



Specific Accreditation Criteria Animal Health ISO/IEC 17025 Appendix

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Animal Health ISO/IEC 17025 Appendix

This appendix provides interpretative criteria and recommendations for the application of ISO/IEC 17025 in Animal Health for both applicant and accredited facilities.

Applicant and accredited facilities must also comply with ISO/IEC 17025 the NATA ISO/IEC 17025 Standard Application Document (SAD), General NATA Documents and NATA General Accreditation Criteria.

The clause numbers in this document follow those of ISO/IEC 17025 but since not all clauses require interpretation the numbering may not be consecutive.

4 Management requirements

4.1 Organisation

4.1.5 Facilities are placed into categories according to the range of testing performed and the supervision arrangements for the facility. These are:

Veterinarian Supervised Laboratory

A facility performing a comprehensive range of veterinary services, as multidiscipline or general laboratories. The diagnostic and clinical oversight is provided by an appropriately qualified and experienced veterinary pathologist and able to provide diagnoses and interpretation of results.

Scientist Supervised Laboratory

A facility performing a specialised or limited range of testing, under the supervision of a person with appropriate qualifications and expertise. Results reported by such laboratories must not include diagnoses and recommended therapies and must not contravene the relevant state Veterinary Surgeons and/or Veterinary Practices Acts.

Veterinary Practice Laboratory

A facility forming part of a veterinary practice and performing testing only for patients of the practice, under the supervision of a veterinarian.

Branch Laboratory

A facility that is an integral part of a NATA-accredited Veterinarian Supervised Laboratory apart from its geographical location. The Branch Laboratory will have a documented agreement with the Veterinarian Supervised Laboratory to ensure that the range of testing provided and the standard of work is under the direction and control of a designated veterinary pathologist or an appropriately qualified senior scientist from the accredited Veterinarian Supervised Laboratory. Diagnosis and interpretation of results from the Branch laboratory can be conducted remotely.

Staff qualifications and supervision

Refer to section 5.10.2 for pathologist definitions for the purposes of reporting
For the interpretation of supervision arrangements, the following definitions are given:

'veterinarian' means a person who is registered with a relevant State authority (e.g. holds a BVSc, BVMS or DVM).

'senior scientist' means a scientist who possesses one of the following qualifications:

- a) a Doctorate of Philosophy in a relevant discipline;
- b) a Fellowship by examination with a relevant association;
- c) a Fellowship of the Australian Institute of Medical Laboratory Scientists;
- d) a qualification and/or experience that is deemed to be the equivalent of a), b) or c) above.

and who has not less than 10 years full time experience in laboratory duties.

'scientist' means a person who possesses one of the following qualifications:

- a) a degree or diploma in applied science, medical technology or a *related field* awarded after not less than 3 years full time study, or an equivalent period of part time study, in subjects related to veterinary testing at a university or other tertiary institutions in Australia;
- b) an associate qualification conferred by the Australian Institute of Medical Technologists before 1 December 1973; or
- c) a qualification that is deemed to be the equivalent of a) or b) above.

For facilities forming part of a *veterinary practice*, the supervisor shall be a veterinarian, registered in the State in which the facility operates.

In all types of facilities, the designated person(s) in charge under whose direction and control the facility operates shall:

- approve and be responsible for operational practices and staffing of the facility;
- ensure appropriate consultation on veterinary and scientific issues;
- ensure regular review of the facility's internal quality control and proficiency testing/external quality assurance data and the methods used, and discussion of all aspects of the facility's performance with the scientific/technical staff;
- ensure that veterinary, scientific and technical staff participate in continuing education;
- ensure the continuity of overall supervision in situations where the supervision is provided by more than one person; and
- ensure that work performed at the facility outside normal working hours is carried out by scientific or technical staff approved to do so by the designated supervisor, having regard to their training and experience.

Veterinarian Supervised Laboratories

There shall be at least one veterinary pathologist working within the laboratory. This supervising pathologist must be registered in the State in which the facility operates, have at least 5 years' experience in a diagnostic facility and shall have at least one of the following:

- membership of the Australian College of Veterinary Scientists in a relevant discipline (or equivalent);

- specialist registration by the state/territory in which the facility operates;
- a higher degree in a relevant discipline;
- a Doctorate of Philosophy in a relevant discipline;
- a Fellowship by examination with a relevant association.

This person shall provide on-site clinical oversight for the testing for which the facility is accredited.

For a *Veterinarian Supervised Laboratory* the technical control of the testing must be provided by either a veterinary pathologist or senior scientist with appropriate qualifications and experience whom must be present during normal working hours, and be available for telephone consultation at other times.

The diagnostic and clinical oversight of a *Veterinarian Supervised Laboratory* must be provided by at least one on-site veterinary pathologist. The veterinary pathologist must be present for consultation during normal working hours of the laboratory.

Where a pathologist is absent from the laboratory for short periods of time (up to seven consecutive days), they must be contactable. This includes:

- Pathologist is providing supervisory visits to a related Branch laboratory;
- absences for professional purposes;
- illness or personal necessity.

