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Understanding of ISO/IEC 17025

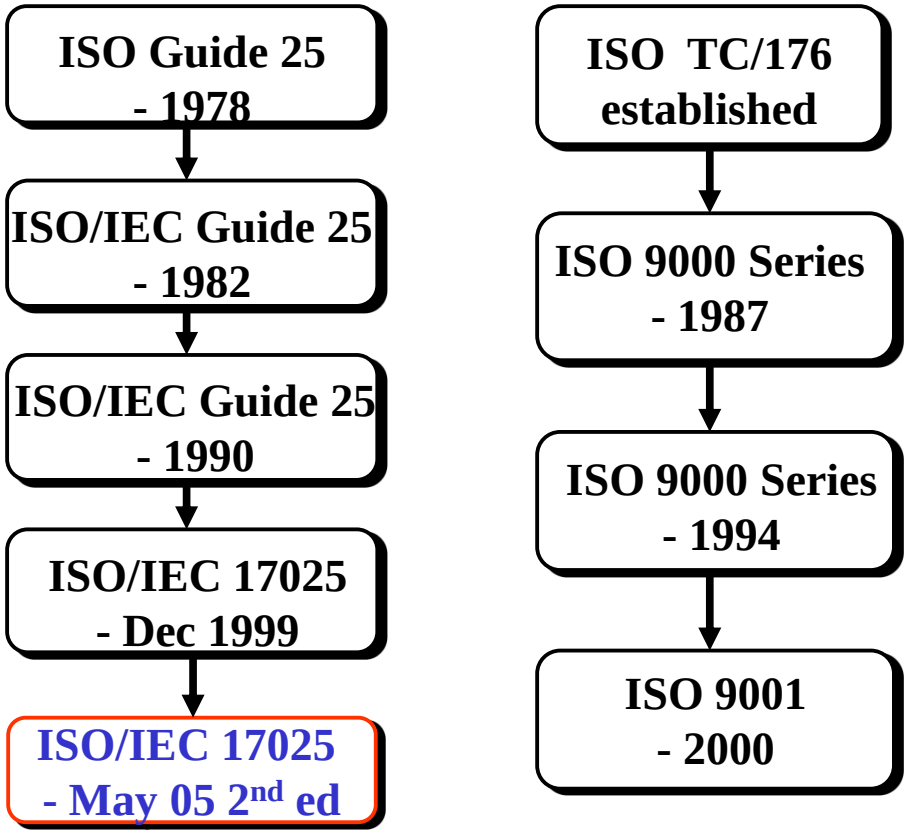
Jing Wang

Quality system

- 1963, MIL-Q-9858A, United States
- 1979, BS 5750, United Kingdom
- The ISO 9000 series of quality standards was established in 1987 for implementing and maintaining a quality system

ISO/IEC 17025 History

Background



The relationship with ISO 9001

Joint ISO-ILAC-IAF Communique on the Management Systems Requirements of ISO/IEC 17025:2005

ISO-International Standardization Organization

ILAC –International Laboratory Accreditation Cooperation Organization

IAF-International Accreditation Forum

Joint ISO-ILAC-IAF Communiqué
on the
Management Systems Requirements of ISO/IEC 17025:2005,
General Requirements for the competence of testing and calibration laboratories

A laboratory's fulfilment of the requirements of ISO/IEC 17025:2005 means the laboratory meets both the technical competence requirements and ***management system requirements*** that are necessary for it to consistently deliver technically valid test results and calibrations. The ***management system requirements*** in ISO/IEC 17025 (Section 4) are written in language relevant to laboratory operations and meet the principles of ISO 9001:2000 ***Quality Management Systems – Requirements*** and are aligned with its pertinent requirements.

ISO Secretary General | ILAC Chair | IAF Chair

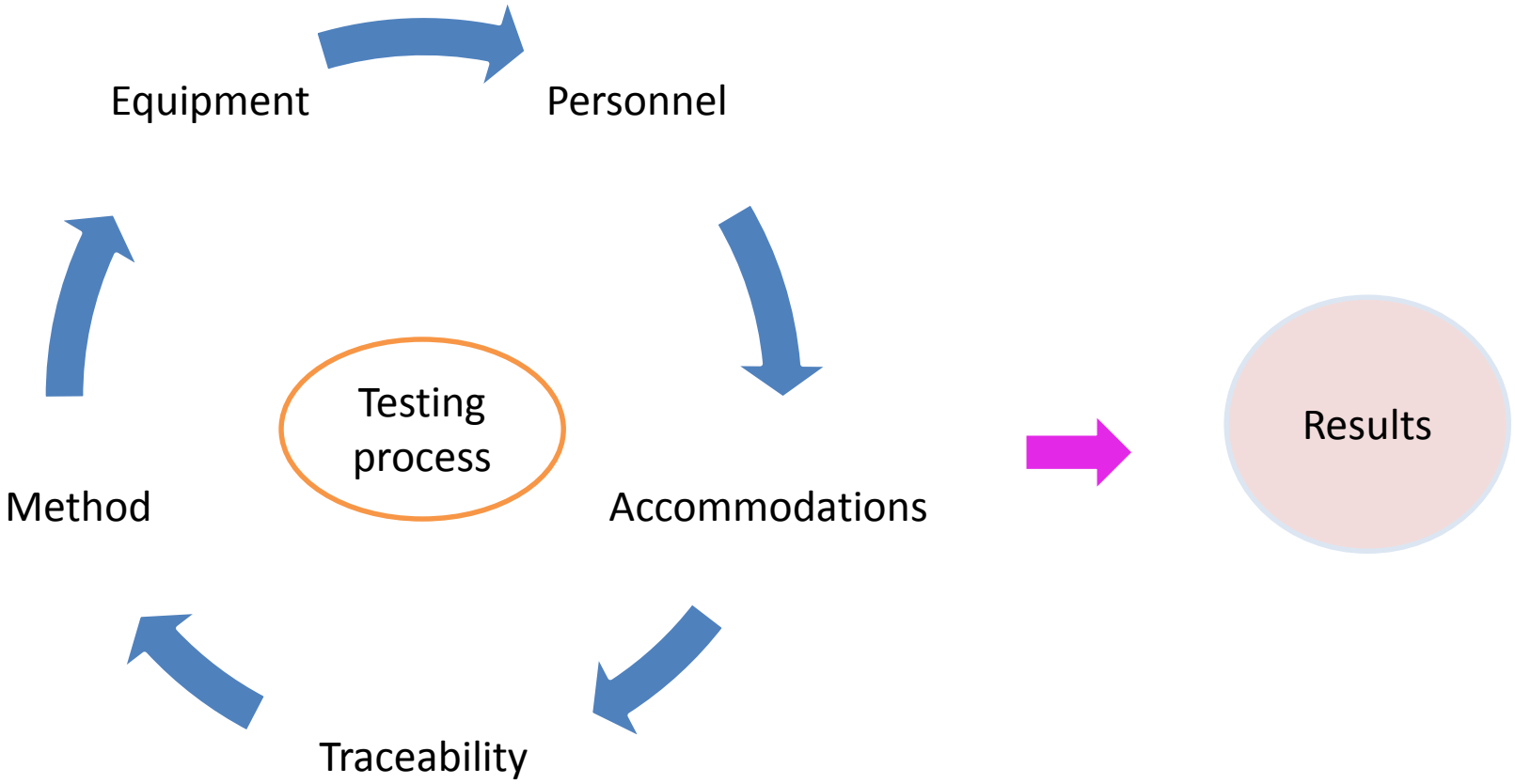
2005-06-18

- A laboratory's fulfillment of the requirements of ISO/IEC 17025 means the laboratory meets both the technical competence requirements and management system requirements that are necessary for it to consistently deliver technically valid test results and calibrations.
- The management system requirements in ISO/IEC 17025 are written in language relevant to laboratory operations and operate generally in accordance with the principles of ISO 9001.

- ISO/IEC 17025 is a global quality standard for testing and calibration laboratories
- It is the basis for accreditation from an accreditation body
- Management requirements & Technical requirements
- Implementing ISO/IEC 17025 has benefits for laboratories, but the work and costs involved should be considered before proceeding.

