



LABORATORY INTERNAL AUDIT TO Quality System of MS ISO/IEC 17025:2005

IN-HOUSE / PUBLIC TRAINING

Course Presenter:
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PROGRAMME

Laboratory Internal Audit to MS ISO 17025:2005

DAY 1	DAY 2
9000-1015 Module 1: Introduction to Quality Audits Exercise 1 1015 – 1030 Break 1030 – 1130 Module 2: Revision of ISO 17025 elements Exercise 2 1130 – 1245 Module 3: Managing the Audit Process <i>Lunch Break</i> 1245 – 1400 Lecture 4: Audit Planning and Preparation 1400 – 1530 <i>Break</i> 1530 – 1545 Workshop 1: 1545 - 1700 Preparation of Audit Plan Preparing Audit Checklist	0900 – 0915 Review of day 1 0915 – 1015 Module 5: Performing the Audit Break 1015 – 1030 <i>Break</i> 1030 – 1100 Role Play 1100 – 1245 Module 6: Reporting the Audit <i>Lunch Break</i> 1245 – 1400 Exercise 3: Writing non-conformances 1400– 1530 <i>Break</i> 1530 - 1545 Module 7: Effective Audits 1545 – 1630 Course Evaluation 1630 – 1700 Closing

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COURSE OBJECTIVES

-  To understand the principles and concept of internal audit
-  To review ISO 9001:2008 and ISO/IEC 17025:2005 requirements
-  How to manage the audit process
-  To understand how to plan an audit
-  To understand how to perform an audit
-  To understand how to write audit report
-  To understand how to conduct corrective action and follow up

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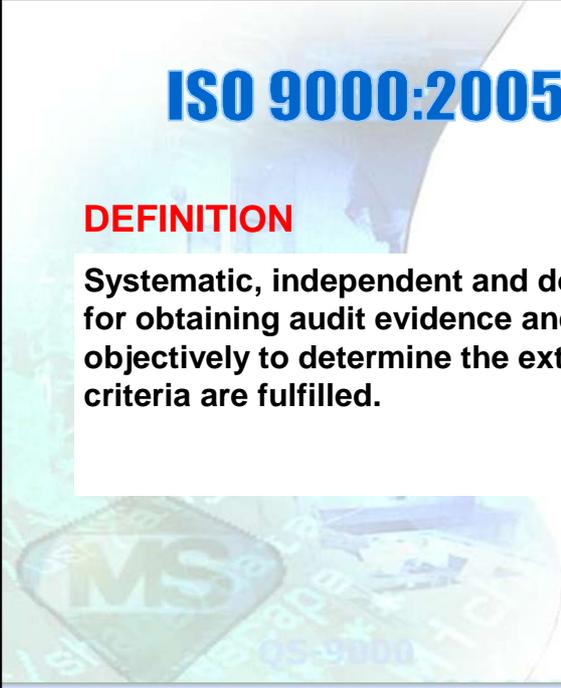
MODULE 1

Introduction to Quality Audits



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ISO 9000:2005 - Audit

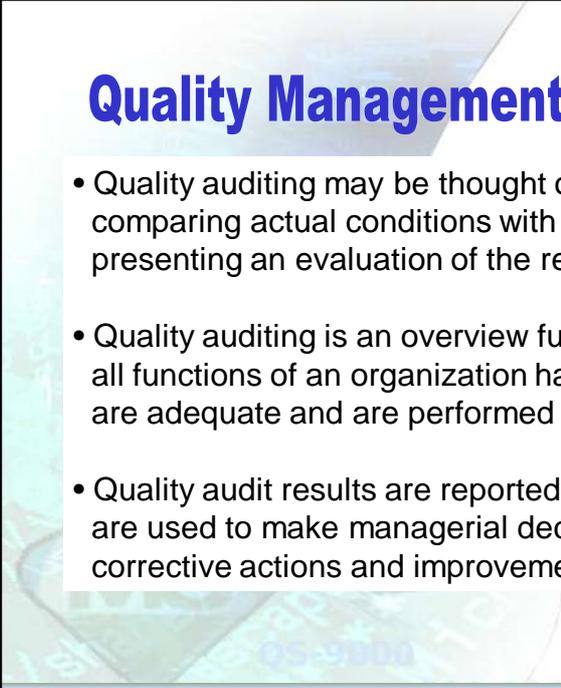
DEFINITION

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

... ISO 9000:2005

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Quality Management System Audit

- Quality auditing may be thought of as the process of comparing actual conditions with requirements and presenting an evaluation of the results to management.
- Quality auditing is an overview function that ensures that all functions of an organization having an affect on quality are adequate and are performed as designed.
- Quality audit results are reported to management and are used to make managerial decisions concerning corrective actions and improvement.

