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AN INTRODUCTION TO
ISO/IEC 17025

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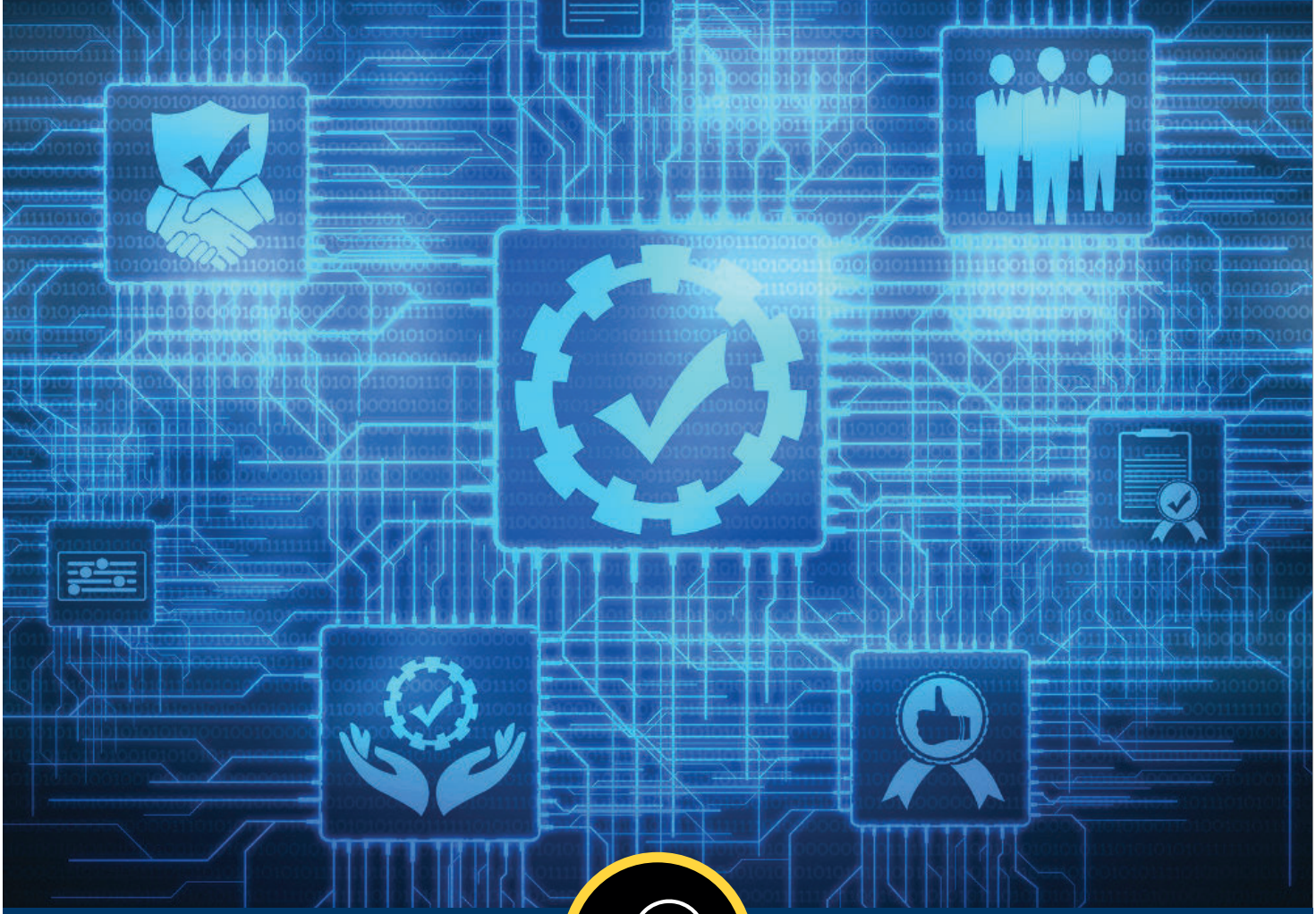


Overview

ISO/IEC 17025 is a global standard for testing and calibration laboratories, developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). It ensures that laboratories produce reliable, accurate, and consistent results. Accreditation under ISO/IEC 17025 is widely recognized, signifying a laboratory's commitment to quality and technical competence.

The standard covers various aspects, including technical competence, measurement traceability, and the evaluation of measurement uncertainty. It also addresses structural, resource, and management requirements essential for maintaining high-quality laboratory operations.

