Understanding and Implementing ISO/IEC 17025

A Primer

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Agilent Technologies

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Preface

This primer is intended to give a brief introduction to ISO/IEC 17025: the global standard for laboratory accreditation.

After reading this primer, laboratory managers, staff, and others who might be affected by ISO/IEC laboratory accreditation should:

- Understand the benefits of laboratory accreditation.
- Have an overview of management and technical requirements.
- Know what steps are required to evaluate whether or not laboratory accreditation makes good business sense.
- Be familiar with implementation steps.
- Know the types of documentation required.
- Know how to prepare a laboratory for internal and external audits.

The concepts and ideas expressed in this primer are my own and do not necessarily reflect official Agilent or LabCompliance policies.

Quality standards are quite dynamic. They are updated every couple of years. Related implementation guidelines, as developed by international committees, are published even more frequently. What is state-of-the art today may not be appropriate tomorrow.

A timely update of all information is important and only possible using online information tools. Web sites with regular updates related to quality standards in laboratories include:

http://www.iso.org
The Web site of the International Organization for Standardization can be used for ordering ISO standards and other documents.

http://www.ilac.org
The Web site of the International Laboratory Accreditation Cooperation contains guidance documents with information on the interpretation of accreditation criteria for specific applications.

http://www.citac.cc/
The Cooperation on International Traceability in Analytical Chemistry Web site has downloads that are helpful for implementing ISO/IEC 17025.

http://www.labcompliance.com

Updated regularly, this Web site includes tutorials relevant to laboratory quality and compliance issues.

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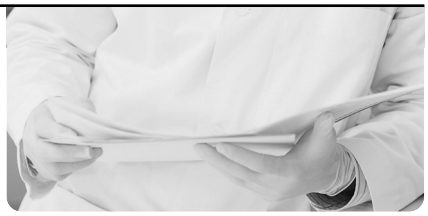
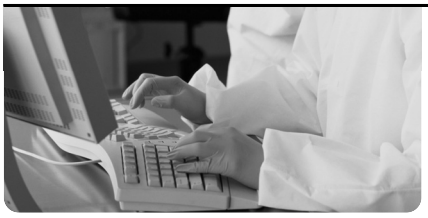


Management Summary



Management Summary

ISO/IEC 17025 is the global quality standard for testing and calibration laboratories. It is the basis for accreditation from an accreditation body. The current release was published in 2005.

There are two main clauses in ISO/IEC 17025 – Management Requirements and Technical Requirements. Management requirements are related to the operation and effectiveness of the quality management system within the laboratory, and this clause has similar requirements to ISO 9001. Technical requirements address the competence of staff; testing methodology; equipment and quality; and reporting of test and calibration results.

Implementing ISO/IEC 17025 has benefits for laboratories, but the work and costs involved should be considered before proceeding.

Main Benefits of Correctly Implemented ISO/IEC 17025:

Implementing ISO/IEC 17025 as part of laboratory quality initiatives provides both laboratory and business benefits such as:

- Having access to more contracts for testing and/or calibration. Some public and private organizations only give contracts to accredited laboratories. Accreditation will also help to get more contracts from organizations that don't mandate accreditation, but do give preference to accredited laboratories in competitive situations.
- 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.

Analytical testing laboratories seeking ISO/IEC 17025 will be impacted in multiple areas. The main difference between good analytical practices and formal accreditation is the amount of documentation to be developed. There is no doubt that any good analytical laboratory uses qualified analysts, checks the performance of equipment used for testing, and validates analytical methods. However, many times the outcome of the tests is not fully documented. ISO/IEC 17025 accreditation requires formal documentation for nearly everything. It is similar to operating in a regulated environment – 'what is not documented is a rumor,' and is viewed by assessors as 'not being done.'

The overall impact of accreditation on an analytical laboratory can be best illustrated by looking at the whole sample/data workflow. **Figure 1** shows a typical laboratory workflow of samples and test data, together with ISO/IEC 17025 requirements.

Requirements Overview:

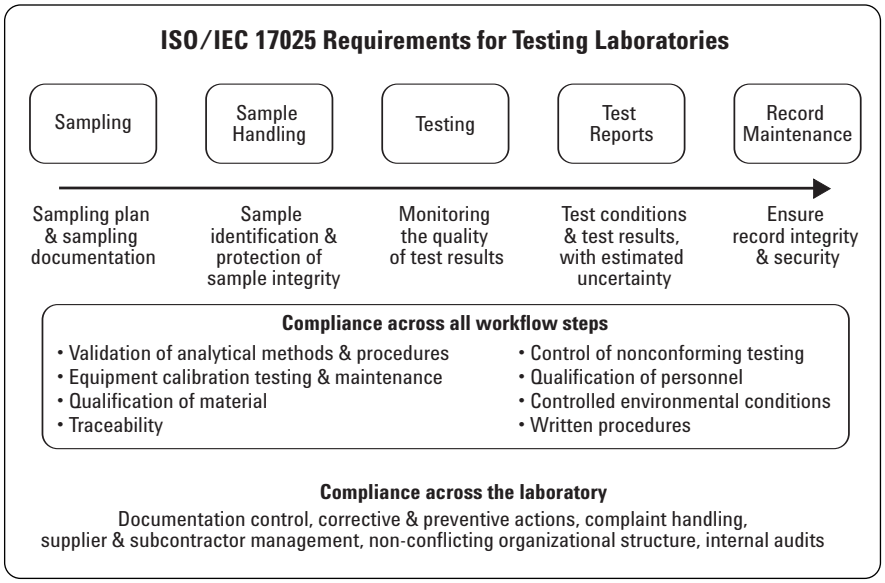


Figure 1: ISO/IEC 17025 Requirements for Testing Laboratories

Specific requirements include:

- Sampling should be performed according to a sampling plan, and all sample details should be documented.
- Samples should be uniquely identified and the sample integrity should be protected during transport and storage.
- The quality of test results should be monitored.
- Test reports should include test results as well as an estimation of the overall measurement uncertainty. The report should also include either detailed information about the sample and test conditions, or a link to a reference document.
- Records should be properly maintained to ensure data integrity and availability.

Some requirements impact more than one workflow step:

- All analytical methods and procedures should be validated. This includes methods and procedures for sampling, testing and data evaluation.
- Equipment used for sampling and testing should be calibrated, tested, and well maintained. Material such as calibration standards should be qualified and traceable to System International (SI) units or to certified reference material.

- Nonconforming test results should be documented and controlled.
- People should be qualified for their assigned tasks through education, experience, or training.
- Environmental conditions such as temperature, humidity, and electromagnetic interference should be monitored and controlled.
- All routine tasks should be performed according to written procedures.

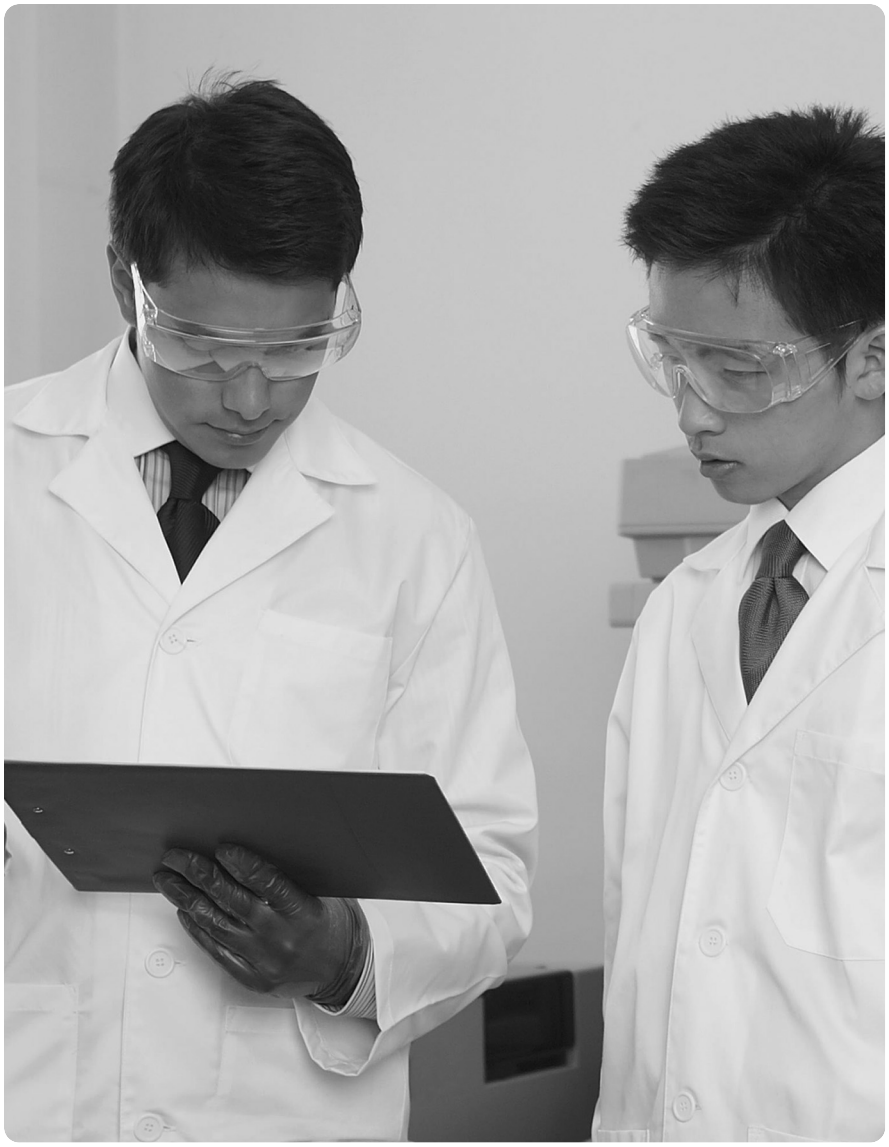
Some additional requirements impact not only sample analysis, but also the organization of the entire laboratory:

- Specific documents should be developed and maintained, including individual policies and a quality plan.
- Known existing problems should be corrected and an action plan should be developed to avoid recurrence of the same or similar problems.
- All complaints from clients should be formally followed up.
- A formal program should be used to manage suppliers, service providers, and subcontractors.
- The organizational structure should be such that there are no conflicting interests that could impact quality.
- Compliance with ISO/IEC 17025 and internal procedures should be assessed during regular internal audits.