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Quality Management System Audit

Audit is ...

- An appraisal of activities or processes.
- A fact finding exercise.
- An instrument towards continuous improvement.
- To detect what is wrong (process that lead to the result).
- To confirm whether or not there is control.
- To provide management with the information necessary to enhance or modify organizational behavior & structure to fulfill quality objectives.

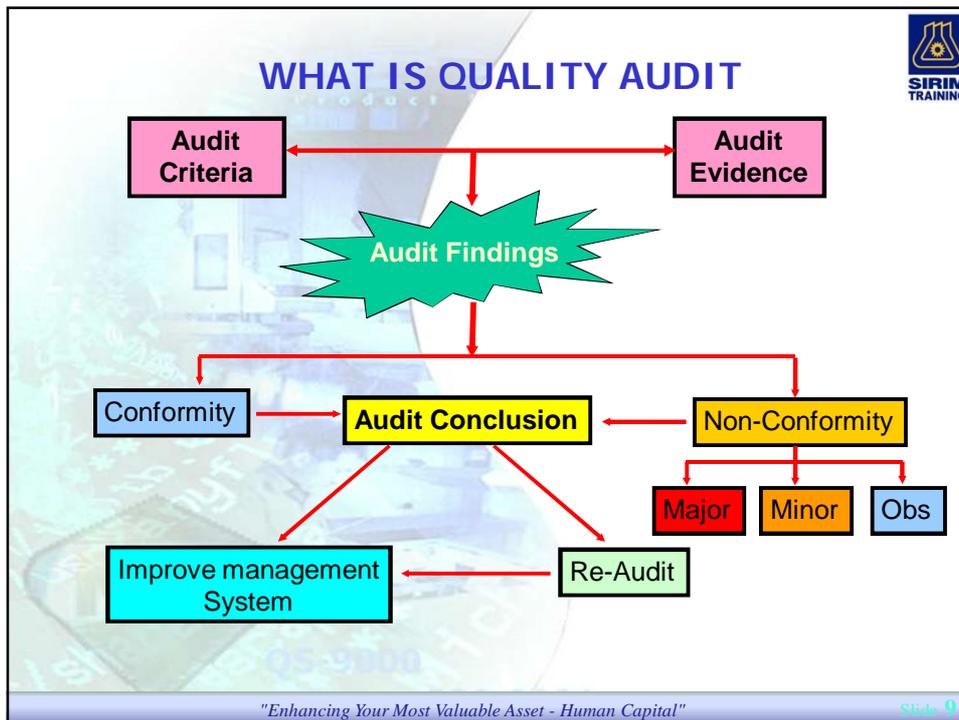
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Quality Management System Audit

is not ...

- **An assessment of product quality**
- **A fault finding exercise**
- **To focus on individual facts**
- **To detect who is wrong**
- **An alternative to an inspection operation**

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What is **AUDIT EVIDENCE**?

Records, statements of fact or other information,
which are relevant to the audit criteria and verifiable.

... Source: ISO 19011



INSPECTIONS

- interviews
- examination of documents
- observation of activities and conditions
- existing results of measurements and tests

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What is **AUDIT CRITERIA**?

Set of policies, procedures or requirements.

... Source: ISO 19011



e.g.:

- Policies, practice, procedure
- Legal and regulatory requirements
- Standard and guidelines

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What is **AUDIT FINDINGS**?

Results of the evaluation of the collected audit evidence against audit criteria.

... Source: ISO 19011



e.g.:

- Conformity
- Non Conformity
- Opportunity for improvement

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What is **AUDIT CONCLUSION**?

