LANCET LABORATORIES
Rwanda

Some history

The development of ISO 15189:2012 was motivated by the recognition of the crucial role that medical laboratories play in the diagnosis, treatment, and monitoring of disease. With the growing demand for high-quality laboratory services, the standard was created to provide a framework for ensuring consistent quality and competence in the delivery of these services.
The ISO 15189:2012 standard covers all aspects of laboratory operations, from pre-analytical processes to reporting of test results, and provides a basis for accreditation by a recognized accreditation body. The standard is intended to benefit both medical laboratories and the patients they serve and is now widely recognized as the benchmark for quality and competence in medical laboratory services.

What does ISO15189:2012 mean for a diagnostic laboratory?

ISO specifies the general requirements for quality management systems, as well as the technical and organizational requirements for the pre-examination, examination, and post-examination processes. The purpose of ISO 15189:2012 is to ensure that medical laboratories provide accurate, reliable, and timely results to their clients and that the laboratory's services meet customer requirements. Adherence to ISO 15189:2012 is a way for a diagnostic laboratory to demonstrate our commitment to quality and to assure patients and healthcare providers of our laboratory's competence.

What are the obligations of our laboratory-accredited ISO 15189?

Our ISO 15189:2012 accredited laboratory has several obligations to maintain its certification. By meeting these obligations, our laboratory ensures that it consistently produces accurate and reliable results, which is critical for our patient's care.

1. Implementing and maintaining a quality management system (QMS) that meets the requirements of ISO 15189:2012
2. Ensuring that all personnel are competent and trained to perform their designated tasks.
3. Regularly monitoring and measuring the performance of the laboratory's processes
4. Ensuring that laboratory equipment is properly maintained and calibrated.
5. Maintaining accurate records and documentation of all laboratory activities.
6. Regularly conducting internal and external audits to assess the effectiveness of the QMS.
7. Continuously improving the QMS through regular review and assessment
8. Cooperating with accreditation bodies for periodic assessments and assessments of significant changes in the laboratory

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What does it mean for our HealthCare provider customers?

We strive to demonstrate our commitment to quality and ensure that our products and services that meet our Healthcare provider customers' high levels of expectations and requirements.

Quality assurance (QA) is a set of practices and processes that are deployed by rigorous implementation of:

1. **Quality management systems that outline the processes and procedures for ensuring consistent quality in products and services.**

   a. Documented policies and procedures for quality control and quality assurance.
   b. Designated roles and responsibilities for quality management.
   c. Documentation of customer requirements and expectations.
   d. Processes for controlling and verifying the quality of products and services.
   e. Monitoring and measurement systems for tracking and analysing performance data.
   f. Continuous improvement processes for evaluating and improving the QMS.

2. **Testing and inspecting products and services to identify and address potential quality issues before they reach customers.**

3. **Supplier management to ensure that the raw materials and components used in products meet quality standards.**

4. **Gathering and incorporating feedback from customers to continuously improve the quality of products and services.**

5. **Regularly reviewing and updating processes and procedures to continuously improve the quality of products and services.**

Why do we keep trainning and upskilling our personnel?

You have the guarantee that our trained personnel will perform their duties correctly, reducing the risk of errors and inaccuracies, which improves accuracy. Our personnel are equipped to consistently deliver high-quality products and services and are typically more efficient and productive.

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When audited, our personnel competencies are meticulously assessed:

1. **Education and training to ensure that they have the knowledge and skills required to perform their duties accurately and effectively.**
2. **Competence evaluation to evaluate the competence of personnel, including performance evaluations and proficiency testing.**
3. **Continuing education, policies, and practices to ensure that personnel continue to develop their knowledge and skills through ongoing training and education.**
4. **Job descriptions to ensure that they accurately reflect the responsibilities and competencies required for each role.**
5. **Performance monitoring and methods used to monitor the performance of personnel, including regular performance evaluations and assessments.**

This assessment attests that our laboratory has the personnel resources it needs to produce accurate and reliable results and to provide high-quality patient care.

How do we obtain and maintain an ISO 15189:2012 accreditation?

The ISO 15189:2012 auditing process assesses the laboratory's quality management system and processes to ensure that we meet the requirements of the **ISO 15189:2012** standard. During an **ISO 15189:2012** audit, the auditor will typically assess the following areas:

1. **Quality management system to ensure that it is documented, implemented and maintained effectively.**
2. **Personnel competence and training personnel to ensure that they are equipped to perform their duties accurately and effectively.**

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3 **Equipment and facilities to ensure that they are appropriate for the tests being performed and are well-maintained and calibrated.**

a. Suitability of equipment and facilities to ensure that they are appropriate for the tests being performed and meet the laboratory's requirements.
b. Maintenance and calibration to ensure that equipment is well-maintained and calibrated and that the laboratory produces accurate and reliable results.
c. Record keeping practices to ensure that records of maintenance, calibration, and repairs are complete, accurate, and consistent with international standards.
d. Laboratory's processes for validating equipment, including the methods used for verifying the performance of equipment, and the procedure for verifying that equipment is suitable for its intended use.
e. Quality control processes to ensure that they include checks on the performance of equipment and that equipment is regularly tested and monitored to ensure that it is producing accurate and reliable results.

4 **Sample management and laboratory processes, including the collection, storage, and transport of samples, to ensure that they meet quality standards.**

5 **Test methods and procedures to ensure that they are validated, accurate, and consistent with international standards.**

6 **Quality control processes to ensure that they are implemented effectively and that the results of quality control tests are recorded and analysed accurately.**

Cerba Lancet Africa Group accreditations on the continent

- The Kenya Accreditation Service (KENAS) is based in Kenya.
- The Southern African Development Community Accreditation Services (SADCAS) is based in Botswana.
- The South African National Accreditation System (SANAS) is based in South Africa.

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