The 2017 update emphasizes a risk-based approach and integrates modern standards like ISO 9001:2015, with a focus on information technology and flexibility in processes.

Achieving ISO/IEC 17025 accreditation offers numerous benefits, such as increased customer confidence, reduced need for retesting, and enhanced international recognition. Laboratories are encouraged to continuously improve by keeping up with technological advancements and industry best practices, ensuring they maintain the accuracy, integrity, and reliability of their testing and calibration results.

An Introduction to ISO/IEC 17025

What is ISO/IEC 17025?

- A quality standard developed by the **International Organization for Standardization** (ISO).
- Ensures quality, reliability, and repeatability of laboratory tests and calibrations.
- Globally recognized as an indicator of laboratory quality.

Why is it Important?

- Accreditation demonstrates a laboratory's commitment to delivering accurate and reliable results.
- Regular evaluations by external certification bodies (e.g., **A2LA**, **UKAS**) ensure compliance.

"ISO/IEC 17025 is a quality standard for testing and calibration laboratories, ensuring they produce reliable and repeatable results. It covers technical competence, measurement traceability, and the evaluation of measurement uncertainty, among other areas. This standard is essential for maintaining high-quality laboratory operations globally."

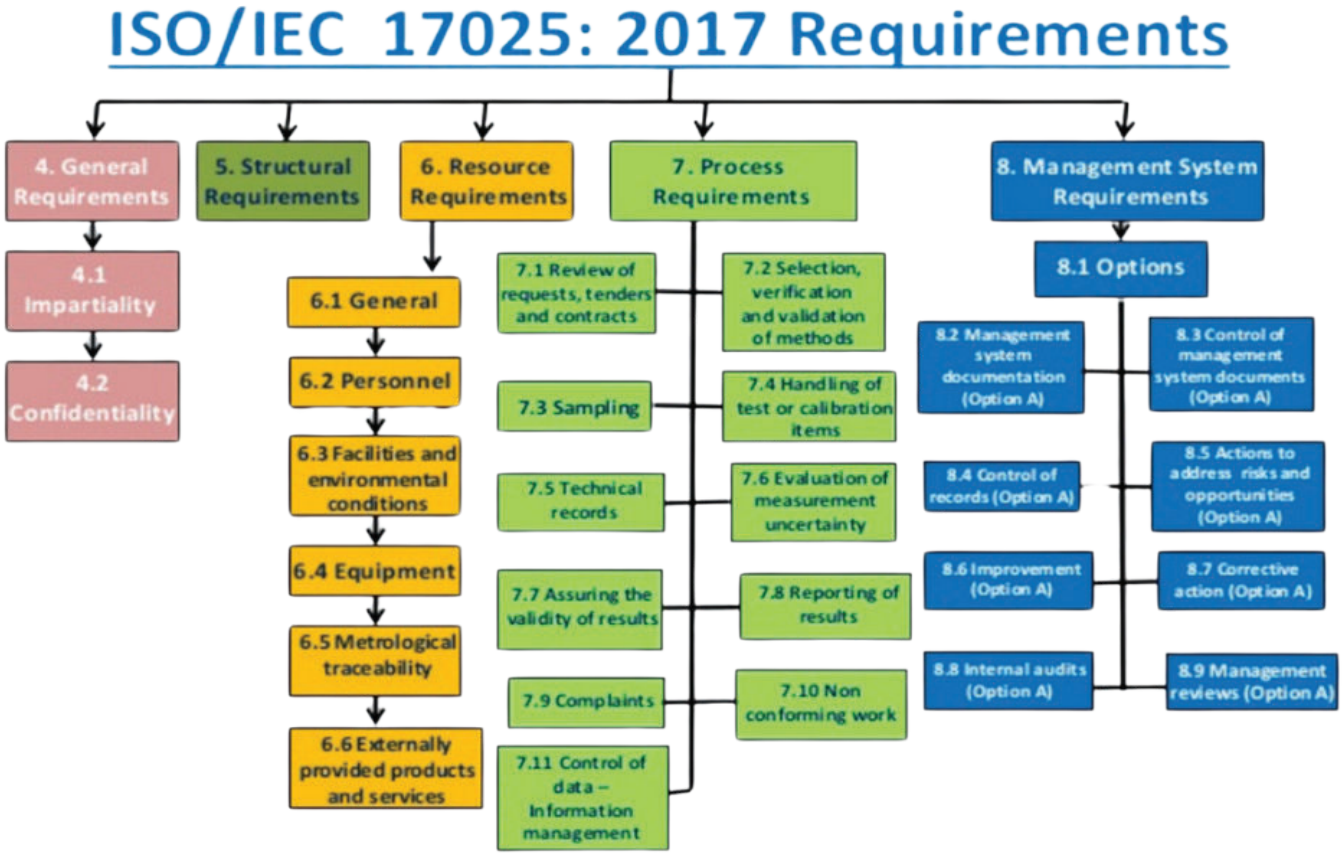
IEC stands for the International Electrotechnical Commission. The standard is jointly developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), both of which are both prominent international standard-setting bodies.