Alternative on-site arrangements must be implemented for longer absences.

Branch Laboratories

On-site staff will include a supervising scientist with qualifications and experience relevant to the facility's operation. Such qualifications and experience would normally be a Science or Applied Science degree in a relevant discipline and a minimum of two years supervised experience. The on-site supervising scientist must be present at the facility during normal working hours. Where more than one scientist provides the supervision, a designated scientist must ensure overall on-site scientific supervision. The adequacy of these arrangements will be reviewed at the assessment.

For a *Branch Laboratory* the designated supervising veterinary pathologist or senior scientist employed by the *Veterinarian Supervised Laboratory*, under whose direction and control the *Branch Laboratory* operates, shall be responsible for ensuring control over the rendering of services, including overseeing of electronic supervision and on-site visits. The following aspects must also be met:

- An integrated internal quality assurance system must be in place between the *Veterinarian Supervised Laboratory* and the *Branch Laboratory*.
- The minimum requirements for electronic supervision and/or off-site reporting by veterinary pathologists are:
 - Electronic (computer, facsimile or other) and/or telephone access to the facility;

- Documented involvement and participation in relevant proficiency testing programs;
- Access to all relevant information including case records;
- Regular participation in continuing education activities.

Off-site pathologists may be contacted by the assessment team during on-site visits to discuss their involvement in the facility.

Where the minimum requirement for electronic supervision is met, veterinarians or scientists from the *Veterinarian Supervised Laboratory* must spend at least 10 full time equivalent days per year at the *Branch Laboratory*. When a scientist(s) from the *Branch Veterinary Laboratory* spends time in supervised training or professional development in the *Veterinarian Supervised Laboratory*, the time spent may be offset against the aforementioned supervisory requirements, up to a maximum of five days per year. Teleconferences or videoconferencing may also be conducted between the *Veterinarian Supervised Laboratory* and the *Branch Veterinary Laboratory* and the time spent may be offset against the aforementioned supervisory requirements, up to a maximum of two days per year.

- Where the minimum requirement for electronic supervision is not met, veterinarians or scientists from the *Veterinarian Supervised Laboratory* must spend at least 50 full time equivalent days per year at the *Branch Laboratory*. When a scientist(s) from the *Branch Laboratory* spends time in supervised training or professional development in the *Veterinarian Supervised Laboratory* the time spent may be offset against the aforementioned supervisory requirements, up to a maximum of 20 days per year.
- External quality assurance must be reviewed and counter signed by a veterinarian or senior scientist in the *Veterinarian Supervised Laboratory*
- A veterinarian or scientist must be available for telephone consultation or equivalent when not personally in attendance at the facility.
- Work performed in the *Branch Veterinary Laboratory* outside normal working hours must be carried out by scientific or technical staff approved to do so by the veterinarian or senior scientist, having regard for their training and experience.
- Supervisory visits must have appropriate technical content and interaction with facility staff. Appropriate supervisory activities may include:
 - General technical discussion;
 - Continuing education sessions; and
 - Internal audits performed by scientific staff with an appropriate technical background.

Records must be kept of attendance by the supervising veterinarian or scientist at the *Branch Veterinary Laboratory*. Sufficient detail should be included to identify the activities undertaken at the visit. Records must also be kept of any supervised training or professional development at the *Veterinarian Supervised Laboratory*.

Scientist Supervised Laboratories

The supervisor shall be appropriately qualified and experienced in the testing performed at the facility. This person must satisfy the requirements for a senior scientist.

For a *Scientist Supervised Laboratory* the supervisor will usually be present during normal working hours unless there are veterinary, scientific or technical support staff approved by the supervisor, whose qualifications and experience are adequate for the work performed at the facility. Where such support staff are available, the supervisor shall maintain regular contact with the facility and be available for consultation at all times.

Veterinary Practice Laboratory

The veterinarian shall be responsible for the proper performance of tests. The veterinarian will usually be present while the testing is being performed. The veterinarian must have a working knowledge of each test procedure and be involved in the resolution of problems encountered with the facility work.

4.5 Subcontracting of tests and calibrations

Specimen referral

Relevant packaging regulations (e.g. IATA) must be considered and staff appropriately trained when referring samples to other facilities, including those within the same organisation.

A record must be kept of specimens referred for testing to other facilities.

If the facility is responsible for ensuring that results of referred tests reach the submitter, records must also be kept of the return of results. There must be a procedure for following-up results which have not been received.

4.5.2 Collection instructions, price lists, facility handbooks, etc. would normally be considered sufficient notification to customers of the referral arrangements.

4.6 Purchasing services and supplies

4.6.2

Media

For requirements relating to media preparation and quality control, refer to NATA's *Quality Control of Prepared Media and Media Preparation*.

Virology

ASM recommends that commercial suppliers of viral culture media be NATA accredited. Facilities should therefore purchase culture media from NATA accredited suppliers.

Kits

Quality Control (QC) must be performed on microbiological identification kits (e.g. API) using relevant test organisms from a recognised type culture. QC must be performed on commencing the use of a batch of kits with a new production lot number, using one or more of the strains of organism recommended by the manufacturer (preferably in rotation).

