Section 8.8 Internal Audit Requirements

Presenter: Michael Kramer
PJLA Calibration/Inspection Program Manager
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Section 8.8 Internal Audit Requirements

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Section 8.8 Internal Audit Requirements

An internal audit is a formal laboratory activity that must be performed in accordance with a predetermined schedule. Laboratories may choose to conduct a full laboratory audit annually or biannually, or to audit parts of their system every month. The internal audit is a self-examination of your laboratories compliance to ISO/IEC 17025:2017, requirements of the accreditation body and compliance to the laboratories own quality management system.

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Internal audits will be used to assess conformity, evaluate the effectiveness of the quality management system and identify opportunities for improvement. An effective internal audit should be conducted objectively. The internal auditor should be independent of the area being audited to ensure objective results. (It is recommended to have more than one auditor to ensure no one is auditing his or her area of responsibilities). Internal auditors should be competent and knowledgeable in regard to the requirements of ISO/IEC 17025:2017 and the testing or calibration activities being performed under the scope of accreditation.

When you do something *objectively*, you do it with an open mind, considering the facts rather than your personal feelings.

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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

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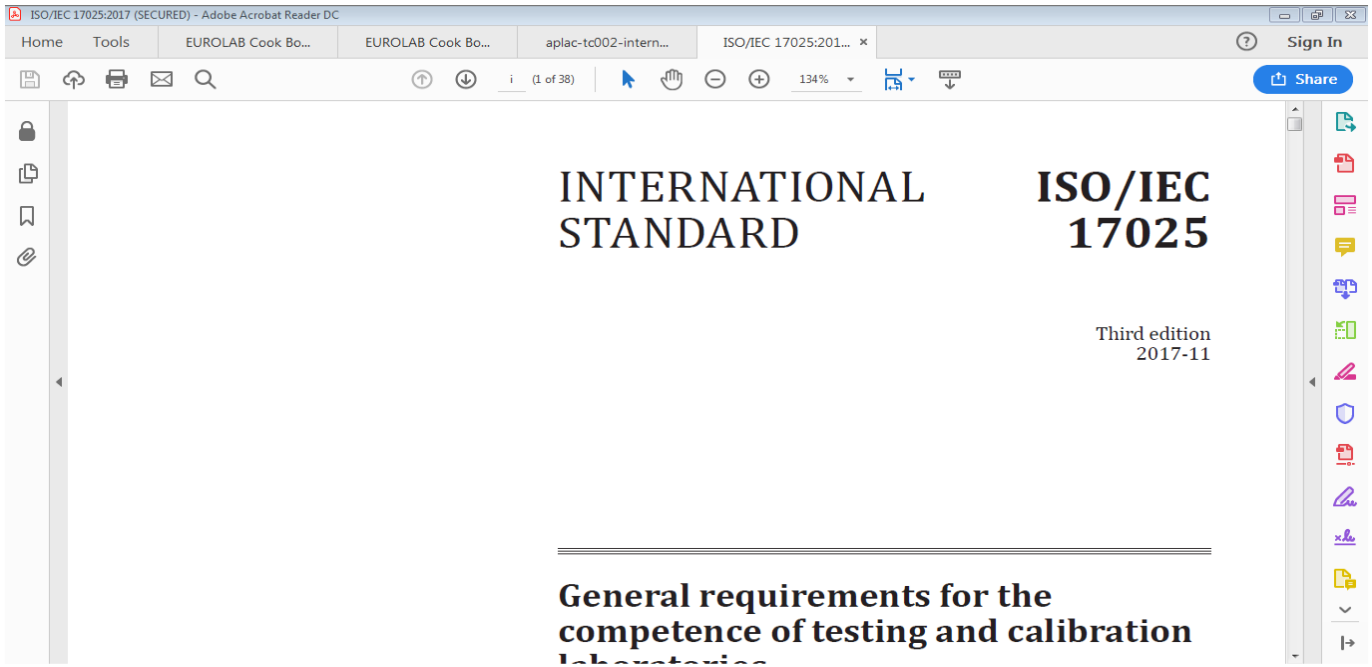
to provide information on whether the management system:

a) conforms to:

— the requirements of this document



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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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Section 8.8 “Internal Audit”

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.

The internal audit is to assure the requirements of ISO/IEC 17025:2017 are met for ABC Calibration Laboratory regarding the Calibration of Mass Force and Weighing Devices.

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- **8.8.2** The laboratory shall:
- c) ensure that the results of the audits are reported to relevant management

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;

If your internal audit yields any nonconformance's then the lab’s protocol for Section 8.7 would be implemented.

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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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What about requirements concerning the internal auditor?

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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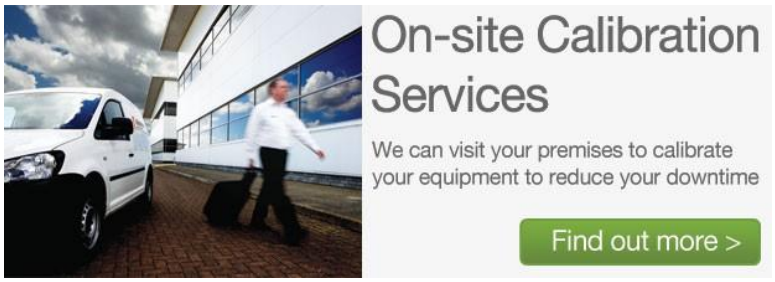
General Information

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 regard 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 , supplier evaluation, 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.

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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;

Shall=Requirement

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 to present the audit findings and to report to management in a way they understand the audit results.

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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

Requirements for Personnel in ISO/IEC 17025:2017 Section 6.2

Thursday, Dec 22nd 2022

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