Outcome of an audit, provided by the audit team after consideration of the audit objectives and all audit findings.

... Source: ISO 19011



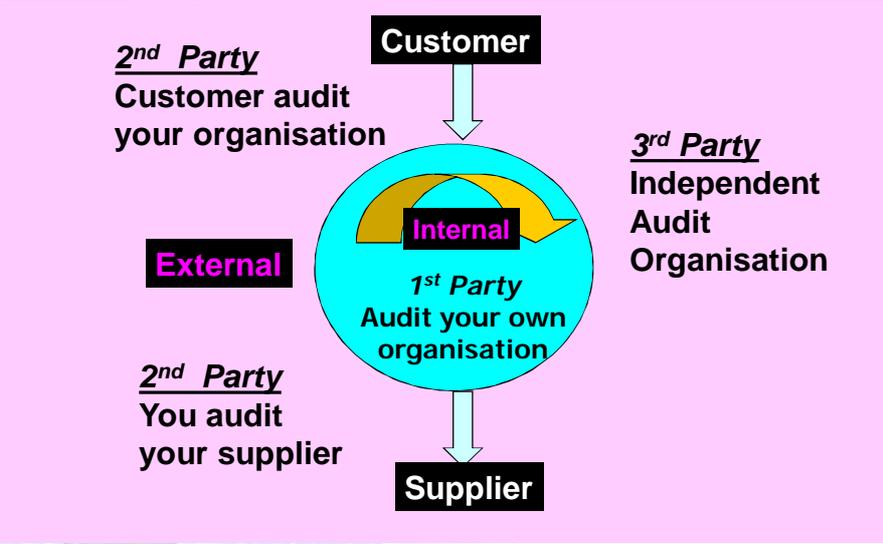
NOTE: Strength and weaknesses of overall quality system including summary of audit finding.

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Audit Classifications



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Internal Audit (1st party) – conducted by, or on behalf of, the organization itself for internal purposes & can form the basis for an organization self-declaration of conformity

