EA LC
Train the Trainer Course
ISO 15189:2022

Overview – changes in the new standard

Chapter 7 (process requirements)

Chapter 7 – what is new?

7.1 General: emphasis of the risk-based approach and focus on patient care

7.2 Pre-examination processes: requirements less prescriptive and more goal-oriented

7.3 Examination processes: update and emphasis on clinical decision making, integration of the requirements related to “ensuring the validity of examination results”

7.4 Post-examination processes: introduction of simplifications in reporting, emphasis of critical results reporting

7.5 Nonconforming work: rearrangement of the requirements related to nonconforming work/non-conformities and focus on patient care

7.6 Control of data and information management: no major changes in the requirements

7.7 Complaints: development of the requirements

7.8 Continuity and emergency preparedness planning: development of requirements

Focus on **POCT** in examination and post-examination processes

7.1 General

Emphasis of the risk-based approach and focus on patient care

- Identification of potential risks to patient care
  - in the pre-examination, examination and post-examination processes
  - assessment and mitigation to the extent possible
  - communication of the residual risk to users as appropriate
- Monitoring of the risks and of the mitigation processes and evaluation according to the potential harm to the patient
- Identification of opportunities to improve patient care (see 8.5)

7.2 Pre-examination processes

No major structural changes : specific subparagraph related to patient consent (7.2.4.3)

Chapter less prescriptive, more goal-oriented

- 7.2.2 The information shall be sufficiently detailed to provide laboratory users with a comprehensive understanding of the laboratory's scope of activities and requirements.
- 7.2.3.1b) The examination request shall provide sufficient information to ensure: […]
- 7.2.4.2 The laboratory shall provide information and instructions for pre-collection activities with sufficient detail to ensure that the integrity of the sample is not compromised.
- 7.2.4.4 To ensure safe, accurate and clinically appropriate sample collection and pre-examination storage, the laboratory shall provide instructions for: […]
- Extra use of « when/where relevant » or « when necessary »

Reference to support documents (notes):

- ISO 20658 "sample collection and transport"
- Different ISO standards for specific samples and specific analytes

7.2 Pre-examination processes

Reinforcement of some requirements

- 7.2.4.1 Any deviation from the established collection procedures shall be clearly recorded. The potential risk and impact on the patient outcome of acceptance or rejection of the sample shall be assessed, recorded and shall be communicated to the appropriate personnel.
- 7.2.4.2 pre-collection activities: order of collecting samples, sample labelling
- 7.2.4.4 collection activities: order of sample collection, separating or dividing the primary sample
- 7.2.5 sample transportation: establishment and periodically evaluation of adequacy of sample transportation systems; immediate notification of the organization responsible for the transport of the sample, if the integrity of a sample has been compromised and there is a health risk
- 7.2.6.2 Sample acceptance exceptions

a) The laboratory shall have a process that considers the best interests of the patient in receiving care, when a sample has been compromised due to …

b) When a compromised clinically critical or irreplaceable sample is accepted, after consideration of the risk to patient safety, the final report shall indicate the nature of the problem and where applicable, advising caution when interpreting results that can be affected.

- 7.2.7.3 sample stability: specific time monitoring where relevant

7.3 Examination processes

Integration of the requirements related to “ensuring the validity of examination results”

Update and emphasis on clinical decision making

- Examination methods
  - 7.3.1a) The laboratory shall select and use examination methods which have been validated for their intended use to assure the clinical accuracy of the examination for patient testing.
  - 7.3.1b) The performance specifications for each examination method shall relate to the intended use of that examination and its impact on patient care.
  - 7.3.1e) Authorized personnel shall periodically evaluate the examination methods provided by the laboratory to ensure they are clinically appropriate for the requests received.
  - 7.3.2c)/7.3.3b) The laboratory shall ensure the extent of the verification/validation of examination methods is sufficient to ensure the validity of results pertinent to clinical decision making.
  - 7.3.2e) If a method is revised by the issuing body, the laboratory shall repeat verification to the extent necessary.

7.3 Examination processes

- Measurement uncertainties : reinforcement of the requirements, reference to ISO/TS 20914 (note) and introduction of 2 recommendations
  - 7.3.4a) The MU of measured quantity values shall be evaluated and maintained for its intended use, where relevant. The MU shall be compared against performance specifications and documented.
  - 7.3.4c) For examination procedures where evaluation of MU is not possible or relevant, the rationale for exclusion from MU estimation shall be documented.
  - 7.3.4e) When users have inquiries on MU, the laboratory's response shall take into account other sources of uncertainty, such as, but not limited to biological variation.
  - 7.3.4f) If the qualitative result of an examination relies on a test which produces quantitative output data and […], MU in the output quantity shall be estimated using representative positive and negative samples.
  - 7.3.4g) For examinations with qualitative results, MU in intermediate measurement steps or IQC results which produce quantitative data should also be considered for key (high risk) parts of the process.
  - 7.3.4h) MU should be taken into consideration when performing verification or validation of a method, when relevant.

