[Organization logo]

[Organization name]

Commented [170251]: All fields in this document marked by square brackets [ ] must be filled in.

QUALITY MANUAL

Commented [170252]: If you want to find out more about the role of the Quality Manual in the new version of the standard, see:

The future of the Quality Manual in ISO 9001:2015
http://advisera.com/9001academy/knowledgebase/the-future-of-the-quality-manual-in-iso-90012015/

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [170253]: All fields in this document marked by square brackets [ ] must be filled in.

Distribution List for Paper-based Documents

Commented [17A4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy No.	Distributed to	Date	Signature	Returned	
				Date	Signature

Change History

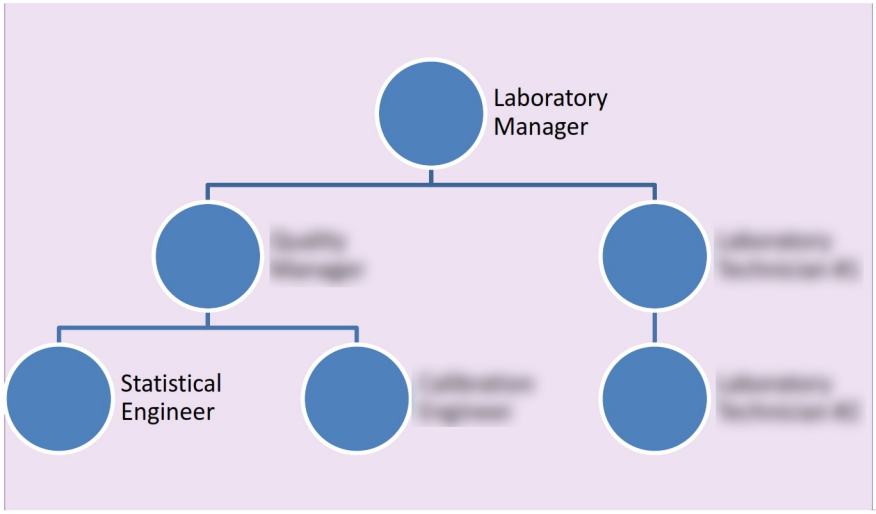
Date	Version	Created by	Description of change
	0.1	17025Academy	Basic document outline

Table of Contents

1. About the Organization

Commented [170255]: Talk about the laboratory's history, location, management and capabilities in this section.

1.1. Organizational structure



Commented [170256]: Adapt to your organization's setup.

The organogram should present the structure of the laboratory (organization and management), as well as the line of communication to top management / board of directors of any parent organization.

The organogram above represents the organizational and management structure of [organization name].

[Organization name] is a legal entity located at [address] with registration number [number]. The

Commented [17A7]: Please include organization's address.

Commented [17A8]: Please enter organization's registration number.

Commented [17A9]: You can delete this sentence if the laboratory is not a part of any other parent organization.

2. Purpose, Scope and Users

Commented [1702510]: Adapt this statement to your organization.

This Quality Manual, based on ISO/IEC 17025:2017, is used to document the Quality Management

for each of the clauses of ISO/IEC 17025:2017 and, where applicable, references the Quality System procedures related to each clause.

3. Terms and Definitions

Commented [1702511]: You may add any unusual terms you may find useful to the reader of this document.

For the purpose of this Quality manual, all terms and definitions in ISO/IEC 17000 and JCGM 200:2012 apply. ISO and IEC maintain terminological databases for use in standardization.

4. General Requirements

4.1. Impartiality

[Organization name] is totally committed to safeguarding impartiality in all aspects of laboratory activities.

The laboratory management is structured to safeguard impartiality and to prevent commercial, financial, and other pressures from compromising the impartiality of laboratory activities. Also, the laboratory management at all levels must identify the risks to impartiality on an ongoing basis and take action to prevent it.

[Job title] ensures that laboratory personnel are free from pressures both internal and external that may compromise the results of their work. Pressures that may come from management, customers, sales or other parties that may be interested in a laboratory results. When risks to the laboratory's impartiality are identified, [job title] must immediately take steps to minimize that risk. See Addressing Risks and Opportunities Procedure.

Commented [1702512]: E.g. Quality Manager

Commented [17A13]: You will find this procedure in the ISO 17025 Toolkit folder "05_Addressing_Risks_and_Opportunities".

