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

1. Purpose

This supplement requirement is specific to veterinary laboratories in compliance with ISO/IEC 17025:2017.

2. Application

This veterinary testing laboratory's additional requirement is specified for the testing of specimens of animal origin for disease diagnosis, disease surveillance, health assessment, monitoring of ☞ treatment, vaccination response, feed or environmental samples, and product related to veterinary. The scope of testing includes the disciplines of microbiology, parasitology, serology, immunology, hematology, biochemistry, toxicology, pathology, virology, genetics, and growth promoters.

☞ 3. References

3.1 National Association of Testing Authorities (NATA), Australia. Specific Accreditation Criteria: ISO/IEC 17025 Application Document, Animal Health - Appendix, June 2022.

3.2 World Organisation for Animal Health (WOAH, founded as OIE) Updated 2024.

3.2.1 Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 13th edition 2024.

3.2.1.1 Validation for diagnostic assays for infectious diseases of Terrestrial Animals. Chapter 1.1.6 (WOAH Terrestrial Manual 2024)

3.2.1.2. Measurement of uncertainty Chapter 2.2.4 (WOAH Terrestrial Manual 2024)

3.2.1.3. Statistical approaches to validation Chapter 2.2.5 (WOAH Terrestrial Manual 2024)

3.2.1.4 Glossary of terms (WOAH Terrestrial Manual 2024)

3.2.2 Manual of Diagnostic Tests for Aquatic Animals, 11th edition 2024.

3.2.2.1 Principles and method of validation of diagnostic assays for infectious diseases. Chapter 1.1.2

3.2.2.2 Glossary of terms (WOAH - Aquatic Animals Health Code 2024)

3.2.3 Standard operating procedure for WOAH Registration of Diagnostic Kits: Guide and Administrative Forms, 2023.

3.3 Pathogens and Animal Toxins Act, B.E. 2558 (2015)

3.4 Newberry KM, Colling A. Quality standards and guidelines for test validation for infectious diseases in veterinary laboratories. Revue Scientifique et Technique, 2021 Jun; 40 (1): 227-237.

3.5 Terminology in Analytical Measurement Introduction to VIM 3 Second edition 2023

4. Definition and Abbreviation

☞ 4.1 Veterinary laboratory

Laboratory carried out diagnostic and clinical veterinary laboratories that conduct commercial, government, academic, and international veterinary testing.

4.2 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.

☞ 4.3 Scientist

A scientist is a person who holds a bachelor's degree in science, such as veterinary technology, medical technology, biology, microbiology, fishery, animal science, or a related field (or an equivalent qualification).

☞ 4.4 Specimen

Specimen is the material, exclusively of animal origin, test food feed, environmental samples, veterinary medical products, chemical product and biological products submitted for testing.

4.5 Sample

Material that is derived from a specimen and used for testing purposes.

☞ 4.6 Verification

Provision of objective evidence that a given item fulfils specified requirements (VIM 2.44)

☞ 4.7 Validation

Verification, where the specified requirements are adequate for an intended use (VIM 2.45)

☞ 4.8 Interlaboratory comparison

Any evaluation of assay performance and/or laboratory competence in the testing of defined samples by two or more laboratories; one laboratory may act as the reference in defining test sample attributes.

4.9 Proficiency testing

☞ Proficiency testing (PT) is the evaluation of participant performance against pre-established criteria using interlaboratory comparisons. (refer to ISO/IEC 17043 Conformity Assessment-General requirements for the competence of proficiency testing providers) that ISO 15189:2022 uses external quality assessment also known as proficiency testing.

☞ 5. Associated document

5.1 R 07 15 001 (T): Policies, Requirements, and conditions for a medical and health laboratory accreditation

5.2 N 07 15 001 (T): Policy and requirements for acceptance of the measurement result of calibration equipment.

5.3 N 07 15 003 (T): Policy and requirements for Proficiency Testing, interlaboratory comparison/ Laboratories performance assessment in a test.

5.4 N 07 15 007 (T): Policy and requirements on an estimation of uncertainty measurement and traceability.

5.5 N 07 15 009 (T): Policy and Conditions for the Use of an Accreditation Symbol or a Statement to Claim Accreditation Status.

5.6 G 07 15 012: Guidelines for inspection and calibration of scientific instruments for laboratory accreditation compliance with ISO/IEC 17025: 2017.