Consumables

Records must be kept of the date of receipt and/or date of initial use of consumables, including diagnostic reagents. Items must be stored in accordance with the manufacturer's recommendations and should be discarded on the expiry date. Consumables used beyond the manufacturer's expiry date must be validated routinely prior to each use. The onus is on the facility to prove that reagents used beyond the manufacturer's recommended date do not adversely affect the outcome of the test.

Reagents and solutions

Details of the preparation of all types of standard solutions and reagents must be recorded. These records must include:

- Ingredients, including manufacturer and manufacturer's batch number (where applicable) and quantities used;
- Date of preparation;
- Identity of the preparer;
- Date of expiry; and
- Safety precautions and/or handling instructions, where relevant.

Further, reagent containers must also be labelled appropriately.

4.7 Service to the customer

4.7.2 Feedback from customers may be sought in a number of ways. This may include but not be limited to customer satisfaction surveys, websites, newsletters, review of test or calibration reports with customers, etc.

5 Technical requirements

5.2 Personnel

5.2.1 Where staff are expected to work in areas, or at times other than those in which they would normally work, (e.g. when relieving other staff or working on a weekend) a program of regular refresher training must be established and records retained.

Staff who work only 'out-of-hours' must have regular contact with routine staff and in particular, supervisory staff. As a guide, one day per month spent in the facility during normal working hours would be appropriate.

The time allocated should, however, be sufficient for the staff member to update all skills required for the out-of-hours service. Records of the above must be available to the assessment team and be sufficiently detailed to demonstrate competence.

5.2.2 Adequate opportunity for continuing education must be provided for all staff. Any education program must include in-house and external components and there must be access to appropriate reference texts and journals.

Components of in-house education may include:

- regular educational presentations
- journal article reviews

- case presentations
- review of proficiency testing educational material
- review of interesting/abnormal blood films, cultures, etc.

Components of external continuing education may include membership of relevant professional societies and attendance at meetings, conferences and workshops. Such attendance must be documented.

5.2.5 Training records must be maintained for all personnel. Such records must include details and dates of:

- relevant academic qualifications;
- participation in the facility's training program;
- Evidence of ongoing competence to carry out assigned work;
- in-house and external training courses undertaken;
- conferences, seminars, workshops etc. attended; and
- relevant publications.

Records must be sufficiently detailed to indicate competence in individual tests.

Proof of qualifications, membership of professional societies and hours of attendance at the facility may be requested as part of the assessment process.

5.3 Accommodation and environmental conditions

Consideration must be given to separating procedures from the main work area where:

- a) these procedures may pose a hazard to other staff (e.g. tests using radioactive isotopes, mycobacteriology);
- b) these procedures may be affected or influenced by not being segregated (e.g. tissue culture);
- c) where a quiet and uninterrupted work environment is required (e.g. microscopy).

Where possible, there should be a clear delineation of 'clean areas', (i.e. areas used for clerical aspects of facility work) and 'dirty' areas, (i.e. areas used for testing procedures).

The design of workbenches, cupboards and shelves, and the finish of all surfaces (benches, floors, ceilings, walls and windows) must facilitate cleaning and sanitation. High standards of housekeeping are essential.

Molecular Testing

Samples of DNA must be separated from PCR product by physical separation and laboratory practice. Separate equipment must be used for each.

Quality control procedures must be in place to monitor any contamination that may occur.

The former Sub-committee on Animal Health Laboratory Standards (SCAHLs) established standards and guidelines for facilities performing nucleic acid detection. The standards included in the former SCAHLs document, *Veterinary*

Laboratory Guidelines for Nucleic Acid Detection Techniques, will be applied as accreditation criteria.

Safety

A Safety Manual detailing the facility's policies and procedures in relation to health and safety must be readily available to all staff.

The NATA assessment process emphasises the importance of safe laboratory practice but the review of safety during an assessment visit does not constitute a formal safety audit.

5.4 Test and calibration methods and method validation

5.4.1 General

Methods manuals

Some manufacturers provide method documentation (kit inserts) for their validated methods with their product and these may be used as the facility's procedure. These must be authorised as per the facility's document control procedures. Where this information is not sufficiently detailed to cover all required elements, it must be supplemented by the facility.

Inserts for new batches received must be checked for changes in procedure and a copy of the new insert retained and accessible. A record of the check must be available, for example by signing and dating the insert.

Reference intervals

It may be necessary for facilities to establish their own reference intervals by statistically valid means. Alternatively, use can be made of published reference intervals. These should, however, be validated for use with the facility's own species population and methods.

Where appropriate, species, age, gender and other relevant information must be considered when establishing reference intervals.

The source of reference intervals must be documented.

Changes in reference intervals must be documented in the same manner as changes in procedures. Where such changes could result in a different interpretation of test results, these must be communicated to users of the facility service in the same manner as other significant changes.

5.4.2 Selection of methods

Facilities should use *Australian and New Zealand Standard Diagnostic Procedures* where appropriate and available. Facilities may be required to use other standard methods. For example, for export testing, the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* may be specified.