> *"Achieving ISO/IEC 17025 accreditation brings numerous benefits, including increased customer confidence, reduced need for retesting, and enhanced international recognition of test results. Accredited laboratories are viewed as competent and reliable, which can lead to increased business opportunities. The accreditation also drives continuous improvement within the laboratory, ensuring that it remains up-to-date with technological advancements and industry best practices."*

Structure of ISO/IEC 17025

ISO/IEC 17025:2017 is divided into several key sections:

1. **Scope**
   - Defines the applicability of the standard.
2. **Normative References**
   - Lists the documents that are essential for the application of the standard.
3. **Terms and Definitions**
   - Provides clarity on specific terminology used throughout the standard.
4. **General Requirements**
   - Addresses impartiality and confidentiality in laboratory operations.
5. **Structural Requirements**
   - Outlines the organizational structure and responsibilities.
6. **Resource Requirements**
   - Covers the resources needed, including personnel, facilities, and equipment.
7. **Process Requirements**
   - Focuses on the laboratory processes that impact the quality of results.
8. **Management Requirements**
   - Details the management system requirements for continual improvement.



The 2017 update aligns with other modern standards like ISO 9001:2015 and emphasizes a process approach and risk-based thinking. It expands the scope to include all laboratory activities and integrates information technology more deeply, such as the use of LIMS and electronic results.

Metrological traceability and sampling have received additional focus, ensuring the validity of laboratory methods and data integrity.

Key Updates in ISO/IEC 17025:2017

- Introduction of a risk-based approach.
- Increased flexibility in requirements for processes, procedures, and documented information.
- Enhanced focus on information technology and the use of computers and software.

The Main Changes

- The **risk-based thinking** applied in this edition has enabled some reduction in prescriptive requirements and their reaplcement by performance-based requirements.
- There is **great flexibility** than in the previous edition in the requirements **for processes, procedures, documented information, and organizational responsibility**.
- A definitely of a **"laboratory"** had been added in the definition.

Implementation and Benefits

Implementing ISO/IEC 17025:

- Ensure your laboratory meets all the technical and management requirements.
- Regular training and updates for staff on the latest changes and best practices.

Benefits of Accreditation:

- Provides a competitive advantage by showcasing your laboratory's commitment to quality.
- Enhances customer confidence and satisfaction.
- Facilitates international trade by ensuring compliance with global standards.

Section 3: Terms and Conditions

3.1 Impartiality

- Presence of Objectivity

Note 1: Objectivity means that conflicts of interest do not exist, or are resolved so as not to adersely influence subsequent activities of the laboratory.

Note 2: Other terms that are useful in conveying the element of impartiality include: "freedom from conflict of interest", "freedom from bias", "lack of prejudice", "neutrality", "fairness", "open-mindedness", "even-handed", "detachment", and "balance".

3.2 Compliant

- Expression of dissatisfaction by any person or organization to a laboratory (3.6), relating to the activities or results of that laboratory, where a response is expected.

3.3 Interlaboratory Comparison

- Organization, performace and evaluation of measurements or tests on the same or similiar item(s) by two or more laboratories in accordance with predetermined conditions.

3.4 Interlaboratory Comparison

- Organization, performace and evaluation of measurements or tests on the same or similiar item(s) within the same laboratory in accordance with predetermined conditions.

3.5 Proficiency Testing

- Evaluation of participants performance against pre-established criteria by means of interlaboratory comparison.

