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# Standards to Support ISO 15189 Implementation for Medical Laboratories Accreditation

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## Goal and Scope

The aim of this research is to identify and evaluate international standards to support the design and implementation of specific medical Laboratory processes in compliance with ISO 15189:2012 requirements.

## Introduction

### The standards ISO 9001, ISO/IEC 17025 and ISO 15189

Laboratory medicine has assumed a fundamental role in guaranteeing the highest possible level of accessibility and appropriateness of patient care. The primary objective of clinical laboratories is to satisfy the needs of users, whether they are patients or healthcare personnel, providing clinically useful information to guide or reduce uncertainty in the clinical decisions that must be taken for diagnosis, prognosis and monitoring patient's state of health and/or disease. This information drive from the analytical activities on human origin samples made up of biological and tissue fluids.

The standard ISO 15189:2012- "Medical laboratories - Requirements for quality and competence" [1] is considered, at international level, the reference for the medical laboratories quality management system.

This document has started an important process of renewal of laboratory medicine and is not to be confused with ISO 9001:2015- "Quality management systems - Requirements" [2] or ISO/IEC 17025:2017- "General requirements for the competence of testing and calibration laboratories" [3,4].

ISO/IEC 17025 standard specifies the general requirements for the competence, impartiality and consistent operation of testing and calibration laboratories.

ISO 15189 and ISO/IEC 17025 evaluate the competence of staff, organization and the adequacy of structures (but have different field of application), while ISO 9001 focuses exclusively on organizational management [5].

Figure 1 schematically shows the different fields of application and the different contents of the three previously cited standards.

Furthermore, and most importantly, the application of ISO 15189 assures users on aspects relevant to a laboratory such as the accuracy, reliability, and traceability of measurement results (analyzes) their uncertainty and more generally the quality assurance of the analysis results.

It should also be emphasized that the adoption of a specific quality management system for facilities that carry out medical laboratory diagnostics does not represent a formal or marketing choice, but rather a gesture of responsibility towards users, patients and people.

### Laboratories accreditation

"Accreditation" is the attestation of competence, independence and impartiality of the so call CAB (Conformity Assessment Body). This process helps to increase trust in the market and promotes the free movement of goods and services subject to verification by accredited bodies and laboratories.

The European Regulation n. 765/2008 [6] underlines the particular value of accreditation as it provides a certificate of the ability to operate that a subject of recognized authority issues towards those who play a role in a given social context. Accreditation certifies the credibility of those who

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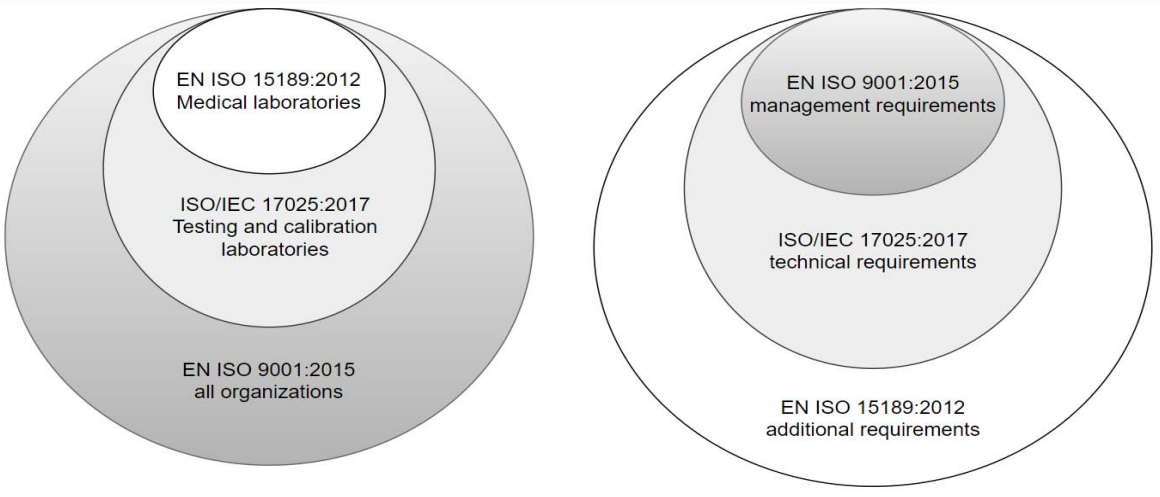


**Figure 1:** ISO 15189 *vs.* ISO/IEC 17025 *vs.* ISO 9001.

declare a standard compliance.

