

PJLA

ISO/IEC 17025:2017 Transition

An Overview of the Changes between
17025:2005 and 17025:2017

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ISO/IEC 17025:2017 Transition

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Foreword

Implementing an ISO/IEC 17025 laboratory management system is a means to ensuring efficiency and technical competency in calibration and testing laboratories. An ISO/IEC 17025 accreditation certificate will show potential customers that your laboratory values quality and that you have taken the steps to ensure that your calibration or testing results are accurate and reliable.

ISO/IEC 17025 accreditation is available for both freestanding laboratories and for laboratories which are part of larger facilities. If you want to solidify your laboratory's rank as a serious competitor, it is imperative that your laboratory management system comply with ISO/IEC 17025.

This booklet regarding the ISO/IEC 17025:2017 transition was created by Perry Johnson Laboratory Accreditation, Inc., to give laboratories interested in learning about the ISO/IEC 17025:2017 transition a clear understanding of the complete process. We hope that this material will provide you with insight and assist you with taking the necessary next steps towards a successful transition.

Tracy Szerszen
PJLA President/Operations Manager



ISO/IEC 17025 Transition

The new ISO/IEC 17025:2017 Standard is making progress within the ISO community. The basic format is similar to other recently revised standards, such as ISO/IEC 17020 (Inspection) and ISO 17034 (Reference Material Production), but is more aligned with ISO 9001:2015 principles on resources and processes. There is an Option A and B introduced in the 2017 Standard, which primarily hinges on the laboratories established compliance in accordance to ISO 9001:2015. In addition, Informative Annexes have been added to aid in the interpretations of the standard, as well metrological traceability.

In comparison to ISO/IEC 17025:2005, the revised 2017 Standard requires labs to implement a risk-based thinking process, which will reduce the former prescriptive requirements and performance based requirements. This revision will allow greater flexibility in the requirements for processes, procedures, documented information, and organizational responsibilities. A definition of 'laboratory' has been added, along with the term 'decision rule', which describes how measurement uncertainty is taken into account when stating conformity with specified requirements. Other differences include the addition of requirements on externally provided products and services, which incorporates requirements for both purchasing and subcontracting, as well as an expansion on the requirement for documented processes associated with customer complaints.

Perry Johnson Laboratory Accreditation, Inc. will be provided a transition period to convert all laboratories to the new 17025:2017 Standard. Laboratories already accredited can transition during this time, either on their reassessment, surveillance, or on a separate assessment. To help with the transition process, PJLA is offering training via free webinars, in addition to physical, on-site courses. To ensure that you receive notifications of any upcoming training events or webinars, please subscribe to our mailing list on our home page at www.pjlab.com.

Please note that we have previously provided a summary of the changes to the standard via webinar, which can be downloaded from our website at www.pjlab.com/training/pjla-webinars/past-webinars.

The Main Changes

Structure

The new standard is aligned with ISO 9001:2015's principles on resources and processes. There is an Option A and B introduced in the new standard, which will primarily hinge on a laboratory's established compliance in accordance to ISO 9001:2015.

The terminology has been updated to be more aligned with today's world. Also, the fact that hard-copies of manuals, records, and reports are slowly being phased out in favor of digital versions has been taken into consideration. The scope of the standard has been amended to now include sampling facilities. An example of these updates include changes to the International Vocabulary of Metrology (VIM) and alignment with ISO/IEC terminology, which has a set of common terms and definitions for all standards dedicated to conformity assessment.

Terms and Definitions – 9 Definitions Added

Impartiality - *presence of objectivity*

Complaints - *expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected.*

Inter-Laboratory Comparison - *organization, performance, and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.*

Intra-Laboratory Comparison - *organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions.*

Proficiency Testing - *evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons.*

Laboratory - *body that performs one or more of the following activities: testing – calibration – sampling, associated with subsequent testing or calibration.*

Decision Rule - *a rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.*

Verification - *provision of objective evidence that a given item fulfils specified requirements.*

Validation - *where the specified requirements are adequate for an intended use.*

Interpretation Verbs

“Shall” - indicates a requirement;

“Should” - indicates a recommendation;

“May” - indicates a permission;

“Can” - indicates a possibility or a capability



ISO 9001 Principles

The revised 17025:2017 Standard puts emphasis on the results of a process management approach, as opposed to the detailed description of required procedures and policies. Formally, ISO 17025:2005 was more prescriptive, deterring laboratories from having the flexibility to incorporate their desired inputs to achieve their desired outputs.