3.6 Laboratory

- Body that performs one or more of the following activities:
  - Testing
  - Calibration
  - Sampling associated with subsequent testing or calibration

3.7 Decision Rule

- Rule that describes how measurement uncertainty is accounted for when stating conformity with a specificed requirement.

3.8 Verification

- Provision of objective evidence that a give item fulfils specified requirements.

3.9 Validation

- Verification (3.8), where the specified requirements are adequate for an intended use.

Risk Management

Laboratories must address risks and opportunities to enhance their quality management system's effectiveness. This approach aims to improve outcomes and prevent negative impacts. The lab determines which risks and opportunities warrant attention.

Implementing Risk Management

- Identify what the risks and opportunities are in your organization.
  - How can I avoid/eliminate/mitigate the risk?
- Plan actions to address the risks.
- Implement the plan – take action.
- Check the effectiveness of the actions – Does it work?

Section 4:

4.1 Impartiality

Ensures that laboratory activities are conducted without any bias, ensuring the integrity of results.

Commitment to Impartiality: Laboratories must establish and maintain policies to ensure impartiality. This involves a top-down commitment from management to uphold unbiased operations.

Impartiality must be included in the laboratory's quality policy or as a standalone policy. Risks to impartiality must be identified and assessed on an ongoing basis. These risks can stem from financial, commercial, or personal relationships.

Laboratories need to document all identified risks and take appropriate actions to mitigate them. Proactively, laboratories should structure activities to avoid pressures that may compromise impartiality. This includes clear policies, staff training, and management oversight.

Reactively, any identified threats to impartiality must be addressed promptly through corrective actions.

4.2 Confidentiality

Safeguards all customer information, ensuring that data is not disclosed without proper authorization.

These principles are essential for maintaining trust and reliability in laboratory results.

Confidentiality requirements apply not only to external communications but also within the laboratory. This includes ensuring that personnel understand and adhere to confidentiality policies.

Laboratories must comply with all relevant legal requirements concerning data protection and confidentiality.

Contracts with customers should clearly outline confidentiality terms and conditions, specifying how information will be handled and protected.

Section 5:

Structural Requirements: Mandates that laboratories must be a legal entity or part of one, responsible for their activities.

ISO/IEC 17025:2017 ensure that a laboratory operates under a well-defined organizational framework. This is essential for maintaining the integrity, consistency, and reliability of laboratory activities and results.

- Legal Entity
- Identify Management
- Define/Document Lab Activities
- Meet the requirements of :
- ISO/IEC 17025:2017
- Customers
- Regulatory Authorities

Laboratory Activity can be:

- Permanent Facilities
- At sites away from its permanent facility
- Temporary
- Mobile Facilities
- Customer Facilities

This section also details the roles and responsibilities of management and personnel, ensuring that the laboratory is properly structured to maintain its integrity and quality of work.

The clause emphasizes the need for a clear organizational structure and defined roles to support laboratory activities effectively.

Personnel with defined authority and sufficient resources must be in place to implement, maintain, and improve the management system. They must also be able to identify and address deviations and report on the performance of the management system to top management.

- Define organization and management structure and relationships betwee management, technical operations, and support services.
- Specificy responsibility, authority and inter-relationship of all personnel who manage, perform, or verify works.
- Document its procedures to ensure consistency of works and validity of the results.

This Ensures:

- The effectiveness of laboratory activities
- Communication takes place regarding the effectiveness of the management system and the importance of meeting customers and other requirements
- Integrity of managemenet systems is maintained when changes to the management system are planned and implemented

Section 6:

Section 6 of ISO/IEC 17025:2017 focuses on the resources necessary for a laboratory to function effectively. This includes personnel, facilities, equipment, metrological traceability, and externally provided products and services.

6.1: Availability of Personnel, Facilities, Equipment, Systems and Support Services.
Laboratories must ensure that all necessary resources, including personnel, facilities, equipment, systems, and support services, are available and managed effectively. This ensures that laboratory activities can be conducted reliably and accurately.

6.2: Personnel

All personnel, whether internal employees or external contractors, must be competent and work within the laboratory's management system.

This involves:

- Documenting job descriptions
- Training
- Supervision, and authorization.
- Ensuring personnel are aware of their duties, responsibilities, and the scope of their work.
- Maintaining records of competence requirements, training, and authorization.

Personnel should:

- Act impartially, be competent and work in accordance with the lab's management system.
- Have evidences of competencies (education, qualifications, training, technical knowledge, skills, and experience).
- Have competence to perform laboratory activities and to evaluate the significance of deviations.
- Communicate to personnel their duties, responsibilities and authorities.