4.2. Confidentiality

Laboratory personnel as well as members of management, contractors, personnel of external bodies or other parties, must keep confidential all information obtained or created during laboratory activities, except as required by law. [Job title] and all laboratory personnel ensure protection of its customer's (internal or external) confidential information and proprietary rights, including electronic storage and transmissions.

The laboratory is responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities. When the laboratory is required by law or authorized contractual arrangements to release confidential information, the customer or individual concerned must, unless prohibited by law, be notified of the information provided.

Information about a customer obtained from sources other than the customer, must be confidential between [Organization name] and the customer. The source of this information must be confidential and not shared with the customer, unless agreed by the source. Except for information that the customer makes publicly available in the news media, all other information is considered proprietary information and must be regarded as confidential. [Organization name] informs the customer according to each procedure in writing, and in advance if it intends to place customer information in the public domain. When the laboratory services are required by law to release confidential information, the customer or other interested party must, unless prohibited by law, be notified of the information provided in writing.

Personnel, including committee members, contractors, personnel of external bodies or individuals acting on the laboratory's behalf, must keep confidential all information obtained or created during the performance of laboratory activities, except as required by law.

5. Structural Requirements

[Organization's name] must ensure that its laboratory activities are carried out in such a way as to meet the requirements of the international standard, all its customers, regulatory authorities and other organizations providing recognition. The laboratory must define the range of laboratory activities for which it conforms to ISO 17025:2017 and shall not claim conformity for activities that are provided by external suppliers on an ongoing basis.

[Organization name] is responsible for activities performed in its permanent facility, at sites away from its facility, mobile facilities and at a customer's facility.

The laboratory identifies management that has overall responsibility for the laboratory, as well as responsible persons of the laboratory, who have overall and partial responsibility for the implementation of procedures in a laboratory.

[Organization name] must ensure that its laboratory is staffed with personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a. The implementation, maintenance and improvement of the management system.
b. Identification of deviations from the management system or from the procedures for performing laboratory activities.
c. The initiation of actions to prevent or minimize such deviations.
d. Reporting to management on the performance of the management system and any need for improvement.
e. Ensuring the required effectiveness of laboratory activities as documented in the laboratory's policies and procedures.

Laboratory management of [Organization name] ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented and that communication regarding the importance of meeting customer and other requirements, as well as the effectiveness of the management system, takes place among the persons responsible for the laboratory.

[Organization name] must ensure that there is sufficient documentation (procedures and records) to address laboratory activities where specific documentation was required by the international standard and where the loss of such documentation would negatively affect laboratory activities.

[Organization name] always takes into consideration the needs and expectations of its interested parties (customers, employees and external suppliers).

6. Resource Requirements

Commented [1702514]: Keep in mind: does your laboratory do tests, calibrations or both? Start adjusting the terminology to match your organization.

6.1. General

[Organization name] must have available, in the laboratory, personnel, facilities, equipment, systems and support services necessary to perform its laboratory activities.

6.2. Personnel

[Organization name] must have available the personnel, facilities, equipment, systems and support services necessary to perform its laboratory activities. Laboratory personnel, either internal or external, must be competent and work in accordance with the laboratory's quality management system and perform their duties with impartiality and confidentiality.

The laboratory ensures that laboratory personnel have the competence to perform laboratory activities for which they are responsible and that they understand the significance of deviations found in laboratory activities.

The laboratory documents the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience. See Competence, Training and Awareness Procedure.

Commented [17A15]: You will find this procedure in the ISO 17025 Toolkit folder "04_Competence_Training_and_Awareness".

6.3. Facilities and environmental conditions

[Organization's name] must ensure that:

- Facilities and environmental conditions are suitable for the laboratory activities and do not adversely affect the validity of results.
- Measures to control facilities are implemented, monitored and periodically reviewed.
- Internal environmental conditions are constant and adequate.

The requirements related to facilities and environmental conditions of the international standard are also ensured when the laboratory performs activities at facilities outside its permanent control. See Facilities and Environmental Conditions Procedure.

Commented [17A16]: You will find this procedure in the ISO 17025 Toolkit folder "07_Facilities_and_Environmental_Conditions".

6.4. Equipment

[Organization's name] must ensure that the laboratory has access to equipment required for the correct performance of the laboratory activities, with special attention to equipment as measuring instruments, calibration equipment, software, etc. which can influence on the accuracy of test results. See Equipment and Calibration Procedure.