Laboratories will now be required to consider risk within their laboratory management system on an on-going basis. This will prevent and/or reduce undesirable impacts and potential failures while improving overall laboratory activities.

Information Technology

The 2017 Standard is tailored more for today's electronic age and the use of computers. Hard copies of documents and records being utilized in laboratories are far less prevalent than they were in 2005. In turn, a section has been added, Section 7.11, which is the control of data and information management.



ISO/IEC 17025:2017 incorporates the use of computer systems, electronic records, and the production of electronic results and reports. Modern-day laboratories work continuously with information and communication technologies, so it was necessary to develop a chapter on this topic.

Management System - Option A vs. Option B

One thing that stands out with the new 2017 Standard is the concept of an Option A or Option B. If a Quality Management System was written to comply with the 17025 Standard, without incorporating the requirements of ISO 9001, then a laboratory would fall under Option A. Therefore, the accreditation body would assess to those requirements stated in the 2017 Standard.

If an organization has written its Quality Management System to comply with ISO 9001:2015, then a laboratory may fall under Option B. Option B recognizes that laboratories that have already certified to ISO 9001 comply with similar requirements outlined in the new ISO/IEC 17025:2017. However, this does not demonstrate the competence of a laboratory to produce technically valid data and results. This will be accomplished through compliance with clauses 4 to 7 of ISO/IEC 17025.

Accreditation bodies have the option to recognize an accredited ISO 9001 laboratory's Quality Management System and adjust their assessment accordingly. They will still look to ensure that testing, calibration, and sampling activities are all still addressed within the QMS.

General Requirements |4.0|

Impartiality

ISO/IEC 17025:2017 defines impartiality as “*presence of objectivity*”. The issue of impartiality is magnified in the 2017 Standard, so a new section, 4.1, was created for dealing with impartiality. It is now more important for laboratories to show how they have handled these issues. The laboratory management shall be committed to impartiality. This can be demonstrated by various means including:

- Regular documented management reviews that address threats to impartiality
- Defined written policies and procedures to minimize threats to impartiality
- Documented training and agreements of staff, including management, on potential threats to impartiality

Responsibility for impartiality is now placed on a laboratory, meaning it is no longer specific to having policy and procedures in place. It is now required to identify risks to impartiality on an ongoing basis. This shall include those risks that arise from its activities, relationships, or from the relationships of its personnel. Some relationships that may threaten impartiality may include:

- Ownership
- Governance
- Management
- Personnel
- Shared resources
- Finances
- Marketing (including branding)
- Payment of a sales commission

4.1.4 “The laboratory shall identify risks to impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel.”

4.1.5 “The lab shall be able to identify how it eliminates or minimizes such risks.”

A term that is often associated with risk-based thinking is *Mitigated Risk*. This can be thought of as a known risk that has been lowered to an acceptable level by the conduct of planned mitigation actions and/or events. Identifying these risks can be demonstrated by evaluating the procedure, policy, or process put in place and determining whether the risk has been eliminated or reduced to an acceptable level. Creating awareness to staff and management will help minimize potential threats to impartiality.

Confidentiality

Confidentiality is addressed in the 2005 Standard, however, the 2017 Standard has more text and is more detailed. However, the basic requirements have not changed. A laboratory is required, through legally enforceable commitments, to keep information confidential. Legally enforceable commitments can be thought of as law governing, contractual agreements.

If required by law or contractual agreement, the customer must be notified; the only exception would be if prohibited by law. Information obtained by sources other than the customer is considered private and these parties shall keep all information confidential.

