HS1-A2
Vol. 24 No. 37
Replaces HS1-A
Vol. 22 No. 13

A Quality Management System Model for Health Care; Approved Guideline—Second Edition

This document provides a model for providers of healthcare services that will assist with implementation and maintenance of effective quality management systems.

A guideline for global application developed through the NCCLS consensus process.

NCCLS...

Global Consensus Standardization for Health Technologies

NCCLS is an international, interdisciplinary, nonprofit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and healthcare services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, NCCLS provides an open and unbiased forum to address critical issues affecting the quality of patient testing and health care.

PUBLICATIONS

An NCCLS document is published as a standard, guideline, or committee report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

Report A document that has not been subjected to consensus review and is released by the Board of Directors.

CONSENSUS PROCESS

The NCCLS voluntary consensus process is a protocol establishing formal criteria for:

- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

Most NCCLS documents are subject to two levels of consensus—"proposed" and "approved." Depending on the need for field evaluation or data collection, documents may also be made available for review at an intermediate consensus level.

Proposed An NCCLS consensus document undergoes the first stage of review by the healthcare community as a proposed standard or guideline. The document should receive a wide and thorough technical review, including an overall review of its scope, approach, and utility, and a line-by-line review of its technical and editorial content.

Approved An approved standard or guideline has achieved consensus within the healthcare community. It should be reviewed to assess the utility of the final document, to ensure attainment of consensus (i.e., that comments on earlier versions have been satisfactorily addressed), and to identify the need for additional consensus documents.

NCCLS standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by materially affected, competent, and interested parties obtained by following NCCLS's established consensus procedures. Provisions in NCCLS standards and guidelines may be more or less stringent than applicable regulations. Consequently, conformance to this voluntary consensus document does not relieve the user of responsibility for compliance with applicable regulations.

COMMENTS

The comments of users are essential to the consensus process. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the NCCLS committee that wrote the document. All comments, including those that result in a change to the document when published at the next consensus level and those that do not result in a change, are responded to by the committee in an appendix to the document. Readers are strongly encouraged to comment in any form and at any time on any NCCLS document. Address comments to the NCCLS Executive Offices, 940 West Valley Road, Suite 1400, Wayne, PA 19087, USA.

VOLUNTEER PARTICIPATION

Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

HS1-A2
ISBN 1-56238-554-2
Volume 24 Number 37 ISSN 0273-3099

A Quality Management System Model for Health Care; Approved Guideline—Second Edition

Lucia M. Berte, M.A., M.T.(ASCP), SBB, DLM; CQA(ASQ)CQMgr.
D. Joe Boone, Ph.D.
Greg Cooper, CLS, MHA
Patricia L. James, M.A.
Anders Kallner, M.D., Ph.D.
Michael A. Noble, M.D., FRCPC
Daniel W. Tholen, M.S.

Abstract

NCCLS document HS1-A2—*A Quality Management System Model for Health Care; Approved Guideline—Second Edition* provides the necessary background information and infrastructure to develop a quality management system that will meet healthcare quality objectives and be consistent with the quality objectives of each organization or service. This guideline provides a structure for a comprehensive, systematic approach to build quality into the healthcare organization or service's processes, assess the organization or service's performance, and implement quality improvements. This document, used with the relevant discipline-specific companion document for individual service areas, can provide the means to apply this model to their respective operations.

NCCLS. *A Quality Management System Model for Health Care; Approved Guideline—Second Edition*. NCCLS document HS1-A2 (ISBN 1-56238-554-2). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

Suggested Citation

(NCCLS. *A Quality Management System Model for Health Care; Approved Guideline—Second Edition.* NCCLS document HS1-A2 [ISBN 1-56238-554-2]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.)

Approved Guideline
August 2002

Approved Guideline—Second Edition
November 2004

ISBN 1-56238-554-2
ISSN 0273-3099

Committee Membership

Area Committee on General Laboratory Practices

Sheila M. Woodcock, A.R.T., M.B.A.
Chairholder
QSE Consulting
Rose Bay, Nova Scotia, Canada

Albert Rabinovitch, M.D., Ph.D.
Vice-Chairholder
Abbott Laboratories
Hematology Business Unit
Santa Clara, California

Eric Arendash, M.T.(ASCP)
Centers for Medicare & Medicaid Services
Philadelphia, Pennsylvania

Miguel Azar, M.D.
Dept. of Veterans Affairs Medical Center
Minneapolis, Minnesota

Lucia M. Berte, M.A., M.T.(ASCP) SBB, DLM; CQA(ASQ)CQMgr.
Quality Management Systems Consultant
Westminster, Colorado

Margaret M. Grimes, M.D.
Medical College of Virginia Campus
Richmond, Virginia

Theresa D. Stokeld, M.B.A., M.T.(ASCP)DLM
Remel, Inc.
Lake Charles, Louisiana

Advisors

Kay M. Creed
St. Mary's Hospital
Richmond, Virginia

Steven I. Gutman, M.D., M.B.A.
FDA Ctr. for Devices/Rad. Health
Rockville, Maryland

Gerald A. Hoeltge, M.D.
The Cleveland Clinic Foundation
Cleveland, Ohio

Stephen J. Sarewitz, M.D.
Valley Medical Center
Renton, Washington

Jennifer Schiffgens, M.B.A., M.T.(ASCP)
California Pacific Medical Center
San Francisco, California

Daniel W. Tholen, M.S.
Dan Tholen Statistical Consulting
Traverse City, Michigan

Marla Thomas
Litton Pathology Associates
Blue Springs, Missouri

Eleanor M. Travers, M.D.
State of Connecticut Department of Public Health
Hartford, Connecticut

Area Committee on Healthcare Services

Judy Dye, M.A.
Chairholder
University of Arizona Medical Center
Tucson, Arizona

Carl D. Mottram, RRT, RPFT, FAARC
Vice-Chairholder
Mayo Clinic
Rochester, Minnesota

Barbara M. Goldsmith, Ph.D.
Lab Alliance/Lab One
Cincinnati, Ohio

Hector Lozano
Respironics, Inc.
Murrysville, Pennsylvania

Toby L. Merlin, M.D.
Centers for Disease Control and Prevention
Atlanta, Georgia

Jeannie Miller, R.N., M.P.H.
Centers for Medicare & Medicaid Services
Baltimore, Maryland

Peter L. Minetti
Fujirebio Diagnostics, Inc.
Malvern, Pennsylvania

Advisors

Lucia M. Berte, M.A., M.T.(ASCP), SBB, DLM; CQA(ASQ)CQMgr.
Quality Management Systems Consultant
Westminster, Colorado

Susan Blonshine, RRT, RPFT, FAARC
TechEd
Mason, Michigan

Susan T. Martin, M.D.
Oconee Memorial Hospital
Seneca, California

Robert K. McNamee
Dianon Systems, Inc.
Stratford, Connecticut

Working Group on Quality Systems

Lucia M. Berte, M.A., M.T.(ASCP), SBB, DLM; CQA(ASQ)CQMgr.
Chairholder
Quality Management Systems Consultant
Westminster, Colorado

D. Joe Boone, Ph.D.
Centers for Disease Control and Prevention
Atlanta, Georgia

Greg Cooper, CLS, MHA
Bio-Rad Laboratories, Inc.
Irvine, California

Patricia L. James, M.A.
Agency for Health Care Administration
Tallahassee, Florida

Anders Kallner, M.D., Ph.D.
Karolinska Hospital
Stockholm, Sweden

Michael A. Noble, M.D., FRCPC
University of British Columbia
Vancouver, British Columbia, Canada

Regina Robertson
National Association of Testing Authorities, Australia
Rhodes, New South Wales, Australia

Daniel W. Tholen, M.S.
Dan Tholen Statistical Consulting
Traverse City, Michigan

Advisors

Judy Dye, M.A.
Univ. of Arizona Medical Center
Tucson, Arizona

Deborah Greene
University of Iowa Hospitals and Clinics
Iowa City, Iowa

Tania Motschman, M.S., M.T.(ASCP) SBB; CQA(ASQ)
Mayo Clinic
Rochester, Minnesota

Carl D. Mottram, B.A., RRT, RPFT, FAARC
Mayo Clinic
Rochester, Minnesota

Albert Rabinovitch, M.D., Ph.D.
Abbott Laboratories, Hematology Business Unit
Santa Clara, California

Sheila M. Woodcock, A.R.T., M.B.A.
QSE Consulting
Rose Bay, Nova Scotia, Canada

Staff

Jennifer K. McGeary, M.T.(ASCP), M.S.H.A.
Staff Liaison
NCCLS
Wayne, Pennsylvania

