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Medical Laboratory Accreditation

Purpose and Challenges in ISO 15189 Accreditation

A white paper for medical laboratory managers.

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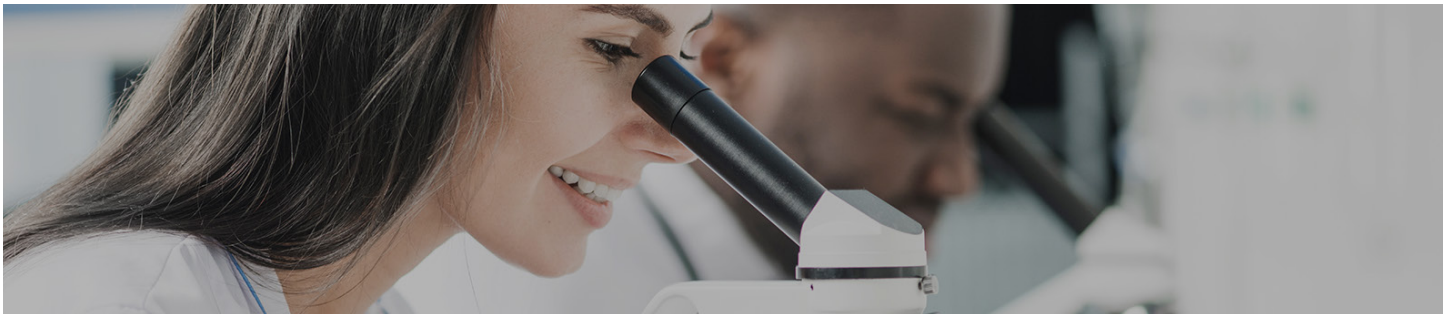
INTRODUCTION

Medical laboratories play an important role in the health care system. The results obtained from medical laboratories are critical for the detection of disease in individuals and populations as well as for the proper treatment provided to the patients. Quality management has been around for a long time, and the quality management system (QMS) model has been adapted to the medical laboratory environment through the use of international standards such as ISO 15189 (Medical laboratories–Requirements for quality & competence) to ensure the welfare of patients, including patient safety and satisfaction of users of medical laboratory services.

Laboratory quality can be defined as the accuracy, reliability, and timeliness of reported test results. To be useful, laboratory results must be as accurate as possible, all aspects of laboratory operations must be reliable, and reporting must be timely. Some significant consequences of poor quality in the laboratory can include unnecessary treatment or treatment complications, failure to provide correct treatment, delayed diagnosis, and unnecessary follow-up diagnostic testing. These consequences result in increased costs in time and work, as well as poor patient outcomes.