- **Benefits**
- Having access to more contracts for testing..
- Improved national and global reputation and image of the laboratory.
- Continually improving data quality and laboratory effectiveness.
- Having a basis for most other quality systems related to laboratories, such as Good Manufacturing Practices and Good Laboratory Practices.

What is laboratory accreditation?



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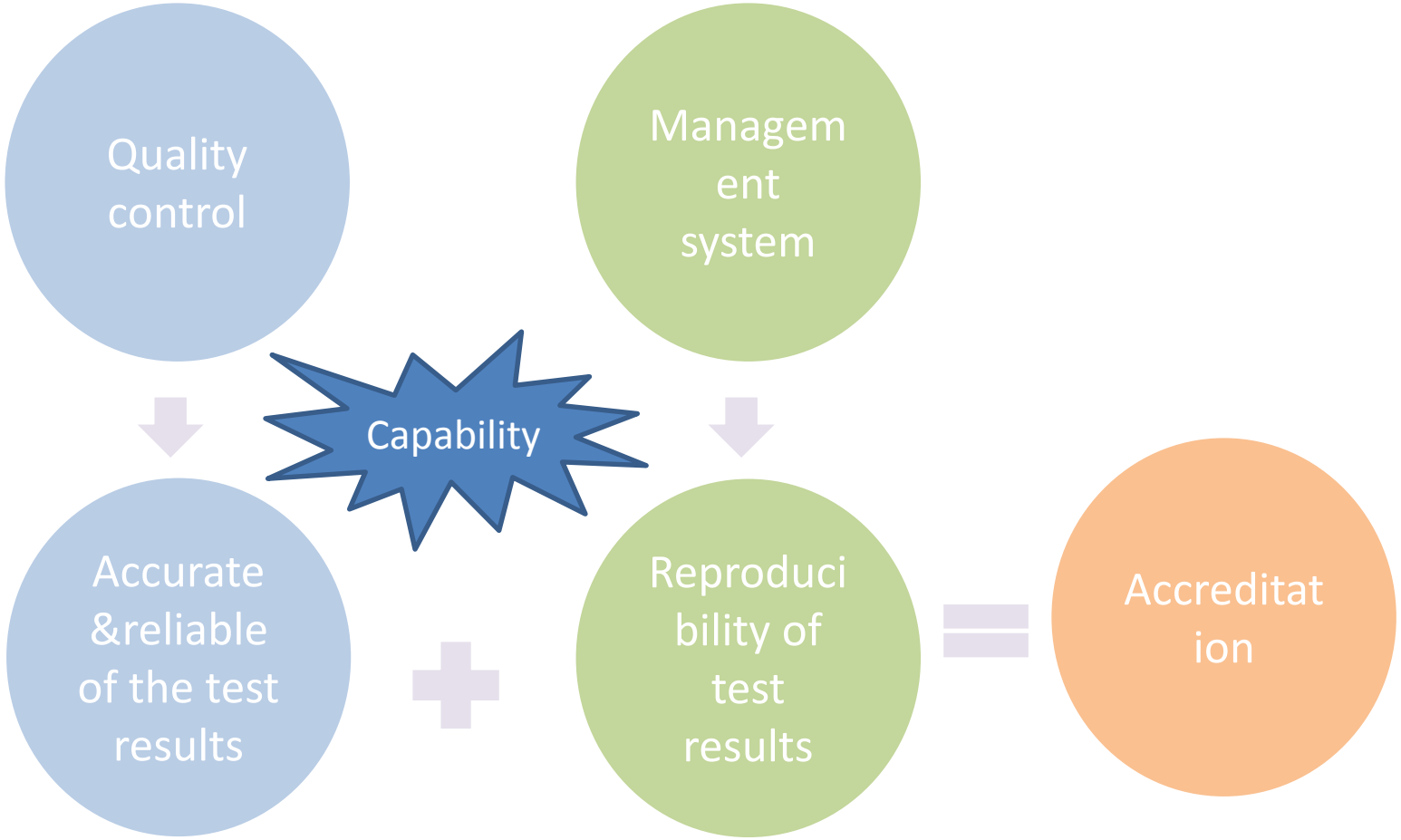

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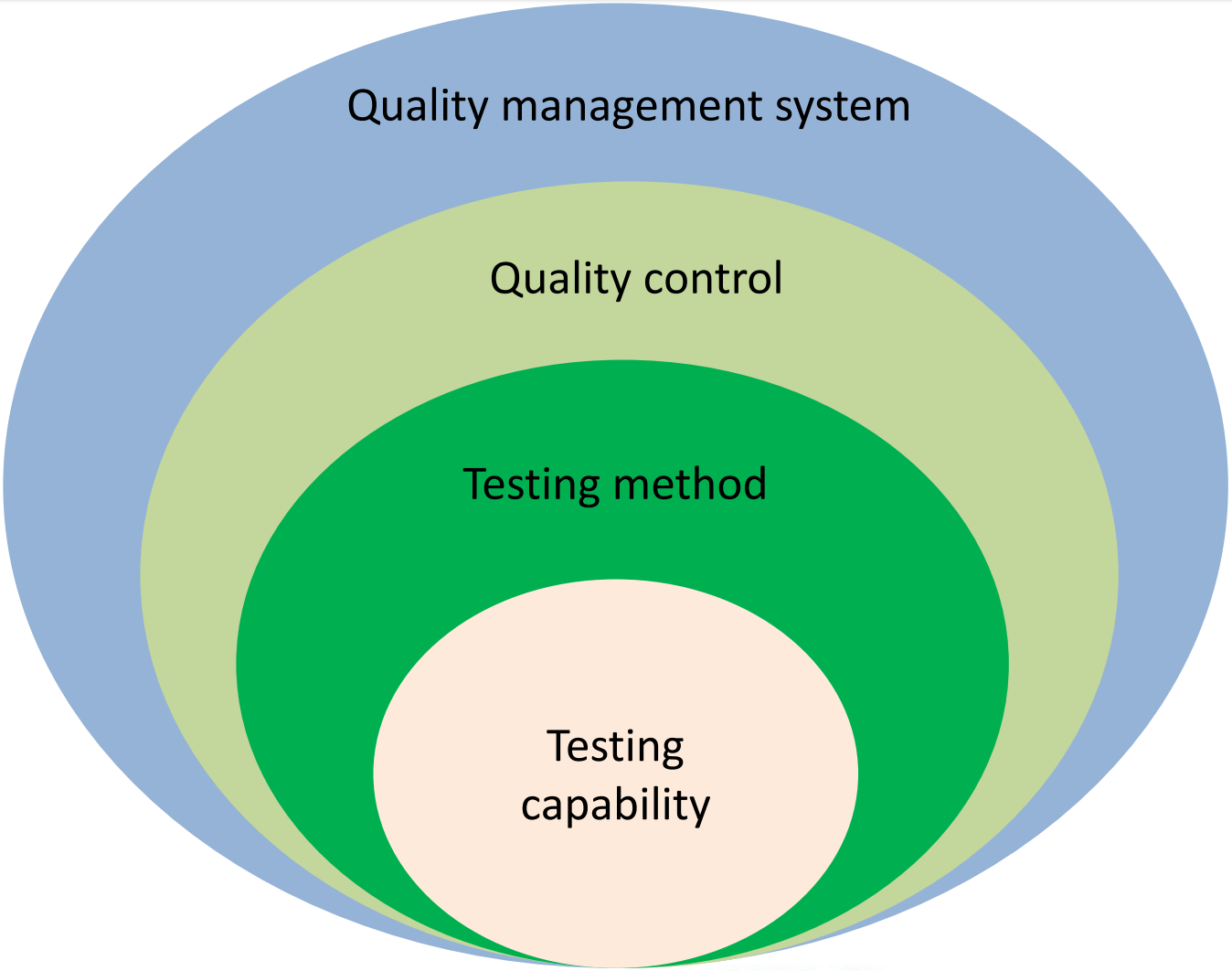

