Department of Primary Industries
Department of Regional NSW

Procedure - Validation of point of care tests for prohibited matter

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Category:	Operations and Industry	Review date:	30 June 2025

Scope:

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This procedure should be read in conjunction with the Policy - Point of Care tests for prohibited matter in NSW, Management of animal biosecurity in NSW, Surveillance for diseases of animals and aquatic pests, Endemic diseases of animals, Prohibited matter pests and diseases of animals and Procedure - Reporting notifiable pests and diseases of animals and biosecurity events. Disease-specific procedures, exemption orders and prohibited matter permits should be consulted prior to the use of any point of care test (PoCT) for a prohibited matter for additional requirements related specific PoCTs

This procedure applies to all PoCT for the purposes of diagnostic and disease surveillance activities of prohibited matter in NSW. This includes any in vitro test developed for the diagnosis or screening for prohibited matter (listed in Schedule 2 of the Biosecurity Act 2015) where its intended use is at any location other than the State Veterinary Diagnostic Laboratory (SVDL). Note: PoCT containing prohibited matter as a reagent or control are outside the scope of this procedure. It is prohibited to develop, manufacture, import, distribute and use tests containing prohibited matter under the Act.

This procedure does not apply to any PoCT to be used to test for biosecurity matter other than prohibited matter. Operators of PoCT for biosecurity matter other than prohibited matter should make their own assessment of fitness for purpose and diagnostic value.

This procedure applies to all developers/ manufacturers of PoCT for the purposes of diagnostic and disease surveillance activities of prohibited matter.

This procedure applies to all operators of PoCT for the purposes of diagnostic and disease surveillance activities of prohibited matter. This includes government veterinarians, private veterinary practitioners and other staff who are authorised to investigate outbreaks of suspected notifiable diseases of animals and/or aquatic pests under the Biosecurity Act 2015, Local Lands Services Act 2013 and Veterinary Practice Act 2003, as well as any other class of persons specified in an exemption order or prohibited matter permit for a specific PoCT.

Sources: [Enter sources]

This procedure applies to domestic animals, animals held in captivity, and wildlife (free-living animals and feral animals). Diseases of animals include conditions caused by both infestation and infection with disease agents, formerly referred to in animal biosecurity policies and procedures as 'pests and diseases of animals.

Management of the biosecurity risk

Point of care tests (PoCT) for prohibited matter need be appropriately validated in order to minimise the biosecurity, animal health, medico-legal and trade risks arising from their use. Provisional recognition for use of these tests under a prohibited matter permit may be granted where the test is deemed fit for its intended purpose and there is a significant demonstrable benefit to clinical outcomes, disease surveillance or emergency response activities.

This procedure describes the process for validation of PoCT for prohibited in NSW and the requirements for test manufacturers, DPI and LLS staff and PoCT operators at each stage of this process.

Biosecurity legislation summary

Biosecurity Duty
A person, other than an authorised officer, who owns or is caring for animals, or a person working in their professional capacity such as a veterinarian has a duty to immediately notify an authorised officer if they suspect, or are aware, that an animal is infested or infected with prohibited matter.

Disclosure of information
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.