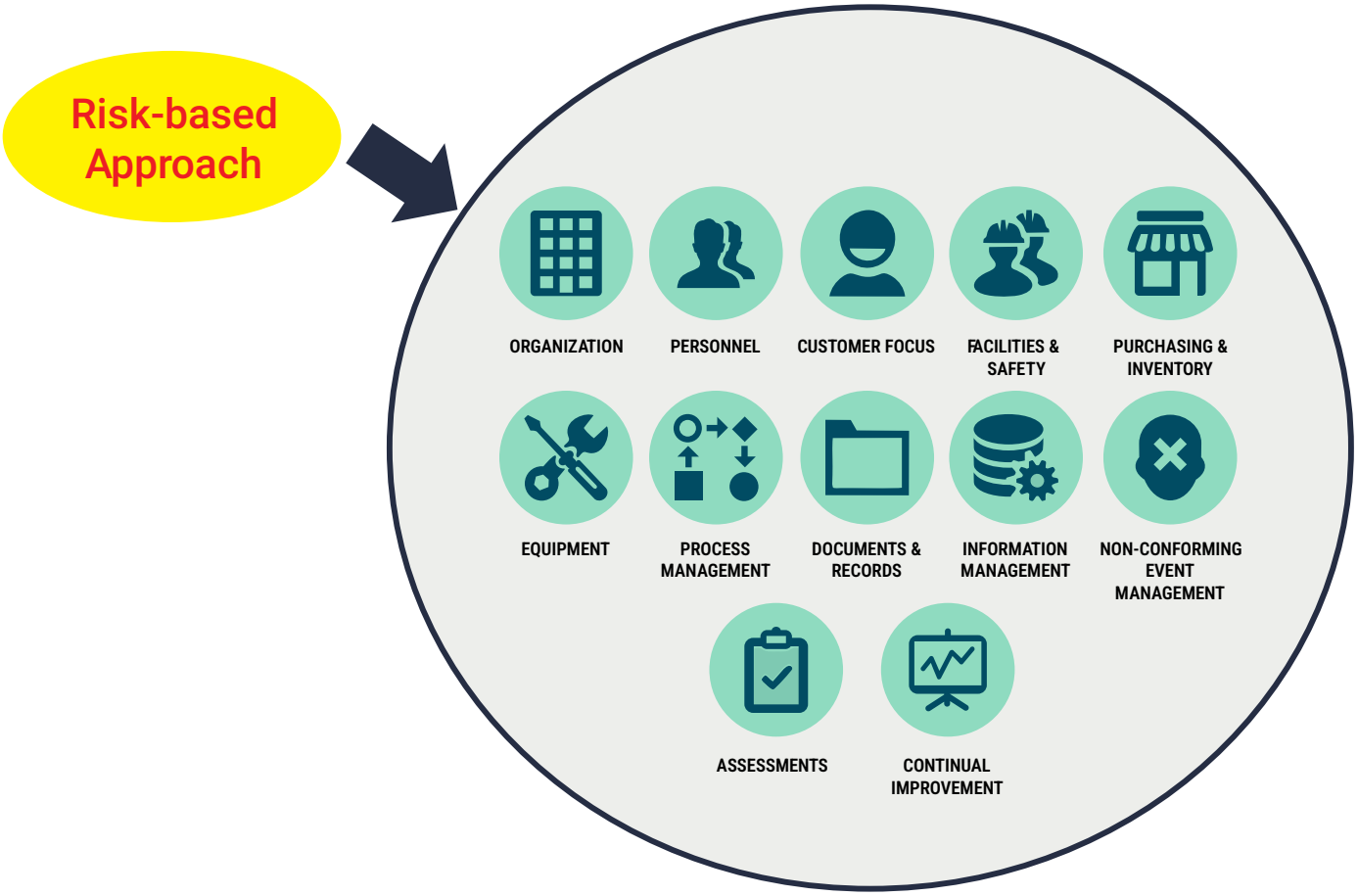
All aspects of the laboratory operation—including the organizational structure, processes, and procedures—need to be attended to in a QMS. ISO 15189 is the international standard that sets the requirements for a quality management system in a medical laboratory environment.



MEDICAL LABORATORY QUALITY MANAGEMENT SYSTEM ESSENTIALS

12 Quality System Essentials

Laboratory errors can be minimized by the implementation of an effective quality management system (QMS). The risk-based approach for all laboratory activities would help to minimize those errors. A laboratory QMS is a systematic, integrated set of activities to establish and control the work processes from pre-analytical through post-analytical processes, including resource management, conducting evaluations, and making continual improvements to ensure quality results are consistent. The new ISO 15189 standard emphasizes the incorporation of risk management into the laboratory operations.



ISO 15189 STANDARD

ISO 15189 is an international standard, prepared by the International Organization for Standardization *(popularly referred to as ISO, which brings together a worldwide federation of national standardization bodies to formulate standards)* that specifies requirements for competence and quality specific to medical laboratories and Point-of-Care Testing (POCT) to meet both the technical competence and management system requirements necessary for delivering consistently valid results.

It is based upon ISO/IEC 17025 (General Requirement for the competence of testing and calibration laboratories) and ISO 9001 (Quality management systems—Requirements) standards and deals with the important aspects and processes in a medical laboratory such as arrangements for examination requests, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, interpretation and reporting of results, etc.

The ISO 15189 standard is intended to be used in the most common disciplines of a medical laboratory *(such as radiological, microbiological, immunological, chemical, hematological, biophysical, cytological, pathological, genetic, or other examination of materials derived from the human body)* for the purpose of providing information for the diagnosis, management, prevention, and treatment of disease in, or assessment of the health of, human beings.

The ISO 15189:2022 is the new version (4th Edition) and it cancels and replaces ISO 15189:2012. This version has been technically revised by aligning with ISO/IEC 17025:2017 and includes requirements for point-of-care testing previously outlined in ISO 22870 (Point-of-Care testing (POCT)—Requirements for quality and competence).

