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

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

- This webinar is being recorded
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- All attendees are muted. However, feel free to utilize the questions tab. They will be reviewed at the end of the session.

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

Why these options?

Growth in the use of management systems generally has increased the need to ensure that laboratories can operate a management system that is seen as conforming to ISO 9001, as well as to ISO/IEC 17025:2017. As a result, ISO/IEC 17025:2017 provides two options for the requirements related to the implementation of a management system.

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

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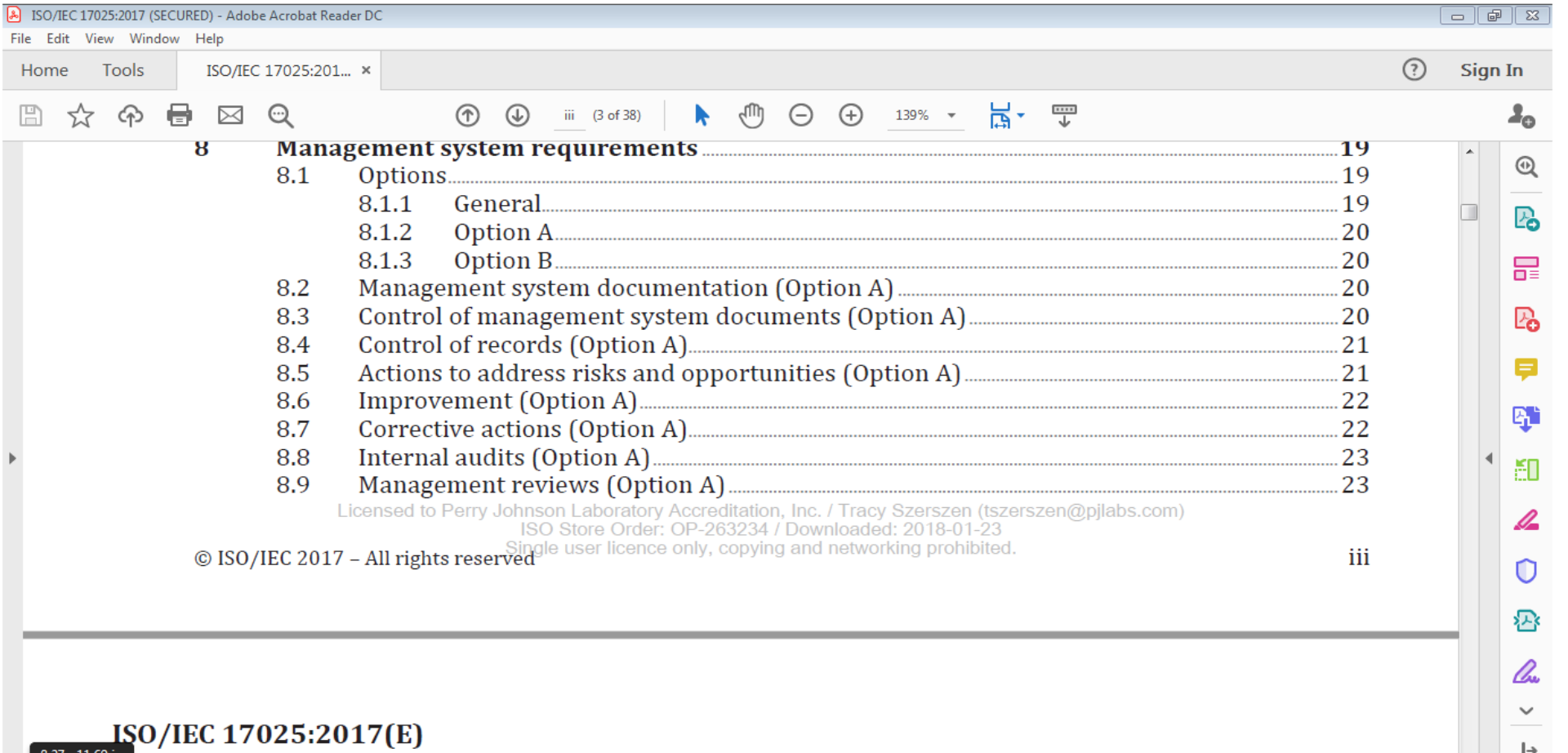
Option A and B as Presented in ISO/IEC 17025:2017

