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.

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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.		
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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.		