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:

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.

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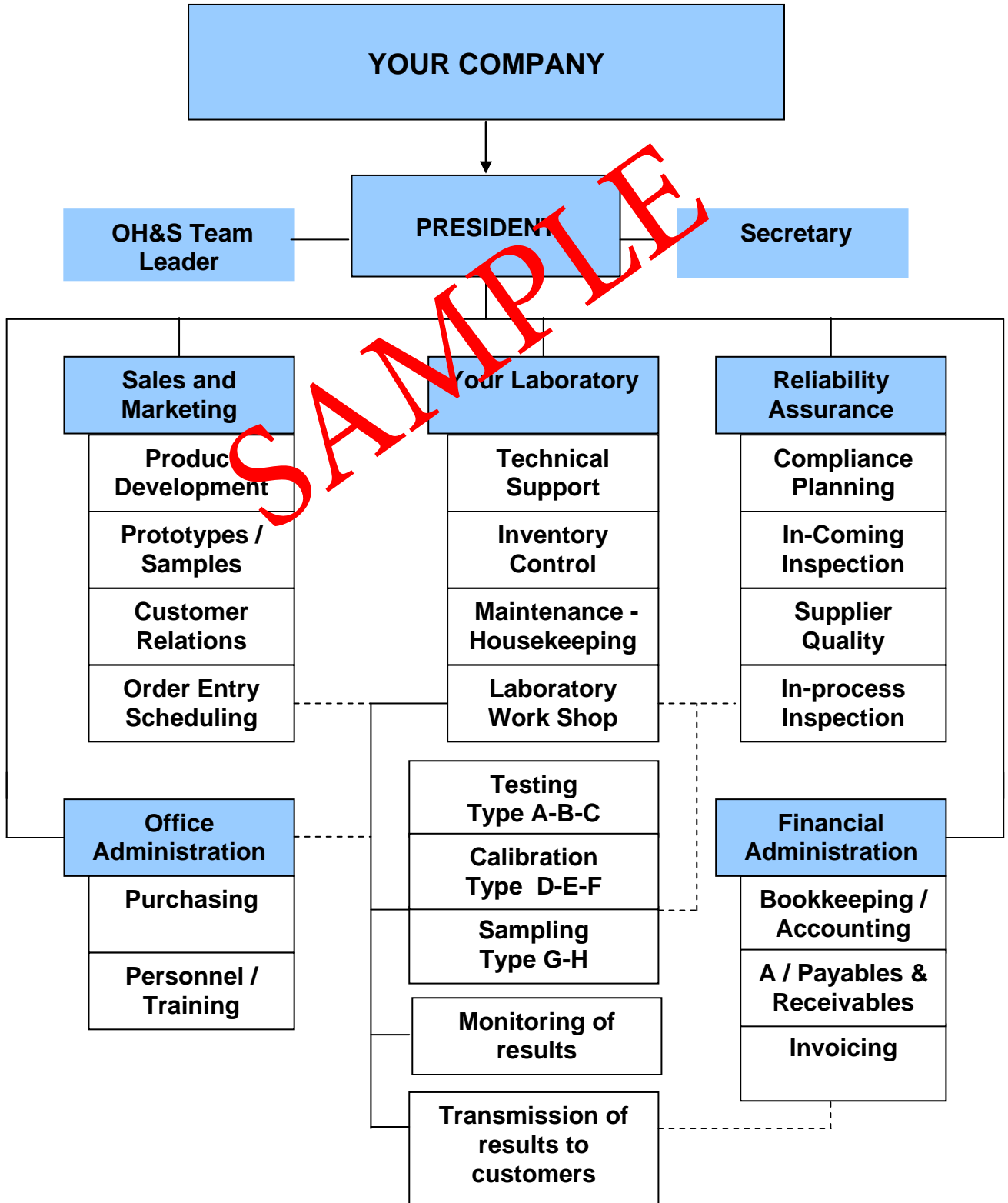
Table of Contents – (this page)

Example of an organization chart

YOUR COMPANY

OH&S Team Leader — **PRESIDENT** — **Secretary**

SAMPLE

Sales and Marketing
- Product Development
- Prototypes / Samples
- Customer Relations
- Order Entry Scheduling

Office Administration
- Purchasing
- Personnel / Training

Your Laboratory
- Technical Support
- Inventory Control
- Maintenance - Housekeeping
- Laboratory Work Shop
- Testing Type A-B-C
- Calibration Type D-E-F
- Sampling Type G-H
- Monitoring of results
- Transmission of results to customers

Reliability Assurance
- Compliance Planning
- In-Coming Inspection
- Supplier Quality
- In-process Inspection

Financial Administration
- Bookkeeping / Accounting
- A / Payables & Receivables
- Invoicing

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.

