

Content Sheet 11-1: Overview of Norms and Accreditation

Role in quality management system

Assessment is the means of determining the effectiveness of a laboratory's quality management system. Standards, as well as other normative documents that provide guidelines, form the basis for assessment. They may be developed at international, national or local level.

Organizations that establish norms or standards, and that provide for accreditation or certification of laboratories, play a vital role in the assessment process.



Overview of the process

An important way for a laboratory to be recognized as delivering accurate and reproducible results is to go through evaluation or assessment processes conducted by a credible, qualified organization. Successful completion of this process gives the laboratory recognition that it is in compliance with the quality standards and norms used for the assessment.

Responsibilities

Laboratory directors need to be aware of the importance of gaining accreditation, certification and licensure, by implementing international or national standards, in line with the scope of laboratory activities, and in accordance with national legislation. A major duty of laboratory managers should be to seek information about appropriate norms and standards, and about accreditation and certification processes, so that these can be used to provide better service.

Quality managers must convey to the laboratory staff the need for compliance with standards, whether international or national. The quality officer will explain the process for meeting standards, and will organize and prepare the laboratory for assessments.

Laboratorians must be aware of requirements of the chosen standards, contribute to the development of tasks for meeting standards, be aware of assessment processes, and help to assure readiness for assessment processes.

Content Sheet 11-2: International Standards and Standardization Bodies

Definitions

Normative document—a document that provides rules, guidelines or characteristics for activities or their results. It covers such documents as standards, technical specifications, codes of practice and regulations.¹

Standard document—a document established by consensus and approved by a recognized body, that provides for common and repeated use, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.²

Regulation—any standard that is mandated by a governmental agency or authoritative body.

Standards may be developed internationally, nationally, or locally. Compliance to a standard may be required by government or another authoritative body, or may be voluntary.



Standards developed internationally may have the broadest consensus or agreement, but may be less specific. Standards developed locally may have the highest degree of applicability, but may not be useful for comparison with other regions or countries.

Standardization bodies

Examples of international organizations are given below.

- **ISO (International Organization for Standardization)**
ISO is the world's largest developer and publisher of international standards, and ISO standards are applicable to many kinds of organizations including clinical and public health laboratories.

ISO is a network of the national standard institutes of 157 countries, one member per country, with a Central Secretariat in Geneva, Switzerland that coordinates the system. It is a non-governmental organization, and it forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries or have been mandated by government. However, many members have roots uniquely in the private sector, having been set up by national partnerships of industry associations. Therefore, ISO enables a consensus to be reached on solutions that meet both the requirements of business and the broader needs of society.

The work of preparing standards is conducted by ISO technical committees. Each member body has the right to be represented on the

^{1&2} ISO/IEC Guide 2:1996 (EN 45020:1998) Standardization and related activities - General vocabulary

committees. International organizations, both governmental and non-governmental, also take part in the committee activities. Draft international standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

- **CLSI (Clinical and Laboratory Standards Institute)**
CLSI is a global, non-profit, standards-developing organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community. CLSI documents are developed by experts working on subcommittees or working groups under the direction and supervision of an area committee. Development of CLSI standards is a dynamic process. Each CLSI area committee is committed to producing consensus documents related to a specific discipline, as described in its mission statement.
- **CEN (European Committee for Standardization)**
CEN was founded in 1961 by the national standards bodies in the European Economic Community and associated countries. The general terms include openness and transparency, consensus, and integration.

Formal adoption of European Standards is decided by a weighted majority vote of the CEN national members and is binding on all of them. The responsibilities are shared between 30 national members from each country, 7 associate members, and 2 counselors, as well as the CEN Management Centre in Brussels.

- **WHO (World Health Organization)**
WHO has developed several standards for disease-specific diagnostic laboratories. One example is polio, where accreditation is required in order for a laboratory to participate in the Polio Network for Eradication of Poliomyelitis. Seven criteria have been selected, including, among others, a minimum activity of 150 samples annually, successful participation in proficiency testing, and accuracy and timeliness of reports of cases to the network.

Content Sheet 11-3: National Standards and Technical Guidelines

Country-specific standards

Standards may be developed within a country to apply only to national use. These may be created by governmental organizations, or may also be developed by a recognized body with a specific area or domain for application.