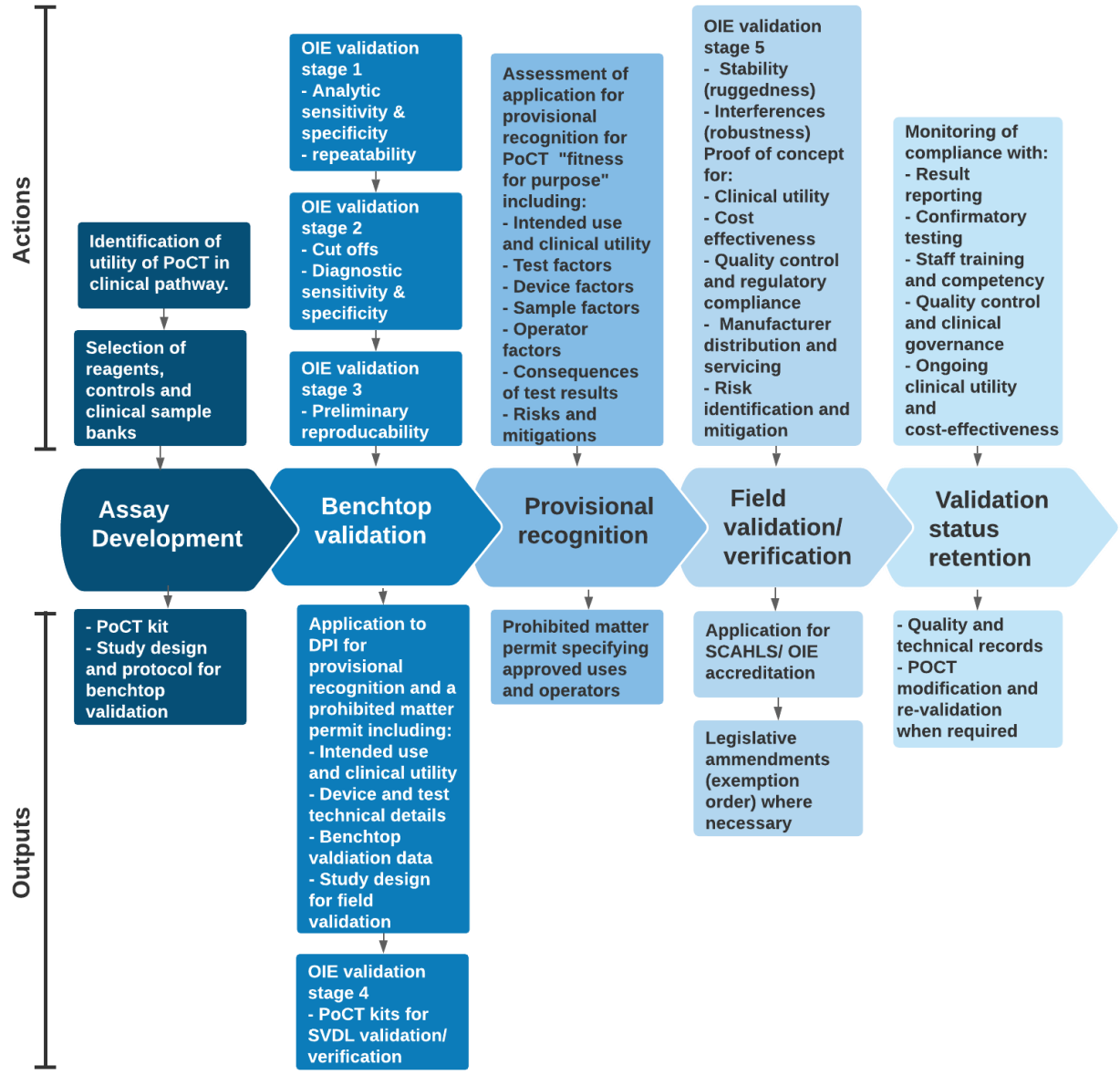
Section 387 (2) of the Act provides authority for the disclosure of information about a person, without the consent of the person: to a public sector agency, or to any other person, but only if the disclosure is reasonably necessary for the purpose of exercising a biosecurity risk function.

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.

Validation Pathway for novel PoCT



Adapted from OIE Standard Operating Procedure for Registration of Diagnostic Kits and Halpin, et al. 2021.

Roles and responsibilities:

PoCT developer/distributor

- When developing a novel PoCT for prohibited matter in NSW, consider:
    - the benefit to clinical outcomes, disease surveillance or emergency response activities that the PoCT offers,
    - practicality of integration of the PoCT in the current diagnostic pathway and the intended purpose of the test,

Sources: [Enter sources]

