EA LC
Train the Trainer Course
ISO 15189:2022

Chapter 4 (General requirements)

Chapter 5 (Structural & governance requirements)

Chapters 4 & 5 - What is new?

4. General requirements

4.1 Impartiality-Enhanced requirement, development of requirements

4.2 Confidentiality-Enhanced requirement, more details on the requirements

4.3 Requirements regarding patients-Introducing requirements regarding patients safety and rights, restructuring of other requirements regarding needs of users/patients

5. Structural and governance requirements

5.1 Legal Entity-No changes

5.2 Laboratory Director-Simplification of requirements, less prescriptive

5.3.1/5.3.2 General/Conformance with requirements: Introduction of defining range of laboratory activities

5.3.3 Advisory Services-No major changes

5.4 Structure and Authority-Simplification and restructure of requirement, less prescriptive

5.5 Objectives and Policies-Restructure of the requirement

5.6 Risk Management-Introduction of requirements identifying risk management of harm to patients & opportunities

General requirements (chapter 4)

4.1 Impartiality

- Impartiality is a requirement ‘not just arrangements in place…to ensure...laboratory’s impartiality’
- Enhanced requirement, emphasizing on the responsibility, operation and the commitment for the impartiality of laboratory activities

a) ‘Laboratory activities shall be undertaken impartially. The laboratory shall be structured and managed to safeguard impartiality’

b) ‘The laboratory management shall be committed to impartiality’

c) ‘The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality’

General requirements (chapter 4)

4.1 Impartiality

- Emphasis on identification of potential threats to impartiality, monitoring the threats, and document actions to mitigate

d) The laboratory shall monitor its activities and its relationships to identify threats to its impartiality. This monitoring shall include relationships of its personnel

e) If a threat to impartiality is identified, the effect shall be eliminated or minimized so that the impartiality is not compromised. The laboratory shall be able to demonstrate how it mitigates such threat

General requirements (chapter 4)

4.2. Confidentiality

- Confidentiality is a requirement ‘not just arrangements in place to ensure…confidentiality of information is maintained’
- Enhances Transparency -The text is in more detail to cover liability
- Emphasizes on the responsibility of the Management of information

4.2.1 Management of Information ‘The laboratory shall be responsible, through legally enforceable agreements, for the management of all patient information obtained or created during the performance of laboratory activities.’…The laboratory shall inform the user/and or the patient in advance of the information it intends to place in the public domain’…

General requirements (chapter 4)

4.2. Confidentiality

- Highlights on Arrangements for **Release of information**…other than the patient, notification of patient, how/when and to whom

4.2.2 Release of information 'When the laboratory is required by law or authorized by contractual arrangements to release confidential information, the patient concerned shall be notified of the information released, unless prohibited by law. Information about the patient from a source other than the patient (e.g. complainant, regulator) shall be kept confidential by the laboratory. The identity of the source shall be kept confidential by the laboratory and shall not be shared with the patient, unless agreed by the source'

- **Reinforces Personnel responsibility**...'shall keep confidential all information obtained or created during laboratory activities'

4.2.3 Personnel responsibility 'Personnel, including any committee members, contractors, personnel of external bodies, or individuals with access to laboratory information acting on the laboratory's behalf, shall keep confidential all information obtained or created during the performance of laboratory activities'

General requirements (chapter 4)

4.3 Requirements regarding patients

- Introduction and emphasis on requirements regarding patients' safety and rights
- Emphasizing on the rights of patients to care, informed consent when required, the disclosure and the provision of transparent information.
- Laboratory management shall ensure that patients' well-being, safety and rights are the primary considerations. The laboratory shall establish and implement processes:

d) where appropriate, disclosure to patients, users and any other relevant persons, of incidents that resulted or could have resulted in patient harm, and records of actions taken to mitigate those harms

g) ensuring the ongoing availability and integrity of retained patient samples and records in the event of the closure, acquisition or merger of the laboratory

f) obtaining informed consent when required

i) upholding the rights of patients to care that is free from discrimination

General requirements (chapter 4)

4.3 Requirements regarding patients

Restructuring and rephrasing of some requirements….The laboratory shall establish and implement processes:

- a) opportunities for patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the examination results
- b) provision of patients and users with publicly available information about the examination process including costs when applicable, and when to expect results
- c) periodic review of the examinations offered by the laboratory to ensure they are clinically appropriate and necessary
- e) treatment of patients, samples, or remains, with due care and respect
- h) making relevant information available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf

Structural and governance requirements (chapter 5)

