



Specific Accreditation Criteria

ISO/IEC 17025 Application Document Animal Health - Appendix

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Specific Accreditation Criteria: Animal Health ISO/IEC 17025 Appendix

Purpose

In addition to the *ISO/IEC 17025 Standard Application Document (SAD)*, this document provides interpretative criteria and recommendations for Animal Health testing for both applicant and accredited facilities.

Facilities must comply with all relevant documents in the NATA Accreditation Criteria (NAC) package for Animal Health (refer to *NATA Procedures for Accreditation*).

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.

5 Structural requirements

5.5 For the interpretation of supervision arrangements, the following definitions apply:

Position	Definition
Veterinarian	means a person who is registered with a relevant State/Territory authority (e.g. holds a BVSc, BVMS or DVM).
Senior scientist	means a scientist who possesses one of the following qualifications: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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.

Facilities are categorised according to the range of testing performed and their supervision arrangements. These categories are:

Laboratory category	Services provided
Veterinarian Supervised Laboratory:	<p>A facility performing a comprehensive range of veterinary services, as multidiscipline or general laboratories.</p> <p>The diagnostic and clinical oversight is provided by an appropriately qualified and experienced veterinary pathologist or veterinarian (hereafter the supervising veterinarian) who can ensure the provision of accurate diagnoses and interpretation of results.</p>
Scientist Supervised Laboratory:	<p>A facility performing a specialised or limited range of testing, under the supervision of a person with appropriate qualifications and expertise.</p> <p>Results reported by such facilities must not include diagnoses and recommended therapies and must not contravene the relevant State/Territory Veterinary Surgeons and/or Veterinary Practices Acts.</p>
Veterinary Practice Laboratory:	<p>A facility forming part of a veterinary practice and performing testing only for patients of the practice, under the supervision of a veterinarian.</p>
Branch Laboratory:	<p>A facility that is an integral part of a <i>Veterinarian Supervised Laboratory</i> apart from its geographical location.</p> <p>A Branch Laboratory will have a documented agreement with the <i>Veterinarian Supervised Laboratory</i> 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 <i>Veterinarian Supervised Laboratory</i>.</p> <p>Diagnosis and interpretation of results from the <i>Branch laboratory</i> can be conducted remotely.</p>

Person in-charge

For facilities forming part of a veterinary practice, the supervisor shall be a veterinarian, registered in the State or Territory 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 Laboratory

There shall be at least one veterinary pathologist or veterinarian working within the laboratory. This supervising veterinarian must have specialist registration in the State/Territory 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);
- a higher degree in a relevant discipline;
- a Doctorate of Philosophy in a relevant discipline;
- a Fellowship or Diploma by examination with a relevant association.

This person shall provide diagnostic and on-site clinical oversight for the testing for which the facility is accredited. This person must also be available for consultation during working hours.

The technical control of the testing must be provided by the supervising veterinarian or a senior scientist (with appropriate qualifications and experience) who is available for consultation during working hours.

The supervising veterinarian must be contactable if absent from the laboratory for short periods of time (up to seven consecutive days). Absence may be due to:

- supervisory visits to a related Branch Laboratory;
- professional purposes;
- illness or personal necessity.

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

Branch Laboratory

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 during the NATA assessment.

The designated supervising veterinarian 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 the supervising veterinarian include:
 - electronic and/or telephone access to the facility;
 - review of documented involvement and participation in relevant proficiency testing programs;
 - access to all relevant information including case records;
 - review of regular participation in continuing education activities.

Off-site supervising veterinarians may be contacted by the NATA assessment team to discuss their involvement with the facility.

Where the minimum requirements for electronic supervision are satisfied, supervising veterinarians or senior 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 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 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 requirements for electronic supervision are not satisfied, supervising 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.

Consideration will be given to remote supervision using virtual technology on a case by case basis.

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.

A supervising veterinarian or scientist must be available for telephone consultation or equivalent when not personally in attendance at the facility.