Each state member designates a single national accreditation body that must join the EA (European co-operation for Accreditation). To ensure the equivalence of the level of competence of CAB, to facilitate mutual recognition and promote the general acceptance of accreditation certificates, national accreditation bodies should use a rigorous and transparent peer assessment system and regularly undergo such evaluation.

EA is a member of IAF (International Accreditation Forum) and ILAC (International Laboratory Accreditation Cooperation). These organizations work together and coordinate their efforts to improve worldwide accreditation and conformity assessment.

The achievement of accreditation is the result of a process that involves all the organization functions, also in terms of commitment and awareness, so that the entire structure is effectively strengthened, in terms of greater transparency and visibility.

For the user, accreditation is an invisible tool which, however, entails real and perceptible advantages and benefits. It ensures that the supplier has fulfilled a whole series of obligations and has deployed all the resources to be able to place on the market a service that actually delivers what it claims. This is particularly significant when the service directly impacts health.

### ISO 15189:2012 standard

Accreditation according to ISO 15189 allows the medical laboratory to give evidence to its users of compliance with the commitments made ensuring also the effectiveness and reliability of the service provided in all its characteristic phases.

The standard is divided into two main sections:

I. Management requirements of the laboratory quality management system (organization, quality management system, document control, service agreements, examination by referral laboratories, external services and supplies, consultancy services, resolution of complaints, identification and control of nonconformities, corrective action, preventive action, continual improvement, control of records, internal audits, management review) and

II. Technical requirements (personnel qualification, accommodation and environmental conditions, equipment, pre-examination processes, examination processes, ensuring quality of examination results, post-examination processes, reporting of results, release of results, information management).

ISO 15189 takes into consideration specific procedures and elements of the quality system concerning the processes related to the main activities of the laboratory's operational flow through an overall approach in quality management that includes all aspects of the functioning from the pre-examination to post-examination process.

The Standard allows the laboratory to define and keep under control the operating methods, procedures, records relating to:

- Reception, preparation and identification of the patient;
- Collection, transport and storage of samples;
- Analysis techniques used and validation and safety procedures;
- Reporting criteria and methods;
- Skills and training of the personnel involved;
- Problem management methods and, more generally, a proactive approach through actions aimed at continuous improvement.

This Standard provides the definition and management of types of aspects, processes and sub-processes: Are there specific standards to help the laboratory in dealing with these activities?

## Materials and Methods

Although the version of ISO 15189:212 is not yet aligned with the most recent management standards, such as ISO 9001:2015 and ISO/IEC 17025:2017 (in terms, for example, of "process approach", "risk based thinking" and “ISO High Level Structure”), it is also possible to identify some relevant and peculiar processes:

- Risk management;
- POCT – Point-of-care testing;
- Measurement uncertainty of measured quantity values;

