

Specific Clauses

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4.1 Impartiality

- Lab activities undertaken impartially
- Management commitment
- Shall not allow commercial, financial or other pressures to compromise impartiality
- Identify risks to impartiality on an on-going basis
- Demonstration how risk is eliminated or minimized

4.2 Confidentiality

- Protection of confidential information, including electronic storage and transmission of results
- Lab shall be responsible through legally enforceable commitments for the management of all information
 - Lab shall notify the customer in advance of information it intends to make public
- If the lab has to release confidential information (e.g., by law), it shall notify the customer (unless prohibited to do so)

4.2 Confidentiality (Cont'd)

- Information about the customer from a 3rd source (e.g., regulator or complainant)
 - Confidential between the lab and the customer
 - Cannot share the source with the customer
- Personnel keep information confidential (except as required by law)

5.6 Maintenance of the management system

- The laboratory shall have personnel with the authority and resources to:
 - Implement, maintain and improve the management system;
 - Identify deviations;
 - Initiate actions to prevent or minimize deviations;
 - Report to lab management on the performance of the management system;
 - Ensure the required validity of lab activities.

6.5 Metrological Traceability

- Differences/ changes:
 - Measurement traceability (ISO/IEC 17025:2005) vs Metrological traceability (DIS)
 - Annex A

7.8.5 Reporting Statements of Conformity

- The lab shall document the decision rule employed
 - Decision rule: A rule that describes how measurement uncertainty will be accounted for when stating conformity with a specified requirement

7.9 Complaints

- Documented process
- A description of the process shall be made available to any interested party on request

7.9 Complaints (Cont'd)

- Process shall include:
 - a description for receiving, validating, investigating the complaint, and deciding on actions
 - tracking and recording complaints and actions taken
 - ensuring appropriate action is taken.

7.9 Complaints (Cont'd)

- Lab shall be responsible for gathering and verifying information to validate the complaint
- Acknowledge receipt, provide progress reports, and the outcome (whenever possible)
- Outcomes shall be made by, or reviewed and approved by, individual(s) not involved in the original lab activities in question
 - *What about 1-2 person labs?*
- Formal notice of the end of the complaint handling (whenever possible)

8 Management Requirements

- Option A
 - Mgmt System Documentation
 - Document Control
 - Control of Records
 - Risks and Opportunities
 - Improvement
 - Corrective Action
 - Internal Audits
 - Management Review
- Option B
 - Management system that conforms to ISO 9001 and that is capable of supporting and demonstrating the consistent fulfillment of Clauses 4-7

8.5 Risks and Opportunities

- Consider risks and opportunities in order to give assurance that the system can achieve intended results, enhance opportunities, prevent or reduce undesired impacts, achieve improvement
- Does this sound familiar?