5.1 Legal Entity

Requirement is the same

'The laboratory or the organization of which the laboratory is a part shall be an entity that can be held legally responsible for its activities'

5.2 Laboratory Director

- Requirements become less prescriptive
- Emphasis on performance based requirements, the competence requirements, qualifications, responsibilities of the director
- Emphasis on the responsibility for planning and implementing actions to address risks so that risks to patient care and opportunities to improve are systematically identified and addressed
- Provides more flexibility…director may delegate to competent and/or qualified personnel either selected duties or responsibilities...these shall also be documented

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Structural and governance requirements (chapter 5)

5.2 Laboratory director

5.2.1 Laboratory director competence

The laboratory shall be directed by a person, or persons however named, with the specified qualifications, competence, delegated authority, responsibility, and resources to fulfil the requirements of this document

5.2.2 Laboratory director responsibilities

The laboratory director is responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed. The duties and responsibilities of the laboratory director shall be documented

5.2.3 Delegation of duties

The laboratory director may delegate either selected duties or responsibilities, or both, to qualified and competent personnel and such delegation shall be documented. However, the laboratory director shall maintain the ultimate responsibility for the overall operation of the laboratory

Structural and governance requirements (chapter 5)

5.3 Laboratory Activities

New requirement: Specification of laboratory activities that conform with the requirements

5.3.1 General

'The laboratory shall specify and document the range of laboratory activities, laboratory activities performed at sites other than the main location (e.g. POCT, sample collection) for which it conforms with this document…which excludes externally provided laboratory activities on an ongoing basis'

- The laboratory shall only claim conformity with this document for the range of laboratory activities it performs
- The laboratory shall specify and document the range of activities performed at each location/site and the main location
- Externally provided part of analysis on an going basis is acceptable as long as the laboratory does not claim to be accredited for that part

5.3.2 Conformance with requirements

Simplification of the requirement, conformance for the specified range of the laboratory activities

'Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the users, regulatory authorities and organizations providing recognition. This applies to the complete range of specified and documented laboratory activities, regardless of where the service is provided'

Structural and governance requirements (chapter 5)

5.3.3 Advisory activities

- No major change: reinforces the requirements
- The Laboratory shall ensure that appropriate laboratory advice and interpretation are available and meet the needs of patients and users
- The laboratory shall establish arrangements for communicating with laboratory users:

  a) advising on choice and use of examinations, including required type of sample, clinical indications and limitations of examination methods, and the frequency of requesting the examination

  b) providing professional judgments on the interpretation of the results of examinations

  c) promoting the effective utilization of laboratory examinations

  d) advising on scientific and logistical matters such as instances of failure of sample(s) to meet acceptability criteria

Structural and governance requirements (chapter 5)

5.4 Structure and Authority

5.4.1 General

- **Less prescriptive requirement**
- **Simplified and restructured**
- No need for a Quality Manual
- No deputies for every function
- It reinforces and emphasizes on specifying **structure, relationships, communication and the availability of procedures**. The laboratory shall:

  a) define its organization and management structure, its place in any parent organization, and the relationships between management, technical operations and support services

  b) specify the responsibility, authority, lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities

  c) specify its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results

2.2 Structural and governance requirements (chapter 5)

5.4.2 Quality management

- **Restructure of the requirement**
- Excludes term ‘Quality Manager’… Relevant responsibilities are assigned to competent personnel
- Less prescriptive requirement
- The laboratory is flexible to assign duties related to the Quality Management to more than one persons
- In small laboratories maybe all the duties will be assigned to one person only
- The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties including:

  a) implementation, maintenance and improvement of the management system

  b) identification of deviations from the management system or from the procedures for performing laboratory activities

  c) initiation of actions to prevent or minimize such deviations

  d) reporting to laboratory management on the performance of the management system and any need for improvement

  e) ensuring the effectiveness of laboratory activities

Structural and governance requirements (chapter 5)

5.5 Objectives and Polices

- Restructuring of the requirement
- Requirements of quality policy are integrated in objectives and policies
- Reinforcement of the requirement to obtain measurable objectives, to set quality indicators and to meet patient needs

- a) Laboratory management shall establish and maintain objectives and policies (see 8.2) to:

  1) meet the needs and requirements of its patients and users

  2) commit to good professional practice

  3) provide examinations that fulfil their intended use

  4) conform to this document

Structural and governance requirements (chapter 5)

