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Laboratories & Accreditation

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❖ Standard

- A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products ...

https://www.iso.org/standards.html

History of standards

- The Engineering Standards Committee was established in London in 1901 as the world's first national standards body.
- It subsequently extended its standardization work and became the British Engineering Standards Association in 1918, adopting the name British Standards Institution in 1931 after receiving its Royal Charter in 1929.

"BSI Group Annual Report and Financial Statements 2010" (PDF). p. 2. Retrieved 3 April 2012.

McWilliam., Robert C. (2001). BSI: The first hundred years. London: Thanet. ISBN 978-0727730206.

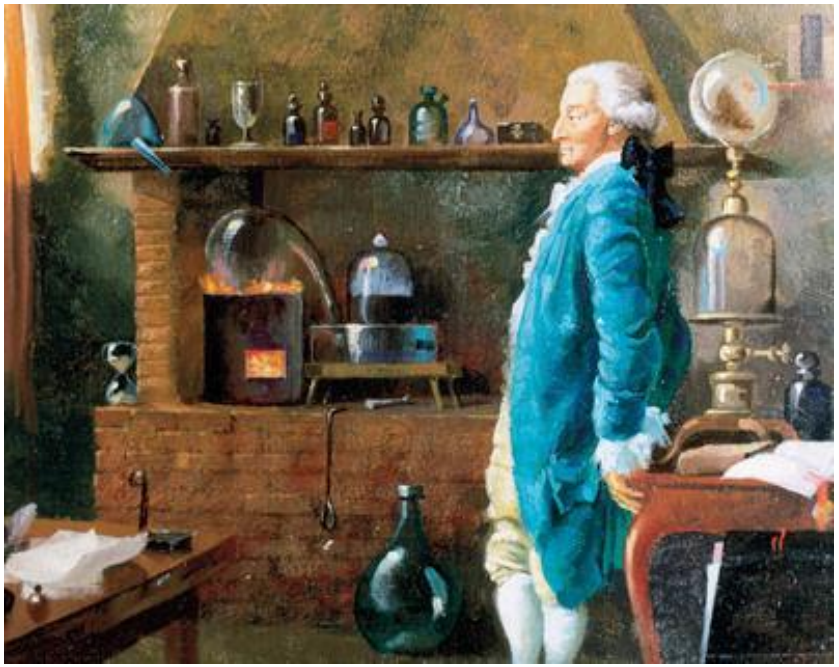
➢ Accreditation

- Accreditation is a process in which certification of competency, authority, or credibility is awarded.
- Accreditation is a process of validation in which, laboratories, industrial companies, management companies, colleges, universities and other institutions of higher learning are evaluated.
- The standards for accreditation are set by a peer review board whose members include faculty from various accredited colleges and universities.
- Moreover, Medical laboratories are the key partners in patient safety.
- Quality of laboratory service is the major factor which directly affects the quality of health care.
- The clinical laboratory as a whole has to provide the best patient care promoting excellence. International Standard ISO 15189, based upon ISO 17025 and ISO 9001 standards, provides requirements for competence and quality of medical laboratories.

History of Accreditation

- Higher Education accreditation in the United States was developed "to protect public health and safety and to serve the public interest."

- The first regional accrediting agencies formed in the 1880s with particular focus on educational standards and admissions procedures.



- who had a large influence on both the history of chemistry and the history of biology.

Antoine Lavoisier was central to the eighteenth-century chemical revolution. *Image: Tarker/Bridgeman*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ISO

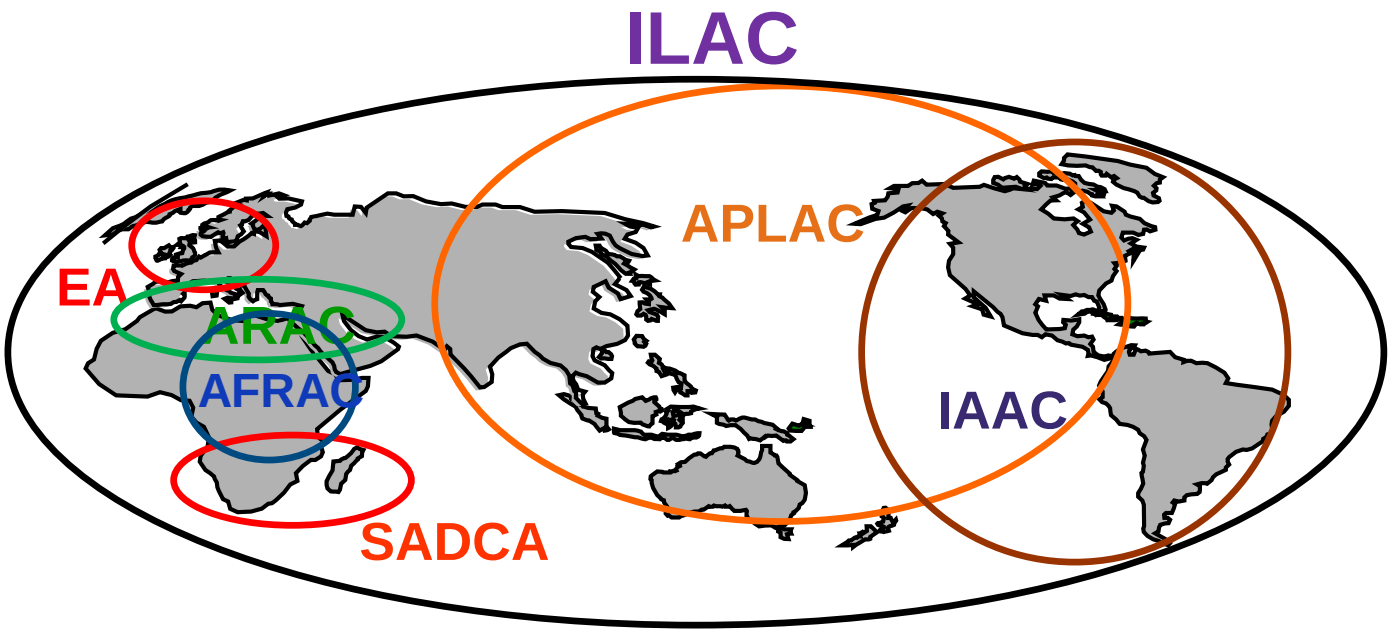

IfIA
International Federation
of Inspection Agencies


UKAS


نظام الإعتماد العراقي
IRAQI ACCREDIATION SYSTEM
IQAS


The American Association
for Laboratory Accreditation
"World Class Accreditation"