In some instances, national standards have been developed based on an international standard such as ISO, and adapting this standard to the culture and general condition of the country.

Guidelines

Guidelines are developed in a variety of situations. Usually ISO standards need more technical guidance for actual implementation in laboratories and in countries. Several national and international organizations have developed those guidelines.

Another use for guidelines is to address a specific kind of testing, or to provide guidance for certain parts of the laboratory. For example, there may be guidelines for performance of HIV rapid testing, or guidelines for obtaining the appropriate biological safety cabinet for the testing being conducted.

Examples

Many national guidelines and standards have been developed. Some examples include the following.

- **GBEA (Guideline for Good Analysis Performance), France**
French legislation created these guidelines to assure the quality of the services offered by the French laboratories in 1994. It was revised in 1999 and 2002. All clinical laboratories in France are required by law to comply with GBEA.
- **BLQS (Bureau of Laboratory Quality Standards), Thailand**
The BLQS of the Department of the Medical Sciences has developed national quality standards for health laboratories based on ISO 17025 and ISO 15189. A check list with 110 items was developed and a stepwise approach was devised. Depending on the score obtained when compared to the checklist, laboratories will be accredited against country-wide national standards, or can apply for the ISO accreditation process.
- **CLIA (Clinical Laboratory Improvement Amendments of 1988), USA**
CLIA was mandated by legislation in 1988, and brings all medical laboratory testing in the United State. under federal regulation. Quality standards are defined based on the complexity of testing performed. The objective of the CLIA program is to ensure quality laboratory testing, regardless of where it is performed (e.g., physician's office, hospital laboratory, health clinic, nursing home).

Content Sheet 11-4: Certification and Accreditation

Applying standards

Standards are used when a laboratory seeks recognition of its ability to use quality practices in carrying out its work. Remember that meeting the standards may be a legal requirement, or may be voluntary. There are three processes that may be used to indicate that the laboratory is complying with defined standards.

- **Certification**—The procedure by which an independent body gives written assurance that a product, process or service conforms to specific requirements.³

In the certification process, a laboratory is visited by representatives from a certification body. These representatives are looking for evidence of compliance with standards, policies, procedures, requirements, and regulations. Primarily, the inspection team checks for physical presence of texts, procedures, and documents.

- **Accreditation**—The procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.⁴

A laboratory is visited by representatives from an accreditation body who are looking for evidence of compliance with standards, policies, procedures, requirements, and regulations, and also observe workers to ensure that they perform functions and duties correctly and competently.



Accreditation provides a higher level of assurance to those using the laboratory that its testing is reliable and accurate because it includes an evaluation of competency.

- **Licensure**—The granting of ability to practice, usually provided by a local governmental agency. Licensure is usually based on demonstrated knowledge, training and skills.⁵ Generally, when laboratory licensure is used, it is a legal requirement for operation.

Elements of accreditation

The accreditation process requires:

- an accreditation body that oversees the assessments and grants accreditation; this body may also set the standards used in the accreditation process;
- standards with which a laboratory must comply in order to gain accreditation;
- knowledgeable assessors or inspectors who seek to establish compliance with the standards by conducting the assessment;
- a user laboratory which is required to, or voluntarily seeks to, comply with the standards by being assessed.

³ ISO/IEC 17000:2004 Conformity assessment—Vocabulary and general principles.

⁴ ISO 15189:2007 Medical laboratories—Particular requirements for quality and competence.

⁵ Wikipedia 2007.

Certification and accreditation bodies

A certification or accreditation body is an organization or agency with the authorized right and authority to inspect a facility, and provide written evidence of its compliance (certification) and competence (accreditation) with a standard.

Certification and accreditation bodies have the following common characteristics.

