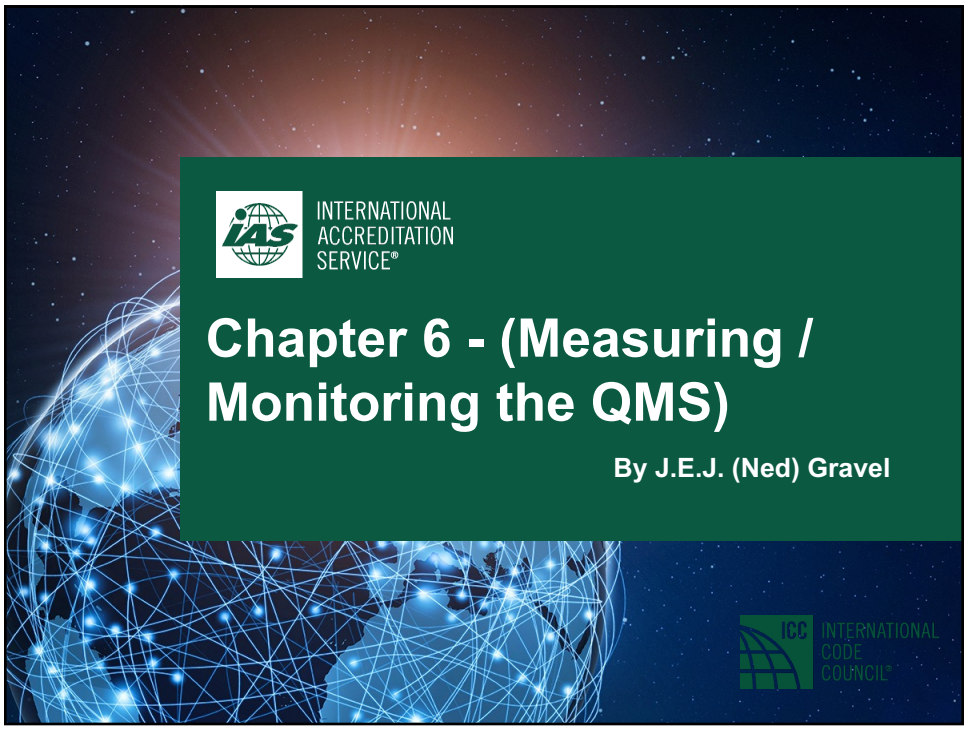


1

INTERNATIONAL ACCREDITATION SERVICE®

## 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

## Outline of Measuring the QMS

- Overview of Basic Concepts
- Purpose of Measuring the QMS
- Internal Audit (Clause 8.8)
- Management Review (Clause 8.9)

4

## Need for QMS Measurement

- Does the quality system continue to conform to requirements?
  - Is the system implemented?
  - Is the quality system effective? Does it support of our production of valid results?
  - Does it allow us to effect continual improvement?

5

## Measurement Processes

ISO/IEC 17025:2017 separates measurement and monitoring functions into two clauses,

- 8.8 – Internal Audits, and
- 8.9 – Management Reviews.

6

## Measurement Requirements

ISO/IEC 17025 provides no indication in Clauses 8.8 and 8.9 on the frequency of measurement.

IAS guidelines provide specifications.

7

## What is an Internal Audit?

An objective comparison of what is required (from the laboratory QMS) to what is actually happening.

This comparison is based on gathering “objective evidence” of current conditions and situations.

Objective evidence is gathered by:

- Document review
- Observation
- Interview

8

## Internal Audit

An internal audit is the best source of information available to an organisation to determine whether or not its quality system continues to meet the needs of the organisation and its people. It provides information on the effectiveness of the operation of the quality system.

It must be systematic, planned, using qualified persons, and documented. Findings must be followed-up.

Once the information has been documented, it can help top management do their job.

9

## Internal Audit - Considerations

- Auditing is a “formal” process. Take no shortcuts. This ensures that all parties are treated with respect.
- The process selected must be one that can be successfully implemented. Time and resources are key.
- Avoid undue costs. Recognise the real benefits. Promote the positive aspects.
- Avoid the damage (hidden costs) of staff perceiving “failure” because of the audit process. This is a leadership challenge, but it is critical to the success of the program.

10

## Internal Audit - Considerations

- Shorter, and more frequent, audits reinforce the requirement to maintain the quality system and result in fewer non-conformances. Longer and less frequent audits cost less in time and personnel.
- Quality documentation must be in place for an audit to take place.
- Properly trained auditors are the single best investment to ensure the success of an audit.

11

## What is Management Review?

- Systematic examination of suitability, adequacy, effectiveness and efficiency of the quality system.
- Can include consideration of the need to adapt the quality policy and objectives in response to changing needs and expectations.
- Review includes determination of the need for actions.
- Sources of information include audit reports, non-conformance logs, feedback (including complaints) logs, proficiency testing results, and external assessment reports.

12

## Management Review Items

ISO/IEC 17025 details the actual agenda items for management review in clause 8.9.

8.9.2 Inputs:

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;
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.

13

## Management Review Items

ISO/IE 17025 details the actual agenda items for management review in clause 8.9.

8.9.3 Outputs:

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.

14

## Close out and Follow-up

- Document the finding / non-conformance/potential non-conformance.
- Import the finding into the laboratory continual improvement processes
- Provide formal close out (for things greater than simple “correction.”)
- Document all instances of corrective and preventive action follow-up. Evidence of prevention to demonstrate effectiveness of the action taken.
- This includes findings from management review.

15