

-5: International laboratory standards A part of quality management is assessment, measuring performance against a standard or benchmark. CLSI has two documents that are very important in the clinical laboratory: y A quality management system model for health care; approved guideline--second edition. The ISO 9000 documents provide guidance for quality in manufacturing and service industries, and can be broadly applied to many other kinds of organizations. 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). 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 9001:2000 addresses general quality management system requirements and applies to laboratories. CLSI uses a consensus process involving many stakeholders for developing standards. General requirements for the competence of testing and calibration laboratories. This model is based on 12 quality system essentials, and is fully compatible with ISO laboratory standards. y Application of a quality management system model for laboratory services; approved guideline--third edition. Medical laboratories--particular requirements for quality and competence. CLSI/NCCLS document HS1-A2. CLSI/NCCLS document GP26-A3. The information in this handbook is based on the CLSI qual There are two ISO standards that are specific to laboratories: y ISO 15189:2007. Geneva: International Organization for Standardization, 2007.