Laboratories will be required to inform customers in advance of any information that will be placed in a public domain. The only exceptions would be if the information is already publicly available or other former agreements have been made. This can include test/calibration reports, customer lists, procedures, and employee names.

Structural Requirements | 5.0 |

As required previously, a laboratory must be a legal entity. There has been a note added which clarifies that government laboratories are considered legal entities based on their government status.



In the 2005 Standard, there were specific requirements in regards to a technical and quality manager. These terms do not appear in the 2017 Standard, however all laboratories are required to identify any management that has overall responsibility for the lab. This can be a quality and technical manager, however it is no longer required.

Requirements specific to responsibilities, along with having appropriate resources and authority to carry out these responsibilities, is defined within the 2017 Standard. As specified earlier, a quality manager can still be utilized to fulfill these requirements, however, it is not required. These responsibilities no longer have defined titles and can be the responsibility of a team. These responsibilities include:

- Implementation, maintenance and improvement of the management system
- Identification of deviations from the management system or from the procedures for performing laboratory activities
- Initiation of actions to prevent or minimize such deviations.
- Reporting to laboratory management on the performance of the management system and any need for improvement
- Ensuring the effectiveness of laboratory activities

The term *Scope of Activities* has been replaced with *Range of Laboratory Activities*. More so, Section 5.3 specifies that a laboratory shall define and document the *Range of Laboratory Activities* to conform to this document. As specified in the 2005 Standard, requirements associated with laboratory activities include actions performed in permanent facilities, in sites other than permanent facilities, in temporary and/or mobile facilities, or in a specific customer's facility.

Resource Requirements | 6.0 |

General

A laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

Personnel

Impartiality and confidentiality appear again in regards to all personnel involved in laboratory activities. This covers personnel involved directly in laboratory activities, as well as internal auditors, purchasing, or maintenance personnel. The concept of contracted personnel meeting the same requirements as permanent personnel, as previously stated in the 2005 Standard, is implied by referencing internal or external personnel.

Laboratory management is responsible to communicate to all personnel their duties, responsibilities, and authorities. There is no longer a requirement for formal job descriptions, as was specified in the 2005 Standard. On the other hand, a job description can now be utilized to communicate to personnel and comply with this clause. In other words, a job description can still be utilized to support compliance with the standard.

The 2005 Standard stated that a laboratory had to capture a date of competence when an individual was authorized to perform a specific test or calibration. A laboratory is still required to record the authorization of personnel, however it is not pinpointing a date of competence, which was previously a requirement.



Something new in this 2017 Standard is the monitoring of personnel. The lab should address this in a procedure and maintain records of the monitoring. For example, this can be the successful completion of proficiency or intra lab testing conducted in the laboratory or the checking of personnel's produced results.

Facilities & Environment

With the exception of some minor changes, everything is intact from the 2005 Standard. However, the 2017 Standard specifies that a laboratory shall ensure that the requirements related to facilities and environmental conditions of this document are met. In instances where perhaps the environmental condition, such as temperature, is outside the specified limits, additional requirements specified for handling of test or calibration items and reporting of results would need to be followed.

Equipment

Overall, the requirements captured in the 2005 Standard are still utilized with some minor changes. The 2017 Standard incorporates the same requirements for having access to the proper equipment, ensuring requirements are met if equipment is not in labs permanent control and having procedures for the safe handling and transport of equipment.

The new 2017 Standard also specifies the requirement to verify equipment conforms to specified requirements before being placed or returned into service. This is stated differently from what is in the 2005 Standard, which specifies that that equipment needed to be calibrated or checked to establish that it meets the laboratory's specification requirements. The 2017 Standards gives specific requirements as to when a calibration is required.

Also as specified in the 2005 Standard, 2017 is specific about the requirement in which equipment being used for measurement being able to achieve measurement accuracy and/or measurement uncertainty required to provide a valid result.

The concept of a calibration program is not anything new as establishing a calibration program was a requirement in the 2015 Standard. The 2017 Standard, however, requires review and adjustment if needed of the calibration program.



