

OIE Booklet on Quality Standard for Veterinary Laboratories

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1



1

Why Quality management system in veterinary testing laboratories?

Valid laboratory results are essential for diagnosis, surveillance, and trade.

Such results are achieved by the use of good management practices, valid test and calibration methods, proper technique, quality control, and quality assurance, all working together within a quality management system.

2



2

Quality management system in veterinary testing laboratories

A good introduction to QMS

Terrestrial Manual

- Chapter 1.1.3

Aquatic Manual

- Chapter 1.1.1



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Terrestrial and Aquatic Manuals

- Chapter 1.1.3./1.1.1., « Quality Management in Veterinary Testing Laboratories »

http://www.oie.int/eng/normes/mmanual/a_summry.htm

http://www.oie.int/eng/normes/fmanual/A_summry.htm

- **Objective:** Outlines the important issues and considerations a laboratory should address in the design and maintenance of its quality management programme.

4



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Terrestrial and Aquatic Manuals

➤ Outline of the Chapter

1. The work, responsibilities, and goals of the laboratory
2. Standards, guides, and references
3. Accreditation
4. Selection of an accreditation body
5. Determination of the scope of the quality management programme and/or of the laboratory's accreditation
6. Test methods
7. Strategic planning

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5

OIE Quality Standard and Guidelines for Veterinary Laboratories

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OIE Quality Standard and Guidelines for Veterinary Laboratories

1st Edition
2002



2nd Edition
2008

Published under the aegis of the Biological Standards Commission

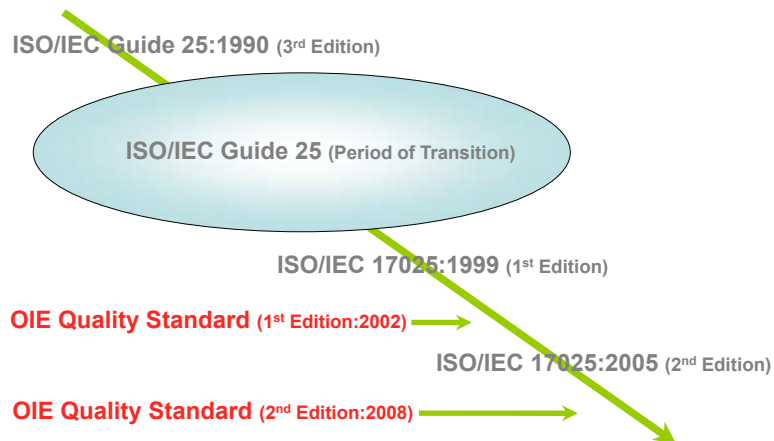
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OIE Quality Standard and Guidelines for Veterinary Laboratories

A brief Historical Perspective



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OIE Quality Standard and Guidelines for Veterinary Laboratories

This publication provides a useful and practical guide to laboratories seeking to improve or to maintain a level of performance that is acceptable to and recognised by national authorities and international organisations.

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9

OIE Quality Standard and Guidelines for Veterinary Laboratories

Publication divided in three parts:

- **I.** First part is the OIE Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Diseases
- **II.** Second part is 4 additional guidelines for veterinary laboratories
- **III.** Third part is a Glossary of Terms

10



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I. OIE Standard for Management and Technical Requirements for Laboratories Conducting tests for Infectious Diseases

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11

OIE Standard for Management & Technical Requirements for Lab. Conducting tests for Inf. Diseases

- Specific interpretation for veterinary laboratories of the ISO/IEC 17025 quality standard for testing laboratory
- Laboratories in compliance with the OIE Standard also operate in accordance with ISO Standard
- May be used by accreditation bodies (e.g. AALA)
- Unique to laboratories conducting tests for infectious animal diseases

12



12

OIE Standard for Management & Technical Requirements for Lab. Conducting tests for Inf. Diseases

➤ General Outline:

1. Scope
2. Normative references
3. Terms and definitions
4. Management requirements
5. Technical requirements
6. References

➤ Special emphasis on Clause 5

13



13

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

14



14

Clause 5 – Technical requirements

5.4 Test Methods

5.4.3 Validation of test methods

➤ “A test method shall be considered appropriate for routine diagnostic purposes only if it has been **validated according to the principles outlined in the OIE Manual and other related OIE references**”

1. Analytical sensitivity & specificity
2. Precision & accuracy
3. Diagnostic sensitivity & specificity
4. Other parameters

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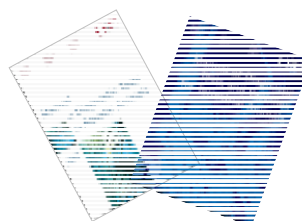
OIE General Principles on Validation

Principles of validation of diagnostic assays or infectious diseases

Combined into one document



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



Terrestrial Manual
• Chapters 1.1.4/5

Aquatic Manual
• Chapters 1.1.2.

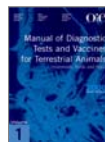
OIE ad hoc Group on Validation of diagnostic assays

16



16

Chapters 1.1.4/5 of the OIE *Terrestrial Manual* and 1.1.2. of the *Aquatic Manual*



- New chapter resulting from the fusion of the two previous chapters on the validation.
- 7 Appendixes are in development.
- Chapter available and downloadable on the OIE website:
http://www.oie.int/eng/normes/mmanual/A_summry.htm
http://www.oie.int/eng/normes/fmanual/A_summry.htm

17



17

II. The 4 additional guidelines for veterinary laboratories

18



18

The 4 Additional Guidelines

➤ They are:

1. Validation of Diagnostic Assays for Infectious Diseases
2. Validation and Quality Control of PCR Methods used for the Diagnosis of Infectious Diseases
3. International Reference Antibody Standards for Antibody Assays
4. Laboratory Proficiency Testing

19



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Guides 1 & 2 on validation of diagn. assays

1. Validation of Diagnostic Assays for Infectious Diseases
 2. Validation and Quality Control of PCR Methods used for the Diagnosis of Infectious Diseases
- Based on the previous version of the chapters on the OIE general principles on validation of diagnostic assays of the *Terrestrial* and the *Aquatic* Manuals.

20



20

Guide 3: International Reference Antibody Standards for Antibody Assays

- It provides guidelines for the preparation, validation and distribution of antibodies as International Reference Standards for antibody assays for infectious diseases of animals.
- Such standard preparations are designated by the OIE as primary reference standards for use in conjunction with tests described in the OIE *Terrestrial Manual*.

21



21

Guide 4: Laboratory Proficiency Testing

- It provides guidelines for evaluation of veterinary laboratory capability to conduct diagnostic tests for infectious diseases.
- Intended for use by OIE Members as part of the evaluation of laboratories that are carrying out tests to qualify animals and animal products for international movement.

22



22

Thank you for your attention



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de la Santé Animale

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23

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23