

CLSI's *The Key to Quality* Released

The Fundamentals for Implementing a Quality Management System in the Clinical Laboratory

DOI: 10.1309/V34WXXK52CKA2NB7

Indicators show that quality is high on health care organizations' priority lists for 2007 and beyond. Strategies to operate with well-defined, documented policies, processes, and procedures have risen to the top of the clinical-laboratory agenda. With recent emphasis on education and communication in the regulatory and accreditation process, laboratories are challenged to boost their efforts to meet requirements and provide the highest level of patient care. Since numerous challenges remain, many health care organizations are still trying to create the right quality-management-systems strategy, and are striving to get organizational commitment, communication, and alignment.

After years of experience with the quality-management-systems approach, the Clinical and Laboratory Standards Institute (CLSI) released a proven model, *The Key to Quality*, designed to assist clinical laboratories with creating, implementing, and refining a quality-management system. A recent CLSI market-research evaluation survey included a prototype for review and comment by laboratory professionals. Results from the survey on its practical application show that laboratory professionals believe *The Key to Quality* would be useful and would ease many of the difficulties in guiding management and staff in implementing a quality-management system in the laboratory.

Susan Whitley, MT(ASCP), laboratory manager for Foxhall Internists PC, Washington, DC, a survey participant who reviewed the product, says: "This new and different way of looking at laboratory management can seem like a very overwhelming task. *The Key to Quality* really spells it out for you and will give managers, especially those not familiar with these concepts, a place to start. Plus, it will really save time and provide an enormous help with staff training on these concepts."

Barbara Kirkley, department administrator, Clinical Pathology, Cleveland Clinic Foundation, OH, agrees. "Many of the templates and charts would be useful for laboratories with established quality-management programs."

Based on the widely-used CLSI quality-management-systems documents—*A Quality Management System Model for Health Care* (HS1-A2); *Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition* (GP2-A5); *Training and Competence Assessment; Approved Guideline—Second Edition* (GP21-A2), as well as their complementary tool kits—*The Key to Quality* also includes elements from both *Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition* (GP26-A3) and the international standard *Medical Laboratories—Particular requirements for quality and competence* (ISO 15189).

With this new release, CLSI aims to help clinical and laboratory professionals meet challenges for implementing a quality-management system now and lay the foundation to monitor and guide future quality improvements. This specialty portfolio showcases the implementation of all 12 quality-system essentials

(QSEs). Survey participants' impressions are that the guide provides a sufficient number of examples for each QSE and clearly shows the interrelationship of ISO 9001, ISO 15189, and CLSI implementation, as well as the relationship of QSEs and the laboratory's path of workflow. *The Key to Quality* includes:

- a PowerPoint introduction to the CLSI concept of quality management and how the material can assist in implementing a quality-management program;
- practical samples and "how-to" details, including ready-to-use forms and easy-to-implement templates for each of the 12 QSEs;
- symbols to help create systematic flowcharts and process documents;
- a cross-referenced guide to the interrelated elements of the quality-management-systems approaches from CLSI, ISO, CAP, and other organizations;
- a compilation of self-assessment checklists to determine and evaluate the effectiveness of implementation, and to monitor and guide quality improvements; and
- a CD-ROM slide-show presentation useful for orienting staff to quality systems, as well as representative examples, checklists, and flowchart tools in an electronic format.

Survey participant Barbara Parsons, MA, MT(ASCP), manager-CQI Office, Department of Pathology, Johns Hopkins Hospital, Baltimore, MD, says: "The slide presentation in the CD-ROM and the chapters in the manual are not only educational, but also will help provide a structure to developing the system. The electronic templates provide good working examples for each QSE. *The Key to Quality* will also be helpful in meeting accreditation and regulatory requirements."

Carla Carter, MS, MT(ASCP), public-health laboratory scientist supervisor, Deer's Head Hospital Laboratory, Salisbury, MD, concludes: "The manual does all the work for you. You'll be able to establish a quality-management system easily by following the guidelines, examples, and checklists provided."

When asked whether this practical resource would work for international laboratories, Michael Noble, MD, FRCP(C), Department of Pathology and Laboratory Medicine, University of British Columbia, says: "It is easily readable, interpretable, and compatible with the concepts and tools common to international quality management and brings together information from CLSI's quality-management guidelines, along with international principles. It would require a lot of time, commitment, and research through international standards, implementation guidelines, critiques, and reviews to gather all of the information provided here, which allows the laboratory to start the process sooner."

Melissa J. D'Archangelo is a marketing and communications consultant based in Chester Springs, PA.

CLSI is a global, non-profit, membership-based organization dedicated to developing standards and guidelines for the health care and medical testing community. For more information about Clinical and Laboratory Standards Institute visit www.clsi.org or call 610.688.0100.