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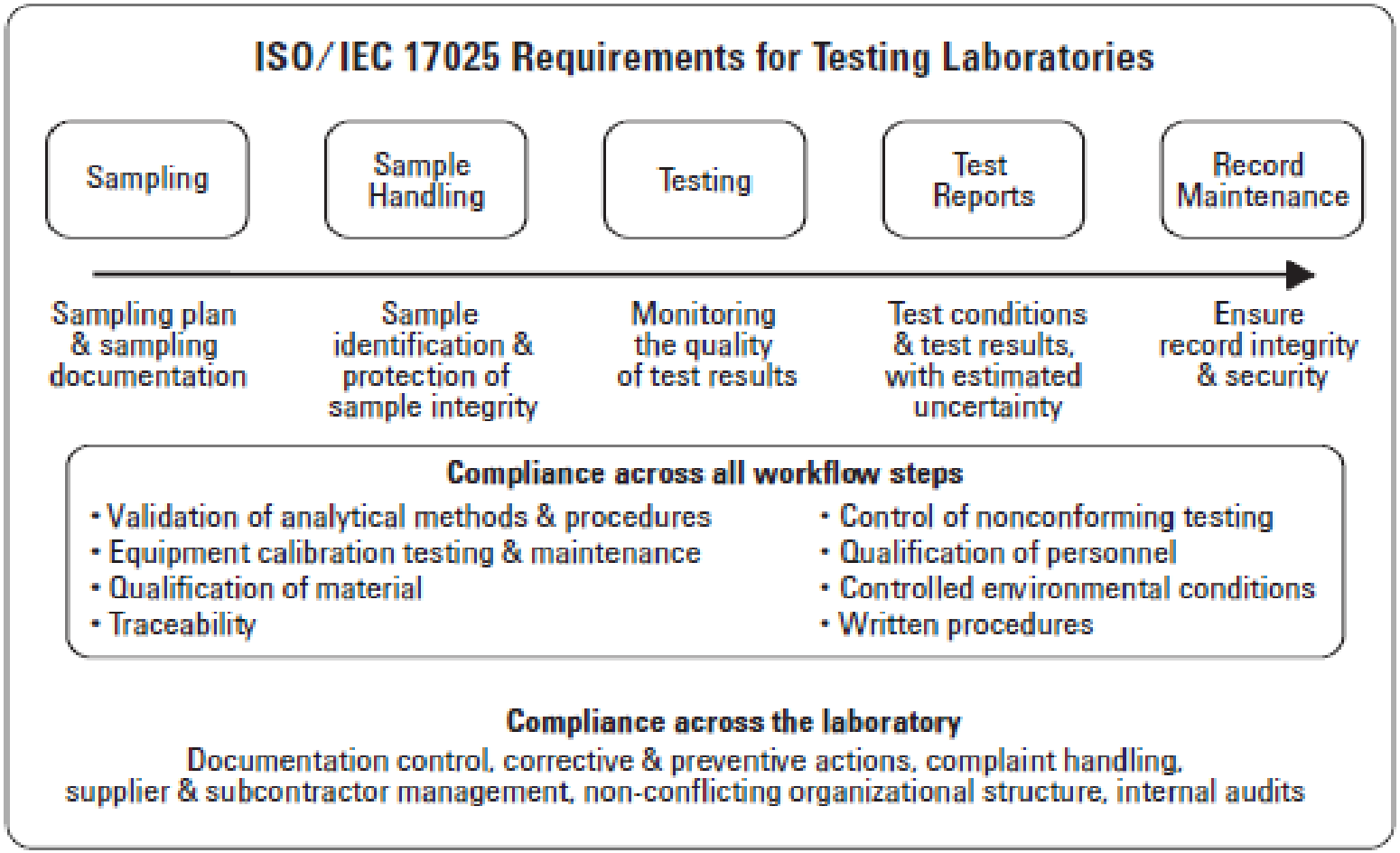
ISO/IEC 17025 is divided into 5 clauses, 2 annexes, and 1 bibliography section:

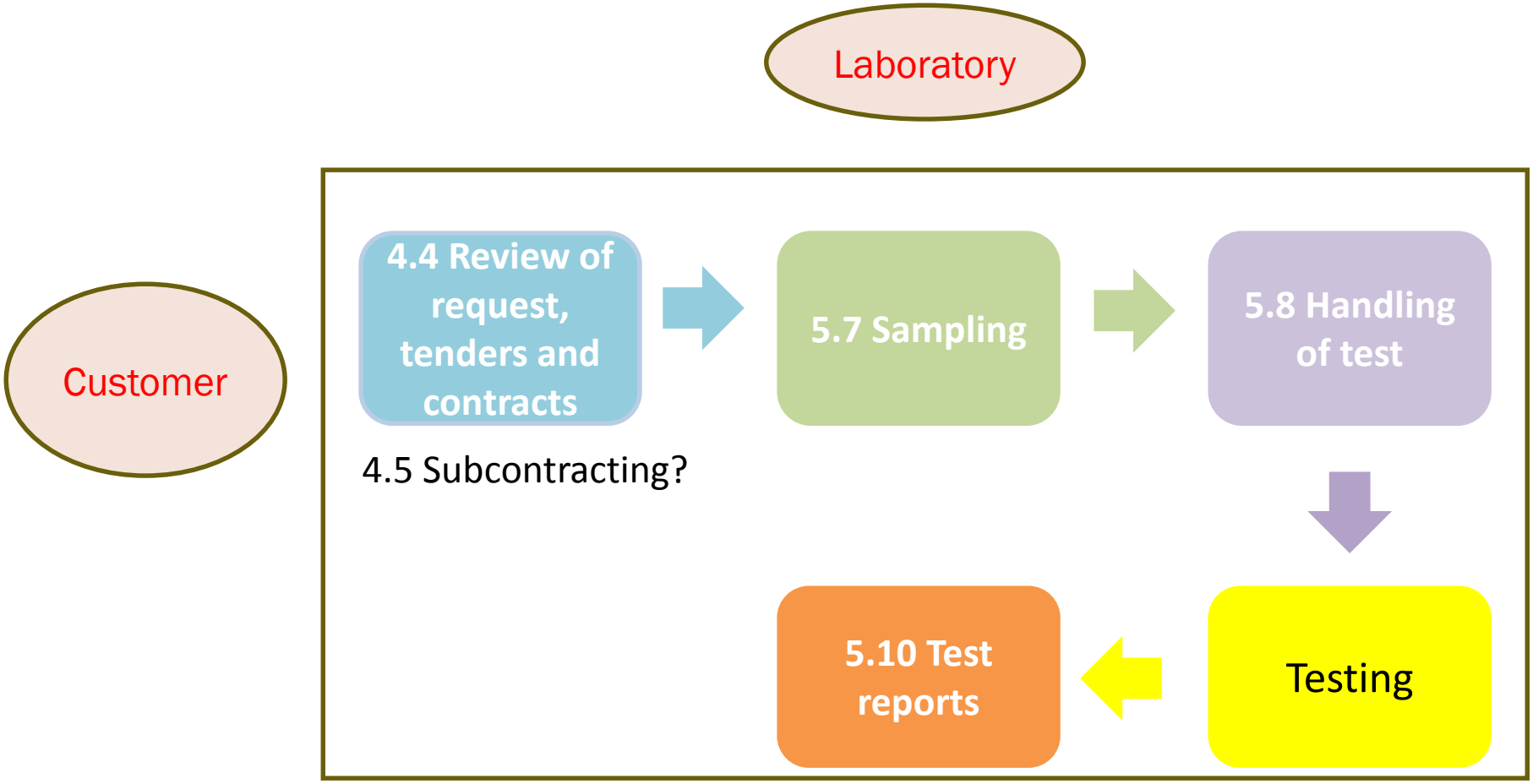
Clause 1: Scope
Clause 2: Normative References
Clause 3: Terms and Definitions
Clause 4: Management Requirements
Clause 5: Technical Requirements
Annex A: Cross References to ISO 9001:2000
Annex B: Guidelines for Establishing Applications for Specific Fields
Bibliography

The most important clauses are clause 4 and 5, describing management and technical requirements. In addition to official requirements, these clauses also include notes with further explanations and recommendations.