    - existing validation data for the test and ability to undertake benchtop validation that meets the requirements for provisional recognition in NSW per the NSW Validation template,
    - animal ethics requirements for any field validation of PoCT for prohibited matter intended to be undertaken in NSW
    - ability to undertake field validation to achieve SCAHLS/OIE accreditation including administration of training and assessment and provision of ongoing technical support for operators.
- When undertaking benchtop validation/verification:
    - Cover all costs associated with benchtop validation studies at appropriate (NATA accredited) laboratories.
    - Supply kits for benchtop validation that are fit for purpose upon leaving the supplier.
    - Supply clear protocols for sample collection and processing, consumable and reagent storage, test methodology, device maintenance and calibration, internal quality control and workplace health and safety.
    - Provide training and assessment in use of the device and ongoing technical support for laboratory staff operating the PoCT
    - Gather and analyse benchtop validation data per the NSW PoCT Validation Template for PoCT for Prohibited Matter.
- When applying for provisional recognition:
    - Submit a completed provisional recognition application and using the NSW PoCT Validation Template,
    - Provide additional validation data or information as necessary to complete the application/assessment when requested by subject matter experts,
    - Demonstrate that animal ethics approval for the study design has been achieved where necessary,
    - Pay any required administrative and/or permit fees for review of a PoCT validation application and provision of a prohibited matter permit under the Permit Procedure and Schedule 5 (Fees) of the Regulation. The assessment period for the application does not start until all fees have been paid in full.
- When undertaking field validation/verification:
    - Cover all costs related to supply and use of PoCT during field validation unless another arrangement is negotiated with the organisations or operators.
    - Supply kits that are fit for use upon leaving the supplier.
    - Supply clear protocols for sample collection and processing, consumable and reagent storage, test methodology, device maintenance, calibration and internal quality control.
    - Ensure that animal ethics standards are met by all operators.

Sources: [Enter sources]

- Provide training in use of the device to approved operators and undertake competency assessments. This training and assessment must occur and records submitted for approval to the PoCT Working Group before commencing testing.
- Provide technical support for PoCT operators.
- Report known or suspected issues that may alter the safety or quality of the POC test to an authorised officer immediately.
- Support NSW Government in management of the risks associated with POC tests for prohibited matter.
- Gather and analyse field validation data.
- Submit an application for SCAHLS/WOAH accreditation of the PoCT.

- Where a PoCT for prohibited matter has undergone field validation outside of NSW, an application for provisional recognition should be submitted that includes field validation data and a protocol for field verification under NSW conditions, however this protocol may be more limited than those for tests requiring comprehensive field validation.

NSW DPI PoCT Working Group

- When considering provisional recognition:
  - Undertake preliminary assessment applications for completeness and quality of PoCT validation using the steps described in the NSW Validation Template for Provisional Recognition of PoCT for Prohibited Matter, National Association testing Authorities (NATA) General Accreditation Guidance – Validation and Verification of Quantitative and Qualitative Test Methods and World Organisation for Animal Health (WOAH) principles and methods for validation of diagnostic assays for infectious diseases and standard operating procedure for the registration of diagnostic kits.
  - Use risk assessment to identify effective and efficient mitigation strategies that can be implemented to manage risks associated with prohibited matter whilst supporting the veterinarians, primary producers and PoCT manufacturers in the development and utilisation of novel diagnostic technology.
  - Submit appropriate applications for review by subject matter experts such that responses will be provided within the maximum response time (6 months).
  - Contact the PoCT manufacturer/developer to request additional validation data/ information necessary to achieve provisional recognition in a timely manner.
  - Provide timely, constructive feedback to PoCT developers/ manufacturers to support future validation and implementation of tests where provisional recognition is not able to be granted during the application period,
  - Undertake a risk assessment for each PoCT in order to provide recommendations to the NSW CVO regarding specific risk mitigation measures and restrictions to PoCT operator class and for prohibited matter permits/exemption orders.

