Food and Agriculture Organization of the United Nations

SUSTAINABLE DEVELOPMENT GOALS

VIRTUAL COURSE

26 March to 15 April 2021

Design of an Active Surveillance for Tilapia Lake Virus (TILV) Disease and Its Implementation

TCP/INT/3707: Strengthening biosecurity (policy and farm level) governance to deal with Tilapia lake virus

Food and Agriculture Organization of the United Nations

SUSTAINABLE DEVELOPMENT GOALS

CHECKLIST 10

13 April 2021

Establishing quality management system (QMS) for aquatic animal disease diagnostic laboratory

Kathy Tang-Nelson
ktangnelson@gmail.com

TCP/INT/3707: Strengthening biosecurity (policy and farm level) governance to deal with Tilapia lake virus

What is quality management system (QMS)?

- Defined as a formalized system that documents responsibilities, processes, and procedures for achieving quality policies and objectives.
- A QMS helps coordinate and direct a lab's activities to meet customer and regulatory requirements
- QMS needs to be continuously improved for its effectiveness

What is quality management system (QMS)?

Components of QMS:

1. Management requirements: address the operation and effectiveness of the quality management system within a laboratory

2. Technical requirements: address the competence of staff, methodology, equipment, environment, and reporting

- QMS is a pre-requisite for the accreditation process

- Accreditation is independent and formal recognition of the **competence** a laboratory to perform specific tests.

Accreditation steps

1. Application for accreditation (by lab)
2. Acknowledgement of intention to apply (from accreditation body)
3. Initial review on quality manual (by assessor of accreditation body)
4. Stage 1 laboratory audit (optional)
5. Final assessment through laboratory audit (by assessor)
6. Initial review on quality manual (by assessor of accreditation body)
7. Recommendations for accreditation (by accreditation body)
8. Approval for accreditation (accreditation body)
9. Accreditation certificate issued by the accreditation body

Accreditation steps

3. Initial review on quality manual (by assessor of accreditation body)

ISO/IEC 17025, ANSI/NCSL Z540-1, And ANAB-specific Requirements Checklist		
CL 2001	Authority: Vice President	Effective: 2015/01/01

An asterisk (*) indicates section where objective evidence is required.

Organization Name: [redacted]

Assessment Dates: June 2, 2015

Lead Assessor: [redacted]

5.9.1.A8 – **ANAB Requirement – Initial Accreditation Assessment**

Requirements	Document Review	Assessment Compliant
Has the laboratory participated in PT/ILC within the last 12 months?	No objective evidence	OFI

9. Accreditation certificate issued by the accreditation body

ANAB

CERTIFICATE OF ACCREDITATION

ANSI-ASQ National Accreditation Board
500 Montgomery Street, Suite 625, Alexandria, VA 22314, 877-344-3044

This is to certify that

[redacted]

ISO/IEC 17025:2005

while demonstrating technical competence in the field of

TESTING

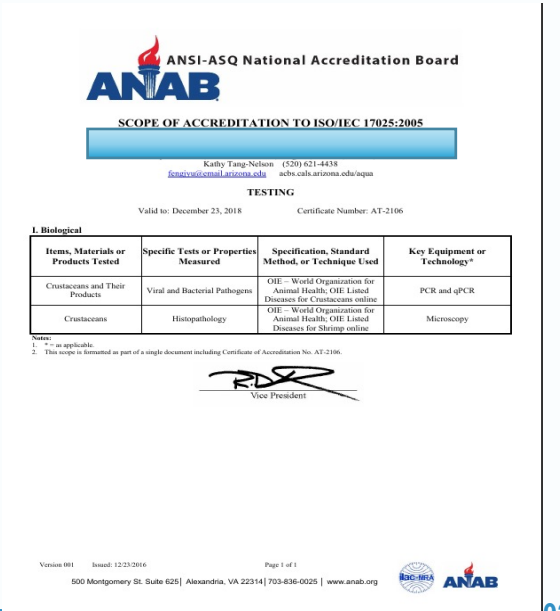
Refer to the accompanying Scope of Accreditation for information regarding the types of tests to which this accreditation applies.

AT-2106
Certificate Number

ANAB Approval

Certificate Valid: 12/23/2016-12/23/2018
Version No. 001 Issued: 12/23/2016

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005. This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (refer to joint ISO-ILAC-IAF Communiqué dated January 2009).



