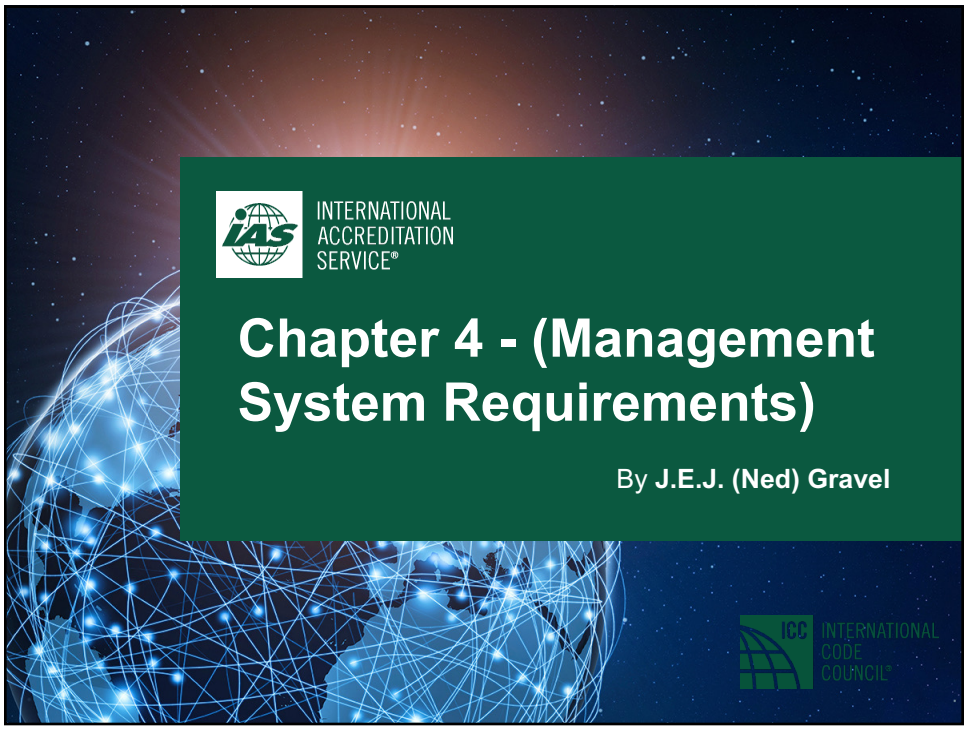


1

Course Outline

- Introduction – Welcome and objectives
- Chapter 1 – Background and principles
- Chapter 2 – Basic technical requirements
- Chapter 3 – Technical measurement requirements

- -

- Chapter 4 – Management system requirements
- Chapter 5 – Continual improvement requirements
- Chapter 6 – Monitoring and measuring the quality system

2

Management System Outline

- Overview of Basic Concepts (Clauses 5 and 8.1)
- Impartiality and Confidentiality (Clause 4)
- Documentation (Clauses 8.2 and 8.3)
- Records (Clauses 7.5 and 8.4)
- Use of IT within the QMS (Clause 7.11)
- Complaints (Clause 7.9)

4

Definitions

- Management System

  Set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives so as to direct and control an organization.