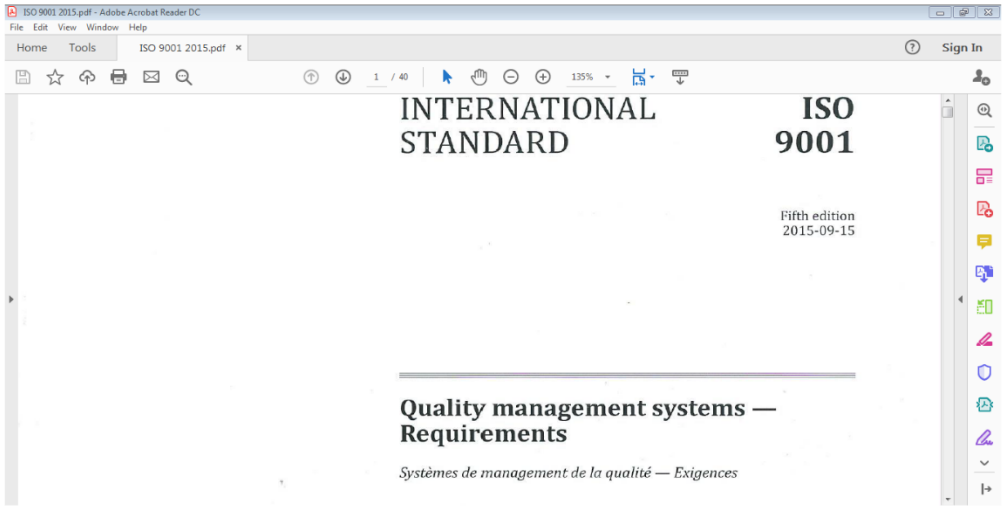
- An Option A facility will comply with all of the requirements specified in Section 8 of ISO/IEC 17025:2017. The assessment body will assess the lab against the requirements as listed in ISO/IEC 17025:2017.



Option 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.

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.



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Option A

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

Laboratories that comply with Clauses 4 to 7 of ISO/IEC 17025:2017, and was assessed and meeting those requirements specified in Section 8 will operate generally in accordance with the principles of ISO 9001

ISO/IEC 17025:2017 Introductions states:

Laboratories that conform to this document will also operate generally in accordance with the principles of ISO 9001.

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Option B

Option B is important for laboratories already meeting ISO 9001 requirements for their management systems. It simply requires a ISO:9001 2015 compliant management system that meets all the relevant requirements of ISO/IEC 17025:2017 “Section 8”. This should make 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 ISO 9001: 2015 compliant processes and documentation, with no need for a separate set of documentation for ISO/IEC:17025:2017.

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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.

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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

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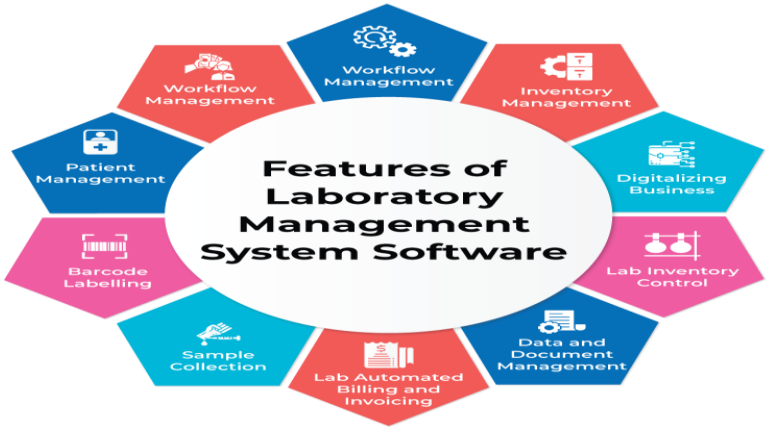
Section 8.2 Management System Documentation

This section offers flexibility in the guidelines for processes, procedures, documented information, and organizational responsibilities. This can be attributed to the greater focus on information technologies, which significantly modernizes the documents.

The laboratory can determine necessary degree of documentation.



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Management System Documentation

There is no requirement specifying a requirement for a quality manual or the realignment of existing quality manuals 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.

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Management System Documentation

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

The good news with ISO/IEC 17025:2017 is you have m flexibility to convert the manual into something more useful for your organization. Considering there are no requirements for the manual therefore no specific requirements within the contents, you have freedom to do whatever you like, without running into conflict with the requirements of the standard or your own quality management system.

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Management System Documentation

The following prescriptive requirements are no longer applicable from ISO/IEC 17025:2005

- The laboratory's management system policies related to quality, including a quality policy statement, **shall** be defined in a quality manual
- 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.
- 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.

