

ISO 15189 - MEDICAL LABORATORIES

WHAT IS ISO 15189?

In January 2003, the International Organization for Standardization (ISO) published the world's first harmonized clinical laboratory practice standard. This standard was updated in November 2012.

Laboratories wishing to have some verification of their quality and performance have for years used ISO 17025 (General requirements for the competence of calibration and testing laboratories). While this standard provided a generic framework for a laboratory quality management system, essential elements relative to clinical laboratories were missing. Consequently, the laboratory community approached the ISO Secretariat about creating a standard specifically for the unique requirements of clinical laboratory practice.

The standard that was published is known as ISO 15189 (Medical laboratories – Particular requirements for quality and competence). Since its publication this standard has gained rapid and widespread acknowledgement and adoption in many countries.

In 2012, the third edition of ISO 15189 was published, with the intent to align it further with ISO 17025.

WHAT IS THE PURPOSE OF ISO 15189?

- Laboratories accredited to ISO 15189 are **formally recognized to be competent**, thus providing a ready means for customers to identify and select medical testing and clinical analysis services.
- Compliance to ISO 15189 aids the laboratories to determine whether they are performing their work correctly and to appropriate standards, and provides them with a **benchmark** for maintaining that competence.
- Compliance to ISO 15189 is an **effective marketing tool** for medical and clinical laboratories and a passport to submit tenders to contractors that require independently verified laboratories.

- **What is ISO 15189?**
- **What is the purpose of ISO 15189?**
- **Claiming ISO 15189 Accreditation**
- **ISO 15189 Accreditation in Malta**
- **ISO 15189 Important Aspects**



ISO 15189 - main objective is to allow laboratories to organize their operational procedures efficiently, meet the expectations of their clients and improve their service.

CLAIMING ISO 15189 ACCREDITATION

Laboratories can only claim that they are accredited to ISO 15189 if they have passed a third party assessment by the NAB-MALTA or any other Accreditation Body recognised by the NAB-MALTA.

Accreditation is a formal recognition of the competence, impartiality, integrity and performance capability of the clinical laboratory to carry out specific tests and analysis.

The list of laboratories accredited to ISO 15189 by the NAB-MALTA is published on the NAB-MALTA website. Each ISO 15189 accredited laboratory monitored by the NAB-MALTA has a unique number.

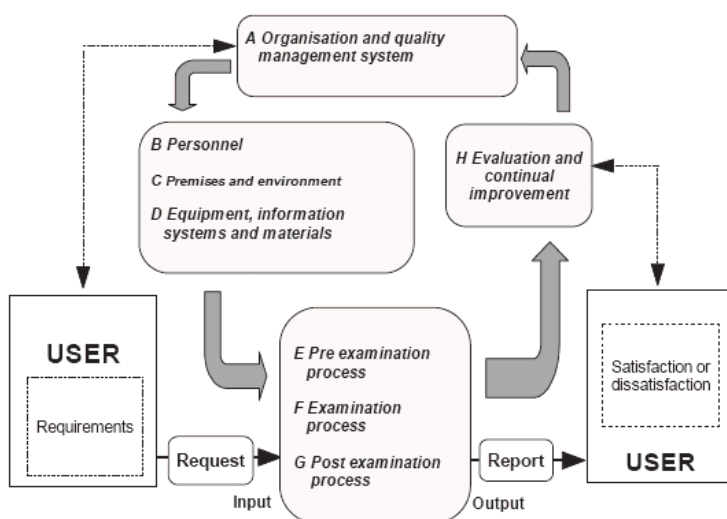
ISO 15189 ACCREDITATION IN MALTA

The Maltese accreditation authority is the National Accreditation Board (NAB-MALTA) by virtue of Legal Notice 306 of 2007. More information about ISO 15189 accreditation in Malta is available on www.nabmalta.org.mt.

ISO 15189 IMPORTANT ASPECTS

The ISO 15189 standard is divided in two major parts:

- **Management requirements:** generic requirements related to quality management systems
- **Technical requirements:** specific requirements related to activities carried out by clinical laboratories. The figure below displays the main activities covered by ISO 15189.



"This International Standard, based upon ISO/IEC 17025 and ISO 9001, provides requirements for competence and quality that are particular to medical laboratories"
- ISO



Mark uniquely identifying that a medical laboratory is accredited for ISO 15189 by NAB-MALTA.



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ISO 15189 - international template for assessing the competence of medical laboratories in their technical capacity and effective quality management