The 2005 Standard required equipment to be labeled where practical to identify the calibration status. Equipment calibration status still needs to be inventible in the 2017 Standard, however it specifies that the calibration status needs to allow the user to readily identify the status. Therefore the concept of a calibration label being placed on the equipment is not required, however the label on the equipment can be used to comply by allowing the user to readily identify the calibration status.

Metrological Traceability

As stated in the 2005 Standard, ISO 17025: 2017 is specific in regards to establishing and maintaining traceability, as well as ensuring that traceability is to the International Units of Units. There has been an informational Annex A added to the 2017, which is informational and closely correlates to the requirements specified in PJLA Policy on Measurements Traceability. Included in this is the utilization of ISO 17025 accredited laboratories as a means of achieving traceability.

Externally Provided Products & Services

The final section under Resource Requirements is externally provided products and services. This section incorporates both purchasing and subcontracting, which had their own sections in the 2005 Standard. The 2005 Standard required that the laboratory list approved suppliers, however, there is no longer a requirement for the list. Due to the electronic environment which we operate in today, it is no longer required.

The 2017 Standard has added a requirement for records and procedures maintained for monitoring and reevaluation of their externally provided products and services. The 2017 states that laboratories are required to communicate their requirements to their vendors. For example, if a lab elects to utilize a purchase order as a means of communicating their requirements, it is still permissible, though not required.

Process Requirements | 7.0 |

Review of Requests, Tenders, and Contracts

Review Request, Tenders, and Contracts concerning reviewing work request and establishing that the laboratory has the capabilities to perform the submitted work are intact. The requirement specifies that when the customer requests a statement of conformity to a specification or standard for the test or calibration, the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with the customer.

Uncertainty may effect when a statement such as pass/fail or in tolerance/out of tolerance is specified on a report. It has always been required that uncertainty be taken into account, but 2017 specifies how this is taken into account. It must be communicated and agreed to up front prior to testing or calibration.

Added Definitions:

Verification:
provision of objective evidence that a given item fulfils specified requirements.

Validation:
where the specified requirements are adequate for an intended use.

Validation of Methods

In general, not many changes in the validation of methods requirements themselves. The section has been re-organized, mainly to differentiate between when the lab has to verify that it can properly perform methods, as opposed to when the lab has to validate methods.

The requirements for validation are still in place, but the 2017 Standard is more specific concerning records that needs to be maintained.

Sampling

A laboratory shall have a sampling plan and method when it carries out sampling of substances, materials, or products for subsequent testing or calibration. The note added to the 2017 standard implies that sampling is different than subsampling.

Additions to these requirements captured in the 2017 Standard include:

- Date and time of sampling
- Data to identify and describe the sample such as number, amount, name
- Identification of the equipment used
- Transport conditions
- Deviations, additions to the exclusions from the sampling method and sampling plan



Handling of Items

A laboratory is still required to maintain a procedure for the handling of test and calibration items. A system for uniquely identifying test or calibration items has been further clarified by adding the word 'unambiguous' in front of identification. The 2017 Standard also requires any relevant environmental conditions when items are stored or conditioned be recorded.

Deviations from specified conditions, such as temperature or humidity, have been expanded on within the 2017 Standard. If conditions are outside prescribed limits it must be discussed with the customer. A record of this consultation needs to be made. If the customer would like the test or calibration to proceed outside of these prescribed limits, a disclaimer would be required to be documented on the final report.

Technical Records

Technical Records are also captured in the 2017 Standard. Whereas both quality and technical record were both captured in the 2005 Standard, quality records are covered separately in a separate section of the 2017 Standard. This updated section is more in-tune with the electronic age, therefore references to 'cross out', 'erased', and 'signed' do not appear.



The basic requirement for technical records remains intact. Laboratories are required to maintain records needed to duplicate the original test or calibration. This would include such things as the personnel involved, raw data obtained, or any pertinent environmental conditions.