6. Procedures

The veterinary laboratory shall establish the policy and procedure to ensure that it complies with this supplement requirement and ISO/IEC 17025:2017.

6.1 Structural requirements

Facilities (meaning veterinary laboratories) are categorized according to the range of testing performed and their supervision arrangements.

6.1.1 The terrestrial animals testing laboratory shall have at least one veterinarian who has at least one of the following qualifications:

a) A professional degree from a veterinary faculty recognized by the National Veterinary Council/authority.

b) Specialist in relevant discipline registered with the Veterinary Council of Thailand.

c) 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.

☞ 6.1.2 The aquatic animal testing laboratory shall have at least one veterinarian or scientist in a field veterinary technology, medical technology, biology, microbiology, fishery or a related discipline (or an equivalent qualification).

6.2 Resource requirements

6.2.1 Personnel

6.2.1.1 An approved signatory shall be a veterinarian or a scientist with relevant experience in veterinary diagnostic assay and testing laboratories.

☞ 6.2.1.2 A person giving opinions and interpretations, including diagnoses, shall be a veterinarian, scientist or specialist with relevant working experience in testing or equivalent postgraduate qualifications e.g. veterinary pathologist, microbiologist, fishery biologist etc.

6.2.1.3 Training programs shall be provided that are appropriate for each type of personnel, such as a regular staff, a refresher, a new staff, and an overtime staff.

6.2.1.4 The training time allocated should be sufficient for the staff member to update all skills required for the in- or out-of-hours service.

6.2.1.5 All staff members should be provided with adequate opportunities for ongoing education and should have access to the proper citations and publications. The continuing education may include membership in appropriate professional associations and participation at gatherings, seminars, and workshops.

6.2.1.6 The details of the training record shall contain sufficient information to demonstrate competence in the performance of the assigned tasks. Each individual's training history shall be recorded, archived, and available for assessment. Every pertinent staff member's record shall show that they participated satisfactorily in any planned internal replicate testing programs, applicable external proficiency testing programs, and other training exercises to keep their operator up-to-date skills sharp and indicate competence in individual tests.

6.2.1.7 The information in the training record shall at least include details, hours of attendance, 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, including the tests able to be performed;
d) in-house or external training courses undertaken;
e) conferences, seminars, workshops, etc., attended; and
f) relevant publications and if any there are relevant publications.

6.2.2 Facilities and environmental conditions.

6.2.2.1 All staff must have easy access to a safety manual outlining the facility's rules and practices on health and safety.

☞ 6.2.2.2 There shall be a distinct separation between areas with incompatible laboratory activities (such as those utilized for a facility's administrative functions) and laboratory area (e.g., those used for testing procedures).

6.2.2.3 Specific areas shall be properly separated from the main working areas, and a clear indication, and there shall be clear definition of the processes. Examples of specific areas include;

a) those that could endanger other employees (such as mycobacteriology and tests using radioactive isotopes).
b) those that might be impacted or influenced by not being segregated (such as tissue culture).
c) those that call for a quiet and uninterrupted work environment. (e.g., microscopy operations).
d) those that protect the potential infection zone, a biosafety cabinet or certificated positive air pressure system to filter air inlets and outputs is required.

6.2.2.4 To lessen the danger of contamination, a laboratory that offers molecular diagnostics shall have distinct rooms or sections or other means that are marked for the preparation of reagents and master mix, sample preparation, nucleic acid extraction, amplification, and manipulation of amplified nucleic acids. Each requires its own set of tools. To keep track of any potential contamination, quality control processes shall be in place.

6.2.2.5 Desk, cabinet, and shelf designs, as well as all surface treatments (bench, floor, ceiling, walls, and windows), shall be hygienic and easy to clean. It's critical to maintain high cleaning standards.

☞ **6.2.3 Equipment**

6.2.3.1 Diagnostic kits shall be approved by international organizations (WOAH, AOAC, EuroProxima etc.) as validated and fit for purpose.

6.2.3.2 For the chemicals and consumables used in the test, shall be tracked down in records.

6.2.3.3 All sorts of standard solutions and reagent preparation procedures shall be documented in detail. Moreover, the labels on the reagent container shall be accurate.

