ISO/IEC 17025:2017 from ISO/IEC 17025:2005 LMS Transition Instructions / Checklist

This instruction / checklist is intended for use in upgrading your Laboratory Management System (LMS) for the transition from ISO 17025:2005 to ISO 17025:2017 for the General requirements for the competence of testing and calibration laboratories.

The above Laboratory Management Systems are compatible with each other and have common requirements.

In ISO 17025:2017, the requirements are described in (5) clauses:

- Clause 4 General requirements
- Clause 5 Structural requirements
- Clause 6 Resource requirements
- Clause 7 Process requirements
- Clause 8 Management system requirements

Previously in ISO 17025:2005, the requirements were described in only (2) clauses:

- Clause 4 Management requirements
- Clause 5 Technical requirements

You have the 2005 version in place and now have the objective of upgrading the system to the 2017 version. The good news is that since you are familiar with formal management systems, this initiative will be relatively straightforward.

Essentially, the documentation package for the management system will contain:

- One condensed Manual to introduce the documented information required for ISO 17025:2017.
- A group of procedure/system documents in your LMS with updates to reflect a document numbering system related to the new clause numbers and to incorporate the upgrades for ISO 17025:2017 requirements,
- A group of forms and attachments needed for the documented information and systems.

The documentation will need to be reviewed, upgraded, and implemented. The first step is to assign a person responsible for the LMS, such as with an LMS team leader to become familiar with the changes for 2017 version of the ISO 17025:2017 standard. Visit http://17025store.com/ for training materials, resources, and information on laboratory management systems requirements.

The following table with detailed instructions focuses on the areas of the documentation required for the ISO 17025:2017 LMS. As you undertake the task of upgrading your management system from the 2005 version to the 2017 version, note that the intent of the main clauses is shown in blue font and the text in *italics* indicates where requirements were included in previous ISO 17025:2005, and corresponding requirements are highlighted in yellow for some (35) clauses and sub-clauses.

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Use a copy of the ISO 17025:2017 standard along with this instruction to pinpoint for your organization the areas that need attention. You may want to make notes and add comments in the space available to the right and the left of the column for reference documentation. Use the upgrade checklist section on the right side of the table to assign the responsibility for the upgrade and to follow up on its completion.

ISO/IEC 17025:2017 from ISO/IEC 17025:2005 LMS Transition Instructions / Checklist

ISO/IEC 17025:2017 Clause	Changes to the existing ISO 17025:2005 Laboratory System	Reference document	Changes in existing documentation	Upgrade Checklist	
				Assigned to:	Date Completed
All	The International Standard Organization / International Electrotechnical Commission ISO/IEC 17025:2017 is restructured and contains 8 sections or clauses 1 through 8.	ISO 17025:2017	The requirement clauses of the standard are the Clause 4 through Clause 8. Your company needs to become familiar with the new structure and the changes and subsequently upgrade the Laboratory Management System (LMS).		
All	As you initiate the transition from ISO 17025:2005 to ISO 17025:2017, here are a few **Short, Quick, and To-the-Point Productivity Tips**. 		• An important first tip is to assign a responsible person, such as an LMS Team Leader or Management Representative, who will be the project manager for the transition project. • You will need a copy of the ISO 17025:2017 standard. Buy the standard at http://17025store.com/buy-standards/ • For the transition from the 2005 version to the 2017 version, keep your employees informed by issuing 'Employee Newsletters'. Refer to http://17025store.com/ for a complete set of newsletters. • Make use of the 'Implementation Plan'. Refer to http://17025store.com/. • Get your free Quick Start Kit at http://17025store.com/ • As required in clause 8.8, your LMS will need to be audited and your internal auditors properly trained to do this. For a complete auditor training package, refer to http://17025store.com/		
All	While the specific requirement for a quality manual is not in ISO 17025:2017, the standard requires that Documented	Manual	Replace / rework your existing Laboratory Manual with a condensed version (document LMS-001) that will introduce the management system.		

			information & handled as confidential.		
4.2.2	---		In P-500 state that when the lab is required by law or authorized to release confidential information, the customer or individual concerned notified of the information provided.		
4.2.3	---		In P-500 describe how the information about the customer obtained from sources other than the customer, such as complainant, or regulators, is kept confidential between the customer and the lab.		
4.2.4	*In ISO 17025:2005, par 4.1.5 c, covers the policies to protect confidential customer information, proprietary rights, electronic storage, and transmission of results*		In P-500 outline how personnel, including committee members, contractors, personnel of external bodies, or individuals acting on behalf of the lab, keep confidential all information obtained or created during the lab activities.		
5	This clause looks at your laboratory as a legal entity where overall responsibilities and activities are identified in order to meet all requirements and ensure valid results. This section also asks the laboratory management to ensure that the organizational roles, responsibilities, and authorities for relevant roles are assigned, communicated, and understood.				
5	In ISO 17025:2017, clause 5, covers the structural requirements and corresponds to ISO 17025:2005 clause 4.1 organization.	Documented information	Review your existing organizational structural for the laboratory management system.		
5	*In ISO17025:2005, the requirement for organization is in par 4.1.* *In ISO17025:2005, the requirement for management system is in par 4.2.*	Procedure	As part of the Structural requirements of clause 5, document the information (in P-500, Management responsibility) to describe the laboratory structure and responsibilities.		
5.1	In ISO 17025:2017, at par 4.1.1, the laboratory is a legally responsible entity.		In P-500 include the requirements for legal entity where the lab is legally responsible for tits activities.		
5.2	*In ISO17025:2005, par 4.1.5 I, covers the appointment of a quality manager* *At par 4.1.5 j appoint other key managerial personnel.* *At par 4.2.2 the LMS policies include quality policy statement in a quality manual.* *At par 4.2.5, the quality manual includes or references the supporting procedures.* *At par 4.2.5, the roles and responsibilities of technical management and the quality manager are defined in the quality manual*		In P-500 identify the management with overall responsibility for your laboratory. You may want to prepare an organization chart to identify functions and responsibilities.		
5.3	*In ISO17025:2005, par 4.2 deals with the management system for the scope of the lab activities.*		In P-500 include the range of laboratory activities for which the lab applies the standard and can claim conformity to ISO 17025:2015.		
5.4	*In ISO17025:2005, par 4.1.2 deals with the*		In P-500 include the activities that are carried out to		