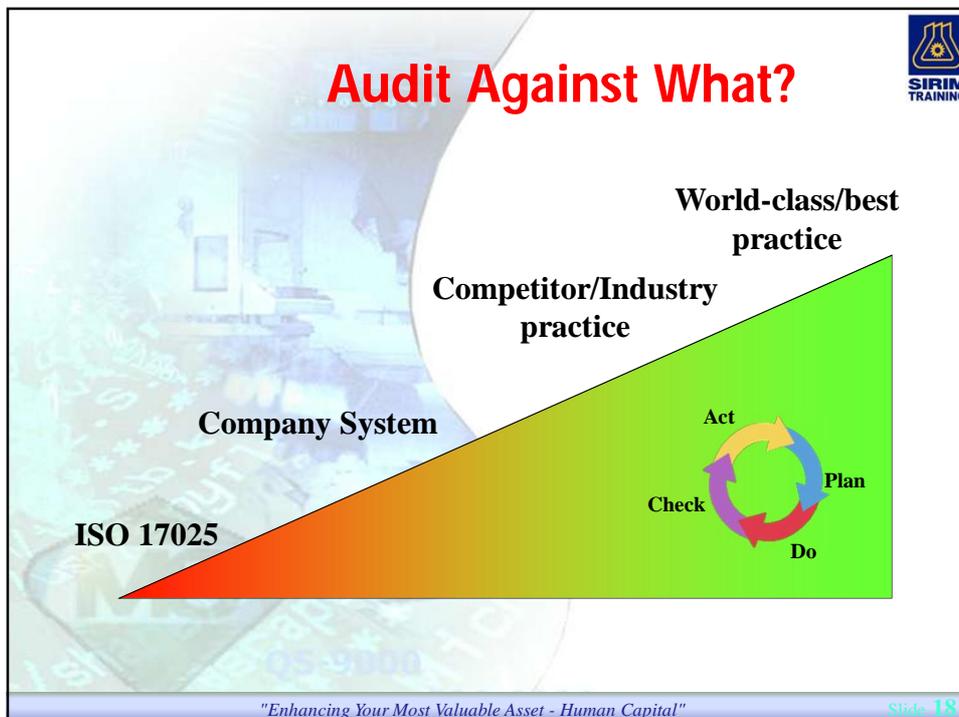
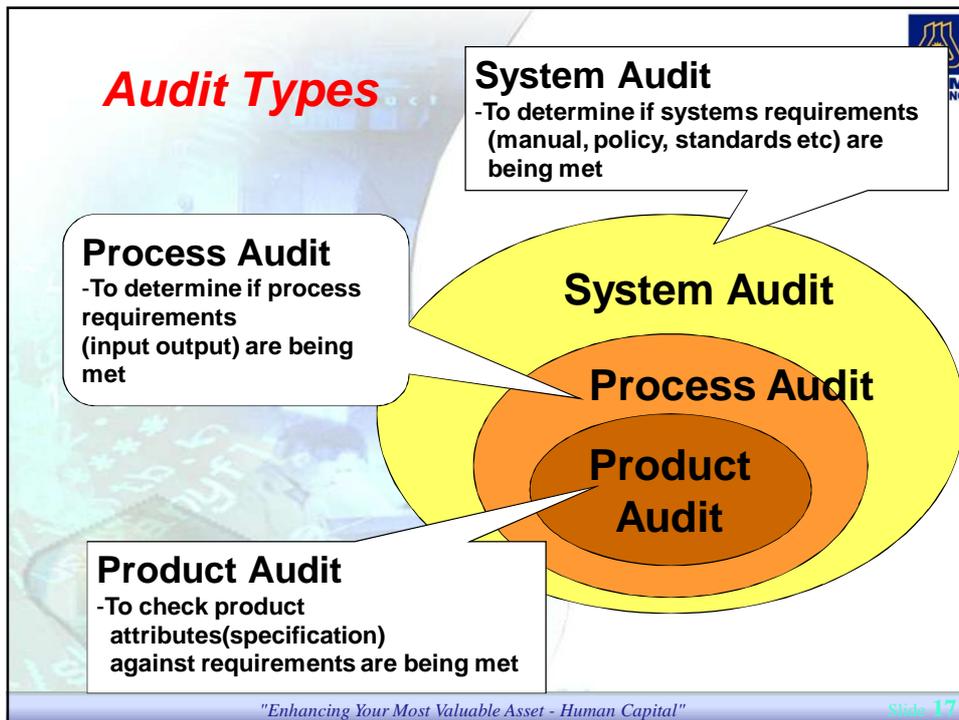
External Audit (2nd party) – conducted by parties having an interest in the Organization, such as customers, or by other persons on their behalf

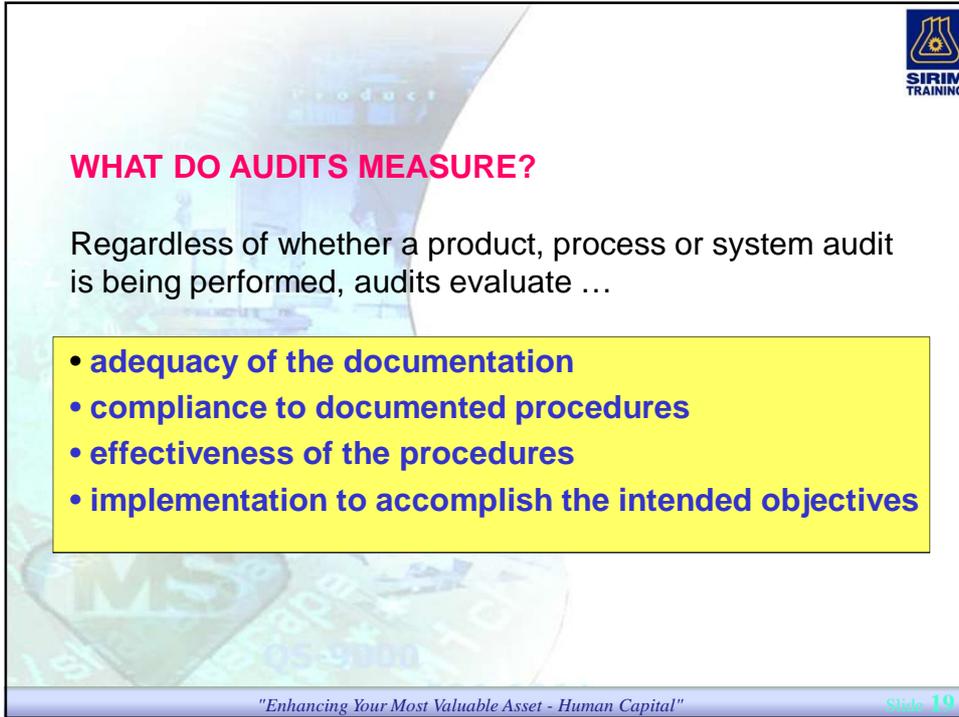
External Audit (3rd party) – conducted by external independent organizations