Donna M. Wilhelm
Editor
NCCLS
Wayne, Pennsylvania

Melissa A. Lewis
Assistant Editor
NCCLS
Wayne, Pennsylvania

Acknowledgement

NCCLS acknowledges the experts and their institutions listed below for their "special review," advice, and help in preparing the approved-level, second edition of this guideline:

Mr. Tsutomu Aoyagi, Japan Accreditation Board for Conformity Assessment
Mr. Aoki, Colby Group International Inc.
Dr. David Burnett, United Kingdom
Ms. Kathryn Connolly, COLA
Dr. Orno Dreazen, Israel Laboratory Accreditation Authority
Dr. Naotaka Hamazaki, Kyusyu University School of Medicine
Mr. Fumio Kariya, Daiichi Chemical Co. Ltd.
Dr. Tadashi Kawaii, International Clinical Pathology Center
Dr. Yasushi Nomura, formerly Hitachi
Ms. Oguchi, Colby Group International, Inc.
Ms. Holly Rapp, M.T.(ASCP)SBB, CQA(ASQ)CQMgr, American Association for Blood Banks

Contents

Contents (Continued)

Foreword

In the present environment of limited resources, quality cannot be taken for granted by those who fund, receive, and provide healthcare services. However, the burgeoning awareness of the horrific personal and economic impact of medical errors on patient safety has focused a national spotlight on quality management in healthcare services. Our historic perspective of quality control and quality assurance as defining quality needs to be superseded by a more global view of internationally accepted quality activities applied to a given scope of work.

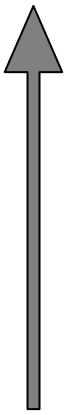
This document defines a quality management system model for healthcare organizations and services that will assist organizations with implementation and maintenance of an effective quality management system. This model is consistent with the quality standards provided by the International Organization for Standardization (ISO) for business, industry, and the medical laboratory.

It is true that other interpretations can be made of the available information. However, this consensus document is intended to be a sound, practical, and user-friendly interpretation that can be easily implemented in any healthcare organization or service. Compliance with this guideline should assist an interested healthcare organization or service that seeks to obtain certification to relevant ISO quality management standards.

This document is intended to provide a practical guide for healthcare organizations that are interested in having quality built into their organizations. Using the examples and definitions available in this guideline and other quality-related documents, organizations—or single service units—can design the quality management system foundation necessary to achieve total quality management.

A hierarchy defining stages of quality,[1] synthesized from the concepts of acknowledged quality experts,[2,3] is described in Table 1 below.

Table 1. Stages of Quality. The quality management system (shaded) is a major level in the healthcare quality hierarchy. Each level incorporates all preceding levels below it.



Stage	Activities Performed
Total Quality Management	Management approach centered on sustained high quality, by focusing on long-term success through customer satisfaction.
Quality Cost Management	Includes the stages below and also the economic aspects of the "cost of quality."
Quality Management System	**Systematic process-oriented approach to quality objectives**.
Quality Assurance	Planned and systematic activities to provide confidence that an organization fulfills requirements for quality.
Quality Control	Operational process control techniques to fulfill requirements for quality and governmental compliance.

Using a scheme similar to Maslow's hierarchy of personal needs,[4] an organization can best obtain the next higher stage by mastering of the preceding one.

An integrated quality management system provides an opportunity to deliver consistent, high quality, and cost-effective health care in any healthcare organization. In healthcare service areas where governmental and accreditation compliance apply, a quality management system will simplify the process.

In most of the world, healthcare organizations and services are operating at or below the stage of quality assurance. Although some healthcare organizations or services are working successfully at the level of a quality management system, many are not. Thus, the need to upgrade to a quality management system approach is becoming evident from groundbreaking reports that describe medical errors in present day healthcare systems.[5,6] The best contribution a healthcare organization or service can make to reducing medical errors that harm patients is to understand and document its processes, train people to be competent in following those processes, identify problematic processes, and improve processes where problems exist.

The foundation of a quality management system, with operations under control, provides a platform for continuous improvement and further transition up the quality hierarchy. If a healthcare organization or service implements the quality management system model described in this guideline, the following outcomes are greatly enhanced:

- ability to reduce or eliminate medical error;
- the likelihood of meeting customer requirements;
- the potential for successful governmental and accreditation assessments; and
- sustainable attainment of quality objectives.

With leadership commitment to building a quality management system, a platform for continuous improvement and further progress toward overall Total Quality Management is established.

Overview of Changes

The revisions in this version of the HS1 guideline are intended principally to include the concepts published in ISO 15189, *Medical laboratories—Particular requirements for quality and competence*.

Although the ISO 15189 requirements are meant for medical laboratories, the quality management system concepts contained therein can be applied to all healthcare services and—if implemented—would greatly contribute to service quality and patient safety, thus their inclusion in HS1-A2, which is a generic overview of the Quality System Essentials (QSEs).

The guideline has been streamlined and examples of forms with general applicability to any healthcare service have been included.

A Note on Terminology

NCCLS, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. NCCLS recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in NCCLS, ISO, and CEN documents; and that legally required use of terms, regional usage, and different consensus timelines are all obstacles to harmonization. In light of this, NCCLS recognizes that harmonization of terms facilitates the global application of standards and is an area of immediate attention. Implementation of this policy must be an evolutionary and educational process that begins with new projects and revisions of existing documents.

Key Words

Quality, quality indicators, quality management system

A Quality Management System Model for Health Care; Approved Guideline—Second Edition

1 Scope

The quality management system model described in this guideline can be developed for any healthcare organization or individual service unit (e.g., laboratory, pharmacy, respiratory, imaging). The quality system essentials are universal and thus can be applied to any service's operations, whether simple or complex. It is recommended that this guideline be used in conjunction with the NCCLS discipline-specific companion documents to establish and maintain technical and managerial quality.

This guideline is intended for use by laboratory directors, managers, supervisors, the quality manager, and others responsible for implementing the policies, processes, procedures, activities, and records that support the quality management activities described herein.

2 Introduction

A quality management system can be described as a set of key quality elements that must be in place for an organization's work operations to function in a manner as to meet the organization's stated quality objectives. Such a system provides the means to direct and control the organization with regard to quality.[7] The increasing complexity of today's healthcare services emphasizes the need for a systematic approach that both promotes and provides for the highest level of service quality and patient safety. A healthcare quality management system describes, documents, implements, measures, and monitors the implementation and effectiveness of the work operations of any organization, service unit, or support operation in the organization.

This document is organized into three major sections. The first section describes a model for a quality management system that is adaptable to any service in a healthcare organization. For ease of use, this model has characterized the fundamental quality elements of all organizations as "the quality system essentials" or "QSEs." Every organization, whatever its size, has some established intent for these QSEs; in many organizations, the implementation guidance for the QSEs is often unwritten. In any organization, functional efficiency depends on well-understood, documented guidance and processes that address each QSE.

The second section introduces 12 quality system essentials and discusses the key elements of each. Information is provided about the processes and procedures that a healthcare organization needs to have in place to ensure that its work operations are functioning as intended to meet customer, governmental, and accreditation requirements, and provide for the highest level of service quality and patient safety.

The third section suggests a sequence of activities for implementing the quality management system model described in this guideline. Guidance for important features of these activities is provided with numerous examples.

3 Definitions

Accident – An undesirable or unfortunate happening that occurs unintentionally.

Audit – A planned, independent, and documented assessment to determine whether agreed-upon requirements are being met (ISO 9000 [3.9.1]).[7]

Calibration – Set of operations that establishes, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards (VIM).[8]

Competence – Demonstrated ability to apply knowledge and skills (ISO 9000 [3.9.12]).[7]

Corrective action – Action to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000 [3.6.5]).[7]

Customer – Organization or person that receives a product (ISO 9000 [3.3.5])[7]; **NOTE:** Employees may be regarded as internal customers.

Document – Information and its supporting medium (ISO 9000 [3.7.2])[7]; **NOTE:** This may be paper-based or electronic.

Error – A deviation from truth, accuracy, or correctness; a mistake.

Error (of measurement) – Result of a measurement minus a true value of a measurand (VIM).[8]

Form – A paper or electronic document on which information or results are captured; **NOTE:** Once completed, a form becomes a record.

Measurement procedure – Set of operations, described specifically, used in the performance of particular measurements according to a given method (VIM).[8]

Occurrence – Something that happens; an event, incident, complaint, nonconformance, or accident.

Path of workflow – Sequential processes in a healthcare organization or service's activities that transform a physician's order into the service's product (e.g., laboratory information, medications, diagnostic images, respiratory care).

