QUALITY MANAGEMENT IN VETERINARY TESTING LABORATORIES

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Maintenance of quality management system certified according to Int’l Standards

- ISO 17025: 69.31%
- No: 13.86%
- In preparation to achieve ISO 17025: 12.38%
- System in place that complies with Chapter 1.1.4 of the OIE Terrestrial Manual: 4.46%

2013

- ISO 17025: 73.76%
- No: 10.40%
- In preparation to achieve ISO 17025: 15.84%

2013 – post follow-up
A quality system is an essential part of the management of the laboratory – not an add on!

A Modern laboratory with a QA system?
Quality management in veterinary testing laboratories

• Good introductions to QM
  • Terrestrial Manual
    • Chapter 1.1.4
  • Aquatic Manual
    • Chapter 1.1.1
OIE Quality Standard and Guidelines for Veterinary Laboratories

• 1st Edition
  • 2002

• 2nd Edition
  • 2008

• NB It is not currently proposed to publish a 3rd Edition

Published under the aegis of the Biological Standards Commission
OIE’s Position

Valid laboratory results are essential for diagnosis, surveillance and trade

An effective Quality Management System requires

- Good management practices
- Valid test and calibration methods
- Trained staff competent in the test methodology
- Quality control and quality assurance practices
- Accreditation to ISO 17025 or equivalent
General (pre-test) matters that are managed in an ISO 17025 accredited Quality System

- Organization and management of the laboratory
- Management review
- Staff and training
- (Appointment of technical managers)
- Accommodation and environment
- Equipment
- Documentation and document control
- Contract review
- Complaints
Key Quality Assurance System Roles

Director

QA Manager / Officer

Technical Managers

Internal Auditors

Equipment Supervisors
Ensuring Commitment

- The Quality Manager is the only post required to be defined

- You do not have to use the title but must identify the person responsible.
QA Manager’s Role

Ensuring Commitment

- Working with top management to impress importance of quality assurance
- Developing a process of management review
QA Manager’s Role

Establishing and Managing Key Committees

- A Quality Assurance Committee
- An Internal Audit Working Group
- An Equipment and Calibration Working Group
QA Manager’s Role

Managing External (Accreditation) Audits

- Work with Accreditation bodies and help to develop a program that suits both parties
- Communicate the Audit Program to relevant staff
Test related matters that are managed in an ISO 17025 accredited Quality System

- Specimen management
- General methods for utilization of laboratory facilities and equipment
- Test development and validation
- Accredited test methods
- Reporting
Over-arching matters that are managed in an ISO 17025 accredited Quality System

- Internal audits
- Control of nonperformance – Corrective actions
- Quality Control (Internal/External)
- Accreditation itself
Why Internal Audits?
Internal Audits

A specific requirement of ISO 17025 & 9001

- In effect, the standards require the organisation to establish an on-going program of internal audits to
  - Monitor the performance of the system
  - Monitor continual improvement
Internal Audits

Internal audits aim to check:

- Compliance with procedures / methods
- Effectiveness of the process
- Improvements
- Identification of training and resource needs
Internal Auditing - linked processes

Audit Schedule → Conduct Audit

Audit Report

Corrective Actions → Management Review
Third Party Interest

- Accreditation bodies will have an interest in the internal audit program and will assess the findings.

- Internal audits should identify major non-conformances before they go to external audits.
Accreditation

• Chapter 1.1.4 Section 3 of the Manual gives the advantages of accreditation.

• Accreditation is formal recognition of the Quality Management System

• Third party verification of conformity with a nominated, internationally accepted standard is required (such as the ISO/IEC 17025 standard)

• In future OIE reference laboratories will be asked to attach a copy of the “Scope of Accreditation” issued by the accrediting authority
Summary of the points raised:
A quality management system

- Is an integral part of the management of the laboratory
- Requires commitment of the Head of Laboratory
- And a person with dedicated responsibilities
- Compliance with a standard (Chapter 1.1.4, ISO 17025)
- 3rd party assessment
- Accreditation – esp our OIE Reference Laboratories!