L3 Standards in Quality Management

IAEA
International Atomic Energy Agency

Objectives
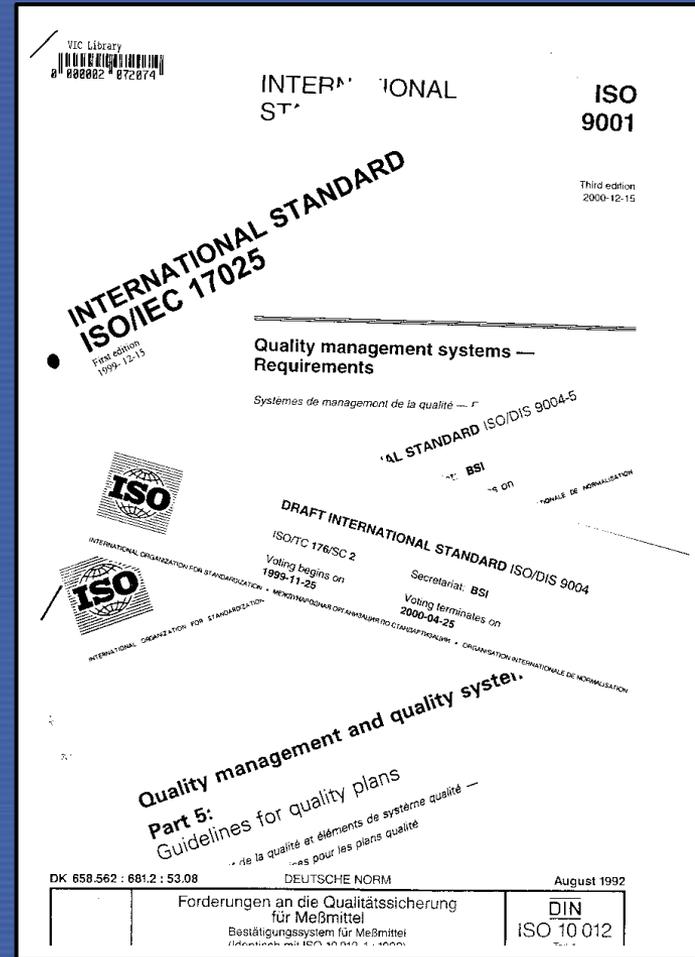
- In this lecture we will discuss different international standards relevant to

  ➢ quality management systems,

  ➢ accreditation,

  ➢ auditing and

  ➢ measurement devices.

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Scope

- This presentation only applies to:

  international standards,

  although many of these standards have also been transformed into national standards.

ISO?

Purpose: make trade easier in terms of quality, safety, heath, environment and consumer protection

ISO: provides for an international acceptance and recognition based upon reliability and good practices

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Testing laboratory standard ISO/IEC 17025:2017

- The standard has been developed with the objective of promoting confidence in the operation of laboratories. It contains requirements for laboratories to enable them to demonstrate they operate competently, and are able to generate valid results. Laboratories that conform to ISO/IEC 17025 will also operate generally in accordance with the principles of ISO 9001.

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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Testing laboratory standard ISO/IEC 17025:2017

- ISO/IEC 17025 requires the laboratory to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system, achieving improved results and preventing negative effects. The laboratory is responsible for deciding which risks and opportunities need to be addressed.

INTERNATIONAL STANDARD

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Testing laboratory standard ISO/IEC 17025:2017

- ISO/IEC 17025 specifies the general requirements for the competence, impartiality and consistent operation of laboratories.

- It is 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 in confirming or recognizing the competence of laboratories.