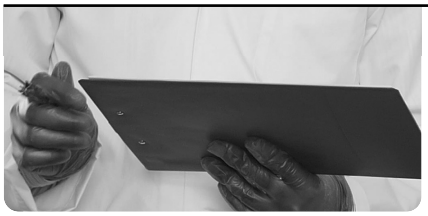
Key Steps towards Accreditation:

There are eight key steps towards laboratory accreditation:

1. Management defines a project owner.
2. The project owner studies details of the standard, supporting literature, and other relevant information.
3. The project owner defines the preliminary scope of accreditation and works with laboratory professionals to prepare a list with requirements.
4. The project owner and laboratory professionals perform a gap analysis to determine the difference between the requirements and what is currently implemented in the laboratory.
5. Based on the outcome of the gap analysis, the project owner, laboratory professionals, financing and documentation professionals, and external consultants estimate the costs for accreditation.
6. Estimated costs are presented to management, along with incremental opportunities.
7. Management decides to proceed with accreditation.
8. The project owner leads implementation steps.



Introduction



Introduction

Companies have to continuously deliver high-quality products and/or services if they want to be successful in the marketplace over the long term. Quality improvement has become a key national and international business strategy. Most companies are using quality systems as a method of assuring the consistency and conformity of products or services to a defined set of standards or customer expectations.

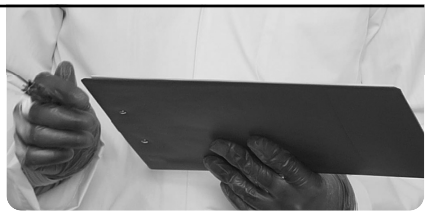
Quality Systems

Several quality system standards were developed in various countries in the 1960s and 1970s. The MIL-Q-9858A was established in the United States in 1963, and the BS 5750 was established in 1979 in the United Kingdom. These are probably the two most important standards from this era. The ISO 9000 series of quality standards was established in 1987 for implementing and maintaining a quality system. This standard is internationally accepted and can be used as a criterion for third-party quality assessment.

ISO/IEC 17025 – Laboratory Quality System

Laboratories play an important role in company quality systems. The ISO/IEC 17025 (1) can be used as a standard to develop and establish a quality system for a laboratory and also for assessment by laboratory clients or third parties. The standard can also be used as a criterion for laboratory accreditation. Working according to global standards is especially important for laboratories to ensure validity and global comparability of test and calibration results. One of the goals of using global standards is to reduce the number of tests required in national and international trading.

The first edition of the "International Standard General Requirements for the Competence of Testing and Calibration Laboratories" was produced as a result of extensive experience in implementing ISO/IEC Guide 25 and EN 45001; it replaced these earlier standards in 1999. This new standard contains all the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a management system, are technically competent, and are able to generate technically valid results.



Management requirements in the first edition refer to ISO 9001:1994 and ISO 9002:1994. These standards have been superseded by ISO 9001:2000, which made an update of ISO/IEC 17025 necessary. In the second edition of ISO/IEC 17025, released in 2005, clauses were amended or added only when considered necessary in the light of ISO 9001:2000

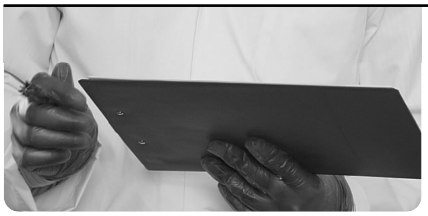
Testing and calibration laboratories that comply with ISO/IEC 17025 will therefore also operate in accordance with ISO 9001.

Accreditation bodies that recognize the competence of testing and calibration laboratories use ISO/IEC 17025 as the basis for their accreditation.

ISO/IEC 17025 is divided into five clauses, two annexes, and one bibliography section:

- Clause 1: Scope
  The standard covers the technical activities of a laboratory as well as the management and organizational aspects to perform the technical activities in a competent way.
- Clause 2: Normative References
- Clause 3: Terms and Definitions
- Clause 4: Management Requirements
  Most of the requirements are similar to those specified in the ISO Standard 9001:2000.
- Clause 5: Technical Requirements
  Most of the requirements come from the ISO Guide 25.
- 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.



Scope and Contents of this Primer

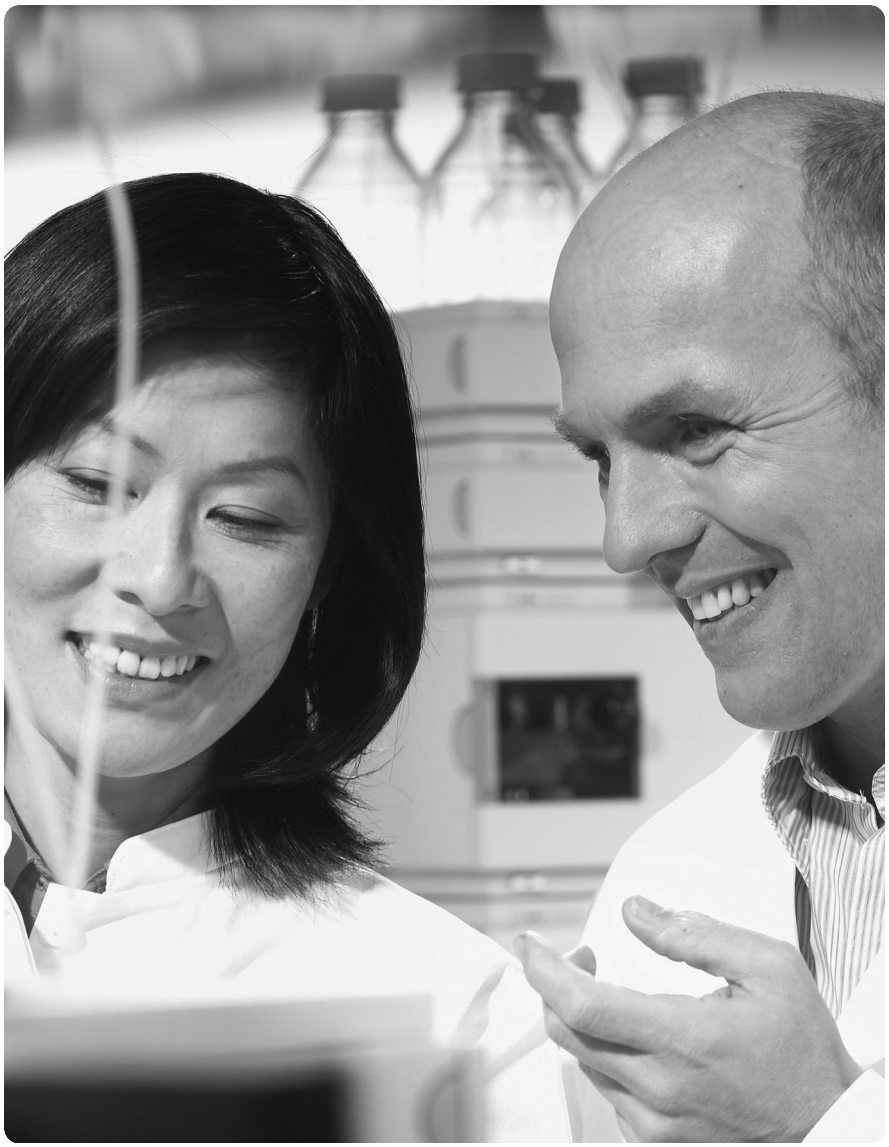
Implementing a quality system such as ISO/IEC 17025 has an impact on laboratory organization and operation. This primer will discuss some of the specific implementation requirements, along with their implications for testing and calibration laboratories.

This primer is especially useful for chemical analytical laboratories seeking accreditation according to an internationally recognized standard. Examples include food testing, environmental testing, chemical testing, clinical testing, pharmaceutical testing, and other testing laboratories. This primer will guide laboratory and QA managers and staff through the entire process of ISO/IEC 17025 accreditation. It also helps laboratories working under different quality systems to efficiently set up procedures for compliance with all requirements.

Covered in this primer:

- Management requirements
- Technical requirements
- Recommendations for Implementation
- Steps toward ISO/IEC 17025 accreditation
- Documentation
- Internal and external audits
- Implementing multiple quality systems

The primer and its reference material should give a good understanding of the importance of ISO/IEC 17025, the requirements, and the key points for implementation. The primer is not a substitute for the standard itself and does not list all requirements. Rather, it focuses on the most important requirements and the ones that need specific attention, according to the opinion and interpretation of the author. The primer also does not include tools such as sample quality manuals, operating procedures, and all the templates that would help to quickly implement ISO/IEC 17025. These items can be obtained as special packages that are available from service providers, for example, the ISO/IEC 17025 Accreditation Package from LabCompliance (2).