CAP
ACCREDITED
COLLEGE of AMERICAN PATHOLOGISTS



ILAC	International Laboratory Accreditation Cooperation
APLAC	Asia Pacific Laboratory Accreditation Cooperation
EA	European co-operation for Accreditation
IAAC	Inter-American Accreditation Cooperation
SADCA	Southern African Development Cooperation for Accreditation
AFRAC	African Accreditation Cooperation
ARAC	Arab Accreditation Council

With the large number of Accreditation Bodies

Patients' Care nowadays is a very huge concern

Lack of Inaccurate Lab Results/ Diagnosis

IMPORTANCE OF MEDICAL LABORATORY

- Medical laboratories are critical part of healthcare system.
- A patient's diagnosis and treatment are often based on test results and incorrect test results could lead to misdiagnosis which could have potentially fatal consequences.
- This is why accurate test results are critical - each and every time the tests are conducted.

ISO 15189
Medical Laboratory Accreditation

❖ Medical Device Certification (ISO 13485)

❖ Medical Laboratory accreditation to ISO 15189

- ISO 15189 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

➢ Scope

- This International Standard specifies requirements for quality and competence in medical laboratories.
- This International Standard can be used by medical laboratories in developing their quality management systems and assessing their own competence.
- It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities and accreditation bodies.

➢ Medical Laboratory Accreditation to ISO 15189

- Accreditation to ISO 15189 involves the independent assessment of a laboratory to determine **competence**, **impartiality** and **consistency**. It addresses the qualifications and on-going competency of personnel involved in medical laboratory examinations, the laboratory accommodation, equipment, re-agents and supplies, pre-analytical and analytical factors, quality assurance considerations, and post-analytical factors.

- **Specialist scientific and clinical assessors, with expertise in the relevant discipline of practice, conduct a thorough evaluation of all factors in the laboratory that affect the production of test data, including:**

- technical competence of staff;
- validity and appropriateness of test methods, including pre and post analytical elements such as sample collection and clear and effective reporting;
- sample quality, including patient identification, handling and transport to maintain sample integrity;
- a review of the history relating to previous patient results and any known clinical diagnoses;
- procedures relating to the use of “referral laboratories” such as specialised testing centres for specific diseases;
- traceability of measurements and calibrations to relevant standards;
- suitability, calibration and maintenance of test equipment;
- testing environment;
- quality assurance of test data;
- acceptable turnaround time;
- application of appropriate ethical values.

❖ Accreditation to ISO 15189 places five additional critical criteria on medical laboratories which include:

- providing advice on the type of sample, and testing that may be required;
- interacting with clinical staff by placing a responsibility on the laboratory to liaise with clinicians who refer patient samples for testing about the quality of their service;
- providing opinions on results of testing in relation to diagnosis and patient care;
- collecting samples or if not, providing information on collection procedures, sample containers and sample volumes;
- ethical practice – first duty is to the patient, not to the ‘customer’.

PT

- To ensure continued compliance, accredited laboratories are regularly reassessed to check that they are maintaining their standards of technical expertise. These laboratories will also be required to participate in regular proficiency testing programs (known as external quality assurance programs or EQAS) as an on-going demonstration of their competence.

Medical / Clinical laboratory

Scope of medical testing laboratories may cover the following areas:

1.Microbiology, Mycology, Virology, Parasitology, Bacteriology

2.Chemistry; Routine chemistry, Endocrinology, Toxicology,

3.Urinalysis

4.Hematology

5.Pathology; Histopathology, Cytology

6.Immunohematology

7.Diagnostic Immunology

8.Clinical Cytogenetics

9.Molecular Genetics

10.Others

What is CAP accreditation?

The CAP Laboratory Accreditation Program is an internationally recognized program that helps laboratories achieve the highest standards of excellence to positively impact patient care. The goal of the CAP Laboratory Accreditation Program is to improve patient safety and patient care by advancing the quality of pathology and laboratory services through medical education and laboratory standardization.

❖ How is CAP accreditation awarded?

- The program is based on rigorous accreditation standards that are translated into detailed and focused checklists of regulatory requirements that laboratories have to meet or exceed.

- These checklists provide quality practice standards for laboratories to follow, and are used by the inspection teams as a guide to assess the overall management and operation of the laboratory.

- Upon successful completion of the inspection process, the laboratory is awarded CAP accreditation for 2 years and becomes part of an exclusive group of more than 7,000 laboratories worldwide that have met the highest standards of excellence.

- This thorough inspection is repeated every 2 years and if all requirements are met accreditation is awarded again.

Lab Accreditation
Benefits to the Customers/Users

- Increased confidence in reports
- Rights of patients are respected and protected
- Savings in terms of time and money as it reduces or eliminates the need of re-testing.
- International Recognition
- Benchmark with best laboratories
- It raises community confidence in the services provided by the laboratory.
- It encourages medical tourism.
- Finally, Accreditation provides an objective system of empanelment by insurance and other third parties.

Thank you