Supplement requirements for veterinary laboratory compliance with ISO/IEC 17025 : 2017

1. Purpose

This supplement requirements is specific requirements for veterinary laboratory compliance with ISO/IEC 17025:2017.

2. Application

This supplement requirements are specified the requirements in the field of veterinary testing covers tests on specimen of animal origin for the purposes of diagnostic and health assessment testing in the disciplines of microbiology, parasitology, serology, immunology, haematology, biochemistry, toxicology, pathology, virology, genetics, growth promoters and drug/chemical residue. The veterinary laboratory shall establish the policy and procedure to ensure that the veterinary laboratory complies with this supplement requirement and ISO/IEC 17025:2017.

3. Reference

3.1 Application Document Supplementary Requirements for accreditation in the field of Animal Health, NATA, July 2018.

3.2 Specific Requirement: Veterinary Laboratory Accreditation Program A2LA, January 8, 2018.

3.3 The World Organization for Animal Health (OIE) Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, Paris, 2008. (Update 2019)

☞ 3.3.1 Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2019 Terrestrial Manual 8th Edition 2018 Volumes 1, 2 and 3 (ISBN 978-92-95108-18-9)

☞ 3.3.2 Manual of Diagnostic Tests and Vaccines for Aquatic Animals 2019 Aquatic Manual 7th Edition 2016 (ISBN 978-92-9044-887-7)

3.4 Policies, requirements and conditions for a medical and health laboratory accreditation. (R 07 15 001).

3.5 Policy and requirements for Proficiency Testing, interlaboratory comparison/ Laboratory's performance assessment in test (N 07 15 003).

☞ 3.6 Policy and Conditions for the Use of an Accreditation Symbol or a Statement to Claim Accreditation Status, (N 07 15 009)

4. Definition and Abbreviation

4.1 Veterinarian

A veterinarian is a person who holds a degree of bachelor of veterinary sciences or doctor of veterinary medicine and is registered with the veterinary council of Thailand or relevant authorities of other countries.

4.2 Scientist

Scientist is a person who has a bachelor degree in applied science, medical or veterinary technology.

4.3 Specimen

Specimen is the material, exclusively of animal origin, submitted for testing.

4.4 Sample

Sample is the material that is derived from a specimen and is used for testing purpose.

4.5 Validation

Validation is the process through which a test method is confirmed to be fit for the intended purpose.

4.6 Term relationships clarified between ISO/IEC 17025:2005 and the OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008 as following:

4.6.1 Sample (of animal origin) = Specimen
4.6.2 Sampling = Collection
4.6.3 Sampler = Collector
4.6.4 Sample location = Collection location
4.6.5 Testing = Infectious animal disease diagnostic testing = Disease diagnostic testing = Diagnostic testing = Diagnostic services = Diagnostics
4.6.6 Opinions and interpretations = Opinions and diagnostic interpretations
4.6.7 Processing = Handling

5. Associated Documents

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6. Procedures

6.1 Structural requirements

Facilities are categorised according to the range of testing performed and their supervision arrangements. The veterinary testing laboratory shall have at least one veterinarian who has at least one of the following qualifications:

- A professional degree from a veterinary faculty recognized by national veterinary council/authority.
- Specialist in relevant discipline registered with the veterinary council of Thailand.
- A Fellowship by examination with a relevant association.

This person shall provide technical control over tests for which the laboratory is accredited and shall have demonstrable experience in those tests.

6.2 Resource requirements

6.2.1 Personnel

The laboratory must have a program of regular refresher training for staff to established and records retained. Records must be available to the assessment team and be sufficiently detailed to demonstrate compliance. Where staff is 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. 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.

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:

a) regular educational presentations
b) journal article reviews
c) case presentations
b) review of proficiency testing educational material
e) 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.

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

a) relevant academic qualifications;
b) participation in the facility's training program;
c) evidence of ongoing competence to carry out assigned work;
d) in-house and external training courses undertaken;
e) 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.

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

6.2.3 Metrological traceability

Metrological traceability depending on method specification. Test and calibration equipment that has a significant effect on the reported results and associated uncertainties of measurement must be calibrated by the national metrology institutes or calibration laboratories accredited by accreditation body (ISO/IEC 17025:2017) and the calibration of references standards must be performed by laboratories appointed as Verifying Authorities under the National Measurement Regulations.

6.2.4 Externally provided products and services

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 organization.

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

6.3 Process requirements

6.3.1 Selection, verification and validation of methods

Test methods

The veterinary laboratory that uses standard methods (methods published in international, regional, or national standards), some in–house evaluation, optimization, and/or validation generally must be done to ensure valid results.