6.2.3.4 These records must include:

a) ingredients, including manufacturer and manufacturer's batch number (where applicable) and quantities used;
b) date of preparation;
c) identity of the preparer;
d) date of expiry; and
e) safety precautions and/or handling instructions, where relevant.

☞ **6.2.4 Metrological traceability**

The requirement of Policy and requirements for acceptance the measurement result of calibration equipment, N 07 15 001 (T) shall be applied. Reference Material (RM) compliance to ISO 17034 provided by competence producer reference material producers fulfilling the requirements of ISO 17034 is considered to be competent. The metrological traceability depends on the method specification.

6.2.4.1 Measuring system or Calibration equipment that has a significant effect on the reported results and associated uncertainties of measurement shall be calibrated by the national metrology institutes or calibration laboratories accredited by the accreditation body (ISO/IEC 17025:2017) or in-house calibrations according to N 07 15 001 (T).

6.2.4.2 Reference materials are crucial for all assay runs, from the original proof of concept in the development phase through every run of the validation route and for monitoring performance in everyday use throughout the duration of the assay. Preferably, the Measuring system should be calibrated using international or national reference standards provided by a competent producer. Reference Material producer fulfilling the requirements of ISO 17034 are considered to be competent. Where international, national or other reference material is available, the measuring system should be calibrated to match the analytical sensitivity in terms of the metrological units assigned to the calibration of that material. These, however, are not always accessible, thus it could be required to develop an internal reference standard from an original source of the test analyte or possibly by spiking a derived analyte into the selected matrix.

6.2.4.3 The incorrect selection of reference materials might result in prejudice and improperly conclusions. Therefore, the reference materials should accurately represent the tests of interest, whether they are natural or artificial. It is essential that these materials accurately represent the target analyte, the range of analyte concentrations to be measured, and the matrix in which it is present in the population for whom the examination is intended.

6.2.4.4 Carefully choose the negative reference population to make sure it is representative and aligns with the positive reference population. A negative reference population, such as a negative reference animal, refers to absence of exposure to or infection with the agent in inquiry.

6.2.4.5 The reference materials may be used for a wide range of purposes, large quantities of them should be collected or prepared and preserved for long-term use. Altering the reference materials used during the validation process can seriously impair the interpretation of experimental results as well as the validity of the development and validation processes. It might be necessary to employ numerous aliquots, which can be done during each experiment run. The number of freeze-thaw cycles for all experiments should be avoided since repeated freezing and thawing of samples can denature antigen and/or facilitates the growth of other unwanted microorganisms.

6.2.4.6 The comprehensive and precise descriptions of all selection criteria, preparation requirements, and testing specifications shall be included into document control. This will provide consistency and assurance throughout the duration of the test.

6.2.5 Externally provided products and services

Many veterinary laboratories carry out work for a range of different customers, the laboratory may choose to establish a capability in-house, conduct contract work with commercial suppliers of services or submit specimens to designated Reference Centers or provide diagnostic and surveillance procedures.

6.2.5.1 The choice of platform should be based on a consideration of the intended purpose, the availability of supporting expertise from the supplier, ancillary equipment needed, the cost of annual licenses or service agreements, and the time required.

6.2.5.2 Where a facility refers specific samples to another testing laboratory, the testing shall be provided by accredited laboratory that meet the requirements of ISO/IEC 17025. A record must be kept of samples referred for testing to other facilities.

6.2.5.3 If the facility is in charge of ensuring that the sender receives the results of referred tests, records of the return of results must also be preserved. It is necessary to have a process in place for checking up on unanticipated findings.

6.2.5.4 The acceptability criteria and requirements for the utilization of outside sources of products and services shall be precisely and clearly specified.

6.2.5.5 The laboratory shall set up a thorough record-keeping system that allows it to monitor how each contractor's continuing tasks are being performed. Every important action shall be documented, including the date it was completed, the identity of the person who performed it, and any crucial measures like temperature and time. Records shall be kept for all goods and services that are supplied from outside sources. For the purposes of the competent control requirement, all records ☞ shall be preserved for at least five years.

6.3 Process requirements

6.3.1 Selection, verification and validation of methods

6.3.1.1 The adoption of standard procedures (methods described in international, regional, or national standards) by veterinary laboratories typically necessitates some internal examination, optimization, and/or validation to guarantee reliable test results.