INTERNATIONAL STANDARD

ISO/IEC 17025

Third edition 2017-11

General requirements for the competence of testing and calibration laboratories

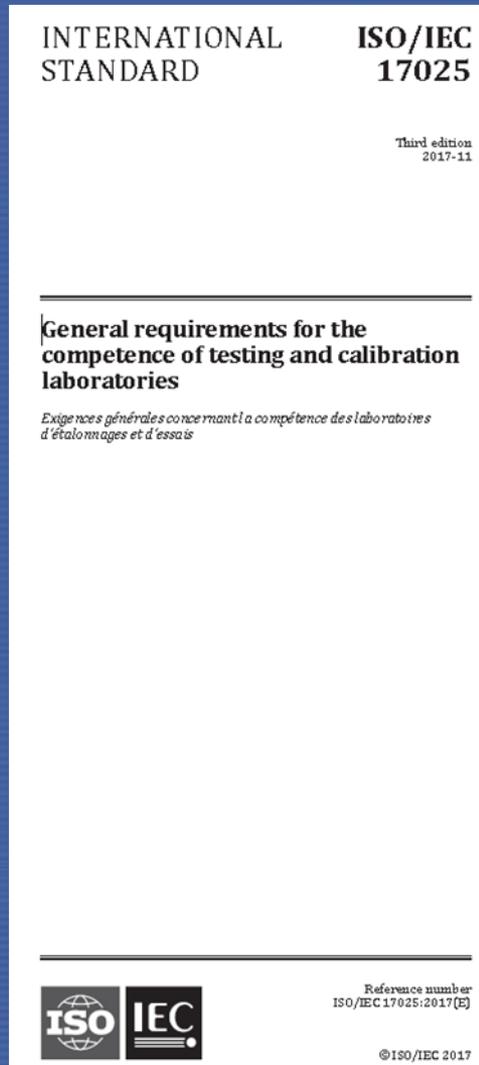Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

Reference number ISO/IEC 17025:2017(E)

©ISO/IEC 2017

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Structure ISO/IEC 17025:2017 (for details see specific lectures)

- 1. Scope
- 2. Normative references
- 3. Terms and definitions
- 4. General requirements
- 5. Structural requirements
- 6. Resource requirements
- 7. Process requirements
- 8. Management requirements
- Annex A Metrological traceability
- Annex B Management system

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ISO/IEC 17025

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ISO 17025 MAIN SECTIONS

| Section 4: General Requirements	Section 5: Structural Requirements	Section 6: Resource Requirements	Section 7: Process Requirements	Section 8: Management Systems Requirements

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Quality Management System Standards

- ISO 9000 is a series of quality management standards e.g ISO 9001 is a standard within the family. The ISO 9000 family contains several standards:
  - ISO 9001:2015 Quality Management Systems - Requirements
  - ISO 9000:2015 Quality Management Systems - Fundamentals and Vocabulary (definitions)
  - ISO 9004:2018 Quality Management - Quality of an Organization - Guidance to Achieve Sustained Success (continuous improvement)
  - ISO 10012:2003 Measurement management systems - Requirements for measurement processes and measuring equipment
  - ISO 19011:2018 Guidelines for Auditing Management Systems

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The process approach in ISO 9001

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ISO 9001

Fifth edition
2015-09-15

Quality management systems — Requirements

*Systèmes de management de la qualité — Exigences*

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.
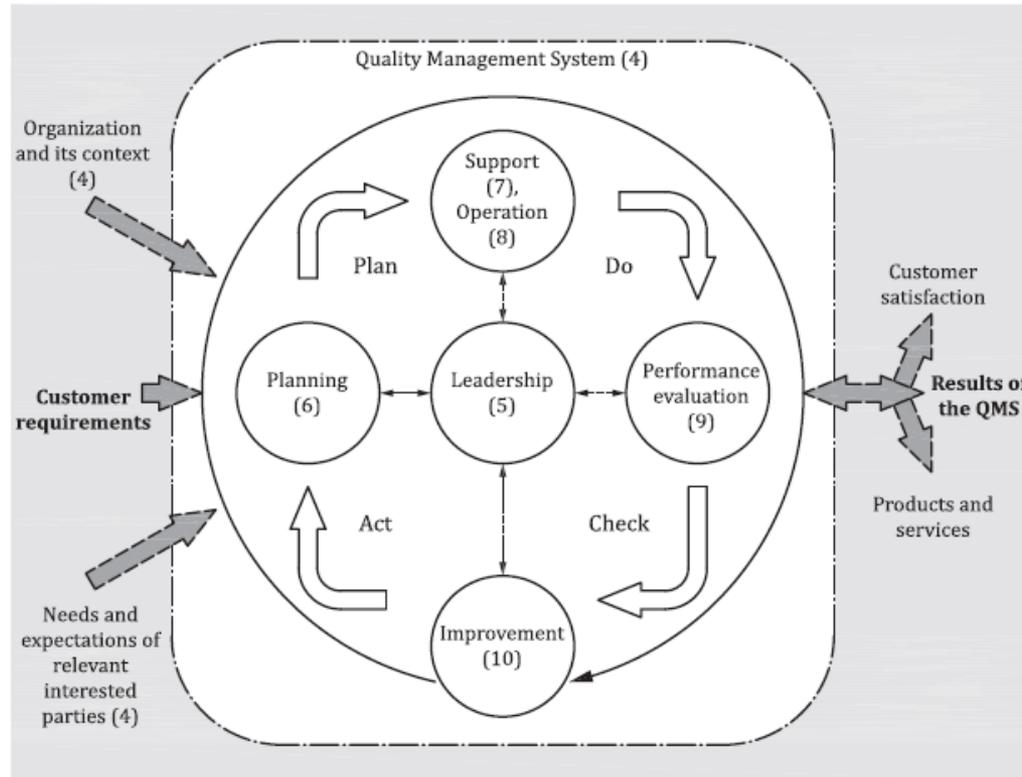
NOTE   Numbers in brackets refer to the clauses in this International Standard.