ANSI-ASQ National Accreditation Board

ANAB

SCOPE OF ACCREDITATION TO ISO/IEC 17025:2005

[redacted]

Kathy Tang-Nelson (520) 621-4438
fengtyn@email.arizona.edu aebs.cals.arizona.edu/aqua

TESTING

Valid to: December 23, 2018 Certificate Number: AT-2106

I. Biological

Items, Materials or Products Tested	Specific Tests or Properties Measured	Specification, Standard Method, or Technique Used	Key Equipment or Technology*
Crustaceans and Their Products	Viral and Bacterial Pathogens	OIE – World Organization for Animal Health; OIE Listed Diseases for Crustaceans online	PCR and qPCR
Crustaceans	Histopathology	OIE – World Organization for Animal Health; OIE Listed Diseases for Shrimp online	Microscopy

Notes:
1. * = as applicable.
2. This scope is formatted as part of a single document including Certificate of Accreditation No. AT-2106.

Vice President

Version 001 Issued: 12/23/2016 Page 1 of 1

500 Montgomery St. Suite 625 | Alexandria, VA 22314 | 703-836-0025 | www.anab.org

What is quality manual?

- The Quality Manual (QM) is a document that describes the quality system implemented in the lab.
- Describes lab's quality policies and objectives
- The manual is a guide for meeting quality assurance
- Refers standard operating procedures (SOPs), processes and management practices, it must always be up to date

The internationally acceptable quality management system:

1. ISO/IEC 17025
2. “OIE Quality Standards and Guidelines for Veterinary Laboratories: infectious diseases (2008)”
3. American Association of Veterinary Laboratory Diagnosticians (AAVLD) in the US.

ISO/IEC 17025: develops and provides the standard for accrediting testing and calibration laboratories

- ISO/IEC 17025 specifies the general requirements for the competence to carry out tests, including sampling.
- Accreditation bodies may use it in confirming or recognizing the competence of laboratories.
- ISO is not an accrediting body.

ISO/IEC 17025:2017

4.0	**General requirements**
4.1	Impartiality (declaration, policy)
4.2	Confidentiality (declaration, policy)
5.0	**Structural requirements**
	Organization chart (legal responsibility)
6.0	**Resource requirements**
6.1	General
6.2	Personnel
6.3	Laboratory facilities & environmental conditions
6.4	Equipment
6.5	Metrological traceability (n/a)
6.6	Externally provided products & services

4.0 General requirements

- Documents no conflict of interest with lab's relationship
- Have policies and procedures to ensure protection of customers' confidential information and proprietary rights
- Have policies in placed to avoid involvement in activities that would negatively affect its competence, impartiality or operational integrity
- Have sufficient numbers of Management and Technical staff with adequate authorities

4.0 General requirement

The AADL (laboratory name) as an example

a) Has a laboratory Director and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the **implementation, maintenance and improvements to the Management system** and to identify the occurrence of deviations from the quality system or from the procedures for performing tests and to initiate actions to prevent or minimize such deviations.

b) Has arrangements to ensure management and personnel are **free** from any undue internal or external commercial, financial and other **pressures and influences that may adversely affect the quality of their work.**

c) Has policies and procedures to **ensure protection of clients' confidential information and proprietary rights**, including procedures for protecting electronic storage and transmission of results.

d) Has policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity. To ensure confidence in laboratory operations a **quality assurance program is implemented**. Impartiality is assessed through internal and external audits and approvals. Judgment is ensured through the hiring of qualified personnel and by continuously improving their skills. Operational integrity is reviewed by management on a regular basis at **management review meetings** to ensure continued suitability and effectiveness of laboratory policies and procedures. Any problems are acted on immediately through **corrective action procedures**.