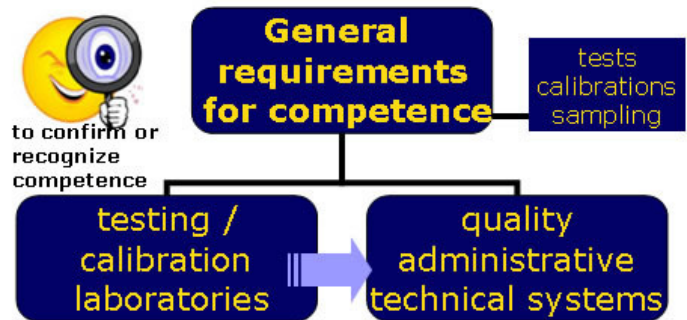
- **Approved**—Accreditation and certification bodies usually require their own accreditation status. This accreditation is commonly performed under the authority of national or international bodies, such as national standards agencies. International accreditation bodies often are accredited to ISO 17011.⁶
- **Knowledgeable**—These bodies must be knowledgeable and skilled in the content and interpretation of the standards against which they accredit, as well as in the discipline they accredit. An accreditation body team includes both discipline content experts and accreditation requirement experts.
- **Standards-based**—Assessments are always based on established standards.
- **Objective**—Interpretation of competence and skill is based on evidence rather than impression. The inspection teams do not write their own rules, but rather measure compliance with given rules or standards.
- **Competent**—These organizations ensure that all staff are trained and skilled, and that auditing teams involve members knowledgeable in both technical and quality management information. The bodies maintain competency because of professionalism, and because of the importance of sustaining their own accredited status.

Commonly used standards for accreditation or certification

Standards may be applicable to accreditation or to certification, or they may be regulatory. Some important examples of accreditation standards include ISO 17025 and ISO 15189, both international standards in wide use. ISO 15189 is a preferred standard for medical laboratories because it applies to the total laboratory, regardless which tests it performs, as opposed to ISO 17025⁵ on an individual test-by-test basis.

ISO 17025 specifies general requirements, including sampling. It is applicable to testing and calibration laboratories, and can be used for developing quality,

Scope of ISO 17025

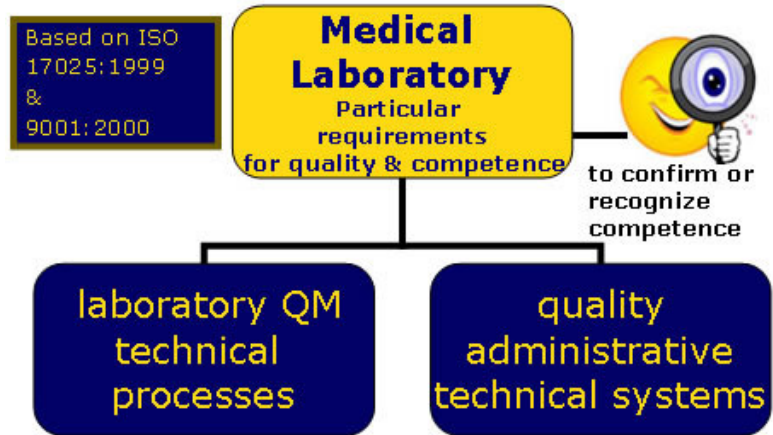


Does not cover compliance with regulatory and safety requirements for laboratory operations

⁶ ISO/IEC 17011:2004 Conformity assessment—General requirements for accreditation bodies accrediting conformity assessment bodies. Geneva: International Organization for Standardization.

administrative, and technical systems that govern operations. It can be used by laboratory clients, regulatory authorities, and accreditation bodies wishing to confirm or recognize competence of laboratories. It does not cover compliance with regulatory and safety requirements.

ISO 15189 is sector specific, meaning that it is designed and intended for use only by *medical* laboratories. ISO 15189 specifies particular requirements for quality and competence of medical laboratories. It provides guidance for laboratory quality management and technical processes to ensure quality in medical laboratory examinations. ISO 15189 is applicable to all currently recognized disciplines of medical laboratory services, and is based on both ISO 17025 and ISO 9001. It is for use by medical laboratories for developing quality, administrative, and technical systems that govern their operations, and is also for use by organizations wishing to confirm or recognize competence of medical laboratories.



Content Sheet 11-5: Process of Accreditation



The decision to pursue accreditation is not one to be taken lightly or without forethought.

Accreditation visits are expensive therefore laboratory directors and quality managers must prepare well in advance of the visits to ensure resources are not wasted. Accreditation could begin with one part of the laboratory and then continue with the other sections.

