OIE Quality Standard for Veterinary Laboratories

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Why Quality Management?

As a testing laboratory:

- Instil confidence & create acceptance
  - Sound management
  - Technical competence
  - Validity of results
Quality management in veterinary testing laboratories

A good introduction to QMS

Terrestrial Manual
- Chapter 1.1.3

Aquatic Manual
- Chapter 1.1.1
OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases

- OIE Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Diseases
  - OIE Guide 1: Validation of diagnostic assays for infectious diseases
  - OIE Guide 2: Validation and quality control of polymerase chain reaction methods used for the diagnosis of infectious diseases
  - OIE Guide 3: International reference antibody standards for antibody assays
  - OIE Guide 4: Laboratory proficiency testing
  - Glossary of Terms
A Brief Historical Perspective


ISO/IEC Guide 25 (Period of Transition)


OIE Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Diseases

- ISO/IEC 17025:2005 - General requirements for the competence of testing and calibration laboratories
- OIE Standard represents an interpretation of the generally stated requirements of the ISO Standard
- OIE Standard may be used by accreditation bodies
- Labs in compliance with the OIE Standard also operate in accordance with the ISO Standard
- Unique to laboratories conducting tests for infectious animal diseases
- Special emphasis on Clause 5 - Technical requirements
Clause 5 - *Technical requirements*

5.4 Test Methods

5.4.1 General

- Relevance of the test method and test results to a specific diagnostic interpretation or application:
  - Suitability or ‘fitness for purpose’
  - Acceptability by scientific and regulatory communities
  - Acceptability to the client / customer
  - Feasibility given laboratory resources
Clause 5 - Technical requirements

5.4 Test Methods

5.4.3 Validation of test methods

- Validation according to the principles outlined in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
  - Analytical sensitivity & specificity
  - Precision & accuracy
  - Diagnostic sensitivity & specificity
  - Other parameters
Validation of Diagnostic Tests

Principles of validation of diagnostic assays for infectious diseases

Validation and quality control of polymerase chain reaction methods used for diagnosis of infectious diseases

Combined into one document

Terrestrial Manual
- Chapters 1.1.4 & 5

Aquatic Manual
- Chapters 1.1.2 & 3

OIE Ad hoc Group on Validation of diagnostic assays
Validation Pathway for Diagnostic Test Methods

- Stage 1 - Analytical characteristics (*Bench*)
- Stage 2 - Diagnostic characteristics (*Field*)
- Stage 3 - Reproducibility (*Ruggedness*)
- Stage 4 - Applications (*Repertoire*)

http://www.oie.int/vcda/eng/en_background_vcda.htm
If one of your goals is to become accredited, just remember……
Standards, Guidelines & Templates

OIE Validation and Certification of Diagnostic Assays
Quality Management Credo

Say what you do…… & do what you say!
Has persistence been rewarded?

"Challenges are what make life interesting; overcoming them is what makes life meaningful." - Mark Twain
Adopted as a Benchmark by the AAVLD

Requirements for an Accredited Veterinary Medical Diagnostic Laboratory

American Association of Veterinary Laboratory Diagnosticians, Inc.

Version 4.3
A.1 Evaluation Criteria

The NAHLN Steering Committee develops criteria for entry into and maintenance of all veterinary diagnostic laboratories in the NAHLN. If a decision is made to introduce a laboratory into the NAHLN in a state, the laboratory must first meet the following criteria:

4. **Licensure/certification** - Must be an American Association of Veterinary Laboratory Diagnosticians (AAVLD) accredited laboratory or other public, not-for-profit, animal disease diagnostic laboratory with an established quality assurance system meeting OIE/ISO 17025 standards and selected by the USDA.

Incorporated into a Veterinary Specialty by A2LA

American Association for Laboratory Accreditation

PRESS RELEASE

A2LA adds new Veterinary Accreditation Program requirements.

……. Veterinary laboratories world-wide may choose to meet the ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories as a stand-alone requirement for accreditation or the combined criteria of ISO/IEC 17025:2005 and the OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008……. (excerpt)

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"All our dreams can come true... if we have the courage..."

Walt Disney

The race for quality has no finish line – so technically, it’s more like an elusive dream.
Quality Management is Central & Essential

- QM impacts many lab activities:
  - Diagnostic testing
  - Research & development
  - Information management
  - Biocontainment & biosecurity
  - Health & safety
The End

Questions?

JOURNEY
A bend in the road is not the end of the road... unless you fail to make the turn!