Records must be kept of attendance by the supervising veterinarian or senior scientist at the Branch Veterinary Laboratory. Sufficient detail should be included to identify the activities undertaken at the visit.

External quality assurance must be reviewed and counter signed by a supervising veterinarian in the Veterinarian Supervised Laboratory.

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.

Records must also be kept of any supervised training or professional development of staff from the Branch Veterinary Laboratory at the Veterinarian Supervised Laboratory.

Scientist Supervised Laboratory

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.

The supervisor will usually be present during normal working hours unless there are 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.

6 Resource requirements

6.2 Personnel

6.2.2 The following standardised terms, informed by NATA's Animal Health Accreditation Advisory Committee 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.

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.

Function or role	Definition
Veterinary Pathologist - Registered Specialist	<p>A veterinarian who holds registration as a veterinary specialist by the Veterinary Surgeons Board in anatomic or clinical pathology. Examples of post graduate qualifications include Fellowship of the Australian and New Zealand College of Veterinary Scientists, Diplomate of the European and/or American College of Veterinary Pathologists.</p> <p>A specialist may also be a veterinarian registered in their State/Territory of occupation holding qualifications and experience in an appropriate laboratory discipline:</p> <ul style="list-style-type: none"> • Aquatic Pathology; • Immunology; • Microbiology; • Molecular Diagnostics; • Parasitology; • Serology; • Toxicology; • Virology.
Veterinary Pathologist	<p>A veterinarian who holds a Membership of the Australian and New Zealand College of Veterinary Scientists in Veterinary Pathology or post graduate qualifications as per a Veterinary Pathologist - Registered Specialist but does not hold registration as a veterinary specialist by a Veterinary Surgeons Board.</p>

6.2.3 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 and be sufficiently detailed to demonstrate competence.

6.2.5

Continuing education

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.

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 external proficiency testing programs and other supplementary activities to maintain operator skills. Records of participation and the results of these activities must be kept.

Staff records

These 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, including the tests able to be performed;
- in-house and external training courses undertaken;
- conferences, seminars, workshops, etc. attended; and
- relevant publications.

Proof of qualifications, membership of professional societies and hours of attendance at the facility may be requested during NATA assessments.

6.2.6 Suitable members of staff, other than the supervising 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 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 supervising veterinarian.

6.3 Facilities and environmental conditions

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

- the procedures may pose a hazard to other staff (e.g. tests using radioactive isotopes, mycobacteriology);
- the procedures may be affected or influenced by not being segregated (e.g. tissue culture);
- 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.

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 Sub-committee of Animal Health Laboratory Standards (SCAHLs) has established standards and guidelines for facilities performing nucleic acid detection. The standards included in the 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.

6.4 Equipment

6.4.3 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.

6.4.4

Consumables

Consumables used beyond the manufacturer's expiry date must be validated prior to each use. The onus is on the facility to demonstrate that reagents used beyond the manufacturer's recommended date do not adversely affect the outcome of the test.

Consumables, in particular tubes containing additives, must be monitored for expiry dates.

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).

Media

Refer to the NATA *General Accreditation Criteria: Media Preparation and Quality Control* for requirements related to media preparation and quality control.

Virology

The Australian Society for Microbiology (ASM) recommends that commercial suppliers of viral culture media be NATA accredited.

6.4.13

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.

6.5 Metrological traceability

6.5.3

Microbiological culture collection management

Refer to the NATA *General Accreditation Criteria: Maintenance of Microbiological Reference Culture Collections (MRCC)* for requirements covering the selection, maintenance, and use of microbiological cultures.

6.6 Externally provided products and services

6.6.2 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.

Where a facility refers specific specimens to another testing laboratory, an appropriate procedure must be available detailing the processes in place.

A record must be kept of specimens referred for testing to other facilities. A record must also be kept of the return of results of referred tests when the facility is responsible for sending the returned result to the person who requested the test.

