# ISO 15189:2022 – A new task for medical laboratories

## A new philosophy in medical laboratories!

The 4th edition of ISO 15189 (the "Standard") was published in December 2022. Following a decision by ILAC, laboratories already accredited must ensure their smooth transition to the new Standard by December 2025. It seems that this transition period is realistic to meet the task. One of the main changes in the revised Standard is the introduction of a risk-based philosophy. The other major change is its structure. However, this is not surprising since it now follows the format of other standards in the ISO 17000 series. These changes make the Standard similar to ISO/IEC 17025 in structure and content; however there are some differences between the requirements in the two texts.

## Main changes

- The structure (see Fig. 1)
- Risks and opportunities
- No reference to preventive actions
- Requirements for point-of-care testing (POCT) previously addressed in ISO 22870 [1] have been incorporated in the Standard
- The management system – no requirement for a quality manual or a Technical/Quality Manager
- A management system according to ISO 9001 [2] could facilitate compliance
- Reference to new standards
- The Annexes

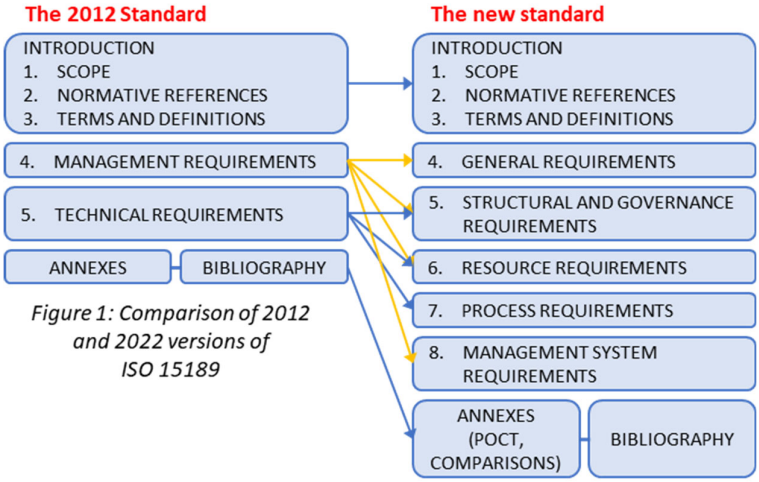


*Figure 1: Comparison of 2012 and 2022 versions of ISO 15189*

## A medical laboratory is…

The Standard defines a medical laboratory as an "entity for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health". These activities include pre-examination, examination and post-examination processes.

## Risks and opportunities

The Standard provides for risk management throughout almost all its clauses. This reflects the need for the laboratory to identify potential risks associated with all processes, i.e. pre-examination, examination and post-examination, taking into account their impact on its work with a focus on the service to the patient and the safety of personnel. The laboratory assesses the impact, the probability of occurrence and the probability of a risk being quickly detected [3]. The task is to prevent or reduce their impact, achieve improvement and efficiency of the management system, mitigate risks to patient care as well as to achieve the purpose and objectives of the laboratory [4]. The laboratory must plan and implement actions to address risks and opportunities towards continual improvement. No reference is made to preventive actions. Opportunities for improvement can be identified through: use of policies; review of procedures, objectives, internal audits, external evaluations and complaints; management reviews; suggestions from personnel, patients and users; analysis of data and external quality assessment (EQA) results.

## The management system

The Standard specifies that a medical laboratory may meet its requirements when maintaining a quality management system, e.g. in accordance with the requirements of ISO 9001 [2], provided that this system supports and demonstrates consistent fulfilment of both management and technical requirements. Although the Standard does not require a quality manual, those laboratories which have already drafted and are using such a manual could keep it. In any case, all the content usually found in a quality manual is expected to appear in other parts of the management system.

## Some other changes

- Detailed requirements for the pre-examination process.
- Reference to a series of standards referring to the collection of samples, including ISO 20658 [5].
- Metrological traceability is addressed in more detail, including alternative approaches to meet the task. Reference is made to standards for medical devices, including ISO 17511 [6].
- Additional tools are listed to ensure the validity of results. More strict requirements are set with regard to participation in EQA.
- More detailed requirements for control of data and information management, taking into account new technology.
- Management review must reflect the various changes, including risks and opportunities.
- Additional requirements are set for externally provided products and services; according to a Note, the latter can include, among others sample collection, calibration, equipment maintenance, EQA programmes, referral laboratories and consultants.

## Some differences from ISO/IEC 17025

- According to ISO 15189, sampling as a stand-alone activity is not included in its scope.
- Components arising from sampling are not taken into account in the evaluation of measurement uncertainty [7].
- Contrary to ISO/IEC 17025, the Standard does not require that measurement uncertainty is included in reports (this was also the case in the 2012 edition of the Standard).
- Specific requirements in ISO 15189 relating to patients' well-being, safety and rights.

## Steps to be followed by medical laboratories

- The new Standard needs to be clearly understood with regard both to its philosophy and provisions.
- Table C1 in Annex C of the Standard provides a comparison with the 2012 edition. This may be of some help although this comparison refers only to titles of the relevant clauses.
- A cross-reference between existing processes and procedures and the relevant clause in the new Standard will facilitate the smooth transition. Existing documentation is not expected to adequately address the widened approach to risk and opportunities as well as other new requirements.
- Internal audit and management review will help to check the appropriateness of the revised system.
- Although a quality manual is not required by the Standard, laboratories may keep it as all its content is undoubtedly useful.
- Laboratories involved in POCT need to address the relevant requirements in ISO 15189, bearing in mind that ISO 22870 [1] has been withdrawn.
- In all cases, the transition period will need to be met (December 2025).

# References


[1] ISO 22870:2016, Point-of-care-testing (POCT) – Requirements for quality and competence (withdrawn)
[2] ISO 9001:2015, Quality management systems – Requirements
[3] Eurolab Cookbook no 18 Risk based approach, https://www.eurolab.org/pubs-cookbooks
[4] ISO 22367:2020, Medical laboratories – Application of risk management to medical laboratories
[5] ISO 20658:2023, Requirements for the collections and transport of samples for medical laboratory examinations
[6] ISO 17511:2020, In vitro diagnostic medical services – Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
[7] ISO/TS 20914:2019, Medical laboratories – Practical guidance for the estimation of measurement uncertainty



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