Amendments to technical records still fall under the realm of 17025 requirements. The lab has flexibility in how to comply with the requirements, but the change needs to be tracked to the original record and must include the specific personnel making the change and date of change.

Uncertainty

Measurement uncertainty was captured in the 2005 Standard within the Section on Test and Calibration methods and method validation. The 2017 standard has devoted a section as the Evaluation of Measurement Uncertainty.

There is no longer a requirement for a procedure in determining uncertainty associated with calibrations. The 2017 standard is focused on identification of the significant uncertainty contributors. Although not required, this can still be accomplished through a procedure.

Validity of Results

Ensuring the validity of results corresponds to "Assuring the Quality of Test and Calibration Results" from the 2005 Standard. This section is divided into internal means along with means of comparisons with external results.

A laboratory participating in proficiency testing is an additional requirement not captured in the 2005 Standard. This would be through a proficiency testing provider. Or the laboratory would have to participate in an inter laboratory type comparison. The standard states the lab must participate in either or both.

PJLA addresses where it may not be feasible to perform a proficiency test or inter-laboratory comparison in PJLA PL-1 regarding proficiency testing. If this is the case, the laboratory may be permitted to perform an intra-lab type comparison and under rare circumstance, repeatability studies may be permissible. If the organization feels they qualify and cannot comply, then PJLA would look at the preface “where available and appropriate”. In these cases, the organization must state, in writing, why a proficiency test or inter-laboratory comparison is not feasible. In addition, they must state how they plan to conduct the intra-lab test or repeatability study to analyze the results in a meaningful way. These requests would then be submitted to PJLA headquarters and evaluated on a case-by-case basis for approval.

The requirement of analyzing data and the determination that the data falls within predefined limits of acceptance is carried over to the 2017 Standard. In addition, a new requirement brings forth that the monitoring activities also be used to control and, if applicable, improve laboratory activities.

Reporting of Results

We find the section on Reporting of Results under general requirements now includes a specified requirement that all reports be reviewed and authorized prior to release. In regards to simplified reporting to the external customer, this is something that still needs to be agreed. However, the requirement for a written agreement is no longer specified in the 2017 Standard. Any information not reported however is still required to be available.

All the common elements specified in Section 5.10.2 of the 2005 Standard are all captured in the 2017 Standard however there are a couple of additions which include:

- The date of issue of the report
- Clear identification when results are from external providers; i.e. subcontractors

Additional Tools

- *The use of alternative instrumentation that has been calibrated*
- *Functional check(s) of measuring and testing equipment*
- *Review of reported results*
- *Intra-laboratory comparisons*
- *Testing of blind samples*

NEW “Key Points”

- *Lab shall be responsible for all information in the report, except when information is provided by the customer*
- *Data provided by the customer shall be clearly identified*
- *Disclaimer put on the report when the information is supplied by the customer and can affect the validity of the results*
- *When the sample is provided by the customer, it shall state in the report that the results apply to the sample “as received”*

ISO 17025:2017 no longer prefaces calibration labs with the preface and/or a statement of compliance. The 2017 requirement is straight forward in that the uncertainty is required to be reported on calibration certificates.

The 2017 Standard also has an entire section under reporting of results devoted to making statements of compliance such as pass/fail, in tolerance/out of tolerance. The changes to reporting statements of compliance centers around the decision rule. The decision rule is how measurement uncertainty is taken into account. The decision rule applied needs to be communicated and agreed upon with the customer. It is then required to document the decision rule on the report.

Two additional requirements captured in the 2017 Standard, in regards to opinion and interpretations, are noted. This includes the insertion of authorized personnel when made on the report, as well as any dialog concerning opinion and interpretation. These will both need to have an accompanying record.

The final section in reporting the results concerning when an issued report needs to be changed, amended or re-issued. Any change of information shall be clearly identified and, where appropriate, the reason for the change is to be included in the report.

Complaints

The 2017 Standard heightens awareness concerning complaints and brings forth some significant changes in this area. The 2017 Standard requires a documented process. A formal policy and procedure is no longer required however a procedure can still be used as a documented process. If in place, it may need to be revised to capture additional requirements.