4.0 General requirement

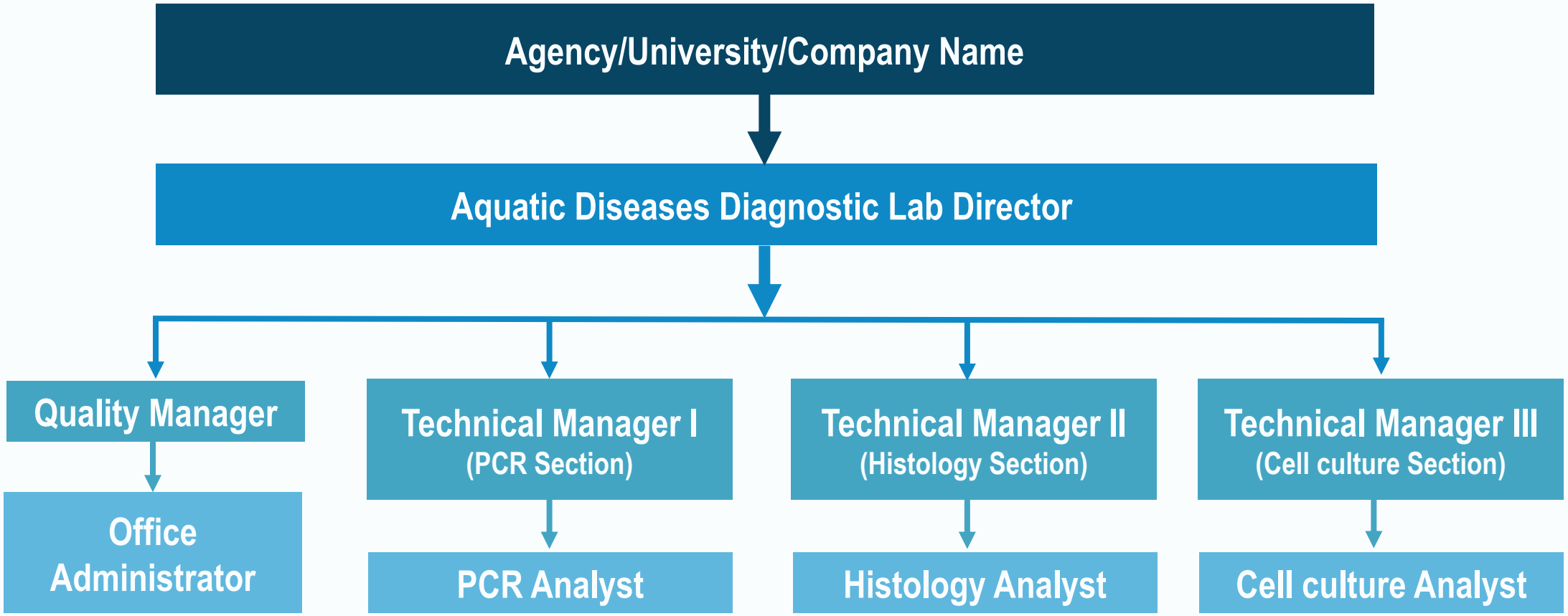
The AADL (laboratory name) as an example

Related Procedures

- AADL has a policy ### **Quality manual**
- AADL has a procedure, QSP xx **Internal audit**
- AADL has a procedure, QSP xx **Management review**
- AADL has a procedure, QSP xx **Employee /student training**
- AADL has a procedure, QSP xx **Corrective actions**

5.0 Structural requirement

Organization Chart:



6.1 General

The laboratory shall have available personnel, facilities, equipment, quality systems and support services necessary to perform its laboratory activities

6.2 Personnel

- Competent, qualified staff on basis of education, training, experience and demonstrated skills
- Supervisors who give opinions and interpretations of test results should have additional qualifications
- Effectiveness of training shall be monitored and documented in training records
- Authorize specific staff for specific work

6.3 Laboratory facilities & environmental conditions

Purpose:

Provide a safe and secure (access controlled) place to correctly perform the tests, which require appropriate conditions for the testing equipment

Procedure:

Implement appropriate and adequate measures to control facilities, these conditions (room separation, room and freezer temperature, humidity) must be monitored and documented.

6.4 Equipment

- The laboratory shall possess or have access to all equipment necessary for the correct performance of testings.
- All equipment shall be identified, properly maintained and calibrated with maintenance and calibration procedures documented.
- Items such as pipettes, balances, pH meter, and instruments such as spectrophotometers, etc. require regular calibration.
- Some items, such as thermocyclers, biosafety cabinets; they need to have annual calibration.

6.6 Purchasing services and supplies

The lab should have a policy and procedure to ensure that services and supplies meet pre-established specifications and will not adversely affect the quality of test results.

Considerations for selection include:

Procedure or equipment specifications, equipment and product availability in the laboratory, cost, laboratory staff competence, regulatory or accreditation requirements, vendor qualifications, ease of use

ISO/IEC 17025:2017

7.0	Process requirements
7.1	Review of requests, tenders and contracts
7.2	Selection, verification & validation of methods
7.3	Sampling
7.4	Handling of test or calibration items
7.5	Technical records
7.6	Evaluation of measurement uncertainty
7.7	Assuring the quality of test results
7.8	Reporting results
7.9	Complaints
7.10	Management of nonconforming work
7.11	Control of data-information management

7.1 Review of requests, tenders, and contracts

- Have procedures in place for this testing
- Have necessary resources
- Differences resolved before acceptance
- Can be oral or documented