7.1.3	---		In P-710 define the specification or standard and the decision rule for the customer needing a statement of conformity and communicate the decision rule to the customer.		
7.1.4	*In ISO 17025:2005, par 4.4.1 deals with resolving differences between the request or tender or the contract.*		In P-710 describe the method to resolve differences between the request, tender and the contract before lab work begin.		
	In ISO 17025:2005, par 4.4.1 covers the acceptance of contracts by the lab and the customer.		In P-710 include the item that each contract is acceptable to both your lab and the customer.		
	---		In P-710 outline how deviations requested by the customer are determined to have no impact on the integrity of the lab or the validity of results.		
7.1.5	*In ISO 17025:2005, par 4.4.4 deals with informing the customer of any deviation from the contract.*		In P-710 state that the customer is informed of any deviation from the contract.		
7.1.6	*In ISO 17025:2005, par 4.4.5 covers the handling of amendments to contracts after work has begun*		In P-710 include the method to review amendments to contracts after work has begun, by repeating the same contract review process, and communicating amendments to all affected personnel.		
7.1.7	*In ISO 17025:2005, par 4.7.1 deals with the willingness to cooperate with customers.*		In P-710 state that your laboratory cooperates with customers in clarifying their request and in monitoring performance in relation to the work done.		
7.1.8	*In ISO 17025:2005, par 4.4.2 covers the maintenance of records of reviews, including any significant changes*		In P-710 include the retention of records of reviews, including any significant changes.		
	In ISO 17025:2005, par 4.4.2 covers the maintenance of records of customer discussions relating to the lab work.		In P-710 include the retention of records of pertinent discussions with a customer relating to their requirements or the results of the lab activities.		
7.2	In ISO 17025:2017, clause 7.2, covers the selection, verification, and validation of methods & corresponds to ISO 17025:2005 clause 5.4 test and calibration methods and method validation.	Procedure	Document the information (in a document P-720 operational planning of methods) to outline the system for using suitable laboratory methods.		
7.2.1	In ISO 17025:2017, clause 7.2.1, covers the selection and verification of methods and corresponds to ISO 17025:2005 clause 5.4.2 selection of methods.		For procedure P-720 review the method for the selection and verification of laboratory methods.		
7.2.1.1	*In ISO 17025:2005, par 5.4.1 deals with the methods and procedures used for all tests and calibrations and includes an estimation of the measurement uncertainty as well as*		In P-720 describe the methods and procedures used for all lab activities and, as needed, for evaluation of the measurement uncertainty, and the statistical techniques for analysis of data.		

ISO 17025:2017

Laboratory Management System

Laboratory Manual / Documented Information

Document No. LMS-001

Street Address

City, State, Zip

Tel,

Cell Phone:

Email:

Web Site:

SAMPLE

Instructions:

This manual is used as a template in developing your ISO 17025:2017 Laboratory Management System.

- Methods and systems used in the development and operation of the LMS vary widely from laboratory to laboratory.
- The amount of documentation will depend largely on the type of activities the laboratory is involved in. Methods and systems included in the LMS documentation provide a great number of the required documents; however, they may not be all inclusive to cover all laboratory test, calibration, sampling, etc. activities.
- The blue text and suggestions displayed in the manual are intended to offer some options and to highlight the areas that need attention / update / replacement.
- Review the text and suggestions and at a minimum replace or update them to reflect the unique / customized information of your laboratory system requirements.
- Delete the blue text after each task is completed.
- Use replace function – enter “Your Company” / “Your laboratory” in find space, enter your company name in replace space – system should make changes throughout the entire document.
- Additional details and instructions in the use of the LMS-001 manual template are included in a separate file “LMS-Template-Instructions”.

Additional documentation review.

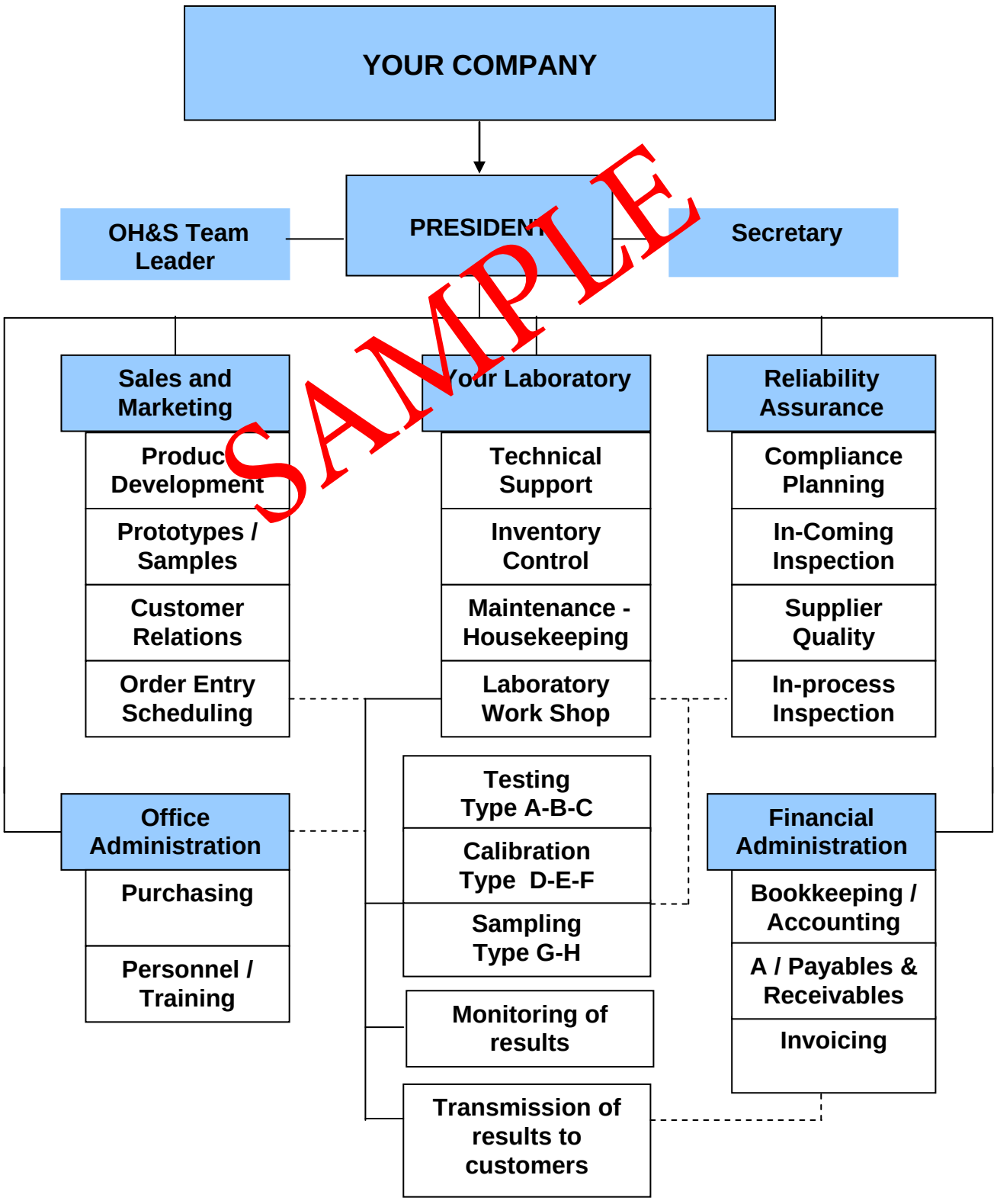
- Similarly, the blue text and suggestions displayed in the LMS documentation (that will follow) for the procedures, instructions, attachments, and forms are intended to offer some options and to highlight the areas that require update or replacement.

Table of Contents – (this page)

INSERT YOUR COMPANY LOGO/NAME HERE

A-560-001
Organization Chart

Example of an organization chart



INSERT YOUR COMPANY LOGO/NAME HERE

F-610-003
Environmental Control Log

Daily Laboratory Environmental Control Log												
Activity	**Testing**			**Calibration**			**Sampling**			**Other**		
Spec	**Temperature:**			**Humidity:**			**Cleanliness**			**Other:**		
Date	Acc.	Rej.	Sign.	Acc.	Rej.	Sign.	Acc.	Rej.	Sign.	Acc.	Rej.	Sign.