COMPARISON



	1st Party	2nd Party	3rdParty
Objective	Assessing internal effectiveness	Ability to Supply requirements	Conformity to Standard
Standard	Internal QMS Documents	Contract	ISO 9001 ISO/IEC 17025
Auditor - Auditee	US on US	US on Them	Them on US
Scope	Top Mgmt - quality function	Client Purchasing/ Operation	Assessment Body



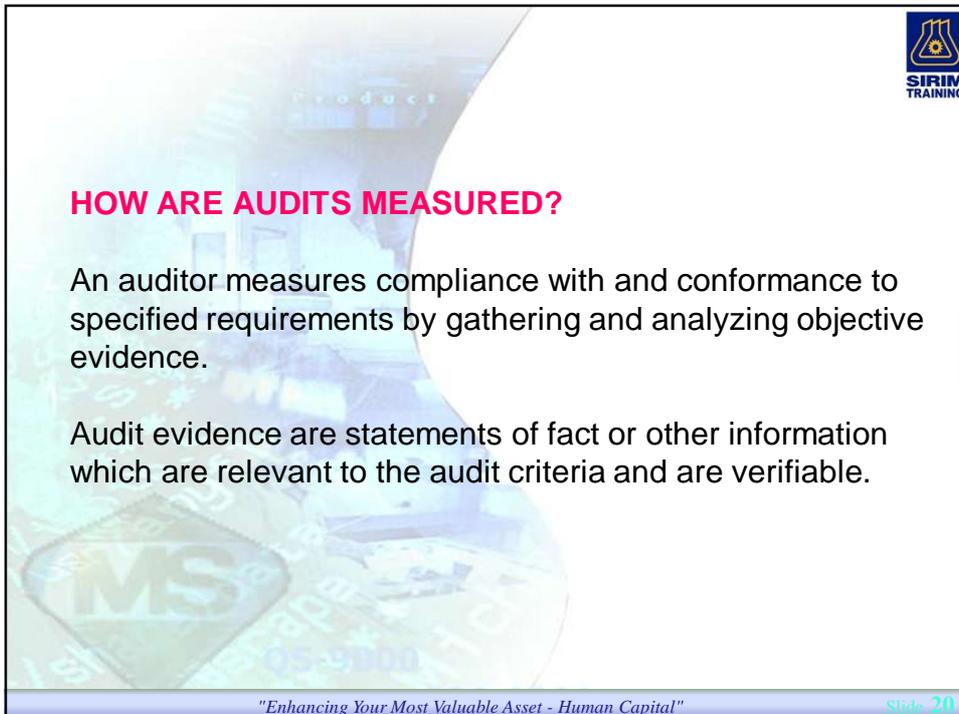


WHAT DO AUDITS MEASURE?

Regardless of whether a product, process or system audit is being performed, audits evaluate ...

- **adequacy of the documentation**
- **compliance to documented procedures**
- **effectiveness of the procedures**
- **implementation to accomplish the intended objectives**

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HOW ARE AUDITS MEASURED?

An auditor measures compliance with and conformance to specified requirements by gathering and analyzing objective evidence.

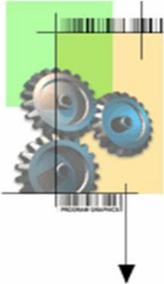
Audit evidence are statements of fact or other information which are relevant to the audit criteria and are verifiable.

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ISO 9001 Requirements on Internal Audit.

