ISO/IEC 17025:2017 and Section 8.8 on Internal Audits

Presented by:

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Section 8.8 "Internal Audit"

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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;

Section 8.8 "Internal Audit"
Option A

The principles of internal audits remain the same

•ISO/IEC 17025:2005 specified that internal audits were the responsibility of the quality manager, however, the new standard no longer specifies this and simply requires personnel to be authorized for given tasks

•The standard now requires the results of previous audits to be taken into account and that the criteria and scope for each audit be defined

Example: Internal audit conducted against the requirements of ISO/IEC 17025:2017, PJLA Policies, and ABC company quality management system and incorporates these requirements with laboratory operations at ABC calibration/testing laboratories.

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There is no recommendations to conduct internal audits every year, but at planned intervals

From ISO/IEC 17025: 2005 Standard

NOTE The cycle for internal auditing should normally be completed in one year

The lab established the planned interval and needs to comply with it.

As per 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.

Section 8.8 "Internal Audit"

8.8.1 The laboratory shall conduct internal audits **at planned intervals** to provide information on whether the management system:

a) conforms to:

— the laboratory's own requirements for its management system, including the laboratory activities;

— the requirements of this document;

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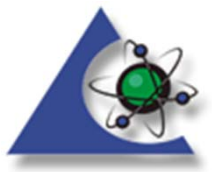
at planned intervals:

The internal audit needs to follow a predetermined schedule established by the laboratory. The audit will need to cover all activities over a reasonable period of time. It may be inconvenient to audit all activities in a single audit, so it can be spread over several quarterly or monthly audits. The schedule for such audits can be conveniently drawn as a matrix covering, for example, a year in which dates are set for each part of the quality system.

Audit Item	Q1	Q2	Q3	Q4
Organization	x			
Documentation		x		
Personnel			x	
Sampling				x
Equipment		x		
Methods			x	
----------				x
Many others	x			



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to provide information on whether the management system:

a) conforms to:

— the laboratory’s own requirements for its management system, including the laboratory activities

Words are meaningless without intent And follow through

Do as you say

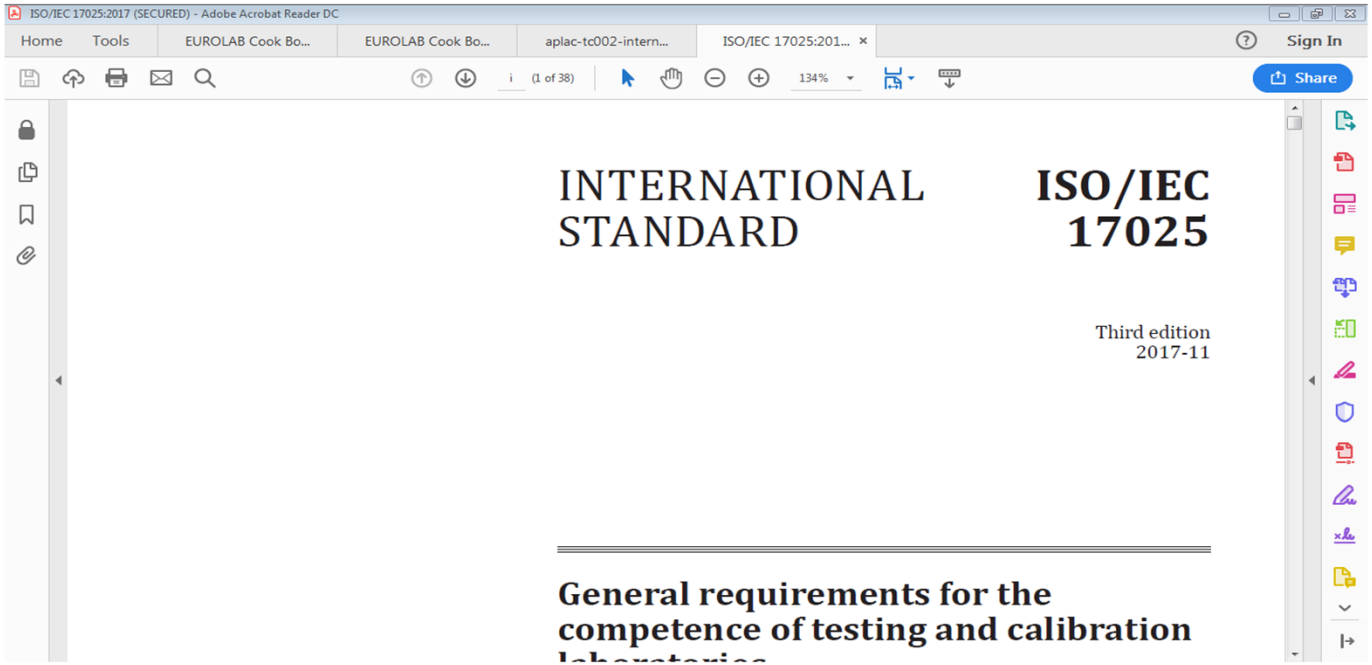
Say as you do

Section 8.8 “Internal Audit”

to provide information on whether the management system:

a) conforms to:

— the requirements of this document



Section 8.8 “Internal Audit”8.8.1 continued

to provide information on whether the management system:

b) is effectively implemented and maintained.

