ISO/IEC 17025:2017 Internal Auditor Training

General Requirements for the Competence of Testing and Calibration Laboratories

QUALITY

OMNEX

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Fifth Edition

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Omnex provides training, consulting and software solutions to the international market with offices in the USA, Canada, Mexico, China (PRC), Germany, India, the Middle East, and SE Asia. Omnex offers over 400 standard and customized training courses in business, quality, environmental, food safety, laboratory and health & safety management systems worldwide.

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Course Objectives

- Provide guidance for the planning, preparation, and delivery of testing and calibration laboratories audits in accordance with the requirements and guidelines of ISO/IEC 17025:2017.
- Provide sufficient knowledge and understanding of the various clauses and requirements of the ISO/IEC 17025:2017 standard.
- Provide an understanding of the relationship between the ISO/IEC 17025:2017 and ISO 9001:2015 standards.
- Develop an audit scheme that will meet the requirements of internal auditing and/or will help to prepare for certification of an independent auditing body.

Agenda

ISO/IEC 17025:2017 Auditor Training

Chapter 1 – Changes to ISO/IEC 17025:2017

Chapter 2 – Introduction to ISO/IEC 17025:2017

- **Breakout Exercise 1 – Definition of a Lab**
- **Written Exercise 1 – Laboratory Management Systems**

Chapter 3 – ISO/IEC 17025:2017 Requirements

- **Breakout Exercise 2A – Key Processes**
- **Written Exercise 2 – Audit Scenarios: Clauses 4-6**
- **Written Exercise 3 – Audit Scenarios: Clauses 7**
- **Breakout Exercise 2B – Risks and Opportunities**
- **Written Exercise 4 – Audit Scenarios: Clauses 8**

Chapter 4 – Process Approach to Auditing, Turtle Diagrams and Audit Trails

Chapter 5 – Audit Guidance, Definitions and Principles

Chapter 6 – The Audit Program

Agenda

ISO/IEC 17025:2017 Auditor Training

Chapter 7 – Audit Planning and Preparation

- **Breakout Exercise 3: Creating an Audit Plan**

Chapter 8 – Conducting the Audit

- **Auditing Breakout Exercise 4: Performing an Audit**

Chapter 9 – Writing Nonconformity Statements

- **Auditing Breakout Exercise 5: Writing Nonconformity Statements**

Chapter 10 – Closing Meeting

Chapter 11 – Completing the Audit Report

Chapter 12 – Corrective Action and Close-Out

- **Management Systems Auditing Exam**

Course Methodology

Breakout Exercises

- The class will be divided into teams of three to six people. The objective is to provide diversified auditing experience to each team.
- The purpose of the breakout exercises is to evaluate those skills important for the audit process by having individuals or teams working on practical situations, as well as help reinforce the discussed topics.

Course Methodology

Individual Presentations

- Each participant will have opportunities to make brief, prepared oral presentations. A certified auditor must be able to communicate effectively both orally (auditor, auditee, team leader, opening and closing meeting participant) and in writing (checklists, pre-audit planning, recording observations and nonconformities, audit reports).

Course Methodology

Written Exercises

- Written exercises will be given to evaluate each student's understanding of subject matter discussed that day. Questions will be multiple choice or short essay style.

Role-Playing

- Participants will have the opportunity to play the role of auditor/auditee, or lead auditor/auditee in simulated audit situations previously discussed in the classroom.

Course Methodology

Evaluation of Individual Participation

- Students will be evaluated on class participation, which encompasses the following aspects:
  - Asking meaningful questions in class. OMNEX
  - Sharing professional auditing experiences
  - Taking an active role in team exercises
  - Engaging in effective role-playing
  - Demonstrating achievement of the learning objectives
- Effective class participation provides the participant with opportunities to demonstrate practical understanding of the many audit principles.

A BRIEF INTRODUCTION TO OMNEX

Omnex Introduction

- International consulting, training and software development organization founded in 1985.
- Specialties:
  - Integrated management system solutions.
  - Elevating the performance of client organizations.
  - Consulting and training services in:
    - Quality Management Systems, e.g., ISO 9001, IATF 16949, AS9100, QOS
    - Environmental Management Systems, e.g., ISO 14001
    - Health and Safety Management Systems, e.g., ISO 45001
- Leader in Lean, Six Sigma and other breakthrough systems and performance enhancement.
  - Provider of Lean Six Sigma services to Automotive Industry via AIAG alliance.

About Omnex

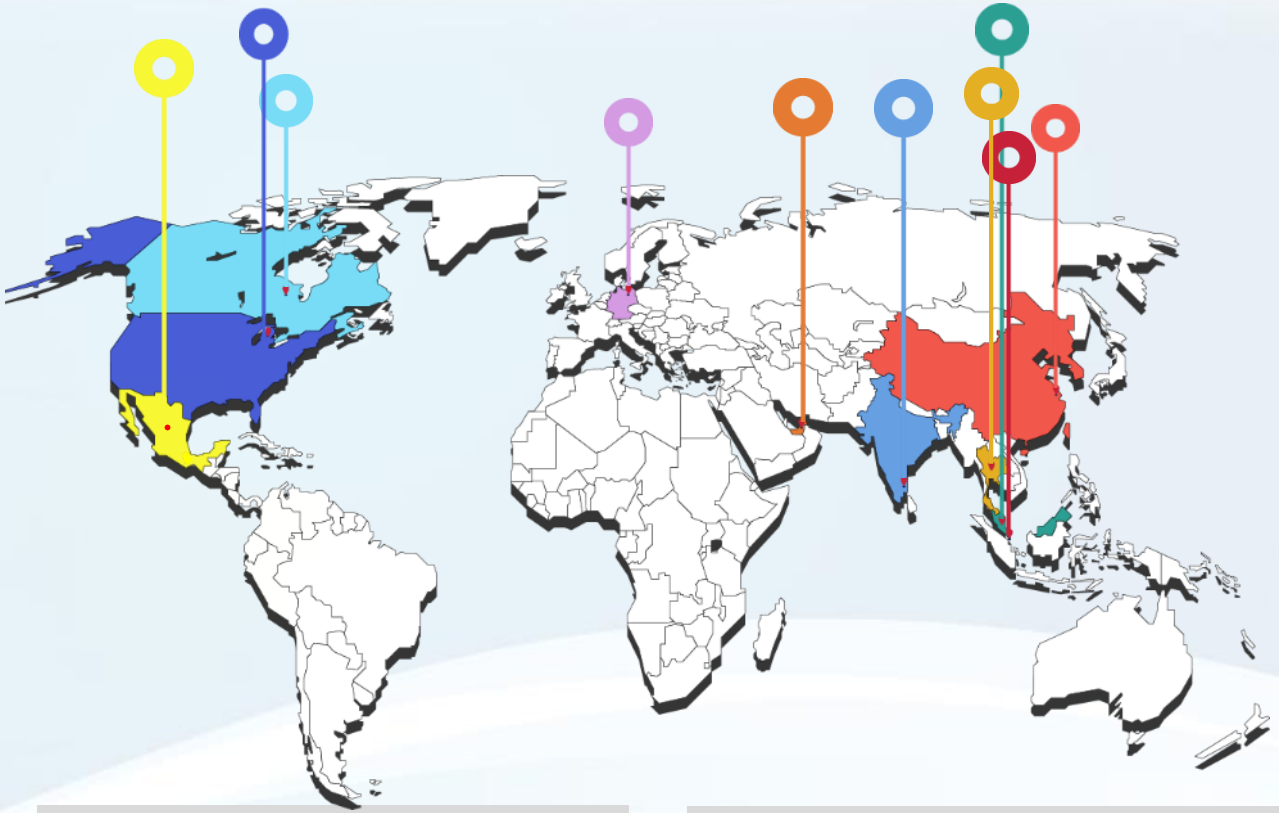
- Headquartered in Ann Arbor, Michigan with offices in major global markets.
- In 1995-97 provided global roll out supplier training and development for Ford Motor Company.
- Trained more than 100,000 individuals in over 30 countries.
- Workforce of over 700 professionals, speaking over a dozen languages.
- Former Delegation Leader of the International Automotive Task Force (IATF) responsible for ISO/TS 16949.
- Served on committees that wrote QOS, ISO 9001, QS-9000, ISO/TS 16949 and its Semiconductor Supplement, and ISO IWA 1 (ISO 9000 for healthcare).
- Former member of AIAG manual writing committees for FMEA, SPC, MSA, Sub-tier Supplier Development, Error Proofing, and Effective Problem Solving (EPS).

Omnex Worldwide Offices

Omnex is headquartered and operates from the United States through offices in Michigan.

The company maintains international operations in many countries to provide comprehensive services to clients throughout Western Europe, Latin America and the Pacific Rim.

www.omnex.com
info@omnex.com



- Omnex Global Head Quarters (Michigan, USA)
  West Coast Operations (San Jose, CA)
- Asia Pacific HQ (Chennai, Pune, Delhi, Bangalore)
- China (Shanghai, Guangzhou, Wuhan, Chengdu)
- Canada (Mississauga)
- Europe (Berlin, Germany)
- Middle East (Dubai, Saudi Arabia, Bahrain)
- Thailand (Bangkok)
- Mexico (Monterrey)
- Singapore
- Malaysia (Kuala Lumpur)

OMNEX

Rules of the Classroom

- ✓ Start and end on time
- ✓ Return from breaks and lunch on time
- ✓ All questions welcome
- ✓ Your input is valuable and is encouraged
- ✓ Don’t interrupt others
- ✓ One meeting at a time
- ✓ Listen – and respect others’ ideas
- ✓ No “buts” – keep an open mind
- ✓ Phones in Do Not Disturb (silent) mode
- ✓ No e-mails, texting or tweeting during class

If you must take a phone call or answer a text please leave the room for as short a period as possible

Icebreaker

- Instructor Information:
  - Name
  - Background
- Student Introductions:
  - Name
  - Position / Responsibilities
  - What is your involvement in the Lab Management System?
  - What are your experiences with ISO/IEC 17025 and Lab Management Systems?
  - What are your expectations for this course?
  - Please share something unique and/or interesting about yourself.

Chapter 1

Changes in ISO/IEC 17025:2017

Chapter 1: Changes in ISO/IEC 17025:2017 — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Explain why ISO/IEC 17025 was revised
- Summarize the revision history of ISO 9001 and ISO/IEC 17025
- Understand the major changes to ISO/IEC 17025 and the relationship to the latest ISO 9001:2015 standard
- Define the transition timeline

Chapter Agenda

- Why was ISO/IEC 17025:2017 Revised?
- Evolution to ISO/IEC 17025
- Customer Expectations
- What are the Major Changes to the 2017 Revision
- ISO 9001:2015 Changes Affecting ISO/IEC 17025
- Key Transition Date to ISO/IEC 17025:2017

Why was ISO/IEC 17025:2017 Revised?

According to the ISO/IEC 17025 "Working Group 44" changes were made in order to:

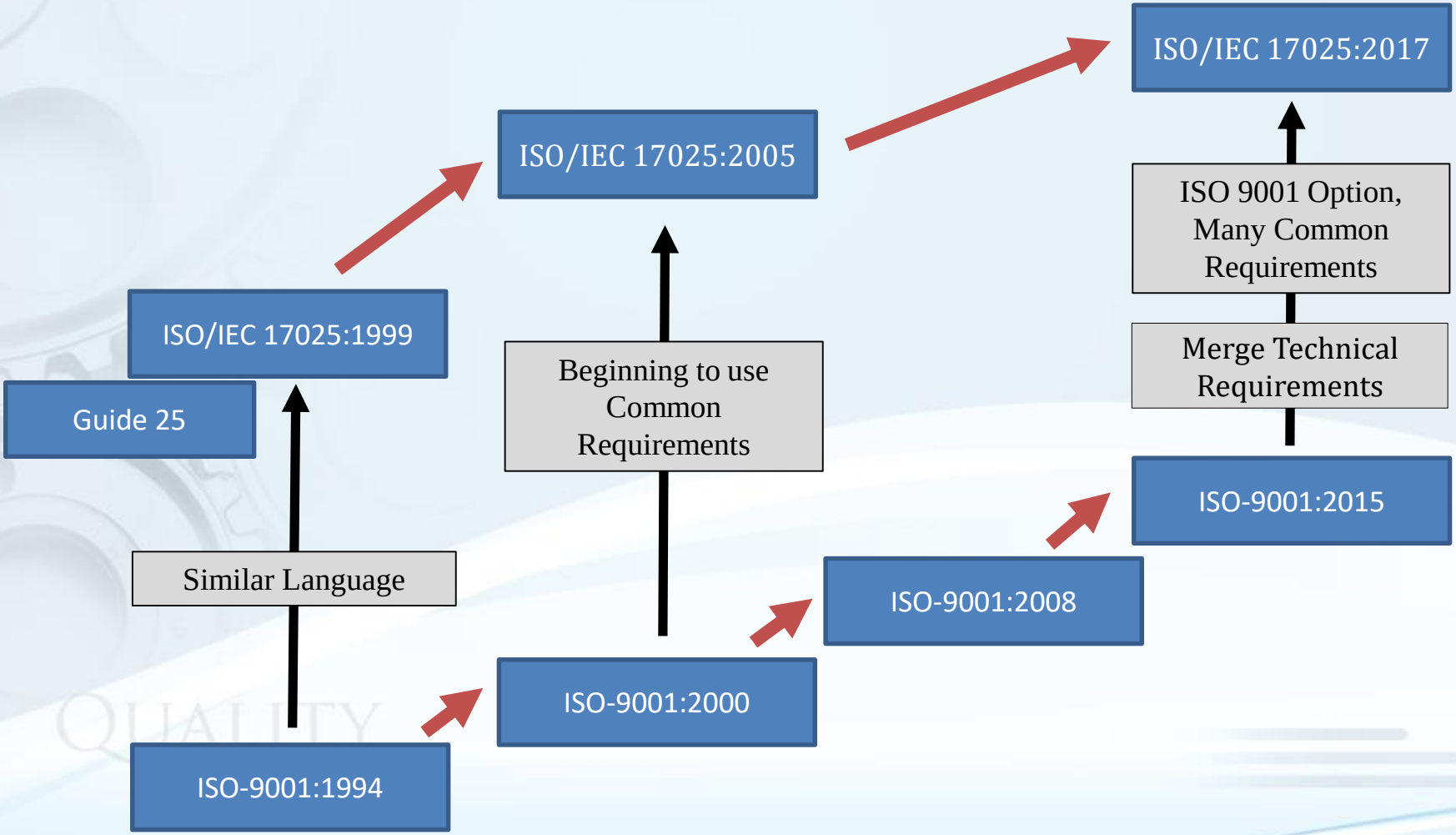
- Reflect the latest changes in market conditions and technology
- Encompass the activities and new ways of working in laboratories today (estimated over 100,000 users of this standard)
- Cover technical changes, vocabulary and developments in IT techniques, and
- Take into consideration the latest revision of ISO 9001 on quality management

Why was ISO/IEC 17025:2017 Revised?

ISO/IEC 17025 also needed to change since ISO 9001 changed in order to:

- Adapt to a changing world
- Enhance an organization's ability to satisfy its customers
- Provide a consistent foundation for the future. o.m.n.ex
- Reflect the increasingly complex environments in which organizations operate
- Ensure the new standard reflects the needs of all interested parties
- Integrate with other management systems

Evolution to ISO/IEC 17025



What are the Major Changes to the 2017 Revision?

- The scope has been revised to cover testing, calibration and sampling associated with subsequent calibration and testing.
- The process approach now matches that of newer standards such as ISO 9001.
- The standard now has a stronger focus on information technologies and incorporates the use of computer systems, electronic records and the production of electronic results and reports.
- A new section introduces the concept of risk-based thinking which has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements.
- There is greater flexibility in the requirements for processes, procedures, documented information and organizational responsibilities.

ISO 9001:2015 Changes Affecting ISO/IEC 17025

High-level Changes

- **NEW –** Total restructure of clauses **(From 4 to now 8)**
- **NEW –** Process Approach – **A.2.3 and 8.2.4 (process and procedure interchangeable)**
- **CHANGED –** Control of data and information management – (**7.11)**
- **NEW –** Actions to Address Risks and Opportunities – **(8.5, there are several other risk considerations in the new standard)**
  - Removed "Preventive Action"
- **NEW –** Option for ISO 9001 – **(8.1)**
- Much broader use of the term **Laboratory Activities**

Not an exhaustive list…. Detailed changes will be highlighted in Chapter 3 – Requirements

The ISO Body has introduced a new High Level Structure for all management system standards. ISO/IEC 17025 followed this numbering structure, but not all clauses specifics (sections and titles)

ISO 9001:2015 Changes Affecting ISO/IEC 17025

Specific Changes

- **Removed –** Preventive Action
- **Removed –** Need for specific Quality & Technical Manager
- **CHANGED –** Improvement to Impartiality and Confidentiality **(4.1 & 4.2)**
- **CHANGED –** Created the term "Range" of Lab activities, not just "Scope" of Testing or Calibration **(5.3)**
- **CHANGED –** Need to document "Competence Requirements" of Lab personnel **(6.2)**
- **NEW –** Added need to control facilities and environmental conditions outside its permanent control **(6.3.5)**
- **CHANGED –** Expanded control of "Externally Provided Products and Services **(6.6)**

ISO 9001:2015 Changes Affecting ISO/IEC 17025

Specific Changes

- **CHANGED –** Greatly improved documentation needs of agreements and on-going communications with the Lab and the Client **(7.1)**
- **CHANGED –** Lab must now be more aware the latest Industry Standards and Methods, plus the clients needs and applications **(7.2)**
- **CHANGED –** Laboratory performing "Testing" shall evaluate measurement uncertainty **(7.6)**
- **NEW –** Added many new monitoring methods for "Ensuring the Validation of Results" (Quality Control) **(7.7)**
- **CHANGED –** Additional improvements to sub-clauses for:
  - Complaints **(7.9)**
  - Nonconforming Work **(7.10)**
  - Control of Data and Information Management **(7.11)**

Key Transition Dates to ISO/IEC 17025:2017

November 2017	**ISO/IEC 17025:2017 released**
November 2020	Have three-year period from the publication date
Consideration	- Current re-accreditation cycle - Need minimum 90 days to close any NCs - Current status of ISO 9001, if applicable - Customer demand - Adding test, calibration or sampling methods to scope? - Accreditation bodies policies and resources

Don't wait too long! Start early!

OMNEX

Chapter 1: Changes in ISO/IEC 17025:2017 — What We Covered

Learning Objectives

You should now be able to:

- Explain why ISO/IEC 17025 was revised
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- Understand the major changes to ISO/IEC 17025 and the relationship to the latest ISO 9001:2015 standard
- Define the transition timeline

Chapter Agenda

- Why was ISO/IEC 17025:2017 Revised?
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Chapter 2

Introduction to ISO/IEC 17025:2017

Chapter 2: Introduction to ISO/IEC 17025:2017 — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Describe the ISO body and the ISO/IEC 17025:2017 International Standard
- Define the intent of ISO/IEC 17025:2017 and its relationship to the requirements of calibration and testing laboratories

Chapter Agenda

- What is ISO / What is IEC?
- ISO/IEC 17025:2017 Overview
- Terms & Definitions
- ISO/IEC 17025 Relation to ISO 9001
- Old to New Standards
- What is ILAC?
- ISO 9000 Series of Quality Management Documents
- **Breakout Exercise 1**
- **Written Exercise 1**

WHAT IS ISO / WHAT IS IEC?

What is ISO?

- ISO is the International Organization for Standardization (**www.iso.org**) – headquartered in Geneva, Switzerland
- The International Organization for Standardization is a worldwide federation of the national standards organizations of 161 countries
  - The U.S. representative to ISO is the American National Standards Institute (ANSI)
  - The Canadian representative is the Standards Council of Canada (SCC)
- The term ISO is derived from the Greek word, *isos*, meaning equal – its mandate is to develop and promote standards of all sorts worldwide

What is ISO?

- As of January 2018, the ISO Catalog lists over 22,000 International Standards
  - These documents address almost all fields, except electrical and electronic engineering standards
  - International Electro-technical Commission has separate responsibility for electrical standards
- ISO work is carried out by 242 technical committees, many of which also have sub-committees
  - ISO/TC 176, Quality Management and Quality Assurance Technical Committee is responsible for quality standards

Every five years, ISO reviews a standard to ensure its continuing suitability; it may or may not be revised at that time

What is IEC?

- The International Electrotechnical Commission (IEC) is the world's leading organization that prepares and publishes International Standards for all electrical, electronic and related technologies
- The IEC is one of three global sister organizations (IEC, ISO, ITU) that develop International Standards
- To ensure that International Standards fit together seamlessly and complement each other, when appropriate, IEC cooperates with
  - ISO (International Organization for Standardization)
  - ITU (International Telecommunication Union)

ISO/IEC 17025:2017 OVERVIEW

ISO/IEC 17025:2017 Overview

ISO/IEC 17025 specifies the general requirements for the competence to carry out testing, calibrations and **sampling associated with subsequent testing or calibration**

- Objective of promoting confidence in the operation of laboratories
- Enable laboratories to demonstrate they operate competently, and are able to generate valid results
- Laboratories that conform to ISO/IEC 17025:2017 **will also operate generally in accordance with the principles of ISO 9001**

ISO/IEC 17025:2017 Overview

- Requires the laboratory to plan and implement actions to address risks and opportunities
- Implementation will:
  - Facilitate cooperation between laboratories and other bodies
  - Assist in the exchange of information and experience, and
  - Harmonization of standards and procedures
- The acceptance of results between countries is simplified if laboratories conform to ISO/IEC 17025

ISO/IEC 17025:2017 Overview

- ISO/IEC 17025:2017 was prepared by the ISO Committee on Conformity Assessment (CASCO)
- ISO/IEC 17025:2017 (Third Edition) cancels and replaces ISO/IEC 17025:2005 (Second Edition)
- This new revision is based on ISO 9001:2015
- Contains all the requirements that testing and calibration laboratories **(and the associated sampling)** must meet if they wish to demonstrate that they:
  - **Lab Specific Requirements (Clauses 4, 5, 6 and 7)**
  - **QMS Requirements – Option A: minimum laboratory management system requirements (Clauses 8.2 to 8.9)**
  - **QMS Requirements – Option B: accordance with an ISO 9001:2015 implementation (Clause 8.1)**

Scope of ISO/IEC 17025:2017

- Specifies the general requirements for the competence, **impartiality** and consistent operation of laboratories.
- Applicable to all organizations performing laboratory activities, **regardless of the number of personnel**.
- Laboratory customers, regulatory authorities, organizations and schemes using **peer-assessment**, accreditation bodies, and others use ISO/IEC 17025 (this document) in confirming or recognizing the competence of laboratories.

General Verbiage

- “Shall” indicates a requirement
- “Should” indicates a recommendation
- “May” indicates a permission
- “Can” indicates a possibility or a capability

ISO/IEC 17025:2017 Normative References

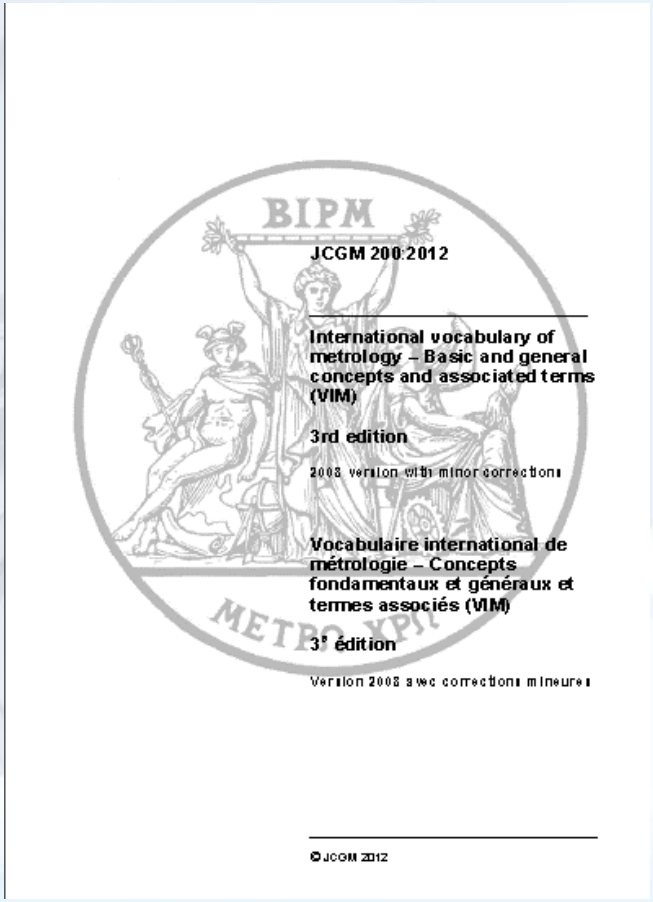
ISO/IEC 17000

ISO/IEC 17000, Conformity Assessment – Vocabulary and General Principles

ISO/IEC Guide 99

ISO/IEC Guide 99, International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM)

International Vocabulary of Basic and General Terms in Metrology (VIM)



The International Bureau of Weights and Measures (BIPM)

Contents

Key Definitions in ISO/IEC 17025:2017

- **Impartiality:** Presence of objectivity.
- **Complaint:** Expression of dissatisfaction by any person or organization to a laboratory, relating to the activities or results of that laboratory, where a response is expected.
- **Interlaboratory Comparison:** Organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions.
- **Intralaboratory Comparison:** Organization, performance and evaluation of measurements or tests on the same or similar items within the same laboratory in accordance with predetermined conditions.
- **Proficiency Testing:** Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

Key Definitions in ISO/IEC 17025:2017

- **Laboratory:** Body that performs one or more of the following activities:
  - Testing;
  - Calibration; or
  - Sampling, associated with subsequent testing or calibration.
- **Decision Rule:** Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.
- **Verification:** Provision of objective evidence that a given item fulfills specified requirements.
- **Validation:** Verification, where the specified requirements are adequate for an intended use.
- **Measurand:** Quantity to be measured.

ISO/IEC 17025 RELATION TO ISO 9001

ISO/IEC 17025 Relation to ISO 9001:2015

- Many of the ISO 9001:2015 requirements have been applied to the latest ISO/IEC 17025 standard
- Portions of the new **High-Level Structure** of ISO 9001 has been applied
- As previously indicated, there is now an option to apply a current ISO 9001 QMS to ISO/IEC 17025
- We will review applicable detailed ISO 9001 requirements while learning the latest ISO/IEC 17025 standard!

ISO/IEC 17025 Relation to ISO 9001

- Accreditation to ISO/IEC 17025:2017 now has an option to use an ISO 9001 QMS to meet intent of all clause 8


INTERNATIONAL STANDARD

ISO/IEC 17025

Third edition
2017-11

General requirements for the competence of testing and calibration laboratories

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

Reference number
ISO/IEC 17025:2017(E)

© ISO/IEC 2017

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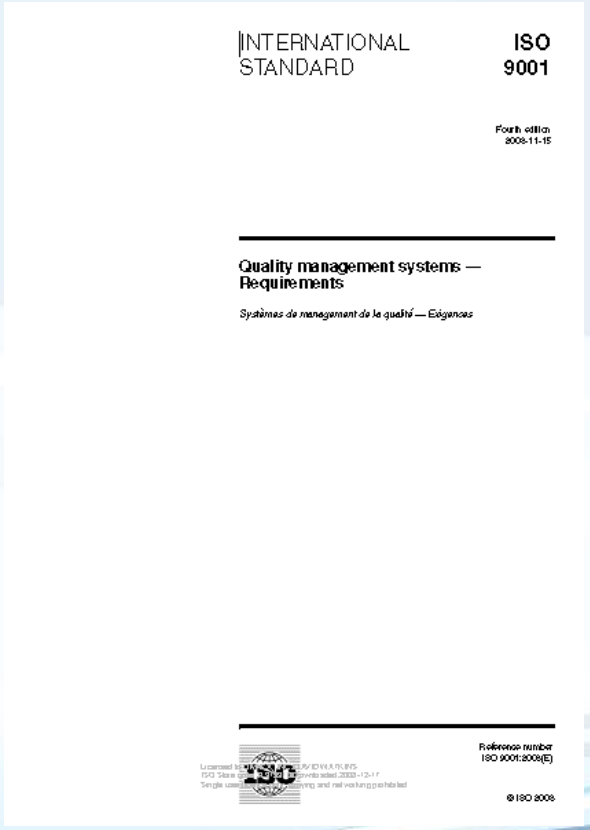
Option


INTERNATIONAL STANDARD

ISO 9001

Fourth edition
2008-11-15

Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

Reference number
ISO 9001:2008(E)

© ISO 2008

High Level Structure – ISO/IEC 17025 vs. ISO 9001

ISO/IEC 17025:2017

1. Scope
2. Normative References
3. Terms and Definitions
4. General Requirements
5. Structural Requirements
6. Resource Requirements
7. Process Requirements
8. Management System Requirements

ISO 9001:2015

1. Scope
2. Normative References
3. Terms and Definitions
4. Context of the Organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance Evaluation
10. Improvement

High Level Structure – ISO/IEC 17025 vs. ISO 9001

The General Relationship Only

New ISO/IEC 17025:2017 vs. Old ISO/IEC 17025:2005

ISO/IEC 17025:2017	ISO/IEC 17025:2005
4. General Requirements 5. Structural Requirements	4.1 & 4.2
6. Resource Requirements	5.2, 5.3, 5.5, 5.6, 4.5, 4.6
7. Process Requirements	4.4, 4.5, 5.4, 5.7, 5.8, 5.9, 5.10, 4.8, 4.9
8. Management Systems Requirements	4.2, 4.3, 4.13, 4.10, 4.11, 4.14, 4.15 Risk (New, replace 4.12)

High Level Only – Detailed Cross-Reference Matrix are Available

WHAT IS ILAC?