Management Requirements

Management Requirements

Management requirements pertain to the operation and effectiveness of the quality management system within the laboratory. The requirements are similar to ISO 9001. This clause is divided into fifteen chapters, described below.

Organization

This chapter ensures that the roles and responsibilities of the laboratory, the management, and key personnel are defined.

Key points:

- An organizational structure, as well as responsibilities and tasks of both management and staff should be defined.
- The organizational structure should be such that departments having conflicting interests do not adversely influence the laboratory's work quality. Examples include commercial marketing or financing departments.
- A quality assurance manager should be appointed.
- All personnel should be free from any commercial or financial pressure that could adversely impact the quality of calibration and test results.

Management System

This chapter describes how to ensure that a management system is implemented, maintained, and continually improved.

Key points:

- There should be policies, standard procedures and work instructions to ensure the quality of test results.
- There should be a quality manual with policy statements that are issued and communicated by top-level management.
- The effectiveness of the management system should be continually improved.

Document Control

Individual paragraphs in this chapter describe how to ensure that all documents related to the management system are uniquely identified and created, approved, issued, and changed following documented procedures.

Key points:

- All official documents should be authorized and controlled.
- Documents should be regularly reviewed and updated if necessary. The review frequency depends on the document itself. Typical review cycles are between one and three years.
- Changes to documents should follow the same review process as for the development of initial documents.

Review of Requests, Tenders, and Contracts

This chapter describes how to ensure that requirements of requests, tenders and contracts are well defined, reviewed, understood, and documented.

Key points:

- The laboratory supervisor's review should ensure that the laboratory has the technical capability and resources to meet the requirements.
- Changes in a contract should follow the same process as the initial contract.

Subcontracting of Tests and Calibrations

This chapter describes how to ensure that tests and calibrations subcontracted to third parties are performed according to the same quality standards as if they were done in the subcontracting laboratory.

Key points:

- The competence of the subcontracted party should be ensured, through a documented quality system, such as ISO/IEC 17025.
- The subcontracting laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or the regulatory body specifies which subcontractor should be used.

Purchasing Services and Supplies

This chapter describes how to ensure that services and supplies delivered by third parties do not adversely impact the quality and effectiveness of laboratory operations.

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.

Service to the Customer

This chapter describes how to ensure that the laboratory continually meets customer requirements.

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.

Complaints

This chapter describes how to ensure that any customer complaints are documented, evaluated, and adequately followed up.

Key points:

- There should be a policy and procedure for the resolution of complaints received from customers.
- Records of complaints and all steps taken when resolving the complaint should be maintained. This includes documentation of investigations and corrective actions.

Control of Nonconforming Testing and/or Calibration Work

Tests, calibrations, and other laboratory operations should conform to previously defined specifications such as laboratory specifications or client-defined specifications. This chapter describes how to ensure that nonconforming test and calibration results are adequately followed up, and that corrections are initiated.

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 or calibration work.
- If necessary, customers should be notified.

Improvement

This chapter describes how to ensure that the effectiveness of the management system is continually improved.

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.

Corrective Action

This chapter describes how to ensure that the root cause of nonconforming work or deviations from laboratory and management procedures are identified and that adequate corrective actions are selected, implemented, documented, and monitored.

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.

Preventive Action

Preventive actions should be initiated when potential sources of nonconformities have been identified. Nonconformities may be technical or related to the management system. The objective is to reduce the likelihood of the occurrence of such potential nonconformities.

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.

Control of Records

This chapter describes how to ensure that all records in a laboratory are uniquely identified, readily available when needed, and protected against unauthorized access for viewing or changing.

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.
- 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.

Internal Audits

Internal audits should verify that the laboratory complies with ISO/IEC 17025 and with internal technical and quality procedures. Internal audits are also an excellent preparation for external assessments and can help to continually improve the quality system.

Key points:

- The laboratory should have a procedure and a schedule for internal audits. 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.

Management Reviews

Requirements in this chapter describe how to ensure the continued suitability and effectiveness of the quality system, policies, and testing and calibration procedures.

Key points:

- There should be a schedule and procedure for periodic management reviews.
- Recommended review frequency is once a year.
- The management review should include a discussion about the outcome of recent internal audits and external assessments, corrective and preventive actions, results of proficiency testing, customer complaints and feedback, and any recommendations for improvements.
- Management should decide on follow-up activities. These activities should be monitored for effectiveness.

Technical Requirements

Technical Requirements

Technical requirements address the competence of staff, sampling and testing methodology, equipment, and the quality and reporting of test and calibration results. This clause is divided into ten chapters.

General

The technical requirements clause starts with a general chapter. This chapter's purpose is to make readers aware that the correctness and reliability of test and calibration results are determined by a variety of factors.

Key points:

- The different factors impacting the quality of results should be documented. They include, for example, sampling, equipment, test methods, and environmental conditions.
- The extent to which impacting factors can contribute to the measurement uncertainty should be taken into account when developing test and calibration methods.

Personnel

Personnel probably have the highest impact on the quality of test and calibration results. This chapter describes how to ensure that all laboratory personnel who can impact test and calibration results are adequately qualified.

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.

- 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.

Accommodation and Environmental Conditions

This chapter has been included to ensure that the calibration and test area environment will not adversely affect the measurement accuracy. It includes five sections with information that is mostly common sense. One clause recommends having effective separation between neighboring areas when the activities therein are incompatible. An example would be to separate laboratories that analyze extremely low traces of a solvent from those which consume large quantities of the same solvent for liquid-liquid extraction.

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. Special attention should be paid to biologic sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, sound, and vibration. Tests should be stopped when the environmental conditions are outside specified ranges.
- Areas with incompatible activities should be separated.
- Access to test and calibration areas should be limited to authorized people. This can be achieved through pass cards.

Test and Calibration Methods and Method Validation

Accurate test and calibration results can only be obtained with appropriate methods that are validated for the intended use. This chapter deals with the selection and validation of laboratory-developed and standard methods and measurement uncertainty and control of data.

Key points for accurate test and calibration 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.
- 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, limit of quantitation, accuracy, selectivity, linearity, repeatability and/or reproducibility, robustness, and linearity.
- Exact validation experiments should be relevant to samples and required information.
- Sometimes, standard and in-house validated methods need to be adjusted or changed to ensure continuing performance. For example, the pH of a HPLC mobile phase may have to be changed to achieve the required separation of chromatographic peaks. In this case, the influence of such changes should be documented, and if appropriate, a new validation should be carried out.

- Validation includes specification of the requirements and scope, determination of the characteristics of the methods, appropriate testing to prove that the requirements can be fulfilled by using the method, and a statement on validity.

Key points for measurement uncertainty:

- The laboratory should have a procedure to estimate the uncertainty of measurement for calibrations and testing.
- For uncertainty estimation the laboratory should identify all the components of uncertainty.
- Sources contributing to the uncertainty can include the reference materials used, the methods and equipment used for sampling and testing, environmental conditions and personnel.

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. Accuracy of data transfer between computers can be automatically checked with MD5 hash sums.
- 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.
- 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.

Equipment

Equipment that is performing well and properly maintained is a prerequisite for the ongoing accuracy of test and calibration results. This chapter deals with the capacity and quality of equipment. The whole idea is to make sure that the instrument is suitable for performing selected tests/calibrations and is well characterized, calibrated, and maintained.

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.

Measurement Traceability

Traceability of equipment to the same standard is a prerequisite for comparability of test and calibration results. Ideally all measurements should be traceable to International System of Units (SI). While this is typically possible for physical measurements such as length (m) and weight (kg), this is more difficult in chemical measurements.

Key points for traceability of calibrations:

- Calibration of equipment should be traceable to the SI units.
- Traceability of laboratory standards to SI may be achieved through an unbroken link of calibration comparisons between the laboratory standard, secondary standard, and primary or national standard.
- If traceability to SI units is not possible, the laboratory should use other appropriate traceability standards. These include the use of certified reference material and the use of consensus standards or methods.

Sampling

This chapter has been added to describe how to ensure that statistically relevant representative samples are taken and that all information on the sample and the sampling procedure is recorded and documented.

Key points for sampling:

- Sampling should follow a documented sampling plan and sampling procedure.
- The sampling plan should be based on statistical methods.
- The sampling procedure should describe the selection and withdrawal of representative samples.
- The sampling location and procedure, the person who took the sample, and any other relevant information about the sampling process should be recorded.

Handling Test and Calibration Items

This chapter describes how to ensure that sample integrity is maintained during transport, storage, and retention and that samples are disposed of safely.

Key points for handling test and calibration items:

- Test and calibration items should be uniquely identified.
- Sample transportation, receipt, handling, protection, storage, retention, and/or disposal should follow documented procedures.
- The procedures should prevent sample deterioration and cross-contamination during storage and transport.

Assuring the Quality of Test and Calibration Results

This chapter describes how to ensure the quality of results on an ongoing basis through, for example, regular analysis of quality control samples or participation of proficiency-testing programs.

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.

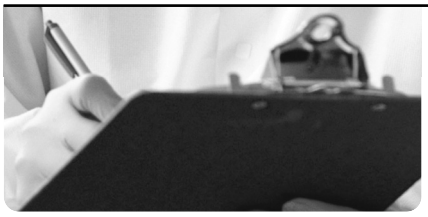
Reporting of Results

This chapter describes how test/calibration results should be reported. This is important for an easy comparison of tests performed in different laboratories. The chapter has some general requirements on test reports such as clarity and accuracy, but it also has very detailed requirements on the contents.