7.3 Examination processes

- Biological reference intervals and clinical decision limits
  - 7.3.5 Biological reference intervals and clinical decision limits, when needed for interpretation of examination results, shall be defined and communicated to users.
  - 7.3.5a) Biological reference intervals and clinical decision limits shall be defined, and their basis recorded, to reflect the patient population served by the laboratory, while considering the risk to patients.
  - 7.3.5b) Biological reference intervals and clinical decision limits shall be periodically reviewed, and any changes communicated to users.

- Documentation of examination procedures : less prescriptive
  - 7.3.6a) The laboratory shall document its examination procedures to the extent necessary to ensure the consistent application of its activities and the validity of its results.

7.3 Examination processes

- Ensuring the validity of the results : more systematic description of the requirements for establishing and monitoring of validity of examination results with IQC, EQA and comparability of results, for a better understanding

- IQC
  - 7.3.7.2a) The laboratory shall have an IQC procedure […] that verifies the attainment of the intended quality and ensures consistent validity pertinent to clinical decision making.
    1) The intended clinical application of the examination should be considered […]
    2) The procedure should also allow for the detection of either lot-to-lot reagent or calibrator variation, or both, of the examination method.
    3) The use of third-party IQC material should be considered […]
  - 7.3.7.2b) The laboratory shall select IQC material that is fit for its intended purpose.
  - 7.3.7.2c) If appropriate IQC material is not available, the laboratory shall consider the use of other methods for IQC.

7.3 Examination processes

- EQA
  - 7.3.7.3d) The EQA programme(s) selected by the laboratory shall, to the extent possible […] fulfill ISO/IEC 17043 requirements.
  - 7.3.7.3e) When selecting EQA programme(s), the laboratory should consider the type of target value offered.
  - 7.3.7.3f) When an EQA programme is either not available, or not considered suitable, the laboratory shall use alternative methodologies to monitor examination method performance. The laboratory shall justify the rationale for the chosen alternative and provide evidence of its effectiveness.

- Comparabilty of examination results
  - 7.3.7.4a) When either different methods or equipment, or both, are used for an examination, and/or the examination is performed at different sites, a procedure for establishing the comparability of results for patient samples throughout the clinically significant intervals shall be specified.
  - 7.3.7.4c) The laboratory shall periodically review the comparability of results.

7.4 Post-examination processes

Reorganisation of chapter 7.4.1 « reporting of the results »

Development of « special approaches »

- Focus on critical results reports:
  - 7.4.1.3 When examination results fall within established critical decision limits:

    a) the user or other authorized person is notified as soon as relevant, based on clinical information available;

    b) actions taken are documented, including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication, and any difficulties encountered in notification;

    c) the laboratory shall have an escalation procedure for laboratory personnel when a responsible person cannot be contacted.

7.4 Post-examination processes

- Introduction of simplifications in reporting
  - 7.4.1.4 a) When agreed with the user, the results may be reported in a simplified way. Any information listed in 7.4.1.6 and 7.4.1.7 that is not reported to the user shall be readily available.
  - 7.4.1.6 Each report shall include the following information, unless the laboratory has documented reasons for omitting any items:

- Some new requirements in the content of the report, ex:
  - 7.4.1.6a) unique patient identification, the date of primary sample collection and the date of the issue of the report, on each page of the report;
  - 7.4.1.6f) identification of the examination method used, where relevant, including, where possible and necessary, harmonized (electronic) identification of the measurand and measurement principle;
  - 7.4.1.6k) and l) identification of any results that need to be considered as preliminary and of critical results;

- Amendments to reported results
  - 7.4.1.8a) The reason for the change is recorded and included in the revised report, when relevant.

7.5 Non-conforming work

Rearrangement of the requirements related to non-conforming work/non-conformities and focus on patient care

- Non-conforming work in relation with laboratories activities (pre-examination, examination and post-examination processes) and examination results
- Other non-conformities adressed in 8.7

- New requirements in the process
  - 7.5 The process shall ensure that:

    b) immediate and long-term actions are specified and based upon the risk analysis process established by the laboratory;

    c) examinations are halted, and reports withheld when there is a risk of harm to patients;

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7.6 Control of data and information management

No major changes of the requirements

Chapter less prescriptive (authorities and responsabilities, …) with some precisions:

- 7.6.2 The laboratory is ultimately responsible for the laboratory information systems.
- 7.6.3 The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:

  c) implemented taking cybersecurity into account, to protect the system from unauthorized access and safeguard data against tampering or loss;

Reference to support documents (notes):