It is not required that standard methods or those published in peer reviewed journals for example, be validated. Such methods shall, however, be verified by the facility to demonstrate that they can operate them within their intended use.

Emergency Animal Disease outbreak investigations

In Australia, the Consultative Committee on Emergency Animal Disease (CCEAD) coordinates the national, technical response to emergency animal disease incidents of animal health, public health or trade significance.

The response to an emergency animal disease outbreak will usually include testing to identify the causative agent and/or detect the host response. NATA recognises that:

- due to the exotic or emerging nature of some diseases, accredited testing facilities may not be able to immediately include testing for their causative agents or host response under their Scope of Accreditation;
- the success of an outbreak response relies on the development of a suitable test method, especially for screening/surveillance purpose, in a relatively short timeframe;
- the urgent need for test data is likely to result in test methods being used prior to the completion of validation;
- test methods are reviewed/recommended favourably by Australian (or as needed overseas) expert diagnosticians through CCEAD or its laboratory network before use;
- test methods may be adopted for use by affected state/territory laboratories, and hence the validation process can be achieved collectively, through cooperation and inter-laboratory comparisons within the CCEAD laboratory network; and
- members of CCEAD are the customer of laboratory testing services during an outbreak response.

The urgent need for the use of a method does not preclude the completion of the validation study in a timely manner and records maintained following an investigation must be sufficient to demonstrate the scientific theory behind the selection of the method, including but not limited to:

- the method followed during the outbreak;
- validation data;
- interpretation of results;
- quality control measures;
- reference to literature utilised;
- details of external expertise requested;
- equivalence data with existing methods.

Documentation for disease outbreak investigations available for review by NATA 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 of possible sources of 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;
- Demonstration of continuous test validation in line with the requirements of this appendix and following the guidance of NATA's *Validation and verification of quantitative and qualitative test methods*.

Recognition of the competency of a facility to undertake testing as part of an emergency animal disease outbreak is limited to those facilities that are part of the Laboratories for Emergency Animal Disease Diagnosis and Response (LEADDR) network. Recognition of the competency of a facility will be based on the facility's demonstrated competencies as described in the Scope of Accreditation current at the time of the outbreak. In doing so, NATA recognises the competency of the facility to undertake testing similar to that requested by the CCEAD and the NATA endorsement can be applied to these results based on the recognition of competency. Where the full validation of the test method has not been completed, test reports must contain the following statement:

'This assay has not been fully validated and results should be interpreted on this basis. Performance of this assay is to serve the relevant Consultative Committee on Emergency Animal Disease in Australia only'.

5.4.3 Laboratory-developed methods

Methods must be documented in a manner that provides clear instructions to an operator and does not allow for difference in interpretation of procedural steps.

5.4.5 Validation of methods

The facility must ensure that methods in use have been appropriately validated for the range of animals (or animal specimens) routinely being tested.

Reference to NATA's *Validation and verification of quantitative and qualitative test methods* is recommended in formulating procedures for validation. Guidance on method validation for serological and nucleic acid testing is also available from the former SCAHLS. Tests approved by the former SCHALS are considered to be standard methods as described under 5.4.2 and method verification only would be required on-site.

5.4.5.3 Facilities must ensure that validation includes review of method performance. This should include the following:

- fitness for intended purpose(s)
- optimisation

- standardisation
- robustness
- repeatability
- analytical sensitivity
- analytical specificity
- threshold/cut-offs
- diagnostic sensitivity
- diagnostic specificity
- reproducibility
- ruggedness

5.4.6 Estimation of uncertainty of measurement

Estimation of uncertainty of measurement only applies to quantitative tests. This includes those tests where a numerical value is reported as a qualitative result, such as serological assays with a 'cut off' value where the numerical result is reported as detected or not detected. In estimating the measurement uncertainty, the facility needs to consider those components under its control. For example, if the facility is not involved in the taking of the sample then it does not have to estimate the measurement uncertainty of this process. It should, however, be clear what components have been included in the uncertainty estimation.

Where results of tests are not numerical (e.g. pass/fail, positive/negative, detected/not detected or other qualitative data) estimates of uncertainty or other variability estimates will not be required. This should not however preclude the facility from developing an understanding of the components that contribute significantly to the variability of the results.

The approach used to estimate uncertainties (including data and calculations) must be recorded and retained so that it is available upon request from a customer, and for review at assessment.

Facilities must identify those tests for which uncertainty of measurement is to be reported and document a protocol for reporting it. It should, however, be noted that relevant data and uncertainty of measurement estimations must also be available for all quantitative test results generated by the facility even if the uncertainty of measurement is not to be reported.

5.6 Measurement traceability

Microbiological culture collection management

Refer to NATA's *Maintenance of Microbiological Reference Culture Collections (MRCC)*.

5.7 Sampling

Specimen collection

Where specimen collection is outside the control of the facility, the collectors must be informed of the facility's collection requirements. For example:

- containers/tubes required for each test;
- amount of specimen required;
- 'order of draw' for multi-sampling vacuum tubes;
- labelling requirements;
- specimen storage requirements (e.g. room temperature vs refrigeration);
- specimen transport requirements;
- requirements with respect to request forms;
- provision of relevant clinical information.