Commented [17A17]: You will find this procedure in the ISO 17025 Toolkit folder "08_Equipment_and_Calibration".

6.5. Metrological traceability

[Organization's name] must establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations of all measurement equipment that contribute to the overall measurement uncertainty. [Organization's name] also ensures that measurement results are traceable to the International System of Units (SI). See Equipment and Calibration Procedure.

6.6. Externally provided products and services

[Organization's name] must assure the suitability of externally provided products and services that affect laboratory activities. With that purpose, the laboratory maintains procedures and records regarding external suppliers.

[Organization's name] must take actions which arise from initial evaluations, monitoring and re-evaluations of the external providers.

The laboratory communicates its requirements to external providers. See Externally Provided Products and Services Procedure.

Commented [17A18]: You will find this procedure in the ISO 17025 Toolkit folder "06_Externally_Provided_Products_and_Services".

7. Process Requirements

Commented [1702519]: Keep in mind, does your laboratory do tests, calibrations or both. Start adjusting the terminology to match your organization.

7.1. Review of requests, tenders and contracts

[Organization's name] must review all requests, tenders and contracts.

When necessary, [Organization's name] informs the customer whether the method requested by the customer is inappropriate or out of date. The customer must always be informed of any deviations from the specifications of a contract in writing.

[Organization's name] can publish a tender as an offer to buy or purchase products or services. See Customer Service Procedure.

Commented [17A20]: You will find this procedure in the ISO 17025 Toolkit folder "09_Customer_Service".

7.2. Selection, verification and validation of methods

[Organization's name] must use appropriate methods and procedures for all laboratory activities and, where appropriate, for the evaluation of the measurement uncertainty as well as statistical techniques for analysis of data. All methods, procedures and supporting documentation must be kept up to date and must be made readily available to laboratory personnel by [add title].

Commented [1702521]: Laboratory or Quality manager.

When the customer does not specify the method to be used, [Organization's name] selects an appropriate method and informs the customer of the method chosen. The laboratory must verify that a method can be properly performed before introducing it.

When method development is required, it must be a planned activity and must be assigned to qualified personnel equipped with adequate resources. The laboratory validates all non-standard methods, laboratory-developed methods and standard methods used outside their intended scope. See Test and Calibration Methods Procedure.

Commented [17A22]: You will find this procedure in the ISO 17025 Toolkit folder "10_Test_and_Calibration_Method".

7.3. Sampling

Commented [1702523]: Omit this section is an exclusion or change the wording to reflect possible future application.

[Organization's name] must address all factors to be controlled to ensure the validity of subsequent testing or calibration if sampling was performed.

The laboratory must develop a sampling plan and procedure and retain records for sampling when it carries out sampling of substances, materials, or products for subsequent testing or calibration. See Sampling Procedure.

Commented [17A24]: You will find this procedure in the ISO 17025 Toolkit folder "12_Sampling".

7.4. Handling of test and calibration items

[Organization's name] must have a procedure for the transportation, receipt, handling, protection, storage, retention and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item and to protect the interests of the laboratory and customer.

Handling instructions, when provided, must be followed.

All test or calibration items in the laboratory must have a system for uniquely identifying them. The identification is retained while the item is under the responsibility of the laboratory.

When items must be stored, or conditioned under specific environmental factors, these conditions must be maintained, monitored and recorded. See Handling of Items Received for Testing Procedure.

Commented [1702525]: Omit the word test or calibration if they do not apply.

Commented [17A26]: You will find this document in the ISO 17025 Toolkit folder "13_Handling_of_Items_Received_for_Testing".

7.5. Technical records

[Organization's name] must ensure that technical records for each laboratory activity contain the report of results, and sufficient information to facilitate the identification of factors affecting the measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records must include the date and identity of personnel responsible for each laboratory activity.

The laboratory ensures that amendments to technical records can be traced back to either previous versions or original observations. The laboratory should retain both versions of the technical record (amended and original) with details of the person responsible for the amendments, the date, and what changes were made. See Document and Record Control Procedure, Testing Report Procedure, and Calibration Report and Certificate Requirements Procedure.

Commented [17A27]: You will find this procedure in the ISO 17025 Toolkit folder "00_Document_and_Record_Control".

Commented [17A28]: You will find this procedure in the ISO 17025 Toolkit folder "16_Testing_Report".

Commented [17A29]: You will find this procedure in the ISO 17025 Toolkit folder "17_Calibration_Report_and_Certificate_Requirements".

