The International Standard ISO 15189:2022

www.metrycal.com

The International Standard **ISO 15189:2022** "Medical laboratories — Requirements for quality and competence" is a standard published by:

ISO: *International Organization for Standardization.*

This is an international standardization body, prestigious and highly recognized worldwide.

The ISO 15189:2022 standard has its origins in the ISO/IEC 17025 standard (formerly Guide 025) "General requirements for the competence of testing and calibration laboratories" and the ISO 9001 standard "Quality management systems -- Requirements".

The objective of this standard is to promote the welfare of patients and satisfaction of laboratory users through confidence in the quality and competence of medical laboratories, increasing the effectiveness of the management system, decreasing probability of invalid results, and reducing potential harm to patients, laboratory personnel, the public and the environment.

This standard is intended for use in different disciplines in medical laboratories, such as:

- Clinical chemistry.
- Bacteriology.
- Immunology and serology.
- Parasitology.
- Pathology.
- Virology.
- Mycology.
- Hematology.
- Urinalysis.
- Etc.

And the ISO 15189 standard in used in other healthcare services, such as:

- Diagnostic imaging.
- Respiratory therapy.
- Physiological sciences.
- Blood banks.
- Transfusion services.
- etc.

The use of this standard facilitates cooperation between medical laboratories and other healthcare services, assists in the exchange of information, and in the harmonization of methods and procedures.

In some countries or regions ISO 15189 adopted different nomenclatures (including year of publication), such as:

- NMX-EC-**15189**-IMNC (Mexico).
- UNE-EN **ISO 15189** (Spain).
- IRAM -**ISO 15189** (Argentina).
- NTC-**ISO 15189** (Colombia).
- NCh-**ISO 15189** (Chile).
- Etc.

ISO 15189 emerged as a reference guide for those laboratories which perform examination activities and seek to demonstrate that:

- **These operate an effective quality management system, which is continuously improving.** The laboratory implements a quality system in order to manage and use its administrative and technical documentation.
- **These are technically competent.** Technical competence of personnel is demonstrated, including facilities and environmental conditions, validated methods, equipment and reliable standards

traceable to the units of the International System of Units (SI).

- **These are capable of reporting reliable examination results.** The laboratory implements programs for quality assurance of results, to generate technically valid results.

- **The Laboratory is impartial and consistent in the performing of its activities.**

The laboratory implements risk management programs and demonstrate the consistent achievement of their policies, objectives and requirements of the standard.

ISO 15189:2022 has been adopted as a reference guide of accreditation bodies to assess the conformity of medical laboratories, and it is used worldwide for accreditation purposes.

The accreditation body is responsible for assessing the conformity of compliance with the requirements of **ISO 15189:2022** and witnesses the laboratory's competence to perform specific tasks of the examination in order to declare the accreditation.

See **ISO 15189:2022** requirements in next table.

Standard ISO 15189:2022	
Managerial and technical requirements	
4. GENERAL REQUIREMENTS. 4.1 Impartiality. 4.2 Confidentiality. 4.3 Requirements regarding patients. 5. STRUCTURAL AND GOVERNANCE REQUIREMENTS. 5.1 Legal entity. 5.2 Laboratory director. 5.3 Laboratory activities. 5.4 Structure and authority. 5.5 Objectives and policies. 5.6 Risk management. 6. RESOURCES REQUIREMENTS. 6.1 General. 6.2 Personnel. 6.3 Facilities and environmental conditions. 6.4 Equipment. 6.5 Equipment calibration and metrological traceability. 6.6 Reagents and consumables. 6.7 Service agreements. 6.8 Externally provided products and services.	7. PROCESS REQUIREMENTS. 7.1 General. 7.2 Pre-examination processes. 7.3 Examination processes. 7.4 Post-examination processes. 7.5 Nonconforming work. 7.6 Control of data and information management. 7.7 Complaints. 7.8 Continuity and emergency preparedness planning. 8. MANAGEMENT SYSTEM REQUIREMENTS. 8.1 General requirements. 8.2 Management system documentation. 8.3 Control of management system documents. 8.4 Control of records. 8.5 Actions to address risks and opportunities for improvement. 8.6 Improvement. 8.7 Nonconformities and corrective actions. 8.8 Evaluations. 8.9 Management reviews.

A medical laboratory seeking accreditation under the International Standard **ISO 15189:2022**, or its equivalent national or regional standard, must satisfy and show evidence of compliance with the requirements contained in the 5 sections of the table above.

These requirements include the preparation and implementation of:

- ✓ A quality manual ISO 15189:2022.
- ✓ Managerial and technical objectives and policies.
- ✓ Managerial and technical procedures.

And the generation of objective evidence of their implementation:

- ✓ Managerial and technical records.

The **Guide M-15189** is a tool that leads the user through the process of implementing the quality system **ISO 15189:2022** in your laboratory with minimal training, in a simple, orderly, reliable, compact way and in the shortest time possible.

Get a **FREE SAMPLE** of the full Quality Manual ISO 15189:2022, Procedures and Forms at **www.metrycal.com**

[Ref]: ISO 15189:2022 "Medical laboratories — Requirements for quality and competence".