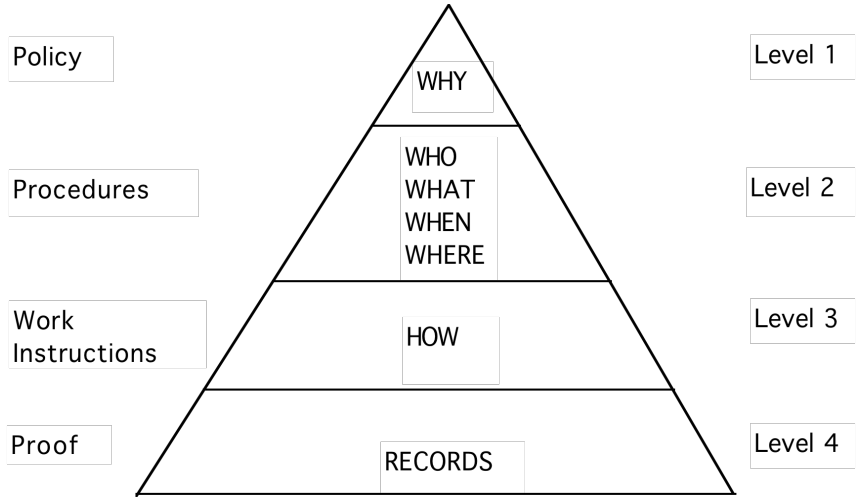
- Management System Documentation

  Documentation, in whatever form the organisation deems appropriate, specifying its management system.

  Note that a quality manual is not required by ISO/IEC 17025:2017!

5

What it Might Look Like



6

Creating the System

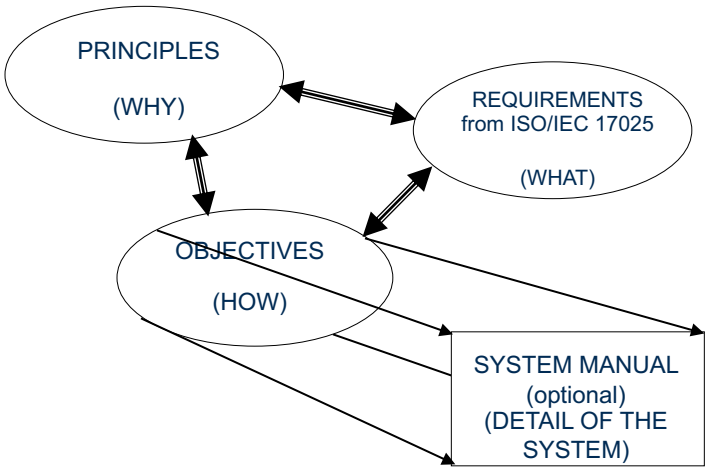
By Requirement
Clause-by-clause formulation directly from the standard. This does not work so well for the lab staff but assessors love it – **Not the best choice.**

By Principle
Ordered/arranged/grouped by the set of principles underlying the standard – **Not really possible.**

By Objective
Objective-oriented formulation based on what the laboratory wishes to accomplish in each area and how it is going to do so.– **Best choice for the lab.**

7

Creating the System



8

Policy and Objectives

1. Implement and maintain a quality system that is documented and incorporates adequate review, audit and internal quality control. Use the system to deliver continual improvement and support impartiality and transparency.

2. Adequately train, supervise and demonstrate continuing proficiency of the persons within the laboratory to carry out assigned activities. Establish goals for this objective and track their attainment.

3. Select and validate/verify appropriate test and calibration methods (and related work instructions) and incorporate adequate quality control of the methods.

9

Policy and Objectives

4. Acquire and make use of facilities, equipment, supplies and services that are appropriate to the work. Ensure they are functioning properly and meet or exceed required specifications.

5. Produce only traceable results, supported by a system of measurement traceable to the SI, through a National Metrology Institute (NMI), and accorded uncertainties appropriate to requirements.

10

Policy and Objectives

6 Handle all samples, from reception to disposal, with adequate security, protection of integrity, and defined processes for their receipt, identification, checking, routing, storage and disposal.

7 Develop and maintain adequate data management procedures that incorporate appropriate security, recording, calculation, validation, authorisation, transmittal, storage and disposal of all test data and related records.

11

Policy and Objectives

8 Manage the workload of the laboratory so as to maintain the ability to produce valid and competent results.

12

Advantages of Objectives

- One objective for each part of the System. One objective for each Chapter of the system documentation.
- Each objective already in line with ISO/IEC 17025
- Identification/allocation of the resources needed in the same Chapter as the objective.
- Identification of the processes/procedures in the same Chapter as the objective
- Management system is one complete and congruent whole
- Clean structure for internal audit and management review.

13

Relating Objectives to Principles

The Principles behind ISO/IEC 17025 do not relate to all Objectives that could be used to develop a laboratory management system. Refer to Section 1.5.2 of the Course Handbook for a short synopsis of how they relate.

