Lab Accreditation following ISO 17025 Standard

Abstract for Poster Presentation

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ISO 17025 documents the general guidelines that will enable different laboratories to demonstrate their competence and obtain valid results. The recommended requirements were drafted to help laboratories to develop and implement action plans that will address various risks and possibilities, enhance the efficacy of the management system, prevent negative implications, and accomplish better results. Furthermore, incorporating these guidelines into existing laboratory practices will foster collaboration with concerned stakeholders, enhance the exchange of information and experience, and ascertain the harmonization of standards and protocols. Most importantly, the conformity of laboratories with the requirements in this document will facilitate the acceptance of their results by organizations that conduct laboratory activities in various countries. This presentation is relevant to regulatory officials, laboratory customers, accreditation bodies, and agencies that rely on peer assessment.

Firstly, the ISO standard provides the scope of the publication and the normative references that served as a basis for establishing the laboratory guidelines and succinct definitions of the different terms used in the document. The first set of general requirements highlights the procedures that must be followed to ensure the objectivity of the laboratory management, address risks to impartiality, and avoid conflicts of interest. This presentation also documents well-established protocols to ensure the confidentiality of customers' information. In contrast, the structural requirements stipulate the need for the lab to be an incorporated business, outline the roles and responsibilities of the laboratory management, and accentuate the duties of personnel in the facility.

The next section of the ISO standard accentuates the general and personnel resources needed to carry out laboratory activities. This presentation also stipulates the required mode of conduct of staff, competence requirements for functions that influence laboratory results and activities, and the need to communicate the duties of employees and authorities in the facility. Furthermore, the standard documents the need to establish procedures and retain records to identify competence requirements, selection of qualified workers, training of staff, supervision of employees, authorization, and personnel monitoring. This presentation also indicates specific laboratory procedures that require the approval of staff. Other resource requirements stipulated in the standard include facilities and environmental conditions, access to the equipment needed for the correct performance of laboratory activities, adherence to the manufacturer’s instructions for using the gadgets, verification of the efficacy of the apparatus, and the development of protocols for the use, handling, transport, storage, and maintenance of equipment. The guidelines for outsourcing laboratory activities and ensuring the metrological traceability of measurement results are also documented in this presentation. These additional requirements include the specification of the measurement, the documentation of appropriate intrinsic, national, and international standards, the evaluation of uncertainty in each phase of the traceability chain, the identification of systematic measurement error, the documentation of standards for tasking readings, and provision of proof of technical competence to ascertain metrological traceability. In addition, comprehensive descriptions of recommended ways to demonstrate meteorological traceability are available in the annex section of the dissertation. These approaches include third-party recognition by an accreditation body, external assessment by customers, or self-assessment.

Subsequent sections of the standard provide the process requirements to ascertain the competence of laboratories are the implementation of procedures to review tenders, requests, and contracts, the development of appropriate selection, verification, and validation methods, the establishment of an effective sampling plan and approach and the incorporation of a reliable system to handle test and calibration items. Additional information on process requirements in this presentation includes the guidelines for the documentation of technical records, evaluation of the uncertainty of measurements, and determination of the validity of

results. Comprehensive information on the general and specific procedures for presenting laboratory results and issuing calibration certificates are also provided in this presentation. Furthermore, the recommended ways to report the sampling procedure, conformity statements, opinions and interpretations, and amendments to results are concisely written in this presentation. The protocols that must be followed to receive, evaluate and make decisions on various types of complaints are also accessible in the presentation. The standard describes the process for handling complaints and the role of laboratory management in addressing these issues. The presentation further accentuates the guidelines that must be implemented when the equipment, environmental conditions, or other aspects of the laboratory's activities or results do not conform with the stipulated requirements or procedures of the customer. The presentation also underscores the need to retain records of nonconforming work and actions and implement corrective actions that are based on the outcome of the evaluation. Other process requirements in this document include the role of authorities in the control of data and information management.

Another aspect of the standard highlights the different protocols to establish, document, incorporate, and maintain an effective management system in the laboratory. One of the options proposed in this presentation involves incorporating the principles of ISO 9001 for establishing and maintaining the laboratory's management system. In contrast, the second alternative in this presentation recommends the minimum requirements for developing a management system in laboratory activities. In this regard, the presentation provides guidelines for management system documentation, the control of records and management system documents, the implementation of actions to address risks and opportunities, improvement of the management system, development of corrective actions, and internal audits to ascertain an efficient management system.

The requirements for management system documentation encompasses the establishment, documentation, and maintenance of policies and objectives that address the impartiality, competence, and consistency of activities in the laboratory. The presentation also emphasizes that the procedures must be acknowledged and incorporated at all laboratory organization levels. Contrastingly, the control of management system documents encompasses the unique identification, periodic review, modification, approval, and regulated distribution of documents by authorized personnel. Additionally, requirements for the control of technical records include implementing regulations for the identification, storage, protection, archive, retrieval, retention time, and disposal of all laboratory records. The standard indicates that the retention of such records by the facility must be consistent with existing contractual obligations between the laboratory and its consumers.

The standard also underscores the need for laboratories to address risks and opportunities to ensure that the management system of the facility achieves the intended outcomes, create avenues to achieve the purpose and objectives of the organization, minimize and prevent potential failures in laboratory activities, and improve the efficacy of the management system. In this regard, the members of the laboratory organization must establish and integrate various actions that can be evaluated to determine their effectiveness in addressing risks and opportunities. The actions taken by the authorities should be proportional to the intended impact on the validity of results obtained at the facility. Suggested ways to improve the efficacy of the management system involve getting positive and negative feedback from customers and suggestions from personnel. Other solutions include the review of operational protocols, existing policies, audit results, corrective actions, assessment of risks, data analysis, and proficiency test results. The presentation also emphasizes the need for periodic management reviews to ensure the suitability, adequacy, and effectiveness of the system.