The 2017 Standard specifies that the laboratory is required to make available its process for handling complaints to any interested party. It specifies that if a confirmation is obtained, then the complaint received is associated with laboratory activities. If so, it specifies that the laboratory is responsible for all decisions at all levels regarding the complaint.

The ISO/IEC 17025:2017 Standard specifies that the lab is required to gather, verify and validate the complaint. The accuracy to the information needs to be confirmed.

The 2017 Standards requires that the lab keep the complainant in the loop. This includes the acknowledgement of the receipt of the complaint along with the progress reports including the final outcome. It is specific in that the outcome to be communicated to the complainant needs to be reviewed and approved by personnel not involved in the original laboratory activities in question.

Required Elements for Capturing Complaints:

- *A description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;*
- *The tracking and recording complaints, including actions undertaken to resolve them;*
- *Ensuring that any appropriate action is taken*

Nonconforming Work

Section 7.10 of the 2017 Standard is the section on Nonconforming Work, which is Section 4.9 of the 2005 Standard. This section brings forth no new requirements, as laboratories are still required to have these procedures in place. All records need to be maintained and, if needed, corrective action shall be implemented.



Control of Data

The final section under process requirements is the control of data and information. The climate today, as opposed to 2005, revolves much more around the use of computers and electronic records. Also, any needed instructions, manuals and reference data relevant to the laboratory information management system(s) must be made readily available to all personnel. In addition, any calculations and data transfers are required to undergo regular, appropriate checks.

The requirements concerning having needed access for laboratory activities, including the validation of software, incorporates the modification of off-the-shelf software. A new addition to the 2017 Standard is a requirement that the information management system must include any recording system failures to include immediate corrective action. Meaning this would address any possible system crashes. In addition, if the information management system is maintained off site or through an external provider, the requirements of ISO 17025 must still be met.

Management System Requirements |8.0|

The entire Section 8 of ISO 17025:2017 specifies to Option A. Section 8.1 specifies the differences between Option A and B. As mentioned earlier in the document, an Option A facility will comply with all the requirements specified in Section 8 of the 2017 Standard. The assessment body will assess the lab against the requirements as listed in the 2017 Standard. Option B maintains a quality management system that is compliant with ISO 9001. As far as the level that the accreditation body needs to assess is currently placed in the hands of the specific accreditation body.

For the purpose of this Transition Guide, we will focus on the requirements of Section 8 in the 2017 Standard and highlight the differences between the 2005 and 2017.