7.6. Evaluation of measurement uncertainty

When performing calibrations, including on the laboratory's own equipment, the laboratory must evaluate the measurement uncertainty for all its calibrations.

When performing sampling or testing, the laboratory must evaluate measurement uncertainty.

When evaluating measurement uncertainty, all components which are of significance in the given situation must be identified and considered, using appropriate methods of analysis. See Evaluation of Measurement Uncertainty Procedure.

Commented [17A30]: You will find this procedure in the ISO 17025 Toolkit folder "15_Evaluation_of_Measurement_Uncertainty".

7.7. Ensuring the validity of results

[Organization's name] must have a procedure for regularly monitoring the validity of laboratory activities undertaken and the quality of the laboratory output. This monitoring must be planned and reviewed and include where appropriate all the recommendations in the international standard.

The laboratory monitors the quality of the laboratory performance by comparing with output of other laboratories, where available and appropriate, through participation in proficiency testing. See Quality Assurance Procedure.

Commented [17A31]: You will find this procedure in the ISO 17025 Toolkit folder "11_Quality_Assurance".

7.8. Reporting the test or Calibration Results

[Organization's name] must provide results accurately, clearly, unambiguously and objectively in a report or calibration certificate and must include all the information agreed with the customer and necessary for the interpretation of the results and required by the method used. All issued records are maintained as technical records.

Test and calibration reports and certificates must meet the content requirements of the international standard and the requirements for additional information on test reports and on calibration reports and certificates must be included.

When [Organization's name] provides a statement of conformity to a specification or standard for test or calibration, the laboratory must document the decision rule employed, considering the level of risk associated with the decision rule employed and apply the decision rule.

All opinions and interpretations expressed in test reports or calibration certificates should be based on the results obtained from the tested or calibrated item and must be clearly marked as such.

When an issued report needs to be changed, amended or re-issued, any change of information must be clearly identified. If it is necessary to issue a completely new report, it must be uniquely identified and contain a reference to the original that it replaces. See Testing Report Procedure, and Calibration Report and Certificate Requirements Procedure.

7.9. Complaints

Upon receipt of a complaint [organization's name] must confirm whether the complaint relates to laboratory activities or other activities such as customer service. If the complaint relates to the laboratory, it must be responsible for all levels of the handling process for complaints.

Whenever possible, the laboratory must acknowledge receipt of the complaint and provide the complainant with progress reports. The outcomes must be communicated to the complainant and whenever possible, notice of the end of the complaint handling process. See Customer Service Procedure and Complaint, Nonconformity and Corrective Action Procedure.

7.10. Nonconforming work

The laboratory of [organization name] must implement its nonconformity procedure when any aspect of its laboratory activities or results of its work do not conform to its own procedures or the agreed requirements of the customer.

Where evaluation indicates that nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the laboratory must implement corrective actions. See Complaint, Nonconformity and Corrective Action Procedure.

7.11. Control of data and information management

Laboratory personnel of [organization name] must have access to the data and information needed to provide laboratory activities.

Commented [1702532]: Omit the word test or calibration if they do not apply.

Commented [17A33]: You will find this procedure in the ISO 17025 Toolkit folder "09_Customer_Service".

Commented [17A34]: You will find this procedure in the ISO 17025 Toolkit folder "14_Complaint_Nonconformity_and_Corrective_Action".

Laboratory information management systems must be validated for functionality and for interfaces [illegible] ensures integrity of the data and information. See Quality Assurance Procedure

Documented information of the Quality Management System is carried out through the following documents:

- Quality Policy
- [illegible]
- [illegible]
- [illegible]
- [illegible]
- Documents from external providers, customers, off-site locations, etc. are given in the List of External Documents

When the laboratory information management system is managed and maintained off-site, the laboratory must ensure that the provider complies with all applicable requirements of the [illegible]

[illegible]

8. Management Requirements

8.1. [Organization name] complies with [Option A or Option B]

Laboratory management of [organization name] must establish, document, implement and maintain [illegible]

8.2. Management system documentation

Laboratory management of [organization name] must establish, document and maintain policies and objectives for the fulfillment of the international standard and ensure those policies and objectives [illegible]

[illegible]

records related to the fulfillment of the international standard must be included, referenced, or

Commented [17A35]: You will find this document in the ISO 17025 Toolkit folder "11_Quality_Assurance".