These requirements must be documented.

In general, specimen containers should not be pre-labelled.

Consumables provided by the facility or used in the facility, in particular tubes containing additives, must be monitored for expiry dates.

5.8 Handling of test and calibration items

5.8.1 Specimen reception

Documented reception procedures must be available to cover the following but not be limited to:

- a) criteria for acceptance/rejection of unsuitable specimens (e.g. containers leaking or broken, specimens collected into wrong containers, specimens unsuitable for the examination requested, inadequately-labelled specimen containers etc.);
- b) action to be taken in the event that an unsuitable specimen is received;
and
- c) procedures for handling urgent specimens.

The date, and if relevant, the time of receipt of specimens at the facility, must be recorded.

Specimens and associated sub-samples and records (worksheets, slides, etc.) must be uniquely identified during all stages of testing, for example, by using a laboratory numbering system.

Transport of specimens

Sample containers must be leak-proof and impervious to contamination during transport. When temperature or other environmental tolerances are specified in test methods, these must be provided to the submitter and must be satisfied during transport and storage.

Specimen referral

Refer to section 4.5 Subcontracting of tests and calibrations.

5.8.2 Specimen labelling requirements

Each specimen container must be labelled with the animal name or other unique identification. Where confusion with another specimen from the same

animal is possible, the container must also be labelled with the type of specimen.

For survey testing, each specimen container must be individually labelled, but need not identify an individual animal.

Note: It is recommended that the date of collection be recorded on the specimen container.

For specimens submitted on glass slides (e.g. cytology and blood films) the required identification must be on the slide itself. The request form received with each specimen (or batch of specimens) is required to provide additional information than the specimen container itself. The required details are:

- animal name or other unique identification;
- name of owner (or representative);
- date of collection;
- type of specimen.

For survey testing, each individual animal need not be identified, but the location where the specimens were collected must be provided (e.g. property name or geographical region).

5.8.3 Where inadequately labelled specimens are received, the facility must assure itself of the identity of the specimen. Where the identity of the specimen cannot be assured and a recollection would be possible, testing should not proceed on the initial specimen.

If specimens that do not meet minimum acceptability criteria are accepted and tested, a record must be kept of the problem and any subsequent action taken. A comment on the unsuitable specimen must be included on test reports (see 5.10.2m).

Upon receipt into the facility, the traceability of batches of samples (e.g. in the case of survey testing) must be ensured and be readily linked to the original submission and assigned accession number where individual labeling is not employed.

5.8.4 Sample preparation

In testing situations where the pooling of samples is considered acceptable practice, the facility must follow a predefined and documented protocol. Any changes to the protocol must be validated and records of the validation kept.

Specimen retention

For viral and cell cultures, inoculated and uninoculated cell cultures must be stored separately.

Unless indicated otherwise, sample containers should be stored under appropriate conditions for 7 days from the date of receipt of the sample or for three days after the issue of the test report, whichever is considered most appropriate. It is assumed that these timelines will be sufficient for the referring veterinarian to review the test report and, if necessary, confirm the identity of the sample with the facility.

The following minimum retention times for specimens are provided for guidance:

Haematology	
Samples of blood, serum, plasma	7 days
Blood film	60 days
Biochemistry	
Samples of serum, plasma, and other body fluids	7 days
Immunology	
Samples of material examined	7 days
Serology	
Samples of material examined	7 days
Microbiology	
Cultures and stained slides	7 days
Swabs, specimens or other material examined	7 days
Parasitology	
Samples of material examined	7 days
Histology*	
Slides	3 years
Blocks	10 years
Unblocked, fixed tissue	30 days
Containers with no residual tissue	Where all of the submitted sample/tissue has been consumed in the testing, a record noting this should be kept.
Cytology	
Slides	3 years
Necropsy	There is no requirement for the retention of fresh tissue after sample collection
Molecular Testing	
Extracted nucleic acid	7 days
Certification and other regulatory testing.	30 days
For samples where retesting and/or referral is likely	30 days

* It is acknowledged that histology specimens can provide a valuable historical resource and facilities are encouraged to retain such specimens for as long as possible.

5.9 Assuring the quality of test and calibration results

General

Many factors will influence the frequency with which quality control is performed. The QC protocol must take into account these factors and be such that the facility has confidence in the results issued. The adequacy of quality control procedures will be reviewed at assessment.

The QC material used must cover the analytical concentrations encountered. Low/normal/high, normal/abnormal, positive/negative, reactive/non-reactive controls, as appropriate for the test and species.

Where appropriate, the use of control material that has a value close to the assay cut-off should be considered (e.g. serology testing).

Where calibration of an assay is required, appropriate material must be used as a calibrator. If the material selected is not intended for use as a calibrator, ascribed calibration values must be traceable.

Acceptable ranges must be defined for internal quality control material.

A protocol for action to be taken where QC results fall outside acceptable ranges must be documented. This must include consideration as to whether test results should be withheld and whether previously issued results should be recalled.