ACCREDITATION AND ITS BENEFITS

Accreditation is by definition (ISO/IEC 17011:2017 (Conformity Assessment—Requirements for accreditation bodies accrediting conformity assessment bodies) a third-party attestation related to a conformity assessment body (such as a medical laboratory. It conveys formal demonstration of its competence to carry out specific conformity assessment tasks, such as testing.

Accreditation is:

- an effective way to demonstrate competence of the laboratory;
- a conformity assessment tool to recognize laboratories world-wide;
- linked to periodic third-party assessments;
- a means to maintain and provide continual improvement of the quality in a laboratory, which leads to high standards in services to clients (patients, health care providers, etc.).

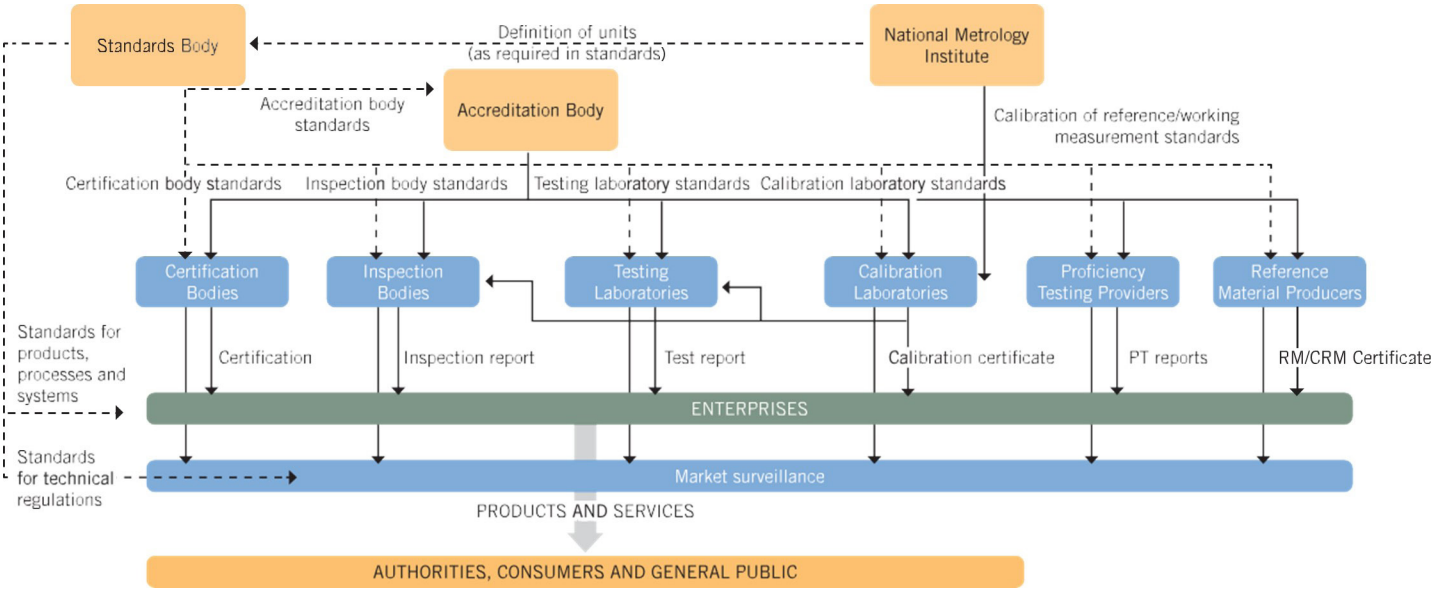
The accreditation of laboratories and POCT improves the facilitation of accurate and rapid diagnostics, enhances treatment efficiency, and reduces errors in the laboratory process. Accreditation is not solely about identifying the best laboratory; rather, it's about identifying the laboratory that has a system of compliance with required standards, documented procedures, and processes. The aim is to improve overall quality in patient safety and care.

Medical laboratories eligible for such accreditation are those offering services in biological, microbiological, immunological, chemical, hematological, biophysical, cytological, pathological, genetic, or other examinations of materials derived from the human body. The purpose is to provide information for the diagnosis, management, prevention, and treatment of diseases in, or assessment of the health of, human beings, and

which may provide consultative advisory services. These activities cover many aspects of medical laboratory testing, including the interpretation of results and advice on further confirmatory tests or investigations, when appropriate.

