Option A and B as Presented in ISO/IEC 17025:2017 Along with the Management System Documentation (8.2)

Presented by:

Michael Kramer

Calibration/Inspection Program Manager

PERRY JOHNSON LABORATORY ACCREDITATION, INC. (PJLA)

25-June-2020; 1:00 PM - 2:00 PM EDT

Option A and B as Presented in ISO/IEC 17025:2017 Along with the Management System Documentation (8.2)

This webinar is being recorded and will be available in it's entirely on the Perry Johnson Laboratory Accreditation Website.

www.pjlabs.com

Go to the link for recorded webinars.

Duration of webinar is set for one hour.

You can type any questions directly into your webinar box; We will review them at the conclusion of today's session;

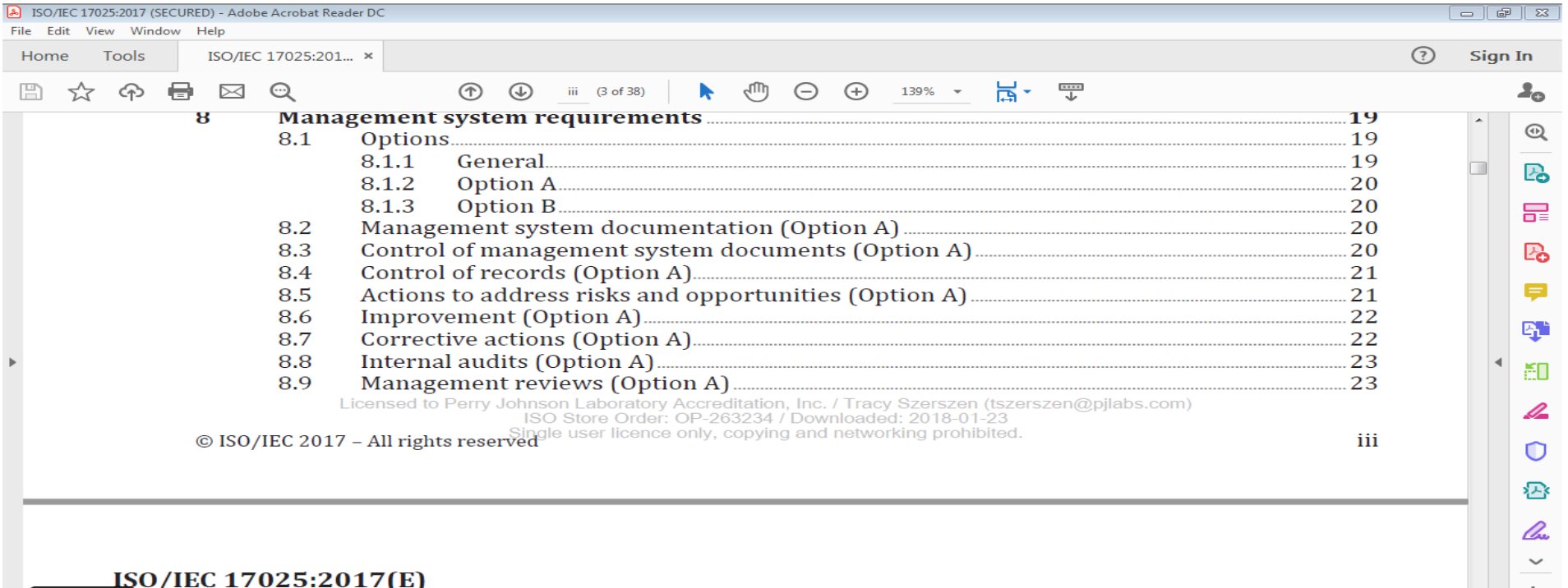
Option A and B as Presented in ISO/IEC 17025:2017

Why this option?

Increased need to ensure that laboratories can operate a system that is seen as conforming to ISO 9001 as well as ISO/IEC17025;

Option A and B as Presented in ISO/IEC 17025:2017

An Option A facility will comply with all of the requirements specified in Section 8 of ISO/IEC 17025:2017. The assessment body will assess the lab against the requirements as listed in ISO/IEC 17025:2017. Option B maintains a quality management system that is compliant with ISO 9001:2015. As far as the level that the accreditation needs to assess, is currently placed in the hands of the accreditation body.



Option A and B as Presented in ISO/IEC 17025:2017

ISO/IEC 17025:2017 is organized to show relevance against the ISO 9001: 2015 Standard. The Standard accounts for a laboratory that may be part of an organization adhering to a Quality Management System based on the ISO 9001 requirements. ISO/IEC 17025:2017 applies to those principles.