Unless otherwise specified in the manufacturer's instructions, QC material must be analysed for each test on each day of testing and at each change of prepared reagent/reagent batch.

Internal quality control results must be recorded. Primary quality control data (e.g. instrument printouts, original worknotes) must be retained for at least 3 years to allow retrospective review. The facility must have a system of long-term monitoring of quality control results to assess method performance.

Graphical presentation of numerical quality control results will assist the early detection of trends.

Details of action taken on unacceptable results must be recorded.

Infrequently performed tests/techniques

Where a facility wishes to include infrequently performed tests and/or animal groups on their Scope of Accreditation, the onus is on the facility to demonstrate ongoing competence for these tests. This should include participation by all relevant staff in scheduled internal replicate testing programs at a frequency relevant to the testing complexities and competencies involved, satisfactory participation in available proficiency testing programs and other supplementary activities to maintain operator skills. Records of participation and the results of these activities must be kept and be available for review at assessment.

Microbiology

An appropriate range of organisms from reliable sources must be held. The stock of organisms must be maintained under appropriate long-term storage conditions (refer to NATA's *Maintenance of Microbiological Reference Culture Collections* for full requirements).

These organisms would be used to quality control:

- anti-microbial susceptibility testing
- media
- identification tests/kits
- antigen or toxin production
- incubation chambers (e.g. anaerobic jars)

A quality control program must be established for identification tests/kits.

Quality control of anti-microbial susceptibility testing must be performed in accordance with the documented method. Departures from the standard method must be validated.

Zone sizes for QC results must be recorded numerically (i.e. in millimetres).

Media

Refer to NATA's *Quality Control of Prepared Media and Media Preparation* for requirements regarding microbiological and virology media.

Haematology

A multi-level control must be run at least once on each day of testing on automated cell counters, taking into account open and closed modes. There must also be a means of monitoring drift.

Where appropriate, coagulation quality control must include normal and abnormal controls at least once on each day testing is performed.

Histopathology

Control slides must be prepared and examined when using special stains.

Control slides must be retained so that they can be retrospectively linked to the patient's slides to which they pertain.

The identification of specimens must be secure through all stages of processing.

Procedures that may be employed to minimise the risk of specimen mix-up include:

- checking of stained sections against the corresponding block prior to reporting;
- checking slides and blocks against the details on the request form prior to reporting;
- handling one case at a time (e.g. at microtomy);
- labelling cassettes and slides for one case at a time.

Chemical pathology

Where possible, control material must be matrix matched (e.g. urine-based controls should be used for assays of urine analytes).

It must be ensured that means and standard deviations supplied by manufacturers of quality control material provide adequate control of assays. The facility should determine the mean and standard deviation using its own data to maintain a tighter control.

Immunology

A positive and negative reaction must be demonstrated as a minimum on every immunofluorescent run and as an optimum on every immunofluorescence slide. Optimally borderline positive controls and/or controls titring to a known end point should be used.

Note: Facilities are able to demonstrate these reactions using either controls or sample specimens.

Reactive controls with defined immunofluorescence patterns for the antibodies under investigation must be tested as a minimum on every new batch of slides. Optimally they should be tested on every run.

Note: Once the specificities detected by the substrate have been confirmed and the slides are stored under monitored correct conditions, and are within expiry date, it is not essential to repeat for every run.

As a minimum, the appropriate working concentration of each new batch of fluorescein labelled immunoglobulin conjugate must be determined by checkerboard titration with each different substrate with which it will be used. Optimally, this should be performed for every new batch of individual substrate.

Note: If using commercial kits this should have already been done by the manufacturer. If conjugates and slides are purchased separately from the same manufacturer, the assay would still need to be validated. If using conjugate from one manufacturer and slides from another or in-house slides, then the conjugate will need to be optimised for individual substrates.

Serology

Appropriate controls must be tested with each run. Optimally, non-kit controls (including a low/weak positive control) should be included to monitor performance over time, and to enable the determination of inter-lot batch variation. Appropriate negative and positive controls/samples must be included on each ELISA plate.

Virus identification

When identifying virus, appropriate positive and negative controls must be included, where available

Facilities should use standard reference sera or reagents for virus identification.

Proficiency testing

NATA's *Proficiency Testing* requires each applicant or accredited facility to participate in appropriate proficiency testing where available.

The terms proficiency testing (PT) and quality assurance programs (QAP) can be used interchangeably.

1. Participation

Where a veterinary specific proficiency testing program/s is/are available and applicable to the testing conducted by the facility, participation is mandatory. The frequency of participation shall be in accordance with the PT provider's schedule and all rounds are required to be completed.

When considering the applicability of a PT program, consideration should be given to such issues as species specificity, Australian based, etc. Where a program is determined relevant then participation shall be required as noted above.

When no PT is available to meet requirements, the facility must investigate alternative means for assuring the quality of test results generated (as highlighted in section 5.9.1 of ISO/IEC 17025:2005), for example, sample exchange programs with other facilities, replicate testing, etc.

