

Biosecurity - Audits

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Management of biosecurity risk

NSW Department of Primary Industries (DPI), an office within the NSW Department of Industry, is committed to maintaining and encouraging a high level of compliance with the *Biosecurity Act 2015* (the Act) to achieve the effective management of biosecurity risks posed to the economy, environment and communities of NSW.

The purpose of this procedure is to outline the types of biosecurity audits, and identify when and how they are to be carried out to ensure compliance with the Act and supporting legislation, policies and procedures.

Scope

The procedure applies NSW DPI and Local Land Services (LLS) staff appointed as a biosecurity auditor under the Act to carry out biosecurity audits. This procedure applies to biosecurity accreditation and compliance audits as defined under the Act.

This procedure covers the conduct of biosecurity audits by appointed biosecurity auditors. It does not cover the conduct of biosecurity audits by 'third party auditors' that is persons who are not authorised officers but may be appointed as biosecurity auditors by either NSW DPI or any other accreditation authority,

Biosecurity legislation summary

Part 15 for the Act provides for biosecurity audits which can be in the form of an accreditation audit and compliance audit. A biosecurity audit is mandatory when required by the Secretary (or delegate) or an accreditation authority. A biosecurity audit is carried out by a biosecurity auditor who has been appointed in accordance with Part 16 of the Act.

Obstruction of a biosecurity audit or providing false or misleading information in a biosecurity audit is a category 2 offence.

The collection, use and disclosure of information in accordance with this procedure, including any internal or external discussion or distribution of information, must be in compliance with the *Privacy and Personal Information Protection Act 1998* or be exempted by the operation of section 387 of the Act.

Section 387 (2) of the Act provides authority for the disclosure of information about a person, without the consent of the person: to a public sector agency, or to any other person, but only if the disclosure is reasonably necessary for the purpose of exercising a biosecurity risk function.

Work health and safety

The *Work Health and Safety Act 2011* places an obligation on the agency (NSW DPI and LLS) as a person conducting a business or undertaking and workers to provide a safe and healthy workplace. Safe Work Method Statements that support activities included in this procedure must be used in identifying, assessing and controlling risks.

NSW DPI and LLS will work together to create a safe and supportive work environment when undertaking any activities for this procedure.

Travel to and from the site by motor vehicle may be hazardous e.g. driving at dawn or dusk, rising flood water, mud or gravel roads. Refer to the SWMS - Driving Vehicles that identifies specific hazards and treatments

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Biosecurity Audit procedure

1. Roles and responsibilities

1.1 NSW Department of Primary Industries:

- set guidelines as the authority responsible for the appointment of biosecurity auditors
- provide training for authorised officers prior to appointment as a biosecurity auditor

- specify qualification requirements for persons seeking appointment as a biosecurity auditor
- identify audit targets
- develop audit procedures and guidelines
- determine the audit frequency for compliance audits for each audit conducted
- provide educational material to industries and the community about how to meet the requirements of this procedure and the Act.

1.2. Biosecurity auditors:

- conduct biosecurity audits consistent with their authorisation and current position description except if the officer is directed to do so
- conduct biosecurity audits consistent with the relevant audit procedure
- maintain records of all biosecurity audits conducted
- report all non-compliance identified at audit
- report all breaches of the Act identified at audit.

2. Types of biosecurity audits

Part 15 of the Act identifies two types of biosecurity audits, an accreditation audit and a compliance audit.

2.1 Accreditation audits

An accreditation audit is carried out for the purposes of assessing an application for the grant or renewal of, or variation to

- biosecurity registration, or
- accreditation as a biosecurity certifier, or
- appointment as a biosecurity auditor, or
- a permit, or
- approval to exercise any of the functions of an accreditation authority under the Act.

Accreditation audits covered by this procedure include:

- application or renewal of biosecurity certifier
- biosecurity permit including individual and group permit applications, and
- biosecurity registration for keeping non-indigenous animals and bees.

Accreditation audits not covered by this procedure include:

- approval as an accreditation authority, and
- appointment as a biosecurity auditor.

2.2 Compliance audits

A compliance audit is carried out for the purpose of assessing and identifying the following:

- compliance with, and capability of complying with, the requirements by or under the Act, and
- any contraventions or suspected contraventions of the requirements imposed by or under the Act, and
- measures for improved compliance with the requirements of the Act.