Overview of the Requirements



ISO/IEC 17025 Structure



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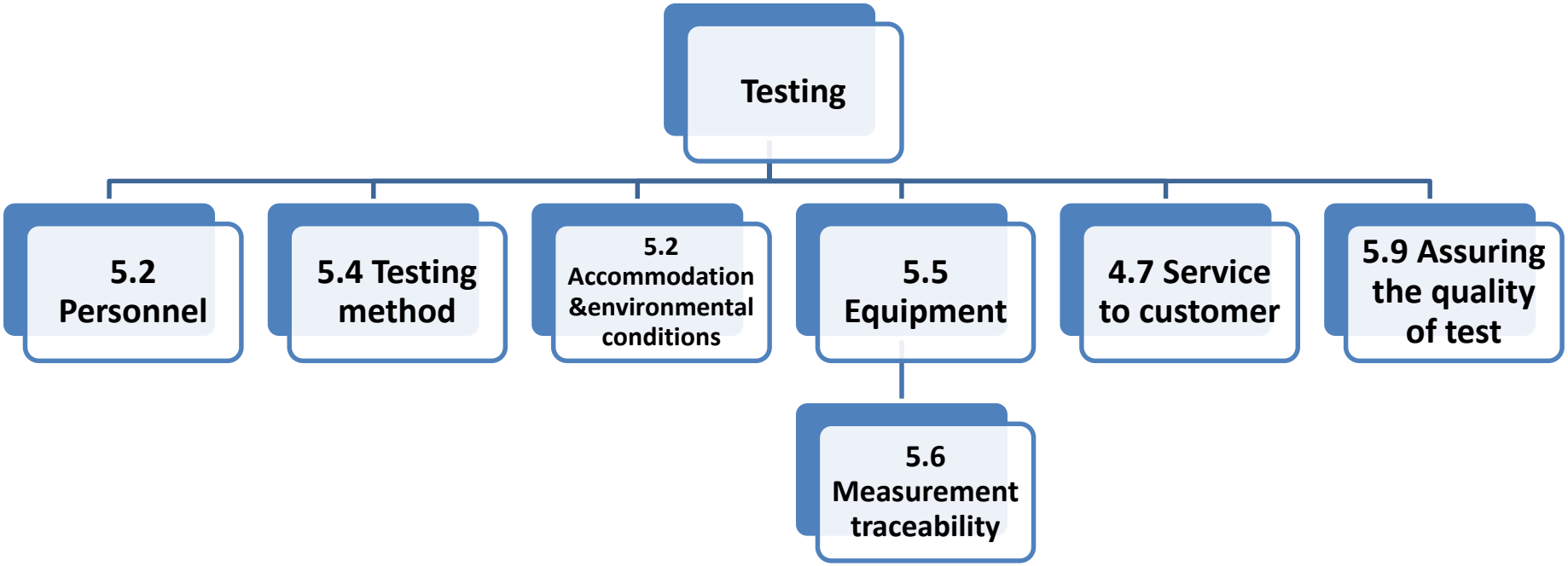
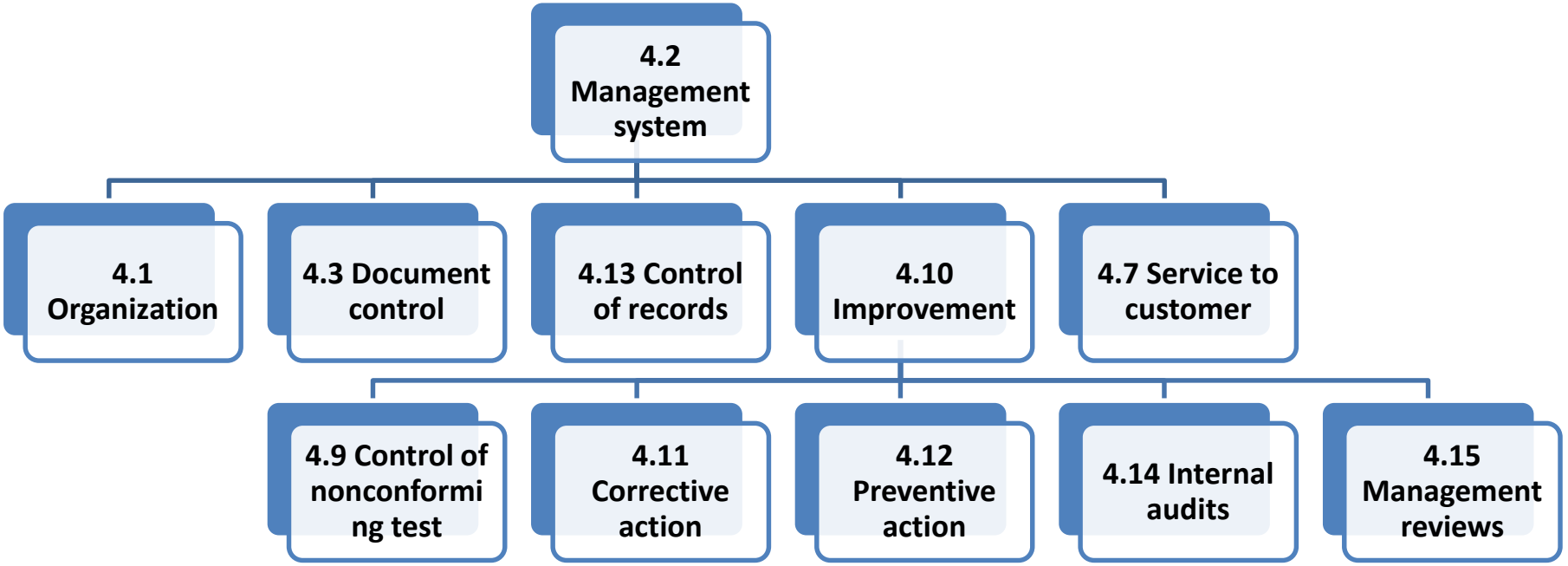