SAMPLE

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.

ISO/IEC 17025:2017 – The Internal Audit Checklist
General Requirements for the Competence of Testing and Calibration Laboratories
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This checklist is based on the information from the ISO/IEC 17025:2017 international standard. The checklist is best used by trained and practicing auditors to evaluate or assess the Laboratory Management System (LMS) for the Competence of Testing and Calibration Laboratories requirements based on the standard. You will see questions on the checklist that refer to the standard and for each clause provisions are made for additional questions.

The auditors are expected to keep in mind that the standard does not requires mandatory procedures for the various LMS processes; however, the auditors will expect documented information to be available because in the clauses of the standard, the phrase such as 'documented procedures' is used to specify that a process, a method, a system, a work instruction, or an arrangement be documented.

The auditors must use a great deal of discretion and therefore must be careful and thoughtful prior to establishing a deficiency against a requirement. Evidence for visible top management leadership, commitment and quality management action must be looked for.

The **bold** numbers and titles used in the first two columns of the checklist indicate the "Requirements" and may be referred to on nonconformity reports prepared by the auditor.

During assessment of each requirement, auditors record the status of the evaluation by indicating in the right-hand column a:

Yes - for Acceptable Condition or **No -** for Deficient Condition

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ISO/IEC 17025:2017 – The Internal Audit Checklist
General Requirements for the Competence of Testing and Calibration Laboratories

---	GENERAL REQUIREMENTS for the COMPETENCE of TESTING and CALIBRATION LABORATORIES	OBSERVATIONS / COMMENTS	STATUS
4	**GENERAL REQUIREMENTS**		
4.1	**Impartiality**		
4.1.1	As an organization, are your laboratory activities undertaken impartially and structured and managed to safeguard impartiality?		
4.1.2	How does the laboratory management demonstrate commitment to 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?		
4.1.4	Has the laboratory identified risks to its impartiality on an on-going basis?		
	• Does this include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel?		
	With reference to the note in 4.1.4:		
	Is a relationship that threatens the 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.?		

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ISO/IEC 17025:2017 – The Internal Audit Checklist
General Requirements for the Competence of Testing and Calibration Laboratories

4.1.5	When a risk to impartiality is identified, how is the laboratory able to demonstrate that it eliminates or minimizes the risk?		
	Additional Questions		
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?		
4.2.2	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		

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ISO/IEC 17025:2017 – The Internal Audit Checklist
General Requirements for the Competence of Testing and Calibration Laboratories

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	the laboratory?		
	• Is the source of this information confidential to the laboratory and not 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?		
	Additional Questions		
5	**STRUCTURAL REQUIREMENTS**		
5.1	Is the laboratory a legal entity, or a defined part of a legal entity, that is legally responsible for its activities?		
	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?		
5.3	Has the laboratory defined and documented the range of activities for which it conforms to ISO/IEC 17025?		

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ISO/IEC 17025:2017 – The Internal Audit Checklist
General Requirements for the Competence of Testing and Calibration Laboratories

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	• Do you only claim conformity with ISO/IEC 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?		
	• 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?		
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?		
	• Specified the responsibility, authority and interrelationship of all personnel who manage, perform, or verify work affecting the results of lab activities?		
	• Documented the procedures needed to ensure the consistent application of the lab activities and the validity of the results?		
5.6	Does your laboratory have personnel who, regardless of other responsibilities, have the authority and resources needed to carry out their duties?		