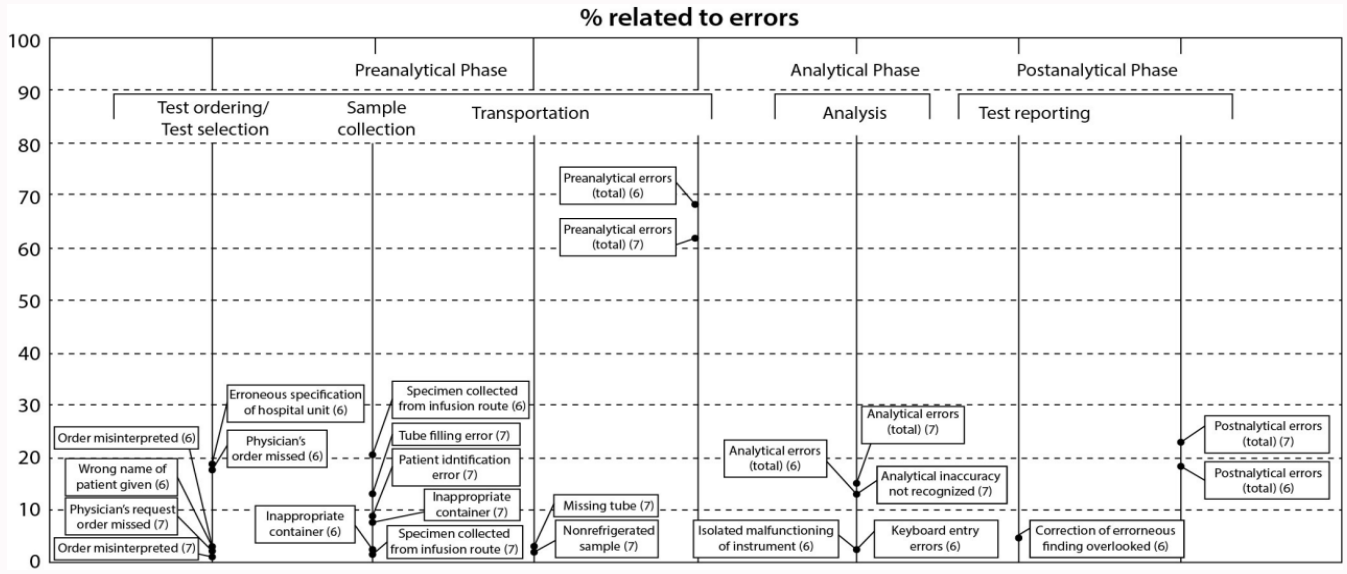


**Figure 2:** Errors in laboratory (Source [7]).

- Security management;
- Audit processes.

Focusing on these, attention should be paid to assess the existence of specific standards that allow the implementation of the requirements in the most exhaustive possible way; interesting reference documents have been identified and following analyzed.

## Risk management

"The laboratory shall evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risk and document decisions and actions taken." (ISO 15189, § 4.14.6) [1].

Laboratory analysis is a fundamental phase in the patient care process. Inaccuracies and errors in laboratory analyses can cause inconvenience and risks for the patient's health, especially as regards the definition of an adequate therapeutic plan. These risks that may concern, for example, contamination that can lead to "false positive" or "false negative" results.

In fact, it is estimated that about 70% of therapeutic decisions are also based on laboratory tests.

A recent study highlighted how the bulk of errors made by a laboratory mainly concerns the preanalytical phase (Figure 2) [7].

To prevent these possible errors, a practical guide is the standard EN ISO 22367:2020 - "Medical laboratories - Application of risk management to medical laboratories" [8].

This document, which replaces the previous version of 2010, specifies the process that a Medical Laboratory must put in place to identify and manage the risks for patients, for laboratory operators and for service providers associated with laboratory examinations.

The process includes the risks identification, estimation, evaluation, control and monitoring.

The Standard requirements are applicable to all aspects of examinations and services offered by the medical laboratory. These include pre-examination and post-examination aspects, examinations, accurate transmission of test results in the medical record and other technical and managerial processes described in ISO 15189 [1].

The standard does not apply to the risks that may arise from the management of post-examination healthcare professionals clinical decisions made.

## POCT – point-of-care testing

"The laboratory shall have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors. The laboratory shall evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work. Where applicable, similar provisions shall be made for primary sample collection and examinations at sites other than the main laboratory premises, for example Point-of-Care Testing (POCT) under the management of the laboratory." (ISO 15189, § 5.2.1) [1].

The methods of providing healthcare are profoundly changing to respond to a patient-centered concept of care, which does not see the hospital as the only diagnosis centre and focuses on efficient primary care and rapid triage.

Over the years, the centralization of the laboratories, which aimed above all at the objectives of cost-effectiveness and standardization, resulted in situations in which timeliness was no longer sufficient and effective.

To respond to these changes, laboratory medicine has initiated processes of reorganization and decentralization thanks to the accreditation of Point of Care tests.

Point of Care Testing are decentralized analyses, performed outside the laboratory, near or at the patient's point of care or assistance, in order to make the result available immediately or in a short time and also allowing management of the emergency situations.