ISO/IEC 17025:2017 addresses the laboratory's quality management system through Option A or Option B requirements for Section 8: Management Requirements

Option A and B as Presented in ISO/IEC 17025:2017

Option A

Requirements of ISO 9001 that are relevant to the scope of laboratory activities that are covered by the management system were incorporated into ISO/IEC 17025 “Section 8”

- Therefore, laboratories that comply with Clauses 4 to 7 of ISO/IEC 17025:2017 and implement Option ‘A’ will also operate generally in accordance with the *principles* of ISO 9001

Option A and B as Presented in ISO/IEC 17025:2017

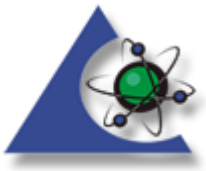
Option A: using ISO/IEC 17025 directly as before "Business as usual in maintaining compliance to ISO/IEC 17025

Option B: using ISO 9001 but ensuring that the Management System meets the technical needs of ISO/IEC 17025

8 Management system requirements

8.1.1 General

The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7, the laboratory shall implement a management system in accordance with Option A or Option B.

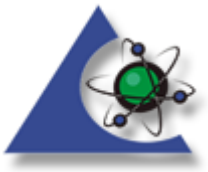


Overview of the Changes to New ISO/IEC 17025 Standard

Option A states minimum requirements

- *Management System Documentation*
- *Control of Management System Documentation*
- *Control of Records*
- *Improvement*
- *Corrective Action*
- *Internal Audits*
- *Management Review*

Option B meets the requirements of ISO 9001 and the rest of ISO/IEC 17025



Annex B informative annex

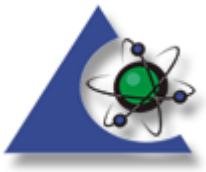
Conformity of the management system within which the laboratory operates to the requirements of ISO 9001 does not, in itself, demonstrate the competence of the laboratory to produce technically valid data and results. This is accomplished through compliance with Clauses 4 to 7.

Both options are intended to achieve the same result in the performance of the management system and compliance with Clauses 4 to 7.

Section 8 Management system requirements

Option B

Option B is important for laboratories already meeting ISO 9001 requirements for management systems. It simply requires a 9001-compliant management system that meets all the relevant requirements of the new 17025. This should makes it simpler for laboratories to manage the implementation of the two standards, as it is much clearer that a laboratory can cover many of the management system requirements using 9001-compliant processes and documentation, with no need for a separate set of documentation for 17025



PJLA and Option B Candidates

Certification through a recognized Registrar to ISO 9001

PERRY JOHNSON REGISTRARS, INC.

Section 8 will be assessed on a limited bases if the laboratory is part of a larger organization certified to ISO 9001 to assure that the laboratory is included in the process. PJLA assessment team has a guidance document in performing this limited assessment of Section 8

Management system documentation (Option A)

Requirements have been softened.

The need of a Quality Policy as well as a Quality Manual has been erased (as in the revised ISO 9001:2015).

From 17025:2005

4.2.2 The laboratory's management system policies related to quality, including a quality policy statement, shall be defined in a quality manual (however named)

ISO/IEC 17025:2017

8.2.1 Laboratory management **shall establish, document, and maintain** policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are **acknowledged** and implemented at all levels of the laboratory organization.

Management system documentation (Option A)

Why the change

Greater flexibility in the guidelines for processes, procedures, documented information, and organizational responsibilities

This change results from the greater focus on information technologies, which significantly modernizes the documents

The laboratory can determine necessary degree of documentation.

- Stronger link to electronic data (data protection, monitoring changes, storage)

Management system documentation (Option A)

There is no requirement specifying an existing quality manual needs to be rewritten or realigned with the ISO/IEC 17025:2017 Standard.

A good quality manual acts as an important internal tool and can still be used to assure policies and objectives are acknowledged and implemented at all levels of the laboratory organization on a consistent basis.

Are required to ensure that the policies and objectives are **acknowledged** and implemented at all levels of the laboratory organization (8.2.1) .

Management system documentation (Option A)

Question: Has your organization utilized a quality manual as an important internal tool?

The good news with ISO/IEC 17025:2017 is you have more flexibility to convert the manual into something more useful. There are no requirements for the manual therefore the specific requirements within it's contents are no longer applicable in ISO/IEC 17025:2017. You have freedom to do whatever you like, without running into conflict with the requirements of the standard or your own quality management system.