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ISO/IEC 17025:2017 – The Internal Audit Checklist
General Requirements for the Competence of Testing and Calibration Laboratories

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	Do the duties of the personnel include:		
	• Implementation, maintenance, and improvement of the management system?		
	• Identification of deviations from the management system or from the procedures for performing lab activities?		
	• Initiation of actions to prevent or minimize any deviations?		
	• Reporting to laboratory management on the performance of the management system and any need for improvement?		
	• Ensuring the effectiveness of lab activities?		
5.7	Does the laboratory management ensure that:		
	• Communication takes place regarding the effectiveness of the management system and the importance of meeting customer and other requirements?		
	• The integrity of the management system is maintained when changes to the management system are planned and implemented?		
	Additional Questions		

ISO/IEC 17025:2017 – The Internal Audit Checklist
General Requirements for the Competence of Testing and Calibration Laboratories

6	RESOURCE REQUIREMENTS		
6.1	**General**		
	Does the laboratory have available the personnel, facilities, equipment, systems, and support services needed to manage and perform the lab activities?		
	Additional Questions		
6.2	**Personnel**		
6.2.1	Are all internal or external laboratory personnel that could influence the lab activities competent, work in accordance with the management system and act impartially?		
6.2.2	Have you documented the competence requirements for each function influencing the results of lab activities, including requirements for education, qualification, training, technical knowledge, skills, and experience?		
6.2.3	Does the laboratory ensure that the personnel have the competence to perform lab activities for which they are responsible and to evaluate the significance of deviations?		
6.2.4	How does the laboratory management communicate to personnel their duties, responsibilities, and authorities?		

INSERT COMPANY NAME/LOGO HERE

ISO/IEC 17025:2017 – The Internal Audit Checklist
General Requirements for the Competence of Testing and Calibration Laboratories

6.2.5	Do you have procedures and retain records for:			
	• Determining the competence requirements?			
	• Selection of personnel?			
	• Training of personnel?			
	• Supervision of personnel?			
	• Authorization of personnel?			
	▪ Monitoring competence of personnel?			
6.2.6	Does the laboratory authorize personnel to perform specific lab activities, such as:			
	• The development, modification, verification, and validation of methods?			
	• The analysis of results, including statements of conformity or opinions and interpretations?			
	• The reporting, review, and authorization of results?			
	Additional Questions			

ISO/IEC 17025:2017 – General Requirements for the Competence of Testing and Calibration Laboratories
The Gap Analysis Checklist

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This gap analysis checklist is prepared for use in evaluating the requirements for the competence of testing and calibration laboratories against the requirements of the international standard ISO/IEC 17025:2017. Each requirement of clauses 4 through 7 along with the management system requirements of clause 8, is expressed as a question that the user (auditor / assessor) can use to evaluate your laboratory capabilities. You will need to have a copy of the standard to use along with this checklist so that you can refer to the requirements. The intent of the main clauses of the new standard is shown in blue font.

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 standard. 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 focus for this audit. Remember that the outcome of this audit should be a list of things that your company needs to do to have a laboratory management system in compliance with the ISO 17025:2017 international standard.

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 17025:2017 – General Requirements for the Competence of Testing and Calibration Laboratories
The Gap Analysis Checklist

---	GENERAL REQUIREMENTS for the COMPETENCE of TESTING and CALIBRATION LABORATORIES	Currently in Place	Compliant YES / NO?	If No - % Completed	Items Needed
4	**GENERAL 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?				
4.1.2	How does the laboratory management demonstrate commitment to 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?				
4.1.4	Has the laboratory identified risks to its impartiality on an on-going basis?				
	• Does this include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel?				
	With reference to the note in 4.1.4:				
	Is a relationship that threatens the impartiality of the				

INSERT COMPANY NAME/LOGO HERE

ISO/IEC 17025:2017 – General Requirements for the Competence of Testing and Calibration Laboratories
The Gap Analysis Checklist

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	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.?				
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?				
4.2.2	When the laboratory is required by law or authorized by contractual arrangements to release confidential information, is the customer or individual involved notified of the information provided?				
4.2.3	Is the information about the customer obtained from sources other than the customer, such as complainant,				

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INSERT COMPANY NAME/LOGO HERE

ISO/IEC 17025:2017 – General Requirements for the Competence of Testing and Calibration Laboratories
The Gap Analysis Checklist

	or regulators, confidential between the customer and the laboratory?				
	• Is the source of this information confidential to the laboratory and not 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?				
5	**STRUCTURAL REQUIREMENTS**				
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?				
	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?				
5.3	Has the laboratory defined and documented the range of activities for which it conforms to ISO 17025?				