INSERT YOUR COMPANY LOGO/NAME HERE

F-660-003
Provider Corrective Action Request

Date:	PCAR No.:

Part / Item:	Part No.:
Dept. / Provider:	Job No. / PO No.:
Qty. Rejected:	Serial / Batch Nos.:

DESCRIPTION OF NONCONFORMANCE

	Identified by (Signature / Date):

Date:	**DISPOSITION**	
Rework ❒ Use AS-IS ❒ Scrap ❒		
Remarks:		
Approved (Signature / Date):	Approved (Signature / Date):	Approved (Signature / Date):

Due Date:	**CLOSEOUT**
Customer Authorize: Yes ❒ No ❒	Customer Authorization Ref.:
Re-inspected: Yes ❒ No ❒	Inspection Report No.:
Corrective Action: Yes ❒ No ❒	Corrective Action No.:
Approved (Signature / Date):	Approved (Signature / Date):

- Development, modification, verification, and validation of methods,
- Analysis of results, statements of conformity, opinions, and interpretations,
- Report, review and authorize results.

5.1.4 In support of resource management, awareness issues are addressed with new employees. They attend orientation training and made aware of:

- The relevant objectives,
- Their contribution to an effective LMS,
- The benefits of improved performance,
- The implications of not conforming to requirements of the LMS,
- The importance of meeting customer requirements and the need for ensuring customer satisfaction,
- The importance of meeting regulatory / statutory requirements,
- The quality policy.

5.1.5 Awareness training is repeated for all employees as supervisors or management or the LMS team identifies the need to retrain employees.

5.2 Human Resources staff maintains records of employee qualifications and documents the education, experience and skills required for each position and job. A job description form such as F-620-003 is used for this purpose.

5.2.1 In support of the management of resources, the level of knowledge needed to achieve conformity to requirements is considered.

- Knowledge is maintained and made available through planned training. Organizational knowledge can include information such as intellectual property and lessons learned.
- When addressing changing needs and trends, the current knowledge is assessed to determine how to acquire new needed knowledge.

5.2.2 The LMS team leader is on alert for opportunities to improve organizational knowledge. An information center / library is maintained to collect and make available information that can enhance knowledge.

5.3 Each supervisor is responsible for identifying job specific training requirements for each position in their area and to maintain the employee training summaries on spreadsheet, form F-620-004 or in a training database.

5.3.1 Actions to acquire the necessary competence can include mentoring, provision of training, the reassignment of current employees, or the hiring or contracting of competent personnel.

5.4 When an employee is hired, changes positions or job requirements change, Human Resources obtains a resume or application from the employee to document their qualifications.

5.4.1 Employee qualifications are compared against the requirements for the position. If there are requirements that the employee's qualifications do not meet, human resources or the employee's supervisor identifies an action plan to provide the employee with the necessary qualifications.

1.0 Purpose/Scope

1.1 The purpose of this procedure is to describe the process for communicating with customers and determining and reviewing requirements related to laboratory services provided by Your laboratory.

1.2 The procedure applies to the review of customer requests, tenders, and contracts, and orders received for laboratory tests, calibrations, and sampling.

2.0 Responsibilities and Authorities

2.1 The Sales and marketing manager has the prime responsibility and approval authority for this procedure.

2.2 In support of the Sales and marketing manager, the Customer service or Sales representatives are responsible for taking orders from clients, determining customer requirements, and reviewing the orders for acceptance.

2.3 Additional responsibilities for sales and marketing / customer service / project or account managers / production control personnel are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 This document relates to clause 7.1 of the ISO 17025:2017 standard, covering the review of requests, tenders, and contracts.

4.0 Resources

4.1 None

5.0 Instructions

5.1 In support of the requirements for processes, this procedure addresses the customer related processes.

5.2 In support of the Sales and marketing manager, the LMS team ensures that customer request, tenders, and contracts are reviewed.

5.2.1 The requests and orders for laboratory services are accepted electronically or by email, phone, fax, or mail.

5.2.2 When a customer service or sales and marketing rep receives a request from a client, the representative identifies and documents customer requirements.

5.2.3 An important first step is to clarify or classify all the test or calibration services that are requested as **“Accredited” or as “Not-Accredited”.**

- Section D of the client assessment report, F-710-001 is used to record the classification for the tests or calibrations.

5.2.4 In support of the requested accredited or not-accredited laboratory services

1.0 Purpose/Scope

1.1 The purpose of this procedure is to establish the process for the monitoring, analysis, and evaluation of technical records, of measurement uncertainty, and of the validity of results at Your laboratory.

1.2 The procedure applies to the laboratory activities where performance is evaluated.

2.0 Responsibilities and Authorities

2.1 The Quality manager has the prime responsibility and approval authority for this procedure.

2.2 In support of the Quality manager, the LMS team is responsible for identifying the appropriate recording, evaluation, and monitoring,

2.3 Additional responsibilities for the LMS team are detailed in relevant paragraphs of section 5.0 below.

3.0 References and Definitions

3.1 This document relates to clause 7.5 of the ISO 17025:2017 standard, dealing with technical records.

3.2 This document also relates to clause 7.6, evaluation of measurement uncertainty, and clause 7.7, ensuring the validity of results.

3.3 Proficiency testing is an evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

4.0 Resources

4.1 None

5.0 Instructions

5.1 In support of the requirements for processes, this procedure addresses the requirements for technical reports, evaluation of measurement uncertainty, and ensuring the validity of results.

5.2 In support of the Quality manager, the LMS team determines what needs to be recorded, evaluated, and monitored, the methods (such as statistical techniques) for these activities, when they are performed, and when the results are to be analyzed and evaluated.

5.3 The LMS team ensues that technical records for each laboratory activity contain the results, report, and sufficient information to allow for the identification of factors affecting the measurement result and its associated measurement uncertainty and to enable the repetition of the laboratory activity under conditions as close as possible to the original.

5.3.1 The technical records include the date and the identity of personnel responsible for each laboratory activity and for checking of data and results.

- Original observations, data and calculations are recorded at the time they are made and are identifiable with the specific task.

1.0 Purpose/Scope

1.1 This instruction describes the numbering system used to identify and control the documented information required for the LMS at Your Company.

1.2 The instruction applies to all documented information essential to the product or service and to the procedures essential to the operation of Your Company.

2.0 Responsibilities and Authorities

2.1 The LMS team leader has the prime responsibility and approval authority for this instruction.

2.2 The document control coordinator is responsible for assigning document numbers, maintaining the master list, making new and revised documents available, distributing hard copies of documents, and revising documents.

3.0 References and Definitions

3.1 Reference

3.1.1 P-820 Control of documented information is the upward procedure that this work instruction is controlled by.

3.2 Definitions

3.2.1 **Attachment**: Document used to further clarify or show examples of information described in the manual, procedures, and work instructions.

3.2.2 **Form**: Pre-formatted document used to make a record.

3.2.3 **Procedure:** Document outlining the controlled conditions for processes used to provide products or services.