The element for Internal Audit is part of clause 8 of ISO 9001:2008 i.e. Measurement, Analysis, Improvement.



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Clause 8.2.2 Internal Audit

The organization shall conduct internal audits at planned intervals to determine whether the QMS:

- a. Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the QMS established by the organization
- b. Is been effectively implemented and maintained

An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

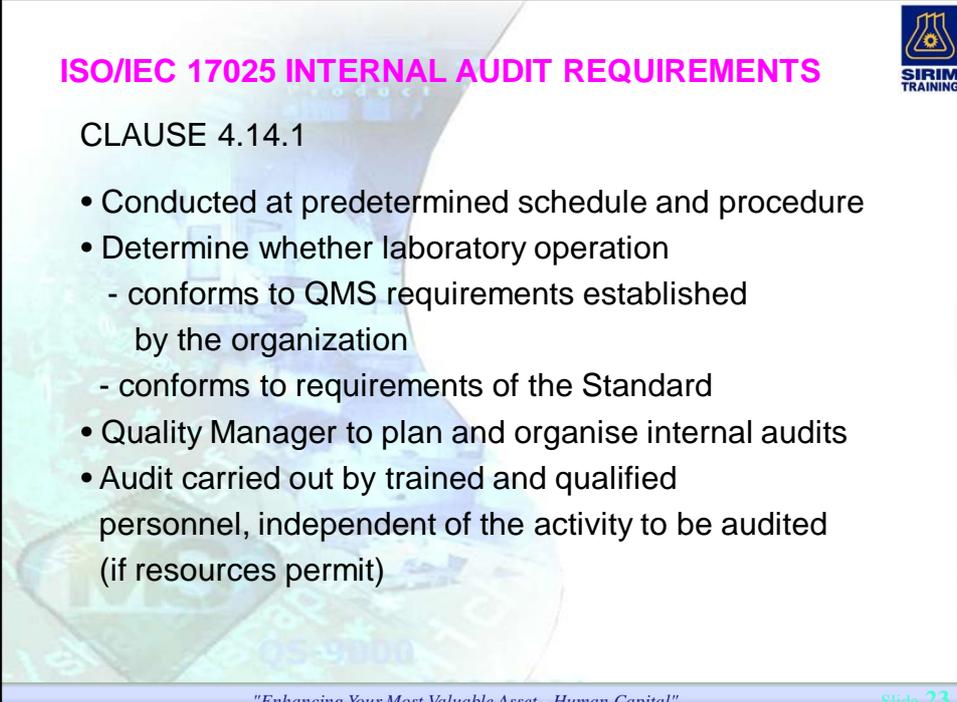
Records of the audits and their results shall be maintained.

The management responsible for the area being audited shall ensure that any necessary corrective actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up actions shall include the verification of the actions taken and the reporting of verification results (see 8.5.2)

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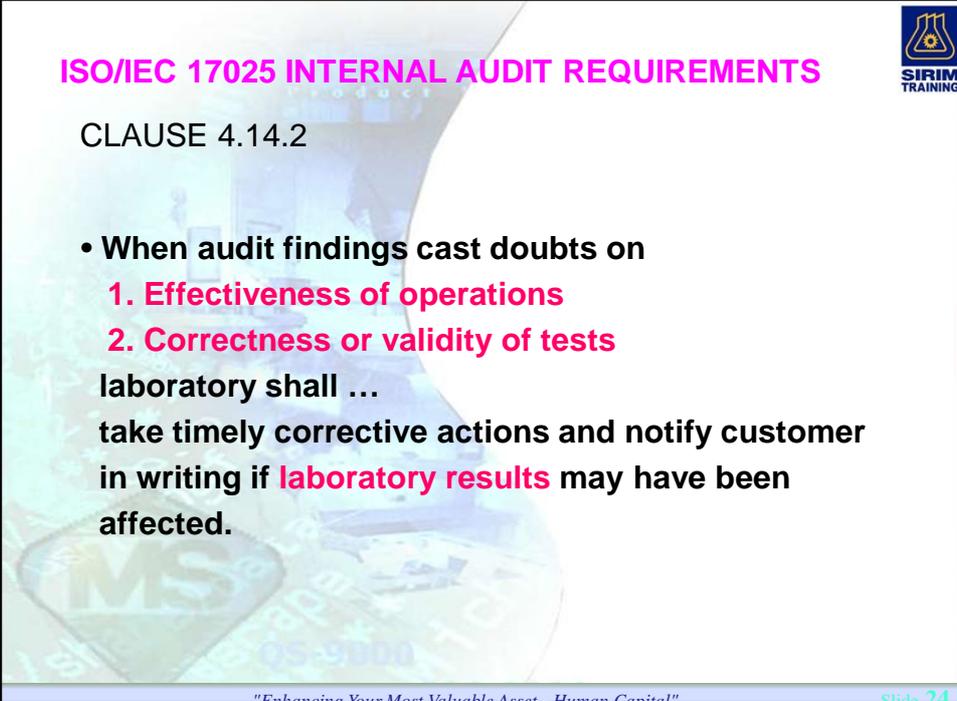


