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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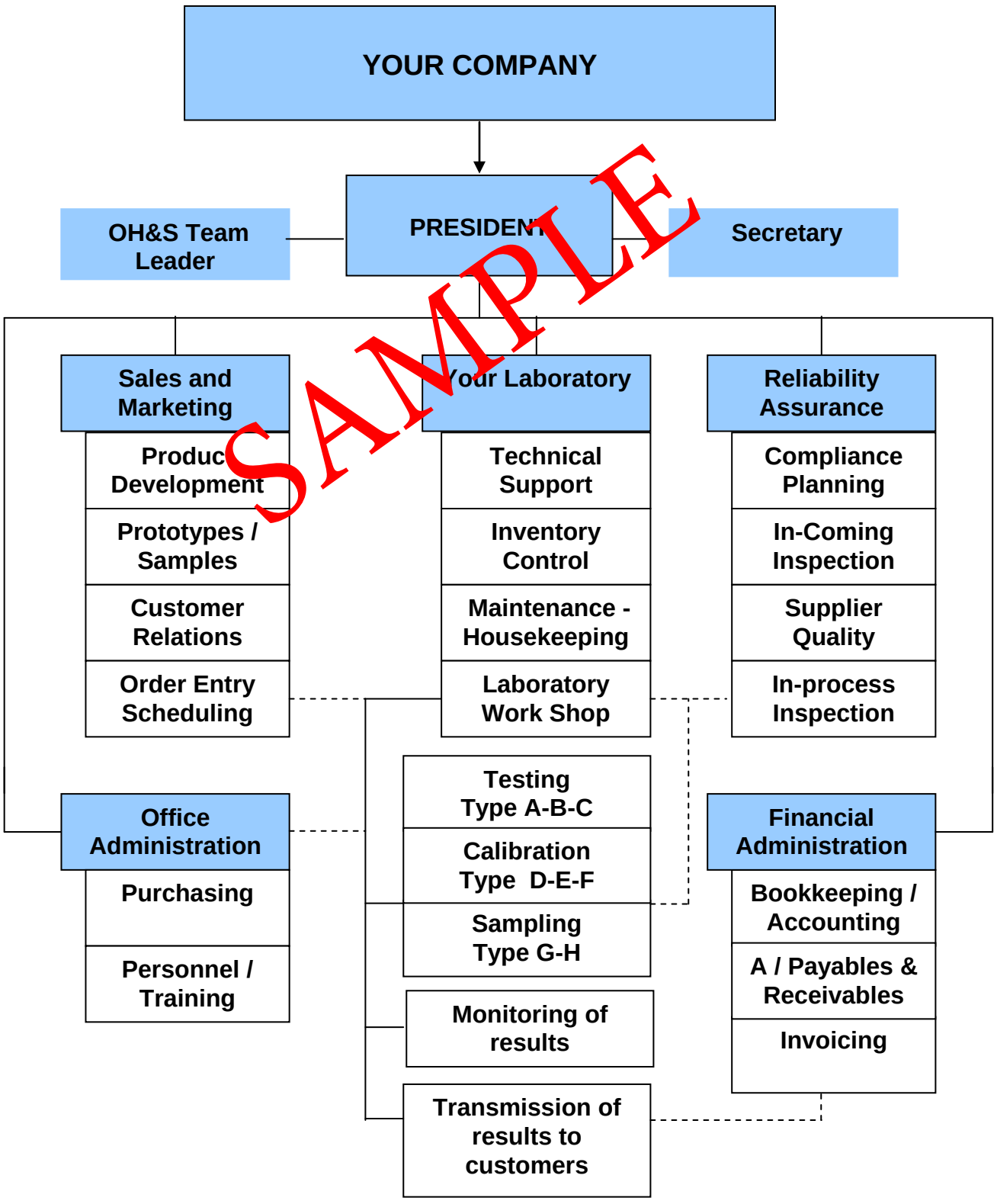
INSERT YOUR COMPANY LOGO/NAME HERE

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.

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.		