    - Recommend to the NSW CVO that the PoCT be granted provisional recognition as an alternative (or additional test) to a laboratory-based service for the purposes of field validation where the PoCT is deemed:
        - Validated as fit for purpose by a panel of subject matter experts,
        - To provide a significant demonstrable benefit to clinical outcomes, disease surveillance or emergency response activities in NSW, and
        - Likely to be successfully validated for field use and achieve SCAHLS/OIE accreditation in the longer term,
        - To not significantly increase the risk of a biosecurity event occurring under the conditions of the prohibited matter permit/exemption order.
- During field validation/verification:
    - Audit training records and competency assessments of PoCT operators.
    - Review reported known or suspected issues that may alter the safety or quality of the PoCT and provide recommendations to the NSW CVO regarding revocation of the prohibited matter permit.
    - Evaluate quality key performance indicators (KPIs) for the application of the PoCT and make an assessment of the clinical effectiveness and success of PoCT integration into the diagnostic pathway.
    - Recommend the NSW CVO support an application for Subcommittee of Animal Health Laboratories standards (SCAHLS) accreditation for PoCT that have undertaken appropriate field validation and demonstrated value and utility in NSW biosecurity system.
- To support validation status retention or modification:
    - Review reported known or suspected issues that may alter the safety or quality of the PoCT.
    - Review ongoing PoCT performance in light of evolving characteristics of field strains of prohibited matter
    - Undertake horizon scanning for new technologies that represent improvements on existing PoCT.
    - Modifications to the validation pathway may be made on a risk-assessed, case by case basis at the discretion of the NSW CVO or PoCT Working Group

NSW DPI Biosecurity and Food Safety and Local Land Services authorised officers

- During field validation/verification and to retain validation status:
    - Staff working for NSW DPI and LLS must report any information regarding suspicion or awareness of prohibited matter or a biosecurity event per the Procedure - Reporting notifiable pests and diseases of animals and biosecurity events.
    - All PoCT results must be entered into an online database per the Procedure - Use of PoCT for prohibited matter.

NSW Chief Veterinary Officer (CVO)

- With the power the Secretary has delegated under section 379 of the Act, the NSW CVO will review and approve prohibited matter permits for PoCT that have been recommended for provisional recognition by the NSW PoCT working group.

PoCT users

- During field validation/verification and to retain validation status
    - PoCT operators/organisations must apply for a prohibited matter permit for use of a provisionally recognised PoCT and must comply with the restrictions of use stated in the prohibited matter permit.
    - PoCT operators must comply with the standards for PoCT use detailed in the prohibited matter permit, Policy - Point of Care tests for prohibited matter in NSW and Procedure – Use of Point of Care tests for prohibited matter. This includes ensuring they have been trained and assessed as competent to undertake sampling, sample preparation and testing and comply with all requirements of the quality management system.
    - PoCT operators are responsible for ensuring that PoCT that do not conform to quality management requirements are identified, reported, and managed to prevent unintended use as required by the relevant pest or disease procedure and the Procedure – Use of Point of Care tests for Prohibited Matter.

Definitions and acronyms:

- **CVO:** Chief Veterinary Offiver
- **PoCT:** Point of care test
- **LLS:** Local Land Services
- **DPI*:*** Department of Primary Industries
- **LHMS*:*** Livestock Health Management system
- **SCAHLS:** Subcommittee for Animal Health Laboratory Standards
- **NATA:** National Association testing Authorities
- **WOAH:** World Organisation for Animal Health
- **The Act:** NSW Biosecurity Act 2015

Documentation:

- Policy - Biosecurity collection, use and disclosure of information
- Policy - Information Security (IND-I-197)
- Policy – Code of Ethics and Conduct
- Procedure - Biosecurity collection, use and disclosure of information
- Policy - Point of Care tests for prohibited matter in NSW
- Policy - Management of animal biosecurity in NSW

Sources: [Enter sources]

- Policy - Surveillance for diseases of animals and aquatic pests
- Policy - Endemic diseases of animals
- Policy - Prohibited matter pests and diseases of animals
- Procedure- Biosecurity collection, use and disclosure of information
- Procedure - Reporting notifiable pests and diseases of animals and biosecurity events
- Procedure – Use of Point of Care tests for prohibited matter.
- NSW PoCT Validation Template

Revision history:

Version	Date issued	Notes	By
1	15 November 2022	New policy developed in response to the Biosecurity Act 2015	Animal Biosecurity

Contact:

- Biosecurity NSW – General Enquires 1800 808 095 biosecurity@dpi.nsw.gov.au

Sources: [Enter sources]