What is ILAC?

- The International Laboratory Accreditation Cooperation (ILAC) is an international cooperation of laboratory and inspection accreditation bodies formed more than 30 years ago to help remove technical barriers to trade.
- Accreditation bodies are established in many countries with the primary purpose of ensuring that conformity assessment bodies are subject to oversight by an authoritative body.
- Accreditation bodies, that have been evaluated by peers as competent, sign arrangements that enhance the acceptance of products and services across national borders.
  - Creates a framework to support international trade through the removal of technical barriers.
- These arrangements are managed by the ILAC in the field of laboratory and inspection accreditation.

Mutual Recognition Agreements

- International recognition of accreditations awarded by national bodies is based on the conclusion of Mutual Recognition Agreements (MRAs) between the national bodies.
- The bodies seeking to agree to recognize each other's accreditations will audit each other's operations against **ISO 17011: Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies.**
- This is the international standard to which assessment bodies are expected to adhere.

ISO 9000 SERIES OF QUALITY MANAGEMENT DOCUMENTS

The ISO 9000 Family of Documents

ISO 9001
System
Requirements

ISO 9001 – Specific Requirements for a Quality Management System

ISO 9000
Fundamentals and
Vocabulary

ISO 9000 – Fundamental Concepts and Principles of Quality Management

ISO 9004
Guidance to Achieve
Sustained Success

ISO 9004 — Guidance for Performance Improvement

Every five years, ISO reviews a standard to ensure its continuing suitability; it may or may not be revised at that time

Quality Management Systems Approach

- Determining the *needs and expectations* of customers and other interested parties
- Establishing the *quality policy* and *quality objectives*
- Determining the *processes and responsibilities* necessary to attain the quality objectives
- Identifying the *interactions* between processes
- Determining and *providing the resources* necessary to attain the quality objectives
- Establishing *methods to measure* the effectiveness and efficiency of each process
- Applying these measures to *determine the effectiveness* and efficicency of each process
- Determining means of *preventing nonconformities* and eliminating their causes
- Establishing and applying a process for *continual improvement* of the QMS

The ISO 9001 Quality Management Principles

- Customer Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence-based Decision Making
- Relationship Management

Breakout Exercise 1

Definition of a Laboratory

Written Exercise 1

Conducted in Groups

Chapter 2: Introduction to ISO/IEC 17025:2017 — What We Covered

Learning Objectives

You should now be able to:

- Describe the ISO body and the ISO/IEC 17025:2017 International Standard
- Define the intent of ISO/IEC 17025:2017 and its relationship to the requirements of calibration and testing laboratories

Chapter Agenda

- What is ISO / What is IEC?
- ISO/IEC 17025:2017 Overview
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- Old to New Standards
- What is ILAC?
- ISO 9000 Series of Quality Management Documents
- **Breakout Exercise 1**
- **Written Exercise 1**

Chapter 3

ISO/IEC 17025:2017 Requirements

Chapter 3: ISO/IEC 17025:2017 Requirements — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Define the requirements of ISO/IEC 17025:2017
- Define the needs for documentation and implementation

Chapter Agenda

- General QMS Requirements
  - **Breakout Exercise 2 – Part A**
- ISO/IEC 17025 Scope
- ISO/IEC 17025:2017 Requirements
  - **Written Exercise 2**
  - **Written Exercise 3**
  - **Breakout Exercise 2 – Part B**
  - **Written Exercise 4**

GENERAL QMS REQUIREMENTS

NOTE: text boxes indicate where a similar requirement could be found in ISO 17025:2005

General Requirements of a QMS

Intent is to Describe the Overall Requirements of a QMS for the Lab

- Ensure effective monitoring, control and improvement of all processes within the management system to fulfill organizational objectives and meet customer requirements
- Identify the lab's key processes, their sequence, and interactions
- Identify the control requirements for the processes including:
  - What to monitor
  - What to measure
  - The goals for each measure
  - **WHO** will measure, monitor, analyze and improve each process

General Requirements of a QMS

The Organization Must Develop, Document, Set Up and Maintain a Management System and Continually Improve its Effectiveness Through Six Activities:

1. Identify the *processes* needed for the QMS and their application
2. Determine *sequence* and *interaction* of these processes
3. Determine *criteria* and *method* needed to ensure that both the operation and monitoring of these processes are effective
4. Ensure the availability of resources and information necessary to *support operation* and *monitoring of processes*
5. *Monitor*, *measure* and *analyze* these processes for both effectiveness and efficiency
6. *Implement actions necessary* to achieve planned results and continual improvement of the processes

- All related activities must conform to the requirements of ISO 9001
- When processes that affect product conformity are outsourced, the management system must contain provisions to ensure control over these processes

Process Characteristics

- Identified by a series of unique, but consistent characteristics
- There are six mandatory characteristics of a process for effective quality management (based on ISO 9001 and best practices):
  1. A process owner exists
  2. The process is defined
  3. The process is documented
  4. The linkages of the process are established
  5. The process is monitored and improved
  6. Records are maintained

Types of Processes

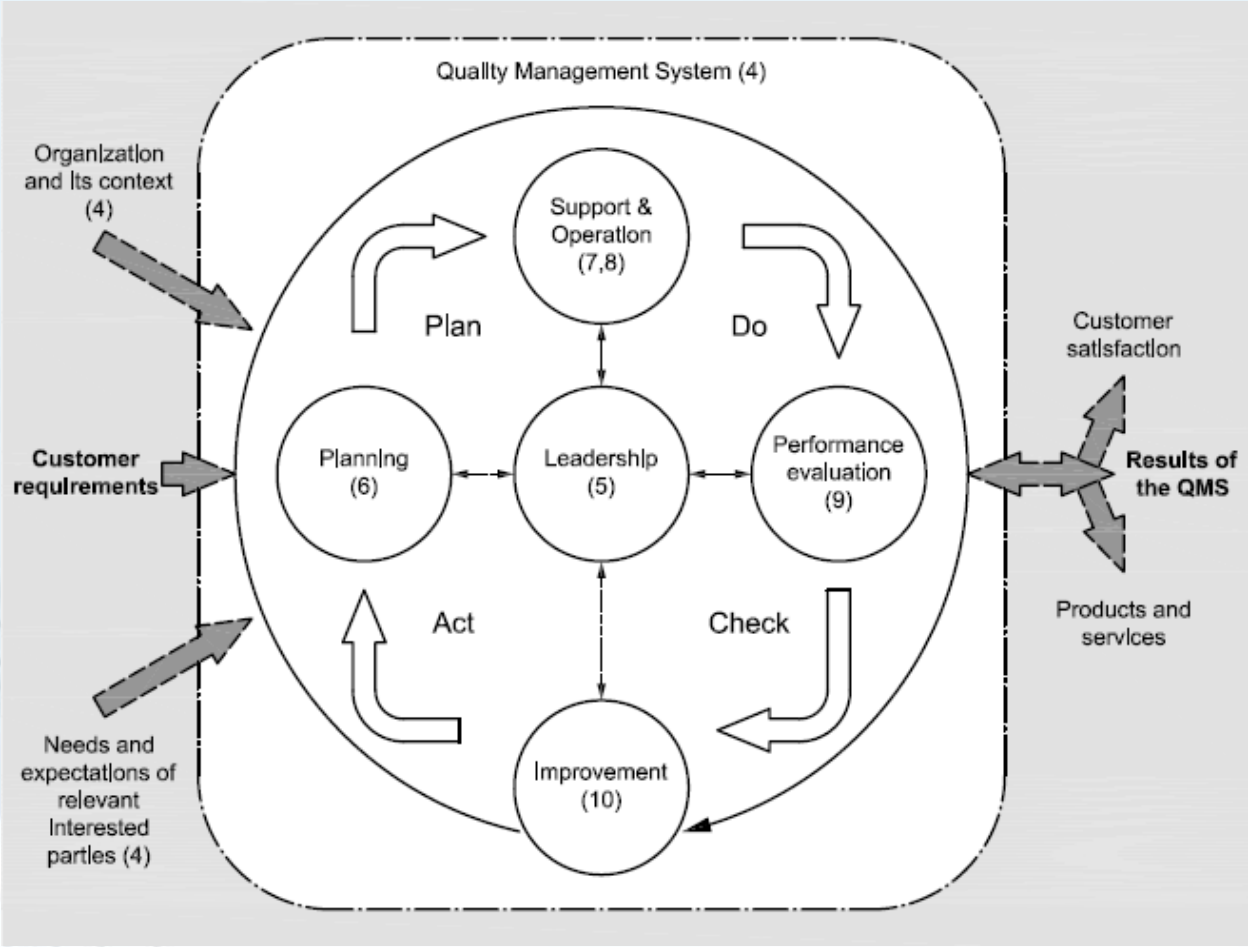
- **Management oriented processes (MOPs)** direct, measure and review the organization, such as business planning, objectives deployment and continual improvement
- **Customer oriented processes (COPs)** receive input from the customer with output going back to the customer
- **Support oriented processes (SOPs)** are the support processes that sustain the COPs and MOPs and aid the overall organization and include operations such as training, purchasing and document control

Types of Processes

The Omnex Approach to Process Focus

- Process Map – Interfaces and linkages between site and remote locations identified
- Process List – Processes well-defined, inputs, outputs, resources, measurement and records
- Business Management System Control Plan
- Alignment Chart

Quality Management System (QMS) Process Model



source: ISO 9001:2015

The PDCA cycle can be applied to all processes and to a QMS in whole

Breakout Exercise 2

Part A – Key Processes

ISO/IEC 17025 SCOPE

Scope of ISO/IEC 17025:2005

- Specifies the general requirements a laboratory has to meet in order to be recognized as competent to carry out tests and/or calibrations, including sampling. O$M$$NEX

- Covers testing and calibrations using standardized methods, methods not covered by standardized methods, and laboratory-developed methods (see clause 5.4.2, 5.4.3, 5.4.4)

- Can be applied to all organizations performing this type of work, including first, second and third party labs, and labs that form part of inspection and product certification

Scope of ISO/IEC 17025:2005

- For use by labs to develop their quality, administrative and technical systems, and to confirm or recognize their competence
- If labs comply with this standard, they will comply with the principles of ISO 9001 when they design/develop new methods and when they use only standardized methods
- Does **not** cover compliance of the lab with relevant regulatory and safety requirements

Accreditation Terms

- **Accreditation:** A formal recognition of competence that a laboratory can perform specific calibrations and/or tests or types of tests. It is available to any calibration or testing laboratory – private, government or independent.
- **Accreditation Body:** An organization with authority – typically from the national government – to accredit bodies such as certification bodies/registrars for quality system certification, test laboratory accreditation, etc.
- **Accredited Laboratory:** A laboratory that has been reviewed and approved by a nationally-recognized accreditation body.

Accredited Laboratories

- In a sense, the term "**accredited laboratory**" is inaccurate!
- Rather a lab is accredited for a specific list of methods
- These are listed in the laboratory "*scope*" statement
- These should be methods that the lab performs routinely, e.g., >12 times per year
- If a laboratory wishes accreditation for part or all of its testing and calibration activities, it should select an accreditation body that operates in accordance with ISO/IEC 17011

Major US Accreditation Bodies for Laboratories

- American Association for Lab Accreditation (A2LA)
- ANSI-ASQ National Accreditation Board (ANAB)
- International Accreditation Service, Inc. (IAS)
- National Voluntary Laboratory Accreditation Program (NVLAP)
- Laboratory Accreditation Bureau (L-A-B)
- Perry Johnson Laboratory Accreditation, Inc. (PJLA)
- AIHA's Laboratory Accreditation Programs, LLC
- American Society of Crime Laboratory Directors / Laboratory Accreditation Board (ASCLD/LAB)

Auto Industry Supplier Requirements

- Commercial/independent laboratory facilities used by the supplier for inspection, test or calibration services shall be accredited facilities to ISO/IEC 17025 or national equivalent
  - NOTE: A commercial/independent laboratory may have a customer-approved second party assessment
- Where a qualified lab does not exist for certain equipment, it may be calibrated by the manufacturer

ISO/IEC 17025:2017 REQUIREMENTS

Detailed Changes to 2017 Version

- There have been many improvement to the standard
- Additions will be ***(Bold, Italic and Underline)***
- Comments to previous 2005 revision cross-reference will be noted where possible or significant
- Comments to the latest ISO 9001:2015 requirements will also be noted where applicable

Impartiality – Clause 4.1 (General Requirements)

4.1.1 Laboratory activities shall be undertaken impartially and ***structured and managed*** so as to safeguard impartiality.

4.1.2 The laboratory management shall be ***committed to impartiality***.

4.1.3 The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality.

4.1.4 ***The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality.***

4.1.5 ***If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.***

ISO/IEC 17025:2005 – 4.1 (d) and 4.1.4

Impartiality Threats – Risks

- This is the first introduction of the “Risk”
- Can be based on
  - Ownership
  - Governance
  - Management
  - Personnel
  - Shared Resources
  - Finances
  - Contracts
  - Marketing (including branding), and
  - Payment of a sales commission or other inducement for the referral of new customers

Confidentiality – Clause 4.2 (General Requirements)

4.2.1 The laboratory shall be responsible, through ***legally enforceable commitments***, for the management of all information obtained or created during the performance of laboratory activities.

- ***The laboratory shall inform the customer in advance, of the information it intends to place in the public domain.***
- ***Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints)***, all other information is considered proprietary information and shall be regarded as confidential.

ISO/IEC 17025:2005 – 4.2.2 (a), 4.1.5 (c)

Confidentiality – Clause 4.2 (General Requirements)

4.2.2 ***When the laboratory is required by law or authorized by contractual arrangements to release confidential information***, the customer or individual concerned shall, ***unless prohibited by law***, be notified of the information provided.

4.2.3 ***Information about the customer obtained from sources other than the customer (e.g. complainant, regulators)*** shall be confidential between the customer and the laboratory. ***The provider (source) of this information shall be confidential to the laboratory and shall not be shared with the customer, unless agreed by the source.***

4.2.4 Personnel, including ***any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities, except as required by law***.

ISO/IEC 17025:2005 – 4.1.5 (c), 5.4.7.2 (b)

Structural Requirements – Clause 5

5.1 The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.

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

5.3 The laboratory shall define and document the ***range*** of laboratory activities for which it conforms with ISO/IEC 17025.

- ***Shall only claim conformity with ISO/IEC 17025 for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.***

❖ ***Range equals Scope***

ISO/IEC 17025:2005 – 4.1.1, 4.1.5 (a), 4.2.1

Structural Requirements – Clause 5

5.4 Laboratory activities shall be carried out in such a way as to meet the requirements of ISO/IEC 17025, the laboratory's customers, regulatory authorities and organizations providing recognition.

- This shall include laboratory activities performed in all its facilities;
  - permanent
  - at sites away from its permanent facilities
  - temporary
  - mobile
  - ***at a customer's facility***

ISO/IEC 17025:2005 – 4.1.1, 4.1.3

Structural Requirements – Clause 5

5.5 The laboratory shall:

a) Define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;

b) Specify the responsibility, authority and interrelationship of all personnel who ***manage***, perform or verify work ***affecting the results of laboratory activities***;

c) Document its procedures to the extent necessary to ensure the ***consistent application of its laboratory activities and the validity*** of the results.

ISO/IEC 17025:2005 – 4.1.5 (e), (f), and 4.2.1

Structural Requirements – Clause 5

5.6 The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:

a) Implementation, maintenance and improvement of the management system;

b) Identification of ***deviations*** from the management system or from the procedures for performing ***laboratory activities;***

c) initiation of actions to prevent or minimize such ***deviations;***

d) Reporting to laboratory management on the performance of the management system and any need for improvement;

e) Ensuring the effectiveness of laboratory activities.

ISO/IEC 17025:2005 – 4.1.5 (a)

Structural Requirements – Clause 5

5.7 Laboratory management shall ensure that:

a) Communication takes place regarding the effectiveness of the management system and the importance of meeting customers' and ***other requirements;***

b) The integrity of the management system is maintained when changes to the management system are planned and implemented.

ISO/IEC 17025:2005 – 4.1.6, 4.2.4, 4.2.7

Resource Requirements – Clause 6

6.1 General

- The laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities.

What does this include in your Lab?

ISO/IEC 17025:2005 – 5.1 (General), 4.2.1

Personnel – Clause 6.2

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.

6.2.2 The laboratory shall ***document the competence requirements*** for each ***function influencing the results of laboratory activities***, including requirements for:

- education
- qualification
- training
- technical knowledge
- skills and experience

ISO/IEC 17025:2005 – 5.2.1, 5.2.3

Personnel – Clause 6.2

6.2.3 The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they ***are responsible and to evaluate the significance of deviations***.

6.2.4 The management of the laboratory shall ***communicate*** to personnel their ***duties***, responsibilities and authorities.

6.2.5 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

ISO/IEC 17025:2005 – 5.2.1, 4.1.5 (f), 5.2.1 (Note), 5.2.5

Personnel – Clause 6.2

6.2.6 The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

a) Development, modification, ***verification*** and validation of methods;

b) Analysis of results, including statements of conformity or opinions and interpretations;

c) Report, ***review and authorization*** of results.

ISO/IEC 17025:2005 – 5.2.4 (Note), 5.2.5

Facilities and Environmental Conditions – Clause 6.3

6.3.1 The facilities and environmental conditions shall be suitable for the ***laboratory activities*** and shall not adversely affect the validity of results.

- (NOTE) Examples of Influences, which affect your lab?
  - microbial contamination and dust
  - electromagnetic disturbances
  - Radiation
  - Humidity
  - electrical supply
  - Temperature
  - sound and vibration.
- **6.3.2** The requirements for facilities and environmental conditions necessary for the performance of the ***laboratory activities*** shall be documented.

ISO/IEC 17025:2005 – 5.3.1, 5.3.2 (now a note in ISO/IEC 17025)

Facilities and Environmental Conditions – Clause 6.3

6.3.3 The laboratory shall monitor, control and record environmental conditions ***in accordance*** with relevant specifications, methods or procedures or where they influence the ***validity*** of the results.

6.3.4 Measures to control ***facilities*** shall be ***implemented, monitored and periodically reviewed*** and shall include, ***but not be limited to***:

a) Access to and use of areas affecting ***laboratory activities***;

b) Prevention of contamination, interference or adverse influences on laboratory activities;

c) Effective separation between areas with incompatible ***laboratory*** activities.

6.3.5 …. ***All the same requirements apply for 6.3 … for activities at sites or facilities outside its permanent control (NEW)***

ISO/IEC 17025:2005 – 5.3.2, 5.3.5, 5.3.4, 5.3.3

Equipment – Clause 6.4

6.4.1 The laboratory shall have access to equipment (including, but not limited to):

- Measuring Instruments
- Software
- ***Measurement Standards***
- ***Reference Materials***
- ***Reference*** Data
- ***Reagents***
- ***Consumables or Auxiliary Apparatus***

that is required for the correct performance of ***laboratory activities*** and that can influence the results.

- NOTE 1: A multitude of names exist for reference materials and certified reference materials…see note if needed.

ISO/IEC 17025:2005 – 5.5.1, 5.5.2 (same in clause 4.6 and 5.6.3)

Equipment – Clause 6.4

6.4.2 When the laboratory uses equipment outside its permanent control, it shall ensure that the requirements ***for equipment of ISO/IEC 17025 are met***.

6.4.3 The laboratory shall have a procedure for:

- Handling
- Transport
- Storage
- Use
- Planned Maintenance

of equipment in order to ensure proper functioning and to prevent contamination or deterioration.

6.4.4 The laboratory shall verify that equipment conforms to specified requirements before being placed ***or returned into service***.

ISO/IEC 17025:2005 – 5.5.1, 5.5.3, 5.5.6, 5.5.2

Equipment – Clause 6.4

6.4.5 The equipment used for measurement shall be capable of achieving the measurement accuracy ***and/or measurement uncertainty required to provide a valid result***. (Also, seen new **7.1** and **7.6**)

6.4.6 Measuring equipment shall be calibrated when:

- The measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or
- Calibration of the equipment is required to establish the ***metrological*** traceability of the reported results.
- ***Those used for the direct measurement of the measurand, e.g. use of a balance to perform a mass measurement;***
- ***Those used to make corrections to the measured value, e.g. temperature measurements;***
- ***Those used to obtain a measurement result calculated from multiple quantities.***

ISO/IEC 17025:2005 – 5.5.2, 5.6.2.1.1 (moved), 5.4.6.2

Equipment – Clause 6.4

6.4.7 The laboratory shall establish a calibration program, which shall be reviewed and ***adjusted as necessary in order to maintain confidence in the status of calibration.***

6.4.8 All equipment requiring calibration ***or which has a defined period of validity*** shall be labelled, coded or otherwise identified ***to allow the user of the equipment to readily identify*** the status of calibration ***or period of validity***.

6.4.9 Equipment that has been subjected to overloading or mishandling, gives ***questionable*** results, or has been shown to be defective or outside specified requirements, shall be taken out of service.

6.4.9 It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been ***verified*** to perform correctly. The laboratory shall examine the effect of the defect or ***deviation*** from specified ***requirements*** and shall ***initiate*** the ***management*** of nonconforming work procedure (see 7.10).

ISO/IEC 17025:2005 – 5.6.2.1.1, 5.5.8, 5.5.7

Equipment – Clause 6.4

6.4.10 When intermediate checks are ***necessary*** to maintain confidence in the ***performance*** of the equipment, these checks shall be carried out according to a procedure.

6.4.11 When calibration ***and reference material data include reference values or correction factors, the laboratory shall ensure the reference values and*** correction factors are updated ***and implemented, as appropriate, to meet specified requirements***.

6.4.12 The laboratory shall ***take practicable measures to prevent unintended*** adjustments of equipment from invalidating results.

ISO/IEC 17025:2005 – 5.5.10, 5.5.11, 5.5.12 5.7

Equipment – Clause 6.4

6.4.13 Records shall be ***retained*** for equipment which can ***influence laboratory activities***. The records shall include the following, ***where applicable***:

a) The identity of equipment, including software ***and firmware*** version;

b) The manufacturer's name, type identification, and serial number or other unique identification;

c) ***Evidence of verification*** that equipment ***conforms with specified requirements***;

d) The current location;

e) ***Calibration*** dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration ***or the calibration interval***;

f) ***Documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity***;

g) The maintenance plan and maintenance carried out to date, ***where relevant to the performance of the equipment***;

h) ***Details of*** any damage, malfunction, modification to, or repair of, the equipment.

ISO/IEC 17025:2005 – 5.5.5

Metrological Traceability – Clause 6.5

6.5.1 The laboratory shall establish and maintain ***metrological*** traceability of its ***measurement results*** by means of a ***documented*** unbroken chain of calibrations, ***each contributing to the measurement uncertainty***, linking them to an appropriate reference.

6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:

a) Calibration provided by a competent laboratory; or

b) Certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or

c) Direct realization of the SI units ensured by comparison, directly or indirectly, with national or international standards.

ISO/IEC 17025:2005 – 5.6.2.1.1

Metrological Traceability – Clause 6.5

6.5.3 When ***metrological*** traceability to the SI units ***is not technically possible***, the laboratory shall demonstrate ***metrological*** traceability to an appropriate ***reference***, e.g.:

a) Certified values of certified reference materials provided by a competent ***producer***;

b) Results of reference measurement ***procedures***, specified methods or consensus standards that are clearly described and ***accepted*** as providing measurement ***results fit for their intended use*** and ensured by suitable comparison.

ISO/IEC 17025:2005 – 5.6.2.1.2

Externally Provided Products and Services – Clause 6.6

6.6.1 The laboratory shall ***ensure that only suitable externally provided products and services that affect laboratory activities*** are used, when such products and services:

a) Are intended for incorporation into the laboratory's own activities;

b) Are provided, in part or in full, directly to the customer by the laboratory, as received from the ***external provider***;

c) Are used to support the operation of the laboratory.

ISO/IEC 17025:2005 – 4.5 and 4.6
External Provider and Service – New term from ISO 9001

Externally Provided Products and Services – Clause 6.6

6.6.2 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***;

b) Defining the ***criteria*** for evaluation, selection, ***monitoring of performance and re-evaluation of the external providers***;

c) Ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of ISO/IEC 17025, ***before they are used or directly*** provided to the customer;

d) Taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

ISO/IEC 17025:2005 – 4.6.1, 4.6.4, 4.6.2

Externally Provided Products and Services – Clause 6.6

6.6.3 The laboratory shall ***communicate*** its requirements to ***external providers*** for:

a) The products and ***services*** to be provided;

b) The acceptance criteria;

c) Competence, including any required qualification of personnel;

d) Activities that the laboratory, or its customer, intends to perform at the external provider's premises.

ISO/IEC 17025:2005 – 4.6.3, 4.6.4, 4.4.3

Written Exercise 2

Conducted in Groups

Process Requirements – Clause 7

7.1 Review of Requests, Tenders and Contracts

7.1.1 The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:

a) The requirements are adequately defined, documented and understood;

b) The laboratory has the capability and resources to meet the requirements;

c) ***Where external providers are used, the requirements of 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer's approval***;

d) The appropriate methods ***or procedures*** are selected and are capable of meeting the customers' requirements.

ISO/IEC 17025:2005 – 4.4.1, 4.4.3

Review of Requests, Tenders and Contracts – Clause 7.1

7.1.2 The laboratory shall inform the customer ***when the method requested by the customer is considered to be inappropriate or out of date.***

7.1.3 ***When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined.***

- ***Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.***

ISO/IEC 17025:2005 – 4.4.1 (partial - mainly new)

Review of Requests, Tenders and Contracts – Clause 7.1

7.1.4 Any differences between the request or tender and the contract shall be ***resolved before laboratory activities commence.***

- Each contract shall be acceptable both to the laboratory and the customer. ***Deviations requested by the customer shall not impact the integrity of the laboratory or the validity of the results.***

7.1.5 The customer shall be informed of any deviation from the contract.

7.1.6 If a contract is amended ***after work has commenced, the contract review shall be repeated and*** any amendments shall be communicated ***to all affected personnel.***

ISO/IEC 17025:2005 – 4.4.1 (last paragraph), 4.4.2

Review of Requests, Tenders and Contracts – Clause 7.1

7.1.7 The laboratory shall cooperate with customers or their representatives in ***clarifying the customer's request and in monitoring the laboratory's performance*** in relation to the work performed.

7.1.8 Records of reviews, including any significant changes, shall be retained.

- Records shall also be retained ***of pertinent discussions*** with a customer relating to the customer's requirements or the results of the laboratory activities.

ISO/IEC 17025:2005 – 4.7.1, 4.7.1 (notes), 4.4.2

Selection, Verification and Validation of Methods – Clause 7.2

7.2.1 Selection and Verification of Methods

7.2.1.1 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.

7.2.1.2 All methods, procedures and supporting documentation, such as

- Instructions,
- Standards,
- Manuals and reference data

relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see **8.3**).

ISO/IEC 17025:2005 – 5.4.1

Selection and Verification of Methods – Clause 7.2.1

7.2.1.3 The laboratory shall ensure that it uses the latest ***valid version of a method*** unless it is not appropriate or possible to do so.

- When necessary, the ***application of the method*** shall be supplemented with additional details to ensure consistent application.

7.2.1.4 When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen.

- Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment, ***are recommended***.
- Laboratory-developed or modified methods can also be used.

ISO/IEC 17025:2005 – 5.4.2

Selection and Verification of Methods – Clause 7.2.1

7.2.1.5 The laboratory shall verify that it can ***properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained.***

- ***If the method is revised by the issuing body, verification shall be repeated to the extent necessary*.**

7.2.1.6 When method development is required, this shall be a planned activity and shall be assigned to ***competent*** personnel equipped with adequate resources.

- As method development proceeds, ***periodic review shall be carried out to confirm that the needs of the customer are still being fulfilled*.**
- ***Any modifications to the development plan shall be approved and authorized.***

7.2.1.7 Deviations from methods for all laboratory ***activities*** shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.