Known PT providers are currently listed on the NATA website www.nata.com.au under “NATA Proficiency Testing Directory”

Facilities should consider the accreditation status of PT providers and are advised to choose accredited providers where possible.

2. Performance

On receipt of results from the program organisers, it must be ensured that:

- a) proficiency testing performance is reviewed and discussed by the veterinarian (or senior scientist for scientist supervised facilities) providing technical control, and all relevant scientific/technical staff;
- b) there is documentation that the review has taken place;
- c) unsatisfactory results and other deficiencies identified by the programs are addressed, with any action taken documented and acceptance of apparent poor performance substantiated; and
- d) the implication of unsatisfactory PT performance to diagnostic test results is considered and a record of the considerations and action taken is kept.

A facility's performance in proficiency testing will be assessed on-site during assessments and surveillance visits. Evidence of review of returned results and any corrective action taken in response to outliers is also required to be available and will be reviewed by the NATA assessment team.

NATA may contemporaneously review a facility's PT performance at the time of release of the results by the PT provider in specific cases e.g. during the investigation of a complaint.

As far as practicable, proficiency testing samples must be treated in the same way as diagnostic test samples. Additionally, consideration should be given to ensuring that all staff (including part-time and evening staff) involved in testing have an opportunity to test proficiency samples.

5.10 Reporting the results

5.10.2 Test reports

In addition to ISO/IEC 17025, reports must include:

- a) specimen receipt and collection date and, where necessary for the interpretation of test results, the time of collection;
- b) source of specimen/type of specimen, where this information significantly affects the test result;
- c) unique patient identification;

- d) date of testing (where this is different to the specimen receipt date and may significantly affect the interpretation of the results);
- e) reference intervals (where appropriate);
- f) test method/technique, where this information significantly affects the test result;
- g) where necessary, comments on inadequacy of specimens.

There may be statutory requirements for additional information to be included on test reports.

Where testing has been conducted on animals (or animal samples) outside of the method validation, details of these limitations must be included on the test report, for example, 'This test has not be validated for xxx species'.

Authorised results may be telephoned to a customer. If a result is conveyed verbally, then a record must be kept of the time and date of issuing the result, recipient of the result and the reporting staff member. It must be clear what results have been conveyed verbally. The facility must have a documented protocol for the handling of telephone enquiries, taking into account the information being requested (e.g. test results, interpretation of results).

The use of photographic, electronic and mechanical means of reproduction of signatures or names of reporting staff members is allowed.

A protocol must be in place to demonstrate that the reporting staff member authorised the test report at the time of its issue, e.g. by use of password protected templates.

Refer to section 4.1.5 for supervision arrangements and qualifications

Automated release of test results

Automated release of test results refers to the reporting of results using an automated process whereby test results falling within predetermined reference ranges are reported to the client without result/report review by a Veterinary Pathologist or Veterinary Scientist.

Automated reporting is limited to clinical chemistry and haematology where interpretation of the results by a Veterinary Scientist or Veterinary Pathologist is not required.

The following criteria must be met before an applicant or accredited facility can issue results using an automated process.

A procedure must be available detailing how the automated process works including the tests to which this applies. This process must be authorised by a Veterinary Pathologist or Veterinary Scientist depending on the category of the facility and must include:

- Only results falling within species specific alert or normal reference intervals can be reported automatically;
- Where flags or alerts are generated the result(s) must be quarantined and referred to an authorised staff member for follow up;
- Species specific reference ranges must be reported with the result(s);

- Reports generated using an automated reporting process must be identified as such by including text such as:
“These results have been generated by an automated process approved by (name of Veterinary Pathologist/Veterinary Scientist). All results are within normal limits for the species, therefore not referred to a pathologist for comment. Any questions, or for further discussion please contact laboratory”.

The procedure must include a process for the rapid suspension of automated selection and reporting.

Validation of the automated reporting process must include:

- Evidence that results exceeding the alert levels are identified and trigger the escalation process for review;
- Reports generated are legible and without transcription errors and delivered to the person/persons authorised to receive them.

Where interim reports are generated automatically a final report must also be produced and forwarded to the person/persons authorised to receive it.

Definition of a Veterinary Pathologist

The following standardised terms, defined in conjunction with NATA’s Veterinary Testing AAC and in consultation with other relevant veterinary authorities, should be used on test reports to purvey a person’s qualifications and their role in reporting results. Please note that the term pathologist is interchangeable with virologist, parasitologist, etc. and should reflect the person’s field of qualifications, training and expertise which will be reviewed during on-site assessments. Individuals in training such as interns, residents, etc. would be expected to undertake and document training for a period of six months in the respective disciplines of their facility prior to issuing test reports in isolation and use an appropriate title and have appropriate supervision until relevant qualifications are obtained.

The use of these terms is optional, however, each facility shall ensure that the ‘function or role’ of the reporting staff member is evident on test reports.

Veterinary Pathologist - Registered Specialist

A veterinarian with or without post graduate qualifications in the field of veterinary pathology who holds registration as a veterinary specialist by the Veterinary Surgeons Board. Examples of post graduate qualifications include Fellowship of the Australian and New Zealand College of Veterinary Scientists, Fellowship of the European College of Veterinary Pathologists or Diplomate of the American College of Veterinary Pathologists.

