements will commence at review level Standard.

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 requests. 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.
Newly approved broker class 19.2 arrangements will start on the review level probation for all commodity groups in AEPCOMM.

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 requests. 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.

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

Audits
Broker class 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.

**Audit results**

Audit results will be determined through the use of the compliance matrix that can be found in Table . For information on noncompliance classification, see Table .

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.

**Noncompliance and corrective action requests**

Major and minor noncompliance will be recorded in the audit report. The department may issue a corrective action requests 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 requests.

**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 1 and category 2 (Figure 2) lodgements.

Table 3 Noncompliance table—broker class approved arrangement audits

<table>
<thead>
<tr>
<th>Number of minor noncompliance</th>
<th>Number of major noncompliance</th>
<th>3 or more</th>
<th>1 or more</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Pass</td>
<td>Fail</td>
<td>Fail</td>
</tr>
<tr>
<td>1</td>
<td>Pass</td>
<td>Pass</td>
<td>Fail</td>
</tr>
<tr>
<td>2</td>
<td>Pass</td>
<td>Fail</td>
<td>Fail</td>
</tr>
<tr>
<td>3 or more</td>
<td>Pass</td>
<td>Fail</td>
<td>Fail</td>
</tr>
<tr>
<td>4</td>
<td>Pass</td>
<td>Fail</td>
<td>Fail</td>
</tr>
<tr>
<td>5 or more</td>
<td>Fail</td>
<td>Fail</td>
<td>Fail</td>
</tr>
</tbody>
</table>

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 matrix in Table.
Noncompliance classification

Table 4 Classification of noncompliance for broker classes 19.1 and 19.2.

<table>
<thead>
<tr>
<th>Type of noncompliance</th>
<th>Noncompliance could be any...</th>
</tr>
</thead>
</table>
| 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: Broker using an old packing declaration that still contains the Prohibited Packing statement.  
• Example 2: Broker fails to enter an AQIS entity identifier number in ICS but the treatment provider is approved. |

For a full list of compliance classifications against each requirement, see the compliance classifications for broker class approved arrangements.

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 present 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 departments charging guidelines.
Appendix 3: 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 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.

Nonconformity classification

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

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical</td>
<td>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.</td>
</tr>
<tr>
<td>Major</td>
<td>A deviation (or multiple deviations) from departmental requirements that may compromise the overall effectiveness and/or integrity of this approved arrangement.</td>
</tr>
<tr>
<td>Minor</td>
<td>A deviation from departmental requirements which does not, by itself, compromise the overall effectiveness and/or integrity of this approved arrangement.</td>
</tr>
</tbody>
</table>

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.
The following figure details the audit result matrix.

<table>
<thead>
<tr>
<th>Minor nonconformities</th>
<th>Major nonconformities</th>
<th>Critical non-conformity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>0</td>
<td>Pass</td>
<td>Pass</td>
</tr>
<tr>
<td>1</td>
<td>Pass</td>
<td>Pass</td>
</tr>
<tr>
<td>2</td>
<td>Pass</td>
<td>Pass</td>
</tr>
<tr>
<td>3</td>
<td>Pass</td>
<td>Fail</td>
</tr>
<tr>
<td>4 or more</td>
<td>Fail</td>
<td>Fail</td>
</tr>
<tr>
<td><strong>Immediate suspension of AA</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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 nonconformity to the biosecurity industry participant. A critical nonconformity may result in either a:
- critical corrective action requests; or
- show cause process; and
- probation audit rate.

**Addressing noncompliance**

Approved arrangements are subject to a range of requirements in accordance with Chapter 7 of the 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.

**Detection of noncompliance**

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

**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, they will be brought to the attention of the biosecurity industry participant at the audit exit meeting. A corrective action requests will be issued if the nonconformity 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 nonconformity 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.

Nonconformity rectification

Corrective action requests will specify a date by which the nonconformity must be rectified. Depending on the classification of nonconformity detected, the rectification timeframe will vary. Once the corrective action requests has 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 nonconformity 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 nonconformity.

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

If the nonconformity in the corrective action requests has not been rectified by the deadline for rectification, a new corrective action requests will be issued. If three successive corrective action requests are issued for the same nonconformity, and the nonconformity 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.

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 are detected at an audit.

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.

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*. 
**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.
Appendix 4: Flowchart of the process for revocation of suspension (reinstatement)

Reinstatement after suspension

- Approved Arrangement
  - Voluntary suspension
  - Pre-approval audit 1
    - Pre-approval audit 2
      - Follow up and close out NCs
        - AA on probation at suspension?
          - No
            - Reinstated on scheduled audit rate
          - Yes
            - Show cause process
    - Follow up and close out NCs
      - AA on probation at suspension?
        - No
          - Reinstated on scheduled audit rate
        - Yes
          - Show cause process
  - Pass - no NCs
    - Reinstated on probation audit rate
  - Pass - with NCs
    - Show cause process
  - Fail
- Pre-approval audit 1
  - Pass - with NCs
    - Pre-approval audit 2
      - Follow up and close out NCs
        - AA on probation at suspension?
          - No
            - Reinstated on scheduled audit rate
          - Yes
            - Show cause process
      - Follow up and close out NCs
      - AA on probation at suspension?
        - No
          - Reinstated on scheduled audit rate
        - Yes
          - Show cause process
      - Pass - no NCs
        - Reinstated on probation audit rate
      - Fail
        - Show cause process
  - Fail
- Pre-approval audit 1
  - Pass - no NCs
    - Reinstated on probation audit rate
  - Fail
- Pre-approval audit 2
  - Pass - no NCs
    - Reinstated on probation audit rate
  - Fail
- Show cause process

A reinstatement on probation rate initiates a new probation period. E.g. if an AA was on probation and had passed one probation audit prior to suspension and was only suspended for a month before being reinstated within 3 months, a new probation period of 6 months would commence on reinstatement.
Appendix 5: Co-location of approved arrangement sites

Pre-requisites 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 between the ‘parent’ and co-located ‘child’ approved arrangement sites that make up the co-located network.

Example 1: One university, one co-located network

In this example ‘the Dean’ is the approved arrangement manager and is responsible for the biosecurity activities at both the School of Science and, Animal Services.

1. 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 Example 2 below).
Example 2: One university, two parent sites

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

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.

2. **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 (i.e. have the same ABN).

**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 department’s [Charging guidelines](#). As the registration levy for approved arrangements is applied at the entity level, co-locating approved arrangement sites has no impact on the annual approved arrangement levy.

**Movement of biosecurity goods between co-located sites**
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.

**Application of the 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 punitive sanctions or actions for noncompliance.