ISO/IEC 17025 Structure

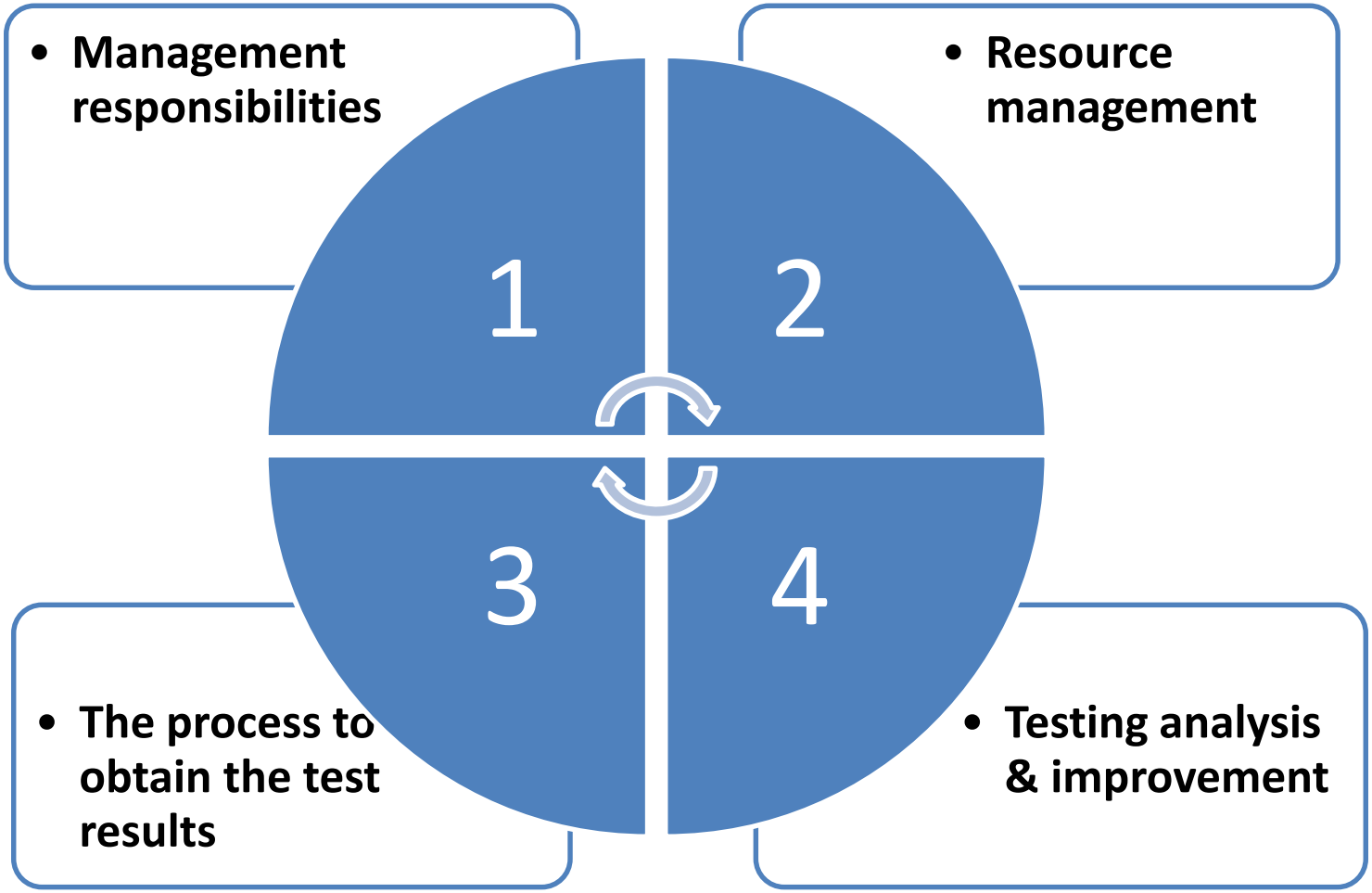


ISO/IEC 17025 introduction

ISO/IEC 17025

Process-based quality management system model

ISO/IEC 17025 introduction



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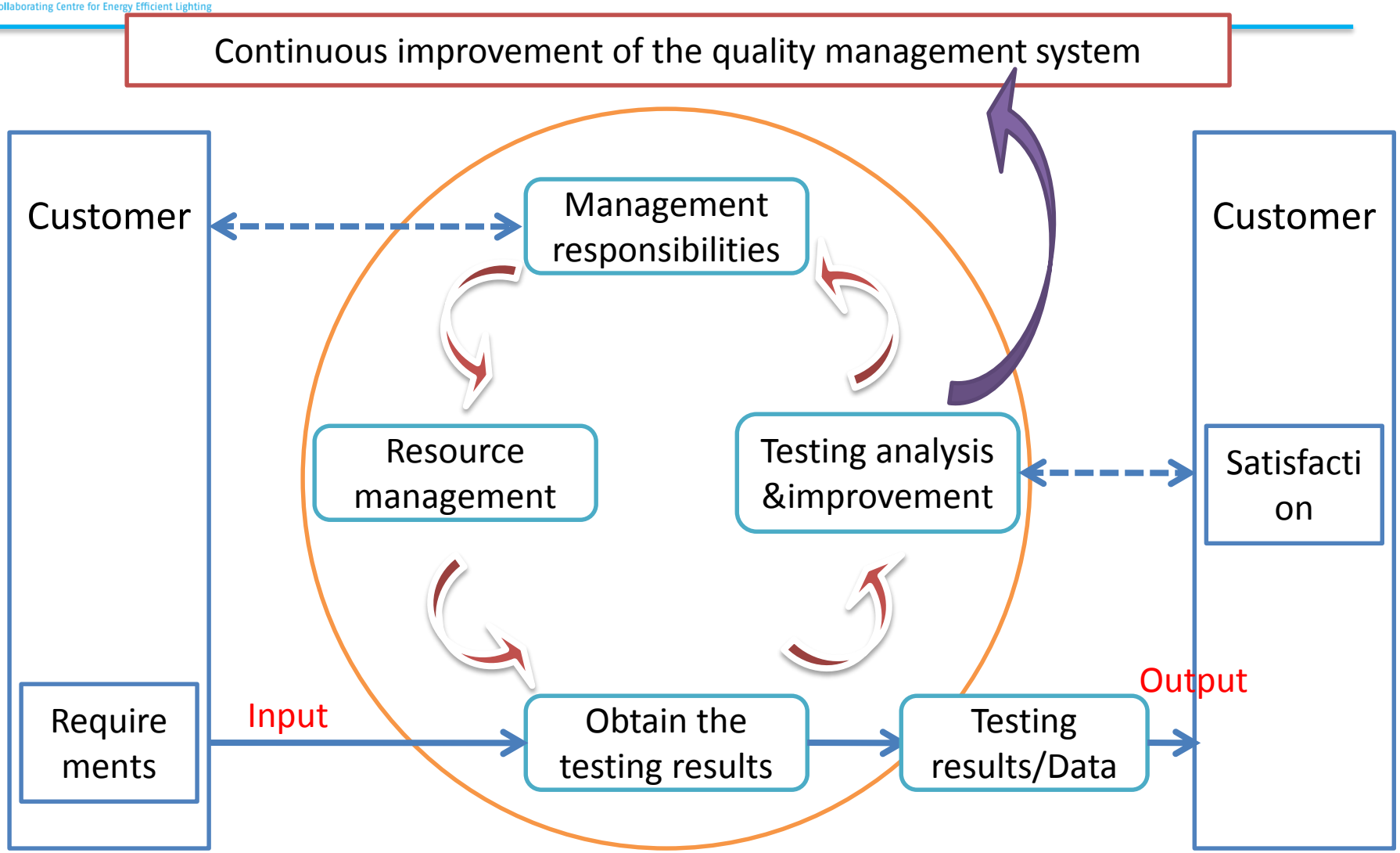

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ISO/IEC 17025 introduction

- **Management responsibilities**
  - **4.1, 4.2, 4.8, 4.10, 4.15, 5.1**
- **Resource management**
  - **4.6 (equipment purchasing), 5.2, 5.3, 5.5, 5.6**
- **The process to obtain the test results**
  - **4.4, 4.5, 4.6, 4.7, 5.1, 5.4, 4.13, 5.7, 5.8, 5.10**
- **Testing analysis & improvement**
  - **4.8, 4.9, 4.10, 4.11, 4.12, 4.14, 5.4.7, 5.9**

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Management responsibilities

- The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.
  - Independent legal entity
  - Authorized by an independent legal entity

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Management responsibilities

- Top management shall establish the management system appropriate to the scope of its activities.

- The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities

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Management responsibilities

- Top management shall specify responsibility, authority, and interrelationships of all personnel, who manage, perform or verify the work, and provide appropriate resources (e.g. Materials, HRs, Information)

- Identify the potential deviations to testing and management and take prevention actions.

