

Biosecurity - Approval of an Accreditation Authority

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Management of the biosecurity risk

The purpose of this procedure is to set out how the NSW Department of Primary Industries (DPI), an office within the NSW Department of Industry, will approve a person to exercise the functions of an accreditation authority under the *Biosecurity Act 2015* (the Act).

Scope

Part 17 of the Act provides for the Secretary, by instrument in writing, to approve any person to exercise the functions of an accreditation authority in relation to the following functions:

- the accreditation of biosecurity certifiers, and
- the appointment of biosecurity auditors.

Approval may be unconditional or subject to conditions or limitations.

Biosecurity legislation summary

Part 17 of the Act provides for the approval of a person to exercise the functions of an accreditation authority. The approval can remain in force for a specified period but cannot exceed five years, after which it can be renewed or cancelled. Subject to section 261 of the Act approvals may be limited to either the accreditation of biosecurity certifiers or the appointment of biosecurity auditors or both. Approval may also be limited in respect of a specified class of biosecurity certificates, biosecurity auditors or biosecurity audits.

Further requirements for the approval of accreditation authorities including the grounds for refusing, suspending or cancelling approval, are prescribed in Part 10 of the Biosecurity Regulation 2017 (the Regulation).

An accreditation authority or former accreditation authority who contravenes a condition of accreditation imposed under section 276 of the Act is guilty of 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 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 the procedure must be used in identifying, assessing and controlling risks.

The agency will work together to create a safe and supportive work environment when undertaking any activities for this procedure.

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Approval of an accreditation authority procedure

1. Roles and responsibilities

1.1 The Secretary (or [delegate](#)) will :

- specify the conditions of an approval of a person to exercise the functions of an accreditation authority
- approve a protocol that specifies the requirements for the intrastate movement (within NSW) of a regulated article
- approve an operational procedure that will ensure a person can certify a regulated article's conformance with the requirements specified in a protocol for the intrastate movement of a regulated article
- specify the minimum qualifications, skills and knowledge requirements of a person for approval as an accreditation authority
- provide or identify the training requirements for an accreditation authority
- implement an audit system to monitor an accreditation authority's compliance with the conditions of their approval
- administer the approval, refusal, suspension and cancellation of an accreditation authority
- maintain a database of approved accreditation authorities, and
- provide reports to national and interstate authorities as required.

1.2 The Accreditation authority:

- must exercise the functions of an accreditation authority consistent with the conditions of an approval specified by the Secretary
- must have an approved operational procedure that ensures a certified product (regulated article) complies with an interstate/intrastate protocol
- must have an approved accreditation policy and ensure that the accreditation of biosecurity certifiers is conducted consistent with that policy
- (if appointing biosecurity auditors) must have an approved biosecurity auditor appointment policy and ensure the appointment of biosecurity auditors is conducted consistent with that policy
- must have an approved audit frequency policy and ensure all compliance audits are conducted consistent with that policy
- must maintain records of all accredited biosecurity certifiers and appointed biosecurity auditors
- must be responsive to the conduct of accreditation and compliance audits
- must implement an audit system to ensure accredited biosecurity certifiers and biosecurity auditors comply with their conditions of accreditation or approval
- must provide reports to the Secretary as required, and
- must provide reports to an interstate authority if requested.

2. Approval of a person to exercise functions of an accreditation authority

Section 261(1) of the Act provides for the Secretary or a delegate by instrument in writing, to approve a person to exercise the functions of an accreditation authority in relation to the:

- Accreditation of biosecurity certifiers, and
- Appointment of biosecurity auditors.

Approvals may be limited to a specified class of biosecurity certificates or biosecurity certifiers or a specified class of biosecurity auditors or biosecurity audits. The instrument should state the conditions and limitations (if any) that apply to the approval.

3. Application for approval as an accreditation authority

Section 263(1) of the Act provides for a person to apply to the Secretary or a delegate for approval to exercise the functions of an accreditation authority.

- Applications must be completed and submitted using the **approved form** and include copies of:
 - a Biosecurity Certifier Accreditation policy,
 - if applying to appoint biosecurity auditors, a Biosecurity Auditor Appointment policy, and
 - an Audit Frequency policy.
- for interstate certification, a copy of the approved operational procedure(s) and/ or
- for intrastate certification, a copy of draft operational procedure(s) for acceptance and endorsement by the Secretary
- any other supporting information or evidence required by the application form, and
- the application fee payable.

The application fee should accompany the application if the application is to be processed in a NSW DPI office or if the application is lodged electronically, the payment can be made on line.

Approval is granted by instrument in writing.

3.1 To accredit Biosecurity Certifiers

Biosecurity Certifier Accreditation policy

Section 192 of the Act requires that an accreditation authority that has the authority to appoint biosecurity certifiers, must adopt an accreditation policy. The policy must make provision for the qualifications, skills and experience required for a person to be accredited as a biosecurity certifier by the accreditation authority.