**ISO/IEC 17025:2017 – General Requirements for the Competence of Testing and Calibration Laboratories
The Gap Analysis Checklist**

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	• 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?				
	• 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?				
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?				
	• Specified the responsibility, authority and interrelationship of all personnel who manage, perform, or verify work affecting the results of lab activities?				
	• Documented the procedures needed to ensure the consistent application of the lab activities and the validity of the results?				
5.6	Does your laboratory have personnel who, regardless of other responsibilities, have the authority and resources needed to carry out their duties?				

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![17025Store logo]

Employee Training

ISO 17025:2017

Student Guide

ISO/IEC 17025:2017 OVERVIEW

Technical ISO standard for the competence of testing and calibration laboratories

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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

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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**

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

ISO/IEC 17025:2017 OVERVIEW

Technical ISO standard for the competence of testing and calibration laboratories

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.

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

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.

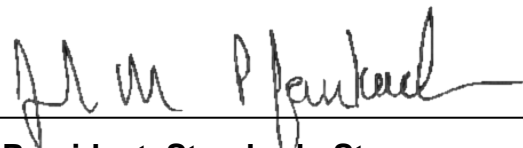# Certificate of Completion

This certifies that

Insert Name

Has successfully completed

IATF 17025:2017 Employee Training

Demonstrating competence by passing the final exam.
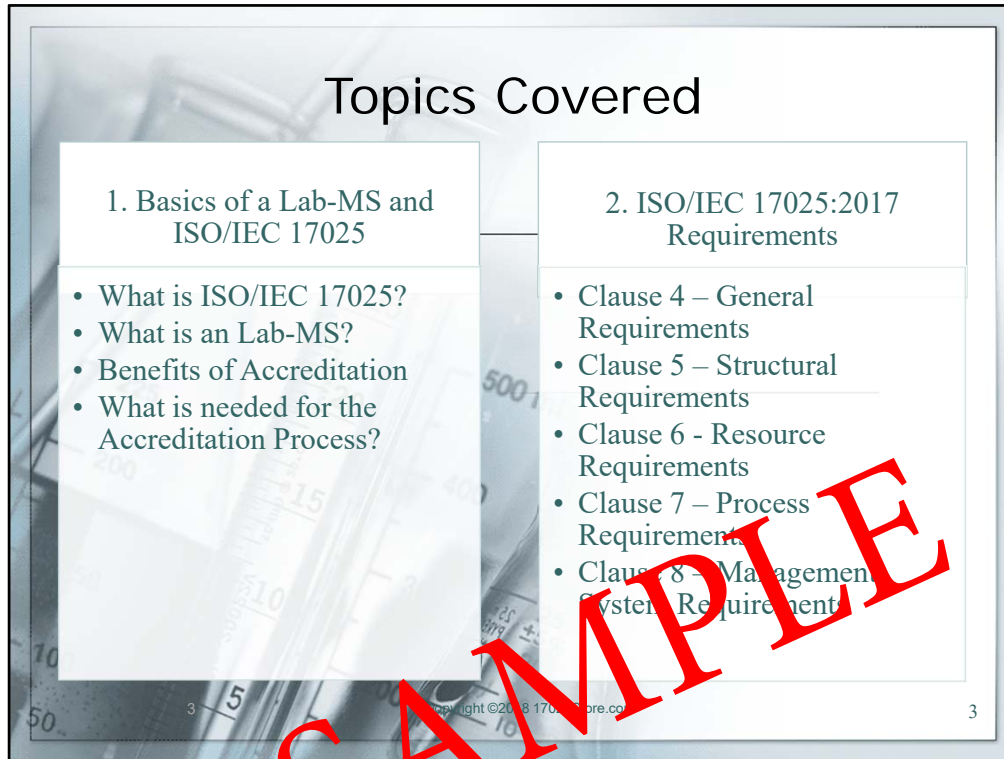
President, Standards-Stores.com

September 12, 2018

Achievement

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Requirements of ISO/IEC 17025:2017

SAMPLE

Trainer Guide

Topics Covered

1. Basics of a Lab-MS and ISO/IEC 17025

- What is ISO/IEC 17025?
- What is an Lab-MS?
- Benefits of Accreditation
- What is needed for the Accreditation Process?

