

Policy – Point of care tests for prohibited matter

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Policy Statement:

Veterinary point of care tests (PoCT) provide field-based or “pen-side” diagnostic information about disease states in animals. Implementation of PoCT tests will support more equitable and efficient access to veterinary testing across NSW, improving animal health outcomes and enhancing surveillance and emergency disease response activities. However, misuse or misinterpretation of tests and inaccurate test results for prohibited matter diseases represents a significant biosecurity risk with implications for producers, vets, communities, and industries. Due to these risks, PoC testing for prohibited matter is prohibited in NSW. It is an offence under Section 28 of the [NSW Biosecurity Act 2015](#) to deal with prohibited matter, and clause 4 of the [Biosecurity Regulation 2017](#) states that testing for the presence of biosecurity matter is a dealing. Use of a PoCT for prohibited matter can only be conducted under an exemption order or prohibited matter permit.

Accreditation of a PoCT by the Australian Sub-committee of Animal Health Laboratory Standards (SCAHLs) or the World Organisation for Animal Health (WOAH) indicates fitness of a novel PoCT, which has been properly developed, optimised and standardised, for an intended purpose. In the absence of such accreditation, novel PoCT for prohibited matter need to be appropriately validated against their intended purpose and used by competent individuals according to manufacturer and regulatory standards to minimise the risk of a biosecurity event occurring. This policy describes the quality objectives and requirements for validation, implementation, management and use of PoCT for the purposes of diagnosis or screening for prohibited matter in NSW. It seeks to harmonise regulation of veterinary PoCT in NSW with other jurisdictions and regulatory approaches for human PoCT and promote a shared responsibility for mitigating biosecurity risk.

Scope:

This policy should be read in conjunction with the [Management of animal biosecurity in NSW](#), [Surveillance for diseases of animals and aquatic pests](#), [Endemic diseases of animals and Prohibited matter pests and diseases of animals](#). Requirements for test/device validation and provisional recognition and use are detailed in [Procedure – Validation for Point of Care tests for Prohibited Matter](#). Requirements for PoCT use, operator competency and clinical governance are included in

the Procedure – Use of Point of Care tests for Prohibited Matter 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 POC test for a prohibited matter for additional requirements related specific PoCTs.

This policy applies to all PoCT intended 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 policy. It is prohibited to develop, manufacture, import, distribute and use tests containing prohibited matter under the Act.

This policy applies to all persons intending to develop, manufacture, distribute and use 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.

This policy 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'.

Requirements:

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 policy 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 policy

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.

Roles and responsibilities:

NSW Biosecurity Food Safety

- All novel PoCT submitted for provisional recognition in NSW will be assessed by a PoCT working group comprising representatives from the Laboratories for Emergency Animal Disease Diagnosis and Response network, Local Land Services, Elizabeth MacArthur Agricultural Institute and the Department of Primary industries. Advice and review by from external technical experts with backgrounds in the specific disease ecology, epidemiology and diagnostic test development will be sought when needed.
- The PoCT working group will be responsible for recommending provisional recognition of novel PoCT for prohibited matter and conditions for prohibited matter permits and exemption orders to the NSW CVO.
- Prohibited matter permits and exemption orders for PoCT may be revoked for individuals or groups on the recommendation of the PoCT working group and at the discretion of the NSW CVO if:
 - PoCT developers/manufacturers or operators fail to comply with this policy and supporting procedures
 - a significant safety issue has occurred
 - the instrumentation is misused or operator competency is deficient
 - there are concerns in relation to accuracy of results
 - there is a lack of clinical effectiveness
 - the expected benefits for using PoCT are not realised.
- Prohibited matter permits or exemption orders for a PoCT may be reinstated on the recommendation of the PoCT working group and at the discretion of the NSW CVO if evidence of remediation or resolution is provided.
- Tests that are provisionally recognised as fit for purpose in NSW may be granted a prohibited matter permit or exemptions order to allow use of the test in NSW.
- PoCT will be assessed against a standard Validation Template for Provisional Recognition of PoCT and reviewed by the PoCT working group.
- Provisional recognition of PoCT for prohibited matter will only be recommended if the PoCT working group deems:
 - there is a significant demonstrable benefit to clinical outcomes, disease surveillance or emergency response activities
 - biosecurity risks associated with conducting and interpreting the test can be appropriately mitigated
 - the test may be feasibly conducted in the field in a cost-effective and sustainable manner
 - preliminary validation data is acceptable, and the test is deemed fit for an intended purpose
 - an appropriate plan (including details of funding, study design, operator training, quality control, regulatory compliance and result reporting) for field validation and use of the test in NSW is provided
 - there is an intention to achieve SCAHLS/OIE accreditation through field validation of the test in NSW

Users of PoCT for prohibited matter in NSW

- Testing for biosecurity matter using point of care testing and reporting of the test results is in accordance with the Biosecurity Act 2015.
- A person's duty to notify an authorised officer if they suspect, or are aware, that an animal is infested or infected with prohibited matter is not nullified by a negative PoCT result.
- PoC testing for prohibited matter will not be performed unless an exemption order or prohibited matter permit has been issued for that particular test, operator and purpose.
- If a point of care tests is to be used to test for prohibited matter, validation as fit for purpose will require SCHALS/OIE accreditation or provisional recognition in NSW.
- PoCT for prohibited matter will only be used by appropriate operators, limited to:
 - government veterinarians
 - private veterinary practitioners or authorised officers at the direction of a government veterinarian
 - other classes of persons specified in an exemption order or prohibited matter permit for a specific PoCT at the direction of a government veterinarian and under the supervision of a veterinarian registered in NSW
- All operators of PoCT for prohibited matter must be trained and assessed as competent to undertake sampling, sample preparation and testing per the Procedure – Use of Point of Care tests for Prohibited Matter.
- PoC testing must be conducted according to the manufacturers instruction or as described in the validated test method and in compliance with the prohibited matter permit and the Procedure – Use of Point of Care tests for Prohibited Matter. This includes adherence to the quality management system (internal quality control, appropriate record keeping and compliance with external auditing) and submission of parallel samples for confirmatory testing at the State Veterinary Diagnostic Laboratory.
- All PoCT results will be reported for the purposes of quality management and field validation as required by the relevant pest or disease procedure and the Procedure – Use of Point of Care tests for Prohibited Matter.
- Results from a PoCT where confirmatory laboratory testing has not been conducted will not be used for trade or property certification without direction from the DPI Species Coordinator or NSW CVO.
- PoCT operators are responsible for ensuring that PoCT that do not conform to requirements are identified and reported as required by the relevant pest or disease procedure and the Procedure – Use of Point of Care tests for Prohibited Matter.
- Operators of PoCT for prohibited matter will be responsible for instating a system of clinical governance to ensure compliance with ISO 22870 PoCT – Requirements for quality and competence, Procedure - Internal Quality Audit, Procedure - Laboratory Equipment Maintenance and Calibration Procedures and Procedure – Use of Point of Care tests for Prohibited Diseases.
- Organisations or operators of PoCT for prohibited matter will keep records of clinical governance activities and will furnish authorised officers with these records when requested for the purposes of method performance verification and auditing of test quality assurance.

Definitions and acronyms:

- **CVO:** Chief Veterinary Officer
- **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 - Management of animal biosecurity in NSW
- 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.
- Procedure – Validation 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:

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