Experiences Auditing to ISO/IEC 17025:2017

Discussion Topics

• Top issues noted during transition assessments

• Assessing performance-based systems
Top Issues

- Impartiality (clause 4.1)
- Metrological traceability (clause 6.5)
- Evaluation of measurement uncertainty (clause 7.6)
- Ensuring the validity of results (clause 7.7)
  - PT/ILC
- Statements of conformity/decision rules (clause 7.8.6)
- Complaint handling (clause 7.9)
- Actions to address risks and opportunities (clause 8.5)

Impartiality

- Impartial lab activities
- Structure and management commitment
- Commercial, financial or other pressures
- Identify risks on an on-going basis
- Demonstrate how risks are eliminated or minimized
Metrological traceability

- Traceable calibrations
- Use of CRMs
- Direct realization of the SI units

Evaluation of measurement uncertainty

- Identify contributions to measurement uncertainty
- Evaluate measurement uncertainty for all calibrations and test methods
  - Estimation where the test method precludes rigorous evaluation of measurement uncertainty
Ensuring validity of results

• Procedure for monitoring validity of results

• Record data to detect trends

• Apply statistical techniques, where practicable

• Plan and review monitoring

• Types of monitoring activities

Ensuring validity of results

• Monitor performance by proficiency testing or interlaboratory comparisons

• Data from monitoring activities

• Data outside pre-defined criteria
Decision rules and statements of conformity

- Decision rule: rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

- Clauses
  - 7.1.3
  - 7.8.6
Complaint handling

- Documented process to receive, evaluate and make decisions on complaints
  - Description of process
  - Tracking and recording
  - Ensuring action is taken

- Available to interested parties

- Confirm whether complaint relates to lab activities

Addressing risks and opportunities

- Risk related to
  - Impartiality
  - Decision rules
  - Actions taken for nonconforming work
  - Corrective action

- Review results of risk identification in management review
Assessing Performance-Based Systems

• Less prescriptive requirements

• Identifying objective evidence for determination of conformance

• Interviewing personnel

• Assessment documentation

Thank you

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