ISO/IEC 17025:2005 – 5.4.3, 5.4.1

Validation of Methods – Clause 7.2.2

7.2.2.1 The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified.

- The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

7.2.2.2 When changes are made to a validated method, the influence of such changes ***shall*** be determined and ***where they are found to affect the original validation***, a new method validation ***shall*** be ***performed***.

ISO/IEC 17025:2005 – 5.4.5.2 and 5.4.5.2 (Note 3 now added)

Validation of Methods – Clause 7.2.2

7.2.2.3 The performance characteristics of validated methods, as assessed for the intended use, shall be relevant to the customers' needs and consistent with specified requirements.

7.2.2.4 The laboratory shall ***retain*** the following records of validation:

a) The validation procedure used;

b) Specification of the requirements;

c) Determination of the performance characteristics of the method;

d) Results obtained;

e) A statement ***on the validity of the method***, detailing its fitness for the intended use.

ISO/IEC 17025:2005 – 5.4.5.1 and 5.4.5.2

Sampling – Clause 7.3

7.3.1 The laboratory shall have a sampling plan and ***method*** when it carries out sampling of

- Substances
- Material
- Products for subsequent testing or calibration

- The sampling ***method*** shall address the factors to be controlled to ensure the validity of ***subsequent*** testing or calibration results.
- The sampling plan and ***method*** shall be available at the ***site*** where sampling is undertaken.
- Sampling plans shall, whenever reasonable, be based on appropriate statistical methods.

ISO/IEC 17025:2005 – 5.7.1

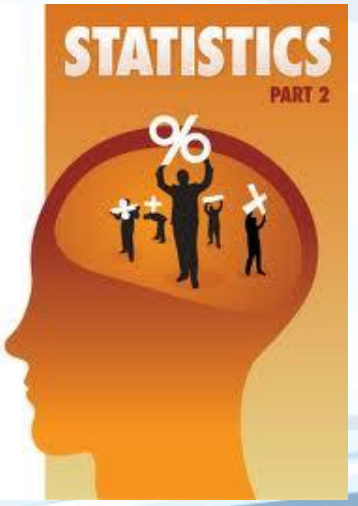
Sampling – Clause 7.3

7.3.2 The sampling method ***shall*** describe:

a) The selection of samples ***or sites;***

b) The sampling plan;

c) The preparation and ***treatment*** of sample(s) from a substance, material or product to yield the ***required item for subsequent testing or calibration.***



ISO/IEC 17025:2005 – 5.7.1 (Note 2 now added)

Sampling – Clause 7.3

7.3.3 The laboratory shall ***retain records*** of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, ***where relevant***:

a) ***Reference*** to the sampling ***method*** used;

b) ***Date and time of sampling;***

c) ***Data to identify and describe the sample (e.g. number, amount, name);***

d) Identification of the personnel performing sampling;

e) Identification of the equipment used;

f) Environmental or ***transport conditions;***

g) Diagrams or other equivalent means to identify the sampling location, when appropriate;

h) Deviations, additions to or exclusions from the sampling method and sampling plan.

ISO/IEC 17025:2005 – 5.7.3, 5.7.2

Handling of Test or Calibration Items – Clause 7.4

7.4.1 The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention and disposal or return of test or calibration items

- Including all provisions necessary to protect the integrity of the test or calibration item, and
- To protect the interests of the laboratory and the customer.

- ***Precautions shall be taken*** to avoid deterioration, ***contamination***, loss or damage to the item during handling, transporting, ***storing/waiting***, and preparation for testing or calibration.
- Handling instructions provided with the item shall be followed.

ISO/IEC 17025:2005 – 5.8.1, 5.8.4 (Note 1 now added)

Handling of Test or Calibration Items – Clause 7.4

7.4.2 The laboratory shall have a ***system*** for the ***unambiguous*** identification of test or calibration items.

- The identification shall be retained ***while the item is under the responsibility*** of the laboratory.
- The ***system shall ensure*** that items will not be confused physically or when referred to in records or other documents.
- The system shall, if appropriate, accommodate a sub-division of an item ***or*** groups of items and the transfer of items.

ISO/IEC 17025:2005 – 5.8.2

Handling of Test or Calibration Items – Clause 7.4

7.4.3 Upon receipt of the test or calibration item, ***deviations*** from specified conditions shall be recorded.

- When there is doubt about the suitability of an item for test or calibration, or when an item does not conform to the description provided, the laboratory shall consult the customer for further instructions before proceeding and shall record the results of this ***consultation***. O*M*N*E*X*
- ***When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.***

7.4.4 When items need to be stored or conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded.

ISO/IEC 17025:2005 – 5.8.3; deviations in 5.10.3.1(a) or 5.10.3.2(f), 4.4.4 and 5.8.4

Technical Records – Clause 7.5

7.5.1 The laboratory shall ***ensure*** that technical records for each laboratory activity contain the results, report and sufficient information to ***facilitate***, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the ***repetition*** of the laboratory activity under conditions ***as close as possible to the original***.

- The technical records shall include the ***date*** and the identity of personnel responsible for each ***laboratory activity*** and for checking ***data*** and results.
- Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable ***with*** the specific task.

ISO/IEC 17025:2005 – 4.13.2.1, 4.13.2.2

Technical Records – Clause 7.5

7.5.2 The laboratory shall ensure that amendments to technical records can be ***tracked to previous versions or to original observations***.

- Both the original and amended data and ***files shall be retained, including the date of alteration, an indication of the altered aspects and the personnel responsible for the alterations***.

❖ Note, not focusing on written reports only (i.e., hand edits)!

ISO/IEC 17025:2005 – 4.13.2.3

Evaluation of Measurement Uncertainty – Clause 7.6

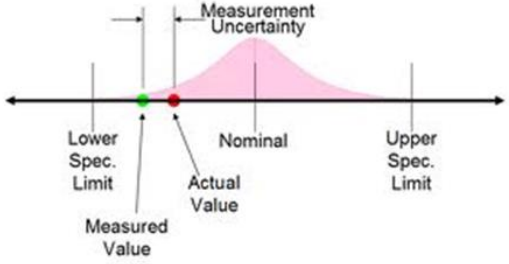
7.6.1 Laboratories shall ***identify the contributions*** to measurement uncertainty.

- When evaluating measurement uncertainty, all ***contributions that are of significance***, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

7.6.2 A laboratory performing calibrations, including of its own equipment, shall ***evaluate*** the measurement uncertainty for all calibrations.

7.6.3 A laboratory performing testing shall ***evaluate*** measurement uncertainty.

- Where the test method precludes rigorous evaluation of measurement uncertainty, ***an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method***.



ISO/IEC 17025:2005 – 5.4.6.1, 5.12, 5.6.4.2, 5.4.6.3, and 5.4.5.2 (portion of Note 2 now added)

Ensuring the Validity of Results – Clause 7.7

7.7.1 The laboratory shall have a procedure for monitoring the validity of results.

- The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results.

ISO/IEC 17025:2005 This replace the "Assuring the quality of test and calibration results" section (5.9.1)

Ensuring the Validity of Results – Clause 7.7

- This monitoring shall be planned and reviewed and ***shall*** include, ***where appropriate***, but not be limited to:
  - a) use of reference materials or quality control materials;
  - ***b) use of alternative instrumentation that has been calibrated to provide traceable results;***
  - ***c) functional check(s) of measuring and testing equipment;***
  - ***d) use of check or working standards with control charts, where applicable;***
  - ***e) intermediate checks on measuring equipment;***
  - f) replicate tests or calibrations using the same or different methods;
  - g) retesting or recalibration of retained items;
  - h) correlation of results for different characteristics of an item;
  - ***i) review of reported results;***
  - j) intralaboratory comparisons;
  - ***k) testing of blind sample(s).***

ISO/IEC 17025:2005 – 5.9.1, but greatly expanded!

Ensuring the Validity of Results – Clause 7.7

7.7.2 ***The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate.***

- ***This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:***
  - a) Participation in proficiency testing;
  - b) Participation in interlaboratory comparisons ***other than proficiency testing***.

7.7.3 Data from ***monitoring activities shall be analyzed, used to control and, if applicable, improve the laboratory's activities***.

- If the results of the analysis of data from ***monitoring activities are found*** to be outside pre-defined criteria, ***appropriate*** action shall be taken to prevent incorrect results from being reported.

ISO/IEC 17025:2005 – 5.9.1 but greatly expanded "Proficiency Test"; also, 5.9.2

General (Reporting of Results) – Clause 7.8.1

7.8.1.1 The results shall be ***reviewed and authorized prior to release***.

7.8.1.2 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g., a test report or a calibration certificate ***or report of sampling***).

- Shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used.
- All issued reports ***shall be retained as technical records***.

7.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in **7.8.2** to **7.8.7** that is not reported to the customer shall be readily available.

ISO/IEC 17025:2005 – 5.10.1

Common Requirements for Reports (Test, Calibration *or Sampling*) – Clause 7.8.2

7.8.2.1 Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, ***thereby minimizing any possibility of misunderstanding or misuse***:

a) A title (e.g., "Test Report", "Calibration Certificate" or ***"Report of Sampling"***);

b) The name and address of the laboratory;

c) The location of ***performance*** of the laboratory activities, ***including when performed at a customer facility or at sites away from the laboratory's permanent facilities, or in associated temporary or mobile facilities;***

d) Unique identification ***that all its components are recognized as a portion of a complete report*** and a clear identification of the end;

e) The name and contact information of the customer;

f) Identification of the method used;

g) A description, unambiguous identification, and, when necessary, the condition of the item;

h) The date of receipt of the test or calibration item(s), ***and the date of sampling***, where this is critical to the validity and application of the results;

OMNEX

ISO/IEC 17025:2005 – 5.10.2

Common Requirements for Reports (Test, Calibration ***or Sampling***) – Clause 7.8.2

7.8.2.1 Each report shall include at least the following information, unless the laboratory has valid reasons for not doing so, ***thereby minimizing any possibility of misunderstanding or misuse***:

i) The date(s) of performance of the ***laboratory activity***;

j) The date of issue of the report;

k) Reference to the sampling plan and ***sampling method*** used by the laboratory or other bodies where these are relevant to the validity or application of the results;

l) A statement to the effect that the results relate only to the items tested, calibrated or sampled;

m) The results with, where appropriate, the units of measurement;

n) Additions to, deviations, or exclusions from the method;

o) Identification of the person(s) authorizing the report;

p) Clear identification when results are from external providers.

Common Requirements for Reports (Test, Calibration *or Sampling*) – Clause 7.8.2

7.8.2.2 ***The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer.***

- ***Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results.***
- ***Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received.***

ISO/IEC 17025:2005 – New/Improved common reporting requirements

Specific Requirements for Test Reports – Clause 7.8.3

7.8.3.1 In addition to the requirements listed in **7.8.2**, test reports shall, where necessary for the interpretation of the test results, include the following:

a) Information on specific test conditions, such as environmental conditions;

b) Where relevant, a statement of conformity with requirements or specifications (see **7.8.6**);

c) Where applicable, the measurement uncertainty ***presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:***

- It is relevant to the validity or application of the test results;
- A customer's instruction so requires, or
- The measurement uncertainty affects conformity to a specification limit;

ISO/IEC 17025:2005 – 5.10.3.1

Specific Requirements for Test Reports – Clause 7.8.3

7.8.3.1 In addition to the requirements listed in **7.8.2**, test reports shall, where necessary for the interpretation of the test results, include the following:

d) Where appropriate, opinions and interpretations (see 7.8.7);

e) Additional information ***that may*** be required by specific methods, ***authorities,*** customers or groups of customers.

7.8.3.2 ***Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.***

ISO/IEC 17025:2005 – 5.10.3.2, improved with reference to sampling (7.8.5)

Specific Requirements for Calibration Certificates Reports – Clause 7.8.4

7.8.4.1 In addition to the requirements listed in 7.8.2, calibration certificates shall include the following:

a) The measurement uncertainty of the measurement ***result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);***

b) The conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;

c) A statement identifying how the measurements are metrologically traceable (see Annex A);

d) The results before and after any adjustment or repair, if available;

e) Where ***relevant***, a statement of conformity with requirements or specifications ***(see 7.8.6);***

f) Where appropriate, opinions and interpretations ***(see 7.8.7).***

ISO/IEC 17025:2005 – 5.10.4.1, 5.10.4.3, 5.10.4.2

Specific Requirements for Calibration Certificates Reports – Clause 7.8.4

7.8.4.2 ***Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results.***

7.8.4.3 A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

ISO/IEC 17025:2005 – 5.10.3.2 and 5.10.4.4, improved for sampling

Reporting Sampling – Specific Requirements – Clause 7.8.5

- Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in **7.8.2**, reports shall include the following, where necessary for the interpretation of results:
  a) The date of sampling;
  b) ***Unique*** identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);
  c) The location of sampling, including any diagrams, sketches or photographs;
  d) A reference to the sampling plan and sampling ***method***;
  e) Details of any environmental conditions during sampling that affect the interpretation of the results;
  f) Information required to ***evaluate measurement uncertainty*** for subsequent testing or calibration.

ISO/IEC 17025:2005 – 5.10.3.2, improved title

Reporting Statements of Conformity – Clause 7.8.6

7.8.6.1 When a statement of conformity to a specification or standard is ***provided, the laboratory shall document the decision rule employed.***

- ***Take into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.***

7.8.6.2 The laboratory shall report on the statement of conformity, such that the statement clearly identifies:

a) To which results the statement of conformity applies;

b) Which specifications, standards or parts thereof are met or not met;

c) The decision rule applied (unless it is inherent in the requested specification or standard).

ISO/IEC 17025:2005 – 5.10.4.2, improved title

Reporting Opinions and Interpretations – Clause 7.8.7

7.8.7.1 When opinions and interpretations are ***expressed, the laboratory shall ensure that only personnel authorized for the expression of opinions and interpretations release the respective statement.***

- The laboratory shall document the basis upon which the opinions and interpretations have been made.

7.8.7.2 The opinions and interpretations ***expressed in reports shall be based on the results obtained from the tested or calibrated item*** and shall be clearly identified as such.

7.8.7.3 ***When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained.***

ISO/IEC 17025:2005 – 5.10.5, Note 3 (dialogue record) now included

Amendments to Reports – Clause 7.8.8

7.8.8.1 ***When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and, where appropriate, the reason for the change included in the report.***

7.8.8.2 Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement "***Amendment*** to Report, serial number... [or as otherwise identified]", or an equivalent form of wording.

- Such amendments shall meet all the requirements of this document (ISO/IEC 17025).

7.8.8.3 When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces.

ISO/IEC 17025:2005 – 5.10.5

Complaints – Clause 7.9

7.9.1 The laboratory shall have a ***documented process*** to receive, ***evaluate and make decisions on complaints.***

7.9.2 ***A description of the handling process for complaints shall be available to any interested party on request.***

- ***Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it.***
- ***The laboratory shall be responsible for all decisions at all levels of the handling process for complaints.***

ISO/IEC 17025:2005 – 4.8, includes many new requirements

Complaints – Clause 7.9

7.9.3 ***The process for handling complaints shall include at least the following elements and methods:***

a) ***Description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;***

b) ***Tracking*** and recording complaints, including actions undertaken to resolve them;

c) ***Ensuring that any appropriate action is taken.***

7.9.4 ***The laboratory receiving the complaint shall be responsible for gathering and verifying all necessary information to validate the complaint.***

ISO/IEC 17025:2005 – 4.8, includes many new requirements

Complaints – Clause 7.9

7.9.5 ***Whenever possible, the laboratory shall acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome.***

7.9.6 ***The outcomes to be communicated to the complainant shall be made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question.***

- ***NOTE This can be performed by external personnel.***

7.9.7 ***Whenever possible, the laboratory shall give formal notice of the end of the complaint handling to the complainant.***

ISO/IEC 17025:2005 – 4.8, includes many new requirements

Nonconforming Work – Clause 7.10

7.10.1 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 ***(e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria).*** The procedure shall ensure that:

a) The responsibilities and authorities for the management of nonconforming work are ***defined***;

b) Actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;

c) An evaluation is made of the significance of the nonconforming work, ***including an impact analysis on previous results***;

ISO/IEC 17025:2005 – 4.9.1

Nonconforming Work – Clause 7.10

7.10.1 The procedure shall ensure that:

d) a decision is taken on the acceptability of the nonconforming work;

e) where necessary, the customer is notified and work is recalled;

f) the responsibility for authorizing the resumption of work is defined.

7.10.2 ***The laboratory shall retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f).***

7.10.3 Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory's operations with its own ***management system***, the laboratory shall implement corrective action.

ISO/IEC 17025:2005 – 4.9.1 and 4.9.2

Control of Data and *Information Management* – Clause 7.11

7.11.1 ***The laboratory shall have access to the data and information needed to perform laboratory activities*.**

7.11.2 The laboratory ***information management system(s)*** used for the

- Collection
- Processing
- Recording
- Reporting
- Storage or Retrieval of Data

shall be validated ***for functionality***, including the proper functioning *of* ***interfaces within the laboratory information management system(s) by the laboratory before introduction.***

ISO/IEC 17025:2005 – 5.4.7.2 with many new requirements

Control of Data and *Information Management* – Clause 7.11

7.11.2 ***Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation.***

7.11.3 The laboratory information management system(s) shall:

a) Be protected from unauthorized access;

b) Be safeguarded against tampering and loss;

c) Be operated in an environment that complies with provider or laboratory specifications or, in ***the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;***

d) Be maintained in a manner that ensures the integrity of the data ***and information***;

e) Include recording system failures and the appropriate immediate and corrective actions.

ISO/IEC 17025:2005 – 5.4.7.2, previously a note that is now included in the standard

Control of Data and *Information Management* – Clause 7.11

7.11.4 ***When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.***

7.11.5 ***The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.***

7.11.6 Calculations and data transfers shall be checked in an appropriate and systematic manner.

ISO/IEC 17025:2005 – 5.4.7.1, many new requirements

Required Documented Information

Clause	Documented Information Required	Document	Procedure	Record
5.3	Range of laboratory activities	X		
5.5	Procedures to the extent necessary to ensure consistent application of the laboratory activities and the validty of results		X	
6.2.2	Competence requirements	X		
6.2.5	Procedures and records for determining the competence requirements		X	X
6.2.5	Procedures and records for selection of personnel		X	X
6.2.5	Procedures and records for training of personnel		X	X
6.2.5	Procedures and records for supervision of personnel		X	X
6.2.5	Procedures and records for authorization of personnel		X	X
6.2.5	Procedures and records for monitoring competence of personnel		X	X
6.4.13	Records of the identity of equipment, including software and firmware version			X
6.4.13	Records of equipment manufacturer's name, type identification, and serial number or other unique identification			X
6.4.13	Evidence of verification that equipment conforms with specified requirements			X
6.4.13	Records of equipment's current location			X
6.4.13	Records of equipment calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval			X
6.4.13	Documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity	X		
6.4.13	Equipment maintenance plan	X		
6.4.13	Records of details of any damage, malfunction to, or repair of, the equipment			X

Required Documented Information

Clause	Documented Information Required	Document	Procedure	Record
6.6.2	Procedure and records for defining, reviewing and approving the labortatory's requirements fo rexternally provided products and services		X	X
6.6.2	Procedure and records for defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers		X	X
6.6.2	Procedure and records for ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of ISO/IEC 17025, before they are used or directly provided to the customer		X	X
6.6.2	Procedure and records for any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers		X	X
7.1.1	Procedure for the review of requests, tenders and contracts		X	
7.2.1.1	Procedures for all laboratory activities		X	
7.2.2.4	Record of the validation procedure used			X
7.2.2.4	Records of the specification of the validation requirements			X
7.2.2.4	Records of determination of the performance characteristics of the validation method			X
7.2.2.4	Records of validation results obtianed			X
7.2.2.4	Record of a statement on the validity of the validation method, detailing its fitness for the intended use			X
7.4.1	Procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items		X	
7.7.1	Procedure for monitoring the validity of labortaotry results		X	
7.10.1	Nonconforming work procedure		X	

Laboratory Operational Processes – Example

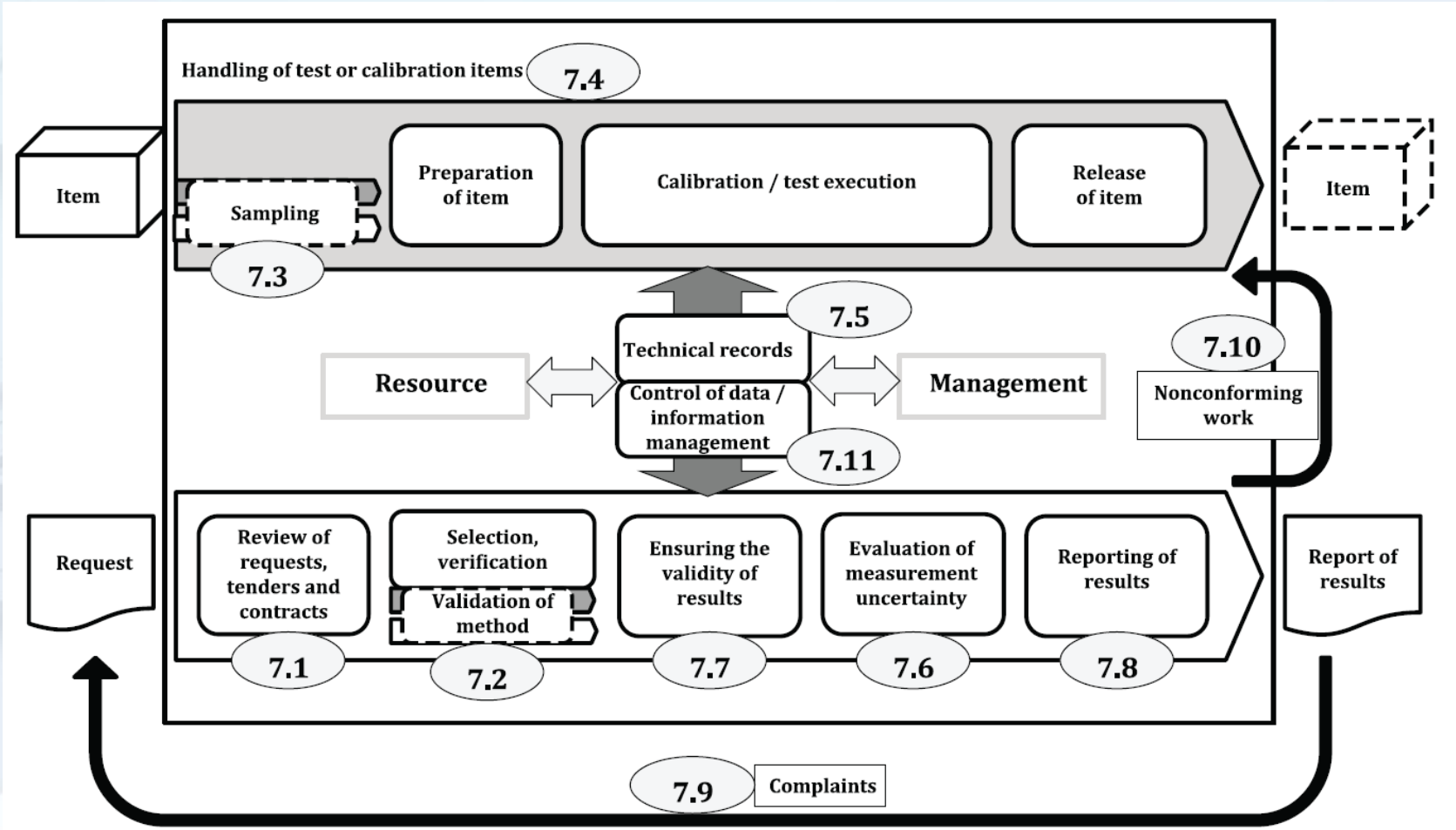


Figure B.1 — Possible schematic representation of the operational processes of a laboratory

Source: ISO/IEC 17025:2017, Figure B.1

Written Exercise 3

Conducted in Groups

ISO/IEC 17025 Relation to ISO 9001

- Accreditation to ISO/IEC 17025:2017 now has an option to use an ISO 9001 QMS to meet intent of all clause 8

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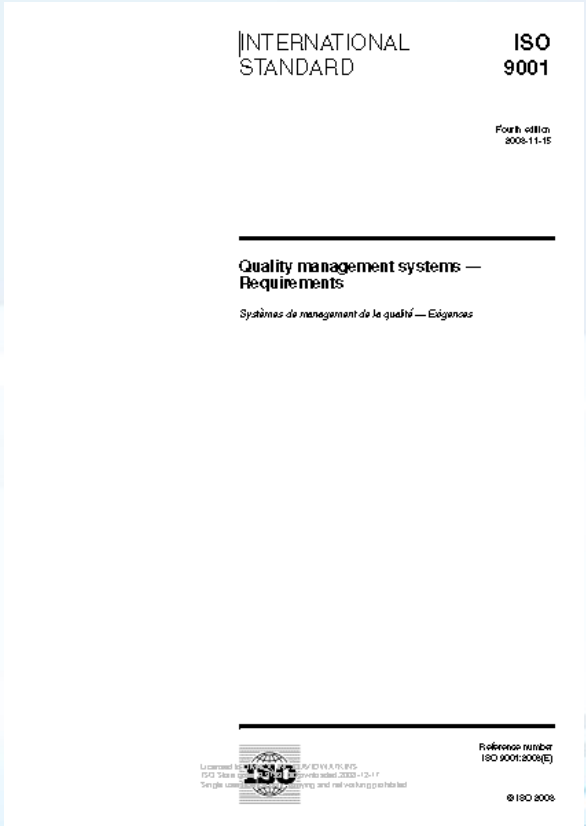
Option



Management System Requirements

8.1 Option – A: Not in accordance with ISO 9001:2015 QMS

8. Management Systems Requirements → Must Implement Clauses 8.2 to 8.9

8.1 Option – B: In accordance with ISO 9001:2015 QMS

Established and maintain a Management System in accordance with the requirements of ISO 9001:2015 → Fulfils intent of Clauses 8.2 to 8.9

Both Options – Must still meet clause 4 to 7 of ISO/IEC 17025:2017

Option A – Clause 8.1.2

- As a minimum, the management system of the laboratory shall address the following:
  - Management system documentation (see **8.2**)
  - Control of management system documents (see **8.3**)
  - Control of records (see **8.4**)
  - ***Actions to address risks and opportunities (see 8.5)*** – **New**
  - Improvement (see **8.6**)
  - Corrective actions (see **8.7**)
  - Internal audits (see **8.8**)
  - Management reviews (see **8.9**)

Similar to most ISO 9001 requirements, but changed to laboratory terms

Option B – Clause 8.1.3

- A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001:2015.
- Capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7.
- Fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.

Must still meet clauses 4 through 7 of ISO/IEC 17025:2017

Management System Documentation (Option A) – Clause 8.2

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.

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

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.

ISO/IEC 17025:2005 – 4.2
ISO 9001:2015 – 4.1 to 4.4, 5.1.2, 5.2, 5.3

Management System Documentation (Option A) – Clause 8.2

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.

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
ISO 9001:2015 – 4.1 to 4.4, 5.1.2, 5.2, 5.3

Control of Management System Documents (Option A) – Clause 8.3

8.3.1 The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document.

8.3.2 The laboratory shall ensure that:

a) Documents are approved for adequacy prior to issue by authorized personnel;

b) Documents are periodically reviewed, and updated as necessary;

c) Changes and the current revision status of documents are identified;

d) Relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

e) Documents are uniquely identified;

f) The unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.

ISO/IEC 17025:2005 – 4.3
ISO 9001:2015 – 7.5

Control of Records (Option A) – Clause 8.4

8.4.1 The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements in this document.

8.4.2 The laboratory shall implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records.

- The laboratory shall retain records for a period consistent with its contractual obligations.
- Access to these records shall be consistent with the confidentiality commitments, and records shall be readily available.
  - NOTE Additional requirements regarding technical records are given in 7.5.