Test reports and calibration certificates should include:

- The name and address of the laboratory.
- Unique identification of the test report or calibration certificate (such as the serial number).
- The name and address of the client.
- Identification of the method.
- A description and identification of the item(s) tested or calibrated.
- Reference to the sampling plan and procedures used by the laboratory.
- The test or calibration results with the units of measurement.
- The name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate.
- A statement on estimated uncertainty of measurement (for test reports 'where applicable').
- When opinions and interpretations are included, documentation of the basis for the opinions and interpretations.
- Opinions and interpretations clearly marked as such on the test report or calibration certificate.

Recommendations for Implementation

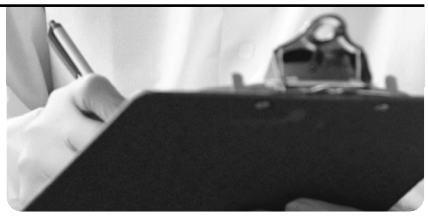


Recommendations for Implementation

Now that you have an overview of required management and technical controls, we will give recommendations on how to efficiently comply with some key requirements. The scope of this primer does not go into all the details and we cannot cover all requirements.

We will focus on topics that most likely are new to laboratories without a quality system. These include: specific organizational structure, formal equipment calibration and testing, measurement traceability and uncertainty. We try to balance the lack of detailed information by providing references to official guidelines, textbooks, and other literature. For example, EURACHEM/CITAC, EUROLAB and ILAC have developed guidance documents for measurement uncertainty and traceability in measurement (3-9). ISO has published a "Guide to the Expression of Uncertainty in Measurement" (10). A EURACHEM-UK working group has developed guidance for qualification of analytical instruments that was published in "Accreditation and Quality Assurance" (11). EUROLAB has published a technical report called "Management of Computers and Software in Laboratories with Reference to ISO/IEC 17025:2005" (12). Huber has authored a textbook "Validation and qualification in Analytical Laboratories" and Thompson et al. gave recommendations for an "International Harmonized Protocol for Proficiency Testing of Chemical Analytical Laboratories" (14).

Help is also readily available from accreditation bodies. For example, A2LA has a "Policy on Measurement Traceability" (15) and LabCompliance provides a complete "ISO/IEC Accreditation Package" with a sample master plan, SOPs, forms, and checklists (2).



Organizational Structure

ISO/IEC requires that organizational arrangements should be such that departments with conflicting interests do not adversely influence compliance with the standard. For example, finance and QA should operate independently from laboratory activities. **Figure 2** gives an example of how this could be accomplished. Finance and QA do not report to laboratory management but rather to the director of the company.

Example for Organizational Structure

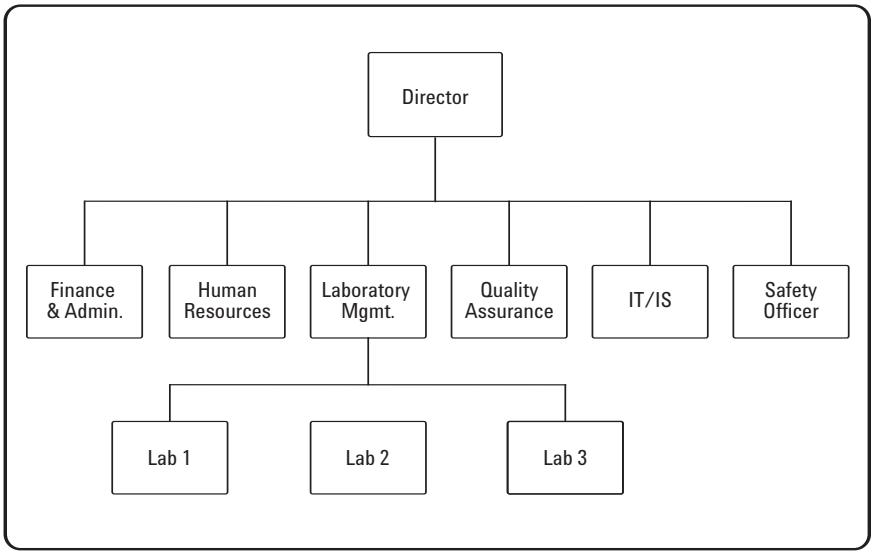
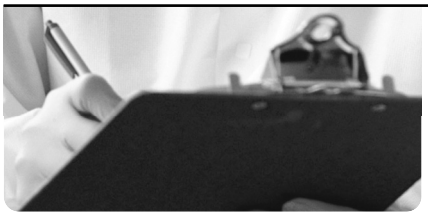


Figure 2: Example for Organizational Structure (from Reference 2)



Equipment

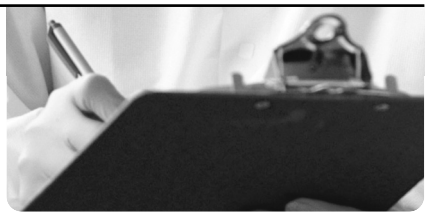
Each laboratory should have a plan for how to ensure adequate equipment function and performance before and during sample measurement. The main activities are calibration and checking to verify specified performance and maintenance. The extent of testing depends on the complexity and use of the equipment. Each laboratory should have processes for how calibration and testing is performed for different types of equipment. Preferably the whole range of equipment should be divided into a few categories such as A, B, and C, and calibration and/or verification tests should be associated with each category. Instruments in the simplest category (A) such as stirrers and mixers usually don't need to be tested but only visually inspected. Category B instruments such as balances and pH meters should be calibrated according to manufacturer SOPs, and more complex instruments such as chromatography systems should be fully tested according to their intended use.

The following paragraphs contain recommendations for how to specify, test, and maintain analytical equipment for ISO/IEC 17025 compliance.

Documenting Specifications

ISO/IEC 17025 requires that equipment and software should comply with specifications that are relevant to the tests. Therefore, the first step in the process is to define and document the equipment specifications.

- For simple equipment, such as balances and pH meters, the use of manufacturer specifications is recommended.
- For more complex equipment hardware, such as gas chromatographs or mass spectrometers, the manufacturer's specifications can also be used. This is only recommended as long as all vendor-specified functions are required by the intended applications over the fully specified range. As an alternative, the user can define specifications according to the intended use of the instrument.
- Commercial software and computer systems typically provide more functionality than required by a specific user. Therefore, for computer systems, the user should define specifications according to the system use. A functional specifications list will help define user specifications.



Selecting a Vendor

A documented procedure and well-defined criteria should be used for selecting equipment suppliers. Useful criteria include:

- Vendor's equipment meets the user's requirement specifications.
- Vendor has leading position in the marketplace.
- Equipment and software design, development, and manufacturing takes place in a quality system environment such as ISO 9001.
- Vendor provides installation, familiarization, and training services.
- Metrology-based calibration and functional testing services are performed through qualified engineers.
- Vendor provides phone and onsite support in local language.

Installation and Documentation

Installation can be performed by the vendor or by the user. Steps include:

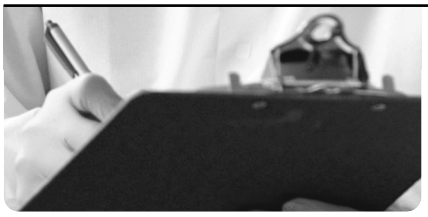
- Verify that the location meets the environmental specifications as defined by the vendor.
- Install equipment hardware according to vendor specifications.
- Install software and start-up according to vendor specifications.
- Create documentation of hardware and software, such as vendor, product number, model number, serial number, and location.

Initial Testing for Calibration and/or Performance Verification

Equipment used for measurement should be tested before initial use to ensure acceptable performance. This is performed through calibration such as the mass of a balance, or through verification of specified performance characteristics such as the sampling precision of a gas chromatograph.

Steps for testing include:

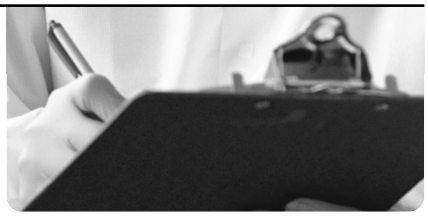
- Develop test procedures and test protocols.
- Define acceptance criteria based on documented specifications.
- Select and order traceable test tools, such as reference weights for calibration of a balance.



- Make sure that test engineers have the appropriate qualifications to perform the tests.
- Perform the tests and document test results.
- Verify that acceptance criteria are met.
- Label the equipment with the status, as well as the dates of last and next calibrations.
- Maintain records of calibration and checks.

These tests can be performed by the vendor or by the user. Advantages of testing by the vendor can be demonstrated using the Agilent Functional Verification Service (FVS) for gas and high-performance liquid chromatography. This service was specifically developed to meet ISO/IEC 17025 requirements:

- Agilent has decades of knowledge and experience with factory and field-testing of equipment. As a result, the test selection and sequence is optimized for the highest speed and lowest instrument downtime, without comprising accuracy or calibration specifications.
- Agilent engineers bring along calibrated test tools that meet traceability requirements.
- Agilent engineers also bring certificates to document qualification.
- Agilent tests are combined with recommended preventive maintenance for all the critical functional components of the equipment.
- Agilent provides global lab-to-lab consistency via standardized and well-recognized maintenance and verification testing protocols.
- Agilent's calibration and test certificates are globally recognized by internal auditors and official assessors.



Testing During Ongoing Use

Equipment characteristics and performance can change over time. Therefore, equipment quality programs should ensure that equipment is routinely tested on an ongoing basis.

The type and frequency of such tests depends on the equipment. For example, on a daily basis, balances can be checked with laboratory reference weights, and chromatographs can be checked using well-defined quality control samples.