6.3.1.2 When necessary, the veterinary laboratory should employ "Standard Diagnostic Procedures". However, other conventional techniques might be necessary. The Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 13th edition 2024, for instance, may be specified for export testing products.

6.3.1.3 If there are multiple methods that can be used to perform a test, the criteria for selecting one must be documented. It is necessary to determine and, if pertinent, record the degree of correlation between the approaches.

6.3.1.4 The ISO/IEC 17025 accredited laboratory is required to validate all internal and modified standard methods and to verify standard methods in order to prove the accuracy of all employed techniques.

☞ 6.3.1.5 When using procedures that are not species-independent, the laboratory shall ensure that the procedures have been suitably validated for the variety of animals (or animal specimens) that are routine tested. The laboratory may select the application as appropriate for the intended use, as mentioned in the WOAH Terrestrial Manual 2024 (Chapter 1.1.6), WOAH Terrestrial Manual 2024 (Chapter 1.1.2) and NATA etc.

6.3.1.6 When a novel technique is used, the laboratory must conduct and record studies to show that it is capable of meeting the requirements for both assay and method validation, which must include an evaluation of method performance. This should incorporate the following:

a) fitness for (an) intended purpose(s)
b) optimization
c) standardization
d) repeatability
e) analytical sensitivity

f) analytical specificity
g) threshold/cut-offs
h) diagnostic sensitivity
i) diagnostic specificity
j) reproducibility
k) ruggedness
l) robustness

6.3.1.7 Table-1 shows an example interpretation of ISO/IEC 17025:2017, World Organization for Animal Health (WOAH) - Chapter 1.1.6. Validation for diagnostic assays for infectious diseases of Terrestrial Animals. (WOAH Terrestrial Manual 2024*)*, Chapter 1.1.2. Principles and method of validation of diagnostic assays for infectious diseases. *(*Manual of Diagnostic Tests for Aquatic Animals 2024) and National Association of Testing Authorities (NATA), Australia. Specific Accreditation Criteria: ISO/IEC 17025 Application Document, Animal Health to conduct characteristics that should be addressed when designing method validation and method verification for veterinary diagnostic assays.

☞ **Table-1: Alignment of validation and verification performance criteria for diagnostic assays.**

Validation criteria for non-standard diagnostic assay	Verification criteria for standard (established) diagnostic assay
1. Definition of intended purpose	Similarly defined fit for intended purpose
2. Optimization of test	Not required
3. Standardization	Not required
4. Robustness–Ruggedness (test development)	Not required
5. Repeatability	Required
6. Analytical sensitivity-quantitative tests only	Required
7. Analytical specificity, or selectivity	Some degree of validation will be required if previous validation did not address similar testing populations, species, required purpose or sample type
8. Diagnostic sensitivity	
9. Diagnostic specificity, or selectivity	
10. Defined threshold (cut-off) values	Verify the defined threshold suits the laboratory's required purpose. If not, further validation required
11. Reproducibility: Precision, Inter-lab and intra-lab	Required
12. Reproducibility: Accuracy, Inter-lab and intra-lab	Required

Validation criteria for non-standard diagnostic assay	Verification criteria for standard (established) diagnostic assay
13. Designation of intended fit for purpose after cut-off values have been determined	Designation of intended fit for purpose after cut-off values have been determined
14. Measurement of uncertainty (MU) for quantitative tests only	Ongoing assessment required for quantitative tests only

(Newberry KM, Colling A. Quality standards and guidelines for test validation for infectious diseases in veterinary laboratories. Revue Scientifique et Technique, 2021 Jun; 40 (1): 227-237.)

6.3.2 Sampling

The standard and suitability of the specimens obtained for examination are crucial for laboratory analysis of animal disease. For many different objectives, sampling can be done on individual animals, communities of animals, or the environment.

6.3.2.1 The process should be set up to ensure that the specimens gathered are adequate for the intended usage, representative of the condition being investigated, and sufficient in quality, volume, and quantity for the planned testing in order to yield scientifically and statistically reliable findings.

☞ 6.3.2.2 Biological products, the animals and tissues sampled need to be identified, and properly packed with leakage control. A primary container, a rigid secondary container, and a rigid outer container should make up the package. To preserve the integrity of the specimens, and prevent environmental contamination and cross-contamination with other specimens, the biological materials packing must be carried.