ISO/IEC 17025:2005 – 4.13
ISO 9001:2015 – 7.5

Laboratory Management System Documentation Requirements

Terms and Definitions Relating to Documents

- According to ISO 9001 clause **3.7.2** a document is "*information and its supporting medium*"
- Documents may be in any form such as: paper ("hard copy"), magnetic, electronic or optical computer disc, photograph, master sample
- Types of documents include:
  - Procedures
  - Quality manuals
  - Specifications
  - Guidelines
  - Recommendations
  - Policies
  - Work instructions
  - Records (a special kind of document)
  - Test/calibration methods
  - Drawings
  - Software
  - Specifications
  - Equipment manuals
  - Data

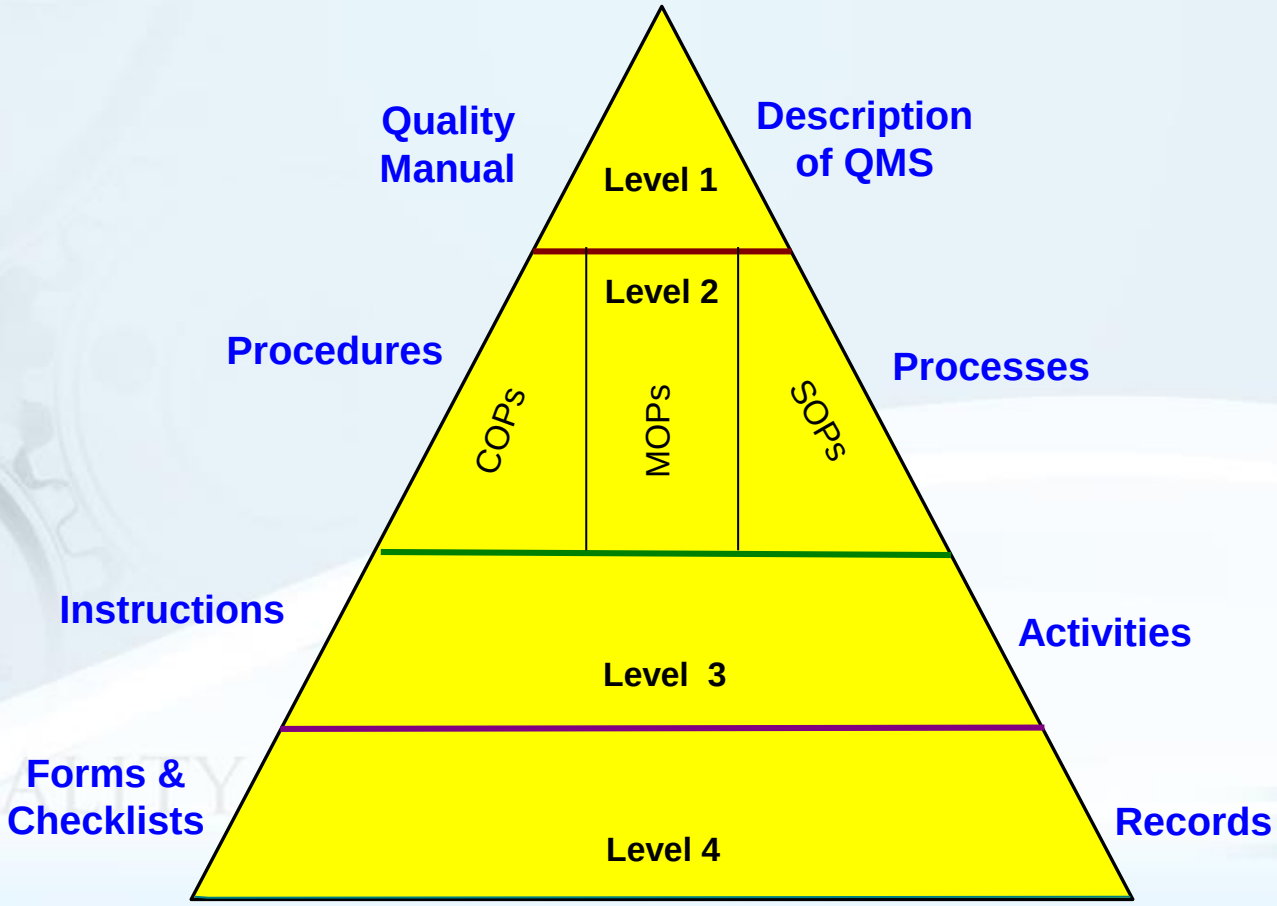
Laboratory Management System Documentation Requirements

The following terms and definitions are taken from ISO 9000:2005

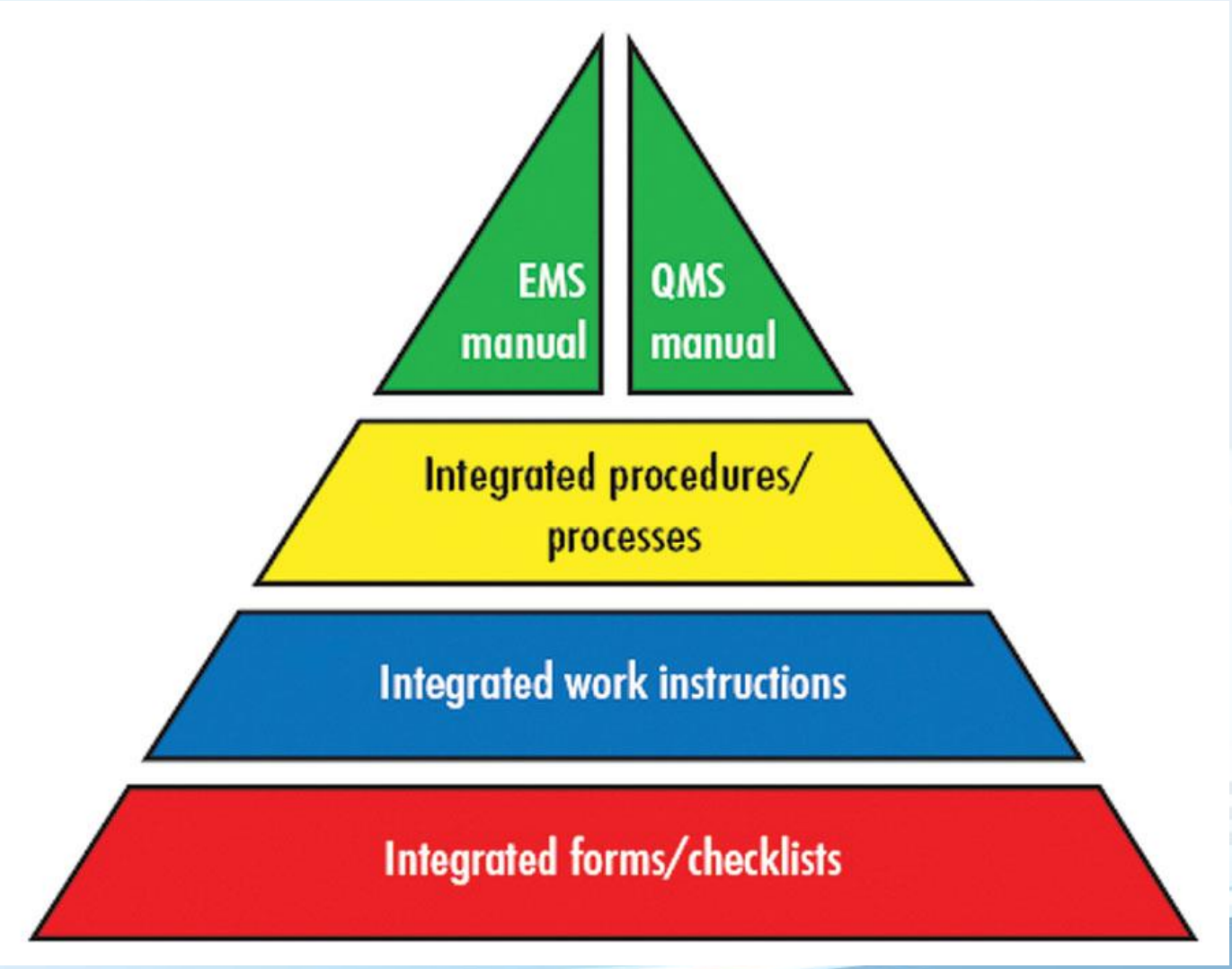
Term	Definition
Document	information and its support medium
Procedure / Processes	specified way to carry out an activity or a process
Quality Manual	document specifying the quality management system of an organization
Test, Calibration and Sampling Plans or Instructions	document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract
Record	document stating results achieved or providing evidence of activities performed
Specification	document stating requirements

Quality Management System Documentation

Best-in-Class Approach



Integration and Standardization Combined



RISK-BASED THINKING

Actions to Address Risks and Opportunities (Option A) – Clause 8.5

8.5.1 The laboratory shall consider the risks and opportunities associated with the laboratory activities in order to:

a) Give assurance that the management system achieves its intended results;

b) Enhance opportunities to achieve the purpose and objectives of the laboratory;

c) Prevent, or reduce, undesired impacts and potential failures in the laboratory activities;

d) Achieve improvement.

ISO/IEC 17025:2005 – none
ISO 9001:2015 – 6.1.1

Actions to Address Risks and Opportunities (Option A) – Clause 8.5

8.5.2 The laboratory shall plan:

a) Actions to address these risks and opportunities;

b) How to:

- integrate and implement these actions into its management system;
- evaluate the effectiveness of these actions.

NOTE Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards.

ISO/IEC 17025:2005 – none
ISO 9001:2015 – 6.1.2

Actions to Address Risks and Opportunities (Option A) – Clause 8.5

8.5.3 Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

ISO/IEC 17025:2005 – none
ISO 9001:2015 – 6.1.2

Risk Is "Immature" Concept in ISO Documents

- 157 ISO standards use the word "**risk**" and together have 45 unique definitions (21 specialized to hazards)
- Of these, most only consider events with negative outcomes:
  - "*A function of the probability of occurrence of a given threat and the potential adverse consequences of that threat's occurrence*"
- There is a subset that takes a broader view of risk, e. g.
  - "*The effect of uncertainty*"
  - "*The combination of the consequences of an event and the associated likelihood of its occurrence*"

Risk-Based Thinking

ISO 9001:2015 makes risk-based thinking a requirement

- Risks and opportunities are determined and addressed:
  - Implement actions to address risk
  - No requirement for formal methods for risk management or a documented risk management process
- QMS is a preventive tool
  - No need to have a separate clause or sub-clause titled **Preventive Action**
  - The concept of preventive action is expressed through a risk-based approach to formulating QMS requirements

Risk-Based Thinking

- Risk is defined in ISO 9000 as the effect of uncertainty.
  - Uncertainty is the state—even partial—of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.
- All processes do not have the same level of risk in terms of the organization's ability to meet its objectives.
- The consequences of process, product, service or system nonconformities are not the same for all organizations.
- Opportunities can arise as a result of a situation favorable to achieving an intended result.
- Opportunity is not the positive side of risk.
- An opportunity is a set of circumstances which makes it possible to do something.
  - Taking or not taking an opportunity then presents different levels of risk.

Number of Times "Risk" Appears in ISO/IEC 17025

- **4.1.4** identify **risks** to its impartiality on an on-going basis. (Four times total)
- **7.8.6.1** When a statement of conformity to a specification or standard is provided, the laboratory shall document the decision rule employed, taking into account the level of **risk** (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.
- **7.10.1b)** actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the **risk** levels established by the laboratory;
- **8.5.1** The laboratory shall consider the **risks** and opportunities associated with the laboratory activities in order to…
- **8.5.2** The laboratory shall plan: a) actions to address these **risks** and opportunities;
- **8.5.3** Actions taken to address **risks** and opportunities shall be proportional to the potential impact on the validity of laboratory results.
- **8.7.1e)** update **risks** and opportunities determined during planning, if necessary;
- **8.9.2m)** results of **risk** identification.

Breakout Exercise 2

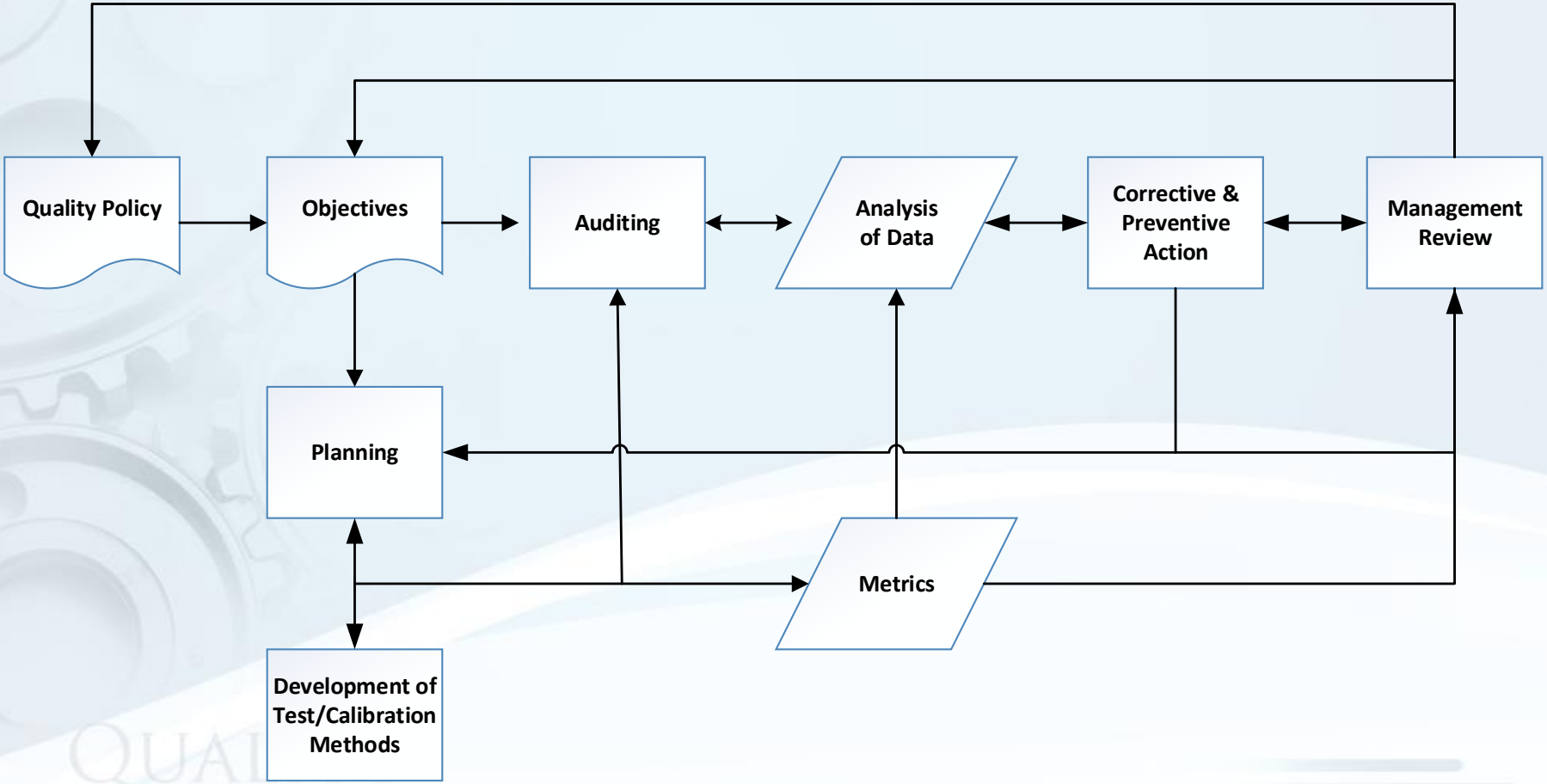
Part B – Risks and Opportunities

Improvement (Option A) – Clause 8.6

- **8.6.1** The laboratory shall identify and select opportunities for improvement and implement any necessary actions.
  - NOTE Opportunities for improvement can be identified through the review of the operational procedures, the use of the policies, overall objectives, audit results, corrective actions, management review, suggestions from personnel, risk assessment, analysis of data, and proficiency testing results.
- **8.6.2** The laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be analyzed and used to improve the management system, laboratory activities and customer service.
  - NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.

ISO/IEC 17025:2005 – 4.10
ISO 9001:2015 – 10.1, 10.3

Improvement – Clause 8.6



Corrective Action (Option A) – Clause 8.7

8.7.1 When a nonconformity occurs, the laboratory shall:

a) React to the nonconformity and, as applicable:
   - take action to control and correct it;
   - address the consequences;

b) Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
   - reviewing and analyzing the nonconformity;
   - determining the causes of the nonconformity;
   - determining if similar nonconformities exist, or could potentially occur;

c) Implement any action needed;

d) Review the effectiveness of any corrective action taken;

ISO/IEC 17025:2005 – 4.11
ISO 9001:2015 – 10.2

Corrective Action (Option A) – Clause 8.7

8.7.1 When a nonconformity occurs, the laboratory shall:

e) Update risks and opportunities determined during planning, if necessary;

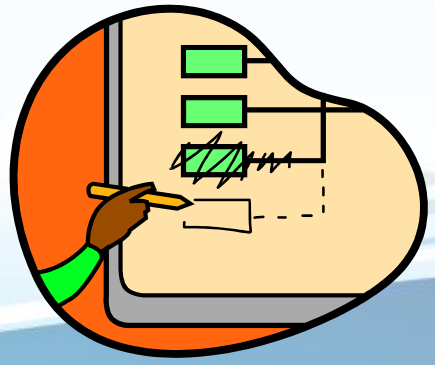
f) Make changes to the management system, if necessary.

8.7.2 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

8.7.3 The laboratory shall retain records as evidence of:

a) The nature of the nonconformities, cause(s) and any subsequent actions taken;

b) The results of any corrective action.



ISO/IEC 17025:2005 – 4.11
ISO 9001:2015 – 10.2

Internal Audits (Option A) – Clause 8.8

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;

b) Is effectively implemented and maintained.

ISO/IEC 17025:2005 – 4.14
ISO 9001:2015 – 9.2

Internal Audits (Option A) – Clause 8.8

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;

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

c) Ensure that the results of the audits are reported to relevant management;

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

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

NOTE ISO 19011 provides guidance for internal audits.

ISO/IEC 17025:2005 – 4.14
ISO 9001:2015 – 9.2

Management Review (Option A) – Clause 8.9

8.9.1 The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document.

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

a) Changes in internal and external issues that are relevant to the laboratory;

b) Fulfilment of objectives;

c) Suitability of policies and procedures;

d) Status of actions from previous management reviews;

e) Outcome of recent internal audits;

f) Corrective actions;

g) Assessments by external bodies;

ISO/IEC 17025:2005 – 4.15
ISO 9001:2015 – 9.3

Management Review (Option A) – Clause 8.9

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

h) Changes in the volume and type of the work or in the range of laboratory activities;

i) Customer and personnel feedback;

j) Complaints;

k) Effectiveness of any implemented improvements;

l) Adequacy of resources;

m) Results of risk identification;

n) Outcomes of the assurance of the validity of results; and

o) Other relevant factors, such as monitoring activities and training.

ISO/IEC 17025:2005 – 4.15
ISO 9001:2015 – 9.3

Management Review (Option A) – Clause 8.9

8.9.3 The outputs from the management review shall record all decisions and actions related to at least:

a) The effectiveness of the management system and its processes;

b) Improvement of the laboratory activities related to the fulfilment of the requirements of this document;

c) Provision of required resources;

d) Any need for change.

ISO/IEC 17025:2005 – 4.15
ISO 9001:2015 – 9.3

Written Exercise 4

Conducted in Groups

Chapter 3: ISO/IEC 17025:2017 Requirements — What We Covered

Learning Objectives

You should now be able to:

- Define the requirements of ISO/IEC 17025:2017
- Define the needs for documentation and implementation

Chapter Agenda

- General QMS Requirements
  - **Breakout Exercise 2 – Part A**
- ISO/IEC 17025 Scope
- ISO/IEC 17025:2017 Requirements
  - **Written Exercise 2**
  - **Written Exercise 3**
  - **Breakout Exercise 2 – Part B**
  - **Written Exercise 4**

Chapter 4

Process Approach to Auditing, Turtle Diagrams, and Audit Trails

Chapter 4: Process Approach to Auditing, Turtle Diagrams and Audit Trails — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Describe Conformance and Performance Audits
- Explain a Process Approach Audit
  - What is a risk-based audit?
- Describe the six elements of a Turtle Diagram
- Explain how to use the turtle concept to conduct an audit using the process approach
- Describe the concept of audit trails

Chapter Agenda

- Conformance and Performance Audits
- Process Approach to Auditing
- Turtle Diagrams
- Audit Trails

Conducting Performance and Conformance Auditing

Performance Auditing

Used with the process approach to auditing.

Used to ensure that processes are performing.

Focus is on process measurables (and performance) that support KPIs and support interested party expectations as it relates to the context. Related to risk in 8.5 and QMS processes.

Poor performance and processes are identified in the Stage I of the audit (prioritizing the audit).

Requires process measurables and goals, and actions if a process is not reaching its target. Finally, the process may have to be rethought if it consistently fails.

Uses a turtle diagram for process analysis.

Conformance Auditing

Typically used when implementing new or revised standards.

Used for Gap Analysis and then to establish the system.

Ensures that the process covers all the “shalls” and includes who, what, and when in document reviews.

Involves sampling of the process to ensure it is being followed.

It ensures intent and effective implementation. While the performance audit ensures that “effectiveness in practice” and risk is handled.

Uses a checklist highlighting “shalls” or a customized checklist showing process requirements of the organization.

Conformance audits need to be the focus of implementation initially. As the processes mature, the focus should become performance. However, both types of audits need to be performed in a system audit.

Conducting Performance and Conformance Auditing

Performance Results

- Auditors should focus on the intended result of the management system throughout the audit process.
- Processes and what they achieve are important but the result of the management system and its performance are most important.
- It is also important to consider the level of the integration of different management systems and their intended results.
- The absence of a process or documentation can be important in a large, high risk or complex organization but not as significant in other organizations, e.g., small organizations.

Conducting Performance and Conformance Auditing

Auditor Responsibilities

- Auditors have to assess if the organization has conducted the following for each clause or process of the audit:
  - **Intent:** has the organization understood the clause of ISO/IEC 17025 correctly?
  - **Effectively Implemented:** is the process implemented, i.e., are they doing what they are saying?
  - **Effectiveness in Practice:** if the process is being followed, is the process providing results?

Conducting Performance and Conformance Auditing

Examples for Discussion

- Receiving Inspection process — What is the intent? How do we assess **Effectiveness in Practice**?

- Internal Audit process — What is the intent? How do we assess **Effectiveness in Practice**?

- What about Continual Improvement? Management Review? Others?

PROCESS APPROACH TO AUDITING

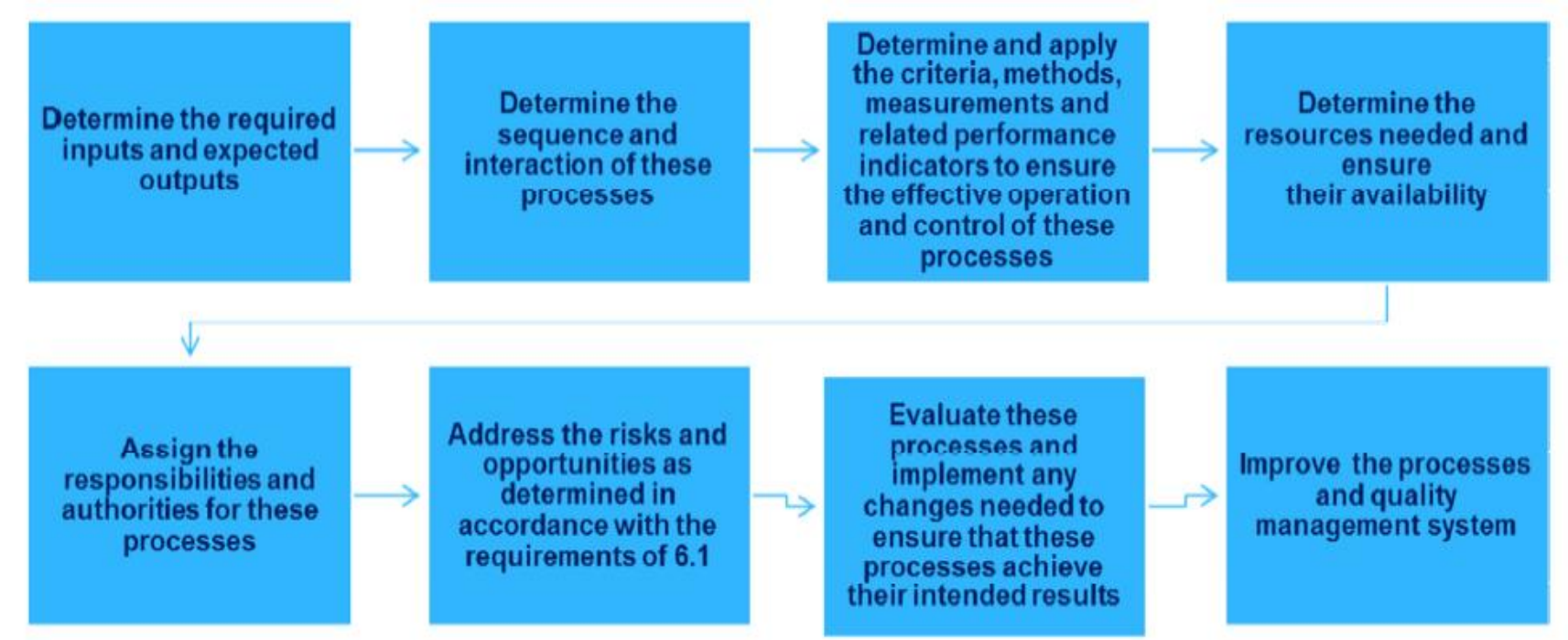
Performance Audits

Process Approach to Auditing

- The use of a “process approach” is a requirement for all ISO management system standards to comply with ISO/IEC Directives, Part 1, Annex SL.
- Auditors should understand that auditing a management system is auditing an organization’s processes and their interactions in relation to one or more management system standard(s).
- Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

Guidance on Process Approach

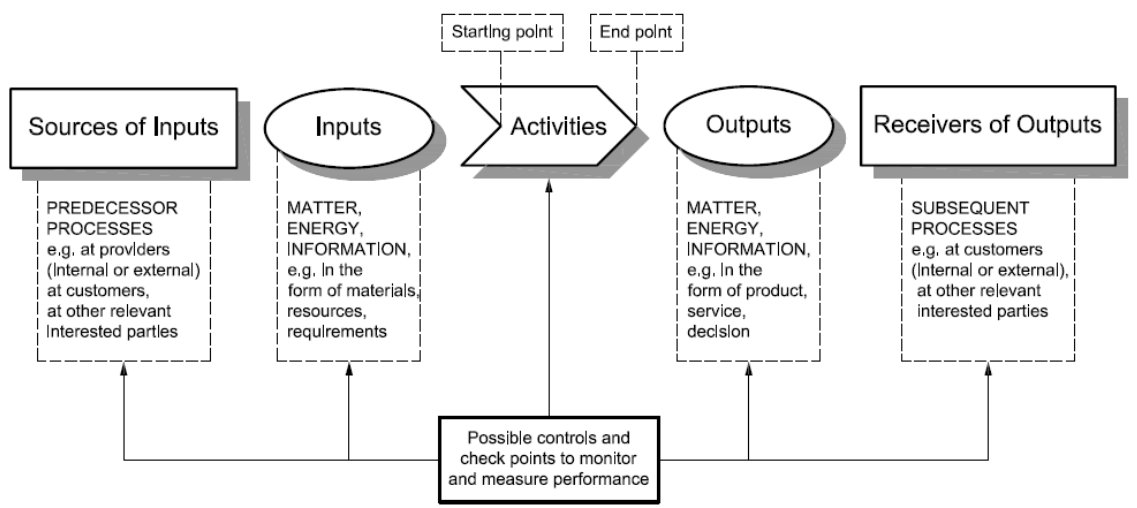
This diagram can assist auditors in establishing the sequence to audit the processes of the organization:



Source: ISO-IAF ISO 9001 Auditing Practice Group Guidance on Processes, January 1, 2016
http://isotc.iso.org/livelink/livelink/fetch/3541460/17525573/APG-Processes2015.pdf?nodeid=17531167&vernum=-2

Quality Management System and its Processes

- The organization implements, maintains and continually improves the quality management system, including the processes needed and their interactions.
- Also required:
  - Inputs
  - Outputs
  - Sequence
  - Interactions
  - Metrics
  - Process Controls
  - Resources
  - Responsibilities and Authorities
  - Addressing Risks and Opportunities
  - Process Evaluation and update as needed
  - Process and QMS Improvements



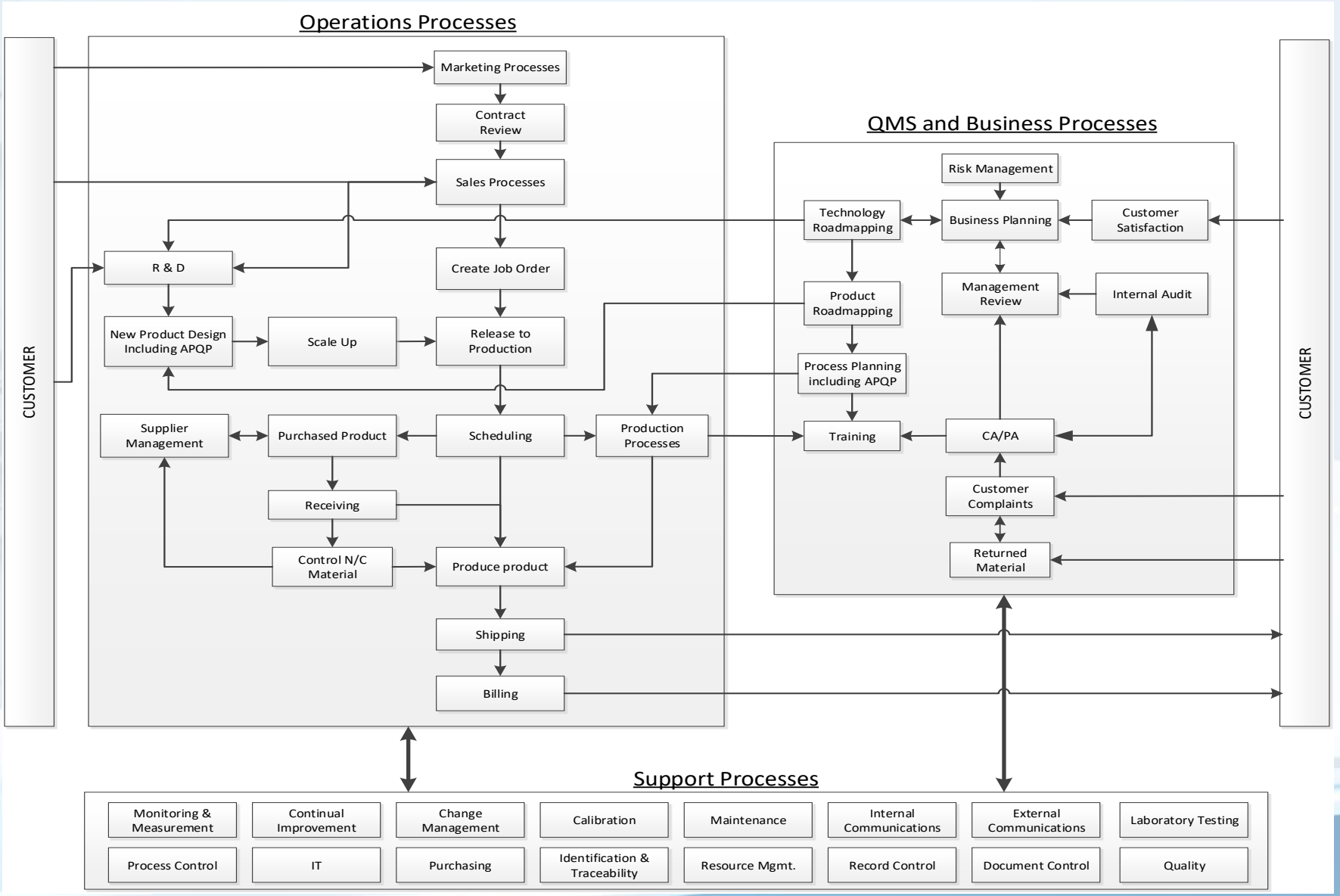
source: ISO 9001:2015, Figure 1 — Schematic Representation of the Elements of a Single Process

Process Characteristics

- A process can be identified by a series of unique, but consistent, characteristics.