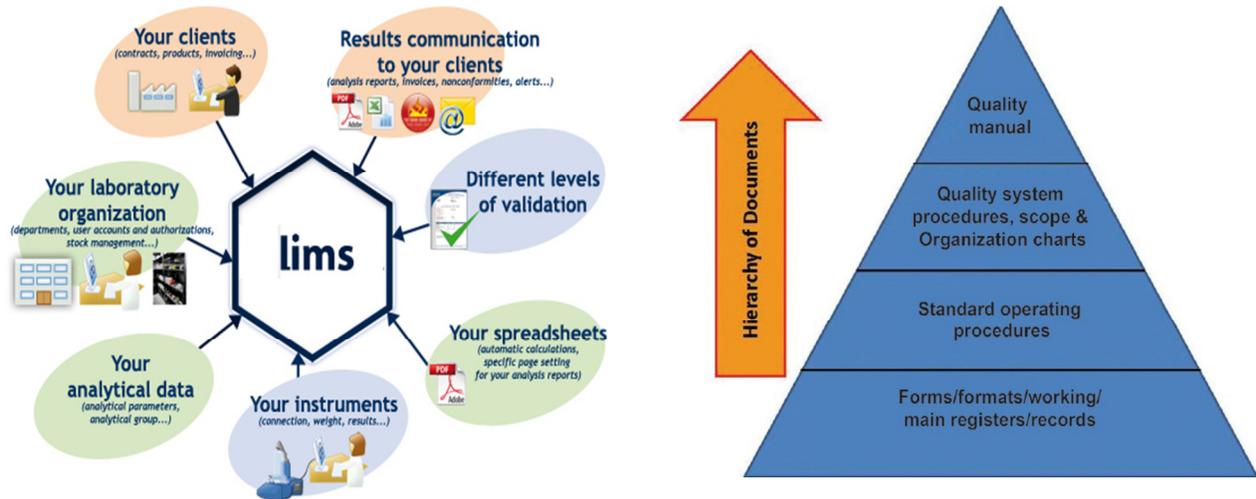
Management System Documentation

The second section is Management System Documentation. The 2017 Standard is less prescriptive than the 2005 Standard, as the 2017 Standard requires policies and objectives be set, but not specific to a prescriptive quality policy statement, as documented in the 2005 Standard.

The 2017 Standard does, however, bring competence and impartiality into management system documentation and requires that these items be addressed. A laboratory needs to ensure that its management system documentation provides a consistent operation of laboratory activities. Decisions as to how this is achieved will be put into the hands of the laboratory. A formal quality policy statement can still be used to communicate objectives of the organization, but it is not a requirement. Also, the requirement to maintain a formal quality manual is no longer a requirement under the 2017 Standard.

The requirement for commitment to the development and implementation of the management system and continually improving effectiveness is still in place, however the 2017 Standard is specific to 'management' as being 'laboratory management'.

As already stated, there is no requirement for a quality manual, however it can still be used. There is also no requirement specifying that if one is going to be used that it needs to realign itself with the 2017 Standard. Yet, all documentation, processes, systems, records, related to the fulfilment of the requirements shall be included in, referenced from, or linked to the management system.



Either one of these two methods above happen to fulfill the requirements stated in the new 2017 Standard. It is written to allow the utilization of electronic systems, but does not ignore the paper systems that labs employed with the development of their ISO 17025: 2005 compliant quality management systems.

Control of Management System Documentation

Both standards intent in terms of Control of Management System Documents is for the control of both internal and external documents. This Section in 17025:2017 is less prescriptive than 2005. There is no requirement for a formal procedure, but the laboratory has to ensure that the requirements are met. A formal procedure can still be used to communicate the labs requirements and ensure all applicable requirements are being met.

A laboratory is **required** to ensure:

- Documents are approved prior to issue by authorized personnel;
- Documents are periodically reviewed, and updated as necessary;
- Changes and the current revision status of documents are identified;
- Relevant versions of are available at points of use and, where necessary, their distribution is controlled;



- Documents are uniquely identified;
- The unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

As opposed to 2005, the requirement for the utilization of a master list is not specified in the 2017 Standard. However, if a lab chooses, it can utilize a master list as a vehicle to control its documents and ensure the requirements specified in the 2017 standard will be met.

Control of Records

In terms of the control of records, all the requirements from the 2005 Standard are intact. Records refers to quality records, such as internal audits, management reviews, and corrective action. In 17025:2017, the need for a formal procedure has not been specified. A laboratory is given flexibility on how it chooses to ensure that the requirements are met.

Addressing Risks and Opportunities

ISO/IEC 17025:2017 states in its introduction: “This document requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.”

If a laboratory knows its risks, it has the capability to assess/prioritize them. Dealing with risks and opportunities in the laboratory is not a novelty. The previous version of 17025 used the term ‘risk’ at any chapter, particularly in the context of corrective and preventive actions. In the introduction of the ISO 17025:2017 Standard it specifies that the standard requires the laboratory to plan and implement actions to address risks and opportunities.

There are many formal methods such as SWOT analysis, Fishbone diagrams, or Paerto Charts, in which a laboratory can utilize as a vehicle to implement risk based thinking. However, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by the standard, through the application of other guidance or standards.

Improvement

One term that you do not see in the 2017 is ‘Preventive Action’. Though not mentioned by name, the concept of preventive action would be captured within this section of the new standard.

Similarly to 2015, Laboratories are required to seek customer feedback. 2017 does not include a separate category for ‘Service to the Customer’, as was in 2005, but the requirements are incorporated within the 2017 Standard.