Policy – A documented statement of overall intentions and directions defined by those in the organization and endorsed by management.

Postservice processes – Processes following service realization including results review; formatting reports or labels; authorization of results, reports, or drugs for release; reporting of results; transmission of the results; and storage of any samples.

Preservice processes – Processes preceding service processes, from the clinician's request, including the ordering requisition, preparation of the patient, collection of any samples, transportation of samples or patients to and within the clinical service area and ending when service realization starts (e.g., laboratory testing, diagnostic imaging, preparation of medication).

Preventive action – Action to eliminate the cause of a potential nonconformity or any other undesirable potential situation (ISO 9000 [3.6.4]).[7]

Preventive maintenance – Scheduled periodic work on a piece of equipment that is not a result of malfunction or failure and is intended to avert such failure.

Procedure – Specified way to carry out an activity of a process (ISO 9000 [3.4.5]).[7]

Process – Set of interrelated or interacting activities that transforms inputs into outputs (ISO 9000 [3.4.1]).[7]

Process improvement – Part of a process management focused on reducing variation and improving process effectiveness and efficiency (ISO 3534 [3.2.1.7]).[9]

Product – Result of a process (ISO 9000 [3.4.1])[7]; **NOTE:** There are four generic product categories, as follows:

a) services (e.g., transport: a healthcare organization processes produce services such as diagnostic testing or imaging, medications, respiratory or rehabilitation treatments, surgery, patient care);
b) software (e.g., computer program, dictionary; generally, healthcare organizations or services do not produce software);
c) hardware (e.g., engine mechanical parts: generally, healthcare organizations or services do not produce hardware);
d) processed materials (e.g., lubricant: generally, healthcare organizations or services do not produce processed materials).

Quality – Degree to which a set of inherent characteristics fulfills requirements (ISO 9000 [3.1.1]).[7]

Quality assurance – Part of quality management focused on providing confidence that quality requirements will be fulfilled (ISO 9000 [3.2.11]).[7]

Quality control – Part of quality management focused on fulfilling quality requirements (ISO 9000 [3.2.10]).[7]

Quality indicators – Observations, statistics, or data defined by the organization or service that typify the performance of a given work process and provide evidence that the organization or service is meeting its quality intentions (AABB).[10]

Quality management – Coordinated activities to direct and control an organization with regard to quality (ISO 9000 [3.2.8]).[7]

Quality management system – Management system to direct and control an organization with regard to quality (ISO 9000 [3.2.3])[7]; **NOTE:** Systematic and process-oriented efforts are essential to meet quality objectives.

Quality policy – Overall intentions and direction of an organization related to quality as formally expressed by top management (ISO 9000 [3.2.4]).[7]

Quality system essentials – Set of coordinated building blocks for quality management.

Record – Document stating results achieved or providing evidence of activities performed (ISO 9000 [3.7.6]).[7]

Root cause analysis – Process for identifying the basic or causal factor(s) that underlies variation in performance, including the occurrence or possible occurrence of a nonconforming event.[11]

Service processes – Activities related to providing the service's product (e.g., laboratory test results, diagnostic images, preparation of medications, provision of pulmonary therapy).

Statistical tools – Methods and techniques used to generate, analyze, interpret, and present data.

Supplier – Organization or person that provides a product or service (ISO 9000 [3.3.6]).[7]

Traceability – Ability to trace the history, application, or location of that which is under consideration

(ISO 9000 [3.5.4])[7]; **NOTE:** When considering a product, traceability can relate to: the origin of materials and parts; the processing of history; and the distribution and location of the product after delivery.

Validation – Confirmation through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled (ISO 9000 [3.8.5])[7]; **NOTE:** Examples include validation of the process to use a new diagnostic tool (such as a new mammography instrument, automated laboratory test system, automated medication dispensing system, or a new pulmonary function assessment device); information system; or evidence-based medicine.

Verification – Confirmation through the provision of objective evidence that specified requirements have been fulfilled (ISO 9000 [3.8.4])[7]; **NOTE:** Examples include calibration verification of results obtained on automated testing analyzers, and patient identification.

4 The Quality Management System Model

The quality management system model suggested in this guideline describes only the generic quality building blocks—the quality system essentials (QSEs) and demonstrates how they are applied to the scope of a healthcare organization or service's operations (i.e., provision of care, treatment, or services) as depicted in Figure 1.

Figure 1. The Quality Management System Model. The 12 QSEs function as the building blocks that are necessary to support any healthcare service's path of workflow.

QSEs are the foundational building blocks in any kind of organization. These elements need to be in place and functioning effectively in order to support the organization's work operations so that they proceed smoothly. If a quality management system essential is missing or not well implemented, work operations will experience problems. For example, if the organization lacks guidance for how to properly install, calibrate, or maintain its equipment so that it is working effectively, any service that uses the equipment will experience problems in service delivery.

Technical requirements for a service's path of workflow can be found in published accreditation requirements for a given service. Examples include the International Organization for Standardization[12]; the Joint Commission on Accreditation of Healthcare Organizations[11]; and the American Association of Blood Banks.[10]

4.1 The Quality System Essentials

For the purposes of the quality management system model described in this guideline, the quality system essentials are:

- Documents and Records;
- Organization;
- Personnel;
- Equipment;
- Purchasing and Inventory;
- Process Control;
- Information Management;
- Occurrence Management;
- Assessment: External and Internal;
- Process Improvement;
- Customer Service; and
- Facilities and Safety.

These QSEs depict the necessary infrastructure in any organization, including healthcare organizations that provide care, treatment, and services to patients. Every organization functions with these essentials in place. However, the information is often not well organized or documented, so breakdowns in communication often occur. These breakdowns have resulted in medical errors that have had grave consequences for patient safety. This guideline sets out a structured approach to organizing, creating, and maintaining the necessary information for the QSEs, so that all employees know how the organization functions and of its commitment to quality.

International guidance related to the QSEs is described in the ISO 9001 standard.[13] ISO 9001 defines a process model for quality that any business should use to manage its operations, and ISO 15189[12] defines standards for quality management in the medical laboratory environment. These references are provided to show how the QSEs can be used to understand a set of standards that are specific for a given healthcare service. Table 2 depicts one way to relate the 12 quality system essentials for the model proposed in this NCCLS guideline with the quality elements described in these two international documents.

Table 2. Comparison of NCCLS QSEs to ISO 9001:2000 and ISO 15189:2003

NCCLS QSEs	ISO 9001:2000[13]	ISO 15189:2003[12]
Organization	4.1 General requirements 5.1 Management commitment 5.3 Quality policy 5.4 Planning 5.5 Responsibility, authority, communication 5.6 Management review 5.7 Provision of resources	4.1 Organization and management 4.2 Quality management system 4.15 Management review Annex C.1 General ethics Annex C.10 Financial arrangements
Personnel	6.2 Human resources	5.1 Personnel
Equipment	7.6 Control of measuring and monitoring devices	5.3 Laboratory equipment Annex B.1 General Annex B.7 Hardware and software Annex B.8 System maintenance
Purchasing and Inventory	7.4 Purchasing	4.4 Review of requests and contracts 4.5 Examination by referral laboratories 4.6 External services and supplies
Process Control	7.1 Planning of product realization 7.2 Customer-related processes 7.3 Design and development 7.5 Production and service provision	5.4 Preexamination procedures 5.5 Examination procedures 5.6 Assuring the quality of examination procedures 5.7 Postexamination process 5.8 Reporting of results Annex C.5 Examination Annex C.6 Reporting results
Documents and Records	4.2 Documentation requirements	4.3 Document control 4.13 Quality and technical records Annex C.7 Storage/retention of medical records

continued on next page

Table 2. (Continued)

NCCLS QSEs	ISO 9001:2000	ISO 15189:2003
Information Management		Annex B.4 System security Annex B.5 Data entry and reports Annex B.6 Data retrieval and storage Annex C.3 Information Annex C.4 Consent Annex C.8 Access to laboratory records Annex C.9 Other purposes
Occurrence Management	8.3 Control of nonconforming product	4.8 Resolution of complaints 4.9 Identification and control of nonconformities 4.10 Corrective action
Assessments: External and Internal	8.1 General 8.2 Monitoring and measurement 8.4 Analysis of data	4.11 Preventive action 4.14 Internal audits
Process Improvement	8.5 Improvement	4.12 Continual improvement
Customer Service	5.2 Customer focus	4.7 Advisory services Annex C.2 General principles
Facilities and Safety	6.2 Infrastructure 6.3 Work environment	5.2 Accommodation and environmental conditions Annex B.2 Environment

4.2 Documenting the Quality Management System

Each healthcare service employee should know, understand, and be able to describe the activities for each QSE that pertains to his or her job responsibilities. To accomplish this objective and to fulfill a common requirement for quality management systems, the policies, processes, and procedures for the QSEs need to be documented. This documentation clearly expresses to both employees and customers the healthcare organization or service's intentions for and implementation of related activities in each QSE.