70% to 80% of diagnoses are formulated on the basis of the results

of laboratory tests; it is therefore evident that the use of POCTs can lead to a reduction in the time and costs of the clinician's decision-making process.

The use of decentralized exams represents an organizational aspect of laboratory medicine to be considered supplementary and not alternative, within a complex service network. Managing the analytical-diagnostic process means integrating all the phases that make up the analytical path, placing the laboratory in the condition of ensuring in real time the control of decentralized instruments, keeping the clinical risk at a low and clinically acceptable level. Health systems must in fact guarantee services that are safe, effective, patient-centered, timely, efficient and equitable also in economic terms.

Despite the spread of POCT systems, supported by the publication of the standard EN ISO 22870:2016 - "Point-of-Care Testing (POCT) - Requirements for quality and competence" [9], there is not much evidence in literature that demonstrate a real advantage in terms of improvement of the outcome (13% of the case studies), however the help that POCT can give in terms of maintaining the quality standards necessary seems very effective for care [10].

### Measurement uncertainty of measured quantity values

"The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patient's samples. The laboratory shall define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty" (ISO 15189, § 5.5.1.4) [1].

In laboratory medicine, measurement results can be determined for both diagnostic decision making and disease prevention.

All clinical laboratories, in order to ensure the quality of the results and their comparability at different times and places, must demonstrate that they use validated test methods, guarantee the metrological traceability of their measurements and indicate the measurement uncertainty associated with each of the results.

The standard ISO/TS 20914:2019 - "Medical laboratories - Practical guidance for the estimation of measurement uncertainty" [11] provides the requirements for its assessment.

This uncertainty must be periodically reviewed and maintained at acceptable levels in relation to the analytical objectives. Measurement uncertainty must also be estimated for the most relevant quantitative phases of the examination processes that provide nominal qualitative results.

Knowledge of uncertainty of the examination performed in the medical laboratory is necessary to be aware of the reliability of its results. The fundamental aspects are repetition and level [12]:

- Whatever the method applied for the laboratory examination, the "accuracy of the uncertainty" is evident from repetitions of the examination on the same material (conditions of repeatability). In support of this comes the Internal Quality Control (CQI) which allows to identify the dispersion of the numerical quantitative results and the frequency of positives for the nominal qualitative results;

- The uncertainty also depends on the level of property measured in the material, both for numerical quantitative and nominal qualitative results.

### Security management

"The laboratory and associated office facilities shall provide an environment suitable for the tasks to be undertaken, to ensure the following conditions are met… Access to areas affecting the quality of examinations is controlled, safety facilities and devices are provided and their functioning regularly verified." (ISO 15189, § 5.2.2) [1].

Laboratories are environments work in which there may be dangers to the health and safety of those who work there.

Security, understood as a "condition free from any danger or risk", represents a "good" that can be duly prosecuted, but it must be remembered that it is a probabilistic state and never a state of certainty.

When risk factors exist in an environment work (for health and/or safety), the protective measures that are put in place must aim to eliminate them or, if this is not possible, to minimize them.

Within the ISO 15189 requirements, the responsibility for safety is attributed to the Laboratory Director; in fact, standard underlined that "The laboratory director shall implement a safe laboratory environment in compliance with good practice and applicable requirements" (ISO 15189, § 4.1.1.4, e) [1].

The standard ISO 15190:2020- "Medical laboratories - Requirements for safety" [13] has not created for accreditation, but explicitly states that it can be used for this purpose by governmental, professional or other authorities. It defines how to establish and maintain a safe working environment in a medical laboratory. The standard states that a work area safety manual must be readily available with mandatory reading for all employees and must contain security policy, fire prevention, electrical safety, chemical safety, radiation exposure, biological risks, and hazardous waste disposal.

The safety manual must include detailed instructions for evacuation from the workplace and the protocols to be put in place to deal with any accidents. The safety program (evaluated with Safety program audits) must be verified and reviewed at least once a year and the premises must be inspected (Safety inspection) at least with the same frequency.

### Audit management

"The laboratory shall conduct internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination:

a) Conform to the requirement of this International Standard and to requirements established by the laboratory, and

b) Are implemented, effective, and maintained." (ISO 15189, § 4.14.5) [1].