- References to supporting documents can be links to networked documents, policies, etc (8.2.4)

Management system documentation (Option A)

8.2.2 The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory

- Greater emphasize on impartiality 4.1 Impartiality

No longer a requirement for a quality policy statement as specified in 2005, however it can still be used to communicate the policies and objectives to the organization.

ISO/IEC 17025:2005

4.2.2 The laboratory's management system policies related to quality, including a quality policy statement, **shall be defined in a quality manual (however named).** The overall objectives shall be established, and shall be reviewed during management review. The quality policy statement shall be issued under the authority of top management. It shall include at least the following (a-e):

Management system documentation (Option A)

8.2.3 Laboratory management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness

From ISO/IEC 17025:2005

4.2.3 Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectivenes

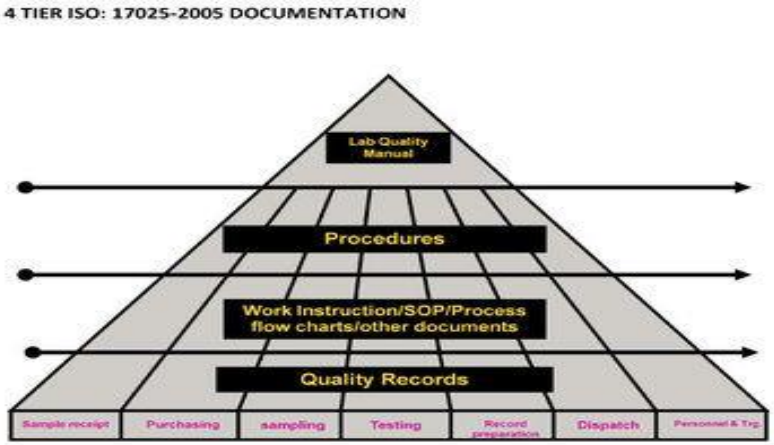
Talking to customers, Investing in resources, providing training opportunities, participation in management reviews, effective internal audit program, encouraging communication between departments.

Management system documentation (Option A)

8.2.4 All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system.

From ISO/IEC 17025:2005

4.2.5 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the management system.



Management system documentation (Option A)

8.2.5 All personnel involved in laboratory activities shall have access to the parts of the management system documentation and related information that are applicable to their responsibilities;

ISO/IEC 17025:2005 (4.2.1)

The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel;

Management system documentation (Option A)

ISO/IEC 17025:2005

4.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this International Standard, **shall be defined in the quality manual**

ISO/IEC 17025:2017

5.2 The laboratory **shall identify** management that has overall responsibility for the laboratory.

Thoughts on Quality Manual

- *It may be better to keep and maintain your Quality Manual for better operation of lab and reference purposes.*
- *ISO/IEC 17025 is a "Quality Assurance / Quality Control" standard for labs - not a management system standard. Regardless of what ISO 9000 specifies, a quality manual may sill be needed for labs.*
- *A quality manual may very well be, useful as a port of reference for policies and procedures.*
- *There is no harm in keeping your quality manual. Sooner or later, you can transform your policies and procedures in a more convenient way which may be electronic, graphic, software, ect.*
- Laboratory management shall establish, document, and maintain policies and objectives for the fulfilment of the purposes of ISO/IEC17025 and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization. A quality manual can still be used for this purpose.

Option A and B as Presented in ISO/IEC 17025:2017 Along with the Management System Documentation (8.2)

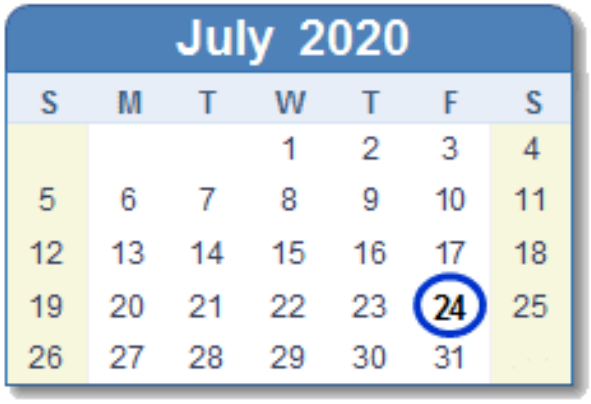
This time is allocated for questions. You should have a space provided for submitting questions.

Save the Date

Next Webinar

Friday; July 24 – 1:00pm EST

Section 6.3 on Facilities and Environmental Conditions Along With Section 6.4 on Equipment



Friday, Jul 24th 2020