5.5 Objectives and Polices

- b) Objectives shall be measurable, and consistent with policies. The laboratory shall ensure that the objectives and policies are implemented at all levels of the laboratory organization
- c) Laboratory management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented
- d) The laboratory shall establish quality indicators to evaluate performance throughout key aspects of pre-examination, examination, and post-examination processes and monitor performance in relation to objectives (see 8.8.2)

- Types of quality indicators include the number of unacceptable samples relative to the number received, the number of errors at either registration or sample receipt, or both, the number of corrected reports, the rate of achievement of specified turnaround times

Structural and governance requirements (chapter 5)

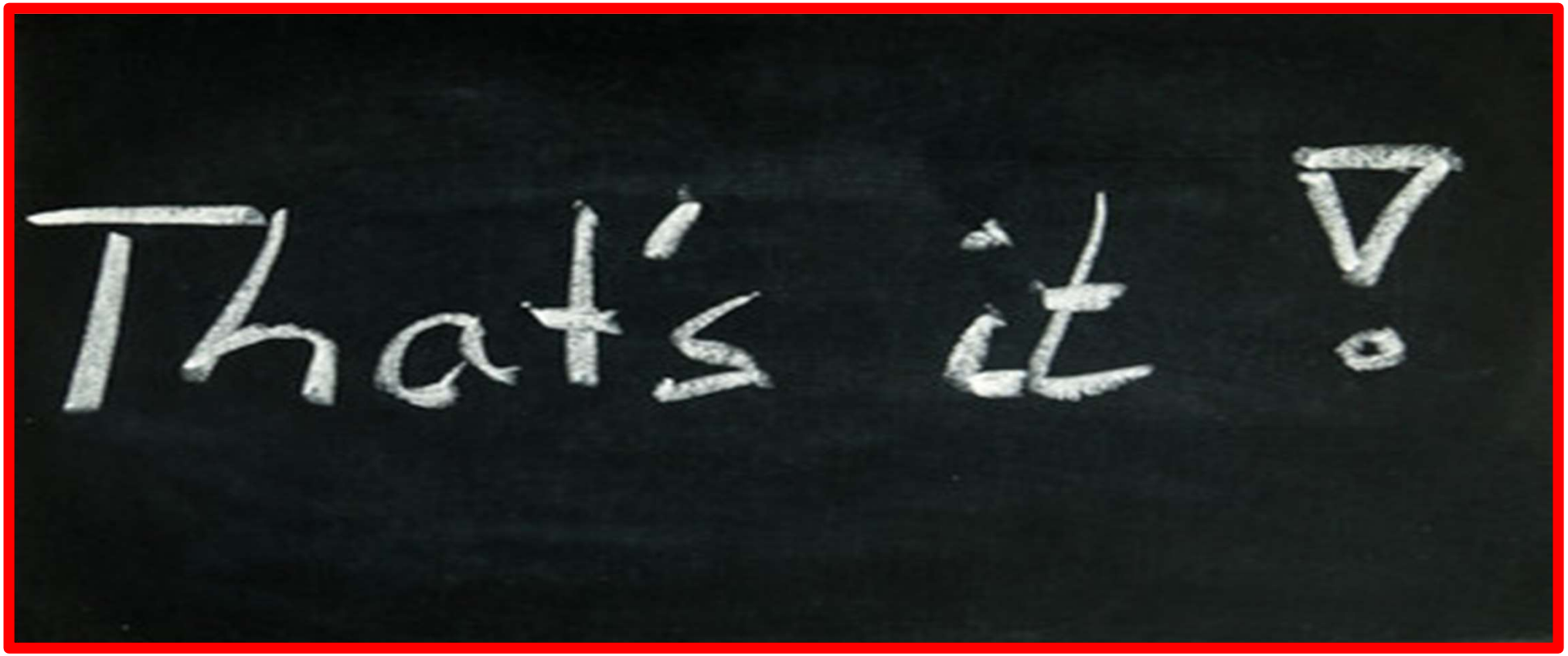
5.6 Risk management

a) Laboratory management shall establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement (see 8.5)

b) The laboratory director shall ensure that these processes are evaluated for effectiveness and modified, when identified as being ineffective

- Emphasis on risk-based approach for identifying risks of harm to patients and identification of opportunities to improve patient care
- Risks of harm to patients should be directed in areas that are likely to influence the outcome of the laboratory activities with potential impact on the validity of laboratory results which could lead to diagnostic errors and treatment and hence risk of harm of patient (i.e. from incidents in the laboratory that can be identified in its examinations and activities or even throughout the operation of the laboratory)
- Opportunities for Improvement should be directed at areas based on the risk identification

Thank you for your attention



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