- ISO 22367: Risks associated with computerized laboratory information systems
- ISO/IEC 27001: Information security controls, strategies and best practices to ensure the preservation of confidentiality, integrity and availability of information

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7.7 Complaints

Reinforcement of the requirements

- Requirement of a process
- Receipt of complaint (7.7.2)
  - a) Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that the laboratory is responsible for and, if so, shall resolve the complaint. (see 8.7.1).
  - b) The laboratory receiving the complaint shall be responsible for gathering all necessary information to determine whether the complaint is substantiated.
  - c) Whenever possible the laboratory shall acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports.
- Resolution of a complaint (7.7.3)
  - Investigation and resolution of complaints shall not result in any discriminatory actions.
  - The resolution of complaints shall be made by, or reviewed and approved by, persons not involved in the subject of the complaint in question. Where resources do not permit this, any alternative approach shall not compromise impartiality.

7.8 Continuity and emergency preparedness planning

Reinforcement of the requirements

The laboratory shall ensure that risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, have been identified, and a coordinated strategy exists that involves plans, procedures, and technical measures to enable continued operations after a disruption.

Plans shall be periodically tested and the planned response capability exercised, where practicable.

The laboratory shall:

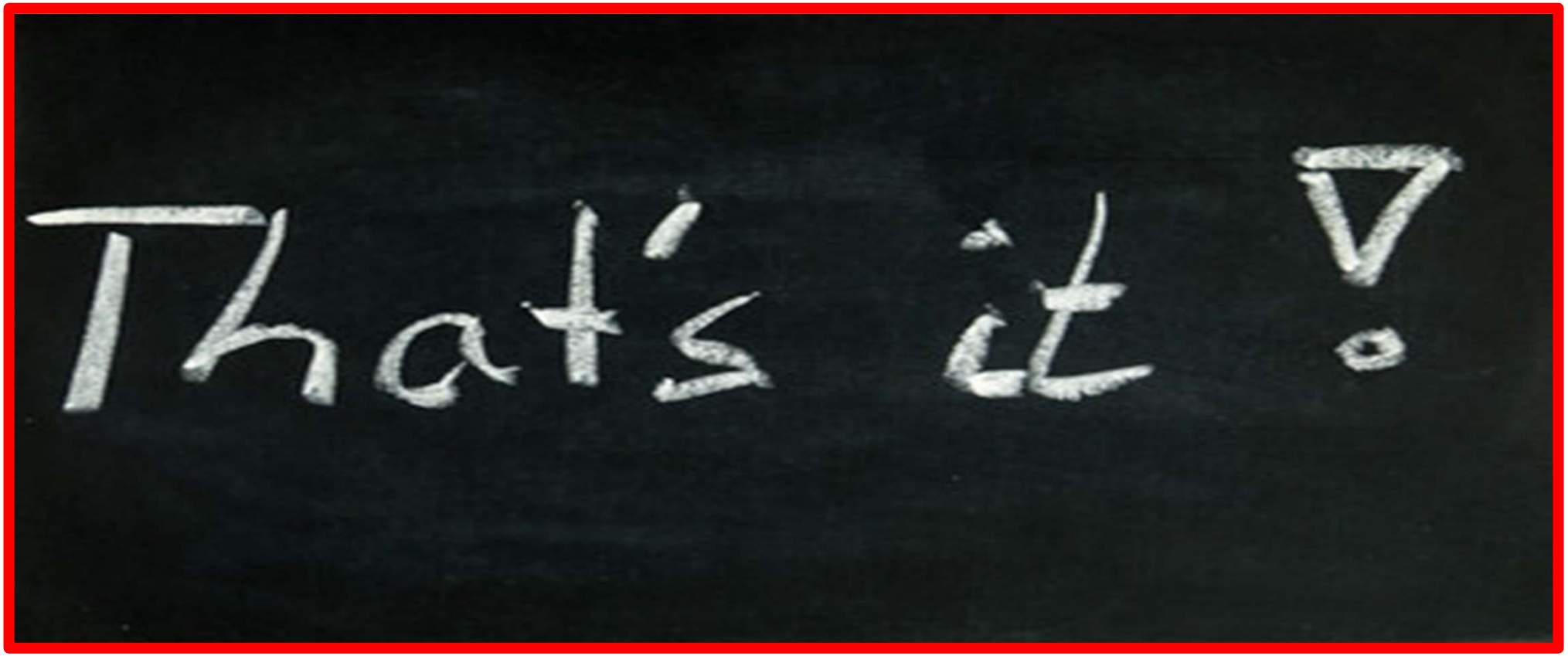
a) establish a planned response to emergency situations, taking into account the needs and capabilities of all relevant laboratory personnel;

b) provide information and training as appropriate to relevant laboratory personnel;

c) respond to actual emergency situations;

d) take action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential impact.

Thank you for your attention



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