7 Process Requirements

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

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

7.2.1.2

Kit Inserts

Some manufacturers provide method documentation (kit inserts) for their validated methods with their product. These may be used as the facility's procedure if they are included in its document control processes. The kit inserts must be supplemented where they are not sufficiently detailed to cover the facility's needs.

Inserts for new batches received must be checked for changes in procedure and a copy of the new insert retained and be accessible. A record of the check must be available (e.g. signing and dating the insert by the responsible person).

Methods Manuals

Methods must be documented in a manner that provides clear instructions to an operator and does not allow for difference(s) in interpretation.

7.2.1.6

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. Records must be sufficiently detailed to demonstrate the scientific theory behind the selection of the method, including but not limited to:

- the method adopted during the outbreak including:
 - description of parameters/quantities, cut-off values etc.;
 - description of the sample types and handling requirements;
 - handling of biosecurity issues, including sample handling and destruction;
 - awareness of possible sources of error, limitations, interferences etc.;
 - interpretation of results;
 - criteria for the rejection of suspect results, repeat testing decisions etc.;
 - applicable quality control measures to ensure the validity of results, including reference samples (positive and negative controls) where possible;
 - reference to literature sources.
- details of external expertise utilised;
- comparative studies and equivalence data with existing methods where available.

Documentation for disease outbreak investigations available for review by NATA post outbreak must include:

- demonstration of continuous test validation in line with the requirements of this appendix. 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 will be based on the facility's demonstrated competencies as covered by its Scope of Accreditation current at the time of the outbreak. In doing so, NATA recognises the facility to undertake testing like that requested by the CCEAD and NATA accreditation can be claimed. Where the full validation of the test method has not been completed, test reports must contain the following statement, or similar:

"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".

7.2.2 Validation of methods

7.2.2.1 The facility must ensure that methods in use have been appropriately validated for the range of animals (or animal specimens) routinely being tested, where the methods are not independent from the species.

Guidance on method validation for serological and nucleic acid testing is available from SCAHLS.

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 recorded.

Changes in reference intervals must be recorded. Where such changes could result in a different interpretation of test results, these must be communicated to users of the facility's service.

7.2.2.3 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.

7.4 Handling of test or calibration items

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

- 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.);
- action to be taken in the event that an unsuitable specimen is received;
- procedures for handling urgent specimens.

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

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 collection

Where specimen collection is outside the control of the facility, the collectors must be informed of the facility's documented 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.

Specimen referral

Refer to section 6.6.2.

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 specimen collector and must be satisfied during transport and storage.

7.4.2

Specimen labelling requirements

In general, specimen containers should not be pre-labelled. Additionally, labelling of lids only is not acceptable.

The use of a laboratory numbering system may be used to uniquely identify specimens, associated sub-samples and records (e.g. worksheets, slides, etc.).

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.

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).

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 labelling is not employed.

7.4.3 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.

7.4.4

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 referrer 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:

Discipline / Specimen types	Retention time
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 (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)	

Discipline / Specimen types	Retention time
Slides	3 years
Blocks	10 years
Unblocked, fixed tissue	30 days
Containers with no residual tissue	Where all 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

7.6 Evaluation of measurement uncertainty

7.6.3 Estimation of measurement uncertainty (MU) 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 MU, 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 MU 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 MU (including data and calculations) must be recorded and retained so that it is available upon request from a customer.

Facilities must identify those tests for which MU is to be reported and document a protocol for reporting it.

7.7 Ensuring the validity of results

7.7.1 Many factors will influence the frequency with which quality control (QC) is performed. The QC protocol must take into account these factors and be such that the facility has confidence in the results issued.

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 method and species tested.

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.

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

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 QC material provide adequate control of assays. The facility should establish its own means and standard deviations using its own data to maintain tighter control.

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 QC 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.

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 titering to a known endpoint should be used. Facilities may 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. Once the specificities detected by the substrate have been confirmed, the slides 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.