As mentioned above, the most recognized and accepted standard for medical laboratory accreditation is ISO 15189. While this International Standard is intended for use throughout the currently recognized disciplines of medical laboratory services, those working in other services and disciplines such as clinical physiology, medical imaging, and medical physics could also find it useful and appropriate. In addition, bodies engaged in the recognition of the competence of medical laboratories will be able to use this International Standard as the basis for their activities. If a laboratory seeks accreditation, it should select an accrediting body that operates a medical laboratory accreditation program in accordance with ISO/IEC 17011 and a signatory to ILAC MRA (mutual recognition arrangement), which takes into account the particular requirements of medical laboratories.

[The National Quality Infrastructure Chart]



Benefits of accreditation for medical laboratories include:

- ✓ International recognition
- ✓ Techniques are up to date
- ✓ Reliable and trusted results
- ✓ Confidence in the competency of staff
- ✓ Commitment for continuous improvement
- ✓ Risk mitigation measures are applied
- ✓ Traceability of measurement

CHALLENGES

On the road to accreditation, laboratories may encounter various challenges inherent in the medical industry sector, as well as related socio-economic issues and laboratory accreditation requirements that demand thorough understanding, such as:

- In developing countries, a majority of patients have to pay towards diagnostic services as an out-of-pocket expense. These services are not covered by any formal healthcare insurance support or through any social security service systems.
- Initial expenses incurred by laboratories to meet accreditation requirements may include costs that were not initially budgeted by laboratory management. These expenses could involve activities related to calibration services, quality control practices, staff training, and regular audits of their QMS, etc. While this may seem daunting, management commitment is vital to overcome this challenge.
- In some countries, many services such as high-end diagnostic services, equipment calibration or maintenance, External Quality Control Programs, and other essential services may not be readily available and would need to be imported from neighboring countries. This could result in significant taxes and service costs. Furthermore, it may necessitate patients to travel abroad for more specialized patient care, further adding to the already burdensome costs.
- Due to budgetary constraints, many reconditioned and refurbished equipment are commonly sold within many economies because they are more affordable for laboratories and hospitals. However, they often have high recurring maintenance costs, and some of this equipment may not even be supported by the original manufacturers.
- In many medical laboratories, there is a lack of consistent training and competency assessment for laboratory personnel. Given that technologies in the medical field are constantly being upgraded and improved, it's crucial to ensure that personnel receive ongoing training to effectively manage patient care.
- Many medical laboratory practitioners offer consulting services to multiple diagnostic centers, hospitals, or other private agencies. This business-oriented approach in healthcare can potentially compromise the quality of services, as many of these consulting practitioners move between laboratories primarily to sign patient reports or release batches of reports.
- Patients and users of the diagnostic services are often not educated about the benefits of accreditation.
- A pricing and incentive-based system is still in practice within the medical industry.
- There is a growing need for competent medical personnel to serve in both urban and rural sectors. Moreover, most rural areas are struggling without basic medical consultation and testing facilities.
- In many countries, government-established laboratories are exempt from the accreditation process, raising concerns about the lack of checks and balances and the promotion of unfair competition in the marketplace. Further, many local Accreditation Bodies do not offer medical laboratory accreditation services.

CONCLUSIONS

- Implementation of ISO 15189 standard requirements improves the overall quality of laboratories and ensures the delivery of accurate results consistently, not only for the tests under the scope of accreditation, but all tests performed in the laboratory.
- Accredited medical laboratories will be able to demonstrate their competence to their users and society.
- Implementation of the ISO 15189 standard improves patient safety and increases customer satisfaction.
- There are a number of challenges that a laboratory must overcome on the road to accreditation.
- If management commitment and resources are available, ISO 15189 compliance is an achievable and sustainable goal.

AUTHORS

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International Accreditation Service

The International Accreditation Service (IAS) is a nonprofit, accreditation body, headquartered in Brea, California, USA. IAS has been providing accreditation services since 1975. IAS is a member of the ICC Family of Solutions. IAS is signatory to APAC MRA and ILAC MRA for medical laboratories. IAS accredits a wide range of companies and organizations including governmental entities, commercial businesses, and professional associations. IAS accreditation programs are based on recognized national and international standards that ensure domestic and/or global acceptance of its accreditations.

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