3.2.4 **Process Flow Diagram**: Graphical representation of the key steps required for a process.

3.2.5 **Record**: Documented information generated as a result of the process intended to provide a product or service and retained to provide evidence of conformity.

3.2.6 **Reference**: External document or sources used in preparing documentation and completing work.

3.2.7 **Related Document**: Other document that reflects the process approach for the LMS and that may need to be altered if the current document is revised or changed.

3.2.8 **Template:** Formatted document used as a guide to create forms or procedures required by the management system.

3.2.9 **Work Instruction**: A document which provides step-by-step directions on how a task should be done.

4.0 Resources

4.1 None, (unless an electronic document control system is used).

5.0 Instructions

5.1 Document numbering. Procedures, work instructions, forms and attachments are numbered using the numbering scheme outlined in this instruction.

5.1.1 A prefix represents the type of document.

- A = Attachment
- F = Form
- P = Procedure
- T = Template
- FD = Flow Diagram
- WI = Work Instruction

5.1.2 The prefix is followed by a 3-digit number, assigned by the document control group, and relates to the requirement clause of the standard.

5.1.3 Procedures are assigned a number associated with the clause number.

Example:

The procedure for control of documented information relates to clause 8.2 of the standard and is assigned number P-820.

5.1.4 Work Instructions have the same three-digit number as their associated procedure and an additional three-digit sequential number as needed.

Example:

This work instruction WI-820-001 is the first instruction related to control of documented information.

WI-820-002 might be the work instruction for maintaining the master list of document numbers, the next work instruction related to procedure P-820.

5.1.5 Forms and attachments have the same three-digit number as their associated procedure and an additional three-digit sequential number as needed.

Example:

F-820-001 (list of documented information) is the first form for the Control of documented information procedure P-820.

INSERT COMPANY NAME/LOGO HERE

ISO/IEC 17025:2017 Laboratory Management System - The ISO 17025:2017 – from - ISO 17025:2005 Gap Analysis Checklist

This gap analysis checklist is prepared for use in evaluating the requirements for the competence of testing and calibration laboratories against the requirements of ISO/IEC 17025:2017 as you transition from ISO/IEC 17025:2005. Each requirement is expressed as a question that the user (auditor / assessor) can ask to evaluate your laboratory capabilities. You will need to have copies of the ISO 17025:2017 and the ISO 17025:2005 standards to use along with this checklist so that you can refer to the requirements if necessary.

While the two versions of the standard do not line up when comparing the requirements:

- New requirements and / or new terminology are highlighted in yellow.
- The intent of the main clauses of the new standard is shown in blue font.
- The 3rd left-hand column in green shade is intended to provide reference / comparison / similarities to and extracts from the ISO 17025:2005 requirements, and to identify and locate where in the new clauses, the former requirements are relevant.
- Comments highlighted in **red font** indicate removed requirements.

After you have prepared an audit schedule and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist for the auditors working with that section. As you work through the checklist take notes on what is in place, and what needs to be developed. In the space for 'currently in place', list or reference the procedures or other documents, or evidence that you have reviewed and that will provide information for the new laboratory management system. Take notes on the status of the documents, that is, will they need to be revised for the new system, or can they be used as is? Also note where processes are in place, but documentation is needed. Focus on what is in place, and what needs to be developed.

While you do want to know if documented information is in place and if procedures and processes are being complied with, compliance is not your main focus for this audit.

Remember that the final outcome of this audit should be a list of things that your company needs to do to comply with ISO 17025:2017.

Note that the checklist relates to Option A introduced in clause 8.1 of the standard. This option lists the minimum requirements for the implementation of a management system in a laboratory setting and incorporates the requirements of ISO 9001 that are relevant to the scope of laboratory activities covered by the management system. By complying with the requirements of clause 4 through clause 7 and implementing clauses 8.2 through 8.9, laboratories can generally operate in accordance with the ISO 9001:2015 principles.

---	ISO/IEC 170025:2017 Requirements for the Competence of Testing and Calibration Laboratories	ISO/IEC 17025:2005 Reference Requirements	Currently in Place	Compliant YES / NO?	If No - % Completed	Items Needed
4	**GENERAL REQUIREMENTS**		**4 Management requirements**			
Intent of clause	This first clause introduces two sub-clauses as general requirements. First is impartiality, where laboratory activities are undertaken and managed in a structured manner in order to safeguard impartiality and provide presence of objectivity. Second is confidentiality, where responsible management of information obtained or created during the operations of a laboratory is considered and treated as confidential.					
4.1	**Impartiality**		**----**			
4.1.1	As an organization, are your laboratory activities undertaken impartially and structured and managed to safeguard impartiality?	4.1.4 Note 2. A third-party laboratory demonstrates that it is impartial.				
4.1.2	How does the laboratory management demonstrate commitment to impartiality?	4.1.5 d) Laboratory policies to avoid activities that diminish confidence in its impartiality.				
4.1.3	Is the laboratory responsible for the impartiality of its activities and does it disallow commercial, financial, or other pressures to affect impartiality?	4.1.5 b) Ensure that the management and personnel are free from any undue pressures and influences that may adversely affect the quality of their work.				
4.1.4	Has the laboratory identified risks to its impartiality on an on-going basis?					
	Does this include those risks that arise from its activities, relationships, or from the relationships of its personnel?					
With reference to the note in 4.1.4:		----				
	Is a relationship that threatens the	4.1.4 If the laboratory is part of a				

	impartiality of the laboratory based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing, branding, and payment of a sales commission or other inducement for the referral of new customers, etc.?	company performing other than lab services, the responsibilities of key personnel are defined to identify any conflicts of interest.				
4.1.5	When a risk to impartiality is identified, how is the laboratory able to demonstrate that it eliminates or minimizes the risk?					
4.2	**Confidentiality**		**----**			
4.2.1	Is your laboratory responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities?					
	• Does the laboratory inform the customer in advance, of the information it intends to place in the public domain?					
	• Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer, such as for responding to complaints, is all other information considered proprietary information and handled as confidential?	4.7.1 The laboratory cooperates with customers providing that confidentiality is assured to other customers.				
4.2.2	When the laboratory is required by law or authorized by contractual					

	arrangements to release confidential information, is the customer or individual concerned notified of the information provided?					
4.2.3	Is the information about the customer obtained from sources other than the customer, such as complainant, or regulators, confidential between the customer and the laboratory?					
	• Is the source of this information confidential to the laboratory and not to be shared with the customer, unless agreed by the source?					
4.2.4	Do the personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on behalf of the laboratory, keep confidential all information obtained or created during the laboratory activities?	4.1.5 c) Policies to protect confidential customer information and proprietary rights, including protecting the electronic storage and transmission of results				
5	**STRUCTURAL REQUIREMENTS**		**4.1 Organization**			
	----		**4.2 Management system**			
Intent of clause	This clause looks at your laboratory as a legal entity where overall responsibilities and activities are identified in order to meet all requirements and ensure valid results. This section also asks the laboratory management to ensure that the organizational roles, responsibilities, and authorities for relevant roles are assigned, communicated, and understood.					
5.1	Is the laboratory a legal entity, or a defined part of a legal entity, that is legally responsible for its activities?	4.1.1 The laboratory is an entity that is legally responsible.				
With reference to the note in 5.1:		----				