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8.8.2 The laboratory shall:

a) plan, establish, implement and maintain an **audit program** including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;

A procedure can be used to meet this requirement however not required “an audit program”

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8.8.2 The laboratory shall:

b) define the audit criteria and scope for each audit;

audit criteria *- set of policies, procedures or* ***requirements****.*
NOTE: ***Audit criteria*** *are used as a reference against which* ***audit*** *evidence is compared.*

. The ***scope*** *is who, what, where, when; and the* ***criteria*** *is what you are* ***auditing*** *against, whether the standard or internal procedures, etc.*

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8.8.2 The laboratory shall:

c) ensure that the results of the audits are reported to relevant management "*new*";

Earlier in the Standard

5 Structural requirements

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

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8.8.2 The laboratory shall:

d) implement appropriate correction and corrective actions without undue delay;

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8.8.2 The laboratory shall:

e) retain records as evidence of the implementation of the audit program and the audit results

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NOTE ISO 19011 provides guidance for internal audits

. ISO 19011 is an international standard that sets forth guidelines for management systems auditing. It is developed by the International Organization for Standardization

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From ISO/IEC 17025:2005

Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited

From ISO/IEC 17025:2017

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

6.2.5 The laboratory shall have procedure(s) and retain records for:

a) determining the competence requirements

b) e) authorization of personnel

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General Information

- Where an organization is accredited for calibration and/or testing and/or inspection at a client's site, or for sampling in the field, these activities should be included in the audit program;
- Audits carried out by other parties, such as customers or an accreditation body, should not be considered as a substitute for internal audits;

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Good Practice fors Internal Auditing

- The key steps of an audit are planning, investigation, analysis, reporting, follow-up corrective action and close-out.
- Conduct an opening meeting and if needed introduce members of the audit team, confirm the audit criteria, review the audit scope, and clarify any relevant details in regards to the audit program, and timetable.,
- While gathering objective evidence ask questions, observe activities, examine facilities, and examine records.
- Auditors should make use of quality management system documents (quality manual, test methods, work instructions, etc.) as reference standards, and verify what the lab is stating as to what is being done, is actually the case.

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Good Practices continued

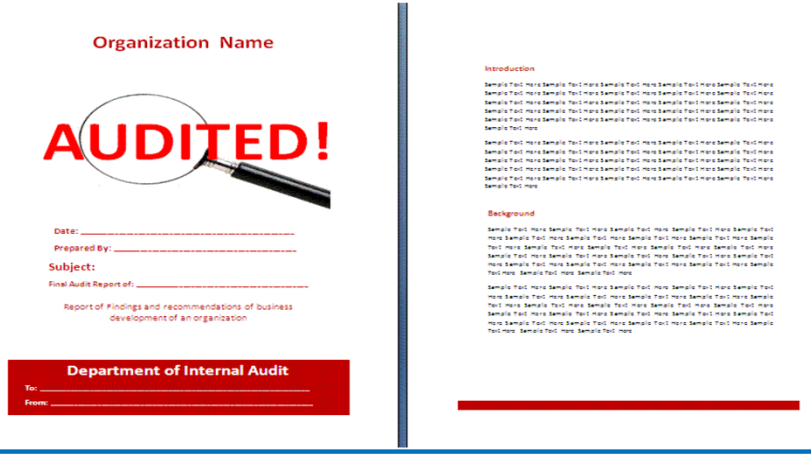
- The auditor should review objective evidence that the management system requirements are being fulfilled. Evidence should be collected as efficiently and effectively as possible. Examples may include master documents list, customer contracts, customer feedback, purchasing document matrits, approved vendors list and evaluations, corrective action reports, risk assessment matrix, management reviews, previous internal audit, personnel training records, customer test or calibration reports, calibration certificates for standards and equipment, proficiency testing results, uncertainty budgets, environmental monitoring, ect;

Objective evidence can also be considered as anything which is heard, seen, or read which was evidence in supporting whether or not compliance was met.

Section 8.8 "Internal Audit"

Good Practices continued

- All audit findings should be recorded, and any nonconformities should be noted and investigated further by the auditor to identify underlying problems (dig deeper)
- After all audit activities have been completed, the audit team should review and analyze all findings to determine which are to be reported as nonconformities and which can be included as recommendations for improvement.
- The audit team should prepare a clear, concise report, supported by objective audit evidence, of nonconformities and recommendations for improvement.



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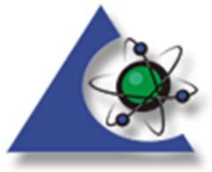
Good Practices continued

- Nonconformities should be identified in terms of the specific requirements of the organization's quality manual and related documents against which the audit has been conducted;
- A closing meeting with the senior management of the organization and those responsible for the functions audited should be held with the main purpose of the meeting as the presentation of the audit findings and to report to management in a manner in which they understand the audit results.

purpose of this meeting is to present audit findings and to report to top laboratory management in such a manner as to ensure that they clearly understand the results of the audit;



Section 8.8 "Internal Audit"

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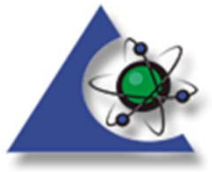

ISO/IEC 17025:2017 Section 8.9 Management Review Requirements

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

Save the Date

Next scheduled webinar is set for 30 December 2020

. ***ISO/IEC 17025:2017 - 7.6 & 7.7 - Evaluation of Measurement Uncertainty & Validity of Results***

Wednesday, Dec 30th 2020