Revision ISO 15189

Chapter 8

Chapter 8 – what is new?

- Requirements to QMS shifted from chapter 4 to chapter 8
- 8.1 different options to establish QMS
- 8.4 additional requirements for amendment of records
- 8.5 new
- 8.7 risk considered
- 8.8 risk considered
- 8.9 additional points

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8.1 General requirements

8.1.1 General

The laboratory **shall** establish, document, implement and maintain a management system to support and demonstrate the consistent fulfilment of the requirements of this document.

As a minimum, the management system of the laboratory **shall** include the following:

- …

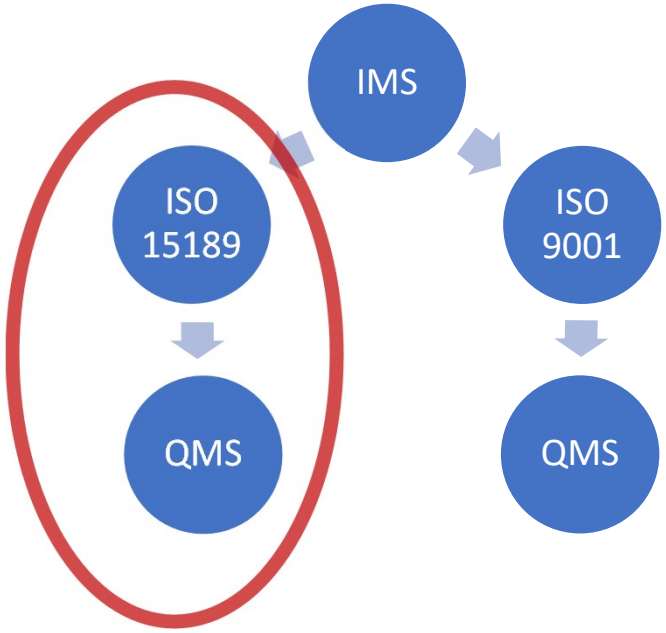
8.1.2 Fulfilment of management system requirements

The laboratory **may** meet 8.1.1 by establishing, implementing, and maintaining a quality management system (e.g. in accordance with the requirements of ISO 9001) (see Table B.1). This quality management system shall support and demonstrate the consistent fulfilment of the requirements of Clauses 4 to 7 and the requirements specified in 8.2 to 8.9.

8.1 General requirements

8.1.1

Assessment



- IMS in organisation e.g. hospital
- QMS according to 15189 in laboratory
- Assessment of all relevant requirements of ISO 15189

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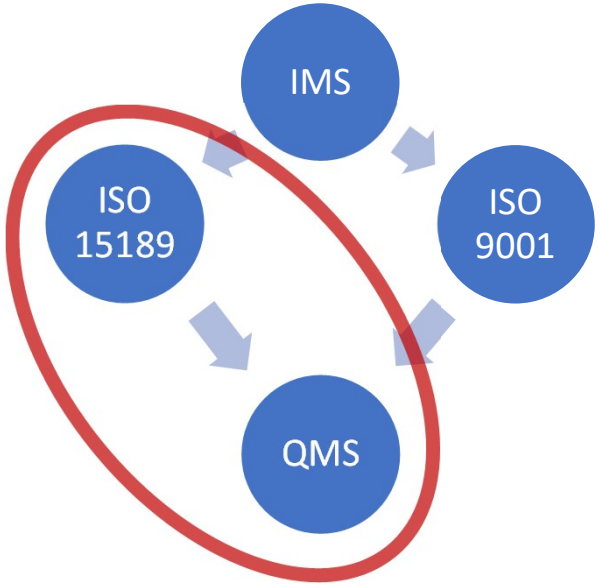
8.1 General requirements

8.1.2

Assessment



- IMS in organisation e.g. hospital
- QMS of the laboratory is part of the IMS
- Assessment of same issues (all relevant requirements of ISO 15189)

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8.1 General requirements

8.1.3 Management system awareness

The laboratory **shall ensure** that persons doing work under the laboratory's control are aware of:

a) relevant objectives and policies;

b) their contribution to the effectiveness of the management system, including the benefits of improved performance;

c) the consequences of not conforming with the management system requirements.

8.2 Management system documentation

8.2.1 General

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

NOTE: The management system documents can, but are not required to, be contained in a quality manual.

8.4 Control of records

8.4.2 Amendment of records

The laboratory shall ensure that amendments to records can be traced to previous versions or to original observations. Both the original and amended data and files shall be kept, including the date and where relevant, the time, of alteration, an indication of the altered aspects and the personnel making the alterations.

8.5 Actions to address risks and opportunities for improvement

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8.5.1 Identification of risks and opportunities for improvement

The laboratory shall identify risks and opportunities for improvement associated with the laboratory activities to:

a) prevent or reduce undesired impacts and potential failures in the laboratory activities;

b) achieve improvement, by acting on opportunities;

c) assure that the management system achieves its intended results;

d) mitigate risks to patient care;

e) help achieve the purpose and objectives of the laboratory.