Ensuring these resources are properly managed is crucial for maintaining the quality and reliability of laboratory results.

6.3 Facilities and Environmental Conditions:
Laboratories must control and monitor their facilities to ensure environmental conditions do not compromise the validity of results.
This includes:

Documenting, controlling, monitoring, and recording conditions such as temperature, humidity, dust, and electrical supply.

- Suitable for laboratory activities and not adversely affect the validity of results
- Documented requirements for facilities and environmental conditions
- Monitor, control and record environmental conditions
- Measures to control facilities including:
  - Access to and use of areas affecting laboratory activities;
  - Prevention of contamination, interference or adverse influences on laboratory activities;
  - Effective separation between areas with incompatible laboratory activities.
- Ensure that environmental conditions are met when performing outside its permanent control

Ensuring laboratory areas are defined, controlled, and separated to prevent contamination and interference.

Section 6: Continued

6.6: Externally Provided Products and Services.

Laboratories must ensure that externally provided products and services meet their requirements. This involves:

- Defining, reviewing, and approving requirements for external products and services.
- Evaluating and selecting external providers.
- Monitoring performance and maintaining records of external providers.
- Communicating acceptance criteria and competence requirements to external providers.

Ensure that suitable externally provided products and services are used when products and services:

- Are intended for incorporation into the laboratory's own activities;
- Are provided ,in part or in full, directly to the customer by the laboratory as received from the external provider;
- Are used to support the operation of the laboratory.

Importance

Effective management of resources ensures the reliability and accuracy of laboratory results, compliance with regulatory standards, and enhanced customer confidence. By adhering to these requirements, laboratories can maintain high standards of quality and integrity in their operations.

Section 7:

Process Requirements outlines the process requirements that laboratories must follow to ensure the validity and reliability of their testing and calibration results. This section includes various clauses that cover essential processes and procedures, ensuring that laboratories operate efficiently and consistently.

7.1: Review of Requests, Tenders, and Contracts

Laboratories must have procedures to review requests, tenders, and contracts to ensure they have the capability and resources to meet the requirements. This review process ensures that all requirements are clearly defined, documented, and understood by both the laboratory and the customer.

- Have a procedure for the review
- Inform customer when method requested by the customer is not appropriate or out of date
- Clearly define a statement of conformity when requested by the customer
- Resolve any difference between the request or tender and the contract before commencing work
- Inform customer of any deviation from the contract
- Repeat contract review... if amended after work and communicate to all affected personnel
- Cooperate with customers or their rep in clarifying the customer request and in monitoring the lab's perfoamce in relation wo tht work performed
- Retain revords of reviews

Section 7: Continued

7.2: Selection, Verification, and Validation of Methods.
Laboratories must select appropriate methods and validate non-standard methods, laboratory-developed methods, and standard methods used outside their intended scope. Verification ensures that the laboratory can meet the specified requirements using these methods.Defining, reviewing, and approving requirements for external products and services.

- Use appropriate methods and procedures for all laboratory activities
- Up to date methods, procedures and supporting documents are kept made readily available to personnel
- Uses the latest version unless not possible to do so
- Select appropriate method when customer does not specify
- Verify methods before introducing them to ensure it can achieve the required performance
- Have an action plan for method development
- Document, technically justify, authorize, and accept by the customer if any deviation from methods
- Validate non-standard methods, laboratory developed methods, and standard methods used outside their intended scope or modify
- Retain records of validation

7.3 Sampling:
When sampling is part of the laboratory activities, laboratories must have a documented procedure for sampling, ensuring samples are representative and properly managed. The sampling method, conditions, and personnel involved must be documented accurately.

7.4: Handling of Test and Calibration Items
Laboratories must have procedures for handling, transporting, storing, and preparing test or calibration items to ensure their integrity is maintained. This includes clear identification and protection from contamination, deterioration, loss, or damage.

- Have a procedure
- Have a stytem for unambiguous identification
- Records of the item
- Facilities to maintain items

7.5: Technical Records
Technical records must be maintained to provide evidence of the laboratory's activities. Records should include observations, data, and calculations, enabling the repeatability of the activities. Any changes to records must be tracked and documented.