	Do you consider a government laboratory to be a legal entity based on its governmental status?					
5.2	Is the management with overall responsibility for the laboratory identified?					
		4.1.5 i) Appoint a member of staff as quality manager who, regardless of other duties, has defined responsibility and authority for ensuring that the system related to quality is implemented and followed. The quality manager has direct access to top management where decisions are made on lab policy or resources.				
		4.1.5 j) Appoint deputies for key managerial personnel.				
		4.2.2 The laboratory's management system policies related to quality, includes quality policy statement, defined in a quality manual. The overall objectives are established and reviewed during management review.				
		4.2.2 The quality policy statement issued under the authority of top management includes at least the following: a) The laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers. b) The management's statement of the laboratory's standard of service. c) The purpose of the management system related to quality. d) A requirement that all personnel concerned with testing and calibration activities within the laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work. e) The laboratory management's commitment to comply with ISO 17025 and to continually improve the effectiveness of the management system.				
		4.2.5 The quality manual includes or references the supporting procedures including technical procedures and outlines the structure of documentation used.				

		4.2.5 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with ISO 17025 are defined in the quality manual (however named).				
5.3	Has the laboratory defined and documented the range of activities for which it conforms to ISO 17025?	4.2.1 Establish, implement, and maintain a management system appropriate to the scope of the lab activities.				
	• Do you only claim conformity with ISO 17025 for this range of lab activities, which excludes ongoing externally provided lab activities?					
5.4	Are the lab activities carried out to meet the requirements of the ISO standard, along with the requirements of customers, of regulatory authorities and of organizations providing recognition?	4.1.2 It is the lab's responsibility to carry out its activities to meet ISO 17025 requirement and to satisfy the needs of customers, regulatory authorities, or others providing recognition.				
	• Does this include lab activities performed in all permanent facilities, at sites away from permanent facilities, in associated temporary or mobile facilities or at a customer facility?	4.1.3 The lab system covers work carried out in permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.				
5.5	For your laboratory have you:	----				
	• Defined the organizational and management structure, its place in any parent company, and the relationships between management, technical operations, and support services?	4.1.5 e) Define the lab structure, its place in a parent company, and the relationships between quality management, technical operations, and support services.				

Employee Training

ISO 17025:2017

Student Guide

ISO/IEC 17025:2017 OVERVIEW

Technical ISO standard for the competence of testing and calibration laboratories

TOPICS COVERED

1. Fundamentals	2. Basics of a Lab-MS and ISO 17025	3. Establishing your Lab-MS	4. Managing the ISO 17025 Lab-MS
• Who is ISO? • What is CA std? • Registration vs accreditation • What is a Management System? • Plan Do Check Act • Process approach • Risk Based Thinking • Scope of accreditation • Technical elements	• What is a Lab-MS ? • What is ISO/IEC 17025? • Benefits of accreditation • Elements of ISO/IEC 17025:2017	• Key Elements • Documenting your Lab-MS • Implementing the MS in your Organization • Training People • Auditing the MS • Accreditation	• Key elements of an ISO/IEC 17025 Lab-MS • ISO/IEC 17025 accreditation

SECTION 1 - FUNDAMENTALS

- Who is ISO?
- What are CA standards?
- Registration vs accreditation
- What is a Management System?
- Plan Do Check Act
- Process approach
- Risk Based Thinking
- Scope of accreditation
- Technical elements

Name_____

Section 4:

1. The ISO/IEC 17025 full element regarding risks and opportunities is found in clause 8 of the new standard.

   a. False b. True

2. Communication channels and content cannot be taken for granted in a quality organization. Requirements are found in the standard not only for what to communicate, but also for to whom, when and how.

   a. False b. True

3. An accredited ISO/IEC 17025 laboratory is required by the standard to issue feedback surveys to all their customers.

   a. False b. True

4. Understanding measurement uncertainty is one of the key challenges to an accredited ISO/IEC 17025 lab.

   a. False b. True

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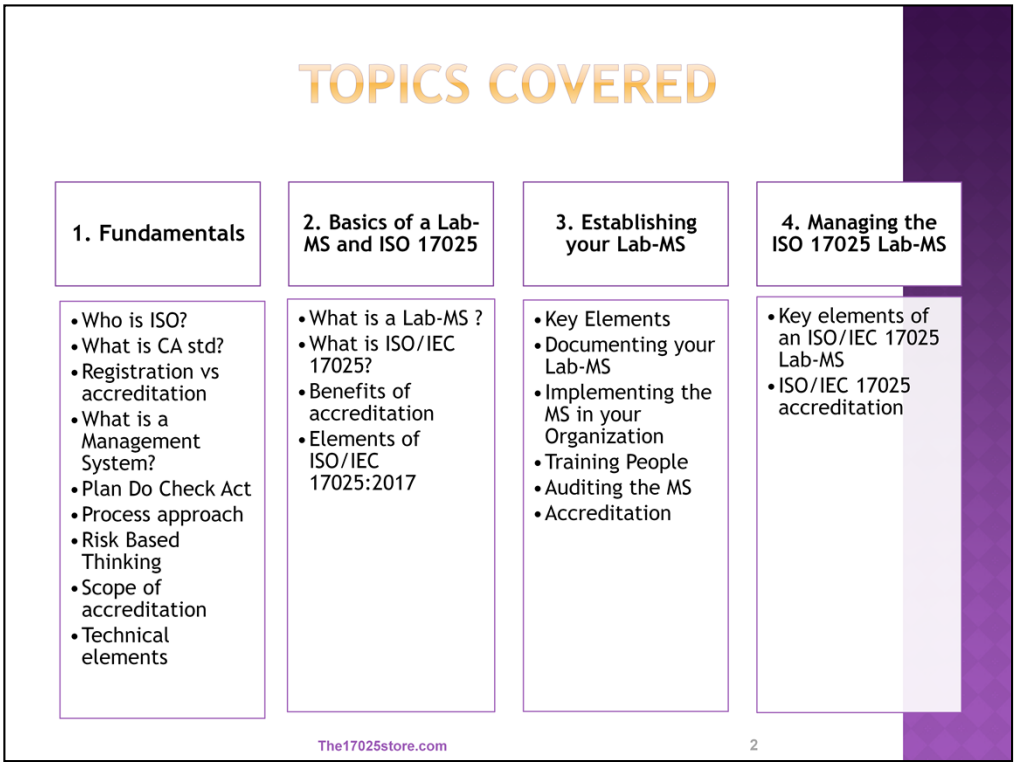
Employee Training

ISO 17025:2017

Trainer's Guide

Every employee in your laboratory has an important role to play in your Laboratory Management System (Lab-MS). Your organization may include thousands of employees, but the entity getting accredited would be limited to the laboratory technical and support staff for their proposed scope tests or calibrations.

You are participating in this training to learn the basics of a Lab-MS and what it means to be ISO/IEC 17025 accredited and how it will affect your job.



Today we will cover the following topics so that you will better understand your company's Management System.

