

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.

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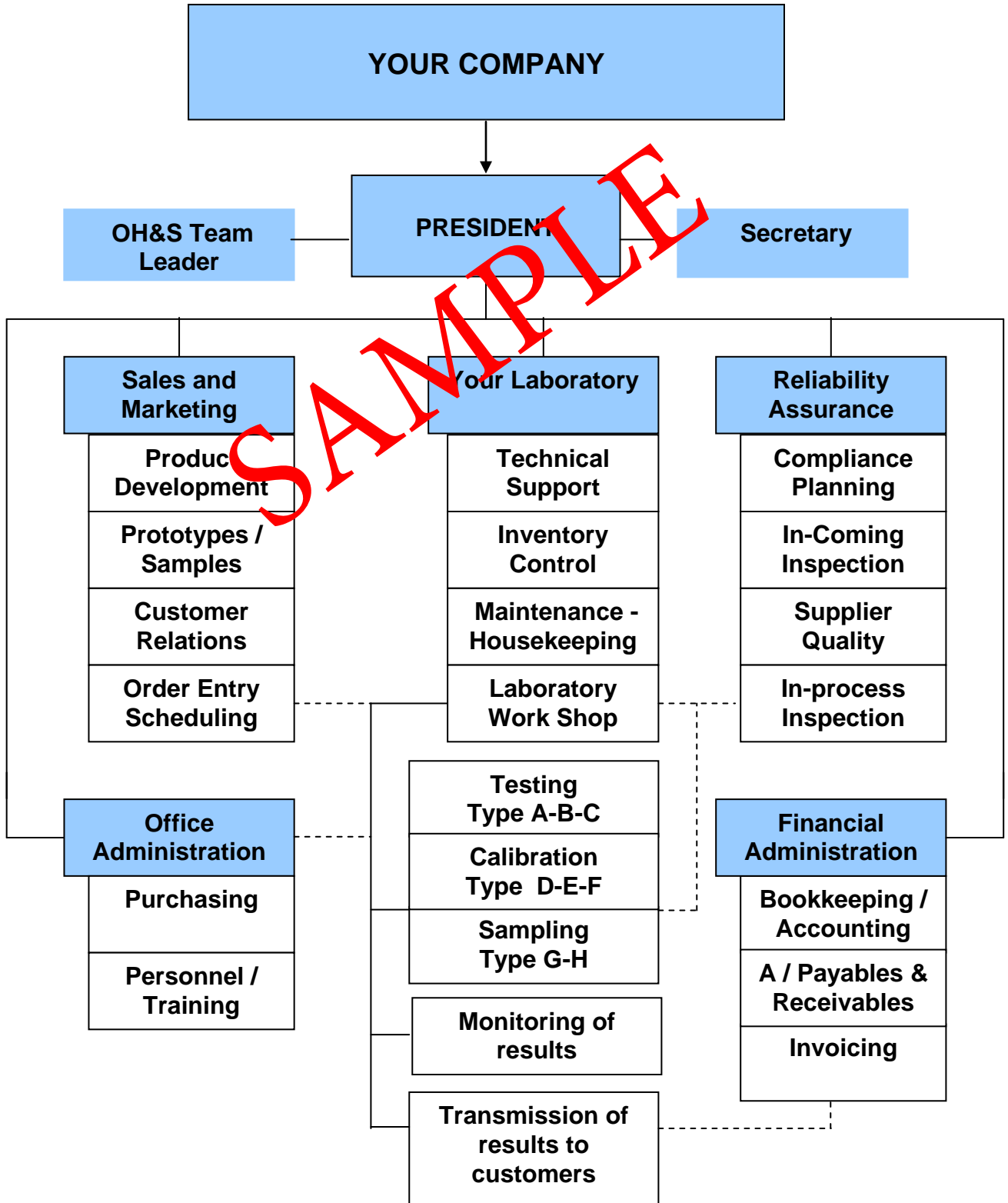
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Example of an organization chart



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 <input type="checkbox"/>	Use AS-IS <input type="checkbox"/>	Scrap <input type="checkbox"/>
Remarks:		
Approved (Signature / Date):	Approved (Signature / Date):	Approved (Signature / Date):
Due Date:	CLOSEOUT	
Customer Authorize: Yes <input type="checkbox"/>	No <input type="checkbox"/>	Customer Authorization Ref.:
Re-inspected: Yes <input type="checkbox"/>	No <input type="checkbox"/>	Inspection Report No.:
Corrective Action: Yes <input type="checkbox"/>	No <input type="checkbox"/>	Corrective Action No.:
Approved (Signature / Date):	Approved (Signature / Date):	

Competence, Awareness and Training

- 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.

Customer Related Processes

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 order 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

LMS-Monitoring, Analysis, and Evaluation

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](#) ensures 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.