- There are six characteristics of a process that are mandatory for an effective management system:
  1. A Process Owner Exists
  2. The Process is Defined
  3. The Process is Documented
  4. Process Linkages are Established
  5. The Process is Monitored and Improved
  6. Records are Maintained

Process Map — Example



Evaluating the Process Map

- Does it provide a description of the sequence and interaction and including identification of the site, remote location, and outsourced processes and their interfaces?*
  - Process Maps help define the "Process Approach" of an organization
    - Process Maps cannot be "Clause Oriented"
    - Process Maps cannot be "Functionally Oriented"
- Description of the remote location and the support they provide
  - Process Maps should define the Enterprise
    - Processes that connect the organization cannot stop within the four walls of an organization
- Evidence that all requirements of ISO/IEC 17025 are addressed by the processes
- Evidence of COPS or Customer Oriented Processes and requisite customer representative or CSR
- Quality Manual including interactions with support functions whether on site or remote

Customer Oriented Processes

1

IN FROM THE CUSTOMER

Customer requires a specific activity done in compliance to their process

I

2

Your Organization

A COP has three criteria

Customer's requirement is met and the output is provided to them in the format or method required

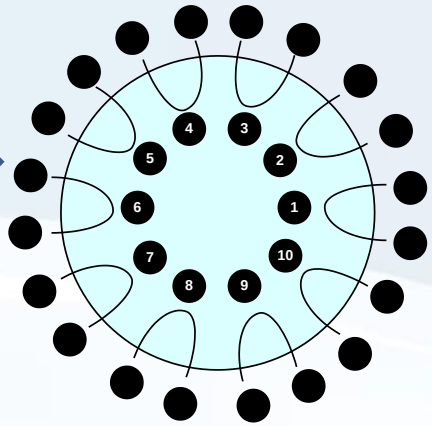
O

3

OUT TO THE CUSTOMER

Requires a sub-process within the organization's process to comply with the specific requirements of the specific customer

The Octopus Model



Categorization of Processes

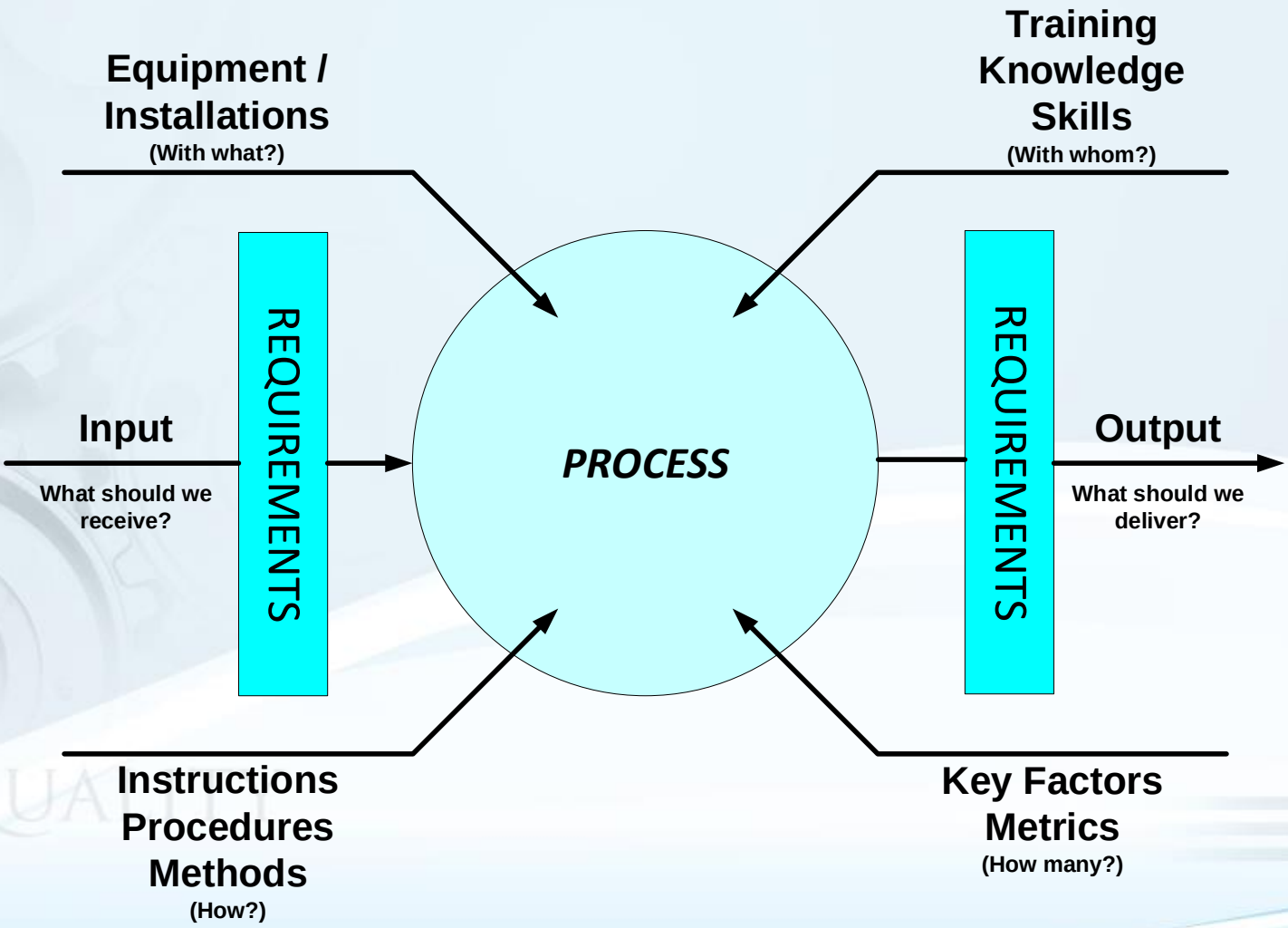
COPs, MOPs, SOPs

TURTLE DIAGRAMS

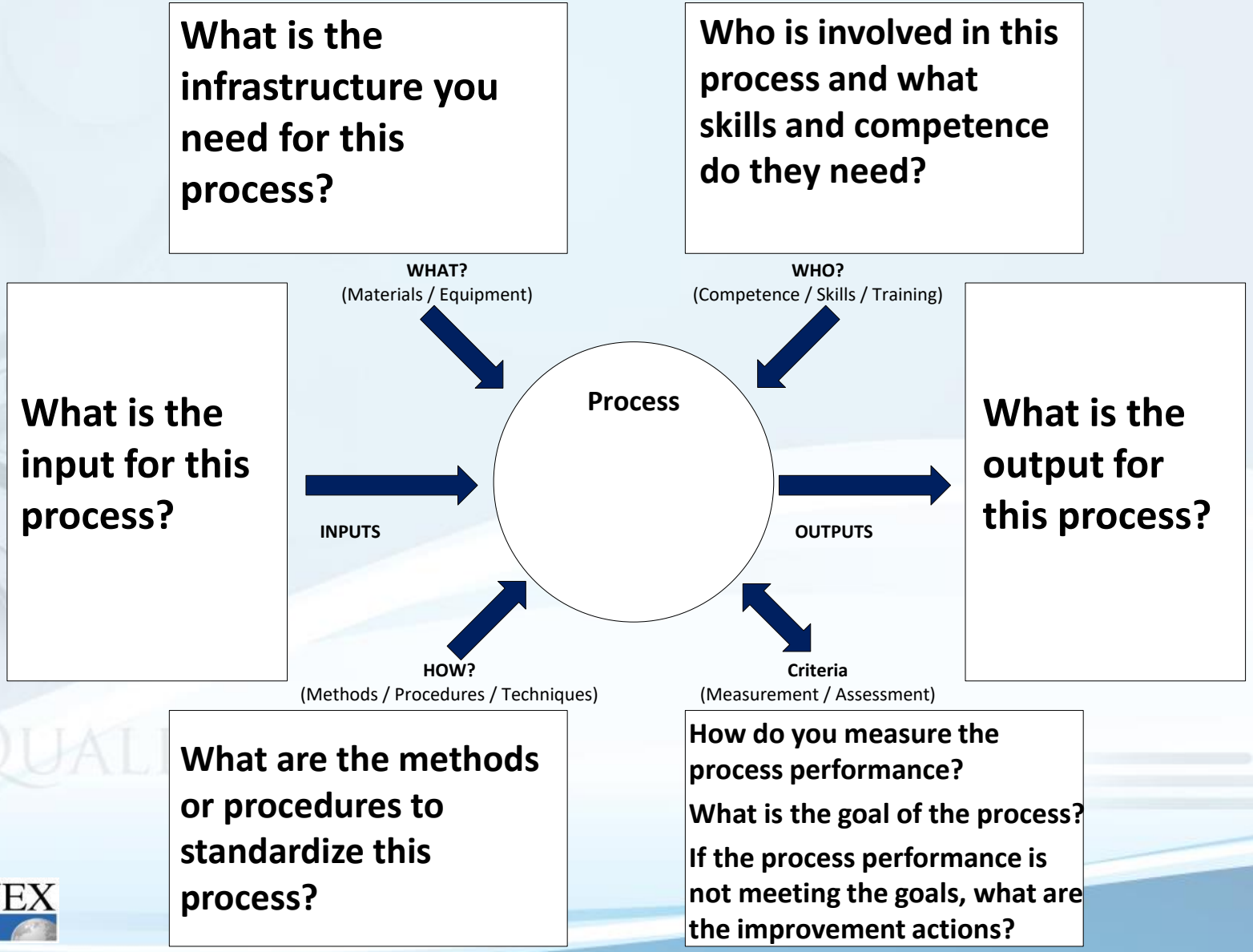
The Turtle Diagram

- A structured document which fully describes a process
- Made up of 6 sections:
  - **Inputs:** Suppliers, Resources, Product, Legal and Other Requirements, etc.
  - **Outputs:** Customers, Product, Service, Objectives/Targets, Program, Continual Improvement
  - **Measurements:** Variables and Effectiveness, Performance Indicators and Metrics
  - **People:** Competencies, Responsibility, Authority
  - **Equipment/Devices:** Machines, Tests/Inspections, Software, Hardware, Fixtures, Gages, Technology, Tools, etc.
  - **Documents:** Procedures, Work Instructions, Job Aids, Standards/Requirements
- Each section describes a specific element of a process
- Covering each section ensures a process approach to the audit

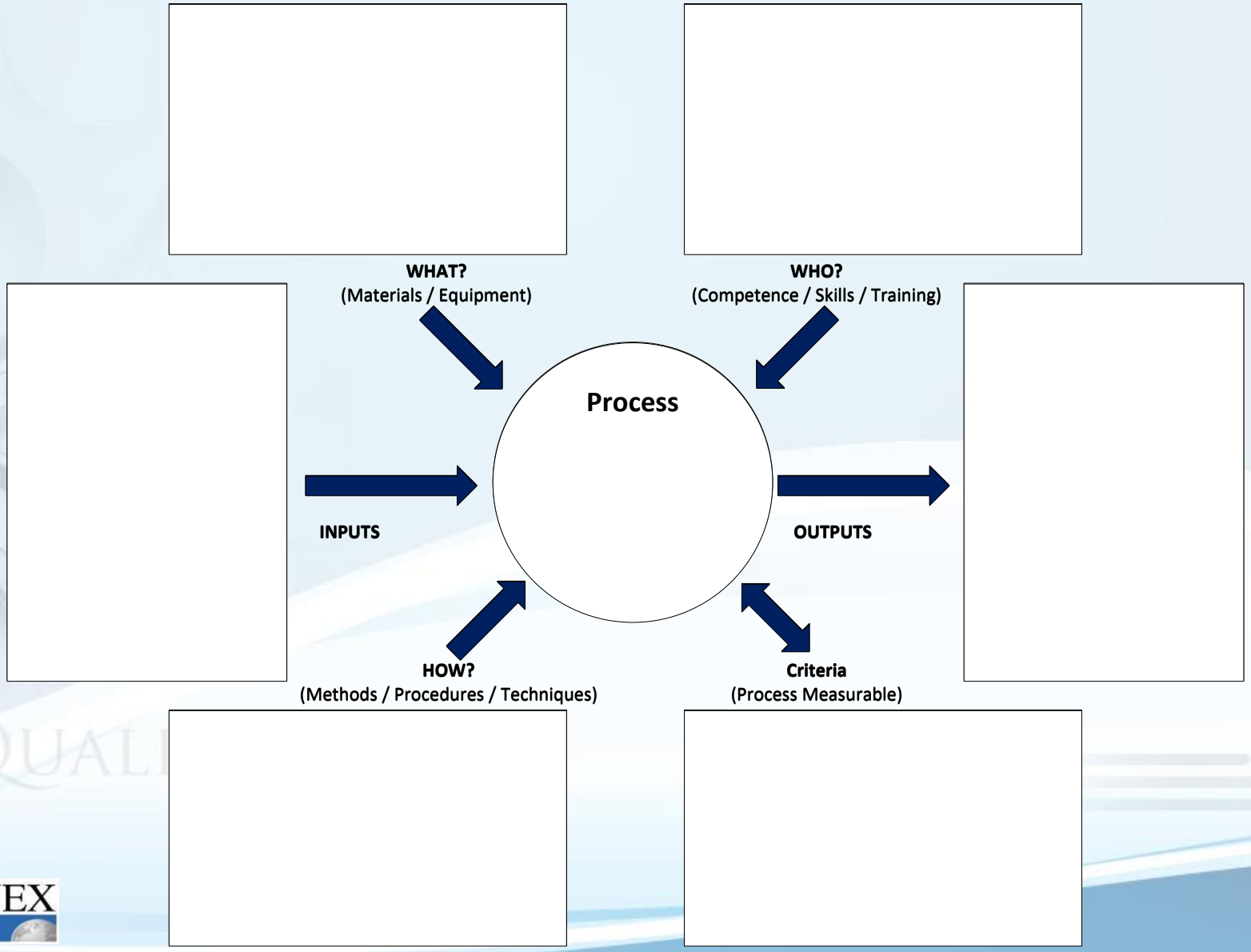
Turtle Diagram



Turtle Diagram



Process Analysis — Instructor-led Example



AUDIT TRAILS

Audit Trails

- Processes are made up of linked activities which make up an "audit trail."
- To audit a management system process, we take samples along the audit trail.
- We ask a series of questions to test conformity with the requirements of the standard at each step of the trail.
- Audit trails are created using an organization's Process Map.

Audit Trails

- **Business Planning and Management Review** – This audit trail is used when auditing strategic planning, business planning, policy deployment, objective setting, customer expectations, management review or operations review.
- **Monitoring and Improvement** – This audit trail is used when auditing any specific test or calibration method. It focuses on overall process control and improvement of that method.
- **New Test / Calibration Method Development** – This audit trail is used when auditing processes related to introducing and validating a new test or calibration method in the lab scope.
- **Testing / Calibration Audit Trail** – This audit trail explains the linkages between clauses when auditing the actual already approved or accredited test or calibration operations.

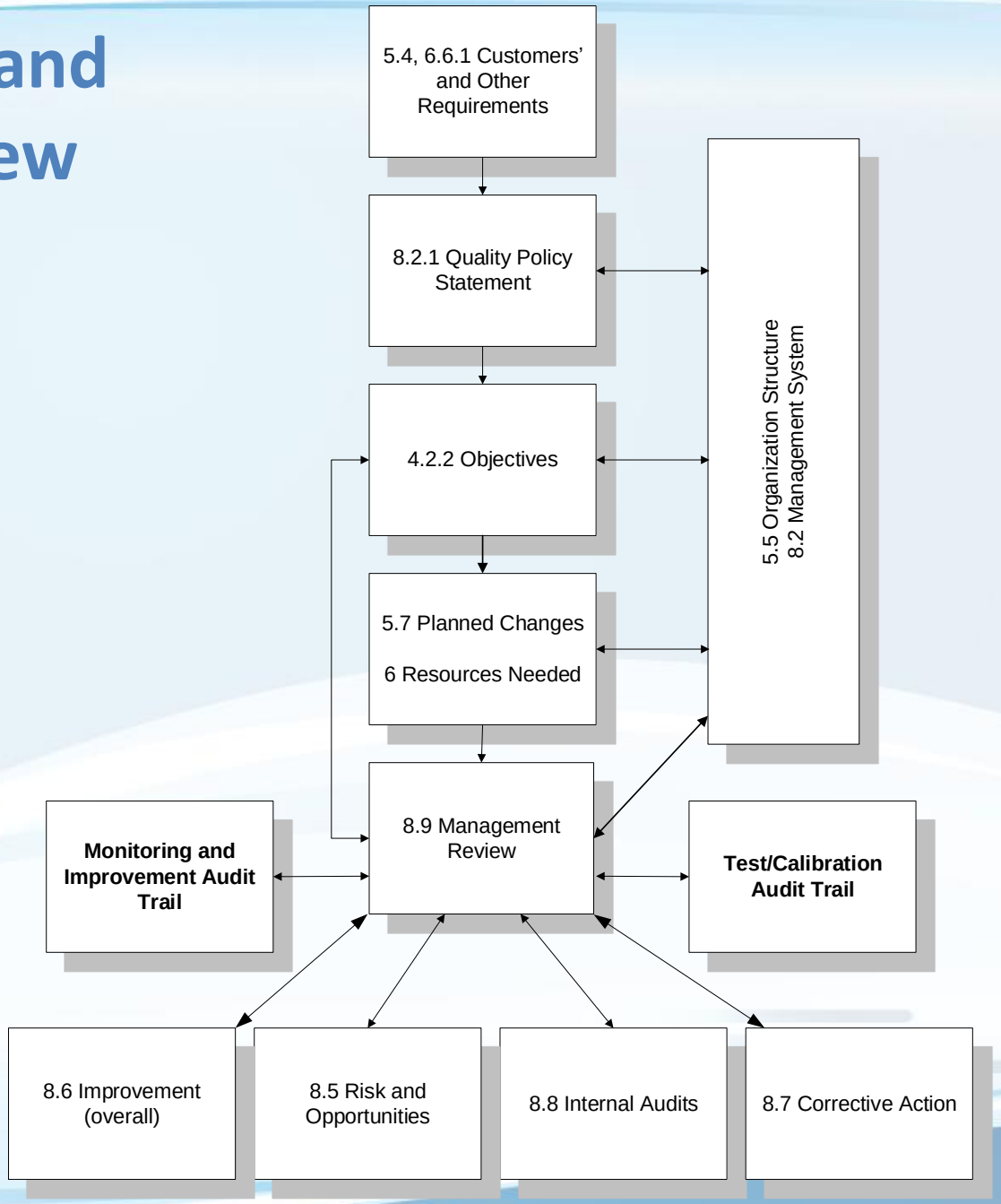
Audit trails will vary from one organization to another. The audit trail flow chart is an aid to the auditor.

How to Use Audit Trails When Auditing Processes

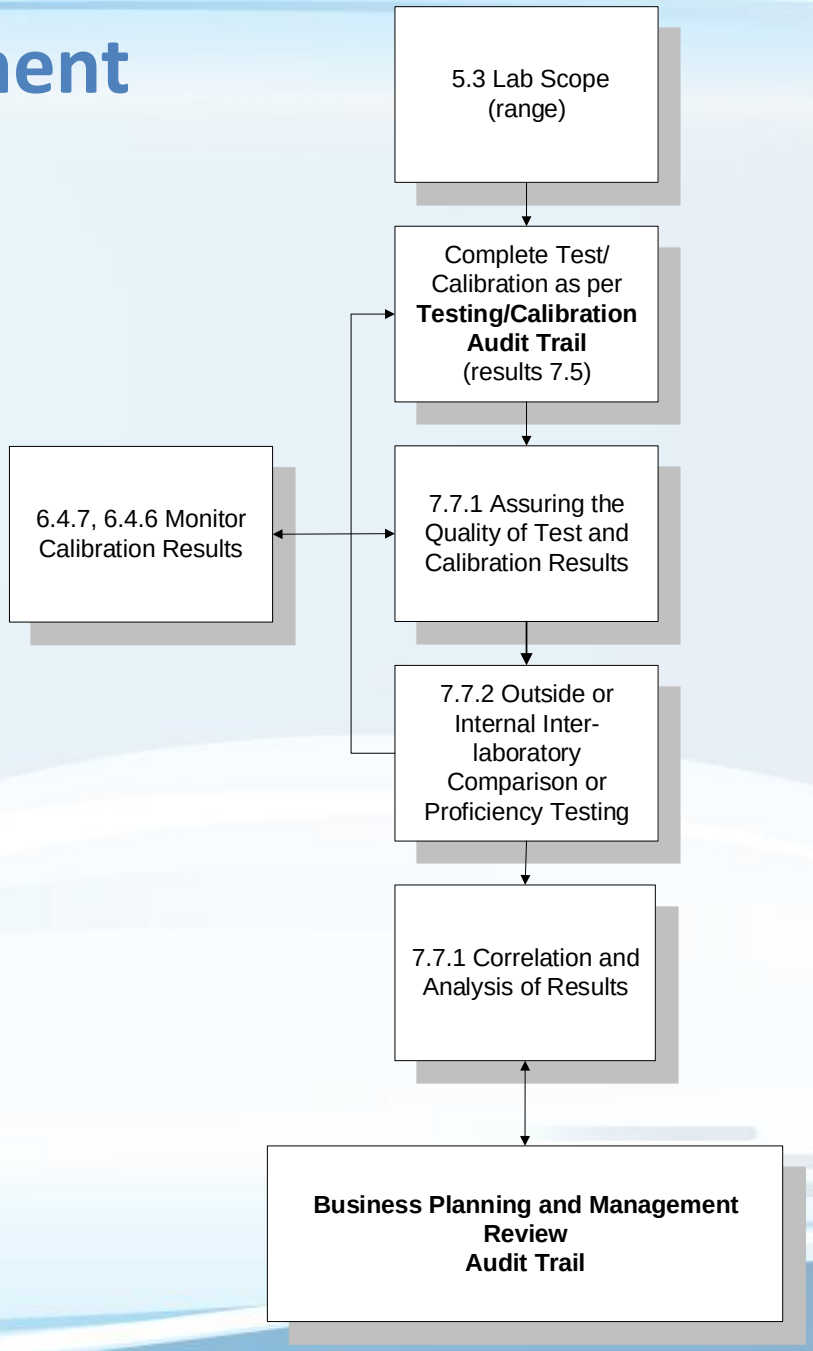
- Use the company's business processes/procedures during the audit

- Use the linkages and sampling described by audit trails to make your audits more effective

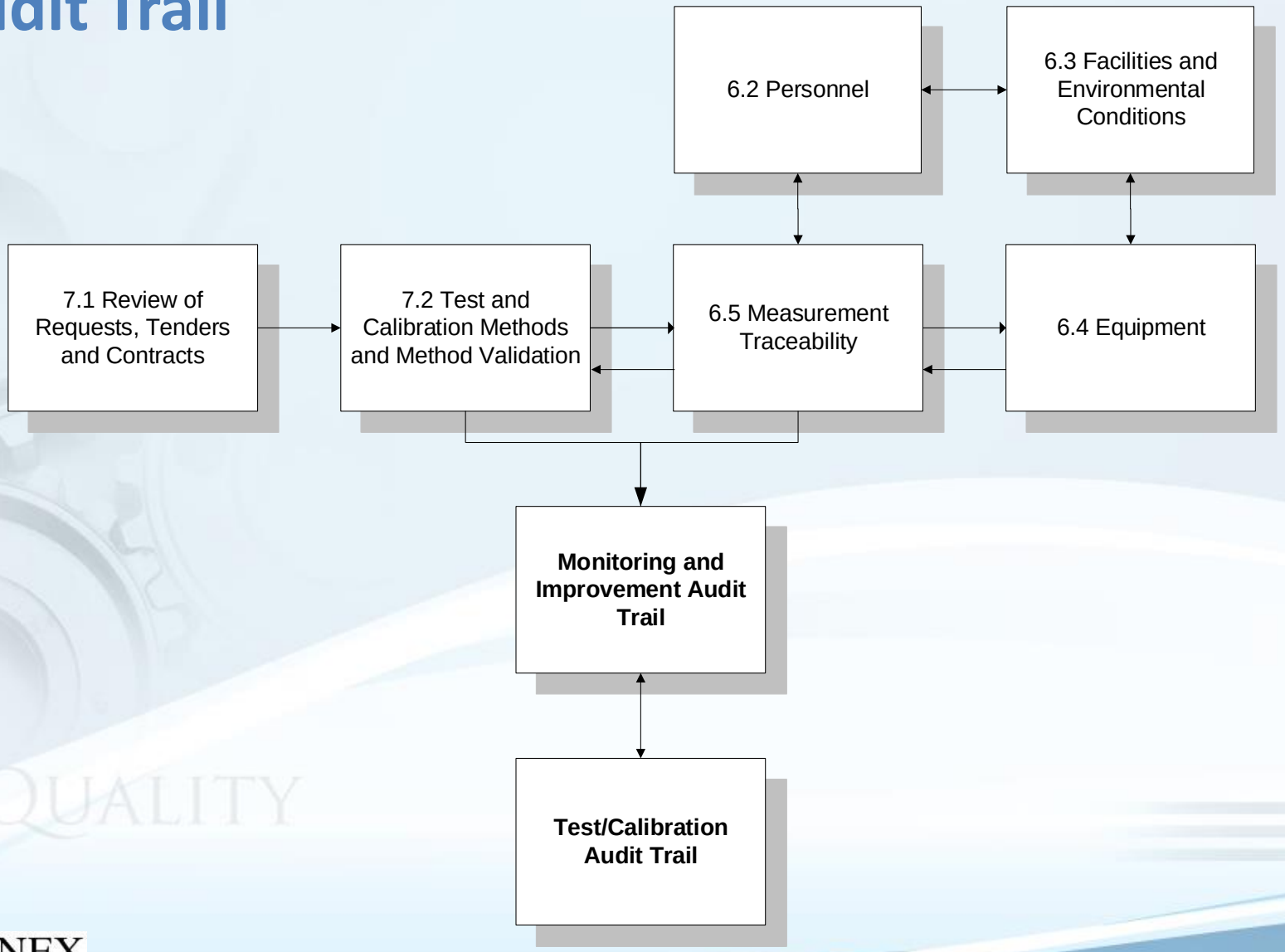
Business Planning and Management Review Audit Trail