I will begin by providing some basic information regarding management systems and ISO standards.
I will then explain:
What is a Lab-MS (Management System) and What is ISO ?
What is a conformity assessment (CA) standard?
What is the international ILAC organization in the global technical community?
Why it is important to your company to achieve ISO/IEC 17025 accreditation?
What is a scope of accreditation?
What key technical elements are involved?
What are the benefits of achieving accreditation?
What are the elements necessary to establish and manage an ISO/IEC 17025 Lab-MS, and How can you support your organization's MS?
For the rest of the training, we will use the term Lab-MS which means the Lab's Management System.

Certificate of Completion

This certifies that

Insert Name

Has successfully completed

IATF 17025:2017 Employee Training

Demonstrating competence by passing the final exam.

President, Standards-Stores.com

September 12, 2018

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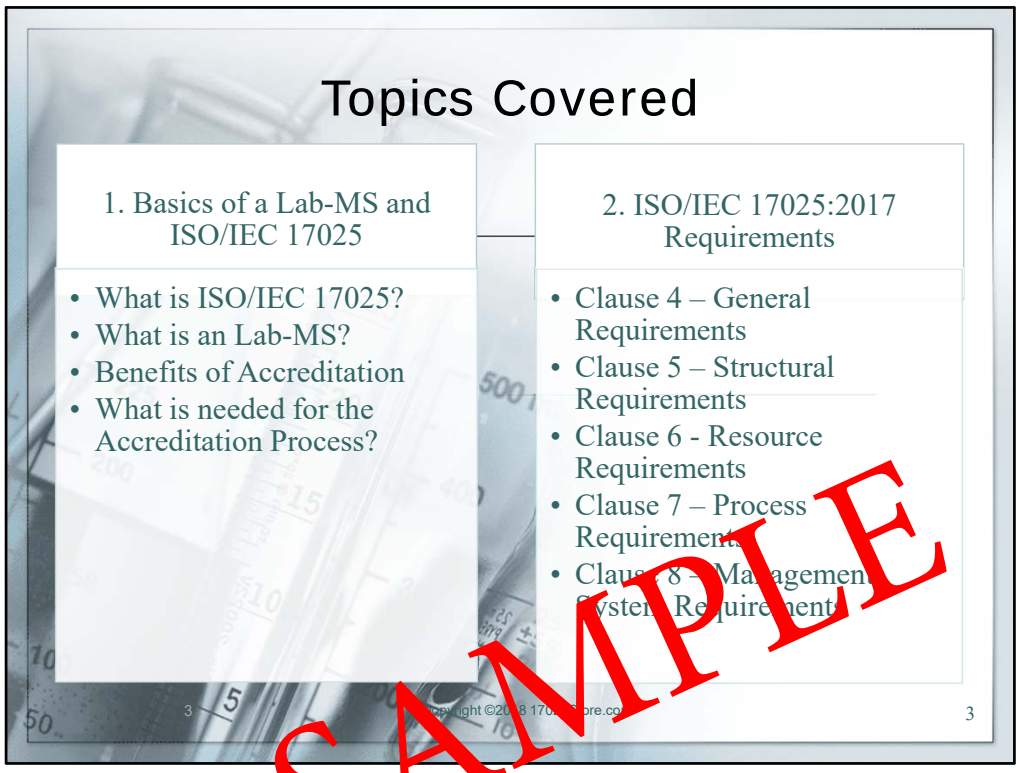
Requirements of ISO/IEC 17025:2017

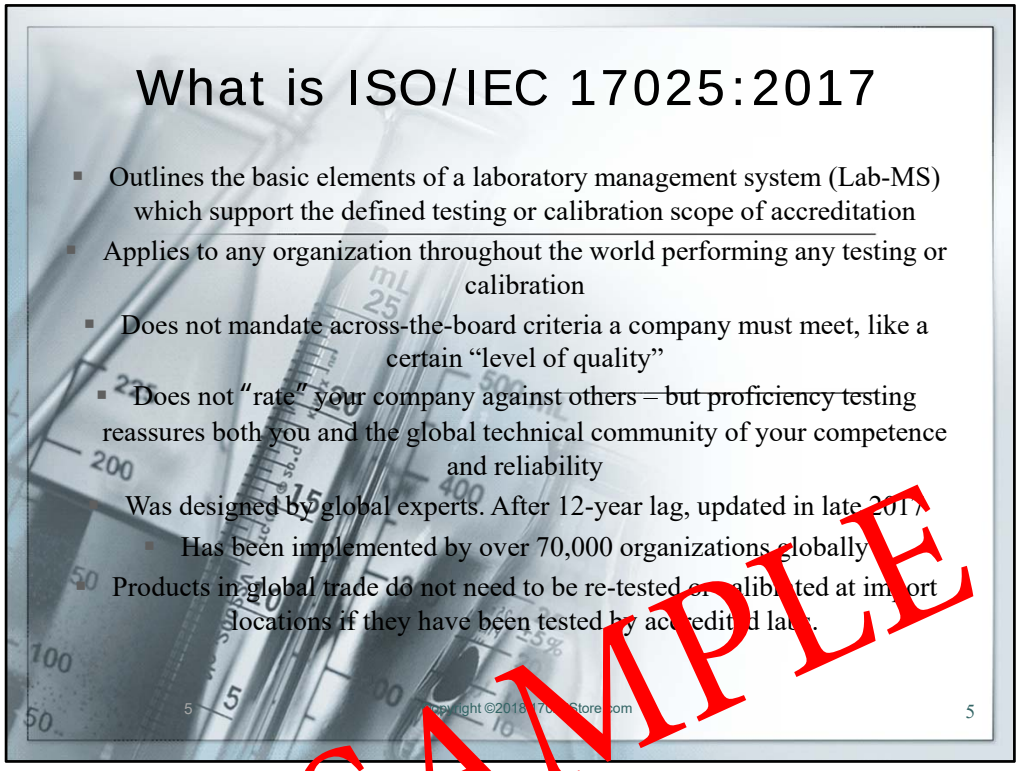
Trainer Guide



Today we will cover the following topics so that you will better understand your company's Laboratory Management System.

What is ISO/IEC 17025 and what is a Lab-MS
What are the benefits of achieving accreditation
What are the elements necessary to establish and manage a ISO/IEC 17025 Lab-MS, and
What is needed for the ISO/IEC 17025 accreditation process
And finally, we will go through the requirements in the clauses of ISO/IEC 17025:2017

Trainer's Guide includes Speakers Notes



ISO/IEC 17025:2017 is an ISO standard used by testing and calibration laboratories to show competence in their ability to perform specific tests or calibrations. Accreditation to the standard is a formal recognition of a demonstration of that competence.

ISO/IEC 17025 was initially published in 1999. A revision was added in 2005 and the standard was recently updated in November 2017.

ISO/IEC 17025 enhances the acceptance of products across national borders. By removing the need for additional calibration, testing, medical testing and/or inspection of imports and exports, technical barriers to trade are reduced. In this way, the free-trade goal of a 'product tested or calibrated once and accepted everywhere' can be realized.

