Veterinary Testing ISO/IEC 17025 Application Document

Annex A: Disease Outbreak Investigations within Australian based Veterinary Testing facilities

July 2014

Disease Outbreak Investigations within Australian based Veterinary Testing Facilities

1. Introduction

This policy is applicable to facilities accredited under NATA's field of Veterinary Testing and involved in disease outbreak investigations as part of a national collaborative approach.

There are a number of emergency animal diseases that are exotic to Australia and can pose significant risks to both public health and trades. As such, a permanent capacity to routinely test and diagnose all of these potential diseases is not possible. However, the Commonwealth and State/Territory government laboratories have a primary responsibility to be called upon to investigate and test for such diseases during an outbreak situation. In some situations, NATA accredited Australian based private animal health laboratories may be engaged by respective governments to undertake such investigation and testing.

As such, proactive measures must be in place to allow for the accreditation of testing activities that are required quickly in response to an outbreak situation.

The testing utilised in such situations will be linked to already accredited competencies identified and assessed. To accommodate this, a new class of test, 20.85 "Disease Outbreak Investigation" (see Section 4) has been created, however, its use is dependent on having accreditation for other specific classes of test. This class of test recognises a facility's ability to perform 'non-routine' investigations resulting from an identified outbreak using defined and established techniques.

2. Implementation of Disease Outbreak Investigations

The use of 20.85 Disease Outbreak Investigations is only applicable if either of the following conditions are met:

- The Consultative Committee on Emergency Animal Disease (CCEAD) for an emergency animal disease is formed and a facility is required to receive submission of specimen(s) for testing for the disease during the initial investigation phase, the emergency response phase and/or the proof-of-freedom phase; or
- A facility receives submission of specimen(s) from an emergency animal disease case for testing as required by the relevant Chief Veterinary Officer(s).

Testing can no longer fall under 20.85 Disease Outbreak Investigations once:

- CCEAD declares freedom of the emergency disease nationally or in jurisdiction(s) to which the outbreak occurred (for example when zoning for proof of freedom is allowed and applied);
- CCEAD declares the eradication or control of the emergency disease is no longer feasible nationally or in jurisdiction(s) to which the facility belongs;

- the facility is no longer required by CCEAD or relevant CVOs to test specimen(s) from the emergency disease at any stage of an outbreak response.

At this stage, the validated testing will fall under the class of test for the prescribed competency, allowing continuation of accreditation following the conclusion of the outbreak investigation phase.

3. Assessment process and accreditation criteria

The assessment of a facility to perform “Disease Outbreak Investigations” is directed, in particular, towards:

- The management of the facility;
- The qualifications, experience and training of personnel who would be involved in the testing;
- The systems in place for the validation or verification of new/modified test methods;
- The procedures together with the equipment used for performing this testing; and
- The records and outcomes supporting the testing.

In addition to the requirements of ISO/IEC 17025:2005, ISO/IEC 17025 Standard Application Document (SAD) and the Veterinary Testing ISO/IEC 17025 Application Document (AD), facilities will need to comply with the requirements detailed below.

During routine reassessments, the process and procedures in place for handling disease outbreaks will be reviewed. Following an outbreak situation, the entire chain of events will be audited, including an extensive review of the scientific decision making and ongoing validations to ensure appropriateness of testing undertaken.

The clause numbers follow those of ISO/IEC 17025:2005 but since not all clause numbers require interpretation the numbering system may not be consecutive.

Management Systems

4.4 Review of request, tenders and contracts

4.4.1 Before accepting any request for disease outbreak investigations the facility must consider whether the proposed work is within its technical capabilities taking into account the instrumentation necessary and the expertise of staff available.

With each situation, the initial request may not clearly define what analyses are required and the extent of new/modified testing required. Accordingly, there will be heavy reliance on the facility’s technical expertise to determine the most suitable testing regime.

4.4.5 If the proposed testing regime requires alteration during the course of investigations, these must be appropriately documented and the customer informed of changes to the testing plan.