Key Differences:

- *More LIMS focus from “Information Management”*
- *No longer references to hand-written amendments*
- *No “Master List” as required in the 2005 Standard*

Corrective Actions

There are a couple of changes which were brought forth by the 2017 Standard in terms of corrective actions. The 2017 Standard recognizes that there may be more than a single root cause that needs to be addressed, therefore the term 'Root Cause' has been replaced by 'Cause(s)'. In addition, risk and opportunities determined during planning have been brought into corrective action and the need to update them, if need be, during planning.

Internal Audits

Similarly to 2005, the objective of the internal audit is compliance. This includes compliance to the 17025 Standard along with compliance to the organizations quality management system, as well as requirements of the accreditation body. There are a few changes, including the wording that internal audits are to be conducted at planned intervals. This is in contrast to the 2005 Standard, which specified a predetermined schedule. We also see an additional requirements that the results of previous audits need to be taken into account and that the results of the internal audit be reported to management.

ISO/IEC 17025:2017 states that all personnel of the laboratory, internal or external, that could influence the laboratory activities shall act impartially, be competent, and work in accordance with the laboratory's management system. 2005 stated that audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. However, this specification would be captured under personnel in regards to the impartiality and competence requirements.

Inputs to Management Review Shall Include:

- a) Changes in internal and external issues that are relevant to the laboratory;*
- b) Fulfilment of objectives;*
- c) Suitability of policies and procedures;*
- d) Status of actions from previous management reviews;*
- e) Outcome of recent internal audits;*
- f) Corrective actions;*
- g) Assessments by external bodies;*
- h) Changes in the volume and type of the work or in the range of laboratory activities;*
- i) Customer and personnel feedback;*
- j) Complaints;*
- k) Effectiveness of any implemented improvements (continued next slide)*
- l) Adequacy of resources;*
- m) Results of risk identification;*
- n) Outcomes of the assurance of the validity of results; and*
- o) Other relevant factors, such as monitoring activities and training.*

Management Reviews

Management review would ideally provide a laboratory opportunities for improvement. Like internal audits, the 2017 Standard requires management review's be conducted at planned intervals.

Exclusively new in the 2017 Standard, we turn our attention to outputs. The requirement here will force the hand of the organization in providing these outputs, which include:

- The effectiveness of the management system and its processes;
- Improvement of the laboratory activities related to the fulfilment of the requirements of this document;
- Provision of required resources;
- Any need for change.

About Perry Johnson Laboratory Accreditation, Inc. (PJLA)



PERRY L. JOHNSON

A company built upon a solid foundation in quality, PJLA knows the field of laboratory quality and thoroughly understands the assessment and accreditation process. PJLA was founded by Perry L. Johnson, one of the world's top experts and authors on ISO 9000 and a leading educator on the theories and practices of Total Quality Management. Based on its heritage, its vast experience in the field of laboratory accreditation, and the expertise of its assessment staff, PJLA is destined to become a prominent and respected accreditation body in the United States.

PJLA is a full-service accreditation body with technical experts and technical assessors on staff. PJLA's technical assessors have years of experience in testing and calibration fields. They have undergone training in ISO/IEC 17025 and other relevant training sessions. PJLA has selected our assessors to conduct ISO/IEC 17025 services due to their extensive work experience in testing or calibration and their years of experience in ISO/IEC 17025 assessing practices.

PJLA is a MRA Signatory of the International Laboratory Accreditation Cooperation (ILAC) and of the Asia Pacific Laboratory Cooperation (APLAC).

With the recognized support of international organizations, our firm will be able to provide tremendous marketing and business advantages to our accredited laboratories, especially those with foreign business interests.

For more information on PJLA's accreditation services, please call: (248) 519-2603, email us: pjlabs@pjlabs.com or write to: Perry Johnson Laboratory Accreditation, Inc., 755 West Big Beaver Road, Suite 1325, Troy, Michigan, 48084 USA.