4.2.1 The Organization's Quality Policy

Executive management staff needs to define an overall quality policy that includes the following information:

- the organization or service's customer-focused intent;
- the scope of the service provided;

- management's statement of the standard of service;
- the objectives of the quality management system;
- the requirement that all personnel familiarize themselves with the quality documentation and implement the policies, processes, and procedures at all times;
- the organization or service's commitment to good professional practice, the quality of its services, and compliance with the quality management system; and
- management's commitment to compliance with all applicable requirements and standards.

All employees need to know and understand the organization's overall quality policy. The quality policy is documented and kept in the quality manual.

4.2.2 The Quality Manual

The quality manual describes the quality management system and the structure of the documentation used in the quality management system. The quality manual communicates the structure and detail of the organization's quality management and documentation systems to its own personnel, customers, and external assessors.

At a minimum, the quality manual needs to provide references to all the organization's documented policies, processes, and procedures, as a "roadmap" for navigating the organization or service's quality management system.

The quality manual needs to be documented for the staff and management of the organization—it defines how the organization functions and meets the applicable requirements. External assessors may also use the quality manual; however, they are not the primary users.

Appendix A provides an example of a table of contents for a quality manual.

4.2.3 Quality Management System Documents

Usually, there are four kinds of documents in a quality management system, distinguished as policies, processes, procedures, and forms and records.

4.2.3.1 Policies for the QSEs

Policies are statements of the organization's intentions or commitments and answer the question, "What do we do?" Quality policies state the organization or service's *intent* regarding the QSEs. The guidance provided for QSE policy contents can be found in international quality standards and guidelines, national healthcare regulations, accreditation requirements, and the organization's own rules. The bulleted lists in the Policy column of the tables in Section 5 provide items for which policy statements should be documented. Each policy should state the intent of the organization or service with regard to each item. The policy should broadly identify the parties or functions responsible for implementing the activities required. There can be either a single policy document for each QSE, or all the policy statements for all the QSEs can be in one document.

The compilation of documented policies for QSEs becomes the framework for the organization's quality manual. Employees should be familiar with the QSE policies in the manual. The quality manual can be shared with customers, external assessors, or other authorities to meet governmental or accreditation requirements, as well as with employees to familiarize them with the organization's quality management

system. Thus, the organization's documented quality policies become the commitment to meet applicable requirements to deliver quality services that meet customer expectations.

It is suggested that a steering group or quality manager adopts the project of developing the quality manual by setting the policies for the QSEs. A sample policy for a single quality system essential is provided in Appendix B.

4.2.3.2 QSE Processes

Quality management system processes describe the activities required to implement the quality policies and answer the question, "How does it happen in this organization?" Quality procedures transform the intent described in the policies into service action. These documents describe:

- the activities necessary to accomplish the intent of the policy;
- the correct sequencing of the activities for the successful outcome of the process; and
- which entities or persons are responsible for each activity in the process.

There are one or more processes for each QSE policy. Each process involves more than one activity that usually occurs over a period of time, as well as more than one person or category of persons. Process descriptions should include the actions taken, the responsible parties or functions, and any supporting documents used or generated. Although the inclusion of quality process descriptions in the quality manual is optional, the manual provides the best access for these documents and facilitates the linking of the facility's intent with regard to requirements (policy) with how the facility executes the required activities (process).

The bulleted lists in the Process column in the tables in Section 5 provide a description of which processes should be designed and documented. In addition, a listing of processes that support each QSE has been provided as Appendix C. This list is not all-inclusive. Some organizations or services may find the need to add additional QSE processes, whereas smaller or less complex organizations or services may not need all the processes suggested.

In addition to writing policies for the QSEs, the quality manager and the steering group should also document how the related quality processes occur.

Quality process descriptions can be documented in flowcharts or tables. These formats provide a sense of how the activities progress across time. Figure 2 shows the Creation, Review, and Approval Process for QSE: Documents and Records as a flowchart. The example process is applied to all service operations by ensuring that whenever any service document needs development or revision, staff members understand the proper sequence of activities for doing so. Table 3 provides the Creation, Review, and Approval Process for QSE: Documents and Records in the table format.

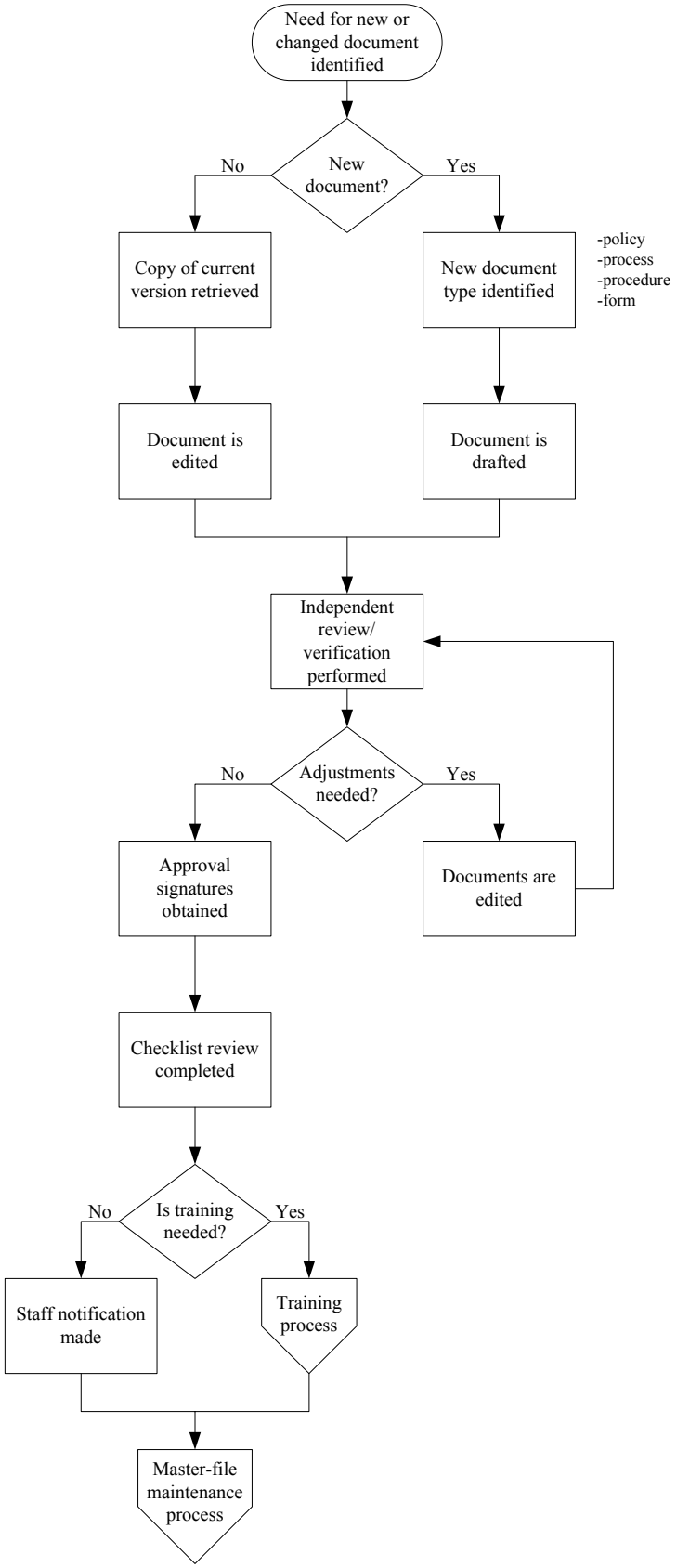


Figure 2. Document Creation, Review, and Approval Process as a Flowchart. This format provides the reader with a visual flow of the process activities.

Table 3. Document Creation, Review, and Approval Process as a Table. This format provides the reader with a text sequencing of the process activities.

Document Creation, Review, and Approval Process Effective Date:
Document #/version #

Document Creation, Review, and Approval Process

Purpose This process describes the sequence of activities for how new and revised documents are created, reviewed, and approved.