See Biosecurity - Powers of Authorised Officer factsheet and the Act for further information.

3. Frequency of audits

3.1 Accreditation audits

For the purpose of this procedure, an accreditation audit occurs when assessing the initial application for the following:

- biosecurity permit
- biosecurity registration, and
- biosecurity certifier.

If the applicant fails the initial audit, then a second audit will be required prior to issuing a permit, registration and/or approval of a biosecurity certifier application. The frequency of accreditation audits will then be annually or whenever they are required to renew their registration or accreditation. This will be specified by the authorised officer approving the registration or permit, or the accreditation authority approving the accreditation of a biosecurity certifier.

3.2 Compliance Audits

The frequencies of compliance audits are determined using an audit frequency policy. Compliance audits will be based on a fixed audit frequency or risk based audit frequency.

The biosecurity audit frequency will decrease in response to identified compliance with the requirements of the Act and the biosecurity audit frequency will increase in response to identified non-compliance with the Act.

For further details refer to Biosecurity - Audit Frequency policy.

3.3 Businesses under the Third Party Auditor Program

To be considered for the third party program, the following requirements must be met:

- have a suitable audit and compliance history
- receive a pass rating at their most recent audit
- have no outstanding enforcement action, and
- make application using the biosecurity audit application form.

The NSW DPI will assess applications and contact the applicant in writing within 60 days of applicant submission with the decision.

Businesses accredited under the schemes listed below may apply to move to the third party auditor system. Facilities with multiple accreditations should contact NSW DPI for clarification. Types of accreditation include:

- Interstate Certification Assurance (ICA)
- Certification Assurance (CA)
- Industrial hemp audits.

Once approved the business must only use an approved auditor from the register.

4. Audit Process

All biosecurity audits are to be conducted in accordance with Australian Government Standards.

4.1 Document Review

As a part of the audit preparation or entry meeting, the auditor is to review copies of any relevant previous audit report including any corrective action requests.

The auditor must ensure that they have access to all relevant legislation, and supporting protocols and programs applicable to the type of activity that is to be audited. Copies of this legislation should be on hand during the audit for easy reference.

4.2 Conducting an accreditation audit

Accredited auditors must use the relevant audit checklists for each audit. These checklists are program specific.

For each accreditation audit, please refer to the relevant procedure to determine whether all requirements are being met:

- Biosecurity - Accreditation for biosecurity certifier
- Biosecurity – Permits
- Biosecurity - Registration.

5.3 Conducting audit

Accredited auditors must use the relevant audit checklists for each audit. These checklists are program/arrangement specific.

The table below outlines the minimum requirements expected when conducting a biosecurity compliance audit.

Table 1: Minimum requirements for conducting a biosecurity audit.

Audit activity	Minimum requirement
<p>Entry meeting Conducted at the start of the audit</p>	<ul style="list-style-type: none"> • Audit target need to have all required documentation is available and on site • Audit target need to have all monitoring records available, up to date and on site. <p>Biosecurity auditor must ensure:</p> <ul style="list-style-type: none"> • appropriate persons are present (such as biosecurity certifier for ICA/CA) • introduce auditor and show auditor identification card • unclosed Corrective Action Requests (CARs) reviewed and discussed, closed or reissued. • detail the scope of the audit • check that the accreditation/application is appropriate for the nominated program • review any changes to biosecurity activities conducted that may affect the businesses risk • review documentation amendments • review of enforcement action.
<p>Conducting the audit</p>	<p>Biosecurity auditor must:</p> <ul style="list-style-type: none"> • review of CARs and corrective action to verify that corrective action has been effective. This is performed in conjunction with the inspection • review of work instructions to ensure currency and accuracy including: <ul style="list-style-type: none"> • flow charts • hazard analysis and control points (as determined by protocol/program) • validation of critical limits • finished product specifications • monitoring records • product testing results, and verification records. • conduct inspection of the biosecurity activities and observation of processing

Audit activity	Minimum requirement
	<p>and treatment practices</p> <ul style="list-style-type: none"> • review of other support programs • establish CARs to be issued and severity • issue of corrective action requests • complete audit report and notes.
<p>Exit meeting Conducted at completion of the audit</p>	<p>Biosecurity auditor must ensure:</p> <ul style="list-style-type: none"> • appropriate management representatives present • audit summary and result (A-E, acceptable or unacceptable) • review corrective action requests and notes • agree close out time frames for CARs raised at audit • advise audit target of future audit frequency • ensure all information recorded on report • ensure audit target is fully aware of what information will be communicated back to accredited authority • appropriate person (eg biosecurity certifier) to sign audit report/attendee sheet • audit records should detail persons present at entry and exit meetings.