ISO/IEC 17025 INTERNAL AUDIT REQUIREMENTS

CLAUSE 4.14.1

- Conducted at predetermined schedule and procedure
- Determine whether laboratory operation
 - conforms to QMS requirements established by the organization
 - conforms to requirements of the Standard
- Quality Manager to plan and organise internal audits
- Audit carried out by trained and qualified personnel, independent of the activity to be audited (if resources permit)

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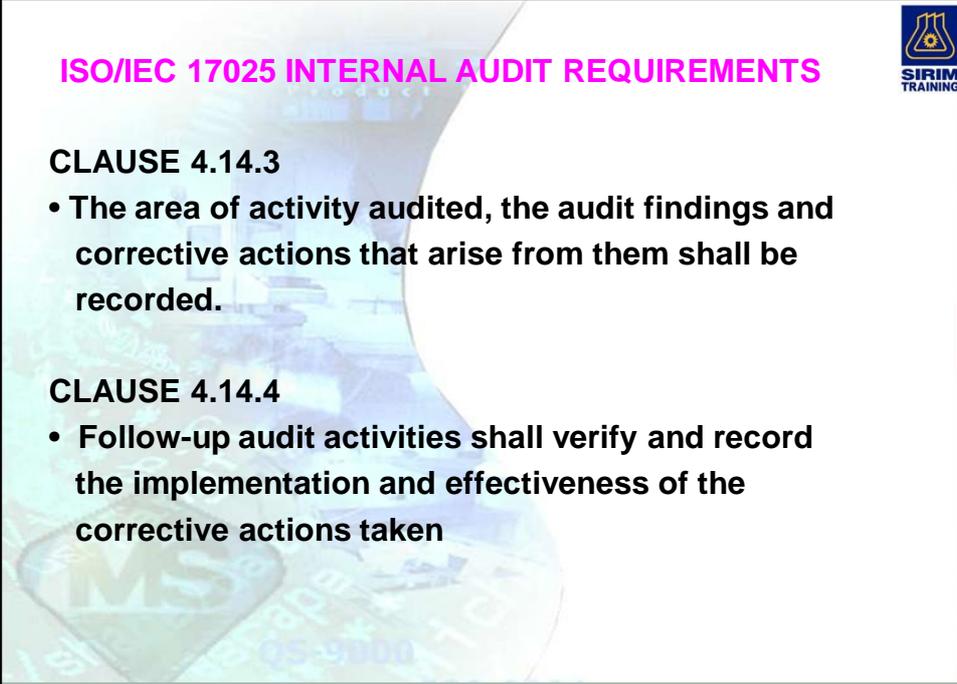


ISO/IEC 17025 INTERNAL AUDIT REQUIREMENTS

CLAUSE 4.14.2

- When audit findings cast doubts on
 1. Effectiveness of operations
 2. Correctness or validity of testslaboratory shall ... take timely corrective actions and notify customer in writing if **laboratory results** may have been affected.

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ISO/IEC 17025 INTERNAL AUDIT REQUIREMENTS

CLAUSE 4.14.3

- The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

CLAUSE 4.14.4

- Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective actions taken

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End of session 1:
Introduction to
quality audits

Thank you very much

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