Process This process is supported by the activities and documents in the table that follows:

What Happens	Who Is Responsible	Procedures/Instructions to Follow
Need for new or changed document is submitted	• Anyone	• "Document Change Request Form"
Copy of current version retrieved	• Document control coordinator	• "Retrieving a 'Revision Copy' From XYZ Document Control Computer System"
New document type identified as: - policy - process - procedure, or - form	• Supervisor	• "Selecting the Appropriate Document Template"
Document is drafted or edited	• Assigned writer	• "How to Complete Document Templates"
Independent review and verification performed	• Assigned reviewer	• "Reviewing New or Revised Documents"
Approval signatures obtained	• Assigned approvers	• "Approving New or Changed Documents in XYZ Document Control Computer System"
Checklist review completed	• Document control coordinator	• "Readying New or Changed Documents for Release"
Staff notification made (or proceed to Staff Training Process)	• Supervisor • See Staff Training Process	• "E-Mail Staff Notification of New or Changed Document"

Facility name/location Page 1 of 1
Filename and path

4.2.3.3 Procedures

Procedure documents provide instructions for how to perform the steps in a given process activity and answer the question, "How do I do this activity?" There should be procedures (instructions) for the critical activities in each QSE process and work process. There is at least one procedure for each activity in a process.

4.2.3.4 Forms and Records

Quality management system documents also include forms used to record data, information, or results from performing procedures. Forms are the blank pages or computer screens, labels, or tags on which data, information, or results are recorded. After data, information, or results are entered onto a form, screen, label, or tag, it becomes a record.

4.2.4 Document Structure

Table 4 below describes the relationship of policy, process, procedure, and forms/records documents. It is important that the organization or service understands this relationship and uses the correct terminology.

Table 4. Comparison of Terms Used to Describe Quality Documents

Document Type	Description

Policy	• statement of intent
	• derived from
	  − established requirements, or
	  − organizational mandate
	• describes "what is done"

Process **NOTE:** ISO documents often use the terms, "procedure," "process," "protocol," and "programme" interchangeably.	• description of "who does what and when" • provides information on "how it happens here"
Procedure	• instructions for how to do a task within the larger process
Forms/Records	• data, information, or results captured from performing a procedure, recorded on a form, label, or tag, or entered into a computer

5 The Quality System Essentials (QSEs)

The tables within each QSE section that follows contain information about the policies, processes, and procedures needed to implement that portion of a quality management system. The bulleted items in each QSE were culled from the requirements of international quality management system guidance,[12,13] national regulations,[14] and healthcare accrediting agencies.[10,11] The bullets in the Policy column represent the main issues for which the organization or service should state its policies in the quality manual. The bullets in the Process column represent activities defined by management and executed by staff so that the policies are realized and the requirements are met. The bullets in the Procedure column represent the instructions needed for specific tasks that personnel are to perform in the QSE processes. Healthcare

organizations and services can use these tables as a roadmap to build a quality management system that is consistent with the requirements in the above-referenced documents.

The tables are followed by explanatory text and reference to relevant examples in the appendices. If a healthcare organization or service defines and implements the policies, processes, and procedures described for each QSE, the following outcomes are greatly enhanced:

- ability to reduce or eliminate medical error;
- the likelihood of meeting customer requirements;
- the potential for successful governmental and accreditation assessments; and
- sustainable attainment of quality objectives.

5.1 QSE: Documents and Records

The table below summarizes the major requirements for QSE: Documents and Records.

Policy	Processes	Procedures and Forms/Records
State your facility's intent and direction for:	*Describe activities that transform the intent into action.*	*Document instructions for:*
Documents • creation, review, and approval of new documents • changes to documents • control of documents • use of external documents • storage and retention Records • creation and legibility • records reviews • change to recorded information • storage and retention • destruction	• Describe the creation, approval, and implementation of new documents and forms. • Describe the revision of approved documents and forms. • Implement a document control system. • Store documents and records in a manner that maintains integrity; prevents unauthorized access; prevents damage, deterioration, or loss; and facilitates retrieval. • Develop a schedule for retention of documents and records. • Develop guidance and the mechanism for destruction of documents and records. • Maintain a current library of laws, regulations, standards, guidelines, and references.	• creating documents and forms using institutionally approved formats • obtaining authorization prior to implementing new documents • changing or replacing approved documents and forms • selecting storage media and location for documents and records • making changes to reports, records, or verified results • storing, including labeling document and records for storage • destroying labeled materials and recording the destruction • acquiring, cataloging, and updating reference materials

5.1.1 System for Controlling Documents

Document control is a means to ensure that only the latest versions of approved documents are available and used and that obsolete documents have been removed from possible use. The organization should appoint someone with the vested responsibility for overseeing the document control system.

Document control includes:

- document creation, review, and approval;
- document identification;
- revisions to approved documents;
- periodic review;
- master file organization and maintenance;
- master index organization and maintenance;
- distribution; and
- archiving.

5.1.1.1 Creation of Documents

The organization needs to establish and follow systematic methods for creating documents. This system needs to identify ownership, location, and responsibility for all documents, including those that are electronic. Figure 2 and Table 3 describe a systematic process for creating documents.

5.1.1.2 Identification of Documents

The organization needs to develop an identification system that includes all quality management system documents. A numbering system could be used that identifies the type of document (quality policy, quality process, quality procedure, operations process, operations procedure), its respective code number, and the version. Although there is no requirement to number documents, and no one correct way to code them, a healthcare organization or service may find such identification useful. The same identification system may be applied to the forms associated with work procedures as well as to the quality management system documents. In some document control software systems, the document number is generated by the system.

Version identification helps ensure that only the latest approved version of a document is in use. Versions can be identified with numbers or letters. The display of an effective date on the document, or using colored paper or stamps are other examples of version identification.

Each document needs to bear unique identification that includes, at a minimum:

- title;
- edition or revision number and effective date;
- number of pages;

- authority for issue; and
- source identification (i.e., facility name and location).

5.1.1.3 Revisions to Approved Documents

A formal means of making revisions ensures that only authorized changes are made to approved documents, that all changes are reviewed and approved before use, and that all copies of the document in use reflect the change. All affected parties should have the opportunity to contribute to the revision. The document revision process includes the distribution of revised approved documents and retrieval and destruction of copies of the previous version; now invalid and obsolete, the old copies should be destroyed. Retention of at least one copy is described in Section 5.1.1.8.

Organizations need also to determine how changing one document could affect needed changes in other documents and how the input of all those affected by the change will be obtained and considered. Appendix D is an example of a document change request form commonly used in quality management systems to request changes to approved documents.

5.1.1.4 Periodic Review of Documents

Documents that have not been reviewed as part of the document change process should be periodically reviewed and approved to be certain they are still correct, complete, and current. A general guideline for periodic review of unchanged documents is to review and approve such documents annually per the organization or service's established schedule.

5.1.1.5 Master File of a Document

Each document has a master file that contains the current version, as well as all previous archived versions. Electronic or hard copy versions of master documents, or both, can be filed. Copies of the document change request form with review and approval signatures are also kept in the master file. The master file serves as the historical record of a particular document from its inception to the present and provides a means to look back in time should there ever be a need to do so.

5.1.1.6 Master Index of Documents (Document Log)

The master index—or document log—is a listing of all documents currently in use, functioning like an extended table of contents of all policy, process, and procedures manuals. Whenever a document is changed and updated to a new version, the master index needs to be updated. The master index provides the means to identify exactly which version of a particular document is to be used. Master indexes can be subdivided by work section or process to make them more manageable. The master index needs to include:

- document name;
- document identification (including revision identification);
- effective date; and
- document location(s).

Control of the master index should reside with a single person and be in a single secure site. If the index is kept in a computer system, it should be under password control to ensure its security.

Software applications for personal computers, such as spreadsheets and databases, are useful for maintaining the master index. Appendix E provides an example of a document index that can be used as a form, spreadsheet, or database. Commercially available document control software commonly used in business and industry is easily adapted for use in a healthcare organization or service.

5.1.1.7 Distribution of Documents

The document master index indicates each location in which active copies (paper or electronic) of a document are placed. For example, copies of an instruction may be placed in the supervisor's office and at one or more areas where the instruction is used in performing the work. Where there is more than one active copy of the instruction, each location is listed on the master index. The master index lists the locations of all documents. Document locations may be added or deleted as needed.

5.1.1.8 Archiving of Documents

The current version of a document (policy, process description, procedure, or form) is stored in its respective master file. It needs to be marked with the date superseded when a new approved version is added to the file.

Document master files are to be stored in a manner to prevent loss or damage and to promote easy retrieval of earlier versions. Duration of retention is defined by regulations or accreditation requirements and the organization's business requirements.

