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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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# MEDICAL LABORATORY ACCREDITATION PURPOSE AND CHALLENGES IN ISO 15189 ACCREDITATION

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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 detection of disease in individuals and populations as well as for the proper treatment provided to the patients. Quality management has been around for 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.

Laboratory quality can be defined as accuracy, reliability, and timeliness of reported test results. To be useful, laboratory results must be as accurate as possible, all aspects of the 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 cost 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 Systems Essentials

Laboratory errors can be minimized by the implementation of an effective quality management system (QMS). 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, conduct evaluations, and make continual improvements to ensure quality results are consistent.





## ISO 15189 STANDARD

ISO 15189 is an international standard, prepared 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 that are specific for medical laboratories to meet both the technical competence and management system requirements necessary for delivering consistent technically valid results.

It is based upon ISO/IEC 17025 and ISO 9001 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.

This standard is intended to be used in the most common disciplines of a medical laboratory (*such as radiological, microbiological, immunological, chemical, immunohaematological, haematological, 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.

ISO 15189 is now on its third edition (2012) and undergoing revision at the time this document was prepared.

## ACCREDITATION AND ITS BENEFITS

Accreditation is by definition (ISO/IEC 17011:2017), a third-party attestation related to a conformity assessment body (such as a medical laboratory) conveying 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 periodical third-party assessments;
- Assist 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 labs improves facilitation of accurate and rapid diagnostics, efficiency of treatment and reduction of errors in the laboratory process. Accreditation is not about identifying the best laboratory but identifying the laboratory which has a system of compliance to the required standard's documented procedures and processes with the aim to improve overall the quality in patient safety and care.

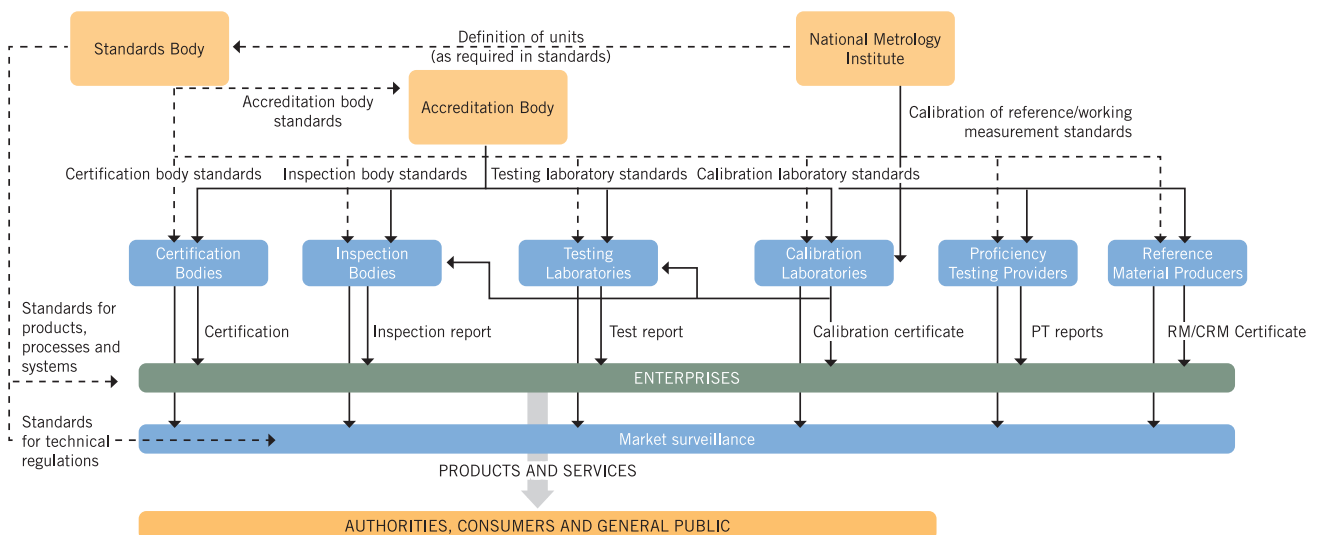
Medical laboratories that are eligible for such accreditation are the ones offering services in the biological, microbiological, immunological, chemical, immuno-haematological, haematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body. The purpose is to provide information for the diagnosis, management, prevention and treatment of disease in, or

assessment of the health of, human beings, and which may provide a consultative advisory service. 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 which operates a medical laboratory accreditation program in accordance with ISO/IEC 17011 and which takes into account the particular requirements of medical laboratories.

Some of the other organizations that have separate conformity accreditation processes which use scheme, national or international standards are the Joint Commission International (JCI), SLIPTA –WHO, Clinical Pathology Accreditation (CPA) in UK, College of American Pathologists (CAP) in USA, CCKL Code of Practice in the Netherlands, etc.

**The National Quality Infrastructure**



Source: World Bank with Revisions from IAS.



Some benefits of accreditation for Medical Laboratories and users are:

- 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, a laboratory may come across a number of challenges existing within the medical industry sector, related socio-economic issues and laboratory accreditation requirements that would require understanding, such as:

- In developing countries majority of patients have to pay towards diagnostic services as an out of pocket expense. Expenses towards diagnostic services in these countries, are not covered by any formal healthcare Insurance support or through any social security service systems.
- Initial expenses towards meeting the requirements for accreditation by the laboratories may include costs not budgeted by the laboratory management for activities related to calibration services, quality control practices, training of their staff, regular audits of their QMS etc. This may be daunting but Management commitment is vital to overcome this challenge.
- In some countries many services such as high-end confirmatory testing, calibration or maintenance of equipment, External Quality Control Programs, and other services are not available and will need to be imported from neighboring countries for which huge taxes and service costs can be incurred. This may even require patients to travel abroad for more skilled patient care adding to the already burdening costs.
- Due to budgetary reasons, many reconditioned and re-fabricated equipment is sold within many economies simply because they are more affordable to laboratories and hospitals, however these have a high recurring maintenance cost. Some of this equipment may not even be supported by the original manufacturers.
- There is no consistent training and competency assessment of laboratory personnel in many medical laboratories. The technologies in the medical area are constantly being upgraded and improved. These need to be delivered downstream to personnel for better management of patient care.
- Many medical laboratory practitioners consult to more than one diagnostic center, hospital or other private agencies. This leads to a business approach in health care resulting in potentially compromising the quality of services with many of these consultant practitioners moving between laboratories to simply sign patient reports and/or release batches of reports.
- Patients and users of the diagnostic services are not educated in the benefits of accreditation.



- 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 many urban and rural sectors. More importantly, most rural areas are struggling without basic medical consultation and testing facilities.
- In many countries the Government established laboratories are waived from the process of accreditation thus raising an issue of lack of check and balance and promotion of unfair competition in the marketplace. Further, many local Accreditation Bodies are not offering the medical laboratory accreditation services.

## CONCLUSIONS

- Implementation of ISO 15189 standard requirements, improves the overall quality of laboratories, 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 the society.
- 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.

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### 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 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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