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Management System Documentation

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.

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Management System Documentation

There are however specific requirements for procedures within ISO/IEC 17025:2017 which the quality management system would need to address including:

- The laboratory shall have procedure(s) and retain records for: a) determining the competence requirements; b) selection of personnel; c) training of personnel; d) supervision of personnel; e) authorization of personnel; f) monitoring competence of personnel (6.2);
- The laboratory shall have a procedure and retain records for: a) defining, reviewing and approving the laboratory's requirements for externally provided products and services (6.6);
- The laboratory shall have a procedure for the review of requests, tenders and contracts (7.1);.

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Required Procedural Information

- The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items (7.4);
- The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data (7.2);
- The laboratory shall have a procedure for monitoring the validity of results (7.7) ;
- The laboratory shall have a documented process to receive, evaluate and make decisions on complaints (7.9);
- The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (7.10);

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Management System Documentation

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

A quality policy statement as can still be used to communicate the policies and objectives to the organization.

From Section 6.2 “Personnel”

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system.

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Management System Documentation

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

- Talking to customers,
- Investing in resources,
- Providing training opportunities,
- Participation in management reviews,
- Effective internal audit program,
- Encouraging communication between departments.

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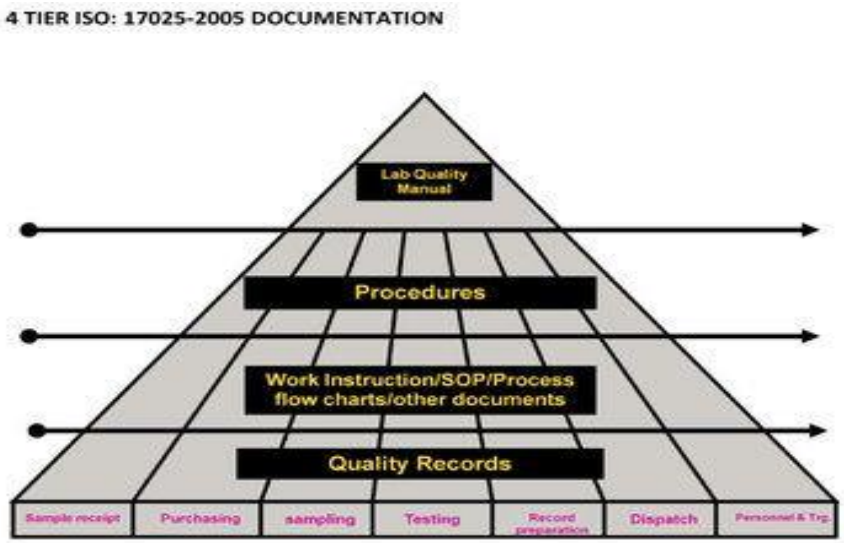
Management System Documentation (Option A)

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;



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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;

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

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If a question is not answered, please submit directly to webinar@pjlabs.com

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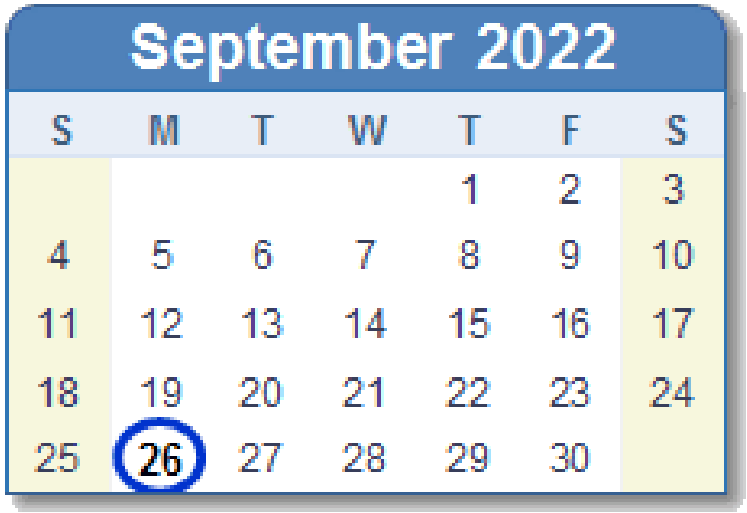
Save the Date

A look at Section 6.3 on Facilities and Environmental Conditions Along with Section 6.4 on Equipment



Monday, Sep 26th 2022

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