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Management responsibilities

- Top management shall commit to customers that have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work

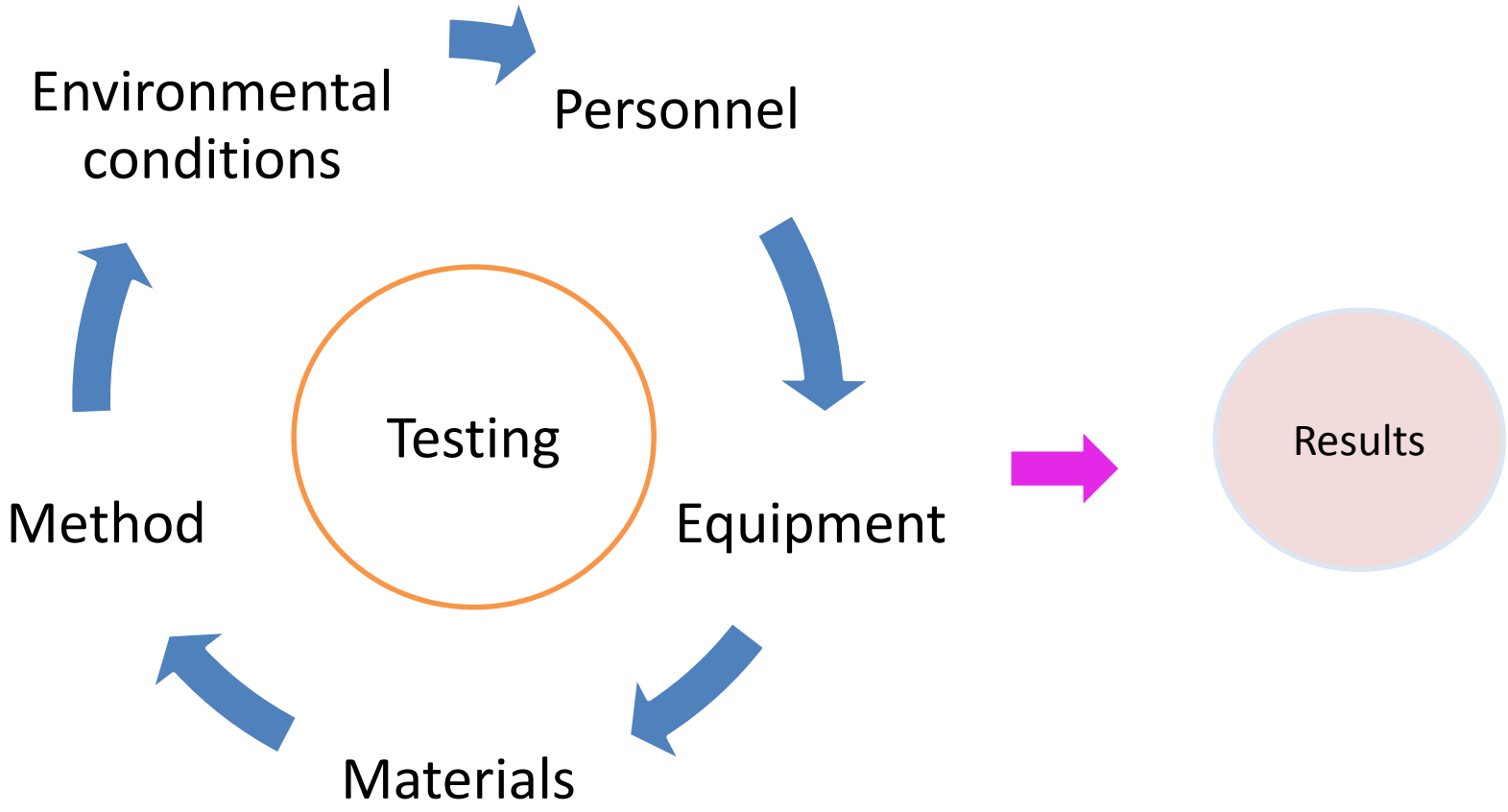
Management responsibilities

- Top management develop the Quality manual and quality policies and objectives, ensure they are appropriate to the laboratory.

- Top management commit to continually improve the effectiveness of the management system.

- Top management shall periodically conduct a review of the laboratory's management system and testing activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements

Management responsibilities



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Management responsibilities

- Personnel - all personnel, who manage, perform or verify the work
- Equipment – testing equipments
- Materials – samples, consumable materials
- Method – testing method
- Environment conditions

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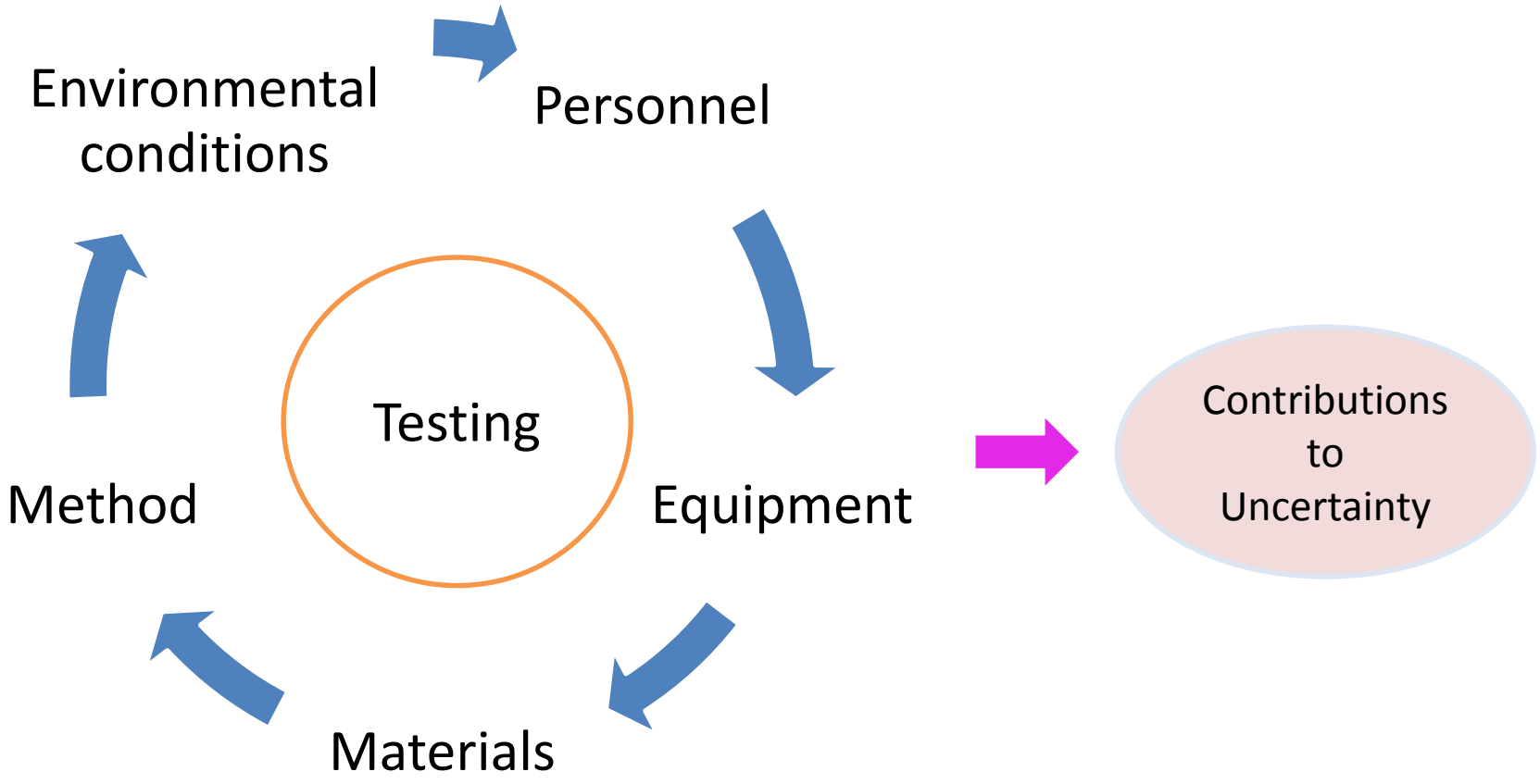
Management responsibilities



Management responsibilities

- Different laboratory, those contributions to uncertainty are different
  - For example: in calibration laboratory, the environment conditions will provide higher influence to the results than the testing laboratory

- In the same laboratory, for different testing items, those contributions are different

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Resource management

- Resource is the essential conditions to establish and implement the quality management system, including human resources, accommodation and environmental conditions, equipment and traceability

Resource management

- Personnel requirement
  - Ensure the competence of all who operate specific equipment, perform tests, evaluation results, and sign test reports
  - Competence mean it is verified to have satisfactory application knowledge and skills
  - Evaluate, verify and authorize specific personnel to perform test, issue test reports, give opinions and interpretations, to operate particular types of equipments

Resource management

- Personnel requirement
  - The laboratory shall use personnel who are employed by, or under contract to, the laboratory.
  - When using staff who are undergoing training, appropriate supervision shall be provided.
  - Maintenance records of the relevant authorization(s), competence, educational and professional qualifications, trainings, skills and experiences

Key points

- Only competent personnel should perform testing and calibrations. This includes part-time as well as full-time employees, as well as all management levels.
- Competence can come from education, experience, or training.
- Management should define and maintain tasks, job descriptions, and required skills for each job.
- Based on required skills and available qualifications, a training program should be developed and implemented for each employee.