8.5 Actions to address risks and opportunities for improvement

8.5 Actions to address risks and opportunities for improvement

8.5.2 Acting on risks and opportunities for improvement

The laboratory shall prioritize and act on identified risks. Actions taken to address risks shall be proportional to the potential impact on laboratory examination results, as well as patient and personnel safety.

The laboratory shall **record** decisions made and actions taken on risks and opportunities.

The laboratory shall integrate and implement actions on identified risks and improvement opportunities into its management system and evaluate their effectiveness.

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8.7 Nonconformities and corrective actions

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8.7.1 Actions when nonconformity occurs

When a nonconformity occurs, the laboratory shall:

f) Update risks and opportunities for improvement, as needed.

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

8.7.2 Corrective action effectiveness

Corrective actions shall be appropriate to the effects of the nonconformities encountered and shall mitigate the identified cause(s).

8.8 Evaluations

8.8.3 Internal audits

8.8.3.2 The laboratory shall plan, establish, implement and maintain an internal audit programme that includes:

a) priority given to risk to patients from laboratory activities;

b) a schedule which takes into consideration identified risks; the outcomes of both external evaluations and previous internal audits; the occurrence of nonconformities, incidents, and complaints; and changes affecting the laboratory activities;

f) ensuring that the results of the audits are reported to relevant personnel;

8.9 Management reviews

8.9.2 Review input

The inputs to management review shall be recorded and shall include evaluations of at least the following:

b) fulfilment of objectives and suitability of policies and procedures;

e) quality assurance of result validity;

j) other relevant factors, such as monitoring activities and training.

8.9 Management reviews

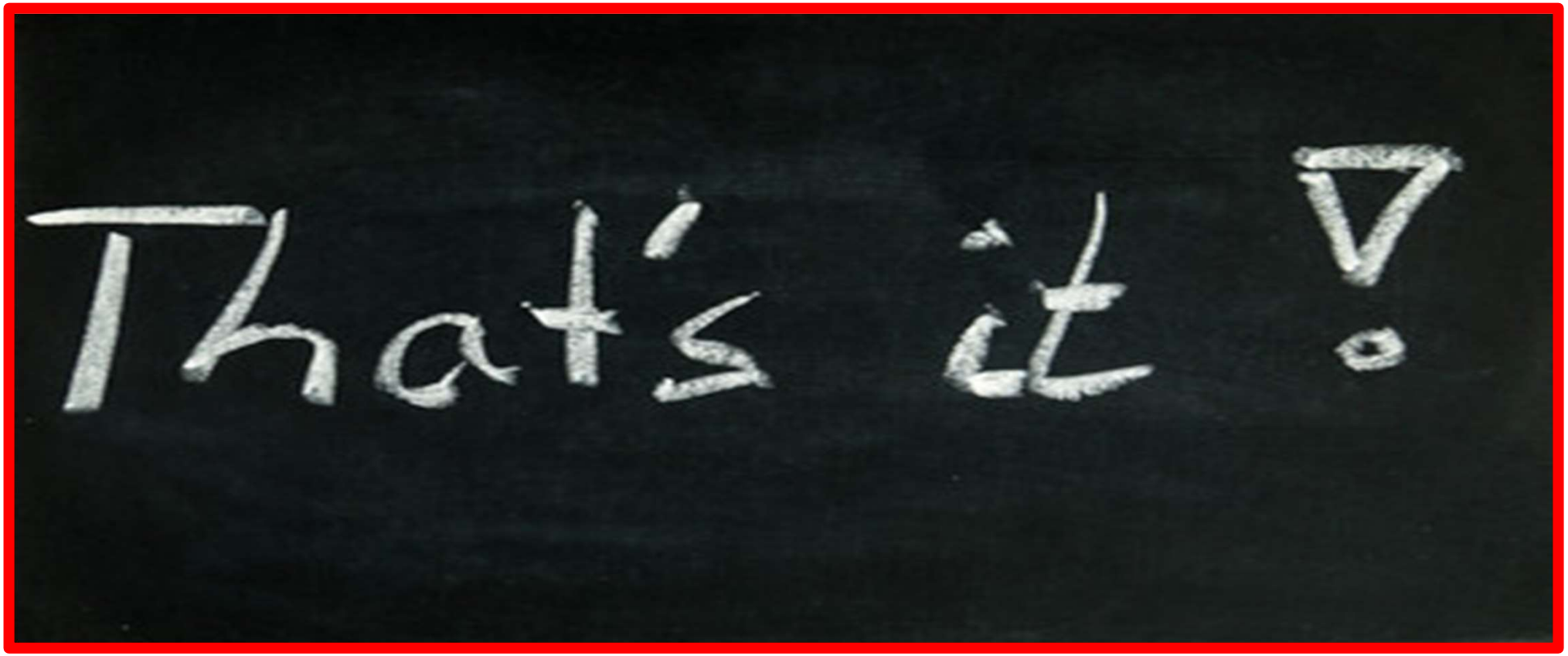
8.9.3 Review output

The output from the management review shall be a record of decisions and actions related to at least:

b) improvement of the laboratory activities related to the fulfilment

e) any need for change.

Thank you for your attention



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