2. ISO/IEC 17025:2017 Requirements

- Clause 4 – General Requirements
- Clause 5 – Structural Requirements
- Clause 6 - Resource Requirements
- Clause 7 – Process Requirements
- Clause 8 – Management System Requirements

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3

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

What is ISO/IEC 17025:2017

- Outlines the basic elements of a laboratory management system (Lab-MS) which support the defined testing or calibration scope of accreditation
- Applies to any organization throughout the world performing any testing or calibration
- Does not mandate across-the-board criteria a company must meet, like a certain "level of quality"
- Does not "rate" your company against others – but proficiency testing reassures both you and the global technical community of your competence and reliability
- Was designed by global experts. After 12-year lag, updated in late 2017
- Has been implemented by over 70,000 organizations globally
- Products in global trade do not need to be re-tested or calibrated at import locations if they have been tested by accredited labs.

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.
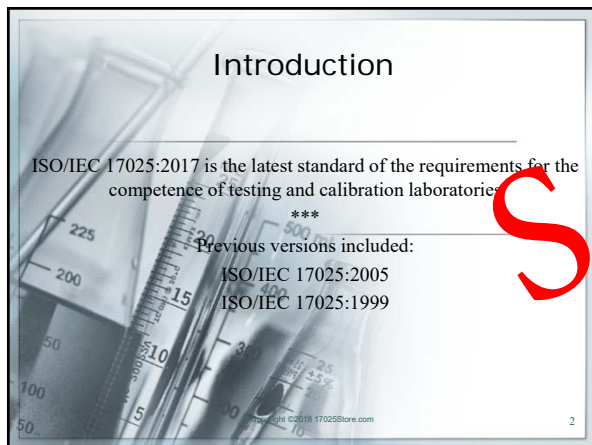
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Requirements of
ISO/IEC 17025:2017

Student Guide

Student's Guide has space for notes

Slide 1

Understanding the Requirements of ISO/IEC 17025:2017

1

Slide 2

Introduction

ISO/IEC 17025:2017 is the latest standard of the requirements for the competence of testing and calibration laboratories

***

Previous versions included:

ISO/IEC 17025:2005

ISO/IEC 17025:1999

2

Slide 3

Topics Covered

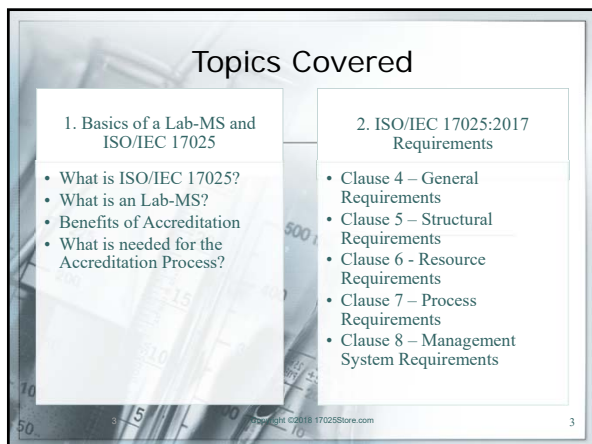| 1. Basics of a Lab-MS and ISO/IEC 17025	2. ISO/IEC 17025:2017 Requirements
• What is ISO/IEC 17025? • What is an Lab-MS? • Benefits of Accreditation • What is needed for the Accreditation Process?	• Clause 4 – General Requirements • Clause 5 – Structural Requirements • Clause 6 - Resource Requirements • Clause 7 – Process Requirements • Clause 8 – Management System Requirements

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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:*

SAMPLE

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

SAMPLE

_____

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.

<u>Notes:</u>
- 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.

4.2 Confidentiality

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.

This means the Laboratory is not to disclose any of this information provided by the clients.

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8.3 Control of management system documents (Option A)

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.

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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:
Date: April 14, 2019	**For Superior Calibration Lab:**
	A Doer, R Ryan, D Delany,
Area(s) audited:	**D Thomas, M T Moore,**
Lab Quality Manual, including	**J Sample, A Bolt,**
Laboratory Facilities,	**+**
Calibration Certificate,	**Auditors: R Richards,**
Equipment and Records,	**A Anderson, R Roberts.**
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**

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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.