The accreditation policy must be approved by the Secretary or a delegate and once approved, the accreditation authority must make the policy publicly available.

3.2 To approve Biosecurity Auditors

Biosecurity Auditor Appointment policy

Section 240 of the Act requires that an accreditation authority that has the authority to appoint biosecurity auditors, must adopt an appointment policy. The policy must make provision for the qualifications, skills and experience required for a person to be appointed as a biosecurity auditor by the accreditation authority.

The appointment policy must be approved by the Secretary or a delegate and once approved, the accreditation authority must make the policy publicly available.

Audit Frequency policy

Section 227 of the Act requires that an accreditation authority must adopt an audit frequency policy. The policy must make provision for the frequency of compliance audits. This includes audits conducted of persons accredited as biosecurity certifiers and persons appointed as biosecurity auditors.

The audit frequency policy must be approved by the Secretary or their delegate and once approved, the accreditation authority must make the policy publicly available.

4. Audit of application

4.1 Application desk audit

Upon receipt the application will be the subject of a desk audit. The purpose of the desk audit is to determine if:

- the application has been completed
- supporting information has been provided, including copies of any required policies
- the applicant is a suitable person to be applicant as an accreditation authority, and.
- the application satisfies the departments requirements for managing, mitigating and preventing a biosecurity risk.

If the desk audit is satisfactory then the applicant should be advised that the next stage of the approval process will require the conduct of an initial (on-site) compliance audit. A Pending Letter of Advice is available for this purpose.

5. Grant or Refusal of Approval

Section 264(1) of the Act provides for the Secretary to grant or refuse approval to exercise the functions of an accreditation authority.

On completion of a successful on-site compliance audit and the approval by the Secretary of the required policies, appointment as an accreditation authority may be granted by instrument in writing. Approval is effective for administrative purposes from this date.

The Secretary may refuse to grant approval if:

- critical non-compliance with a condition of approval is identified at the on-site compliance audit
- the applicant does not comply with any requirement imposed by or under the Act
- the applicant does not have the qualifications, skills, knowledge and experience required
- the applicant fails to pay the application fee or any fees charged for the conduct of the audit, or
- the Secretary has not approved the relevant policies required for the applicant to function as an accreditation authority, and.
- the operational procedure(s) have not been endorsed and accepted by the relevant interstate authority or the Secretary for certification to meet intrastate requirements.

The Regulation requires the Secretary to give an applicant notice in writing of a decision to grant, refuse or renew an approval within **60 days** after the application was made. After 60 days, the application is taken to have been refused if no notice is given. Clause 106(2) of the Regulation provides more detail as to how the 60-day period should apply.

Section 277 (1) of the Act provides for a person aggrieved by a decision of the Secretary to refuse approval, refuse to renew approval, suspend or cancel approval, impose any condition on

approval or to vary approval as an accreditation authority, to appeal to the Land and Environment Court against the decision.

The Regulation at clause 104 prescribes additional grounds for the refusal, suspension or cancellation of an approval and clause 105 prescribes additional grounds the refusal, suspension or cancellation of an approval. They include but are not limited to:

- the person has made a statement or furnished information that is false
- the person has previously been granted approval and that approval was cancelled within the previous 2 years (and not overturned on appeal)
- whether the person has the capacity to properly discharge the person's functions as an accreditation authority, and
- the person's history of compliance with the Act, the Regulation or any other Act or law.

6. Compliance audits

The first compliance audit should be conducted approximately 6 months after the grant of approval as an accreditation authority.

Thereafter compliance audits should be conducted subject to the accreditation authority's conditions of approval and consistent with NSW DPI's audit frequency policy. Audits may also be conducted at defined intervals specified in the person's conditions of approval.

Compliance audits may also be conducted to investigate a report of non-compliance. An accredited biosecurity certifier may also be the subject of random audits.

All compliance audits, except random audits, should be the subject of the compliance audit fee.

Refer to NSW DPI Biosecurity Audit Procedure for more information on compliance audits.

7. Duration of approval

Section 265(1) of the Act provides for the Secretary to specify the duration of an approval to exercise the functions of an accreditation authority. The duration of an approval cannot exceed a period of five years, after which the approval should be renewed or cancelled.

8. Variation of approval

Section 266(1) of the Act provides for the Secretary to vary at any time by notice in writing, the approval of a person to exercise the functions of an accreditation authority. Although the Regulation provides for a fee for the variation of an approval to function as an accreditation authority, there is no fee for a variation of an approval at this time.

9. Renewal of approval

Section 267 of the Act provides for the renewal of an approval to function as an accreditation authority. This will be required annually or at an interval specified in the conditions of the approval. The duration of an approval can extend to 5 years although the current fees payable for approval are required every 2 years.

An approved accreditation authority will be sent an application for renewal a minimum of 6 weeks before their approval is due to expire.