In addition to the more frequent tests that only challenge a subset of all specifications, annual repetition of all initial tests is recommended to repeat all the initial tests as described above, for example, for chromatographs, once a year. A balance is also typically calibrated once a year by the vendor with calibrated and traceable standard weights.

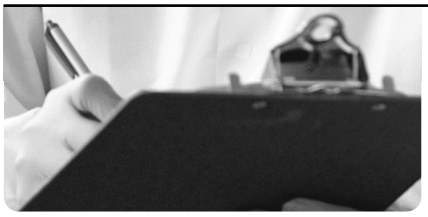
Maintenance and Repair

The laboratory should have a maintenance plan to carry out preventive maintenance activities and a procedure for unplanned repair to ensure ongoing performance and reliability.

- Defective equipment should not be used for tests and calibration. Smaller devices should be taken out of the laboratory and bigger instruments should be clearly labeled as being defective. Specified functioning and performance should be verified after repair.
- Records of maintenance and repairs should be maintained.

Software and Computer Systems

ISO/IEC 17025 requires computer systems and software used for acquisition, processing, recording, reporting, storage and retrieval of test and calibration data be validated when the software is developed, configured, or customized by the user.



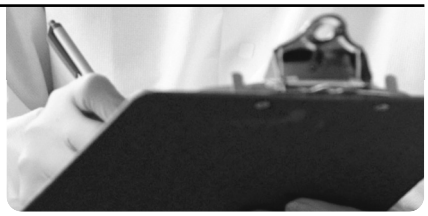
EUROLAB has developed a technical report with recommendations for "Management of Computers and Software in Laboratories with Reference to ISO/IEC 17025:2005" (12). This report provides advice on validation steps for different software and system risk categories, as well as recommendations for how to ensure the security, availability, integrity, and confidentiality of electronic records.

The report divides software into five categories as listed in **Figure 3** and described below::

1. Operating systems
2. Firmware as built into automated equipment
3.. Standard software packages such as word processors and non-configurable computerized analytical systems
4. Configured software packages such as Excel formulas and configurable computerized analytical systems
5. Custom built software

Category	Type	Activities
1	Operating System	Record product & version.
2	Firmware	Qualify as part of equipment hardware. Record version.
3	Standard Software	Only for high-risk systems: Document requirement specifications, document installation, perform acceptance test.
4	Configurable Software	Document requirement specifications, document installation and configuration, test configurations.
5	Custom Built Software	Document requirement specifications, structural test, document installation and configuration, perform acceptance test.

Figure 3: Validation Activities for Software Categories (Simplified)



Measurement Traceability

ISO/IEC 17025 requires reference material used for calibration of measurement equipment to be traceable to SI Units, where possible. Typically, laboratories use their own internal reference material for calibration. Traceability of such material to SI units can be achieved through an unbroken chain of comparisons between laboratory reference material and SI units. An example is shown in **Figure 4**.

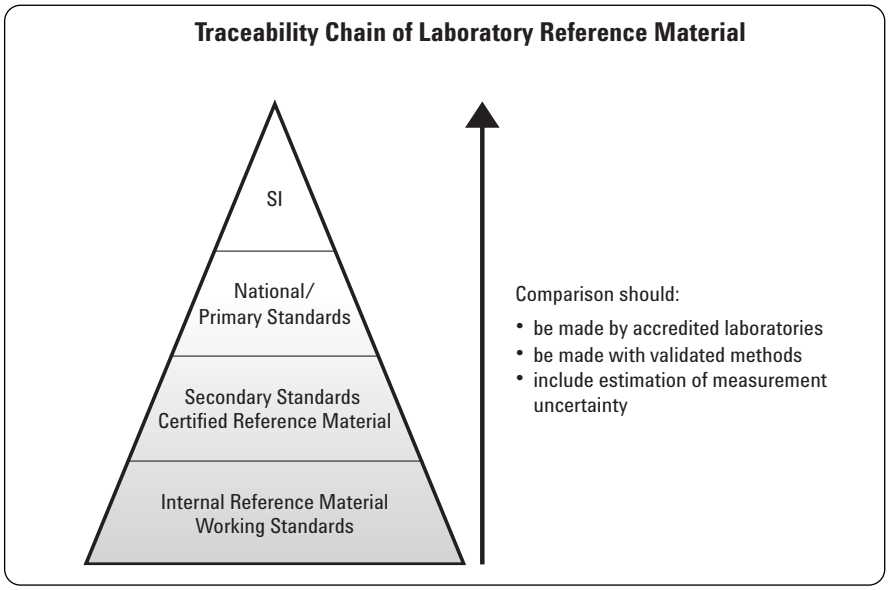
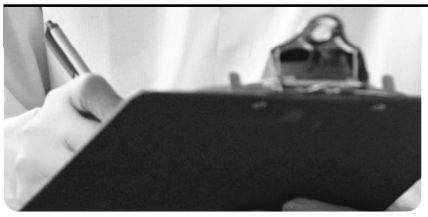


Figure 4: Traceability Chain of Laboratory Reference Material

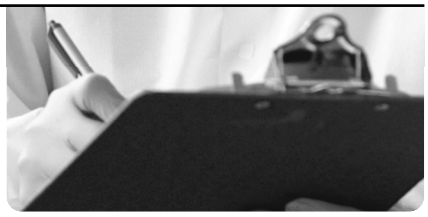


Working standards are regularly compared with secondary standards by an accredited laboratory. These secondary standards are calibrated by a national metrology institute or an accredited reference laboratory. For this kind of comparison, the measurement uncertainty should be known and documented in calibration certificates so that the measurement uncertainty of the working standard can be estimated and reported.

This concept works well for physical measurement such as meter (m) for length, kilogram (kg) for mass, and Kelvin (K) for temperature. For this reason, reference balance masses, thermometers and thermocouples should be traceable to SI Units through an unbroken chain of comparisons performed by accredited laboratories and national metrology institutes.

For most reference material used for chemical measurements, traceability to SI units is very difficult and not practical. The traceability chain in **Figure 4** ends at the lower level, at suppliers of standard reference material (NIST, for example), at suppliers of certified reference material, or at a company's accredited metrology laboratory. When traceability to SI is not possible, ISO/IEC 17025 recommends the use of well-characterized certified reference material that is provided by a competent supplier. Alternative well-defined methods (also called primary or definitive methods) agreed upon by all parties can also be used to establish traceability. This topic has been discussed in different working groups. Detailed recommendations have been published by ILAC (7) and EURACHEM/CITAC (8).

X.R. Pan (17) suggested a classification scheme of reference material used for chemical measurements. The classification as described on the following page is well accepted in chemical laboratories.



Primary Reference Material

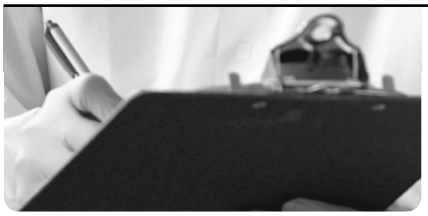
- Also called primary standards.
- Developed by a national metrology laboratory.
- Certified by primary/consensus method.
- Traced back to SI units and/or verified by international comparison.

Certified Reference Material

- Also called secondary standards.
- Derived from primary reference material with statement of uncertainty.
- Usually prepared by a specialized reference laboratory.
- Certified by reference methods or comparison methods.
- Recognized by national or otherwise specialized authoritative organization.

Working Reference Material

- Also called internal reference material.
- Derived from certified reference material.
- Accuracy verified by well-characterized and validated methods.



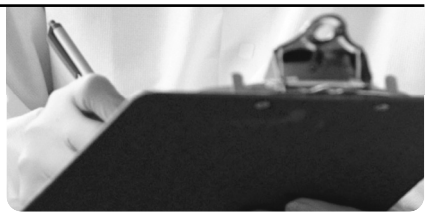
Measurement Uncertainty

There is uncertainty associated with every test and calibration. For testing, this is due to errors arising at the various stages of sampling, sample preparation, measurement, and data evaluation. In other words, whenever any quantitative measurement is performed, the value obtained is only an approximation of the true value. Users of the measurement data should have an idea of how much the reported result may deviate from the true value. ISO/IEC 17025 recommends reporting the results of quantitative measurement both as a single value and with the possible deviation from the true value. This is logical for any report with quantitative results. It is, for example, of no use if a report on a food sample states 0.1 percent of compound X, and the user of the data is still unsure whether this could be 0.05 or 0.4 percent due to the level of uncertainty. An uncertainty statement provides the user with information on the approximate measurement tolerances and the expected limits within which the true value of the measurement, such as analyte concentration, is supposed to lie. Without documenting the uncertainty, although the analyst can estimate the level of uncertainty, the client or user of the data cannot.

Information on uncertainty is of particular importance if a specification limit is to be verified and reported. For example, if a purchasing agreement specifies that a product can only be released if compound X is below 0.5 percent, the test report may not contain a statement about compliance if the measurement results range including the measurement uncertainty is above 0.5 percent.

When parameters are claimed to be within a specified tolerance, the measurement values range, including the estimated uncertainty of measurement, shall fall within the specification limit.

ISO has published a “Guide to the Expression of Uncertainty in Measurement” (10). It establishes general rules for evaluating and expressing uncertainty in measurement across a broad spectrum of measurements.



EURACHEM has produced an excellent document containing great detail about how the concepts of the ISO guide can be applied in chemical measurement (4). The whole process of measurement uncertainty is schematically shown in **Figure 5**. The basic ideas are explained in this primer, but for more detailed information, readers are encouraged to study the EURACHEM document (4).