4.4 Corrective Action Requests

Appointed biosecurity auditors must act on non-conformances observed during the audit by raising them as Corrective Action Requests (CARs).

CAR requests have numerical values that NSW DPI use as a rating system to determine audit performance. CARs identified during audits are rated as minor, major or critical, depending on their severity and impact on risk.

CARs identified during audits can be rated as minor, major or critical, depending on their severity and risk on biosecurity. Each CAR attracts a numerical value.

Each CAR attracts a numerical value, the total point score is tallied at the end of the audit which then determines the audit rating and audit frequency for the business.

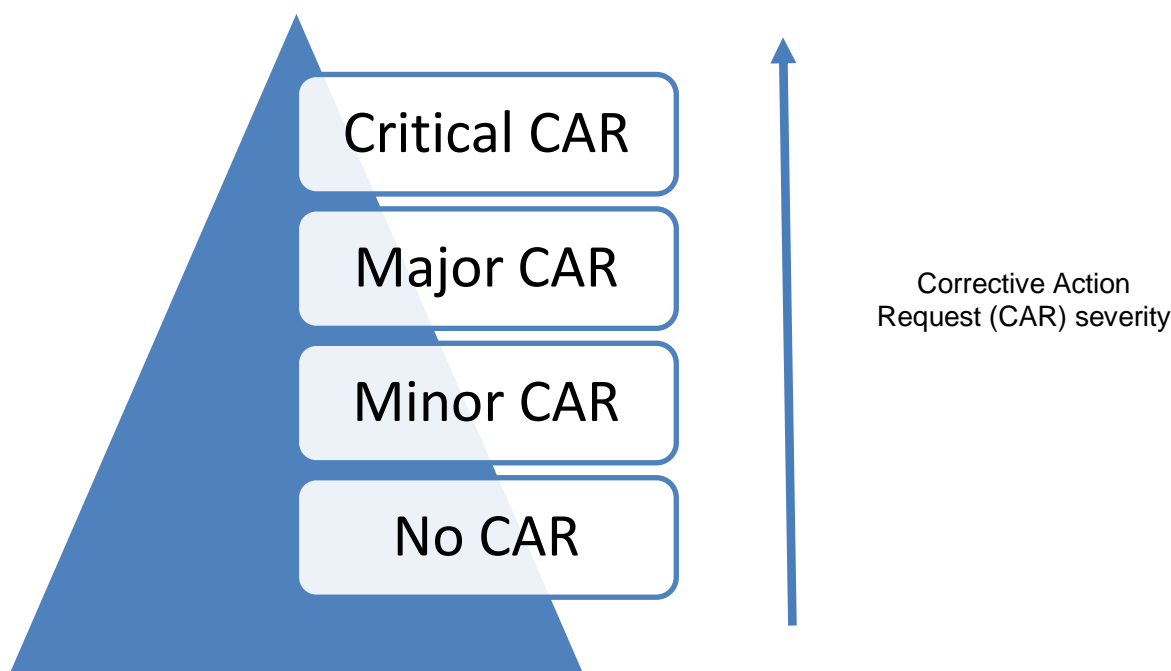
Table 2: CAR ratings and numerical values

CAR rating	Score
No corrective action required	0
Minor	2
Major	8
Critical	64

Table 3: Audit outcome

Total number of allocated points	Rating	Audit result
0-15	A	Acceptable
16-31	B	Acceptable
32-47	C	Marginal
48-63	D	Unacceptable
64 and above	E	Unacceptable

Figure 1. Severity of Corrective Action Request



NOTE: The above CAR rating is generic and will be used by the majority of registered or accredited businesses. It is the responsibility of the business owners to be aware of regulations and requirements.