Note: In the above and following definitions, the terms pathology and pathologist may be interchanged for any of the following as appropriate:
microbiology/microbiologist, virology/virologist, immunology/immunologist, parasitology/parasitologist, toxicology/toxicologist, clinical pathology/clinical pathologist, anatomical pathology/anatomical pathologist and/or fish pathology/fish pathologist.

Veterinary Pathologist

A veterinarian who has completed an approved graduate education program in veterinary pathology and/or completed a post graduate examination process by an appropriate examining body, such as Membership of the Australian and New Zealand College of Veterinary Scientists.

Note: Examples of post graduate qualification could also include a higher degree or doctorate of philosophy in a relevant discipline with demonstrated experience in diagnostic techniques.

Note: Individuals who do not possess relevant post graduation qualifications but have demonstrated and related experience may be 'grandfathered'.

Veterinary Pathology Intern

A veterinarian who is in a veterinary pathology training program with the goal to becoming a Veterinary Pathologist.

Note: The term intern also includes the positions of resident, registrar or trainee.

Veterinary Pathology Diagnostician

A veterinarian with experience in veterinary pathology but without the formal qualifications of a Veterinary Pathologist. This term could also be used for relief or locum veterinarians.

Aquatic Diagnostician

A veterinary pathologist with a special interest in fish pathology who has satisfactorily completed the ANZCVSc Aquatic Animal Chapter examinations or equivalent course of research post graduate qualification that included a large component of aquatic animal pathology.

OR

A non-veterinarian who has completed an approved graduate education program in fish pathology and has completed a minimum of three years professional level full-time fish health work experience including a substantial pathology/histopathology component; and is authorised to make a diagnosis under the relevant state legislation in the jurisdiction in which the facility operates.

Note: Examples of post graduate qualification could include a higher degree or doctorate of philosophy in a relevant discipline with demonstrated experience in diagnostic techniques. Three years full-time work experience (minimum 0.75 FTE) is in line with the requirements of the American Fisheries Society (who register both veterinary and non-veterinary people as 'fish pathologists' after examination).

Issue of test results by non-veterinarians

Suitable members of staff, other than registered veterinarians, may issue test results for specific services. A list shall be maintained of such members of staff and the services for which they may issue test results. It is desirable that such persons have relevant experience and postgraduate qualifications or equivalent. However, where diagnosis is required, the test results must be issued by a registered veterinarian.

The suitability of these arrangements will be evaluated at assessment.

5.10.5 Opinions and interpretations

When opinions and interpretations are included in test reports, they must be in accordance with Commonwealth and State regulations.

Any person providing diagnoses shall be a registered veterinarian in the State in which the facility operates.

Organisations engaged in testing performed on human specimens may not include any opinions or interpretations on test reports for the purposes of diagnosis, treatment or monitoring of a patient. Where opinions or interpretations are to be reported, accreditation against ISO 15189 in the field of Medical Testing is to be sought.

5.10.6 Testing and calibration results obtained from sub-contractors

Where testing is performed within an accredited facility group, the group must be able to establish the facility in which testing was performed.

Note: A 'facility group' is defined as a group of facilities operating under the same parent company and/or the same corporate accreditation number.

References

This section lists publications referenced in this document. The year of publication is not included as it is expected that only current versions of the references shall be used.

Australian Standards

AS 2929 Test methods-Guide to the format, style and content

NATA Publications

General Accreditation Criteria: *Proficiency Testing*

General Accreditation Criteria: *Maintenance of Microbiological Reference Culture Collections (MRCC)*

General Accreditation Criteria: *Quality Control of Prepared Media and Media Preparation*

General Accreditation Guidance: *Validation and Verification of Quantitative and Qualitative Test Methods*

Other Publications

CLSI M2-A9 *Performance standards for antimicrobial disk susceptibility tests; Approved standard* 9th Edition 2006

IATA *Dangerous Goods Regulations* 51th edition, 2010

Former Subcommittee of Animal Health Laboratory Standards (SCAHLs) *Veterinary Laboratory Guidelines for Nucleic Acid Detection Techniques*.

World Organisation for Animal Health, *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, Paris, 2008*

Guidance documents covering the implementation of specific accreditation requirements are also available from the ILAC (www.ilac.org) and APLAC (www.aplac.org) websites.

Information on standard procedures (ANZSDP) and other areas that may be of interest to the veterinary testing laboratory may be accessed through the [Animal Health Laboratories](http://www.animalhealthlaboratories.gov.au) website of the Department of Agriculture and Water Resources
<http://www.agriculture.gov.au/animal/health/laboratories>

Amendment Table

The table below provides a summary of changes made to the document with this issue.

AMENDMENT TABLE	
Section or Clause	Amendment
New document	<p>This document represents a direct adoption of the former Veterinary Testing ISO/IEC 17025 Application Document.</p> <p>The document has been reviewed and updated to reflect the new accreditation criteria documentation structure.</p>