ISO 15189 requires that a documented procedure for the management of audits must be in place that an audit program must be defined that includes the treatment of all elements of the management system. Internal audits must be carried out by competent and independent personnel (with respect to the activity being audited) and the standard EN ISO 19011:2018 - "Guidelines for auditing management systems" [14] is expressly mentioned as a guide to follow for the execution.

This standard has aligned with many recently published ISO standards by including a risk-based approach: An audit approach that considers risks and opportunities of the audit activities.

The risk-based approach influences planning, conduct and reporting of audits in order to ensure that the latter are focused on significant issues for the client and to achieve the audit program objectives.

The process approach is central to this standard as auditors should understand that conducting a management system audit means auditing an organization's processes and their interactions in relation to one or more standards of management systems. Results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that act as an organic system.

The investigation techniques, therefore, should include interviews guided by the 5 "key questions" of a process audit structured according to the logical PDCA (Plan-Do-Check-Act) sequence:

1. What are you trying to achieve? (PLAN: What are the objectives, plans and how are they managed?);

2. How did you work/are you working to get it? (DO: What are the operational activities and the related support elements and how are they carried out?);

3. How do you know if you have achieved what you want? (CHECK: What are the measurements and monitoring and how are they carried out?);

4. How do you know if what you are adopting is the best way to achieve what you want? (ACT: What improvement actions have been planned and carried out?);

5. How can you be sure that what you are trying to achieve is right? (How is the overall consistency of the system guaranteed? Is there continuity between strategic and operational objectives?).

## Conclusion

By analyzing the standard ISO 15189 it is clear that there are various requirements that need precise and specific details. For this purpose, there are various standards to support a Medical Laboratory to guide it in the implementation of a management system compliant with ISO 15189; these standards provide more details to demonstrate the compliance of key processes with the requirements of the standard and guide the laboratory towards planning and implementing actions to address the risks and opportunities of the various processes involved. This represents the basis for increasing the effectiveness of the management system, obtaining better results and preventing negative effects that could cause harm to patients, laboratory staff and environment.

The consistency of diagnostic results between different laboratories (even from different countries) is facilitated when medical laboratories comply with these standards in the correct, complete, effective and efficient implementation of their ISO 15189 system.

## References

1. ISO 15189:2012 – Medical laboratories - Requirements for quality and competence. ISO. 2012.
2. ISO 9001:2015 – Quality management systems – Requirements. ISO. 2015.
3. ISO 17025:2017 – General requirements for the competence of testing and calibration laboratories. ISO. 2017.
4. Pradella M. Experience with using ISO 15189 as an option for accrediting pathology laboratories. ECIBC Plenary 2016: When Science and Policy collaborate for health. Ville Ponti. 2016.
5. Accredia. La differenza tra accreditamento ISO/IEC 17025 e certificazione ISO 9001 per i laboratori di prova e taratura. 2013.
6. EU Parliament, 2008. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93; Strasbourg. 2008.
7. Mrazek C, Lippi G, Keppel MH, Felder T, Oberkofler H, Haschke-Becher E, et al. Errors within the total laboratory testing process, from test selection to medical decision-making - A review of causes, consequences, surveillance and solutions. Biochem Med (Zagreb) 2020;30(2):020502.
8. EN ISO 22367: 2020 – Medical laboratories - Application of risk management to medical laboratories. EN ISO. 2020.
9. EN ISO 22870:2016 – Point-of-Care Testing (POCT) - Requirements for quality and competence. EN ISO. 2016.
10. Pecoraro V, Germagnoli L, Banfi G. Point-of-care testing: Where is the evidence? A systematic survey. Clin Chem Lab Med. 2014;52(3):313-26.
11. ISO/TS 20914:2019 – Medical laboratories - Practical guidance for the estimation of measurement uncertainty. ISO. 2019.
12. Pradella M. Recommendations for estimating measurement uncertainty in medical laboratories (ISO 15189 and ISO 20914). Sipmel. 2021.
13. ISO 15190:2020 – Medical laboratories - Requirements for safety. ISO. 2020.
14. EN ISO 19011:2018 – Guidelines for auditing management systems. EN ISO. 2018.