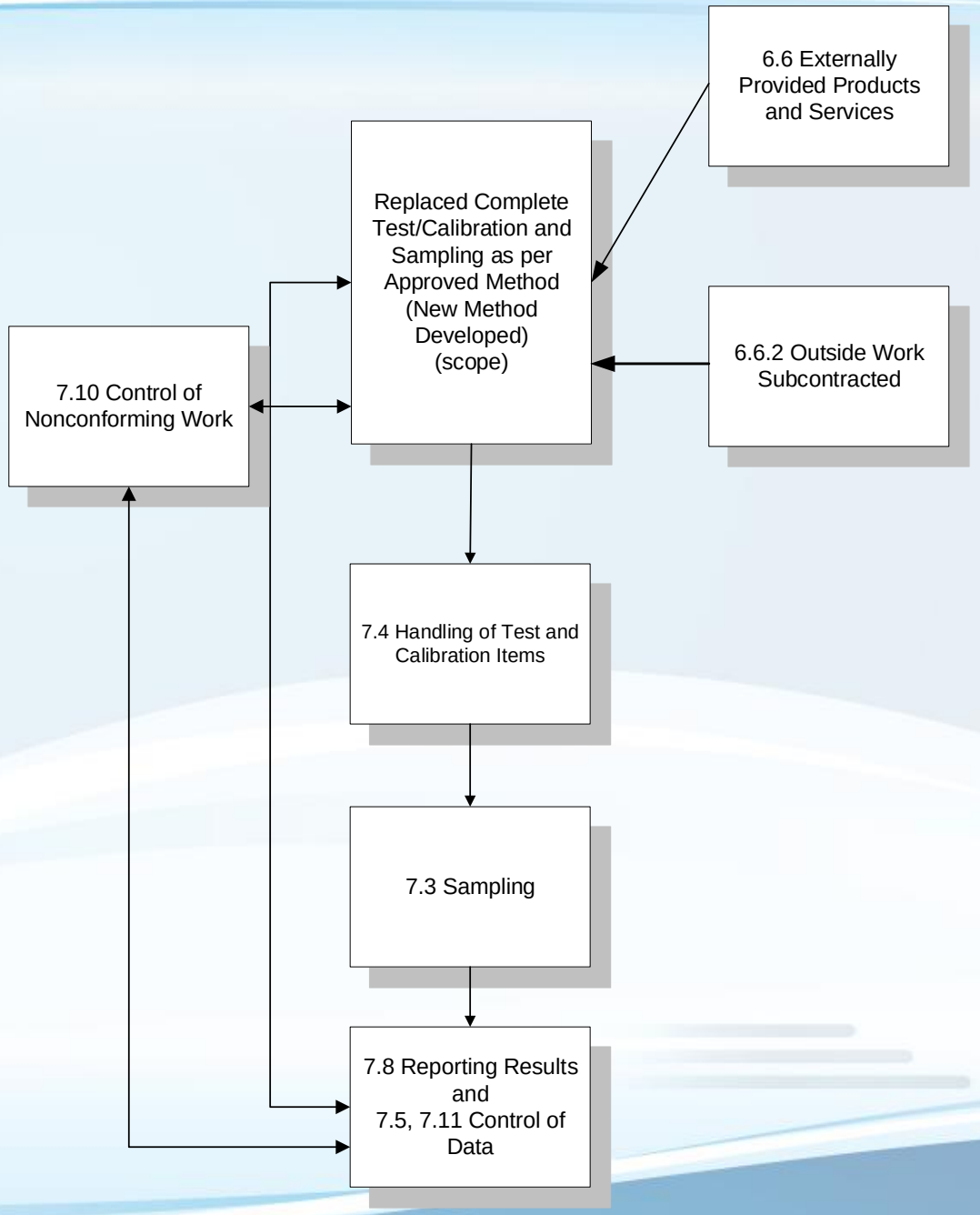
Monitoring and Improvement
Audit Trail



New Test / Calibration Method Development Audit Trail



Testing / Calibration Audit Trail



Chapter 4: Process Approach to Auditing, Turtle Diagrams and Audit Trails — What We Covered

Learning Objectives

You should now be able to:

- Describe Conformance and Performance Audits
- Explain a Process Approach Audit
  - What is a risk-based audit?
- Describe the six elements of a Turtle Diagram
- Explain how to use the turtle concept to conduct an audit using the process approach
- Describe the concept of audit trails

Chapter Agenda

- Conformance and Performance Audits
- Process Approach to Auditing
- Turtle Diagrams
- Audit Trails

Chapter 5

Audit Guidance, Definitions and Principles

Chapter 5: Audit Guidance, Definitions and Principles — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- State key definitions related to audit activities
- Describe the three types of audits
- Explain the importance of audit principles
- Define an auditor's personal behaviors
- Define the responsibilities, roles and authorities for an audit
- Describe an overall audit program

Chapter Agenda

- Audit Definitions and Guidance
- Types of Audits
- Audit Principles and Auditor Behaviors
- Responsibilities, Roles and Authorities

ISO 19011:2018 Applicability

- ISO 19011:2018 provides **guidance** on the management of audit programs, planning and conduct of management system audits, and the competence and evaluation of auditors and audit teams **FOR ALL TYPES OF AUDITS.**
- ISO 19011:2018 concentrates on internal audits (first party) and audits conducted by organizations on their external providers and other external interested parties (second party).
- It can be used for external audits conducted for purposes other than third party management system certification.
  - ISO/IEC 17021-1 provides requirements for auditing management systems for third party certification.
- It can also be used for the purpose of self-declaration and can be useful to organizations involved in auditor training or personnel certification.
- ISO 19011:2018 is applicable to all organizations that need to plan and conduct internal or external audits or manage an audit program.

AUDIT DEFINITIONS AND GUIDANCE

ISO 19011:2018

Audit Definitions — ISO 19011

Audit: systematic, independent and documented **process** for obtaining **objective evidence** and evaluating it fully to determine the extent to which **audit criteria** are fulfilled.

Process: set of interrelated or interacting activities that use inputs to deliver an intended result.

Combined (or Integrated) Audit: audit carried out together at a single auditee on two or more management systems.

Joint Audit: audit carried out as a single auditee by two or more auditing organizations.

Audit Definitions — ISO 19011

Audit Criteria: set of **requirements** used as a reference against which **objective evidence** is compared.

Objective Evidence: data supporting the existence or verity of something.

Audit Evidence: records, statements of fact or other information, which are relevant to the **objective evidence** and verifiable.

Audit evidence characteristics:
- **Uninfluenced by emotion or prejudice**
- **Can be stated**
- **Can be documented**
- **Can be verified (i.e., documented/based on observable phenomena)**

Audit Definitions — ISO 19011

Audit Program: arrangements for a set of one or more audits, planned for a specific time frame and directed towards a specific purpose.

Audit Scope: extent and boundaries of an audit.

Audit Plan: description of the activities and arrangements for an audit.

Audit Findings: results of the evaluation of the collected audit evidence against audit criteria.

Audit Conclusion: outcome of an audit after consideration of the audit objectives and all audit findings.

Audit Definitions — ISO 19011

Audit Client: Organization or person requesting an audit.

Auditee: Organization as a whole or parts thereof being audited.

Audit Team: One or more persons conducting an audit, supported if needed by technical experts.

Auditor: Person who conducts an audit.

Technical Expert: Person who provides specific knowledge or expertise to the audit team.

Observer: Individual who accompanies the audit team but does not act as an auditor.

Audit Definitions — ISO 19011

Risk: effect of uncertainty.

Management System: set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives.

- Note 1 to entry: A management system can address a single discipline or several disciplines, e.g., quality management, financial management or environmental management
- Note 2 to entry: The management system elements establish the organization's structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives and processes to achieve those objectives.

Audit Definitions — ISO 19011

Requirement: need or expectation that is stated, generally implied or obligatory.

Effectiveness: extent to which planned activities are realized and planned results achieved.

Performance: measurable result.

TYPES OF AUDITS

Types of Audits

- All audits can be classified into one of three types:
  - ***A First Party Audit (Internal Audit):*** Carried out by an organization on itself, using one of its own staff or a sub-contractor as the auditor.
  - ***A Second Party Audit (External Audit):*** Carried out by, or on behalf of, the customer on a supplier or potential supplier of goods or services.
  - ***A Third Party Audit:*** A company hires an organization to carry out an audit with the objective of obtaining independent certification of conformance with a particular standard.

1st Party Audit	2nd Party Audit	3rd Party Audit
Internal Audit	External Provider Audit	Certification and/or Accreditation Audit
	Other External Interested Party Audit	Statutory, Regulatory and Similar Audit

1st Party Audit — Internal Audit Purpose

- An internal unbiased look at a company's processes…
  - To determine the gap between the system that is written and that which is actually practiced
- Should be a "management instrument" in the development of procedures and systems and efforts toward Continual Improvement

2nd Party Audit — External Audit Purpose

- Evaluate a potential supplier to determine if they have the capabilities to meet the organization's requirements
- React to a supplier issue with an audit of the effectiveness of corrective actions
- Ongoing evaluation of a supplier

3rd Party Audit — Certification Audit Purpose

- Independent review of the management system for conformance and effectiveness
- Meet customer requirements for a certified management system
- Marketing tool to pursue new business or new markets

Third Party Audit Structure

- Information and Discussion
- Certification Application
- Pre-Assessment (optional)
- Stage 1 – Planning an Audit
- Stage 2 – On-site Audit
- Corrective Action and Follow-up
- Certificate Decision
- Certificate Issuance
- Surveillance
- Recertification

Auditing Principles

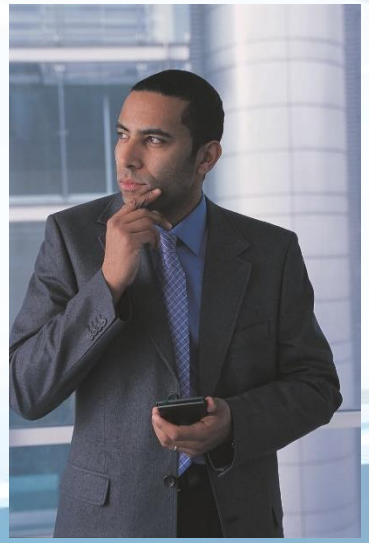
- Auditing principles help to make the audit an effective and reliable tool in support of management policies and controls by providing information upon which an organization can act in order to improve its performance.
- Adherence to these principles is needed in order to provide:
  - Audit conclusions that are relevant and sufficient.
  - For enabling auditors, working independently from one another, to reach similar conclusions in similar circumstances.

Auditing Principles

- **Integrity:** Foundation of professionalism
- **Fair Presentation:** Obligation to report truthfully and accurately
- **Due Professional Care:** Application of diligence and judgment in auditing
- **Confidentiality:** Security of information
  - Audit information should not be used inappropriately for personal gain by the auditor or the audit client, or in a manner detrimental to the auditee
- **Independence:** Impartiality of the audit and objectivity in audit conclusions
- **Evidence-based Approach:** Rational method for reaching reliable and reproducible audit conclusions in a systematic audit process
- **Risk-based Approach:** An audit approach that considers risks and opportunities
  - Ensures audits are target areas of significance for the audit client and for achieving the audit program objectives

Auditor Personal Behaviors

- Ethical
- Open-minded
- Diplomatic
- Observant
- Perceptive
- Versatile
- Tenacious
- Decisive
- Self-reliant
- Able to act responsibly and ethically
- Open to improvement
- Culturally sensitive
- Collaborative



RESPONSIBILITIES, ROLES AND AUTHORITIES

Roles, Responsibilities and Authorities

- Based on the context of the organization, several roles may be defined. The related responsibilities with authority should be defined within the Management System.

- **The Auditee's Management Should…**
  - Inform employees about the objectives and scope of the audit
  - Provide resources needed for the audit team
  - Provide access to the facilities and evidential material
  - Cooperate with the auditors during the audit
  - Determine and initiate corrective actions when required

Roles, Responsibilities and Authorities

Individual(s) Managing the Audit Program

a) Establish the extent of the audit program according to the relevant objectives and any constraints

b) Determine the external and internal issues, and risks and opportunities, then implement and integrate actions to address them in auditing activities

c) Ensuring the selection and competence of audit teams by assigning roles, responsibilities and authorities, and supporting leadership

d) Establish all relevant processes including processes for:
   - Coordination and scheduling of all audits within the audit program
   - Establishment of audit objectives, scope(s) and criteria, determining audit methods and selecting the audit team
   - Evaluating auditors
   - Establishment of communication processes
   - Resolution of disputes and handling complaints
   - Audit follow-up
   - Reporting to the audit client and interested parties

Roles, Responsibilities and Authorities

Individual(s) Managing the Audit Program

e) Determine and ensure provision of necessary resources

f) Ensure documented information is prepared and maintained, including audit program records

g) Monitor, review and improve the audit program

h) Communicate the audit program to the audit client and relevant interested parties

The audit program should be reviewed and approved by the audit client

Roles, Responsibilities and Authorities

Lead Auditor

- Ultimate responsibility for all phases of the audit
- Submits the audit report
- Determines what follow-up action, if any, is to be taken and informs the auditee of the actions to be taken
- Assist with the selection of team members
- Preparation of the audit plan
- Define the requirements of each audit assignment
- Evaluate and address risks of the audit
- Define the requirements of each audit assignment, including the required auditor qualifications
- Represent the audit team

Roles, Responsibilities and Authorities

All Auditors

- Comply with applicable auditing requirements
- Prepare working documents
- Review current documentation
- Retain and safeguard documents – ensure confidentiality
- Retain privileged information with discretion
- Report nonconformities to the auditee immediately
- Report on the audit results clearly and conclusively
- Verify the effectiveness of corrective actions taken

Roles, Responsibilities and Authorities

Expert

- The expert provides technical assistance to audit team members in special or specific areas where the audit team members do not possess the necessary experience within that functional area or audit scope

Guides

- Witness the audit on behalf of the auditee and the auditor
- Provide clarification or assist in collecting information
- Assist the auditors in identifying individuals to participate in interviews, confirming timings, and arranging access to specific locations of the auditee
- Ensure that rules concerning location safety and security procedures are known and respected by the audit team members and observers

Roles, Responsibilities and Authorities

Observers

- Represent an interested party
- Opportunity to learn auditing skills
- Do not participate in the audit

Interpreter

- Required when the audit team needs to have, or have access to, the skills necessary to deal with issues raised by language and/or culture
- The need is met by having an interpreter as a member of the team
- Interpreter should not be provided by the audit client

Chapter 5: Audit Guidance, Definitions and Principles — What We Covered

Learning Objectives

You should now be able to:

- State key definitions related to audit activities
- Describe the three types of audits
- Explain the importance of audit principles
- Define an auditor's personal behaviors
- Define the responsibilities, roles and authorities for an audit
- Describe an overall audit program

Chapter Agenda

- Audit Definitions and Guidance
- Types of Audits
- Audit Principles and Auditor Behaviors
- Responsibilities, Roles and Authorities

Chapter 6

The Audit Program

Chapter 6: The Audit Program — What We Will Cover

Learning Objectives

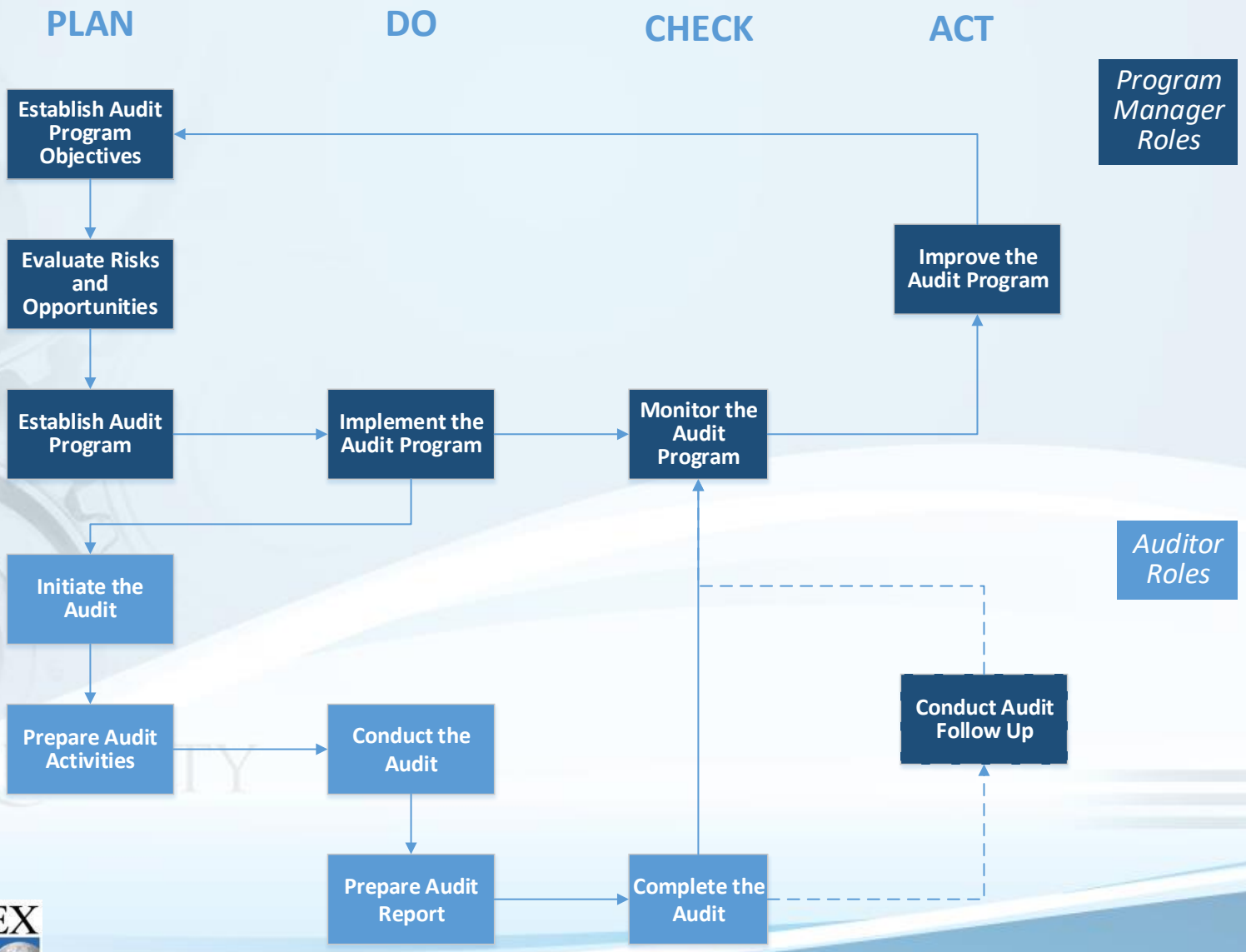
At the end of this chapter, you will be able to:

- Define the purpose and objectives of an audit program
- Describe the competency necessary for an auditor within the audit program
- List the risks associated with an audit program

Chapter Agenda

- Audit Program
- Audit Program Objectives
- Audit Program Competencies
- Audit Program Risks

Audit Program



Audit Program

- An audit program can include audits addressing one or more management system standards **(MSS)** or other requirements, and can be conducted separately or in a combined audit.
- The extent of an audit program should be based on the:
  - Size and nature of the auditee
  - MSS functionality and complexity
  - Type of risks and opportunities
  - Level of maturity of the management system
- The MSS functionality can be more complex when functions are outsourced and managed by other organizations.
- Particular attention needs to be focused on the top management of the management system.

Audit Program

- For multiple locations/sites or where important functions are outsourced, particular attention should be paid to the design, planning and ***validation*** of the audit program.
- For smaller or less complex organizations, the audit program can be scaled down.
- To understand the context of the auditee, the audit program should take into account:
  - Organizational objectives
  - Relevant external and internal issues
  - Needs and expectations of relevant interested parties
  - Information security and confidentiality requirements
- The planning of internal audit programs can be arranged to contribute to other objectives of the organization.

Guidance: What is Validation?

- As defined by ISO 9000, validation is confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled.
  - The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.
- An audit program can be validated by reviewing documented information including records.

Audit Program Objectives

- The audit client should ensure audit program objectives are established and implemented effectively.
- Objectives should be consistent with the strategic direction and support management system policy and objectives based on consideration of:
  - Needs and expectations of relevant interested parties
  - Characteristics of and requirements for processes, products, services and projects including any changes to them
  - Management system requirements
  - Need for evaluation of external providers
  - Audited MSS level of performance and level of maturity as evidenced by KPIs, any nonconformities or complaints from interested parties
  - Identified risks and opportunities to the auditee
  - Results of previous audits

Audit Program Objectives

- Examples of audit program objectives include:
  - Identify opportunities for MSS improvement
  - Evaluate the capability of the auditee to determine its context
  - Evaluate the capability of the auditee to determine risks and opportunities and implement effective actions to address them
  - Conform to all specified requirements, e.g., regulatory requirements, requirements for certification to a management system standard
  - Determine the capability of an external provider
  - Determine the continuing suitability, adequacy and effectiveness of the auditee's management system
  - Evaluate the compatibility and alignment of the management system objectives with the strategic direction of the organization

Managing an Audit Program

- Those managing the audit program should ensure the integrity of the audit is maintained and that there is no undue influence exerted over the audit.
- Audit priority should be given to allocating resources and methods to processes or activities with higher risk and lower level of performance.
- Competent individuals should manage the audit program.
- Implementation should be monitored and measured on an ongoing basis.
- Audit program should be reviewed to identify the need for changes and opportunities for improvement.

Managing an Audit Program

- The audit program should identify resources necessary to allow the audit to be conducted effectively and efficiently in the defined time frame and should include:
  - Audit program objectives
  - Audit program risks and opportunities and actions to address them
  - Scope of each audit in the audit program
  - Audit schedule (number/duration/frequency)
  - Audits types, i.e., internal or external
  - Audit criteria
  - Audit methods
  - Audit team selection criteria
  - Relevant documented information

Managing Audit Program Competence

"If you get a golf lesson in the morning, don't expect to shoot par in the afternoon"

- Competence for the Audit Program is critical to meeting the overall objectives of a successful audit process.
- Audit program competencies should include:
  - Determination of competencies needed
  - Determination of the methods to obtain the necessary competencies
  - Determination of the effectiveness of the methods used to obtain competencies

Managing Audit Program Competence

Determining Auditor Competence

- Determination of the necessary competence for an audit should consider the following:
  - Size, nature, complexity, products, services and processes of auditees
  - Audit methods
  - Management system to be audited
  - Complexity and processes of the management system to be audited
  - Risks and opportunities addressed by the management system
  - Objectives and extent of the audit program
  - Uncertainty in achieving audit objectives
  - Other requirements, such as those imposed by the audit client or other relevant interested parties

Managing Audit Program Competence

Knowledge and Skills of Auditors

- Understand risks and opportunities associated with auditing and the principles of the risk-based approach to auditing
- Effectively plan and organize work
- Perform the audit within the agreed schedule
- Prioritize and focus on matters of significance
- Communicate effectively, both orally and in writing
- Collect information through effective interviewing, listening, observing and reviewing documented information including records and data
- Understand appropriate use and consequences of sampling techniques
- Understand and consider technical experts' opinions
- Audit a process from start to finish, including interrelations with other processes and different functions as appropriate
- Verify relevance and accuracy of collected information
- Confirm audit evidence supports audit findings and conclusions, and assess those factors that may affect the reliability of these findings

Managing Audit Program Competence

Maintaining and Improving Auditor Competence

- Auditors and audit team leader should continually improve their competence through regular participation in management system audits and continual professional development, such as additional work experience, training, private study, coaching, attendance at meetings, seminars and conferences or other relevant activities taking into account:
  - Changes in the needs of the individual and the organization responsible for conducting the audit
  - Developments in auditing practices, including the use of technology
  - Relevant standards and guidance/supporting documents and other requirements
  - Changes in sector of disciplines
- Those managing the audit program should establish suitable methods for continual evaluation on the performance of auditors and audit team leaders.

Audit Program Risks

- The risks associated with establishing, implementing, monitoring, reviewing and improving an audit program that may impact the achievement of audit program objectives must be considered when developing an audit program.
- Those managing the audit program should identify the risks and opportunities when developing the audit program, including resource requirements, for the audit client so they can be addressed.
- Examples of risks include:
  - Planning, e. g., failure to set relevant audit objectives and determine the extent of the audit program
  - Resources, e. g. allowing insufficient time for audit program development
  - Audit team selection, e. g., the audit team lacks the necessary competence to achieve the audit objectives
  - Implementation, e. g. ineffective communication of the audit program
  - Ineffective evaluation of audit teams and their continual professional development
  - Records and their control, e. g., failure to adequately protect audit records
  - Monitoring, reviewing and improving the audit program, e. g., ineffective monitoring of outcomes

Audit Program Risks

- The lead auditor must evaluate and address audit risks
- There can be risks associated with the following:
  - Products
  - Supply Chain
  - Resources
  - Audit Program Management
  - Change Management
  - Communications
  - Control of Documented Information
  - Cooperation of Auditee and Availability of Evidence to be Sampled
  - Infrastructure, Work Environment, Health and Safety
  - Others!
  - Processes
  - Planning
  - Objectives
  - Competence
  - Selection of the Audit Teams
  - Implementation of Processes

Evaluating Risks and Opportunities

- Opportunities for improving the audit program include:
  - Establishing metrics that provide visibility to the overall effectiveness of the management systems to be audited
  - Conducting multiple audits in a single visit
  - Auditing integrated management systems
  - Minimizing time and/or travelling distance
  - Matching the level of competence of the audit team to the level of competence needed to achieve the audit objectives
  - Aligning audit dates with the availability of auditee's key staff

Chapter 6: The Audit Program — What We Covered

Learning Objectives

You should now be able to:

- Define the purpose and objectives of an audit program
- Describe the competency necessary for an auditor within the audit program
- List the risks associated with an audit program

Chapter Agenda

- Audit Program
- Audit Program Objectives
- Audit Program Competencies
- Audit Program Risks

Chapter 7

Audit Planning and Preparation

Chapter 7: Audit Planning and Preparation — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Describe the risk-based approach to auditing
- Identify the steps in preparing an audit
- Write objective and scope statements
- Describe the elements that should be considered when determining the audit resource requirements
- Explain the purpose of a Stage 1 audit
- Create an audit plan
- Describe the benefits and risks of checklists

Chapter Agenda

- Risk-based Approach to Auditing
- Audit Objectives, Scope and Criteria
- Determine Resources
- Contact Auditee
- Document and Data Analysis – Stage 1 Audit
- Prepare Work Documents
- **Breakout Exercise 3**

Objectives of Planning and Preparation

- **For the auditor**

  To make the auditor aware of the purpose of the audit that is to be performed, the scope of the investigation required and to allow the auditor enough time to conduct a preliminary investigation of the audit.

- **For the auditee**

  To make the auditee aware of the purpose and scope of the audit and the audit schedule to enable preparations to be made to ensure that the audit can proceed smoothly and achieve valid results.

RISK-BASED APPROACH TO AUDIT PLANNING

Auditing Risks and Opportunities

- Core objectives when auditing risks and opportunities are to:
  - Give assurance on the credibility of the risk and opportunity process(es)
  - Verify that risks and opportunities are correctly determined and addressed
- Risks and opportunities should be audited throughout the management system including with top management, not as an independent process.
- An auditor should collect objective evidence:
  - Inputs used which may include:
    - Analysis of context, e .g. external and internal issues
    - Strategic direction of the organization
    - Interested parties and their requirements
    - Potential sources of risk, e.g., environmental aspects, safety hazards
  - Method by which risks and opportunities are evaluated, which can differ between disciplines and sectors
- Auditors need to apply good professional judgment when assessing the organization's methods for addressing risks and opportunities.

Auditing Risk-Based Thinking
IAF Guidance

- An audit of risk-based thinking in an organization cannot be performed as a stand-alone activity; it should be implicit during the entire audit of a QMS, including when interviewing top management.
- Objective evidence of adequate risk determination could include:
  - Meeting minutes
  - SWOT analysis
  - Reports on customer feedback
  - Brain-storming activities
  - Competitor analysis
  - Planning, analysis and evaluation activities for various processes
  - Management review
  - Risk determination or evaluation records
- Actions needed for risk treatment can include the revising or establishing objectives, action plans, training, work instructions.