The concept of evaluating uncertainty is fairly straightforward. It requires a detailed knowledge of the nature of the items being measured and of the measurement method, rather than an in-depth understanding of statistics.

1. Develop the specifications by writing a clear statement of exactly what is to be measured and the relationship between this and the parameters on which it depends. For example, if the measurement temperature has an influence on the result, the measurement temperature should also be defined.
2. Develop a workflow diagram for the entire sample collection, sample preparation, calibration, measurement, data evaluation, and data transcription process (see **Figure 1** for analytical sample testing).
3. Identify and list sources of uncertainty for each part of the process or for each parameter. Possible sources for errors may be derived from non-representative sampling, operator bias, a wrongly calibrated instrument, lack of ideal measurement conditions, chemicals with impurities, and errors in data evaluation.

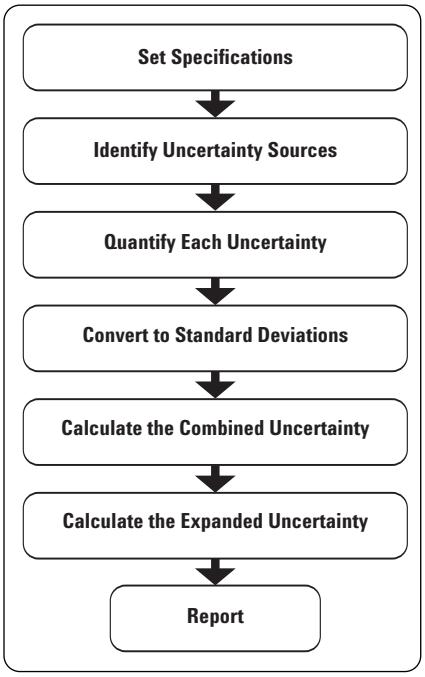
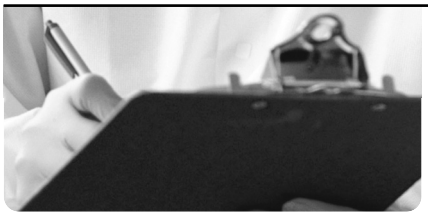


Figure 5: Estimating Measurement Uncertainty



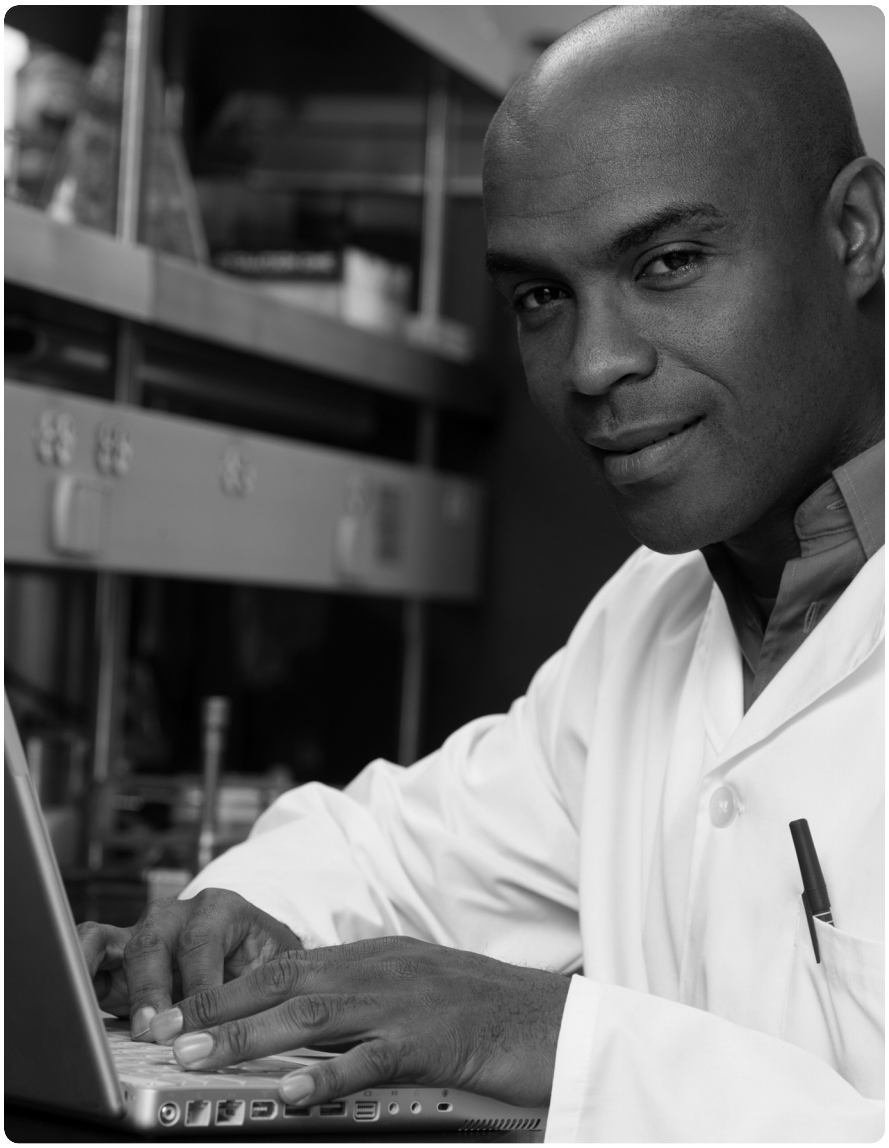
4. Estimate and document the size of each uncertainty, for example, as standard deviations or as RSDs. The data should be gathered from a series of measurements. Where experimental evaluation is impossible or impractical, the individual contributions should be estimated from whatever sources are available. Sources for this kind of estimation can be found in the supplier's information or in the results of inter-laboratory studies or proficiency testing. The procedures and thoughts behind the way the contributions have been measured or estimated should be documented.
5. Combine separate contributions in order to give an overall value. For example, where individual sources of uncertainty are independent, the overall uncertainty can be calculated as a multiple of the sum of squared contributing uncertainty components, all expressed as standard deviations. Computer software or spreadsheet programs can help automate this calculation.

The whole procedure should be documented in such a way that sufficient information is available for the result to be reevaluated if new information or data become available. A complete set of documentation should include:

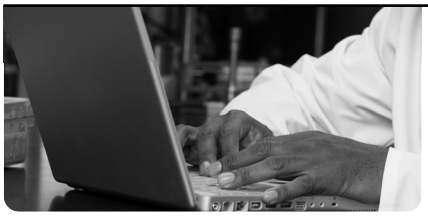
- A description of the methods used to calculate the measurement result and its uncertainty from the experimental measurements
- The values and sources of all corrections
- A list of all components of uncertainty with full documentation about how each of these was evaluated

Reference 4 includes many practical examples with data from different analyses, as well as formulas for evaluating, calculating, and reporting standard and expanded uncertainties. Sample analysis reports should include an uncertainty number, which is typically expressed as:

Result = x ± u (units)
or
Result = x (units)
Uncertainty = u (units)



Steps Toward ISO/IEC 17025 Accreditation



Steps Toward ISO/IEC 17025 Accreditation

ISO/IEC 17025 accreditation should be carefully thought out and properly prepared. It can be quite expensive but can also have big benefits. The balance between costs and benefits should be calculated and documented. Implementing ISO/IEC 17025 will impact the entire laboratory and also supporting services such as human resources, documentation and finance departments. Therefore, while the decision to initiate and fund the project will be made by management, all affected departments should be involved in the process. The entire process is divided into two phases: investigation phase and implementation phase. **Figure 6** illustrates the steps for both phases.

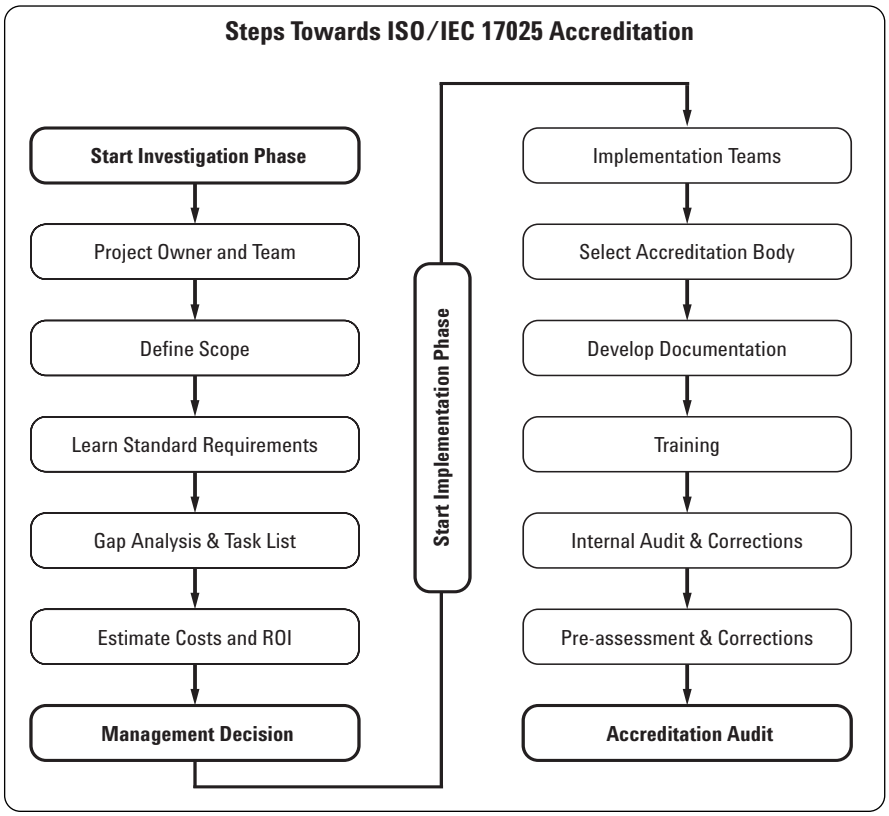
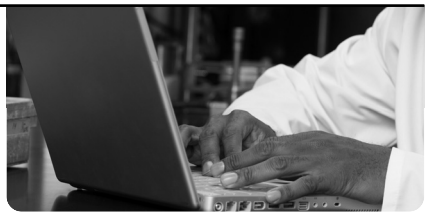


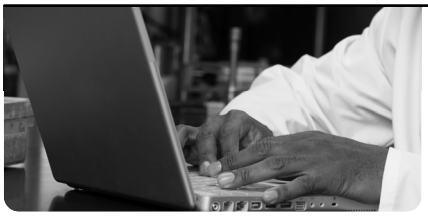
Figure 6 Steps Towards ISO/IEC 17025 Accreditation.