7.2 Selection, verification & validation of methods

Selection of methods

- Proficiency of the analysts
- Validate before running routine diagnostic work, with appropriate controls in place to ensure the test results are reliable

Validation of test methods

- When is a method considered validated? (see OIE aquatic manual chapter 1.1.2 “Principles and methods of validation of diagnostic assays for infectious diseases”)
- Retention of validation data

Criteria for selection of testing methods*

- Acceptance by scientific and international communities
- Suitable performance characteristics (e.g. diagnostic sensitivity and specificity, repeatability, reproducibility)
- Suitability of the test for its intended use (e.g. trade, surveillance, diagnostic)
- Feasibility of the method given available laboratory resources (reference materials and proficiency testing schemes)
- Sample type (e.g. blood, tissues) and its expected quality/state on arrival at the laboratory
- Test turnaround time
- Resources and time available for development, evaluation
- Customer expectations
- Cost of test, per sample

*OIE aquatic manual, chapter 1.1.1. - Quality management in veterinary testing laboratories

7.3 Sampling

- The selection of samples or sites
- Sampling plan
- Sample handling (Safety consideration), transport, storage and final disposal
- Conditions for acceptance of sample as fit for testing
- Sample preparation prior to testing

7.4 Handling of test or calibration items

- Equipment, reagents, supplies, software required for the testing
- Calibration of equipment used for testing
- Operation of equipment proficiently

7.5 Technical records

- The collection procedure
- Identification of the collector
- Relevant environmental conditions in the collection site
- Statistics used to determine the sampling plan

7.7 Assuring the quality of test results

Required to have written procedures for monitoring the validity of test results through the use of:

- Blind proficiency testing
- International reference materials
- Replicate tests
- Re-testing of retained specimens
- Inter-laboratory comparisons

7.8 Reporting of results

- Each test result must be reported accurately, clearly, objectively, and in accordance with the test method.

- Reports must include: A title, name and address of the testing lab, unique ID of the case, name and address of client, specimen ID, date of receipt, test method(s), test results, diagnostic interpretations, name of person authorizing report.

7.10 Management of nonconforming work

- A nonconformance is an event (client complaint), result (testing discrepancies, proficient test problem) or procedure (audit finding) that does not comply or agree with documents, procedures, policies of QMS requirements
- Implement policies and procedures for dealing with noncomformance.
- Initiation of corrective action (CA)

ISO/IEC 17025:2017

8.0	Management requirements
8.1	Option A
8.2	Management system (MS) documentation
8.3	Control of MS documents
8.4	Control of records
8.5	Actions to address risks & opportunities
8.6	Improvement
8.7	Corrective action
8.8	Internal audits
8.9	Management review (agenda)

8.2 Management System (MS) documentation

- The laboratory must implement document management policies and objectives that address the competence, impartiality and consistent operation of the laboratory
- Ensure that all procedures, processes and records are included, referenced or linked to the quality manual
- Understood by all the Lab members, and communicated to all personnel
- Ensure all personnel have access to the relevant parts of the MS documentation applicable to them

8.3 Control of MS documents

Lab must ensure that:

- documents are approved by authorized personnel prior to issue
- documents are periodically reviewed and updated
- documents are uniquely identified
- changes and the current revision status of documents are identified and dated

8.6 Improvement

The lab must identify opportunities for improvement through implementing any necessary actions. The activities that help for improvement:

Corrective action, internal audit, management review, periodic review of SOPs, feedback from clients.

Analyse these activities and use them to improve the management system and testing activities.

8.7 Corrective action

- When nonconformity occurs, the top management must implement Corrective Action
- Start with a cause analysis (analysis of all potential causing factors)
- Identify all potential corrective actions (select and implement)
- Shall monitor corrective actions effectiveness
- The entire process should be documented

8.8 Internal audits

- Done periodically– All elements of system
- Done by trained and qualified staff, by persons independent of activities to be audited

8.9 Management Review

Identifies what should be considered

- Objectives of lab
- Actions performed from previous management reviews
- Effectiveness of corrective actions
- Period (12 months)

Food and Agriculture Organization of the United Nations

SUSTAINABLE DEVELOPMENT GOALS

Thank you for your attention!

Kathy Tang-Nelson
ktangnelson@gmail.com

TCP/INT/3707:
Strengthening biosecurity (policy and farm level) governance to deal with Tilapia lake virus

This was also made possible with the support of the Norwegian Agency for Development Cooperation under the project GCP/GLO/979/NOR Improving Biosecurity Governance and Legal Framework for Efficient and Sustainable Aquaculture Production.

Norad