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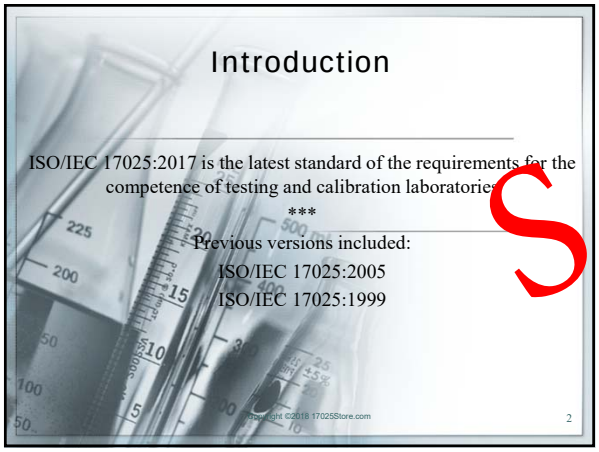
Requirements of ISO/IEC 17025:2017

Student Guide

Student's Guide has space for notes

1



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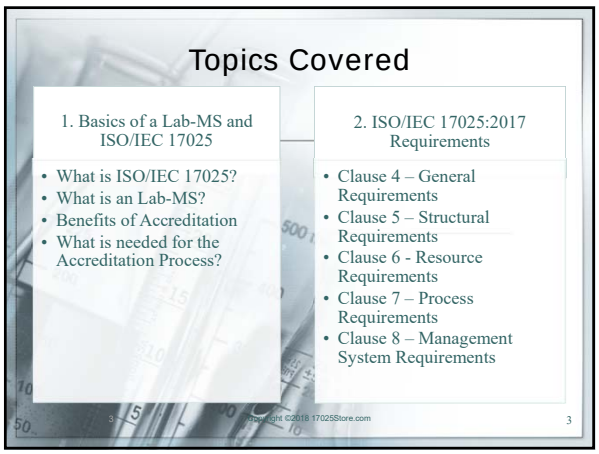

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Is it a Requirement?

The standard requires that: If the requirement is true, circle True and list the clause. If it is false, circle False and list the clause used.	**True**	**False**
1. The laboratory shall establish a management system that is capable of assuring the quality of the laboratory results	T *Clause:*	F *Clause:*
2. Reports do not need to include the contact information of the customer.	T *Clause:*	F *Clause:*
3. Records shall be retained for equipment which can influence laboratory activities.	T *Clause:*	F *Clause:*
4. The laboratory does not need to be a legal entity or be legally responsible for its laboratory activities.	T *Clause:*	F *Clause:*
5. The laboratory does not need to retain records for the supervision of personnel.	T *Clause:*	F *Clause:*
6. Management must review the management system at least every quarter of the year.	T *Clause:*	F *Clause:*
7. The laboratory shall document the competence requirements for each function influencing the results of laboratory activities.	T *Clause:*	F *Clause:*
8. Upon receipt of the test or calibration item, deviations from specified conditions need to be recorded.	T *Clause:*	F *Clause:*
9. Any differences between the request or tender and the contract shall be resolved at the end of the calibration or testing.	T *Clause:*	F *Clause:*
10. The laboratory shall identify and select opportunities for improvement.	T *Clause:*	F *Clause:*
11. Information about the customer obtained from sources other than the customer need to be confidential between the customer and the laboratory.	T *Clause:*	F *Clause:*
12. The laboratory needs to retain records for at least two years.	T *Clause:*	F *Clause:*
13. Actions to address risks and opportunities need to be determined for the laboratory's activities.	T *Clause:*	F *Clause:*
14. The laboratory shall provide the complainant with progress reports and the outcome of the complaint.	T *Clause:*	F *Clause:*

Certificate of Completion

Insert your Company Name Here

This certifies that

Insert Name

Has successfully completed
the training course in

Requirements of ISO 17025:2017

Insert Trainer's Name & Title

January 9, 2019

ISO/IEC 17025:2017

Internal Auditor Training

Trainer's Guide

Overview

These course materials are meant to train people to conduct internal quality audits within your organization, which are necessary to meet the internal audit requirements of the ISO/IEC 17025:2017 standard.

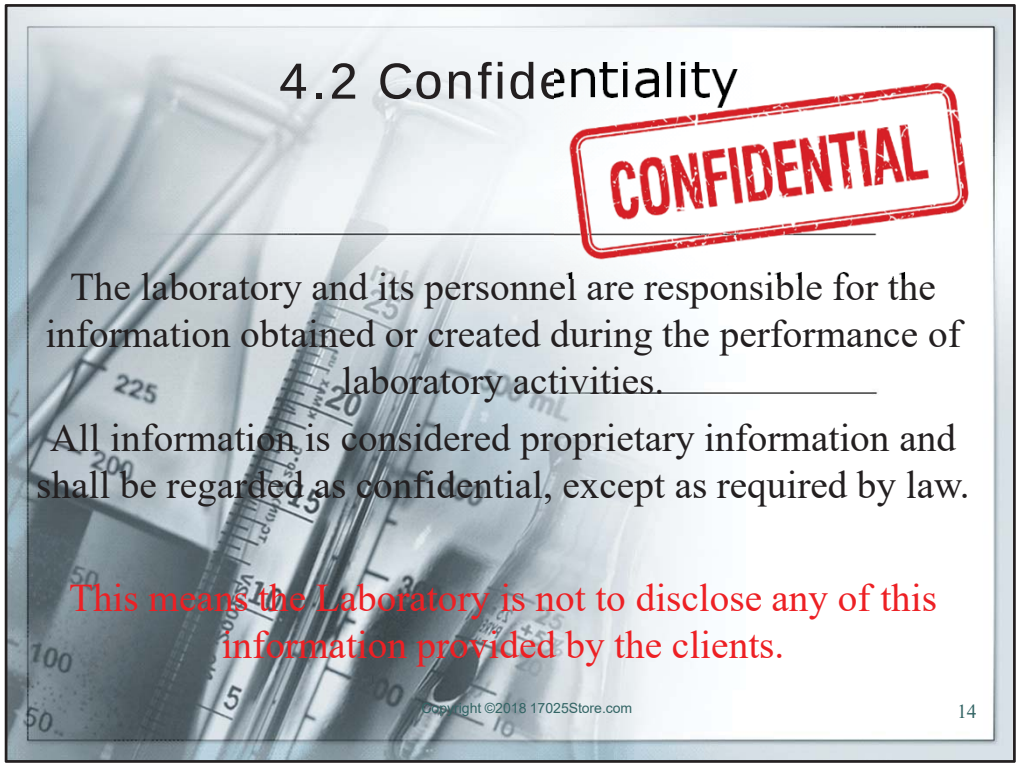
The course is divided into two sections:

1. The first section will familiarize the students with the ISO/IEC 17025:2017 requirements for laboratory quality management
    - Allow 4 hours for this section.
2. The second section is devoted to the auditing process. The students will go through all the steps required for an audit, with hands on involvement in performing each step by conducting a mock audit of a fictitious company.
    - Allow 8 hours for this section.