14

Relating Objectives to Requirements

OBJECTIVES	ISO/IEC 17025 Requirements
• Quality system and Impartiality	• 4, 5, 7.1, 7.5, 7.7, 7.9-11, 8
• Personnel	• 6.2
• Methods	• 7.2
• Traceability	• 6.5, 7.6, Annex A
• Facilities Equipment, Services and Supplies	• 6.3-4, 6.6
• Sample Management	• 7.3-4
• Data Management	• 7.8
• Workload Management	• 8.9.2 l)

15

17025 Management System Issues

1. There are 16 questions in this Chapter.
2. What does the standard require?
3. Participants select their own answers.
4. The whole group is balloted for the most appropriate response.
5. Clapping indicates a correctly answered question. Buzzer indicates an incorrectly answered question.
6. The citation from the standard is displayed next to the most correct answer.
7. The quiz then advances to the next question.

Press Continue

16

17025 Management System Issues

5 Structural requirements:

Labs **MUST** be legal entities.

A. TRUE
B. FALSE
C. NOT APPLICABLE

17

17025 Management System Issues

5 Structural requirements:

The laboratory **is not allowed** to identify and appoint a person to have overall responsibility of the laboratory.

A. TRUE
B. FALSE
C. NOT APPLICABLE

19

17025 Management System Issues

5 Structural requirements:

Labs **MUST** follow the rules of their accreditation body.

A. TRUE
B. FALSE
C. NOT APPLICABLE

21

17025 Management System Issues

5 Structural requirements:

Labs **DO NOT NEED** to allocate any resources to prevent non-conformances.

A. TRUE
B. FALSE
C. NOT APPLICABLE

23

17025 Management System Issues

8 Management system requirements:

Labs can build their Management System using ISO 9001.

A. TRUE
B. FALSE
C. NOT APPLICABLE

25

17025 Management System Issues

8 Management system requirements:

A Management System built against ISO 9001 **AUTOMATICALLY** meets **ALL** the requirements of 17025.

A. TRUE
B. FALSE
C. NOT APPLICABLE

27

17025 Management System Issues

4.1 Impartiality:

Labs **MUST** continually identify risks to impartiality. This includes those risks that arise from its relationships, or from the relationships of its personnel.

A. TRUE
B. FALSE
C. NOT APPLICABLE

29

17025 Management System Issues

4.1 Impartiality:

Once a risk to impartiality is identified, the laboratory **SHALL** mitigate it.

A. TRUE
B. FALSE
C. NOT APPLICABLE

31

17025 Management System Issues

4.2 Confidentiality:

Laboratories **must always** release confidential information to any lawyer when asked to do so.

A. TRUE
B. FALSE
C. NOT APPLICABLE

33

17025 Management System Issues

4.2 Confidentiality:

The laboratory **SHALL** release the name of **ANY** complainant to the client, against whom the complaint was raised.

A. TRUE
B. FALSE
C. NOT APPLICABLE

35

17025 Management System Issues

8.2 Management system documentation:

The laboratory **SHALL** document its policies and objectives.

A. TRUE
B. FALSE
C. NOT APPLICABLE

37

17025 Management System Issues

8.3 Control of management system documents:

The laboratory **MUST** control external documents related to their operations or referred to in their Management System.

A. TRUE
B. FALSE
C. NOT APPLICABLE

39

17025 Management System Issues

7.5 Technical records

Laboratory records **DO NOT** need to contain sufficient information to reproduce results.

A. TRUE
B. FALSE
C. NOT APPLICABLE

41

17025 Management System Issues

8.4 Control of records

Laboratory records are to demonstrate fulfilment of Management System requirements.

A. TRUE
B. FALSE
C. NOT APPLICABLE

43

17025 Management System Issues

7.11 Control of data and information management

ALL data systems (software and hardware) used in the lab **MUST** be validated before any use.

A. TRUE
B. FALSE
C. NOT APPLICABLE

45