7.6: Evaluation of Measurement Uncertainty
Laboratories must identify and evaluate measurement uncertainty for all calibrations and significant tests. This involves understanding all contributing factors and ensuring accurate uncertainty estimation.

Section 7: Continued

7.7: Ensuring the Validity of Results

Laboratories must monitor the validity of results through procedures such as internal quality control, proficiency testing, and interlaboratory comparisons. This ensures ongoing accuracy and reliability of results.

- Have a procedure for monitoring the validity of results
- Monitor its performance by comparison with results of other laboratories
- Analyze and use data from monitoring to control and improve the laboratory's activities
- Take action when data from the monitoring are found to be outside pre-defined criteria

7.8: Reporting of Results

Results must be reported clearly, accurately, and comprehensively. This includes general requirements for reports, specific requirements for test reports and calibration certificates, and provisions for statements of conformity and opinions or interpretations.

- General - review and authorize prior to release
- Common requirements for reports
- Specific requirements for test reports
- Specific requirements for calibration certificates
- Specific requirements for reporting sampling
- Reporting statements of conformity
- Reporting opinions and interpretations
- Amendments to reports

7.9.1: Complaint Handling Process

Laboratories must establish a documented procedure for handling complaints. This includes steps for receiving, evaluating, and investigating complaints.

The procedure should ensure that all complaints are taken seriously and addressed promptly.

7.9.2: Responsibility and Authority

Laboratories must designate personnel responsible for managing complaints. This includes analyzing the nature of the complaint, initiating actions to resolve it, and keeping detailed records of these actions.

Communication with the complainant should be maintained to ensure they are informed about the progress and resolution of the complaint.

- Have a documented process to receive, evaluate and make decision on complaints
- Responsible for all decisions at all levels of handling process of complaints and made availability of description of handling process for complaints to interested party
- Include at least the following elements and method:
  - Description of the process
  - Tracking and recording complaints
  - Ensuring that appropriate oction is taken
- Responsible for gathering and verifying all information to validate the complaint
- Acknowledge receipt.of the complaint, and provide the complainant with progress report and outcome Review, approve the outcomes by individual (s) not involved in the original laboratory activities in question
- Give formal notice of the end of the complaint handling to the complainant

Section 7: Continued

7.9.3: Investigation and Resolution
A thorough investigation must be conducted to determine the root cause of the complaint. This may involve soliciting more details from the complainant and performing a root cause analysis.

Corrective actions should be implemented to address the root cause and prevent recurrence. These actions must be documented and their effectiveness verified.

7.9.4: Record Keeping
All records related to the complaint, including the initial report, investigation details, corrective actions, and follow-up verifications, must be maintained.

These records help demonstrate compliance with the complaint handling process and can be reviewed during audits.

7.9.5: Communication with Complainant
The laboratory must provide progress reports to the complainant if necessary and inform them about the outcome of the investigation.

Written responses, such as formal notices of complaint closure or progress reports, should be authorized by appropriate personnel and attached to the complaint records.

7.10.1: Identification and Documentation
Laboratories must have a procedure to identify and manage nonconforming work. This involves promptly identifying deviations from procedures or customer requirements.

Once identified, the nonconforming work must be documented, detailing the nature of the nonconformance, its impact, and the actions taken.

7.10.2: Evalution and Non-Comformity
The laboratory must evaluate the significance of the nonconforming work to determine its impact on the validity of results.

Based on this evaluation, the laboratory must decide whether to:

- Accept the nonconforming work with or without correction.
- Reject the nonconforming work and retest or recalibrate.
- Suspend the work until corrective actions are implemented.

Have procedures ensure that:

- Responsibilities and authorities for the management of NC work are defined;
- Actions are based upon the risk levels established by the laboratory;
- An evaluation is made of the significance of NC work, including an impact analysis on previous results;
- A decision is taken on the acceptability of NC work;
- Where necessary the customer is notified and work is recalled;
- The responsibility for authorizing the resumption of work is defined.
- Retain records of NC work and actions
- Implement corrective action where the evaluation indicates that the NC work could recur or is doubt about the conformity of laboratory's operation

7.10.3: Corrective Action
If nonconforming work is identified, appropriate corrective actions must be taken to prevent recurrence. This may include revising procedures, retraining personnel, or improving equipment.

The laboratory must implement corrective actions promptly and verify their effectiveness.