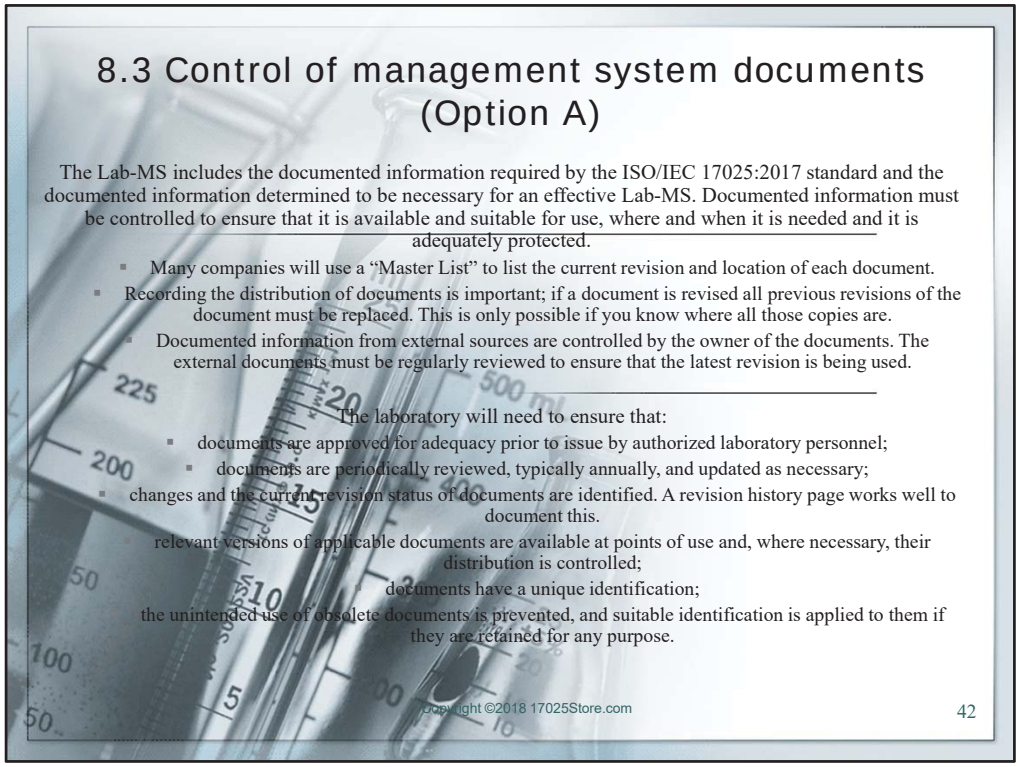
We recommend that you print this guide as you'll need the PowerPoint speaker notes to lead the class. This guide contains everything the instructor needs to lead the class.

Notes:

- It is assumed that the instructor has the education, credentials and/or equivalent experience. This is not meant as a self study course.
- It is recommended that the first audit the student is involved with be under the leadership of a lead auditor who has audit experience.



The laboratory and its personnel are responsible for the information obtained or created during the performance of laboratory activities. All information is considered proprietary information and shall be regarded as confidential, except as required by law.



The Lab-MS includes the documented information required by the ISO/IEC 17025:2017 standard and the documented information determined to be necessary for an effective Lab-MS. Documented information must be controlled to ensure that it is available and suitable for use, where and when it is needed and it is adequately protected.

- Many companies will use a "Master List" to list the current revision and location of each document.
- Recording the distribution of documents is important; if a document is revised all previous revisions of the document must be replaced. This is only possible if you know where all those copies are.
- Documented information from external sources are controlled by the owner of the documents. The external documents must be regularly reviewed to ensure that the latest revision is being used.

The laboratory will need to ensure that:

- documents are approved for adequacy prior to issue by authorized laboratory personnel;
- documents are periodically reviewed, typically annually, and updated as necessary;
- changes and the current revision status of documents are identified. A revision history page works well to document this.
- relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
- documents have a unique identification;
- the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

Closing Meeting

The agenda for the closing meeting includes:

- Thank the people involved
- Have the attendees sign-in
- Remind the auditees that the audit is a sampling and that you did not look at everything
- Each auditor presents their findings
- Lead presents overall status of the system
- Answer questions

Sample Audit Report – page 1

Example of Internal Audit Report

Audit Number: 1 **Page 1**	**Closing Meeting Attendees:** For Superior Calibration Lab: A Doer, R Ryan, D Delany, D Thomas, M T Moore, J Sample, A Bolt, + Auditors: R Richards, A Anderson, R Roberts.
Date: April 14, 2019	
Area(s) audited: Lab Quality Manual, including Laboratory Facilities, Calibration Certificate, Equipment and Records, Laboratory Management	
Changes to Scope of Audit: No changes, areas audited as planned.	
Lead auditor: Richard Richards; Auditors: Ander Anderson, Robbie Roberts	
Audit Record (Describe what you did, who you spoke to, what records you examined below):	
General Comments: All involved were very helpful and open when audited. The documents and records requested were promptly provided.	
List of documents reviewed:	
Documented information: Quality Manual, CR-01 'Calibrated Equipment List', Calibration Certificate, Calibration Data	
List of persons interviewed:	
President, Albert S Doer	**Manufacturing, R Ryan**
Human resources, M T Moore	**Laboratory Manager, J Sample**
Technical support, A Bolt	**Materials, D Delany**

Have Students create a meeting agenda, page 1

Welcome to ISO/IEC 17025:2017

Our Company is working on becoming ISO/IEC 17025:2017 accredited. This international standard provides for the general requirements for the competence of testing and calibration laboratories and outlines some good basic business practices that we need to have in place. By implementing a Laboratory Quality Management System (LQMS) that complies with the international standard, we will join an elite group of accredited laboratories.

Why does our company want to become ISO/IEC 17025 accredited?

The main reason is that it is the right thing to do! All of us want to do our part in having accurate and valid laboratory test and calibration results.
Not only do we want to be competent and impartial, we want to improve our performance in a confidential and professional way.
An important benefit is that we will be able to maintain our position in the market place because more and more customers and countries are becoming results conscious and are requiring that laboratories show proof of sound commitment and services.

What will employees need to do for the ISO/IEC 17025:2017 Laboratory Quality Management System?

First, management will be looking at our activities, processes, and services and will identify our "Key Operations" ranging from the review of requests, tenders, and contracts to control of data and information management.
Those are the processes that affect the quality of our laboratory test and calibration services. Then they will determine how we will control these processes to make sure that we are all doing them the same way, and the best way our laboratory has identified.
Controlling the processes means documenting the procedures and work instructions, training employees and finding ways to make sure that the lab activities are done consistently.
This means that employees may be required to have specialized training, or to follow specific work instructions. All employees will need to be aware that, "It is Everyone's Job to Ensure Accurate and Valid Results".

ISO/IEC 17025 Highlights: Things that you will be hearing about as we proceed with this project….

Our Quality Policy

We will identify our Quality Policy and will be communicating it to all staff and employees. While the policy is not formally required, we believe it is important that all of us are aware of what this statement says about what our vision is for meeting our commitments.

Accreditation Audit

To become ISO/IEC 17025:2017 accredited, we will be audited by an Accreditation Body. This will happen after we have set up the systems to meet all the requirements of the standard.
The Accreditation Body will send an auditor or audit team to our facilities and evaluate the LQMS we have in place.
They will check to see if the processes meet the requirements of the standard and see if we follow our processes.
If everything looks good, we will be recommended for accreditation and be awarded a certificate and be recognized globally!

Watch for our next newsletter for more introduction to ISO/IEC 17025:2017, what it will mean to you and your coworkers.