ISO 15189 ACCREDITATION FOR MEDICAL LABORATORIES

WHITE PAPER

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WHAT IS ISO 15189?

ISO 15189 Medical laboratories — *a Particular requirement for quality and competence specifies* the quality management system requirements particular to medical laboratories.

The standard was developed by the International Organization for Standardization. General requirements for the competence of testing and calibration laboratories. This working group included provision of advice to users of the laboratory service, the collection of patient samples, the interpretation of test results, acceptable turnaround times, how testing is to be provided in a medical emergency and the lab's role in the education and training of health care staff.

While the standard is based on ISO/IEC 17025 and ISO 9001, it is a unique document that takes into consideration the specific requirements of the medical environment and the importance of the medical laboratory to patient care.

BENEFITS OF ISO 15189

1. NATIONAL & INTERNATION RECOGNITION.
2. RECOGNIZES THE TECHNICAL COMPETENCE OF LABORATORY STAFF.
3. ASSURES THE CLIENT THAT RESULTS ARE TECHNICALLY VALID.
4. PROVIDES COMPARABILTY IN MEASUREMENTS.
5. DECISION MAKERS CAN RELY ON TEST RESULT.
6. IMPROVES STAFF MOTIVATION.
7. ENSURES BETTER SUPPORT IN THE EVENT OF LEGAL CHALLANGE.
8. TO ASSIST IN THE DEVELOPMENT OF NEW PROGRAMMES.
9. TO REDUCE TECHNICAL BARRIERS IN TRADE.
10. SAVES MONEY BY GETTING IT RIGHT FIRST TIME.

What does QuickISO.com Offers in the field of ISO 15189 MEDICAL LABORATORIES?

The medical laboratory quality management professionals at Quick ISO, have considerable experience helping our clients to design and implement ISO 15189 Medical laboratory. In addition to planning, development, and implementation, we help our clients cooperatively work with ISO 15189 accreditation organizations - National Accreditation Board for Laboratories - DAC.
QuickISO offers comprehensive services that will help you achieve your ISO 15189 quality goals. We can:

- Conduct an initial gap analysis
- Help you establish policies and objectives.
- Identify documentation requirements
- Coordinate document preparation, reviews, approvals, and issuance.
- Manage implementation schedules, training, follow-up actions
- Help you select a Registrar that has experience in your industry and achieve successful accreditation.

In addition to consulting (onsite and online), we provide following training

- "ISO 15189 Overview Training"
- "ISO 15189 for the Small Laboratory"
- "Developing Your Laboratory Quality System Documentation"
- "Internal Auditor training"
- "Estimation of Measurement Uncertainty"
- “ISO 15189 implementation training”

GENERAL REQUIREMENTS FOR THE ISO 15189

Quality system requires implementation of two sets of requirements/standards and activities.
The essential components are :

☐ Management requirements[Clause 4]
☐ Technical requirements [Clause 5]

MANAGEMENT REQUIREMENTS

4.1: Organisation and Management
4.2: Quality Management System
4.3: Document Control
4.4: Review of Contracts
4.5: Examination by Referral Laboratories
4.6: External Services and Supplies
4.7: Advisory Services
4.8: Resolution of Complaints
4.9: Identification and Control of Nonconformities
4.10: Corrective Action
4.11: Preventive Action
4.12: Continual Improvement
4.13: Quality and Technical Records
4.14: Internal Audits
4.15: Management Review

TECHNICAL REQUIREMENTS

5.1. Personnel
5.2. Accommodation and environmental conditions
5.3. Lab equipment
5.4. Pre-examination procedures
5.5. Examination procedures
5.6. Assuring quality of examination procedures
5.7. Post-examination procedures

5.8. Reporting of results

Measurement of uncertainty is a requirement of the ISO/IEC 15189 standard. When estimating the uncertainty of measurement , all uncertainty components which are of importance given situation shall be taken into account:
1. Reference stds. and reference materials with reported uncertainty in the calibration certificate.
2. Method employed.
3. Equipment used with reported uncertainty in the calibration certificate.
4. Environmental conditions.
5. Properties and condition of the item being tested/calibrated.

INTERLABORATORY TEST PROGRAM/ PROFICIENCY TESTING & METHOD VALIDATION

It is the one of the powerful method of checking the validate of the test and / or calibration results.