Investigation

In the investigation phase, information is collected to decide if becoming accredited makes good business sense and typically follows these steps:

1. Management initiates, funds, and otherwise supports the investigation.
2. Management nominates a project owner. Ideally the person should have experience in laboratory operations, good business sense, an understanding of quality systems and excellent communication skills.
3. The project manager with support from management recruits a project team. Members should come from laboratory management, QA, finance, human resources, training, and documentation groups.
4. The project team defines the scope of the intended accreditation. This could include all calibrations and/or tests performed in a lab, or just part of them.
5. The project team studies the accreditation requirements in detail. The main source is the standard ISO/IEC 17025, with additional support from official guidelines, other literature, and external expert advice.
6. The project team develops a requirements list. The list should include all documents as required by the standard, for example, policies, a quality plan, and procedures for most of the requirements.
7. The project team prepares a gap analysis by comparing ISO requirements as listed above with what is already available and implemented. A gap exists where existing policies, processes or procedures do not fully meet the stated requirements. This analysis should include all processes and procedures for management controls and technical controls, such as for sampling, method validation, equipment calibration, qualification and maintenance, employee qualifications, and others.
8. Using the outcome of the gap analysis, the project team develops a task list. The list is completed with additional tasks such as selecting and dealing with an accreditation body.
9. The project team, together with the help of an external consultant, makes an estimation of the overall ISO/IEC implementation costs, which should include costs for initial set-up and also for maintaining the quality system. The costs are compared with the direct and tangible estimated additional returns that come from getting accreditation status. Tangible returns are, for example, savings through more efficient operation.
10. The team makes a rough estimation of the return on investment for both the short and long term views, and makes a recommendation to management.
11. Management decides to accept or reject the proposal and whether to proceed with accreditation.



Implementation

Once the decision for ISO/IEC 17025 accreditation is made, the laboratory develops and implements documentation in preparation for the accreditation assessment. Typically implementation follows these steps:

1. The project owner forms implementation teams for different areas. It is critical that all affected departments at all management levels are represented in the teams.
2. The project owner with the help of QA searches for an accreditation body and selects the one that best fits the laboratory's needs. There are several ways to find accreditation bodies. Probably the best way is to ask other accredited laboratories about their experiences.
3. The teams develop documentation such as procedures under the supervision of the project owner.
4. The project owner arranges for staff training.
5. Quality assurance performs an internal audit and initiates corrective actions, if necessary.
6. The selected accreditation company performs a pre-assessment.
7. The project owner initiates corrective actions.
8. The accreditation company performs an accreditation audit.

Documentation

Documentation

ISO/IEC 17025 requires different types of documentation, as illustrated in the documentation pyramid in **Figure 7**.

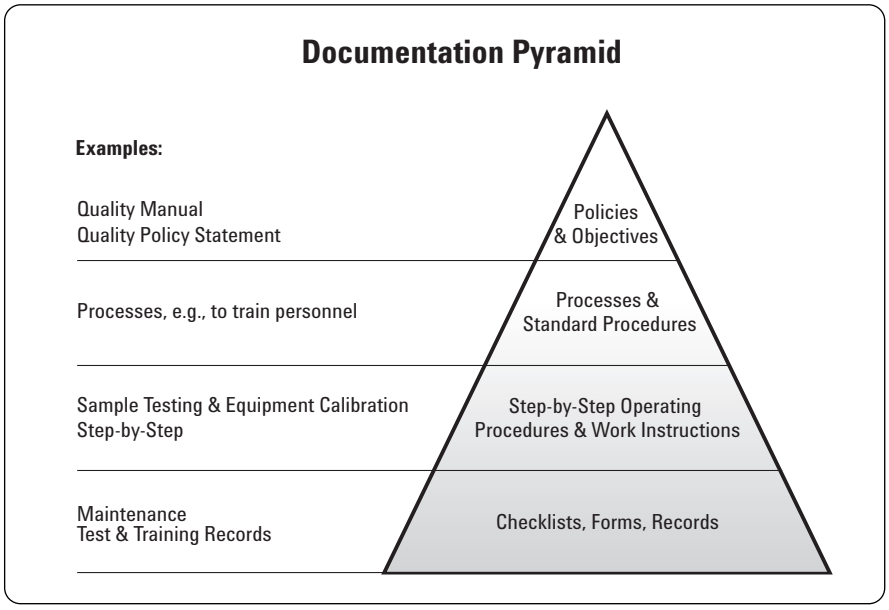


Figure 7: Documentation Pyramid

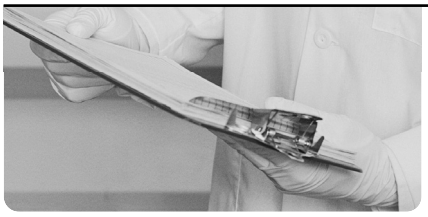
A policy documents the laboratory's intent to implement ISO/IEC 17025. The Quality Manual is the top tier of the document hierarchy. It describes the approaches to achieve quality data. It also includes policy statements describing the laboratory's intention to conform to ISO/IEC 17025 requirements. For example, a policy statement could be: *All personnel involved in calibration and testing should be competent for the assigned task.*

A process or generic procedure describes how various quality requirements can be achieved. For example, it describes how the requirement *'Personnel should be competent for the assigned task'* can be implemented.

Standard operating procedures (SOPs) or Working Procedures are step-by-step instructions for how to exactly perform a specific task, such as calibrating a specific instrument.

Records are generated on a day-by-day basis, such as analytical results from product tests or calibration records of a balance.

All documents should be properly controlled. For example, each change should be authorized and logged, and the updated document should get a new revision number or code.



Policies and Quality Manual

Policies including the quality policy statement should be documented in the Quality Manual. Senior management should write the quality policy statement, which should outline the laboratory's commitment to quality. The quality manual describes the quality system and documents the laboratory's goal and overall concept for how to conform to ISO/IEC 17025. It should also describe how the remainder of the quality system documentation is organized. It should be developed by working groups representing different departments.

Processes

Processes or standard procedures describe how various ISO/IEC 17025 requirements can be achieved. For example, it describes how the requirement *'All personnel involved in calibration and testing should be competent for the assigned task'* can be implemented. Another example is the laboratory's approach to calibrating and checking different types of equipment. For a better understanding, process flowcharts should be included in a process description.

Standard Operating Procedures (SOPs) and Work Instructions

Routine activities follow documented procedures. These are typically defined as standard operating procedures (SOPs) or work instructions. While quality manuals and processes describe tasks and approaches, procedures and work instructions give step-by-step instructions on performing tasks. Examples of SOPs are procedures for checking and calibration of equipment. All laboratory SOPs should use the same format, to make writing and reading easier. A good practice is to have an SOP for how to author, review, approve, distribute, and update SOPs. Preferably senior members of anticipated user groups should write SOPs. This helps ensure that SOPs have the right level of information and are used and followed.

Records

Records to demonstrate conformity with ISO/IEC 17025 and as required by customers should be retained for a specific amount of time. Examples are original laboratory observations, test results, supporting documents such as chromatograms, and training certificates and equipment calibration protocols.

Checklists, forms, templates, and examples help implement quality work effectively and consistently. Examples of these include checklists and worksheets for vendor assessment, handling nonconforming test results, and for internal audits. These items help document specific tasks consistently and effectively.

Document Control

Development and maintenance of documentation should be controlled through document control and management procedures that are part of the management system. Documents include both internal, such as SOPs, quality manuals, and training plans and external documents, such as regulations, standards, test methods, and instrument operating manuals.

The procedure for document control should ensure that:

- Official documents are created or acquired, reviewed, and approved prior to use.
- Documents are uniquely identified with document and revision number, date of revision, and issuing authority.
- A quality list with all controlled documents is maintained by QA. The list includes document and revision number, title, date of issue, date of last review, and locations.
- Internal documents include page numbers and total number of pages on each page.
- Users of the documents are adequately trained before the documents are released.
- Current authorized versions of documents are readily available at the user's workspace.