4.13 Control of records

4.13.2.1 Records maintained following an investigation must be sufficient to demonstrate the scientific theory behind the selection of method, including but not limited to:

- the method followed during the outbreak;
- interpretation of results;
- control measures;
- reference to literature utilised; and
- details of external expertise requested.

4.13.2.3 Any significant alteration to data must also include the reason for the change.

4.14 Internal audits

4.14.1 Critical phases of the facility's investigative testing procedures must be included in the facility's internal audit schedule.

Any investigations undertaken must be audited during the course of the outbreak at intervals relevant to the criticality of the investigations.

Technical Requirements

5.2 Personnel

5.2.1 Facility management shall appoint personnel with the responsibility to supervise investigative testing work. Such personnel shall have the necessary scientific expertise and experience to understand the uses and limitations of the procedures to a new disease agent.

Specifically, such supervisory personnel shall:

- Be responsible for the work undertaken;
- Exercise a high level of judgement regarding the testing approach to be taken and interpretation of results;
- Demonstrate experience with the testing approach adopted, including any limitations;
- Have access to current literature and up-to-date knowledge on the best approaches to test the particular disease agent (including sample types, timeframes, interferences etc); and
- Demonstrate experience in method validation, in accordance with the facility's own procedures for validation.

5.2.5 Records shall be maintained for all staff deemed competent to supervise and/or perform investigative testing.

5.4 Test and calibration methods and method validation

5.4.1 A procedure describing the approach to be taken for conducting investigative testing must be documented.

Facilities must be able to demonstrate during testing and retrospectively that the methods used were adequate and have subsequently met the relevant requirements for validation and/or verification.

Documentation for Disease Outbreak Investigation available for review post outbreak must include the following:

- Description of the test method utilised;
- Description of the sample types and handling requirements;
- Description of parameters/quantities/cut-off values etc;
- Handling of biosecurity issues, including sample handling and destruction;
- Awareness and details of possible sources or error, limitations, interferences etc;
- Quality control measures applicable to ensure the validity of results (positive and negative controls where possible)
- Criteria for the rejection of suspect results, repeat testing decisions etc;
- All required data/observations recorded;
- demonstration of continuous test validation during use in line with the Veterinary Testing AD and following the guidance of Technical Note 17 – *Guidelines for the validation and verification of quantitative and qualitative test methods*.

5.4.6 An estimation of the uncertainty of measurement shall be applied to all quantitative work undertaken, following the processing of sufficient numbers.

It is noted, however, that a rigorous evaluation may not be possible at all times, in which case a greater emphasis is placed on professional judgement to obtain a reasonable estimate.

5.9 Assuring the quality of test and calibration results

5.9.1 Positive and negative controls must be tested where available. Where these may not be available, the facility shall identify other suitable means for monitoring the reliability of results.

Where possible, facilities must participate in proficiency testing or inter-laboratory collaborations to ensure consistency in result reporting across facilities involved during a disease outbreak

5.10 Reporting the results

Where reports have been issued prior to full validation/verification studies being completed as per ISO/IEC 17025:2005, the test reports must include a statement detailing the extent of validation that has been conducted. For example:

“Due to the urgent nature of the testing required, the test used has not yet been fully validated and results should be interpreted accordingly”

4. Scope of accreditation

To ensure that all relevant stakeholders and facilities are aware of which facilities may be capable of involvement in disease outbreak investigations, the scope of accreditation will be required to reflect the competencies which may be employed during an outbreak. As previously stated, the subclasses provided will be based on already accredited subclasses and species for which the facility has been deemed competent.

Any withdrawal, cancellation or suspension of a competency will automatically result in the linked disease outbreak subclass also being withdrawn, cancelled or suspended.

Available class of testing is detailed below:

20.85 Emergency Disease Investigations

For any or all of the subclasses on the scope of accreditation (excluding 20.37 and 20.60)

5. Further Information

To apply for accreditation of disease outbreak investigations under Class of Test 20.85 or for further information, please contact your Client Manager or Lisa Bartlett, Deputy Sector Manager, Life Sciences by telephone on (03) 9274 8200 or email lisa.bartlett@nata.com.au