Testing the Testing Laboratory – ISO/IEC 17025.

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ISO 17025:2005 (Reviewed in 2010)

- ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.
- It is applicable to all organizations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where **testing and/or calibration forms part of inspection and product certification.**

Assessment of Microbiology Laboratories in Canada using ISO 17025:2005

- **Canadian Food Inspection Agency (CFIA)**
  - Central Laboratory (Nepean, Ontario)
  - CFIA Charlottetown (National potato laboratory – Potato quality and fungus laboratory)
  - CFIA Lethbridge – includes anthrax, *Yersinia pestis*, Chronic wasting disease, rabies, TB. Brucellosis.
  - CFIA Saskatoon – Parasitic diseases, *Trichinella*, food borne parasites.
  - CFIA Winnipeg - Canadian Science Centre for Human and Animal Health
  - **CFIA St. Hyacinthe** – Porcine and retroviral diseases.
  - CFIA Calgary – Enteric pathogens in foods
  - CFIA Burnaby – Microbial pathogens in foods

- **Department of Fisheries and Oceans (DFO).**
  - Winnipeg, Moncton**, Naniamo, Charlottetown**, Dartmouth,

Purpose

- Assure the quality of laboratory investigations into practically everything Canadians put in their mouths or are exposed to.
- Assure the quality of animals, meats and materials that are sent for export. .
  - Animals – Brucellosis, *Salmonella, Shigella*, *Campylobacter, Yersinia, Listeria*, anthrax, tuberculosis, rabies, etc.
  - Foods – Potatoes, lettuce, etc.
  - Seafood, Fish (fresh and saltwater), crustaceans (muscles, scallops)

Assessment and Accreditation by Standards Council of Canada (SCC)

- Every two years
- Assessments are not blinded
- Assessments according to Scope of Testing provided by laboratory
  - CFIA, DFO determine what that scope will be.
- Scheduling determined by SCC
- Lead Assessor and technical assessors determined from pool of expertise of professionals who regularly undertake training updates from SCC.
- Testing laboratories provide SOPs (uncontrolled) to auditors as required prior to the audit.
- Most laboratories have relatively small numbers of SOPS for each discipline. (e.g. 7 – 10)
- Audits require 2 – 3 days of intense investigation.

Components of the Inspection according to ISO 17025 (Can-P-4E)

Management Requirements

- Organization
- Quality system
- Document Control
- Review of Requests, Tenders and Contracts
- Subcontracting of tests and calibrations
- Purchasing of Services and Supplies
- Service to the Client
- Complaints
- Control of Non-conforming testing and/or calibrations
- Corrective Action
- Preventative Action
- Control of Records
- Internal Audits
- Management Reviews

Components of the Inspection according to ISO 17025 (CAN-P-4E)

Technical requirements

- General (human factors, environmental, equipment, etc.)
- Personnel
- Accommodations and Environmental Conditions
- Test and calibrations methods and method validation
- Equipment
- Measurement traceability
- Sampling
- Handling of test and calibration items
- Assuring the quality of test and calibration results.
- Reporting of Results.

Responsibilities of the Assessors

- **Team Lead**
  - Confers with Assessors prior to inspection to determine and confirm that appropriate expertise is in place for the Scope of Accreditation.
    - At least one Assessor for each component of the laboratory – microbiology, chemistry, toxicology, etc.
  - Ensures that Assessors have required SOPs prior to the on-site assessment for pre-review.
  - Undertakes the management aspects of the laboratory review
  - Confers with management and directors regarding, staffing, personnel, quality management systems, computers, etc.
  - Confers with the assessors to ensure that all aspects of the technical review have been completed, and that non-conformities cited are legitimate and referable to an ISO 17025 (CAN-P-4E) requirement.
  - Organizes and ensures that the follow-up responses are reviewed by the Assessors and that the responses are appropriate for the Scope of Accreditation

Responsibilities of the Assessors.

- **Technical Assessors**
  - Comprehensive review of the Scope of Accreditation for their area of expertise prior to the on-site assessment.
  - Assessment of all aspects of the Technical Requirements of ISO 17025 for each component of the Scope of Accreditation
    - e.g. Environment, personnel, equipment, testing and test validation, traceability , external quality assurance, quality of the result, safety, etc.
    - Pre-analytic, analytic and post-analytic observations.
  - Responsibility for objective and scientific evidence for non-conformities.

Testing the quality of the laboratory – important regular features

- Over-arching quality management system
  - Is there a program in place that covers all aspects of the laboratory?
  - Is there a defined quality manager with defined responsibilities?
  - Are there regular quality meetings with documentation of issues raised and documented solutions?

