INTRODUCTION TO ISO/IEC 17025:2017 ~ transition

CLAUSE 8 – Management

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Module 4 – Clause 8 Requirements

8. Management Requirements

- 8.1 Option
- 8.1.1 General
- The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. In addition to meeting the requirements of Clauses 4 to 7,
- the laboratory shall implement a management system in accordance with Option A or Option B.

- NOTE See Annex B for more information.

8.1 Option

- **8.1.2 Option A**
- 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);
– improvement (see 8.6);
– corrective action (see 8.7);
– internal audits (see 8.8);
– management reviews (see 8.9).

- **8.1.3 Option B**
- A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9

8.2 Management system documentation (option A)

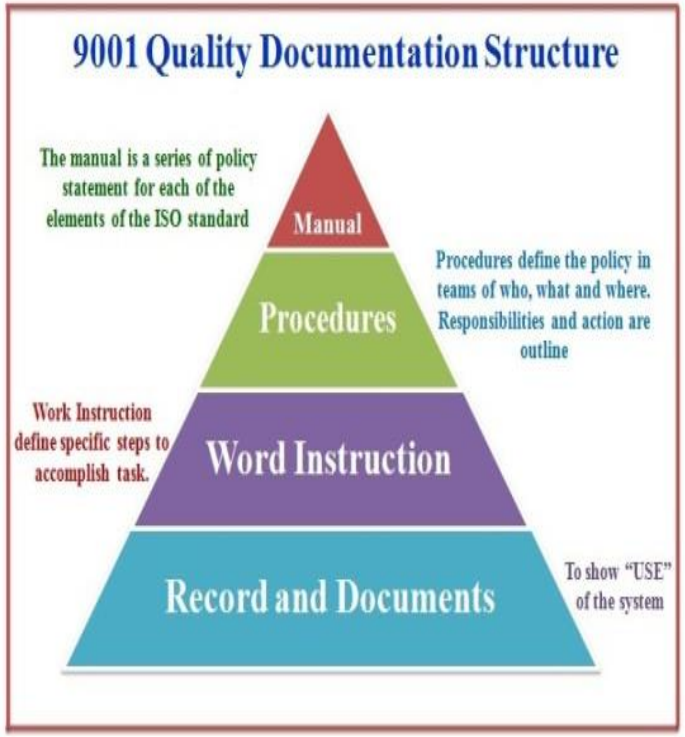
- 8.2.1 Establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and shall ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization.

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

- 8.2.3 Provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

- 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 Management system documentation and related information are accessible by all personnel involved in laboratory activities.



8.2 Management system documentation (option A)

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

NOTE: In this context, "document" can be policy statements, procedures, specifications, manufacturer's instructions, calibration tables, charts, text books, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

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.

8.4 Control of record (Option A)

- The laboratory shall :

8.4.1 Establish and retain legible records to demonstrate fulfilment of the requirements in this document.

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

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.

8.5 Actions to address risks and opportunities (Option A)

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.

8.5.2 The laboratory shall plan:

a) actions to address these risks and opportunities;

b) how to:

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

NOTE : Although this document specifies that the organization 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.

8.5 Actions to address risks and opportunities (Option A)

Clause 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.

8.6 Improvement (Option A)

- 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 analysed 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.*

8.7 Corrective action (Option A)

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 analysing 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;

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.

8.8 Internal audits (Option A)

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.

The laboratory shall:

a) plan, establish, implement and maintain an audit programme 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 programme and the audit results.

NOTE : ISO 19011 provides guidance for internal audits.

8.9 Management reviews (Option A)

8.9.1 Review 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 be recorded as 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;
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.

8.9 Management reviews (Option A)

• 8.9.3 The outputs 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.

Exercise 4

Refer to the standard, please find the answer and write the appropriate clause.

Duration: 30 minutes

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