Reference number
ISO 9001:2015(E)

© ISO 2015

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Common structure for MSs

- Introduction
- 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.

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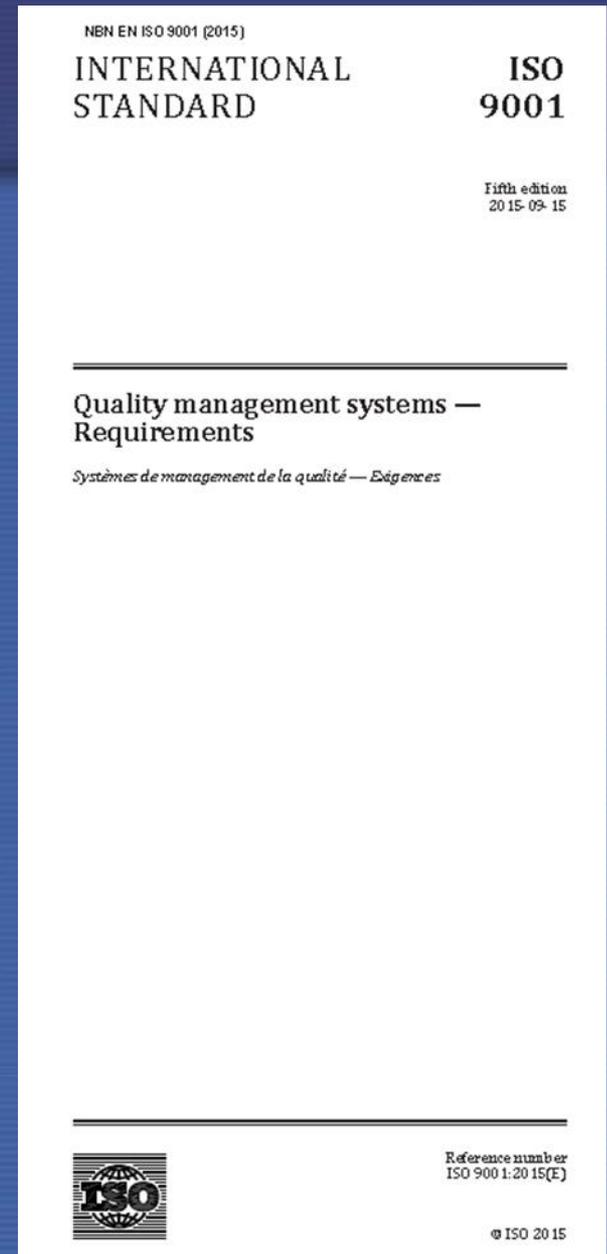
ISO 9001:2015 Contents

- 1. Scope
- 2. Normative references
- 3. Terms and definitions
- 4.   Context of the organization
  - Understanding the organization and its context
  - Understanding the needs and expectations of interested parties
  - Determining the scope Of QMS
  - Quality management system and its processes
- 5.   Leadership
  - Leadership and commitment
  - Quality Policy
  - Organizational roles, responsibilities and authorities
- 6.   Planning
      - Actions to address risks and opportunities
  - Quality objectives and planning to achieve them
  - Planning of changes

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ISO 9001:2015 Contents

7. Support
  - Resources   - Organizational knowledge
  - Competence
  - Awareness
  - Communication
  - Documented information

8. Operation
  - Operational planning and control
  - Requirements for products and services
  - Design and development of products and services
  - Control of externally provided processes, products and services
  - Production and service provision - Post Delivery, Control of change
  - Release of products and services
  - Control of nonconforming outputs

9. Performance evaluation
  - Monitoring, measurement, analysis and evaluation
 - Internal audit
  - Management review

10. Improvement
  - General
  - Nonconformity and corrective action
  - Continual improvement

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ISO 10012:2003

- ISO 10012:2003 specifies generic requirements and provides guidance for the management of measurement processes and metrological confirmation of measuring equipment used to support and demonstrate compliance with metrological requirements. It specifies quality management requirements of a measurement management system that can be used by an organization performing measurements as part of the overall management system, and to ensure metrological requirements are met.