Commented [17A36]: You will find this document in the ISO 17025 Toolkit folder "02_Quality_Policy_and_Quality_Objectives".

Commented [17A37]: You will find this document in the ISO 17025 Toolkit folder "00_Document_and_Record_Control".

Commented [17A38]: You will find this document in the ISO 17025 Toolkit folder "00_Document_and_Record_Control".

Commented [1702539]: Insert the Option A or Option B for your laboratory:

[illegible]

-The laboratory must separately provide satisfactory evidence of compliance with clauses 4 to 7 of the ISO/IEC 17025 standard.

Commented [1702540]: Needs to be addressed by Option A Laboratories.

linked to the management system. This is achieved through this Quality Manual and / or Document and Record Control Procedure.

All laboratory personnel must have access to the parts of the management system documentation related to their responsibilities. See Document and Record Control Procedure.

8.3. Control of management system documentation

Commented [1702541]: Needs to be addressed by Option A Laboratories.

Laboratory management of [organization name] must control all documents, internal and external, that relate to the international standard.

The laboratory ensures all documents are approved prior to issue, are periodically reviewed and updated and that changes and current revision status are identified.

Documents are available at the points of use and distribution is controlled.

All documents are uniquely identified, the unintended use of obsolete documents is prevented, and suitable identification is applied to them. See Document and Record Control Procedure.

8.4. Control of records

Commented [1702542]: Needs to be addressed by Option A Laboratories.

Laboratory management of [organization name] must:

- Establish and maintain legible records and show fulfillment of the requirements of the international standard.
- Implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention times and disposal of its records.
- Retain records for a period consistent with its contracts and legal obligations.

Access to records will be consistent with the confidentiality arrangements and records will be readily available. See Document and Records Control Procedure.

8.5. Actions to address risks and opportunities

Commented [1702543]: Needs to be addressed by Option A Laboratories.

Laboratory management of [organization name] must:

- Consider the risks and opportunities associated with laboratory activities.
- Plan actions to address those risks and opportunities and how to integrate and implement them into the management system.
- Evaluate the effectiveness of those actions.

Any actions taken to address risks and opportunities will be proportionate to the potential impact on the validity of laboratory results. See Addressing Risks and Opportunities Procedure.

Commented [17A44]: You will find this document in the ISO 17025 Toolkit folder "05_Addressing_Risks_and_Opportunities".

8.6. Improvement

Commented [1702545]: Needs to be addressed by Option A Laboratories.

Laboratory management of [organization name] must identify and select opportunities for improvement and implement any necessary actions.

Opportunities for improvement can come from the review of procedures, the use of policies and objectives, audit results, corrective actions, management review, risk assessment, data analysis or proficiency testing results.

Laboratory management must seek feedback, both positive and negative from its customers analyze all feedback and use them to improve the management system, laboratory activities and customer service. See Customer Service Procedure, and Complaint, Nonconformity and Corrective Action Procedure.

8.7. Corrective action

When nonconformity occurs, the laboratory of [organization name] must react to the nonconformity and start to control and correct it while also dealing with the consequences.

The laboratory must evaluate the need for action and eliminate the cause(s) in order that it does not recur or occur elsewhere. Then, the laboratory must implement any actions needed to correct the nonconformity.

All corrective actions must be appropriate to the effects of the nonconformity. See Complaint, Nonconformity and Corrective Action Procedure.

8.8. Internal audits

Laboratory management of [organization name] must plan, establish, implement and maintain an audit program.

The laboratory conducts internal audits at planned intervals to provide information on whether the management system conforms to the laboratory's requirements for its management system, including the laboratory activities and requirements of the international standard. See Internal Audit Procedure.

8.9. Management reviews

Laboratory management of [organization name] must review its management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness.

All inputs of the management reviews are recorded as well as decisions and actions related to the outputs. See Management Review Procedure.

Commented [1702546]: Needs to be addressed by Option A Laboratories.

Commented [1702547]: Needs to be addressed by Option A Laboratories.

Commented [17A48]: You will find this document in the ISO 17025 Toolkit folder "18_Internal_Audit".

Commented [1702549]: Needs to be addressed by Option A Laboratories.

Commented [1702550]: E.g. records, minutes of previous reviews, observations of audits made and similar, see the examples in appendix to the procedure.

Commented [17A51]: You will find this document in the ISO 17025 Toolkit folder "19_Management_Review".