Selection of methods

The laboratory should use "Standard Diagnostic Procedures", where appropriate. It may require to use other standard methods. Example, for export testing, the OIE Manual of Standards for Diagnostic tests and Vaccines may be specified. Where a test can be performed by more than one method, there must have the documented criteria for method selection. The degree of correlation between the methods must be established and documented, when relevant.

Validation of methods

The laboratory that uses a new method must perform and document investigations to demonstrate the laboratory's ability to obtain valid results with that method and assay validation criteria and that must ensure that validation includes review of method performance. This should include the following:

a) fitness for an intended purpose(s)
b) optimization
c) standardization
d) robustness
e) repeatability
f) analytical sensitivity
g) analytical specificity
h) threshold/cut-offs
i) diagnostic sensitivity
j) diagnostic specificity
k) reproducibility
l) ruggedness

☞ and follow by detailed in the OIE Quality Standard and Guidelines for Veterinary Laboratories : Infectious Diseases, 2008 (Update 2019).

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.

6.3.2 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;
- labeling 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-labeled. Consumables provided by the facility or used in the facility, in particular tubes containing additives, must be monitored for expiry dates.

6.3.3 Evaluation of measurement uncertainty

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 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 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

6.3.4 Ensuring the validity of results

Proficiency testing

BLQS's Proficiency Testing Policy (N 07 15 003) requires each applicant or accredited facility to participate in appropriate proficiency testing where available. The laboratory shall participate the proficiency testing with PT provider which has been accredited by accreditation body. Staff shall be evaluated their performance by comparison the re-examination and blind specimen with the other staffs from internal and external laboratory.

6.3.5 Reporting of results

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) date of testing (where this is different to the specimen receipt date and may significantly affect the interpretation of the results);
d) test method/technique;
e) where necessary, comments on inadequacy of specimens.

There may be statutory requirements for additional information to be included on test reports. The test results must be issued by a registered veterinarian, whenever in the case of test results by non-veterinarians is desirable that such persons have relevant experience in those tests and ☞ shall execute accordance with Policy and Conditions for the Use of an Accreditation Symbol or a Statement to Claim Accreditation Status, (N 07 15 009)**.**

6.4 Management system requirements

6.4.1 Improvement (Option A)

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.

7. Data records and used document

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8. History of change

Revision No.	Documentation Changes	Prepared / Revised by	Date Issued
00	New SOP	Ms. Amornrat Tatsanakit	-
01	Update details guideline to clearly such as: - add words in clause 2 scopes - add details in clause 4 term and definitions - add details the qualification for the veterinary testing	Ms. Amornrat Tatsanakit	4 February 2010
02	Update the reference to current in clause 3	Ms. Piyawan Chainarongkuekul	18 September 2013

Revision No.	Documentation Changes	Prepared / Revised by	Date Issued
03	- Update and add the reference to current in clause 3 - Correct of all typing error in clause 4.3: Specimen is the material, exclusively of animal origin, submitted for testing. - Add Term relationships clarified between ISO/IEC 17025:2005 and the OIE in clause 4.6 - Add details to clearly in clause 6.1 and 6.2	Ms. Piyawan Chainarongkuekul	13 November 2017
04	- Page 1/8 Updated references to 17025 to address both the 2017 versions. - Page 1/8 Updated references in clause 3.1 - 3.2 - Edit details in clause 6 to conformity ISO/IEC 17025: 2017 - Page 3/8 add “A Safety Manual detailing the facility’s policies and procedures in relation to health and safety must be readily available to all staff.” in clause 6.2.2 - Page 5/8 add “Facilities must identify those tests for which MU is to be reported and document a protocol for reporting it” in clause 6.3.3	Ms. Piyawan Chainarongkuekul	10 January 2019
05	- Page 1/9 updated references OIE to 2019 and add Terrestrial Manual Aquatic Manual - Page 1/9 add reference “Policy and Conditions of BLQS, (N 07 15 009)” in clause 3.6 - Page 5/9 updated references OIE add “update 2019” - Page 7/9 add “shall execute accordance with Policy and Conditions of BLQS, (N 07 15 009)” in clause 6.3.5	Ms. Piyawan Chainarongkuekul	

Controlled copy list

1. Director of Bureau of Laboratory Quality Standards Code no. 07 00
2. Head Laboratory Accreditation Section 1 Code no. 07 03
3. Head Laboratory Accreditation Section 2 Code no. 07 04
4. Quality Manager of Laboratory Accreditation Code no. QM 007
5. Ms. Piyawan Chainarongkuekul