

1-5: International laboratory standards

Need for international laboratory standards

A part of quality management is assessment, measuring performance against a standard or benchmark. The concept of quality management requires that standards be set, and again industry has been in the lead.

Important laboratory standards organizations

Using a set of standards established by the United States of America military for the manufacture and production of equipment, the ISO established standards for industrial manufacturing; we know these standards as ISO standards.

ISO

The ISO 9000 documents provide guidance for quality in manufacturing and service industries, and can be broadly applied to many other kinds of organizations. ISO 9001:2000 addresses general quality management system requirements and applies to laboratories. There are two ISO standards that are specific to laboratories:

- ISO 15189:2007. *Medical laboratories—particular requirements for quality and competence*. Geneva: International Organization for Standardization, 2007.
- ISO/IEC 17025:2005. *General requirements for the competence of testing and calibration laboratories*. Geneva: International Organization for Standardization, 2005.

CLSI

Another important international standards organization for laboratories is the Clinical and Laboratory Standards Institute, or CLSI, formerly known as the National Committee for Clinical Laboratory Standards (NCCLS). CLSI uses a consensus process involving many stakeholders for developing standards. CLSI developed the quality management system model used in this handbook. This model is based on 12 quality system essentials, and is fully compatible with ISO laboratory standards.

CLSI has two documents that are very important in the clinical laboratory:

- *A quality management system model for health care; approved guideline—second edition*. CLSI/NCCLS document HS1-A2. Wayne, PA, NCCLS, 2004.
- *Application of a quality management system model for laboratory services; approved guideline—third edition*. CLSI/NCCLS document GP26-A3. Wayne, PA, NCCLS, 2004.



Other standards

The information in this handbook is based on the CLSI quality management system model and the ISO 15189 standard.

There are many other standards organizations, and many examples of laboratory standards. Some countries have established national laboratory quality standards that apply specifically to laboratories within the country. Some laboratory standards apply only to specific areas in the laboratory or only to specific tests. The World Health Organization has established standards for some specific programmes and areas.