IAF Guidance — Audit Risk Classification Examples

- **High Risk:** Where product failure could cause economic catastrophe or puts life at risk
  - Examples: food, pharma, aerospace, chemical, healthcare
- **Medium Risk:** Where failure of product could cause injury or illness
  - Examples: construction, metal fabricating, optical equipment
- **Low Risk:** Where product failure is unlikely to cause injury or illness
  - Examples: textiles, clothing, paper products, hotels, education

source: IAF MD5 Risk Classification

Health and Safety Audit Risks

- The audit program manager should communicate any health and safety requirements for the audit to the team leader who should communicate these to the audit team, any observers and technical experts needed.
  - Examples: personal protective equipment (PPE) such as safety glasses, side shields, gloves, steel-toed safety shoes; hard hats, vests, quarantined or restricted areas, gowns, hair or beard covers and any required gowning procedure.
- The team leader should confirm any health and safety requirements in the initial contact with the auditee.
- Risks to the auditee can result from the presence of the audit team members adversely influencing the auditee's arrangements for health and safety, environment and quality, and its products, services, personnel or infrastructure (e.g. contamination in clean room facilities).
- Relevant access, health and safety, security, emergency and other arrangements for the audit team should be reviewed in the opening meeting.

Preparing for an Audit

Preparing for an Audit – Five Steps

1. Define the Audit Objectives, Scope, Criteria and Methods
2. Determine the Resources Required
   - Determine audit methods
   - Audit Team
   - Audit Team Leader
   - Other (hardware, software, etc.)
3. Contact the Auditee
   - Determine audit feasibility
   - Obtain documentation
4. Data Analysis and Document Review – Stage 1 Audit
   - Evaluate customer focus and performance
   - Conduct document review
5. Prepare Work Documents
   - Prepare audit plans
   - Prepare work documents

Six Steps of Conducting an Audit

1. **Initiate the Audit**
2. **Prepare Audit Activities**
3. **Conduct Audit Activities**
4. **Prepare Audit Report**
5. **Complete Audit**
6. **Conduct Audit Follow-up**

AUDIT OBJECTIVES, SCOPE AND CRITERIA

Audit Objectives, Scope and Criteria

- The **audit objectives** describe what will be audited, the type of audit to be conducted and what the audit findings will be compared against.
- The audit **scope** describes the extent and boundaries of the audit.
- The audit **criteria** is a reference against to which conformity is determined.

Audit Objectives

- Determination of the extent of conformity of the management system to be audited, or parts of it, with audit criteria
- Conformance to a standard or requirement
- Determination of the extent of conformity of activities, processes and products with the requirements and procedures of the management system
- Conformance to an organization's documented system
- Evaluation of the capability of the management system to ensure compliance with legal and contractual requirements and other requirements to which the organization is committed
- Conformance to a contract
- Evaluation of the effectiveness of the management system in meeting its specified objectives
- Conformance of a project toward meeting stated objectives
- Identification of areas for potential improvement of the management system
- Provide management with feedback related to either preventive action or continual improvement

Audit Scope

- Scope of the Audit – consistent with audit program and objectives (as needed for clarity)
  - Which product
  - Portion of company
  - Geographic sites or operating unit
  - Processes to be audited
  - Number of audit days

Although not required, it can be helpful to list the audit criteria, such as the standard against which the system will be audited and any exclusions, to the Audit Scope statement

Example:

- Design and manufacture of stampings for the automotive industry manufactured in Saline, Michigan with corporate HQ in Troy, MI. No exclusions.
- Transportation services located in Southfield, MI. Product design excluded.

Audit Criteria

- Audit Criteria – specified requirements against which conformity is determined
  - Policies
  - Processes
  - Procedures
  - Performance criteria, including objectives, statutory and regulatory requirements
  - Management System Requirements
  - Information on the organizational context and risks and opportunities as determined by the auditee, including external/internal parties' requirements
  - Codes of Practice

DETERMINE RESOURCES

Determine Resources Required

- How many days will the audit take?
- How many days should be spent in each area?
  - On-site versus remote auditing
  - Sampling methods
  - Minimize disruption
  - Enough time to be thorough
- How many auditors?
- Are technical experts required?
- Appoint the audit team leader

Audit Methods

Audit methods are defined by the Team Leader and the Audit Program Manager

- **Remote Auditing**
  - Any audit activities that take place at a location other than the site of the auditee.
  - Any technology that allows the auditor and the auditee to communicate while the auditor is located at a remote location. Methods such as conference calls, video conferencing, web/internet meetings could be used.
- **On-site Auditing**
  - Audit activities conducted at the site of the auditee.
- **Human Interaction**
  - Interacting with the auditee either during on-site or remote audit activities.
- **No Human Interaction**
  - No interaction with the auditee either during on-site or remote audit activities.

Audit Methods

Extent of Involvement Between the Auditor and Auditee	Location of the Auditor	
	On-site	**Remote**
Human Interaction	Conducting interviews Completing checklists and questionnaires with auditee participation Sampling	Via interactive communication means: – conducting interviews – completing checklists and questionnaires – conducting document review with auditee participation
No Human Interaction	Conducting document review (e.g., records, data analysis) Observing work performed Conducting on-site visit Completing checklists Sampling (e.g., products)	Conducting document review (e.g., records, data analysis Observing work performed via surveillance means, considering social and statutory and regulatory requirements Analyzing data

On-site audit activities are performed at the location of the auditee. Remote audit activities are performed at any place other than the location of the auditee, regardless of distance.
Interactive audit activities involve interaction between the auditee's personnel and the audit team. Non-interactive audit activities involve no human interaction with individuals representing the auditee but do involve interaction with equipment, facilities and documentation.

The feasibility of remote activities depends on several factors, such as the level of risk to achieving the audit objectives, the level of confidence between auditor and auditee personnel, and regulatory requirements

source: ISO 19011:2018 Annex A.1

Auditing Virtual Activities and Locations

- Auditing of a virtual location, aka “virtual audits” are conducted when an organization performs work or provides a service using an on-line environment.
- Remote audits refer to using technology to gather information and to interview an auditee when “face-to-face” methods are not possible or desired.
- A virtual audit follows the standard audit process while using technology to verify objective evidence.
- Appropriate technology requirements for virtual audits can include:
  - Ensuring the audit team is using agreed remote access protocols
  - Verifying the system(s) to be used prior to the audit to prevent any technical issues
  - Ensuring contingency plans are known regarding potential interruption of access including provision for any extra audit time needed

Auditing Virtual Activities and Locations

- When planning a virtual audit, the auditor should consider:
  - Risks associated with virtual or remote audits
  - Using floor plans/diagrams of remote locations for reference or mapping of electronic information
  - Prevention of background noise disruptions and interruptions
  - Asking for permission in advance to take photos, videos or screen shots of documents, considering confidentiality and security matters
  - Ensuring confidentiality and privacy during audit breaks e.g. by muting microphones, pausing cameras
  - Limitations of non-verbal communication in virtual settings focusing instead on the type of questions to use in finding objective evidence

Auditing Virtual Activities and Locations

- For any virtual audit activities:
  - Ensure the audit team is using agreed remote access protocols
  - If taking photos or copies of any document, ask for permission in advance and consider confidentiality and security matters including any video recording
  - If an incident occurs during the remote access, the audit team leader should review the situation with the auditee and the audit client to reach agreement on whether the audit should be continued
  - Use floor plans/diagrams of the remote location for reference
  - Maintain respect for privacy during audit breaks

Audit Sampling

- In the context of auditing, our goal is to select an appropriate sample for auditors to be confident that the audit objectives will be achieved.
- Risks may be associated with the sampling methods used and variability within the population of information.
  - Samples may not be representative of the population from which they are selected, thus the auditor's conclusion may be biased and be different from that which would be reached if the whole population was examined.
  - There may be other risks depending on the variability within the population to be sampled and the method chosen.
- Sampling should be carefully planned, considering the objectives of sampling, extent and composition of the population to be sampled, sampling methods, and sample sizes.
- ISO 19011 discusses two fundamental means of sampling — judgment-based and statistical-based.

Judgment-Based Sampling

- Judgment-based sampling relies on the knowledge, skills and experiences of the audit team; the risk is that there can be no statistical estimate of sampling uncertainty.
- Judgment-based sampling should consider:
  - Previous audit experience within the audit scope
  - Complexity of requirements (including statutory and legal requirements)
  - Complexity and interaction of the organization's processes and management system elements
  - Changes in technology, human factor or management system
  - Key risk areas
  - Areas of improvement
  - Output from monitoring of management systems

A drawback to judgment-based sampling is that there can be no statistical estimate of the effect of uncertainty in the audit findings and conclusions

Statistical-Based Sampling

- Statistical sampling should be based on the audit objectives and known characteristics of the population to be sampled.
- Auditors should use sound statistical techniques for sampling, and consider the use of attribute or variable-based sampling as appropriate.
  - Attribute-based sampling is used when there are only two possible sample outcomes (e.g., correct/incorrect, pass/fail)
  - Variable-based sampling is used when the sample outcomes occur in a continuous range (e.g., occurrence of food safety incidents, number of security breaches)
- The level of sampling risk to be accepted should be considered (e.g., acceptable confidence levels).
- The sampling plan, criteria and methods used should be documented as part of the audit record.

Statistical-Based Sampling

- Elements that can affect the audit sampling plan include:
  - Context, size, nature and complexity of the organization
  - Number of competent auditors
  - Frequency of audits
  - Time of individual audit
  - Any externally required confidence levels
  - Occurrence of undesirable and/or unexpected events

Audit Sampling

- Factors to consider when choosing samples:
  - **Relevance:** do samples in fact provide appropriate evidence?
  - **Representative:** are the samples representative of current process methods?
  - **Range:** do the samples represent the full range of conditions that exist?

Audit Tip – Remember not to make audit samples too big.

Don't Nit Pick!

Audit Sampling

- **Benefits of Sampling:**
  - Allows auditor to focus on processes and their effectiveness
  - Allows for better time management

- **Risks of Sampling:**
  - Sampling uncertainty
  - Sample may not be representative if not selected carefully

Contact the Auditee

- Confirm communication channels with the auditee's representatives
- Confirm authority to audit
- Provide relevant information on audit objectives, scope, criteria, methods, and audit team composition, including any technical experts
- Request access to relevant information for planning, including information on risks and opportunities the organization has identified and how they are addressed
- Determine applicable statutory/regulatory requirements and other requirements relevant to the activities, processes, products and services of the auditee
- Confirm agreement with auditee regarding disclosure and treatment of confidential information
- Make arrangements for the audit including the schedule
- Determine any location-specific arrangements for access, health and safety, security, confidentiality, etc.
- Agree on observers and need for guides or interpreters
- Determine any areas of interest, concern or risks to the auditee
- Resolve issues regarding audit team composition with the auditee or audit client

Determining the Feasibility of the Audit

- Feasibility is determined in order to provide reasonable confidence that the audit objectives can be achieved.
- Feasibility should be determined by considering:
  - Availability of sufficient and appropriate information
  - Cooperation of the auditee
  - Adequate time and resources for conducting the audit
- Where the audit is not feasible, an alternative should be proposed.

DOCUMENT AND DATA ANALYSIS

Stage 1 Audit

Document and Data Analysis

- Stage 1 Audit includes the following:
  - Evaluate Customer Focus and Performance
  - Conduct Document Review
  - Identify Audit Risks and Feasibility
  - Finalize Audit Plans
  - Prepare Work Documents
    - Turtle Diagrams
    - Auditor Checklists

Review Performance

- Obtain evidence of system and/or process performance by:
  - Studying customer scorecards and customer quality history
  - Examining historic performance and previous problems
  - Identifying current quality, product and service requirements
  - Examining past audits

Identifying Suspect Processes — Risk-Based Auditing

- Identify poorly performing customer and or internal metrics

- Identify poorly performing related processes

Prioritize the audit by ensuring that processes at risk are identified and targeted in the audit plan.
Other targets are Customer Oriented Processes since they affect the customer.

Review of Documented Information

- The relevant management system documented information should be reviewed in order to:
  - Understand the auditee's operations and to prepare audit activities and applicable audit work documents
  - establish an overview of the extent of the documented information to determine possible conformity to the audit criteria and detect possible areas of concern, such as deficiencies, omissions or conflicts
- Should include, but not be limited to management system documents and records, previous audit reports
- Should take into account the context of the auditee's organization, such as its size, nature and complexity, related risks and opportunities, and the audit scope, criteria and objectives

Review of Documented Information

- Conducting a Document Review:
  - Determine the degree of conformity of the system as documented
  - Identify processes of possible concern
- The following documentation may be needed:
  - Quality Manual with process list, key process map, organization chart
  - Internal Audit Reports
  - Management Review Agendas and Meeting Minutes
  - Internal and Customer Scorecards
  - Lists of Context Issues (4.1), Interested Party Needs (4.2), Risks and Opportunities (6.1), Regulatory Requirements (5.1.2, 8.2.2)
- Auditors should study the process documentation to determine the feasibility of conducting the onsite audit based on any omissions or gaps to the audit criteria.

Sectors can specify additional documentation to be reviewed in Stage 1

PREPARE WORK DOCUMENTS

The Audit Plan

- The audit team leader prepares an audit plan with input from the audit team.
- An audit plan…
  - Is a description of the activities for an audit
  - Facilitates scheduling and coordination of activities
  - Is sufficiently flexible to permit changes when they become necessary
  - Extent of the audit plan is based on the complexity of the audit

Preparing the Audit Plan

- The audit plan should cover the following:
  - Audit objectives
  - Audit criteria and reference documents
  - Audit scope
  - Dates and places where audit activities are to be conducted
  - Expected time and duration of audit activities
    - including meetings with auditee's management, and
    - audit team meetings
  - Audit methods to be used
  - Roles and responsibilities of the audit team members
  - Allocation of resources to critical areas of the audit

Preparing the Audit Plan

- The audit plan could also cover, as appropriate:
  - Identification of the auditee's representative for each process audited
  - Working and reporting language of the audit
  - Logistic arrangements (travel, on-site facilities, etc.) and schedule
  - Actions to address risks to achieving audit objectives and opportunities
  - Matters related to confidentiality and information security
  - Any follow-up actions
- The plan should be reviewed and accepted by the auditee and the audit program manager before the audit activities begin.

Preparing the Audit Plan

- Look for and prioritize poorly performing and suspect processes
- Opening meeting, a plant tour and closing meeting are recommended
- In System Audits, management commitment, business planning and management review should come first
  - Expect to have top management in the audit. Is top management accountable for the QMS?
- Individual audit schedule **(Audit Plan Schedule)** is organized following the organization's processes **NOT** by ISO clauses
- Sample customer and regulatory requirements to see if the processes for determining and addressing them are effective
- Evidence of conformance to customer and regulatory requirements should be verified and may require assessment of a subject matter expert
- An appropriate amount of time should be used for auditor meetings or report writing
- Make sure the audit plan covers all shifts

Audit Plan

Date and Time – Day 1		
8:00am	Opening Meeting	Top Management and Management
8:30am	Lab Tour	
9:00am	Customer Focus (5.1, 5.2)	Marketing Manager
11:00am	Documented Information (7.5)	Quality Department
12:00pm	Lunch	

Process-Driven Audit Plan

Date and Time – Day 1		
8:00am	Opening Meeting	Top Managers and Management
8:30am	Lab Tour	
9:00am	Customer Satisfaction and Performance Data Review*	Top Management
11:00am	Operational Review*	Top Management
12:00pm	Lunch	

*** The processes on the audit plan have to match the processes in the Process Map**

Example
Audit Schedule

OMNEX
325 E. Eisenhower, Suite 4
Ann Arbor, MI 48108
Phone: (734)761-4940 Fax: (734)761-4966

Organization: ___ACME Company_____ Date: ___1/2/08_____

Auditor(s) Name: ___W.E. Coyote_____

Audit Plan

Date	Time	Activity	Person(s) Interviewed
1/14/08	8:00	Opening Meeting	
	8:30	Plant Tour	
	9:30	Bid Tender Process	
	12:00	Lunch	
	12:45	Design and Development Process	
	2:15	Order/Request Process	
	3:30	Delivery Process	
	5:00	Adjourn	
1/15/08	8:00	Review Meeting with ACME	
	8:30	Production Processes	
	12:00	Lunch	
	12:45	Warranty Service Process	
	3:15	Payment Process	
	3:45	Write-up Nonconformities	
	4:30	Close Meeting with ACME	
	5:00	Adjourn	

Clause	Processes Audited			
	Leadership & Management	New Product Development	Operations	Support
4.1 Understanding the organization and its context	X			
4.2 Needs and expectations of interested parties	X			
4.3 Determining the scope of the QMS	X			
4.4 Quality management system and its processes				X
5.1.1 Leadership - General	X			
5.1.2 Customer focus				X
5.2 Policy	X			
5.3 Organizational roles, responsibilities and authorities				X
6.1 Actions to address risks and opportunities		X		X
6.2 Quality objectives and planning	X			
6.3 Planning of changes		X	X	
7.1.1 Resources - General	X			
7.1.2 People				X
7.1.3 Infrastructure			X	
7.1.4 Environment for the operation of processes			X	
7.1.5 Monitoring and measuring resources				X
7.1.6 Organizational knowledge				X
7.2 Competence				X
7.3 Awareness				X
7.4 Communication	X			
7.5 Documented information				X
8.1 Operational planning and control			X	
8.2 Requirements for products and services		X		
8.2.1 Customer communication				X
8.2.2 Determining product/service requirements		X		X
8.2.3 Review of requirements related to products and services				X
8.2.4 Changes to requirements for products and services		X	X	
8.3 Design and Development		X		
8.4 Control of externally provided processes, products/services				X
8.5.1 Control of production and service provision			X	
8.5.2 Identification and traceability			X	
8.5.3 Property belonging to customers or external providers				X
8.5.4 Preservation			X	
8.5.5 Post-delivery activities				X
8.5.6 Control of changes including design 8.3.6		X	X	
8.6 Release of products and services		X		
8.7 Control of nonconforming outputs			X	
9.1.1 Monitoring and measurement - General			X	X
9.1.2 Customer satisfaction	X			X
9.1.3 Analysis and evaluation	X			
9.2 Internal audit				X
9.3 Management review	X			
10.1 Improvement - General			X	X
10.2 Nonconformity and corrective action			X	X
10.3 Continual improvement			X	X

Audit Plan Matrix

- The audit plan matrix is used in the beginning for planning purposes and ensures that the system includes all clauses of the standard and that it covers all organizational areas.
- After the audit, this document can also be used as objective evidence to show that the audit met all objectives.

Audit Checklists and Conformance Audits

- Audit checklists should be a fresh list of facts to be verified, not standard questions
- Checklists should identify specific areas of concern
- Checklists can identify specific evidence that needs to be gathered
- Checklists act as reminders to ensure that all audit objectives have been met
- The use of checklists and forms should not restrict audit activities
- Audit Checklists are used primarily with conformance audits

Audit Checklists

- **Benefits of Checklists:**
  - Keep audit objective clear
  - Evidence of planning
  - Maintain audit pace and continuity
  - Reduce auditor bias
  - Reduce work load during audit

- **Risks of Checklists:**
  - May restrict auditor versatility and scope (too narrow)
  - Auditor might focus too much on “clauses” vs. “process approach”

Breakout Exercise 3

Creating an Audit Plan

Chapter 7: Audit Planning and Preparation — What We Covered

Learning Objectives

You should now be able to:

- Describe the risk-based approach to auditing
- Identify the steps in preparing an audit
- Write objective and scope statements
- Describe the elements that should be considered when determining the audit resource requirements
- Explain the purpose of a Stage 1 audit
- Create an audit plan
- Describe the benefits and risks of checklists

Chapter Agenda

- Risk-based Approach to Auditing
- Audit Objectives, Scope and Criteria
- Determine Resources
- Contact Auditee
- Document and Data Analysis – Stage 1 Audit
- Prepare Work Documents
- **Breakout Exercise 3**

Chapter 8

Conducting the Audit

Chapter 8: Conducting the Audit — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- List items that should be included in an opening meeting
- Describe the purpose of meeting with Top Management
- Explain methods to gather evidence
- Describe the things to do and not do for interviews
- Describe how to prevent negative reactions to audits

Chapter Agenda

- Opening Meeting
- Facility Tour
- Meet with Top Management
- Gather Evidence
- Conducting Interviews
- Negative Reactions to Audits
- **Breakout Exercise 4**

Conducting the Audit

- There are six steps in conducting audit activities (Phase II)
  1. Opening Meeting
  2. Conduct Facility Tour (optional)
  3. Meet with Top Management
  4. Gather Objective Evidence
  5. Prepare Nonconformity Statements
  6. Closing Meeting

Six Steps of Conducting an Audit

1. **Initiate the Audit**
2. **Prepare Audit Activities**
3. **Conduct Audit Activities**
4. **Prepare Audit Report**
5. **Complete Audit**
6. **Conduct Audit Follow-up**

- The first four are covered in this chapter

Communication During the Audit

- The audit team should meet periodically to exchange information.
- The audit team leader should periodically communicate with the auditee's management.
- Evidence that suggests a significant risk should be reported to the auditee immediately.
- Changes to the audit scope should be reviewed with and approved by the audit client and the auditee.

OPENING MEETING

Opening Meeting

Conducting the Opening Meeting

- An opening meeting should be held with the auditee's management and the process owners of the functions to be audited.
- The purpose of an opening meeting is to:
  - Introduce the audit team and their roles and other participants such as observers, guides and interpreters
  - Confirm the audit plan and ensure all planned activities can be conducted
  - Provide a short summary of how the audit activities will be undertaken
  - Establish communication channels during the audit
  - Provide an opportunity for the auditee to ask questions

Opening Meeting

Opening Meeting Checklist

- Introduce audit team and auditee/audit client attendees and their roles
- Confirm attendance
- Describe the audit process **(Process Approach Audit)**
- Review objectives, scope and criteria
- Summary of methods and procedures used for audit
  - Notes
  - Sampling
  - Small groups
  - Notification of findings
  - Questions for the lead auditor

Opening Meeting

Opening Meeting Checklist *(cont'd)*

- Confirm resources and facilities needed (guides, etc.)
- Confirm quality manual status (if applicable)
- Confidentiality
- Confirm time and date of closing meeting
- Confirm relevant safety, emergency and security procedures
- Appeals process (only for 3rd party audits)

FACILITY TOUR

Facility Tour

- Normally only conducted for 2nd or 3rd party audits:
  - A quick tour to familiarize the auditor with the layout and manufacturing processes of the organization
  - Do not let the tour drag on; take notes for reference
  - Stay with your guide and follow safety requirements
  - The tour is not an interviewing activity
  - Observe activities and the flow of materials
  - Start at receiving and walk the process through shipping

Visiting the Auditee's Location

- To minimize auditors interfering with the auditee's processes and to ensure the health and safety of the audit team during a visit, the following should be considered when planning a visit:
  - Ensure permission and access to those parts of the auditee's location, to be visited in accordance with the audit scope
  - Provide adequate information to auditors on security, health (e.g., quarantine, vaccinations), occupational health and safety, cultural norms and working hours
  - Confirm if any required personal protective equipment (PPE) will be available
  - Except for unscheduled ad-hoc audits, ensure personnel being visited will be informed about the audit objectives and scope
  - Confirm the use of any mobile devices and cameras including policy on the recording of information, e.g., photographs, screen shot copies or photocopies, taking into consideration security and confidentiality matters

Taking notes is a standard and expected practice in auditing, it is not necessary to obtain permission to take notes

Visiting the Auditee's Location

- To minimize auditors interfering with the auditee's processes and to ensure the health and safety of the audit team during a visit, the following should also be considered:
  - Avoid any unnecessary disturbance of the operational processes
  - Use of any PPE properly
  - Ensure emergency procedures are communicated
  - Schedule communication to minimize disruption
  - Use an appropriate size of the audit in order to avoid interference with the operational processes as far as practicable
  - Do not touch or manipulate any equipment, unless explicitly permitted
  - If an incident occurs during the on-site visit, the audit team leader should review the situation with the auditee and, if necessary, with the audit client and decide how to proceed, e.g., terminate, reschedule or continue
  - If taking copies of documents in any media, ask for permission in advance and consider confidentiality and security matters
  - Avoid collecting personal information unless required by the audit objectives or audit criteria

MEET WITH TOP MANAGEMENT

Top Management

- All audits should begin with a Top Management interview
  - Review the following:
    - Involvement in decision-making regarding the management system
    - Management Commitment and Accountability
    - Performance Measurements – Customer Focus
    - Policy, Goals and Objectives
    - Management Reviews
    - Identified Issues
    - Corrective Actions Taken – Status of Actions

Auditing Leadership and Commitment

- Many ISO standards have increased requirements for top management which include demonstrating commitment by taking accountability for the effectiveness of the management system and fulfilling a number of responsibilities, some of which cannot be delegated.
- Auditors should obtain objective evidence of the degree to which top management is involved in decision-making related to the management system and how they meet the specified requirements.
  - Examples include reviewing process results, policies, objectives, available resources, communications and by interviewing staff.
- Auditors should also interview top management to confirm they have an adequate understanding of the relevant issues and to ensure the management system achieves its intended results.
- Auditors should audit leadership and commitment at various levels of management, as appropriate.

Auditing Top Management
IAF Guidance

- It is important to change the focus of attention from just the quality manager to the top management of the organization.
- Top management activities are processes so audit them accordingly.
- When planning, identify top management processes, and
  - understand the organization and its management structure by reviewing information, e. g. org charts, annual reports, business plans, company profiles;
  - make time on the audit plan to interview top management;
  - understand the organization culture and adjust the audit plan accordingly;
  - maintain a professional appearance considering any dress code;
  - plan the timing of interviews to ensure convenience and punctuality.

- Assign an auditor with appropriate auditing and decision-making experience to interview top management.

Auditing Top Management
IAF Guidance

- When conducting the interview, ask relevant questions that:
  - obtains evidence of top management commitment to quality and its relevance to the organization's overall objectives and management system;
  - establish evidence of conformity to the specified requirements;
  - give special consideration to the allocation of the responsibilities and authorities for what was the “management representative” position.
- The audit team should confirm the answers received from top management including:
  - the availability and relevance of policies and objectives;
  - the establishment of linkage between the policies and objectives;
  - evidence these policies and objectives are effective and understood;
  - determining if the policies and objectives are appropriate for continual improvement of the management system and customer satisfaction;
  - confirming top management are involved in management reviews.
- Additional interviewing and gathering of evidence may be needed to provide the necessary corroboration.

GATHER OBJECTIVE EVIDENCE

Objective Evidence

- Three fundamental questions to be answered by the auditor in an audit:
  - Does the system meet the intent of the requirements?
  - Is the system effectively implemented?
  - Is the system effective in practice?

Auditing Organizational Processes

An auditor is expected to perform the following while conducting an audit of organizational processes:

- Demonstrate the use of the process approach audit
- Use the audit plan and the organization's defined processes, including sequence and interaction
- Focus on the performance of suspect processes including customer oriented processes
- Audit processes to determine if each is capable of meeting the key process indicators and customer-specific requirements
- Ensure that the customer-specific requirements are identified, addressed and maintained in the QMS
- Conduct interviews with those that are involved with the process at their location
- Document both conformities and nonconformities – the information should be clear enough for an independent review by a third party if necessary

Conducting a Process Approach Audit

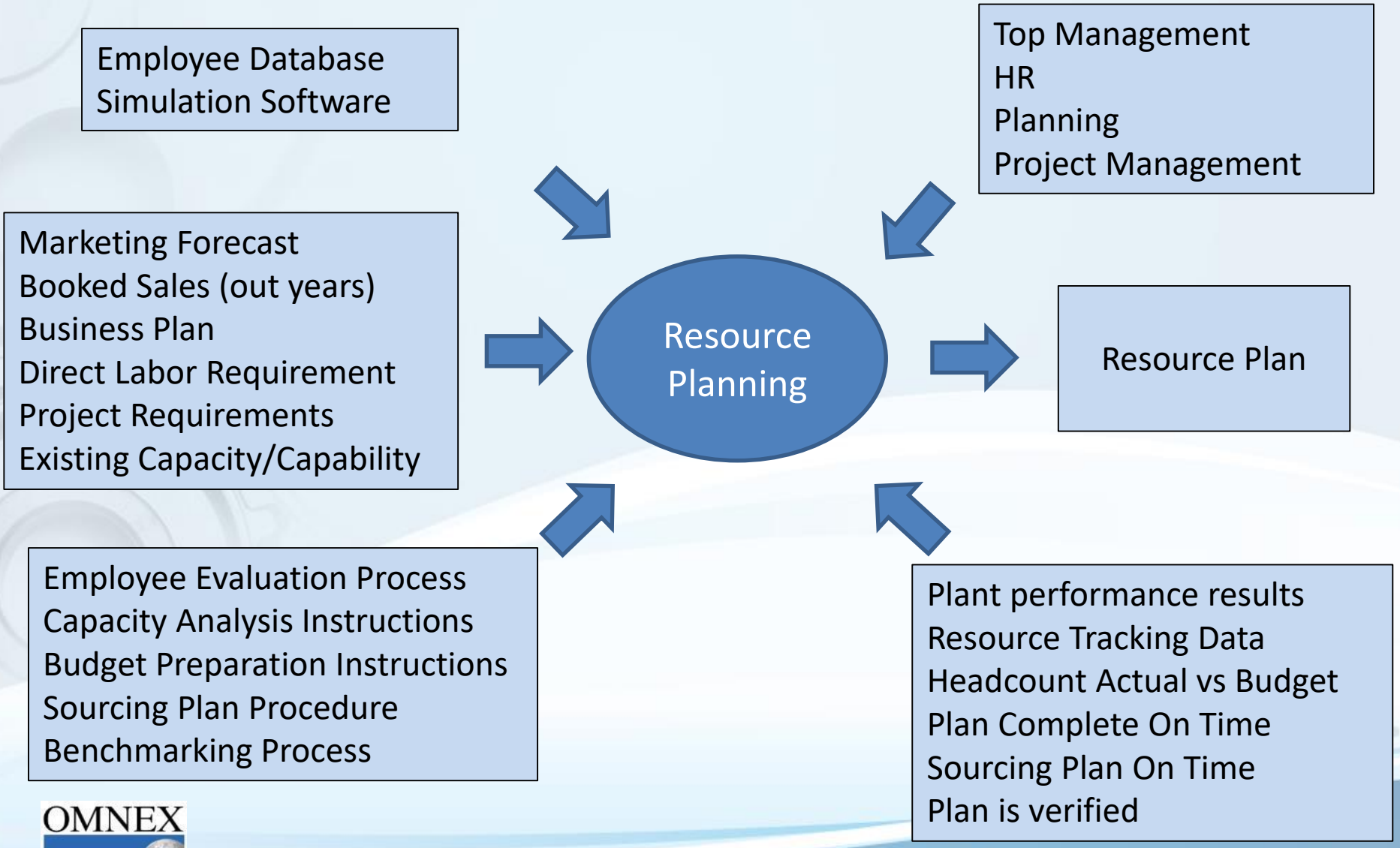
- The process approach audit is meant to **add value:**
  - It should start with a performance analysis of customer data that identifies areas of weakness or areas for improvement noted during the Stage 1 audit.
  - It should end with the identification of variations (**nonconformities**) in the process that, if eliminated, would lead to process improvement.