The payment of a fee is required for the renewal of an approval.

Applications for the renewal of an approval should be the subject of a compliance audit. The purpose of the compliance audit is to determine the person's compliance with their conditions of approval. If the compliance audit identifies a satisfactory level of compliance, approval can be renewed.

10. Conditions of approval

Approval of a person to exercise the functions of an accreditation authority will be the subject of conditions. Those conditions will be specified in the application for approval and/or the instrument granting their approval. Conditions of approval should include:

- An approved operational procedure to ensure certified product complies with an interstate/intrastate certification protocol.
- A requirement to provide any interstate authority when requested, with regular updates of biosecurity certifier accreditations and/or biosecurity auditor appointments
- Notifying NSW DPI when a critical non-compliance is reported by an interstate authority of product the subject of a biosecurity certificate issued by an accredited biosecurity certifier
- Notifying NSW DPI when a critical non-compliance is identified with product the subject of a biosecurity certificate issued for intrastate movement by an accredited biosecurity certifier
- Notifying NSW DPI when a critical non-compliance by an accredited biosecurity certifier has been identified at audit
- Maintain records, and provide when requested of all:
 - biosecurity certifier and biosecurity auditor applications
 - audits of accredited biosecurity certifiers and appointed biosecurity auditors.

Section 269A of the Act includes as a condition of approval that the functions of an accreditation authority can only be carried out by individuals who are notified to the Secretary as individuals who can carry out the functions of the accreditation authority.

11. Grounds for suspension or cancellation of an approval

Section 270 of the Act provides the Secretary with grounds for suspending or cancelling an approval. The grounds include when the Secretary:

- is of the opinion that the accreditation authority has contravened a requirement imposed by or under the Act
- is not satisfied that the accreditation authority is not a suitable person to exercise the functions of an accreditation authority
- receives information about the person that would have been grounds for refusing an application for approval if it were known at the time of application, and
- identifies the grounds for suspension or cancellation included in clauses 104 and 105 of the Regulation.

Cancellation or suspension of accreditation must be by notice in writing to the biosecurity certifier. The notice of suspension must specify:

- the date the suspension or cancellation takes effect
- the period of suspension, and
- the grounds for suspension or cancellation.

11.1 Suspension of an approval

Section 271 provides that the Secretary may suspend an approval by notice in writing if there are grounds for suspension of the approval.

The notice must specify the date or time the suspension takes effect, the period of suspension and the grounds for the suspension.

11.2 Accreditation authority to be given opportunity to make submission about suspension

Section 272 of the Act requires before suspending an approval to exercise the functions of an accreditation authority the Secretary must give notice in writing of the Secretary's intention to suspend accreditation and invite the accreditation authority to make a submission within at least 30 days of the notice being given.

If the accreditation authority does suspend an approval, the accreditation authority must:

- give notice in writing of the Secretary's intention to suspend the approval, and
- invite the biosecurity certifier to make a submission with 30 days of receipt of the notice, and
- take into account a submission made to the Secretary by the accreditation authority.

11.3 Cancellation of approval

Section 273 provides that the Secretary may by notice in writing cancel approval to exercise the functions of an accreditation authority if there are grounds for the cancellation of approval or the accreditation authority requests cancellation.

The notice of cancellation must specify the date or time from which cancellation takes effect and the grounds for cancellation.

11.4 Accreditation authority to be given opportunity to make submission about cancellation

Section 274 of the Act requires before cancelling an approval to exercise the functions of an accreditation authority the Secretary must give notice in writing of the Secretary's intention to suspend accreditation and invite the accreditation authority to make a submission within at least 30 days of the notice being given.

The accreditation authority is not required to give notice of a proposed cancellation if:

- the approval of the accreditation authority is suspended, or
- the accreditation authority has applied for cancellation of approval.

11.5 Effect of suspension or cancellation on conditions

Section 275 of the Act provides that an approval may be suspended or cancelled unconditionally or subject to conditions imposed by the Secretary. The Secretary may impose new conditions or vary or revoke any existing conditions.

12. Definitions and Acronyms

NSW DPI: NSW Department of Primary Industries

13. Documentation

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
Policy – Biosecurity - Accreditation of biosecurity certifiers
Procedure – Biosecurity – Accreditation of biosecurity certifiers
Procedure - Biosecurity collection, use and disclosure of information
Procedure – Biosecurity certificates
Procedure – Biosecurity audits
Application form – Accreditation Authority
Pending Letter of Advice
Accreditation Authority Guidelines

14. Revision History

Version	Date issued	Notes	By
1.0	18/08/2018	New procedure developed in response to the <i>Biosecurity Act 2015</i> .	Policy, Legislation, Performance and Consultation Branch

15. Contact

Compliance Systems Coordinator
Biosecurity and Food Safety Compliance
02 6391 3698