5.1.2 System for Controlling Records

Record control includes the following activities:

- identification;
- collection and review;
- indexing;
- access;
- storage;
- maintenance; and
- disposal.

5.1.2.1 Identification of Records

Records to be created are specified by regulations, accreditation requirements, national or regional authorities, parent organizations, and the service itself. The service needs to create a master list of records to be collected and verify that required records are being generated.

5.1.2.2 Collection and Review of Records

Records are created when entering information onto a computer screen, completing a paper worksheet, or filling out a label or tag. All records are to be legible. The instructions for creating records need to be part of each documented procedure in which the results achieved when performing the procedure are documented.

Reviews of records are performed according to regulations and accreditation requirements, and the organization's own policies and procedures. All reviews are to be documented. Common examples include supervisory review of quality control results and work results.

5.1.2.3 Indexing

Records are to be indexed in a manner that provides for cross referencing where needed or required.

5.1.2.4 Access to Records

The facilities for record storage need to provide an environment that prevents unauthorized access, provides safeguards against tampering, and facilitates retrieval.

5.1.2.5 Storage of Records

Records may be stored on any appropriate medium. The facilities for record storage need to provide an environment that prevents damage, deterioration, or loss, and facilitates retrieval. There needs to be a process to ensure that records stored electronically can be accessed with later versions of software.

5.1.2.6 Retention of Records

Duration of retention is defined by governmental and accreditation requirements, and by the organization's business requirements. The organization or service needs to develop a record retention schedule that accommodates all these requirements. An example of a record retention schedule for laboratory documents is provided in NCCLS document GP26—*Application of a Quality Management System Model for Laboratory Services.*

5.1.2.7 Disposal of Records

The storage system for records should indicate the last date of retention after which the record may appropriately be destroyed. The mechanism of destruction needs to be such that the confidentiality of the records' contents is not violated.

5.2 QSE: Organization

The table below summarizes the major requirements for QSE: Organization.

Policy	Processes	Procedures and Forms/Records
State intent and direction for:	*Describe activities that transform the intent into action.*	*Document instructions for:*
• quality in the organization − in compliance with all governmental, accreditation, and organizational requirements − designed to meet patient needs and needs of clinical personnel responsible for patient care − for the services offered to remove undue pressures and conflicts that could compromise objectivity or quality • the organizational structure to ensure quality • risk assessment of the organization or service's work operations processes • planning for quality • allocation of resources for the quality management system and service operations • periodic review of status of effectiveness of the quality management system	• Define the levels of authority and responsibility for all personnel. • Create and publish organizational structure. • Use a delegated team of executive management to design, implement, maintain, and improve the quality management system. • Create and maintain a quality manual. • Perform ongoing strategic planning that centers on quality. • Appoint a quality manager who reports to top management and has authority to manage the quality system. • Allocate sufficient facility, material, and human resources to operate, review, improve, and maintain the quality management system and work operations. • Communicate the policies, processes, and procedures of the quality management system in a manner that is understood and implemented. • Review the status of the quality management system, prioritize improvements where needed, and allocate necessary resources for improvement.	• maintaining an organizational chart that identifies the quality management structure • tasks performed by a quality review committee/work group member • monitoring the budget for sufficient facility, material, and human resources • communicating quality principles so that all employees understand and implement those activities that describe their responsibilities • management's scheduled reviews of the quality management system

5.2.1 Management Involvement

Experience has shown that a quality management system will not be successfully implemented without support from the top level of the organization—frequently called "executive management." Active participation on the part of the organization's executive management, and the administrative directors, medical directors, managers, and supervisors of each healthcare service, is key to establishing and maintaining a quality culture.

To accomplish the objective of improving operations and services to customers, the healthcare organization's executive management must actively support the establishment and maintenance of the quality management system. Visible participation of the organization's management in setting its quality policy, seeking customer feedback, and receiving and acting upon information derived from quality status reports is essential to the successful implementation of the quality management system.

5.2.2 Quality Planning

Management needs to plan for quality. In addition to developing the mission and vision statements, management needs to take a leadership role in developing policies for each QSE and determining that adequate processes and procedures are in place for implementing them. In particular, all agreements entered into by executive management should reflect the organization's policies for quality. Management needs to receive reports of periodic reviews of its quality management system so that resource allocation to align activities with business goals and strategies can be prioritized.

A detailed discussion of management commitment to quality through quality planning and actualization is included in NCCLS document GP22—*Continuous Quality Improvement: Integrating Five Key Quality System Components*.

5.2.3 Quality Manager

The healthcare organization or service needs to appoint a quality manager (however named) with delegated responsibility and authority to oversee compliance with the requirements of the quality management system. The quality manager is to report directly to the level of management at which decisions are made on policy and resources. Whether the quality manager provides full or partial focus to these responsibilities depends upon the complexity of the organization or service, the quality management system, or other management requirements. A quality manager should have all of the following qualifications to function within an organization-wide environment:

- formal training in quality system management;
- training and experience in auditing techniques;
- good verbal and written communication skills; and
- good negotiation skills.

5.2.4 Quality Steering Group

It is advisable to select a steering group, composed of a broad representation of personnel that will actively participate and oversee the implementation of the quality management system phases listed in Section 6.2. This steering group or quality manager will assign implementation projects, provide support, and track progress in implementing the quality management system. The relationship of the quality steering group to executive management needs to be defined.

5.3 QSE: Personnel

The table below summarizes the major requirements for QSE: Personnel.

Policy	Process	Procedures and Forms/Records
State intent and direction for:	*Describe activities that transform the intent into action.*	*Document instructions for:*
• job qualifications • job descriptions with specified responsibilities • orientation of new personnel to the organization • training of personnel • assessment of competence of personnel after initial training and periodically thereafter • continuing education program • professional development • other personnel policies such as hiring, performance appraisal, grievance, and end of employment	• Create and maintain job descriptions for all personnel. • Establish mechanisms for recruitment and appointment. • Create an orientation program for new personnel. • Create a training program for new personnel and ongoing training for all personnel as needed. • Establish a means of periodically assessing individual competence. • Establish a plan to ensure adequate staffing for the work to be done. • Establish availability for continuing education for all personnel. • Establish a means to maintain records of qualifications, experience, training, and competence assessment. • Establish grievance and termination procedures consistent with applicable laws and regulations.	• establishing job qualifications • writing job descriptions • creating and maintaining personnel files • conducting an orientation program • developing training guides and programs for − quality management − safety − computer systems − ethics − work processes and procedures • conducting and documenting training • conducting and documenting competency assessments • performing employee appraisals • recording continuing education activities

People are the most valuable resources of the organization. Policies and processes for obtaining and retaining only highly qualified personnel should be explicitly indicated by the organization or service.

5.3.1 Job Qualifications and Job Descriptions

The organization or service's management needs to set job qualifications for each job title and document those qualifications in a job description that is kept current. Note that qualifications may be defined at the

national, regional/state, or professional level and need to be considered when developing job descriptions. Job descriptions need to specify the work processes and/or tasks authorized for persons with that job title.

Employees who make professional judgments with reference to diagnostic testing or interpretations need to have the applicable theoretical and practical background as well as experience, which need to be in accordance with any national, regional/state, local, and organizational requirements.

5.3.2 Orientation

Orientation is not the same as training; rather, it is an introduction to the organization's facility and culture. All new staff members should receive orientation to both the organization as a whole and to the service in which they will work. A suggested content for orientation programs is shown in Appendix F.

5.3.3 Training

There should be a documented description of the training process:

- of new employees;
- when new processes and procedures will be implemented;
- when processes and procedures are to be changed; and
- whenever the need for additional training is identified (e.g., a failed competence assessment).

Training and assessment of competence for all staff members needs to take place at several levels. All staff need to have training in the following areas:[a]

- quality management system;
- safety;
- computer system(s); and
- job tasks.

A suggested content for training programs is shown in Appendix G. Training programs need to include reference to relevant standards and applicable literature.

5.3.4 Competency Assessment

Criteria for determination of competence initially after training and ongoing throughout employment need to be established. Employees need to have their competence assessed initially and periodically thereafter to determine if they possess and continue to demonstrate the skills in which they were trained. Competency assessment applies to all employees. When assessments fail to meet established criteria, evaluations into the root cause need to be undertaken and retraining initiated and documented when indicated.

[a] In the U.S. only, Medicare Fraud and Abuse reporting.

5.3.5 Training and Competency Assessment Programs

The organization needs to develop a system to document and track employee training and competency assessment. Documentation systems can be manual or computerized.