Key points

- The effectiveness of the training should be evaluated. If the training is related to a specific test method, the trainee can demonstrate adequate qualification through successfully running a quality control or proficiency test sample. A statement from the trainee such as 'I have read through the test procedure' is not enough.
- Management should authorize personnel to perform specific tasks, for example, to operate specific types of instruments, to issue test reports, to interpret specific test results, and to train or supervise other personnel.
- The date of this authorization should be recorded. The associated tasks should not be performed before the authorization date.

Resource management

- Facility requirement
  - Laboratory facilities, including but not limited to electricity, water, lighting, IT, office equipments, security measures.

Resource management

- Equipment requirement
  - The equipment and its software used for testing and significant to the test results, when practicable, be uniquely identified.
  - Whenever practicable, all equipment under the control and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.
  - Develop the calibration plan
  - Calibrate or verify the equipment before use it

Resource management

- Equipment requirement
  - The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration
  - Equipment that has been subjected to overloading or mishandling, gives suspect results, or have been shown to be defective or outside specified limits**, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service** until it has been repaired and shown by calibration or test to perform correctly

Resource management

- Equipment requirement
  - For whatever reason, equipment goes outside the direct control of the laboratory, it should be checked the function and calibration status and shown to be satisfactory before the equipment is returned to service
  - When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure. (e.g. key performance, poor stability, high frequency of use, poor environment of use)

Resource management

- Equipment requirement
  - When calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.
  - Test equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test results. (how?)
  - Up-to-date instruction on the use and maintenance of equipment shall be readily available for use by the appropriate personnel

Key points

- Equipment should conform to specifications relevant to the tests. This means that equipment specifications should first be defined so that when conforming to defined specifications the equipment is suitable to perform the tests.
- Equipment and its software should be identified and documented.
- Equipment should be calibrated and/or checked to establish that it meets the laboratory's specification requirements.
- Records of equipment and its software should be maintained and updated if necessary. This includes version numbers of firmware and software. It also includes calibration and test protocols.
- Calibration status should be indicated on the instrument along with the last and the next calibration dates.

Resource management

- Environmental conditions requirement
  - For example: temperature, humidity, dust, vibration, electromagnetic disturbances, radiation, electrical supply;
  - The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods, and procedures or where they influence the quality of the results.
  - Tests shall be stopped when the environmental conditions jeopardize the results of the tests.

Resource management

- Environmental conditions requirement
  - There shall be effective separation between neighboring areas in which there are incompatible activities
  - The laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurements. The technical requirements for environmental conditions that can affect the results shall be documented.

Resource management

- Environmental conditions requirement
  - Access to and use of areas affecting the equality of tests shall be controlled. And the laboratory determine the extent of control based on its particular circumstances.

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Key points

- Environmental conditions should not adversely affect the required quality of tests. This means, for example, that equipment should operate within the manufacturer's specifications for humidity and temperature.
- The laboratory should monitor, control, and record environmental conditions. Tests should be stopped when the environmental conditions are outside specified ranges.
- Areas with incompatible activities should be separated.
- Access to test areas should be limited to authorized people. This can be achieved through pass cards.

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The process to obtain the test results

- Testing process requirement
  - All the processes (review of requests, tenders and contracts, subcontracting, service to customer, complaints, test methods and method validation, sampling, purchasing services and supplies, handling of test items, reporting the results)

The process to obtain the test results

- Testing process requirement – review of requests, tenders and contracts
  - This is the source of the testing process
  - Through the review to ensure the laboratory correctly understands the testing related requirements (including methods,), has capability and resource to meet the requirements, and select appropriate test method
  - A contract may be any written or oral agreement to provide a customer with testing service

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The process to obtain the test results

- Testing process requirement – review of requests, tenders and contracts
  - Any differences between the request/tender/contract shall be resolved before any work commences
  - If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

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The process to obtain the test results

- Testing process requirement – review of requests, tenders and contracts
  - Records of reviews, including any significant change, shall be maintained.
  - **The results of review of requests/tenders/contracts are the input to the other processes**

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Service to the client

- What cooperation might be included?
- Client Feedback, both positive & negative

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Key points

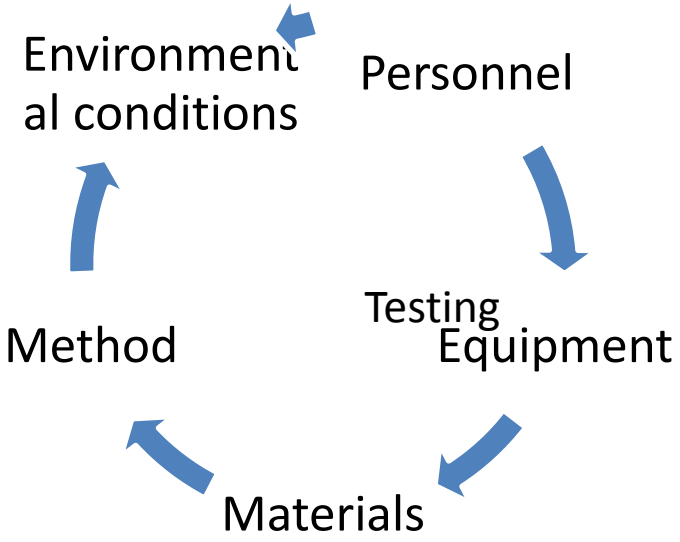
- The laboratory should communicate with customers to clarify requests and get customer input.
- The laboratory should have a formal program to collect feedback from customers on an ongoing basis.
- The laboratory should allow customers to audit the laboratory.

The process to obtain the test results

- Testing process requirement – Test methods and method validation
  - Test methods include sampling, handling, transport, and preparation of items to be tested, and where appropriate, an estimation of measurement uncertainty as well as statistical techniques for analysis of test data
  - Selection of methods

The process to obtain the test results

- Testing process requirement – Test methods and method validation
  - Validation if the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled



The process to obtain the test results

- Testing process requirement – Test methods and method validation
  - The laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing, where the absence of such instructions could jeopardize the results.
  - All instructions, standards, manuals and reference data shall be kept up to date and made readily available for personnel

The process to obtain the test results

- Testing process requirement – Test methods and method validation
  - Deviation from test methods shall occur only if the deviation has been documented, technically justified, authorized and accepted by the customer.
  - Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement

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Key points for accurate test results

- Methods and procedures should be used within their scope. This means the scope should be clearly defined.
- The laboratory should have up-to-date instructions on the use of methods and equipment.
- If standard methods are available for a specific sample test, the most recent edition should be used.
- Deviations from standard methods or from otherwise agreed-upon methods should be reported to the customer and their agreement obtained.
- When using standard methods, the laboratory should verify its competence to successfully run the standard method. This can be achieved through repeating one or two critical validation experiments, and/or through running method specific quality control and/or proficiency test samples.

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Key points for accurate test results

- Standard methods should also be validated if they are partly or fully out of the scope of the test requirement.
- Methods as published in literature or developed by the laboratory can be used, but should be fully validated. Clients should be informed and agree to the selected method.
- Introduction of laboratory-developed methods should proceed according to a plan.
- The following parameters should be considered for validating in-house developed methods: limit of detection, accuracy, selectivity, linearity, repeatability and/or reproducibility, robustness, and linearity.

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The process to obtain the test results

- Testing process requirement – Technical record
  - The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trial, staff records, and a copy of reach test report issued, for a defined period.
  - The record for each test shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test to be repeated under considerations as close as possible to the original.

The process to obtain the test results

- Testing process requirement – Technical record
  - The records shall include the identity of personnel responsible for the sampling, performance of each test and checking of the results
  - When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and correct value entered alongside. All such alteration to records shall be signed or initialed by the person making the correction.