Testing the quality of the laboratory – important regular features

- Personnel
  - Records of education, training, continuing education. Expertise for assigned tasks.
- Document control
  - Regular review and sign off of documents
  - Control of documents and records
  - Computer system and security

Testing the quality of the laboratory – important regular features

- Services
  - Service to the Client.
    - Who are the clients? – Usually veterinarians with contracts with CFIA or DFO
    - Includes purchase of services
    - Subcontracting of services.
    - Tests, requests and contracts

Testing the quality of the laboratory – important regular features

- Corrective Actions
  - Control of non- conforming tests and calibrations.
  - Complaints
  - Preventive action
- Management Reviews
  - Internal audits
  - Review of management policies

Walking the Talk - testing the test. Examples from the field

- Reference Materials – intermediate checks.
  - Checks to maintain confidence in the calibration status of reference, primary, transfer, or working standards and reference materials ---
    - Rabies virus control documentation from 2000 back to 1968.
- Sub-contracting
  - The laboratory performing the work shall issue the calibration certificate to the contracting laboratory
    - Subcontractor not an accredited laboratory – No ISO, or any other accreditation.

Walking the Talk - testing the test. Examples from the field

- Validation of test methods
  - Laboratory shall validate non-standard, lab-designed or developed, or standard methods used outside their scope, and validate the accuracy, detection limits, reproducibility, etc. of the methods.
    - e.g. Validation done by external laboratory. Quality control at test laboratory showed consistent high end of range. Validation data obtained from external lab showed incorrect decimal place

Walking the Talk - testing the test. Examples from the field

- Safety
  - Essential wearing of gloves for performance of a test was not consistent among personnel – Not identified in Safety documents.
- Sample quality
  - Samples on a loading dock not clearly identified and stored at appropriate temperature prior to testing – opportunities for error.

How do I test the test – It's all about quality!

- Review of SOPs prior to and at beginning of inspection
- Follow samples for each test in the Scope of Accreditation
  - Pre-analytic:
    - Sample from farm to laboratory – documentation, storage, identification, set-up according to SOP, retention.
  - Analytic:
    - Set-up of test, training records, quality control, validation of test method, physical environment, (incubators, fridges), equipment (pipettes, centrifuges, etc), external quality assurance (PT)
  - Post-analytic
    - Review of results, turn-around to the client, documentation, complaints, corrective and preventive actions.

Areas of Uncertainty

- Uncertainty of Measurement
  - For quantitative assays, uncertainty of measurement can be determined, but difficult for qualitative measurements.
  - Many investigations are positive/negative with no positives on clinical samples (thank goodness!) (e.g. *Brucella*) . For these tests EQA is essential
  - Can apply uncertainty to each aspect of an investigation (e.g. pipettors required to dilute a sample or add a reagent). These are additive.
  - Laboratories can document areas of uncertainty and be aware of the potential cumulative effect even if not directly measureable.

Areas of Uncertainty

- External Quality Assurance (PT).
  - Many examinations in CFIA/DFO laboratories do not have national or international EQA agencies.
    - Blinded panels prepared by supervisory personnel for testing personnel.
    - CFIA/DFO inter-lab comparisons
    - Panels from expert researchers in the field. E
    - Samples from other ISO certified laboratories in the world willing to share

    Issue: EQA may not be done often enough – Once per year

Summary of Findings.

- Non-conformities
  - Unlike CAP and previous iterations of SCC guidance, no longer levels of non-conformity . All non-conformities are treated equally.
    - Prevents Assessor/Team Lead bias.
    - Reduces need to attach a level of criticality to an observation.
    - More objective.

Summary of Findings

- Opportunities for Improvement.
  - Also attached to an ISO 17025 - CAN-P-4E item number
    - Not essential to the operation or result generated by the laboratory.
    - Meant to document ways to apply continuous quality improvement. (e.g. Validation data from central laboratory to assist testing laboratory to assure quality of results.)
  - Commendations.
    - Laboratory and personal accolades are always helpful. (e.g. staff are more accommodating if external reviewers support the quality of their work.

The Non-Conformity Trail

- Part 1. General Information – lab, location, customer representative, lead assessor
- Part 2. Details of Non-conformity.
  - Assessor
  - Applicable standard and reference within the standard (i.e. 17025: CAN-P-4E: 5.3.3)
    - Effective separation of incompatible activities.
    - Objective evidence (what the assessor saw).
  - Non-conformity – i.e. the requirements were not met.

The Non-Conformity Trail

- Part 3. Causes of Non-Conformity, Corrections and Proposed Corrective Action (response by laboratory in 30 days)
  - Why did it occur
  - Changes implemented to solve the non-conformity
  - Long term changes proposed
- Part 4. Evaluation of Part 3 Responses.
  - Satisfactory, Unsatisfactory , Incomplete. (Assessor responds to all unsatisfactory and incomplete responses

The Non-Conformity Trail

- Part 5. Corrective Actions (response by the laboratory in 90 days)
  - Response by the laboratory – corrective actions taken with respective objective evidence. (e.g. Diagram to show how incompatible activities have been separated).
- Part 6. Review of the completed responses.
  - Satisfactory,
  - Satisfactory – but evaluation for full implementation at the next assessment
  - Not Satisfactory – evidence for concerns noted to be submitted as a follow up response.
  - Incomplete.
  - ALL Corrective Actions verified at next assessment.

Summary

- Testing the testing laboratory provides objective evidence of laboratory quality on an ongoing and regular basis – also of the quality of the assessors (evaluation by the laboratory)
- Using active experts in the field supports continuous quality improvement and advances in technology
- ISO (SCC) Accreditation process provides confidence to consumers that products are safe for our use and consumption.