Preparation

Seeking accreditation requires the following.

- **Commitment**—The path towards meeting standards and recognition is rarely straightforward. When the process becomes difficult, challenging and requires time and effort, it is not uncommon to quit or postpone the process. Once stopped, it becomes very difficult to begin again.
- **Planning**—The path towards accreditation will take time. Laboratories should organize their staff and time to ensure that the process goes to completion with a minimum of obstruction.
- **Knowledge**—Application of standards requires knowledge of the standards and how to interpret them. If there are not people in the laboratory that have that knowledge, the laboratory may consider sending staff for special training or hiring a consultant.
- **Resources**—The process to accreditation may require reorganization, restructuring, trained staff, or additional equipment. Recognition of potential costs should be considered in the planning phase at the start of the process.

Interpretation of terms

When using standards to prepare for accreditation, keep in mind the following interpretations of terms commonly used in standards.

- **Consensus**—Agreement between delegations representing all the stakeholders concerned—suppliers, users, government regulators and other interest groups. Consensus is not a numeric or majority determination. Consensus represents general agreement in the absence of strong and compelling objection.
- **Normative Statement**—Information within a document that is a required and essential part of the standard. Includes the word “shall”.
- **Informative Statement**—Information within a document that is informational only; often it is in the form of a ‘note’. Information may be explanatory, or cautionary, or provide an example.
- **Compliance**—Meets both the text and the spirit of a requirement.
- **Non-conformity**—Failure to fulfill the requirements of a specified process, structure or service. May be categorized as major (complete) or minor (partial).
- **Verification of conformity**—Confirmation by examination of evidence.

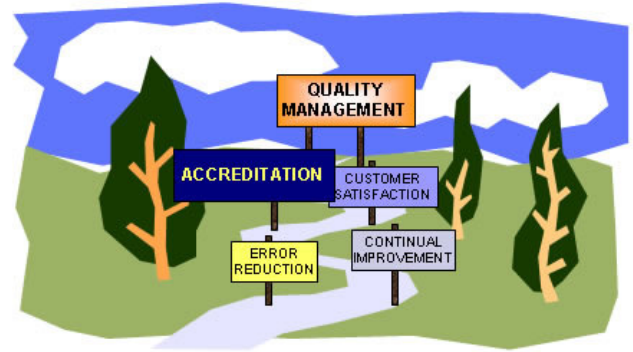
Content Sheet 11-6: Benefits of Accreditation

Value of accreditation

It is through the accreditation of third-party evaluators that the laboratory's clients can have confidence that when something is measured, calibrated, inspected, tested or certified, the job has been done competently.

Accreditation does not *guarantee* success, it is only one step along the quality journey

The essential aspect of accreditation is that it promotes confidence in results and services because it is a valid means of verifying claims about quality, performance, and reliability. The use of internationally-recognized standards as the reference criteria for laboratory accreditation is the key to building trust across borders and promoting best practices worldwide.



Outcomes

The outcomes of accreditation are:

- Measurement of strength and integrity of the quality system ;
- continual monitoring of the quality system;
- recognition for your efforts.

Accredited laboratories tend to perform better on proficiency testing and are more likely to have a working quality management system.

Accreditation as a tool

Accreditation is a valuable tool to determine the effectiveness of the quality system. However, it is not the ultimate goal. Once accreditation status is obtained, the important challenge will be to maintain that status.

A well-managed laboratory will know that it is meeting its goals. The laboratory should look at accreditation as one form of audit that the quality managed laboratory puts into place to ensure that the system is working properly.

Accreditation status must be renewed regularly and the laboratory challenged each time to maintain and improve the quality level.

Content Sheet 11-7: Summary

Summary

Standards or norms provide guidelines that form the basis for quality practices in the laboratory. They are developed by organizations, often through a consensus process. Accreditation and certification are two processes that can allow for recognition that a laboratory is meeting designated standards.

When a laboratory seeks this recognition, careful planning will be needed to have a successful outcome. An active quality management program can assure that a laboratory is in a constant state of "accreditation-readiness".

Key message

- Accreditation is an important step in the continual improvement of the quality management system.
- It is an accomplishment to be accredited; it is an achievement to maintain accreditation.