Commercial kits should have this already performed by the manufacturer. Validation is required if:

- conjugates and slides are purchased separately from the same manufacturer;
- using conjugate from one manufacturer and slides from another or in-house slides.

Media

Refer to the *NATA General Accreditation Criteria: Media Preparation and Quality Control* for requirements regarding microbiological and virology media.

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

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).

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 a virus, appropriate and available positive and negative controls must be included.

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

7.7.2 Also refer to the NATA *General Accreditation Criteria: Proficiency Testing Policy*.

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

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.

When no PT is available to meet requirements, the facility must investigate alternative means for assuring the quality of test results, for example, sample exchange programs with other facilities, replicate testing, etc.

Performance

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

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

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 has an opportunity to test proficiency samples.

7.7.3

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

A system for long-term monitoring of QC results to assess method performance must be available. Accordingly, primary QC data (e.g. instrument printouts, original work notes) must be retained to allow retrospective review.

7.8 Reporting of results

7.8.1 General

7.8.1.1 Also refer to 6.2.2 regarding titles of persons reporting results.

Where the test method used has not been validated for the animals or animal specimens, details of this limitation 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).

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 customer without result/report review by a supervising veterinarian or senior scientist.

Automated reporting is limited to clinical chemistry and haematology where interpretation of the results by a supervising veterinarian is not required.

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

A procedure must be available detailing how the automated process functions, including the tests to which it applies. This process must be authorised by a supervising veterinarian or senior scientist depending on the category of the facility and must include:

- only results falling within species specific alert or normal reference intervals can be subject to automated reporting;
- 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 must be identified by including text such as:

“These results have been generated by an automated process approved by (name of Supervising Veterinarian / Senior Scientist). All results are within normal limits for the species, therefore not referred to a Supervising Veterinarian for comment. Any questions, or for further discussion please contact the 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 customer authorised to receive them.

7.8.2 Common requirements for reports (test, calibration or sampling)

7.8.2.1 Where testing is performed within a multi-site facility, the facility must be able to establish the site at which testing was performed.

Reports must include:

- specimen collection and receipt date and, where necessary for the interpretation of test results, the time of collection;
- source / type of specimen, where this information significantly affects the test result;
- unique animal identification;
- date of testing (where this is different to the specimen receipt date and may significantly affect the interpretation of the results);
- reference intervals (where appropriate);
- test method / technique, where this information significantly affects the test result.

7.8.3 Specific requirements for test reports

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

Refer to 7.2.1.6 for the reporting of results on the investigation of emergency animal disease outbreaks.

7.8.7 Reporting opinions and interpretations

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

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

Facilities engaged in testing performed on human specimens shall 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 is to be sought.

Testing on human specimens may also be subject to the Therapeutic Goods Administration (TGA) In-Vitro Diagnostic (IVD) medical device Framework which requires assessment against the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices (IVDs)*.

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.

Standards

ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*

NATA Publications

NATA Accreditation Criteria (NAC) package for Animal Health

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

General Accreditation Criteria *Proficiency Testing Policy*

General Accreditation Criteria *Media Preparation and Quality Control*

Other Publications

Aquatic and terrestrial Australian and New Zealand standard diagnostic procedures (ANZSDPs): these may be of interest to veterinary testing laboratories and accessible through the Animal Health Laboratories website of the Department of Agriculture and Water Resources
(<http://www.agriculture.gov.au/animal/health/laboratories>)

CLSI M02 *Performance Standards for Antimicrobial Disk Susceptibility Tests*

IATA Dangerous Goods Regulations

National Pathology Accreditation Advisory Council (NPAAC), *Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices (IVDs)*

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

Amendment Table

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

Section or Clause	Amendment
Whole document	Editorial updates.
7.2.1.6, 7.2.2.1 and NATA Publications	Removed reference to withdrawn General Accreditation Guidance: <i>Validation and verification of quantitative and qualitative test methods</i> .