- Documents are reviewed according to a schedule, and revised to ensure suitability and ongoing conformance with regulations and internal procedures.
- Invalid and obsolete documents are promptly removed from all points of issue or use, or marked as uncontrolled to ensure that only current authorized versions of appropriate documents are available for active use at relevant locations.
- Obsolete documents, retained for either legal or knowledge preservation, are marked as 'Archived,' dated, and signed. The retention period for the documents conforms to internal procedures.
- Changes to a document are reviewed, approved, and communicated to users.
- The changes are recorded in a document change log. The log information indicates the reason and the nature of the change.
- When documents are created, signed, and maintained in electronic form, the computer system and records comply with national or international regulations and guidelines for electronic or digital signatures.

Internal and External Audits

Internal and External Audits

Quality managers manage internal audits. They verify conformance to the ISO/IEC 17025 requirements and also to company policies, processes and procedures. Internal audits are also quite useful in preparation for external audits. External auditors can come from clients or from accreditation bodies. They verify that the laboratory is operating in compliance with ISO/IEC 17025.

There should be procedures for staff responsibilities before, during, and after internal and external audits. Overall owners should be defined, and all employees who may be affected by the audit should be trained. This chapter summarizes recommendations for audits. To make best use of internal audits, they should be designed, executed, and followed up very much in the same way as expected external audits. The recommendations for audit preparation, performance, documentation, and follow-up are written for the audited departments, not for the auditors.

Internal Audit Schedule

Internal auditing should follow a predetermined schedule covering all activities over a reasonable period of time. It is inconvenient to audit all activities in a single audit, so it should be spread over several quarterly or monthly audits. The schedule for such audits is conveniently drawn as a matrix covering, for example, a year in which dates are set for each part of the quality system. Audit schedules can be organized as horizontal or vertical. A vertical audit checks compliance of, for example, a single test through all steps from sampling to archiving of records. A horizontal audit examines every aspect of a single requirement, for example, equipment. **Figure 8** shows an example of a horizontal audit.

Audit Item	Q1	Q2	Q3	Q4
Organization	X			
Documentation		X		
Personnel			X	
Sampling				X
Equipment		X		
Methods			X	
----------				X
Many others	X			

Figure 8: Example for Horizontal Audit Schedule

Audit Phases

Internal audit activities are spread over different phases which included preparation, conduct, close and follow-up. Typical steps for each phase are listed below:

Preparation

- Assign an overall owner and host for the audit.
- Assign a technical contact to get access to and review the completeness of records and other documentation for items to be audited. The assigned technical contact should be present all the time.
- Set up a work area for the inspectors.
- Review the schedule.
- Prepare and train staff.
- An audit may be a tough experience for all people involved, so everyone needs to be informed about what will happen and what questions may be asked.

Conduct

- Maintain a continuous log of the audit.
- Provide copies (do not give originals away).
- Keep duplicates of all information supplied to auditors.
- Take immediate corrective action, when appropriate.
- Hold a daily debriefing meeting to assess the progress.
- Keep all documents in the work area.
- Accompany the auditor at all times.
- Be courteous and cooperative.
- Answer only questions that are asked.
- If you are unable to answer, tell the auditor openly.
- Protect proprietary information.

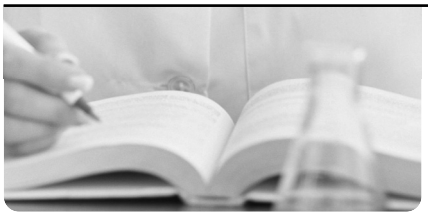
Close

- Clarify any open questions or causes for dissatisfaction in the exit meeting.

Follow-up

- Develop a corrective action plan (owners, tasks, deliverables, and schedule).
- Develop a preventive action plan (owners, tasks, deliverables, and schedule).
- Monitor the plan.

Dealing with Multiple Regulations and Quality Standards

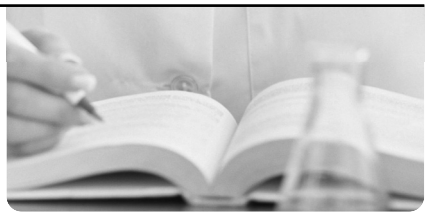


Dealing with Multiple Regulations and Quality Standards

Laboratories are frequently faced with situations where they have to comply with both regulations and quality standards at the same time.

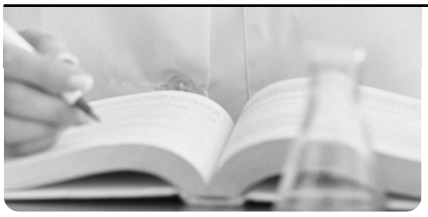
Examples are:

- A clinical laboratory performs contract analyses from pre-clinical and clinical studies for pharmaceutical companies. The laboratory also performs special tests for hospitals. The laboratory has to operate in compliance with U.S. FDA and EU GLP and GCP regulations for clinical and pre-clinical study tests. Some customers also require laboratory accreditation according to ISO/IEC 17025, others according to ISO 15189, a standard for medical laboratories.
- A chemical company is certified for ISO 9001. The scope of the certification also covers the analytical service laboratory. In addition, the laboratory performs contract analyses for other companies and has received laboratory accreditation in compliance with ISO/IEC 17025. The laboratory has to work in compliance with ISO 9001 and with ISO/IEC 17025.
- An independent test laboratory performs GLP studies as a subcontractor for a pharmaceutical company. Occasionally, the laboratory also performs analyses for pharmaceutical manufacturing control departments. The laboratory has also received laboratory accreditation for specific food analyses according to ISO/IEC 17025. The laboratory has to comply with ISO/IEC 17025 and with GLP and cGMP regulations.



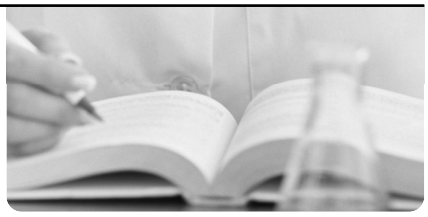
International companies frequently face this kind of problem. Their laboratories have to comply with regulations from different countries simultaneously with quality and accreditation standards. The solution to this problem is to combine all regulations and quality standards in a single quality manual and a single set of operating procedures. The recommended documents and how they relate to each other are shown in **Figure 7**.

The quality manual should place the company's own quality system first and foremost. This may be based on a well-known laboratory quality standard, such as ISO/IEC 17025. The quality manual and operating procedures should include aspects of various regulations and quality standards applied within the company. For specific requirements of single regulations, the quality manual and procedures should include sections that only apply to those particular regulations. For example, the 'responsibility' section would mention that for GLP studies, the function of a study director is required. The tasks and responsibilities should be described in an SOP.



References

1. ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories, 2005.
2. LabCompliance, ISO/IEC 17025 Accreditation Package, 2009. http://www.labcompliance.com/books/iso17025
3. EURACHEM/CITAC Guide, Use of Uncertainty Information in Compliance Assessment, 2007.
4. EURACHEM/CITAC Guide CG4, Quantifying Uncertainty in Analytical Measurement, ISBN 0-948926-15-5, 2000.
5. EUROLAB, Measurement Uncertainty Revisited: Alternative Approaches to Uncertainty Evaluation, 2007.
6. ILAC, Introducing the Concept of Uncertainty in Association with the Application of the Standard ISO/IEC 17025, 2002.
7. ILAC Policy on Traceability of Measurement Results, 2002.
8. EURACHEM/CITAC Guide, Traceability in Chemical Measurement: A Guide to Achieving Comparable Results in Chemical Measurement, 2003.
9. EUROLAB, Guide to the Evaluation of Measurement Uncertainty for Quantitative Test Results, 2006.
10. ISO Guide 98-3, Uncertainty of measurement – Part 3: Guide to the Expression of Uncertainty in Measurement (GUM:1995), Geneve, Switzerland, 2008.
11. P. Bedson and M. Sargent, The Development and Application of Guidance on Equipment Qualification of Analytical Instruments, Accreditation and Quality Assurance, 1 (6), 265-274 (1996).
12. EUROLAB Technical Report 2/2006, Management of Computers and Software in Laboratories with Reference to ISO/IEC 17025:2005.
13. L. Huber, Validation and Qualification in Analytical Laboratories, Interpharm, Informa Healthcare, New York, USA, 1998. Second revision 2007.
14. M. Thompson, S. Ellison and R. Wood, International Harmonized Protocol for Proficiency Testing of Chemical Analytical Laboratories, Pure Appl. Chem., Vol. 78, No. 1, pp. 145-196, 2006, www.iupac.org/publications/pac/2006/pdf/7801x0145.pdf.
15. American Association for Laboratory Accreditation, A2LA Policy on Measurement Traceability, 2005.
16. ISO/IEC Guide 2, Standardization and Related Activities: General Vocabulary, 2005.
17. X. R. Pan, Hierarchy of Reference Materials Certified for Chemical Composition, Metrologia 34 (1997) 35-39.



Glossary

A2LA	American Association for Laboratory Accreditation
Accreditation	Procedure by which an authoritative body gives formal recognition that a person or body is competent to carry out a specific task (16).
CITAC	Cooperation on International Traceability in Analytical Chemistry. A forum for worldwide cooperation collaboration on the mechanisms needed to ensure the validity and comparability of analytical data on a global basis.
CRM	Certified Reference Material
EURACHEM	Provides a focus for analytical chemistry and quality related issues. Develops useful guidance documents for analytical chemists in the area of laboratory accreditation.
IEC	International Electrotechnical Commission. An international standards organization dealing with electrical, electronic, and related technologies.
ILAC	International Laboratory Accreditation Cooperation. An international cooperation of laboratory and inspection accreditation bodies.
ISO	International Organization for Standardization
NIST	National Institute of Standards and Technology (in the United States)
QA	Quality Assurance
SI	System International
SOP	Standard Operating Procedure
SRM	Standard Reference Material

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