7.10.4: Notification and Customer Communication
The laboratory must communicate with affected customers if the nonconforming work impacts their results. This includes informing them of the nature of the nonconformance, the corrective actions taken, and any additional testing or calibration required.

Ensuring clear and timely communication helps maintain customer trust and transparency.

7.10.5: Record-Keeping
Detailed records of nonconforming work, including the investigation, decision-making process, corrective actions, and communication with customers, must be maintained.

These records are crucial for audits and reviews, demonstrating the laboratory's commitment to continuous improvement and compliance with ISO/IEC 17025:2017.

Implementing a robust nonconforming work management process ensures that laboratories can promptly address and correct any issues that arise, maintaining the reliability and accuracy of their results. It also enhances customer satisfaction by ensuring transparency and proactive problem-solving.

7.11: Control of Data and Information Management
Section 7.11 outlines the requirements for controlling data and information management within a laboratory. This section ensures that laboratories manage their data effectively to maintain the accuracy, integrity, and security of the information related to testing and calibration activities.

Effective control of data and information management is critical for maintaining the credibility and reliability of laboratory results. By implementing robust data management practices, laboratories can ensure data accuracy, integrity, and security, which are essential for compliance with ISO/IEC 17025:2017 and for maintaining customer confidence.

7.11.1: Data Management
Laboratories must have documented procedures for the management of data, including the acquisition, recording, processing, analysis, reporting, storage, and retrieval of data.

These procedures must ensure that data handling processes are consistent, reliable, and secure.

- Have eccess to the data and information needed to perform laboratory activities
- Validate information management system for functionolity
- Protect from unauthorized access, safeguard against tampering and loss, operate in suitable environment, maintain integrity of dta, record system failures and corrective actions
- Ensure the provider or operator of the system complies when manage and maintains off-site or through an external provider
- Ensure that instructions, manuals and reference data relevant to laboratory information system are made readily available to personnel
- Check calculations and data transfers in an appropriate and systematic manner

7.11.2: Data Integrity

Measures must be taken to protect the integrity of data at all stages of the data lifecycle. This includes preventing unauthorized access, modifications, or loss of data.

Data integrity must be maintained through secure systems and practices that ensure data is accurately recorded and maintained.

7.11.3: Electronic Data and Software

For laboratories using electronic data management systems, appropriate validation must be conducted to ensure that software and systems are functioning correctly and producing accurate results.

Laboratories must control changes to software and ensure that any modifications are authorized, documented, and validated before use.

7.11.4: Access Control

Access to data and information must be controlled and restricted to authorized personnel only. This ensures that sensitive information is protected from unauthorized access or breaches.

Procedures should be in place to manage user access, including authentication and authorization protocols.

7.11.5: Backup and Recovery

Laboratories must implement backup and recovery procedures to protect data from loss or damage. Regular backups should be performed, and data should be stored in secure, redundant locations.

Recovery procedures should be tested periodically to ensure that data can be restored in case of a system failure or data loss incident.

7.11.6: Data Storage and Retention

Data storage systems must be designed to ensure the long-term preservation and accessibility of data. This includes maintaining data in formats that are durable and can be accessed in the future.

Laboratories must define and document data retention periods in compliance with regulatory requirements and organizational policies.

Section 8:

Laboratories can choose between two options: integrating the requirements into an existing ISO 9001 management system or developing a standalone management system.

This clause covers documentation requirements, management reviews, internal audits, and actions to address risks and opportunities. It ensures that the laboratory's management system supports consistent quality in all laboratory activities."

8.2: Management System Documentation
Laboratories must establish, document, and maintain policies and objectives for the management system. This includes documenting processes, procedures, and records to demonstrate compliance and continual improvement.

MS Documentation - Policies & Objectives for the fulfilment of the purpose of ISO/IEC 17025

- Establish, document and maintain
- Acknowledge and implement at all levels of the laboratory organization Address the competence, impartiality and consistent of the operation / Make reference or link to other documents / Easy to access by relevant personnel

Evidences of commitment to the development and implementation of the MS and to continually improving its effectiveness.

8.3: Control of Management System Documents
Procedures for document control must ensure that documents are approved, reviewed, updated, and accessible to relevant personnel. Obsolete documents must be controlled to prevent unintended use. Ensure:

- Approve prior to issue
- Review / update
- Identification of current revision / changes
- Available at point of use
- Uniquely identify
- Unintended use of obsolete documents

8.4: Control of Records
Laboratories must implement controls for the identification, storage, protection, retrieval, retention, and disposal of records. Records must be legible, readily identifiable, and retrievable.