NCCLS document GP21—*Training and Competence Assessment* describes a complete program for design, development, implementation, and evaluation of an organization or service's training and competence assessment programs based on the work processes and procedures staff will perform in any healthcare service. Several useful examples of processes, procedures, and forms are included.

5.3.6 Continuing Education and Professional Development

The organization or service needs to provide opportunities for all levels of staff to participate in continuing education. Staff members should be encouraged to seek their own opportunities in addition to those provided by the organization or service.

Professional personnel need to take part in regular professional development or other professional liaison.

5.4 QSE: Equipment

The table below summarizes the major requirements for QSE: Equipment.

Policy	Processes	Procedures and Forms/Records
State intent and direction for:	*Describe activities that transform the intent into action.*	*Document instructions for:*
• selection • acquisition • installation qualification • identification • validation or verification • calibration program • maintenance program • service and repair • equipment files and records	• Establish an organizational mechanism to determine criteria and methods for: – acquisition or replacement – installation – identification – calibration – maintenance – operation – inspection – troubleshooting, service, and repair of all equipment, including computer hardware and software. • Develop a means to uniquely identify equipment, its status of calibration, and due date. • Develop a mechanism for validating before use that new equipment performs in the facility as intended. • Develop a means to remove defective (or suspected) equipment from service and determine the effect of defect on previous service. Develop a means to reverify proper equipment performance before returning it to service. • Develop criteria and a mechanism for retiring outmoded or obsolete equipment. • Maintain records of above items for each piece of equipment that contributes to quality.	• using (operating) the equipment • performing routine calibrations and calibration verifications • maintaining, inspecting, troubleshooting, servicing, and repairing equipment per manufacturer's instructions • decontaminating equipment before repair or decommission • maintaining computer software

This QSE refers to general and service-specific equipment, instruments, and analytical systems, and includes computer system hardware and software. The organization or service needs to be provided with all items of equipment required for the provision of its services. Any additional regulations and accreditation requirements for specific healthcare services are to be followed.

5.4.1 Equipment Acquisition, Installation, and Identification

The processes for equipment acquisition and selection should take into account the use of energy, the impact on the environment, and future disposal. A healthcare organization or service may need to collaborate with the organization's capital equipment acquisition process.

There should be a process for evaluating all new pieces of equipment and instrumentation to verify proper functioning before use in the live environment. Consideration needs to be given to the following:

- load-bearing capacity of the surface on which the equipment will rest;
- space requirements specified by the manufacturer;
- electrical requirements (i.e., need for dedicated line);
- ventilation and air quality;
- humidity;
- temperature;
- water type and quality;
- potential hazards; and
- other requirements specified by the manufacturer.

Each item of equipment needs to be uniquely labeled, marked, or otherwise identified.

5.4.2 Equipment Validation

All equipment, instruments, analytical systems, integral computer functions, new computer systems, and changes to computer programs that will be used in a new or changed process need to be validated as described in Section 5.6.2. All validations are to be documented.

5.4.3 Equipment Maintenance, Calibration, and Use

The organization or service needs to identify equipment that affects patient safety, such as that used in patient care or treatment, or making decisions regarding patient care or treatment, or used to generate results of any examinations. The organization or service also needs to develop calibration plans for this equipment that include:

- the schedule for calibrations and intermediate calibration checks;
- the analysis of the results of calibrations or intermediate calibration checks; and
- actions to be taken on the results.

The organization or service needs to maintain a schedule, instructions, and records for preventive maintenance, calibration, and calibration verification of equipment that follow the manufacturer's instructions and any other applicable requirements. The maintenance program should include evaluation of any electrical safety and emergency stop features so that the equipment is kept in safe working condition.

Equipment under the service's control that requires calibration or calibration verification needs to be labeled or otherwise coded to indicate the status of calibration or calibration verification, and the date when recalibration or reverification is due.

Equipment should be operated only by persons authorized and trained to use it according to manufacturer's operator's manuals, specification, and instructions. Instructions for use are to be kept current and readily available to personnel.

5.4.4 Troubleshooting, Service, and Repair

When problems occur, there should be documented processes to follow for troubleshooting, repair, and postrepair recalibration or revalidation. The effects of any problems or defects on the organization or service need to be determined and followed up according to an established process.

Any piece of equipment that leaves the service's control, for any reason or for any amount of time, needs to be verified for suitability upon return, before replacing it into use.

5.4.5 Equipment Records

A master file should be kept to track the history of a given piece of equipment from request to decommission. At a minimum, the records to be kept in a file for each piece of equipment should include the following:

- name of the equipment;
- manufacturer's name, model, serial number, and facility identification;
- manufacturer's service and support contact information;
- dates of receipt and entry into service;
- current location, where appropriate;
- installation records that confirm the equipment's suitability for use;
- maintenance records, to include follow-up actions of unexpected or outlying results;
- calibration records, to include analysis of data obtained by calibrations and intermediate calibration checks, and any follow-up actions taken;
- maintenance and calibration records;
- problem log;
- service and repair performed and records thereof; and

- decommission or final disposition.

5.5 QSE: Purchasing and Inventory

The table below summarizes the major requirements for QSE: Purchasing and Inventory.

Policy	Processes	Procedures and Forms/Records
State intent and direction for:	*Describe activities that transform the intent into action.*	*Document instructions for:*
• identification of critical materials and services • vendor qualification • purchase agreements and review • inspection and testing of received materials • storage and handling of materials • inventory management • critical materials tracing • vendor evaluation	• Establish a system to qualify and select vendors of equipment, supplies, and services. • Establish a system to define, document, periodically review, and make changes to purchase agreements. • Establish a system to receive, inspect (and test where needed), accept, store, and inventory incoming materials, including special handling. • Establish a mechanism to connect materials to appropriate patients, activities, or records. • Establish a mechanism for evaluation of and feedback to vendors.	• defining criteria for supplies and services to be purchased • maintaining and distributing an approved vendor listing • receiving, inspecting, (testing where needed), and storing incoming materials • tracking supplies to individual patients • assessing and maintaining inventory • evaluating a vendor's materials or services

Efficient and cost-effective operations need the uninterrupted availability of reagents, supplies, and services. The organization or service should set expectations, and build and maintain good relationships with providers of materials and services.

5.5.1 Purchasing

The following activities should be conducted in partnership with the organization's purchasing function.

5.5.1.1 Critical Supplies and Services

The organization or service needs to identify critical supplies and services and define the necessary characteristics or functional requirements for each. These expectations should be communicated to the respective vendors who are then evaluated for their ability to meet the organization or service's requirements.

5.5.1.2 Vendor Qualification and Evaluation

Vendors may be approved based on criteria such as licensure or approval of methods, reagents, or instruments; external certification of the vendor's quality management system (e.g., ISO 9001 registration); a review of past history with the vendor; or any other facility-determined criteria. A listing of approved vendors needs to be maintained as well as records of vendor evaluations.

5.5.1.3 Contract Review

Contracts to *obtain* critical supplies, materials, referral, and other needed services are to be reviewed to ensure that each party's expectations are defined. Any amendments or other changes are also to be reviewed and approved by both parties.

Contracts to *provide* critical supplies, materials, referral, and other needed services to other organizations are to be developed and reviewed to ensure that each party's expectations are defined. Any amendments or other changes are also to be reviewed and approved by both parties.

5.5.2 Inventory

The organization or service needs to have processes for receiving and evaluating incoming critical materials to ensure that necessary quality requirements have been fulfilled. Received supplies that affect the quality of service are not to be used until they have been verified as complying with specified acceptance criteria or requirements—including testing—where required or indicated.

The organization or service needs to have procedures for storage of consumable materials and processes to maintain adequate supplies on-hand. For identified critical materials, records are to be maintained of:

- date received;
- lot number;
- whether or not acceptance criteria were met and any follow-up; and
- date material is placed in service, or disposition if not used.

5.6 QSE: Process Control

The table below summarizes the major requirements for QSE: Process Control.

Policy	Processes	Procedures and Forms/Records
State intent and direction for:	*Describe activities that transform the intent into action.*	*Document instructions for:*
• analysis and design of all work processes • incorporation of governmental, accreditation, and industry requirements • process validation • process documentation • control of changes to established processes • quality control, statistical process control, or other process or outcome measurements	• Determine customer needs and expectations to be met by the product or service design. • Design and document current, new, and changed work operations processes with customer needs and expectations in mind. • Determine and validate or verify performance specifications of equipment and supplies. • Establish turnaround time for production of product or provision of service. • Validate or verify that new and changed processes meet intent and customer expectations. • Ensure that documented procedures are available in all work areas. • Develop and implement a quality control program. • Select and use appropriate statistical tools to monitor and document process performance.	• designing and documenting work processes • performing service-specific tasks • performing each quality control task • defining acceptance criteria • performing validations or verifications • performing statistical analyses

This QSE concerns all the work operations in the organization or service's path of workflow. It is only through understanding and controlling the organization's many processes that it can become both more effective in meeting requirements and more efficient in the use of costly human and other resources.