4.4.1 Biosecurity Business Ratings

Once the audit is completed, a rating will be determined and applied to the business based on the cumulative CAR score accrued at the audit. This rating is then used to determine the audit result and frequency.

4.4.2 Corrective Action Request Escalation

There is a procedure for escalating CAR's issued. Failure by businesses to rectify any minor or major CARs by the required timeframe must be escalated and dealt with by way of a major or critical CAR.

4.5 Follow up audit/ Compliance action

If an audit target has received an unacceptable audit, (D or E rating), they may receive additional audits from the NSW DPI.

The purpose of these additional audits is to provide NSW DPI with evidence that the audit target has taken steps to comply with their requirements and has sustained compliance over a period of time.

If the business continues to not comply, appropriate enforcement action will be taken by an authorised officer of NSW DPI in line with the enforcement policy.

A failure to comply with a biosecurity audit is an offence under section 237 or section 238 of the Act and a penalty notice offence in the Biosecurity Regulation 2017. These can occur when a person obstructs or hinders a biosecurity auditor or if false or misleading information is provided the auditor.

4.6 Reporting requirements

A biosecurity auditor must prepare a documented report for each audit. The report must be provided to the audit target and the person who requested the audit.

Reports must be submitted within 48 hours of completion. Where applicable reports are to be completed using the BYTE Mobile auditing application and will be provided once the audit has been completed.

If a critical non-compliance is identified, or failed audit result is determined, the auditor must notify their line supervisor within 24 hours for reporting requirements of the Act to be satisfied, and enforcement action to be considered.

The report must contain the following information:

- address whether or not the audit target is complying with the requirements of the Act
- the requirements of the Act the audit target is not complying with
- list all contraventions or deficiencies from the biosecurity audit
- specify actions required to fix the contraventions or deficiencies from the biosecurity audit
- whether previous biosecurity audits indicated any contraventions or other deficiencies and if audit target had completed required action from previous audit.

The biosecurity auditor must report in writing any changes to biosecurity activities that would alter the risk classification or accreditation of the audit target.

5. Certain matters to be reported immediately

Biosecurity auditors are to report the following matters to their line supervisor or accreditation authority by verbal communication as soon as possible and within 24 hours. This needs to be followed by a written report within five days. Issues that require immediate reporting include:

- a serious compliance breach by the audit target
- an imminent or serious biosecurity risk exists
- the audit cannot be performed or completed
- abuse, intimidation, obstruction or anything else happens that may restrict the ability of the auditor to perform the audit
- if any false or misleading biosecurity certificate has been issued
- if any person that is in possession of biosecurity matter in contravention of a requirement imposed by or under the Act.

This may be done by reporting these to the appropriate supervisor or the NSW/ACT Quarantine Domestic Helpline 1800 084 811.

6. Fees and charges for biosecurity audits

6.1 Recoverable fees

The Act provides for the charging of a reasonable fee for carrying out an accreditation audit and a compliance audit.

A fee for a compliance audit can only be charged if the audit target is a biosecurity participant.

Biosecurity participant is a person who is, or formally was:

- a registered entity, or
- a biosecurity certifier, or

- a biosecurity auditor, or
- the holder of an individual permit, or
- applicant for a group permit that was granted, or
- a person who has given a biosecurity undertaking, or
- an accreditation authority.

The department will determine fees and charges for audits, and when these will be applied.

7. Definitions and Acronyms

NSW DPI NSW Department of Primary Industries

LLS Local Land Services

CAR Corrective Action Request

8. Documentation

Policy – Biosecurity Audit Frequency

Procedure - Biosecurity Certifiers

Procedure – Fees and Charges

Procedure - Biosecurity collection, use and disclosure of information

Policy - Biosecurity Certifiers

Policy - Records Management (IND-I-177)

Policy - Information Security (IND-I-197)

Policy - Classified Information (IND-I-196)

Policy -Government Information (Public Access) (IND-I-178)

Policy - Biosecurity collection, use and disclosure of information

Safe Work Method Statement - Driving Vehicles

9. Records

Not applicable

10. Revision History

Version	Date issued	Notes	By
1.0	01/07/2017	New procedure developed in response to the <i>Biosecurity Act 2015</i> .	Compliance Systems Coordinator

11. Contact

Compliance Systems Coordinator
02 6391 3698

Appendix 1: Audit System Flow Chart