Key points

- There should be procedures for identification, collection, indexing, storage, retrieval, and disposal of records.
- Records should be stored such that their security, confidentiality, quality and integrity are ensured throughout the required retention time.
- For technical records such as test reports of analytical measurements, original observations should be retained, along with processing parameters that will allow tracking final results back to the original observations.
- Record format can be hard copies or electronic media. There should be procedures to protect and back-up electronic records and to prevent unauthorized access.

Key points

- Records can be corrected if there are mistakes. The original record should be crossed out, but still visible.
- When electronic record systems are used, the same principle applies. The laboratory should ensure that original records are not overwritten by the system and that corrections are recorded together with the original records. Using a system that prevents overwriting original records and stores changes in an electronic audit trail that can be viewed and printed is highly recommended.

The process to obtain the test results

- Testing process requirement – data control
  - Data and results are the products of the laboratory.
  - When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage, or retrieval of test data, the laboratory shall ensure:
    - Commercial off-the shelf software (e.g. word-processing, database, statistical programmes) in general use within their designed application range may be considered to be sufficient validated
    - Laboratory self-developed software is documented in sufficient details and is suitably validated as being adequate for use
    - Procedures are established and implemented for protecting data
    - Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operation conditions necessary to maintain the integrity of test data.

Key points for control of data

- Calculations used for data evaluation should be checked. This is best done during software and computer system validation. As an example, spreadsheet formulas defined by a specific user should be verified with an independent device such as a handheld calculator. Data transfer accuracy should be checked.
- Computer software used for instrument control, data acquisition, processing, reporting, data transfer, archiving, and retrieval developed by or for a specific user should be validated. The suitability of the complete computer system for the intended use should also be validated.

Key points for control of data

- Any modification or configuration of a commercial computer system should be validated. Examples include defining report layouts, setting up IP addresses of network devices, and selecting parameters from a drop-down menu.
- Electronic data should be protected to ensure integrity and confidentiality of electronic records. For example, computers and electronic media should be maintained under environmental and operating conditions to ensure integrity of data.

Purchasing services and suppliers

- What constitutes services and supplies?
- What constitutes inspected prior to use?
- What kind of records would be needed?
- Purchase documents should contain what information?
- What methods could the laboratory use to evaluate suppliers?

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Key points

- Suppliers should be selected and formally evaluated to ensure that services and supplies are of adequate quality.
- Records of the selection and evaluation process should be maintained.
- The quality of incoming material should be verified against predefined specifications.

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The process to obtain the test results

- Testing process requirement – handling of samples
  - The laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and disposal of test samples.
  - The laboratory shall have a system for identifying test samples, The identification shall be retained throughout the life of the item in the laboratory.
  - Abnormalities or departures from normal or specified conditions, as described in the test method, shall be recorded.

The process to obtain the test results

- Testing process requirement – reporting the results
  - The output of the testing process
  - The test reports shall include requests by the custom, and all the necessary information for stating the specific methods, opinions and interpretations

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Testing analysis & improvement

- Complaints
- Control of nonconforming test work
- Improvement
- Corrective action
- Preventive action
- Internal audit
- Data analysis
- Assurance the quality of test results

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Complaints

- What is a compliant?
- Is there always a problem?
- What method used to resolve?

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Testing analysis & improvement

- Complaints
  - The laboratory shall have a policy and procedure for resolution of complaints received from customers other parties.
  - Survey the feedbacks from consumers (either positive and negative)

Control of nonconforming work

- What constitutes nonconforming work?
- What should be done when nonconforming work is noted? Who is responsible?

Testing analysis & improvement

- Control of nonconforming test work
  - The laboratory shall have a policy and procedure that shall be implemented when any aspect of its testing work, or results do not conform to its own procedures or the agreed requirements of the customer.
  - The responsibilities and authorities
  - An evaluation of the significance
  - Correction is taken immediately
  - When necessary, the customer is notified and the work is recall
  - The responsibility for authorizing the resumption of the work

Key points

- There should be a policy and process that come into effect when results do not conform to procedures.
- Corrective actions should be taken immediately to avoid recurrence.
- The significance of nonconforming work should be evaluated, for example, the possible impact on other testing work.
- If necessary, customers should be notified.

Testing analysis & improvement

- Improvement
  - The laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, objectives, audit results, analysis of data, corrective and preventive actions and management review.

Improvement

- The laboratory shall show evidence of improvement:
- Continuous improvement program
- Addressed and items identified during management review and other activity
- All documented and evidence of follow-up or effective improvement

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Key points

- Suggestions for improvements should be taken from audit reports, analysis of data, customer complaints and suggestions, corrective and preventive actions, and management reviews.
- Suggestions should be collected over time and reviewed by management for suitable actions.

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Testing analysis & improvement

- Corrective action
  - A problem may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers and from staff observations.
  - Implement corrective actions when the nonconforming work has been identified

Testing analysis & improvement

- Problems may be identified through?
- Steps for a good corrective action procedure are:
  - Cause analysis

    is there always a problem?
  - Selection and implementation of corrective actions

    What is the goal of the corrective action?
  - Monitoring of corrective actions

    How might a laboratory monitor corrective actions?
  - Additional audits

Key points

- Corrective actions can be triggered through nonconforming tests or other work, customer complaints, internal or external audits, management reviews, and observations by staff.
- Corrective actions should be selected and implemented to eliminate the specific problem and prevent recurrence of the same problem.
- As the first step in the process, the root cause of the nonconformity should be identified.
- The effectiveness of the corrective action should be monitored and evaluated.

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Preventive Action

- What is preventive action?
- Define how one would identify preventive actions?

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Testing analysis & improvement

- Preventive action
  - Preventive action is a pro-active process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.
  - When improvement opportunities are identified or if preventive action is required, action plains shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities.

Testing analysis & improvement

- Preventive action
  - Identify the potential nonconformity work and conduct cause analysis (including trend and risk analysis and PT results)
  - Selection and implementation of preventive actions
  - Monitoring of preventive actions

Key points

- There should be a procedure to identify potential sources of nonconformities and define preventive actions to prevent occurrence of these nonconformities.
- The effectiveness of the preventive action should be monitored and evaluated.

- Define corrective & Preventive Actions

- What are the primary differences?

Testing analysis & improvement

- Internal audit
  - The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits to verify its operations continue to comply with the requirements of the management system

Key points

- Internal audits can either cover the whole laboratory and all elements of the quality system at one specific period of time or can be divided into several subsections.
- The schedule should be such that each element of the quality system and each section of the laboratory are audited yearly.
- The audit program should be managed by the quality manager.
- Audit findings related to the quality of test and calibration results should be reported to customers.
- Audit follow-up activities should include corrective and preventive action plans (CAPA). The effectiveness of the plans should be monitored.

Testing analysis & improvement

- Data analysis
  - The laboratory shall identify, collect and analysis appropriate data to verify the suitability and effectiveness of the quality management system.
  - Custom satisfactory, compliance to the requirements, process characteristics and development trend, suppliers

Testing analysis & improvement

- Assurance the quality of test results
  - Monitoring and measurement of the process
  - Participation in IC or PT
  - Replicate tests using the same or different methods
  - Retesting of retained items
  - Correlation of results for different characteristics and an item
  - Quality control data should be analyzed and where they found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported

Key points

- The validity of test results should be monitored on an ongoing basis.
- The type and frequency of tests should be planned, justified, documented, and reviewed.
- Quality control checks can include the regular use of certified reference materials, replicating tests or calibrations using the same or different methods, and retesting or recalibration of retained items.

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CLIMATE TECHNOLOGY CENTRE & NETWORK

The Climate Technology Centre and Network (CTCN) fosters technology transfer and deployment at the request of developing countries through three core services: technical assistance, capacity building and scaling up international collaboration. The Centre is the operational arm of the UNFCCC Technology Mechanism, it is hosted and managed by the United Nations Environment and the United Nations Industrial Development Organization (UNIDO), and supported by more than 300 network partners around the world.

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