Conducting a Process Approach Audit

The following steps are used while conducting a process approach audit:

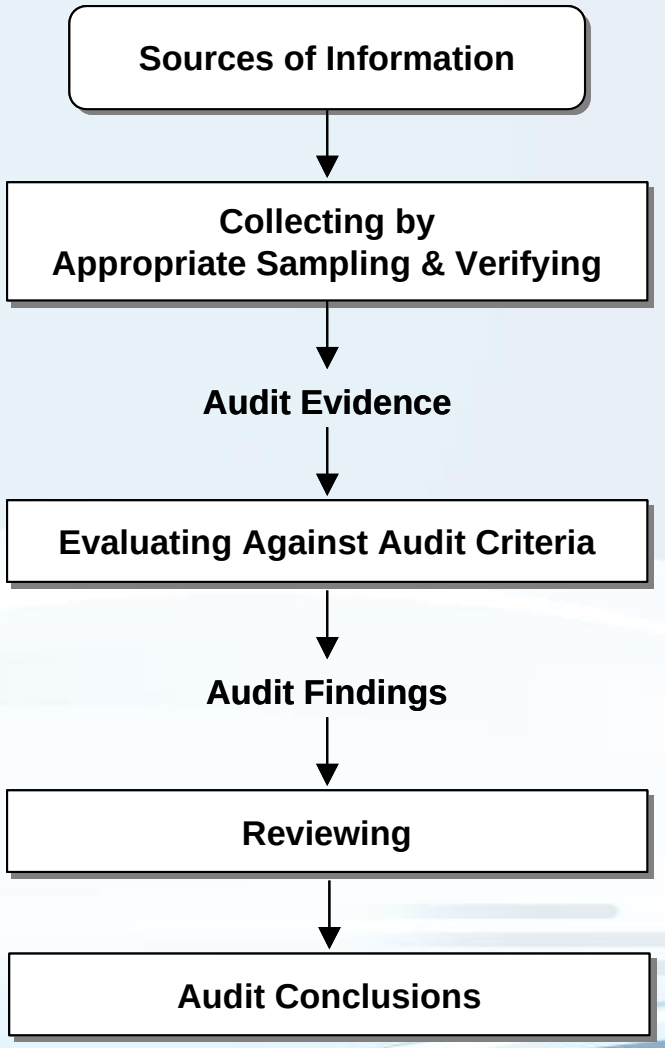
- Identify and probe process weakness:
  - Identify what is expected and the indicators and objectives of the actual performance.
  - How is the performance being improved?
  - How was the process planned?
- Follow the process using their documented flow or procedure:
  - Is the process being carried out as designed? Are the methods being applied?
  - Sample the process as applicable where the work is performed (e.g., engineering, shop floor, or workstation).
- Refer to process analysis (Turtle Diagram) as needed to identify sources of variation in support processes.

Turtle Example: Resource Planning



Collecting and Verifying Information

- During the audit, information relevant to the audit objectives, scope and criteria, and interfaces between functions, activities and processes should be collected by appropriate sampling and should be ***verified***.
  - Only information that is verifiable may be audit evidence.
  - Audit evidence should be recorded.
- The audit evidence is based on samples of the available information.



Guidance: What is Verification?

- As defined in ISO 9000, verification is confirmation through the provision of objective evidence that specified requirements have been fulfilled.
  - The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Objective Evidence

- Checked against:
  - What the management system standard requires
  - What the quality manual, procedures or working instructions state
  - What a department manager or authorized person states to be approved practice
  - Requirement of a contract, recognized standard, specification, statutory regulation, or code of practice
  - Any specified requirement

Objective Evidence

- Objective evidence can be:
  - Something you see/observe
  - Something you are told by a member of management is company policy or practice
  - Something you are told by an operator, describing their own understanding of operating procedures or work practices
- Objective evidence includes:
  - Identification of documents or products
  - Where the evidence was observed
  - Who was present during the observation

Objective Evidence

- Objective evidence examples:
  - Name and position of person interviewed
  - Statement made by person interviewed
  - Identity and revision status of documents
  - Identity and serial number of equipment or components
  - Range of samples examined
  - Location
  - Time and place of an event
  - Description of environmental conditions

Recording Evidence

- Record evidence of conformity or nonconformity
- Evaluate the document's record-pertinent data and return the document
- There is no need to copy every document
- Evidence can be hand-written and scanned electronically for records
- Objective evidence must demonstrate requirements are being met, such as, is it:
  - Complete, e.g., all expected content is provided
  - Correct, e.g., content aligns with reliable sources such as standards
  - Consistent within itself and with related documents
  - Current or up-to-date

Generating Audit Findings

- Audit evidence should be evaluated against audit criteria to generate the audit findings.
- The audit team should meet as necessary to review the audit findings.
- Conformity with audit criteria should be summarized to indicate locations, functions or processes that were audited.
- Individual audit findings of conformity and their supporting evidence should also be recorded.
- Nonconformities and their supporting evidence should be recorded.

CONDUCTING INTERVIEWS

Interviews

- Maintaining Control of an Audit:
  - Be aware (**BEWARE**) of time
  - Stick to the audit plan (don't allow diversions!)
  - Take a sample and find objective evidence for observations and then move on
  - Document objective evidence **BOTH** positive and negative

Interviews

- Interview individuals from appropriate levels and functions performing activities or tasks within the audit scope
- Interview during normal working hours and at the auditee's workplace
- Try to put the auditee at ease prior to and during the interview
- Explain the reason for the interview and any note taking
- Interviews may be initiated by asking individuals to describe their work
- Use a process approach, e.g., start with open questions probing each element of their process, use closed questions to finish, avoid leading questions as they bias the answer
- Focus in virtual auditing should be on the type of questions to use due to the limited non-verbal communication available
- Summarize the results from the interview and thank the auditee

Interviews

- **Do:**
  - Introduce yourself and others
  - Interview the person doing the job
  - Use your knowledge and experience
  - Make frequent reference to your checklist and audit plan
  - Make notes as you go; the more the better
  - Be calm, courteous and in firm control at all times
  - Seek facts, not inference
  - Select your samples carefully
  - Inform the auditee of a nonconformity finding promptly
  - Be fair and honest and if you are wrong, admit it

Interviews

- **Don't:**
  - Be late
  - Lecture or talk down to the auditee
  - Give recommendations
  - Criticize management
  - Make comparisons with other people or departments
  - Be longwinded—keep questions short and direct
  - Be afraid to say you don't understand—seek clarification
  - Nit pick

Questioning

- **Invitation to Talk**
  Open-ended question most often used to initiate the interview by asking the auditee to describe their work.
  - "Would you please explain to me what happens here?"
  - "What do you do if someone is absent?"

- **Direct Questions**
  Ask a direct question to have the auditee explain the process.
  - "What do you do next?"
  - "How are these reports distributed?"
  - "Who approves the issue of these licenses?"
  - "When (or how frequently) is this plan reviewed?"
  - "Where are these items stored when not in use?"
  - "Why is it done that way?"

Questioning

- **Closed Question**

  Solicits either a “yes” or “no” answer. Used only to confirm information.

  – *“You said that there were only two of you that do this job, is that correct?”*

- **Silent Question**

  The auditor simply asks a question and then waits; this can encourage an additional response.

- **Naïve Question**

  Often asked when the auditor already knows the answer in order to ensure the auditee understand the process. It is important to determine the knowledge of the person doing the job.

Questioning

- **Hypothetical Question**

  A “what-if” question used to identify what happens when the process doesn’t work.

- **Listening**
  - Ask the question
  - Stop talking
  - Listen to all of the answer
  - Seek clarification
  - Make notes
  - Ask another question

Questioning

- **Observing**

  Together with questioning and listening, observing provides the auditor with virtually all the tools necessary to carry out an effective audit.

- **Verifying**

  Before information becomes fact it must be verified as true:

  – Checking the records
  – Observing the activity being carried out

NEGATIVE REACTIONS TO AUDITS

Negative Reactions to Audit

- **Authority**

  The auditee becomes protective of their department.

- **Antagonism**

  Occasionally the auditee can become hostile and aggressive to auditors.

- **Diversionary Tactics**

  Anything which uses up time that was otherwise planned for auditing.

- **Internal Conflicts**

  Sometimes findings turned up in an audit instigate an argument between auditee members of staff.

- **Continual Challenge**

  The auditee has the right to challenge the auditor; however, if the auditor puts up a firm and factual case for the reached conclusion, then the auditee must accept them.

- **Enlisting Help**

  The auditee may purposely lead the auditors to deficient areas if they are having difficulty in getting management to react.

Preventing Negative Reactions

Avoiding difficult audits

- Don’t take it personally
- At the opening of the audit, try to establish a friendly cooperative environment – Don’t be overbearing
- Keep the auditee informed of how the audit is going – inform the auditee of nonconformities as they are identified
- Maintain control without taking control
- Make sure that the nonconformities you write are value added
- Don’t nit pick
- Use proper format for writing nonconformities

Breakout Exercise 4

Conducting the Audit

Chapter 8: Performing the Audit — What We Covered

Learning Objectives

You should now be able to:

- List items that should be included in an opening meeting
- Describe the purpose of meeting with Top Management
- Explain methods to gather evidence
- Describe the things to do and not do for interviews
- Describe how to prevent negative reactions to audits

Chapter Agenda

- Opening Meeting
- Facility Tour
- Meet with Top Management
- Gather Evidence
- Conducting Interviews
- Negative Reactions to Audits
- **Breakout Exercise 4**

Chapter 9

Writing Nonconformity Statements

Chapter 9: Writing Nonconformity Statements — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- State the flow of activities to reach audit conclusions
- Identify the three parts of a nonconformity statement
- State the difference between major and minor nonconformities

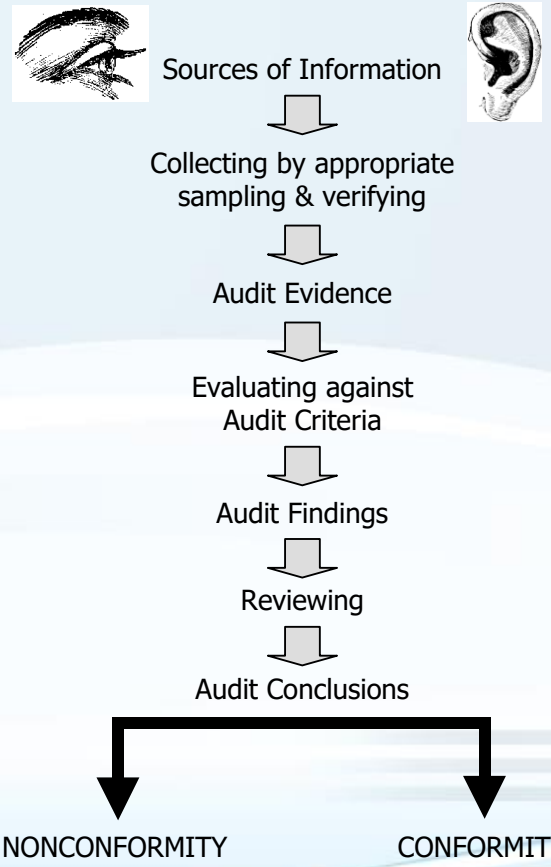
Chapter Agenda

- Audit Findings
- Nonconformity Statements
- Types of Nonconformities
- Review Findings and Conclusions
- **Breakout Exercise 5**

Audit Findings

ISO 19011 defines nonconformity as "non-fulfillment of a requirement"

- Audit findings are the results of an evaluation of the collected **audit evidence** against **audit criteria.**
- Audit findings can indicate either conformity or nonconformity with audit criteria, or opportunities for improvement.



Generating Audit Findings — Nonconformities

- Nonconformities and their supporting audit evidence, including references to audit criteria, related findings, and a formal declaration of nonconformity should be recorded.
  - Nonconformities may be graded.
  - They should be reviewed with the auditee to obtain acknowledgement that the audit evidence is accurate, and that the nonconformities are understood.
  - Every attempt should be made to resolve any diverging opinions concerning the audit evidence and/or findings, and unresolved points should be recorded.
  - Audit findings can indicate either conformity or nonconformity with audit criteria.
  - When specified by the audit objectives, audit findings can identify an opportunity for improvement.

NONCONFORMITY STATEMENTS

What are Nonconformity Statements?

A nonconformity statement is…

- A record of the evidence on which an auditor bases the conclusions of the audit, so that there is nothing in the conclusions that cannot be substantiated by reading the nonconformity statements.
- Information to both the auditor's own management and the auditee's management concerning the ways in which the company's management system fails to meet requirements.
- A starting point for corrective action by the auditee to resolve the nonconformity.

Reasons for a Nonconformity

- When evaluating any clauses of the standard, you must evaluate all three situations:
  - Intent
  - Effective implementation
  - Effectiveness in practice
- If a breakdown exists in any one of these situations:
  - A nonconformity exists
  - A nonconformity statement must be written

Reasons for a Nonconformity

- **Intent**

  The organization is conforming to a standard practice

- **Effective Implementation**

  The functions are being performed to:

  - Standard practice
  - All employees involved understand the standard practice
  - All employees involved are adhering to the standard practice
  - No deviations from standard practice

- **Effectiveness in Practice**

  Results are consistent with what is expected from the intent and implementation stages:

  - Are results showing improvement?
  - Are changes made if system is not producing desired results?

Nonconformity Statements

It is much better to:

- Verbally communicate the nature of the nonconformity and the evidence for it to the process owner as soon as it is established, and get verbal agreement that the facts are correct and that the observation is accepted.
- Ensure that your notes are adequate before proceeding with the investigation.
- At the end of that part of the audit plan, review the notes and write up all nonconformity statements.
- Review all nonconformities with your audit team and lead auditor prior to writing or reviewing them with the auditee.
- Review observations with the process owner.
- Do not leave the writing of nonconformity statements until the end of the audit since you will then have to write the statements resulting from the final audit session.

Writing Nonconformity Statements

- The nonconformity statement is a criticism of the auditee's management system.
  - No one likes being criticized, so an auditor must expect to be challenged if there are any errors in the nonconformity statement – Facts can be very hard to establish.
- In order to follow a best practices approach, nonconformity statements should be based upon issues related to the system, not the symptom.
  - Major and minor nonconformities must be categorized.

Writing Nonconformity Statements

- First, review all the notes that have been taken then try to express the nonconformity in the following terms:
  - A statement of nonconformity (system level)
  - Reference to the requirement not being met
  - Objective evidence (documents, product, contracts, etc.)
- The purpose of the nonconformity statement is to describe the breakdown of the system and should not be confused with the incident-specific objective evidence.
- It is important to write nonconformities that define the system problem; otherwise, the organization may only address the specific incident instead of the system that is causing the nonconformity.
  - If the statement of nonconformity is expressed in terms of a person or incident, it is objective evidence.

Checking Nonconformity Statements

- **Correct and Complete**

  The nonconformity statement will not be correct and understandable if it omits important evidence or information regarding the nature of the requirement and the way it is being contravened.

- **Clear**

  It is no good stating all the evidence and information if it is not written in a way that can be understood. Always check very carefully what you have actually written, not what you think you have written.

- **Concise**

  Using unnecessary words in your nonconformity statement makes it unclear.

Writing Nonconformity Statements

Example

- **Nonconformity:** Competency requirements are not fully defined.
- **Requirement:** ISO/IEC 17025:2017 6.2.2 requires that "*the laboratory shall document the competence requirements for each function influencing the results of laboratory activities including requirements for education, qualification, training, technical knowledge, skills and experience.*"
- **Objective Evidence:** Education and training requirements could not be provided for all personnel in the testing lab.

Corrective Action Request

F17-3
Revision B

Part A	Audit Information		
Department/Auditee	Human Resources	Audit Number	101
Activity Audited	Training	Car Number	DAD-05
Auditor	Bob Roberts	Date Issued	3/15/xx
Auditee		Reference	17025: 6.2.2

Part B — Nonconformity

Nonconformity:
Competency requirements are not fully defined.

Requirement:
ISO/IEC 17025:2017 6.2.2 requires that "*the laboratory shall document the competence requirements for each function influencing the results of laboratory activities including requirements for education, qualification, training, technical knowledge, skills and experience*"

Objective Evidence:
Education and training requirements could not be provided for all personnel in the testing lab.

Auditor	Date	Department Representative	Date

Part C — Corrective/Preventive Action

Immediate Action

Preventive Action

Root Cause

Corrective Action

Auditor	Date	Department Representative	Date

Part D — Verification of Corrective Action

Follow-up Details

TYPES OF NONCONFORMITIES

Types of Nonconformities

Major Nonconformity

- Nonconformity that affects the capability of the management system to achieve the intended results.
- NOTE: Nonconformities could be classified as a major in the following circumstances:
  - If there is a significant doubt that the effective process control is in place, or that products or services will meet specified requirements;
  - A number of minor nonconformities associated with the same requirements or issue could demonstrate a systemic failure and thus constitute a major nonconformity.

Minor Nonconformity

- Nonconformity that does not affect the capability of the management system to achieve the intended results.

These definitions are taken from ISO 17021:2015

REVIEW FINDINGS AND CONCLUSIONS

Reviewing Findings

- Time should be allowed within the audit program to review findings.

- It is good practice to do this at the end of each day while the information is fresh in the mind of the auditors; it also enables the auditor to:
  - Confirm that all audit objectives have been met
  - Detect any errors, omissions, or misunderstandings and, if time permits, resolve them
  - Avoid having to sift through large amounts of recorded information at a time

Preparing Audit Conclusions

- The audit team should confer prior to the closing meeting to:
  - Review the audit findings – and any other appropriate information collected during the audit – against the audit objectives
  - Agree on the audit conclusions, taking into account the uncertainty inherent in the audit process
  - Prepare opportunities for improvement, if specified by the audit objectives
  - Discuss audit follow-up, if included in the audit plan

Breakout Exercise 5

Writing Nonconformity Statements

Chapter 9: Writing Nonconformity Statements — What We Covered

Learning Objectives

You should now be able to:

- State the flow of activities to reach audit conclusions
- Identify the three parts of a nonconformity statement
- State the difference between major and minor nonconformities

Chapter Agenda

- Audit Findings
- Nonconformity Statements
- Types of Nonconformities
- Review Findings and Conclusions
- **Breakout Exercise 5**

Chapter 10

Closing Meeting

Chapter 10: Closing Meeting — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Describe the purpose of a closing meeting
- List the elements covered in a closing meeting
- Explain how to prevent a problematic closing meeting
- Write a summary statement
- Explain concerns about giving recommendations

Chapter Agenda

- Closing Meeting
- Summary Statement
- Recommendations

Closing Meeting Purpose

- A closing meeting, chaired by the audit team leader, should be held to present the audit findings and to agree on the timeframe to present a corrective and preventive action plan.
- Any diverging opinions regarding the audit findings and/or conclusions between the audit team and the auditee should be discussed and, if possible, resolved.
- If specified by the audit objectives, opportunities for improvements may be presented, but it must be emphasized that these recommendations are non-binding.

Closing Meeting Checklist

- Attendance list and statement of thanks
- Summary Scope, objectives and criteria
- Significance of audit sample and possibility that it may not be fully representative of overall process effectiveness
- Audit summary (see next slide for more detail)
  - Nonconformity statements and opportunities for improvement, if applicable
  - Clarification of nonconformity statements and summary
- How audit findings should be addressed and possible consequences for not addressing them
- Confidentiality
- Follow-up activities
- Appeals process (only for 3rd party audits)
- Close

Summary Statement

- Lead auditor provides a verbal summary at the closing meeting:
  - Positive statements about the organization audited
  - Systems working particularly well
  - Summary of nonconformities
  - Systems not working well
  - Positive statement to offer encouragement

Giving Recommendations

- Do you know all the facts?
- You may be undermining managers' responsibilities and authority
- Who will carry the costs?
- What if the advice is wrong?

3rd party auditors cannot provide recommendations

Problematic Closing Meeting

- **Senior management is not present at the Closing Meeting**
  - Senior Management should be at the closing meeting.
  - If they are not there, the team leader can ask whether someone senior is available, but cannot demand it.
  - For internal audits, the manager or supervisor of the area audited (the process owner) should be at the closing meeting.

Problematic Closing Meeting

- **Corrective action taken or additional evidence presented at the closing meeting**
  - Additional evidence cannot be presented at the closing meeting.
    - If evidence was not provided during the audit then there is another problem with the control of documented information (e.g., **8.2.5 —** *All personnel involved in laboratory activities shall have access to the management system documentation and related information that are applicable to their responsibilities*).
  - Corrective action cannot be submitted during the closing meeting.
    - Corrective action must be planned, implemented, verified and validated prior to acceptance. While it is feasible that corrective action could be planned and implemented during the audit, it is highly unlikely that corrective action could be verified as effective and validated during the audit.
  - At this point, a nonconformity stays a nonconformity.

Chapter 10: Closing Meeting — What We Covered

Learning Objectives

You should now be able to:

- Describe the purpose of a closing meeting
- List the elements covered in a closing meeting
- Explain how to prevent a problematic closing meeting
- Write a summary statement
- Explain concerns about giving recommendations

Chapter Agenda

- Closing Meeting
- Summary Statement
- Recommendations

Chapter 11

Completing the Audit Report

Chapter 11: Completing the Audit Report — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- List the items contained in the audit report
- Describe confidentiality of the audit report
- List the items in an overall set of audit records

Chapter Agenda

- Preparing the Audit Report
- Completing the Audit Report
- Audit Records

The Audit Report

- The audit team leader prepares the audit report
- The audit report provides a complete, accurate, and concise record of the audit, and should include:
  - The audit objectives
  - The audit scope
  - Identification of the audit client
  - Identification of audit team and auditee's participants
  - The dates and places where the audit activities were conducted
  - The audit criteria
  - The audit findings and related evidence
  - The audit conclusions
  - Statement regarding the degree to which audit criteria have been fulfilled
  - Any unresolved diverging opinions between the audit team and auditee
  - Statement indicating that the audit is a sampling exercise and there is risk that the observed audit evidence is not representative

The Audit Report

- The audit report may also include the following:
  - The audit plan
  - A summary of the audit process, including obstacles that may decrease reliability of the audit conclusions
  - Confirmation that the audit objectives have been accomplished within the audit scope
  - Any areas not covered, although within the audit scope
  - Summary of the audit conclusions and the findings that support them
  - Good practices identified
  - Agreed follow-up action plans
  - A statement of the confidential nature of the contents
  - Any implications for the audit program or subsequent audits

Completing the Audit

Distributing the Audit Report

- The audit report should be…
  - Dated, reviewed and accepted
  - Issued within the agreed time period
  - Distributed to designated recipients
- The audit report is the property of the audit client and confidentiality must be respected.

Completing the Audit

- The audit is completed when…
  - All activities described in the audit plan have been carried out, and
  - The approved audit report has been distributed
- Documents pertaining to the audit should be retained or destroyed by agreement between the participating parties.

Audit Program Records

- Records should be maintained to demonstrate the implementation of the audit program and should include the following:
  - Audit plans
  - Audit reports
  - Nonconformity reports
  - Corrective and preventive action reports
  - Audit follow-up reports
  - Results of audit program review
  - Records related to audit personnel
  - Audit team selection
  - Maintenance and improvement of competence
- Records should be retained and suitably safeguarded

Chapter 11: Completing the Audit Report — What We Covered

Learning Objectives

You should now be able to:

- List the items contained in the audit report
- Describe confidentiality of the audit report
- List the items in an overall set of audit records

Chapter Agenda

- Preparing the Audit Report
- Completing the Audit Report
- Audit Records

Chapter 12: Corrective Action and Close-Out — What We Will Cover

Learning Objectives

At the end of this chapter, you will be able to:

- Describe the purpose of corrective actions for audit findings
- List auditor's responsibilities for closeout

Chapter Agenda

- Corrective Actions
- Auditor Responsibilities
- Close-out – Recommended Method
- **Management Systems Auditing Exam**

Corrective Action

Following most audits, the auditee will be requested to take action to resolve nonconformities.

- In third party situations…
  - verification is necessary before a registration certificate is issued.
- In second party audits…
  - the auditing organization should follow-up.
- For supplier selection audits (also 2nd Party)…
  - the auditing organization would be most unlikely to follow-up on an audit where the results were unsatisfactory.

Corrective Action Components

- The process owner is responsible for:
  - Determining the extent of the problem
  - A corrective action plan
  - Forming a team
  - Implementing and verifying interim actions
  - Finding and verifying root causes
  - Selecting permanent corrective action
  - Implementing permanent corrective action
  - Verification and validation of corrective action
  - Preventing system problems (other similar processes)

Corrective Action — Root Causes

- Corrective Action should address three root causes:
  - **Occurrence Root Cause**
    - What occurred in the process that resulted in a nonconformity?
  - **Escape Root Cause**
    - Why did the controls fail to find the nonconformity?
  - **Systemic Root Cause**
    - Why did the system or planning process fail to identify a concern?

Auditor Responsibility for Close-Out

- The auditor is responsible for:
  - Verifying that corrective action has been taken
  - Verifying that corrective action is effective
  - Closing out the nonconformity

For a minor nonconformity, this is typically handled by reviewing a corrective action report and verifying those actions during the next audit.

For a major nonconformity, this is typically handled by conducting a special audit that is scheduled to confirm effective closure of the major nonconformance.

Conducting Close-Out

This seven step process is recommended to conduct an effective close-out:

1. Has the organization expressed the problem as a system issue?

2. Has the organization taken containment actions on the specific incidents cited by the audit team in their objective evidence?
   - If external customers could be impacted, then containment actions need to be taken.

3. Has the organization found the root cause(s) of the problem in their system that allowed the incidents cited by the audit team to occur?
   - Does the organization answer the question: **What in our system failed that allowed this to happen?**

Conducting Close-Out

4. Does the corrective action determined by the organization:
   - Address changes to the system, not specific employees or machines?
   - Address the root cause(s) they have identified?

5. Has the organization reviewed its associated FMEAs (design and/or process) based upon the nonconformities?
   - Do the occurrence or detection ratings need to change?
   - Is the FMEA treated as a living document?

6. Has the organization reviewed its associated control plans, work instructions and inspection instructions, etc.?
   - Are the plant floor instructions and the control plan treated as a living document?

7. Has the audit team verified that corrective action is implemented?

Chapter 12: Corrective Action and Close-Out — What We Covered

Learning Objectives

You should now be able to:

- Describe the purpose of corrective actions for audit findings
- List auditor's responsibilities for closeout

Chapter Agenda

- Corrective Actions
- Auditor Responsibilities
- Close-out – Recommended Method
- **Management Systems Auditing Exam**

Management Systems Auditing Exam

Work Independently

Thank You!

Questions?

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