

Complimentary Educational Webinar: ISO Accreditation: New Trends and Global Differences

Questions and Answers Forum

Questions from Chat window:

Q1: What about the Point of Care testing procedure accreditation in India?

Ans: POCT procedure accreditation for medical testing comes under ISO 15189:2012.

Q2: Do you recommend that we try to have certification ISO 9001 before obtaining 15189 accreditation?

Ans: ISO 15189:2012 is developed from ILAC Guide 25, ISO 17025 and ISO 9000. So, ISO 15189:2012 accreditation is one needed for Medical Laboratories Quality & Competence.

ISO 9001 is not very appropriate for lab medicine, you should rather try ISO 17025 accreditation (Verification of result quality only) before 15189 accreditation (affects many responsibilities to the lab director, it also includes requirements about personnel security and advisory services, guidelines for ethics and informatics).

Q3: Are there any recommendations apart from ISO 15189 for microbiological testing?

Ans: For microbiology, we follow the European recommendations from EUCAST. We have some joint recommendations from our scientific society and EUCAST and some national documents (please refer to the SFM website at <http://www.sfm-microbiologie.org/> for more information).

The **International** organisations working to develop the **Standards** are:

ISO(International Organization for Standardization), **CLSI**(Clinical and Laboratory Standards Institute), **CEN**(European Committee for Standardization), **WHO**(World Health Organization).

Many **National Agencies** are also working to develop standards are:

BLQS (Bureau of Laboratory quality standards, Thailand), **CLIA** (Clinical laboratory improvement amendments, USA)

Medical Laboratory Accreditation is widely accepted through **ISO 15189:2012** and **CAP** (College of American Pathologists)

Comment: Thanks for the great updates please include statistics from african countries also. Very well organized.

Ans: Thanks for suggestions. We will work in this direction as well.

Q4: What is the difference between testing and medical laboratory?

NABL, India provide accreditation in all major fields of Engineering & Medical Testing such as,

Testing Facilities: Biological, Chemical, Electrical, Electronics, Mechanical, Fluid-Flow, Non-Destructive, Photometry, Radiological, Thermal & Forensics

Calibration Facilities: Electro-Technical, Mechanical, Fluid Flow, Thermal, Optical & Radiological

Medical Testing Laboratories: Clinical Biochemistry, Clinical Pathology, Haematology, Immunohaematology, Microbiology & Serology, Histopathology, Cytopathology, Genetics, Nuclear Medicine (*in-vitro tests only*)