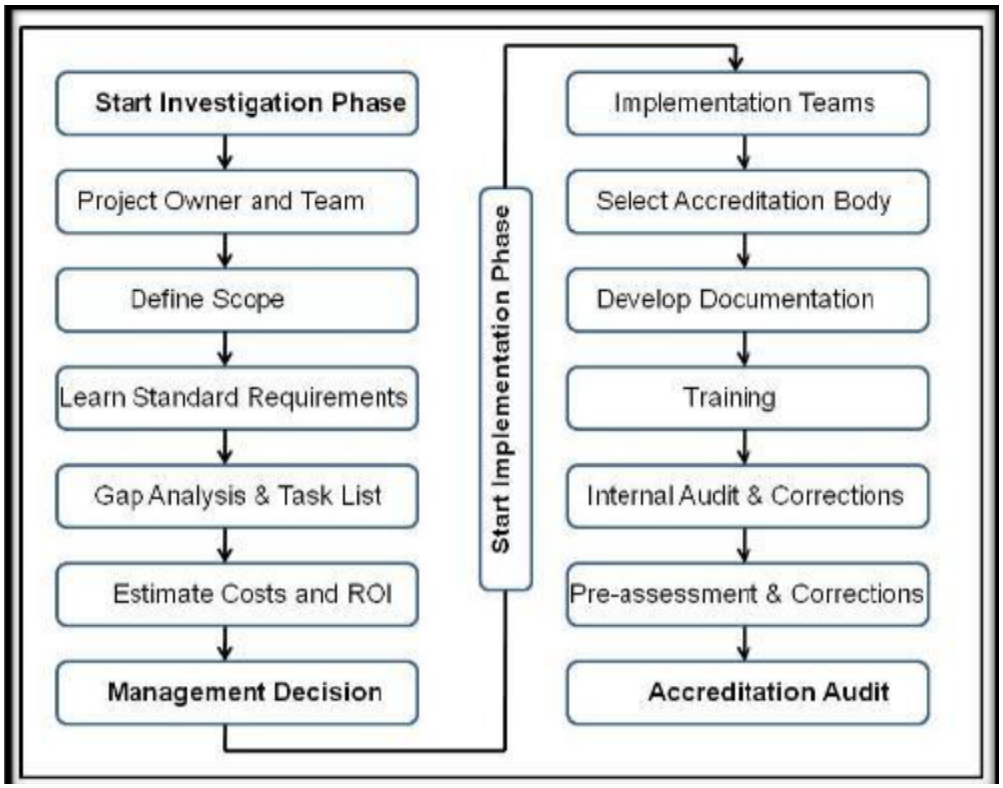
All DAC accredited testing and calibration laboratories are required to participate in proficiency testing programmes conducted by DAC or the nodule organizations appointed by DAC.

Key steps towards accreditation are:

ISO 15189 accreditation should be well thought out and well prepared. It can be quite expensive but can also have big benefits. The balance between costs and benefits should be worked out and documented.
Going for ISO 15189 will impact the entire laboratory and supporting services such as human resources, documentation and finance departments. Therefore, while the decision to initiate and fund the project will be made by management, all affected departments should be involved in the process.

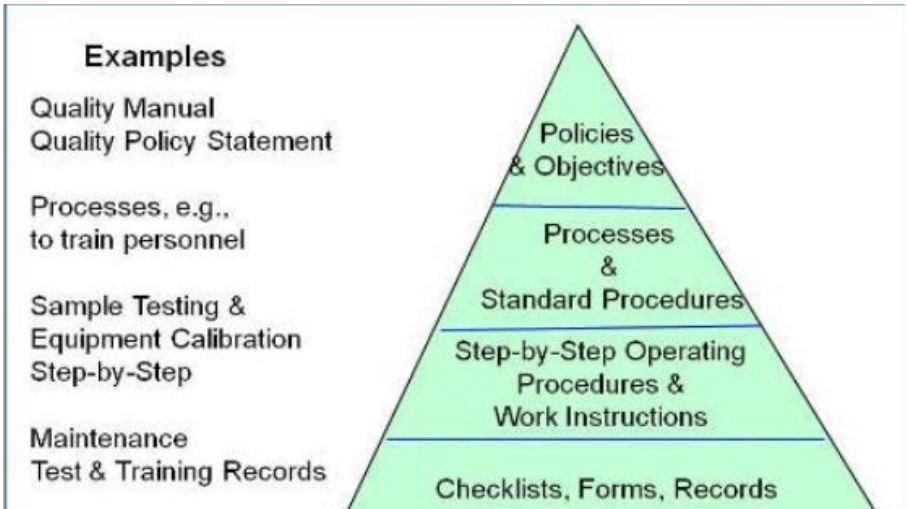
The entire process is divided into two phases: Investigation phase and implementation phase. In the investigation phase information is collected to decide if going for accreditation makes business sense. Once the decision is made the laboratory develops and implements documentation in preparation for the accreditation assessment.

Accreditation Process:



Documentation

ISO/IEC requires different types of documentation as illustrated in the documentation pyramid below.



- A policy documents the laboratory intent and goal of the laboratory to conform to ISO /IEC requirements.
- Quality manual describes the approaches to achieve quality data. It includes quality policy.
- A process describes how various quality requirements can be achieved.
- Standard operating procedures or working procedures are step by step instructions on how to exactly perform a specific task.
- Records are generated on day by day basis.
- All records should be well controlled.