Figure 1 — Model of measurement management system
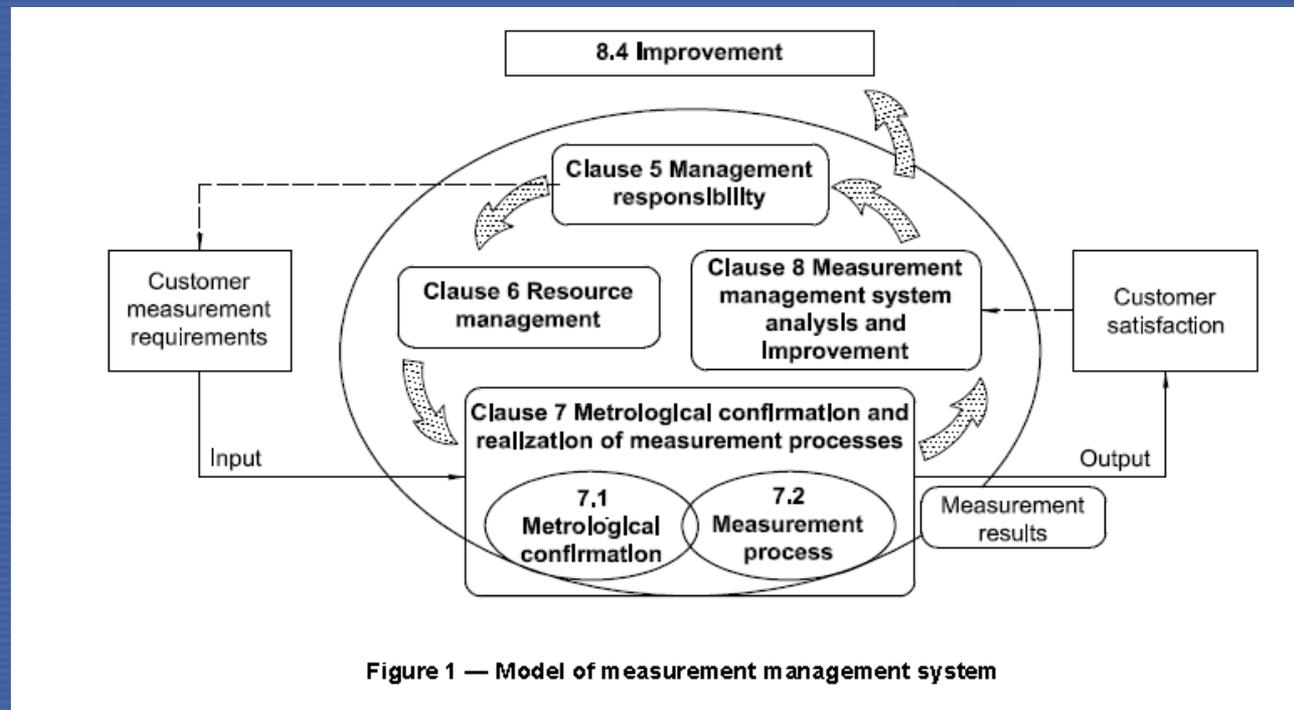
ISO 19011:2018

- This standard presents guidance for auditing quality management systems:

Figure 1: Process flow for the management of an audit programme

PLAN	DO	CHECK	ACT

5.2 Establishing audit programme objectives

5.3 Determining and evaluating audit programme risks and opportunities

5.4 Establishing audit programme

5.5 Implementing audit programme

5.6 Monitoring audit programme

5.7 Reviewing and improving audit programme

Clause 5

Clause 6

6.2 Initiating audit

6.3 Preparing audit activities

6.4 Conducting audit activities

6.5 Preparing and distributing audit report

6.6 Completing audit

6.7 Conducting audit follow-up

PLAN	DO	CHECK	ACT

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ISO 19011:2018   contents

1   Scope

2   Normative references

3   Terms and definitions

4   Principles of auditing

5   Managing an audit programme

6   Conducting an audit

7   Competence and evaluation of auditors

INTERNATIONAL STANDARD

ISO 19011

Third edition
2018-07

Guidelines for auditing management systems

Lignes directrices pour l'audit des systèmes de management

Reference number
ISO 19011:2018(E)

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