8.5: Actions to Address Risks and Opportunities
Laboratories must identify risks and opportunities that can affect the conformity of services and the ability to enhance customer satisfaction. Appropriate actions must be planned and implemented to address these risks and opportunities.

- Action plan to address risks and opportunities
- Integrate and implement actions
- Evaluate the effectiveness of actions

Actions taken shall be proportional to the potential impact on the validity of laboratory results

8.6: Improvement
Continual improvement processes must be in place to enhance the management system's effectiveness. This includes monitoring, measuring, analyzing, and evaluating improvements.

- Identify and select opportunities for improvement
- Implementation
- Seek feed back & use and analyze feed back to improve the MS

Section 8: Continued

8.7: Corrective Actions

Procedures for corrective actions must address nonconformities by identifying root causes, implementing actions to prevent recurrence, and verifying the effectiveness of these actions.

- React to NC
- Evaluate the need for action & implement
- Review the effectiveness
- Update risk & opportunities
- Make changes to the MS
- Retain records

8.8: Internal Audits

Regular internal audits must be conducted to ensure the management system's effectiveness and identify areas for improvement. The audit program should cover all activities and be based on the importance of processes and areas to be audited.

- Conduct as planned intervals
- Plan, establish and maintain audit program
- Define the audit criteria and scope for each audit
- Report the results to relevant management
- Implement correction and corrective actions without undue delay
- Retain records

8.9: Management Reviews

Management reviews must be conducted periodically to ensure the management system's continuing suitability, adequacy, and effectiveness. Inputs for review include results of internal audits, feedback from customers, performance indicators, and opportunities for improvement.

- Review at planned intervals
- Record all inputs to the management review
- Record all decisions and actions of output

Annex A

Annex A provides additional details on metrological traceability, which is crucial for ensuring the accuracy and reliability of measurement results.

Traceability established by:

- Definition of the measurand
- Unbroken chain of comparisons/cals
- Measurement uncertainty
- Performed in accordance with documented information
- Competence

Demonstration of Traceability

- Evaluate the technical competence of the calibration provider and claimed metrological traceability as per the requirements of this standard
- CMCs peer reviewed by international arrangement
- CIPM MRA or ILAC

It outlines the requirements for establishing traceability to international standards and the need for calibration laboratories to maintain this traceability. This annex supports laboratories in demonstrating that their measurement results are accurate and comparable over time.

Annex B

Annex B discusses the management system options in more detail, providing guidance on implementing a management system that complies with ISO/IEC 17025:2017.

- **Option A of clause 8:** operate generally in accordance with the principles of ISO 9001.
- **Option B of clause 8:** allow to establish and maintain a management system in accordance with the requirements of ISO 9001.
- Both options are intended to achieve the same result in the performance system and compliance with Clauses 4 to 7.

It helps laboratories understand how to integrate these requirements into their existing quality management systems or develop a new system that meets the standard's requirements.

This annex is particularly useful for laboratories seeking to align their processes with ISO 9001.

Calibration Certificates

Calibration certificates issued by ISO/IEC 17025 accredited laboratories will cover the following parameters:

- **Size Setting Error:** The size setting error is the deviation from the particle counter's programmed sizes. The pass/fail criteria as per ISO 21501-4:2018 is ±10% of the particle size. The uncertainty of each particle size is stated in µm.
- **Counting Efficiency:** The counting efficiency is determined by comparing a unit to a NIST (National Institute of Standards and Technology) traceable unit with a higher sensitivity. The ISO 21501-4 standard dictates a tolerance of 50% (±20%) of the minimum detectable size, and 100% (±10%) of a size 1.5 - 2 times larger than the minimum. The uncertainty is stated in percent counting efficiency.
- **Sample Flow Rate Error:** The sampling flow rate tolerance is ±5% of the stated rate for the unit. The flow value uncertainty is stated in the LPM.
- **Size Resolution:** The size resolution willbe stated with the particle size used in µm and the criteria of less than 15% as stated per ISO 21501-4. The uncertainty will be stated in percent size resolution.
- **Fale Count:** The false count (also known as a zero-count test) is the number of particles detected on the minimum detectable channel in a certain colume of air stated at a 95%.