6.3.2.3 A solid understanding of the epidemiology and etiology of the disease under examine is required in order to properly sample the tissues or fluids that are most likely to contain the infectious agent or signs of the infection.

6.3.2.4 The right biosafety and containment techniques shall be used when collecting samples in order to prevent contamination of the environment, animal handlers, samplers, and specimens themselves, as well as the exposure of people and other animals to potentially infectious materials. The guidelines for collecting samples shall be made available. The people performing the sample shall also be well trained. To ensure that they are competent, their training history must be made transparent in this matter. In addition to health and safety issues, all veterinary laboratories who ☞ have a responsibility to contain pathogens that might threaten neighboring human or animal populations, or the environment shall adhere to Pathogens and Animal Toxins Act, B.E. 2558 (2015)

6.3.2.5 The precise information on diagnostic specimens shall be crucial, and detailed in sampling written evidence, such as the use of chemical euthanasia or anesthetic for animal restraint prior to specimen collection since the chemicals have an influence on the test outcome (for example, toxicological testing).

6.3.2.6 The collectors shall be kept aware of the facility's collection requirements in cases when specimen collecting is not under the facility's control. These requirements must be documented and available.

6.3.2.7 Example of the collection requirements:

a) containers/tubes required for each test;
b) amount of specimen required;
c) “order of draw” for multi-sampling vacuum tubes;
d) labeling requirements;
e) specimen storage requirements (e.g., room temperature vs refrigeration);
f) specimen transport requirements;
g) requirements with respect to request forms;
h) provision of relevant clinical information.

6.3.2.8 In general, pre-labeling of specimen containers is not recommended. Consumables provided by the facility or used in the facility, in particular tubes containing additives, must be monitored for expiry dates.

☞ **6.3.3 Handling of test or calibration items**

The laboratory may co-locate with other facility where samples are handled. At the reception, there shall be instructions on how to receive documented specimens.

6.3.3.1 The documented specimen procedure shall be to cover the following but not be limited to:

a) criteria for acceptance or 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;
c) procedures for handling urgent specimens.

6.3.3.2 The facility shall keep a record of the date and, the time that specimens were received.

6.3.3.3 The facility is required to conform to a predetermined and recorded process when pooling samples is accepted practice during testing.

6.3.3.4 The validity of any modifications to the protocol will be verified, and verification records shall be maintained.

6.3.3.5 To ensure accurate testing of samples and minimize exposure of employees, cross-contamination must be avoided during receiving, unpacking, and aliquoting specimens.

6.3.3.6 The biological risk assessment protocol shall be carried out to ascertain how the biohazard is handled and manipulated in their specific circumstances.

6.3.4 Evaluation of measurement uncertainty

The two main categories of tests are qualitative (bacterial culture, parasite identification, virus isolation, endpoint PCR, immunofluorescence, etc.) and quantitative (biochemical assays, enzyme-linked immunosorbent assays [ELISA], titrations, real-time polymerase chain reactions [PCR], pathogen enumeration, etc.). Only quantitative tests are covered by the evaluation of measurement uncertainty (MU). This applies to tests where a numerical result is presented as a qualitative outcome, such as serological assays with a "cutoff" value where the numerical result is presented as detected or not detected.

6.3.4.1 The facility must take into account those elements it may influence when evaluating measurement uncertainty. For instance, if the facility is not participating in the sample collection procedure, it is not required to estimate the measurement uncertainty of this activity. However, it must be obvious which elements have been taken into account when estimating uncertainty.

6.3.4.2 Estimates of uncertainty or other variability will not be necessary for tests when the findings are qualitative (such as pass/fail, positive/negative, detected/not detected, or other qualitative data). Nevertheless, this should not prevent the laboratory from learning about the factors that significantly increase the results' variability.

6.3.4.3 It is necessary to document and keep track of the methodology for estimating uncertainties (together with the data and computations) so that it is accessible to customers upon request.

6.3.4.4 Facilities are required to specify which tests must have MU reported, along with a methodology for reporting it.

☞ **6.3.5 Ensuring the validity of results**

6.3.5.1 The frequency of quality control (QC) operations is influenced by a variety of factors. These considerations must be included into the QC methodology in order for the facility to feel confident in the results.

6.3.5.2 The quality control material employed must cover the range of analytical concentrations found. According on the technique and species under test, the controls used might be low/normal/high concentrations, normal/abnormal, positive/negative, or reactive/non- reactive.

6.3.5.3 Using a control sample with a value close to the assay cut-off (such as through serology testing) should be taken into consideration.

6.3.5.4 When an assay needs to be calibrated, the proper substance must be employed as a calibrator. The calibration values given must be traceable if the material chosen is not meant to be used as a calibrator.

6.3.5.5 QC material must be evaluated for each test on every testing day and at any change of a prepared reagent or reagent batch, unless otherwise specified in the manufacturer's instructions.

6.3.5.6 An assay in regular usage is evaluated by external quality assurance methods to ensure uniform performance and give overall validity in test results. One way to figure out laboratory competency is through proficiency testing, which is developed through interlaboratory comparison. Each accredited PTP or accredited facility is required by BLQS's Proficiency Testing Policy (N 07 15 003) to engage in relevant proficiency testing where available. The laboratory must participate in the proficiency testing scheme with a proficiency testing provider that has been accredited by an accreditation body. To the greatest extent possible, proficiency testing samples must be treated in the same manner as diagnostic test samples.

6.3.5.7 The performance of staff members will be assessed by comparing re-examination and blind specimen results with other employees from internal and external laboratories. Furthermore, consideration should be given to ensuring that all personnel involved in testing (including part-time and evening personnel) have the opportunity to test proficiency samples.

6.3.6 Reporting of results

6.3.6.1 Each test report must contain the following information in addition to those required by ISO/IEC 17025 for reports:

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.

6.3.6.2 For the purpose of processing telephone inquiries, the laboratory shall have a written method that takes into account the information being sought (such as test results and interpretation of results).

6.3.6.3 If test results are given to clients orally, a record of the date, time, reporting staff, recipient, and information conveyed must be kept. A written report must be submitted after any verbally reported. The inclusion of additional information on test reports may be required by law.

7. Data record and Used document

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8. Supplementary notes

8.1 Notification of Bureau of Laboratory Quality Standards. Subject on the Technical Working Group for the Development of Specific Requirements for the Accreditation of Veterinary Laboratories in accordance with ISO/IEC 17025:2017. Appointment of Appoint No. 3/2024, and 6/2024, dated February 8, 2024 and March 7, 2024.

9. 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
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

Revision No.	Documentation Changes	Prepared/ Revised by	Date Issued
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	11 October 2019
06	- Add details the Application for feed, environmental samples and, product related to veterinary in clause 2: Application. - Update the references in clause 3 - Add field of science that focuses on veterinary laboratory in clause 4.2 - Add details specimen to submitted for testing in clause 4.3 - Edit definition of validation and in clause 4.5 - Add definition of verification, Interlaboratory comparison and PT in clause 4.6, 4.7 and 4.8 - Add associated document in clause 5 - Add structure requirements detailing the aquatic animal testing laboratory in clause 6.1.2 - Add qualifications for the approved signatory and person giving opinions, and interpretations in clause 6.2.1.2 - Add more details of incompatible laboratory activities in clause 6.2.2.4. - Add equipment requirements clause 6.2.3	Ms. Piyawan Chainarongkuekul	

Revision No.	Documentation Changes	Prepared/ Revised by	Date Issued
06	- Add Reference Material (RM) in clause 6.2.4 - Add collection and storage of all records for at least five years.in clause 6.2.5.5 - Add references to Chapter 1.1.6. Validation for diagnostic assays for infectious diseases of Terrestrial Animals. (WOAH Terrestrial Manual 2024) and Chapter 1.1.2. Principles and method of validation of diagnostic assays for infectious diseases. (Manual of Diagnostic Tests for Aquatic Animals 2024) in clause 6.3.1.5 - Add validation and verification performance criteria for diagnostic assays in table 1 - Add sampling covering biological product in clause 6.3.2.2 - Add references to Pathogens and Animal Toxins Act, B.E. 2558 (2015) in clause 6.3.2.4 - Add requirement of Handling of test or calibration items in clause 6.3.3 - Add details concerning to quality control and performance in test in clause 6.3.5 - Deleted clause 6.4: Management System Requirements.	Ms. Piyawan Chainarongkuekul	