Each healthcare organization or service should identify the work processes in its operations and document them through flowcharting or other visual means. Operations processes need to be validated to ensure

they work as expected before implementation and meet the customers' needs. The service is to use quality controls to detect errors, and process controls where needed or required to prevent errors.

5.6.1 Developing Flowcharts for Organization Processes

Ideally, process flowcharts should be prepared for all activities in each QSE *and* for all operations in the organization or service's path of workflow. Guidance for the types of processes that could be flowcharted for the QSEs is given in the "Processes" column of the tables in Section 5. A summary of processes by QSE with a listing of corresponding NCCLS guidance is provided in Appendix C (previously described).

Guidance for the processes that should be flowcharted for the paths of workflow for common healthcare clinical services can be found in the following NCCLS documents:

GP26—*Application of a Quality System Management Model for Laboratory Services*;
HS4—*Application of a Quality System Model for Respiratory Services*;
HS5—*Application of a Quality System Model for Medical Imaging Services*; and
HS10—*Application of a Quality System Model for Inpatient Medication Use*.

Flowcharts can be documented manually or by using any of several available software programs. Work process flowcharts identify activities where procedures are needed to communicate to staff how to perform work tasks. Once a process is outlined on a flowchart, problems that may result in miscommunication or quality failures or cause inefficiencies, can be identified. Revised processes can then be implemented to improve or correct performance.

5.6.2 Process Validation or Verification

Processes that are critical to the quality of the organization or service's product (defined as patient care, treatments, point-of-care testing, and medical reports) need to be validated or verified. If the process is developed by the organization or service, the process must be both validated and verified before implementation. If the process is not developed by the organization or service (e.g., the process employed to use a manufacturer's test system such as for an imaging device or laboratory analyzer), the process needs only to be verified.

Validation consists of a plan for personnel to challenge and document the results of a new or modified process to ensure that the process works as intended before actual implementation, taking into consideration the activities of all involved parties. Whenever a change is necessary, the revised process should be validated to ensure that the results would continue to meet the organization's needs and expectations, as well as those of its customers and all involved parties.

Validation or verification includes the use of all the equipment, instruments, analytical systems, integral computer functions, and documented procedures that will be a part of the new or changed process to verify that they are capable of achieving the required performance before actual use. New computer systems and changes to computer programs are also to be validated before use. All validations are to be documented. Revalidation or reverification of processes may need to occur at regular intervals.

Questions to be considered when designing a validation include:

- Which processes need to be validated?
- How is a process validation performed?
- Who should perform the validation?

- How should the validation protocol be designed?
- Who should approve the validation protocol design and the results of the validation?
- Who should review the validation reports?
- Who should authorize the validated process?
- What can be measured on an ongoing basis to determine if the process is functioning as intended?

Examples of ways to validate healthcare processes can include:

- side-by-side analysis
  - old procedure vs. new procedure, or
  - new procedure vs. gold standard and comparisons
- diagnostic utility or clinical relevancy.

A sample outline for the contents of a validation protocol is provided in Appendix H.

5.6.3 Identifying and Writing Procedures

Well-documented work procedures and instructions that are understood and used by the organization or service's staff members are key to communicating process requirements and ensuring consistency in performance.

There should be documented procedures for critical activities in the QSEs. Guidance for procedure development for the QSEs is given in the "Procedures" column of the tables in Section 5. Personnel who will be performing procedures in the QSEs need to be trained in those procedures as well as in their technical responsibilities.

NOTE: These lists are not meant to be all-inclusive, but rather provide some examples of the main procedures that support the related processes.

The organization or service's path of workflow identifies the work processes required to deliver its product or service. In turn, the process flowcharts or tables identify where documented procedures are needed.

Documented procedures are needed for all operations in the organization or service's path of workflow. Procedures need to be easy to read, use, and follow. In the examples provided in NCCLS document GP2—*Clinical Laboratory Technical Procedure Manuals*, note how the use of columns, bullets, and tables simplifies these documents and provides necessary information in a visually pleasing format.

5.6.4 Process Control

Once a quality management system is put into place, each operation needs to be monitored to ensure that it is functioning as designed and that it contributes to achieving the goals and objectives stated in the quality manual. Tools available for monitoring processes include:

- a quality control program that reflects the internal procedures and methods of the service and meets minimum governmental requirements;

- external assessment programs that offer an external peer-based assessment of process output (e.g., proficiency testing);
- occurrence logs which itemize and characterize nonconformances in process or product output;
- statistical techniques which help personnel to understand process performance and analyze trends; and
- quality indicators with thresholds that cause staff and managers to review the process.

5.6.4.1 Use of Statistical Tools

Statistical tools have been described and used for controlling processes. These may include:

- run charts;
- Pareto charts;
- histograms;
- control charts; and
- process capability charts.

More information on the use of statistical tools can be found in a large number of publications on quality management tools.

5.7 QSE: Information Management

The table below summarizes the major requirements for QSE: Information Management.

Policy	Processes	Procedures and Forms/Records
State intent and direction for:	*Describe activities that transform the intent into action.*	*Document instructions for:*
• privacy and confidentiality of all patient information • security for data access • authority levels • integrity of data transmissions • provision for information availability during downtime • charging and billing practices (where required)	• Communicate organizational commitment to confidentiality and privacy of patient-related information, including written and electronic transmission to external sources. • Establish a process for receiving external information and disseminating it appropriately, for both written and electronic transmission. • Define which persons can access and use computer systems. • Define which computer functions can be performed at which levels of access. • Develop a means to protect data integrity at all times for computer and automated testing equipment. • Develop a means to label and store data storage media and protect from damage or unauthorized use. • Develop a means for availability of data in case of downtime. • Develop a protocol for handling requests for patient information. • Establish a plan to ensure that governmental and/or industry standards for the service's charging and billing practices are met (where required).	• maintaining privacy and confidentiality of patient information • receiving patient records and other materials from external sources • transporting or transmitting current documents • changing a computer password • changing a computer access level • verifying data integrity after transmission or downtime • charging for services and handling bills (where required)

The organization's commitment to quality in the flow of information between service units within the organization, as well as communication with external entities, needs to be defined unequivocally to include security of data access and the integrity of data transfers.

5.7.1 Focus of Information Management

Whereas important guidance for computer system hardware and software programs is provided in QSE: Equipment, QSE: Information Management concerns itself with guidance for managing the information generated and entered into the computer or other recordkeeping system, (e.g., patient demographics, test results, interpretations, care, treatments) and disseminated electronically or otherwise to users or other computer systems (e.g., verbal requests, automatic faxing, e-mail, interfaces). Information management includes assessment of information needs, planning and designing to meet those needs, and dissemination of information throughout the organization in a timely and accurate manner.

5.7.2 Incoming and Outgoing Information

Organizations need to establish processes for managing incoming and outgoing information, whether written or electronic. Systems for creating documentation for use within an organization may not be appropriate for managing the flow of information from such external sources as governmental agencies, accrediting and certifying bodies, etc. Compliance with national or regional research guidelines, reimbursement requirements, and the reporting of device or product failures are only a few examples of this type of information management.

5.7.3 Computer Access and Security

The organization or service needs to establish and document processes and procedures for:

- identifying appropriate levels of computer access for each job title;
- assigning passwords and changing them at regular intervals;
- changing verified results or interpretations, or adding an addendum;
- altering computer programs;
- maintaining confidentiality; and
- changing charging or billing.

The process should include an audit mechanism that allows for identification of any individual who has entered or modified patient data, control files, or computer programs. Computer programs need to have adequate protection to prevent alteration or destruction by casual or unauthorized users.

One service's computer system (e.g., laboratory, pharmacy, imaging, hospital) should not be allowed to jeopardize the data security of the other services' systems; therefore, there needs to be appropriate security measures to prevent unauthorized access to data and information in one computer system that can be accessed from other systems.

5.7.4 Data Integrity

The organization or service should have a process to verify data integrity by comparing patient information on reports and video displays with original input at defined intervals to detect errors in data transmission, storage, or processing. There should be periodic verification and documentation of review of calculations performed on patient data by the computer system.

5.7.5 Information System "Downtime"

Processes need to be in place so that in the event of hardware or software failure, the organization or service's work operations and availability of patient data are not compromised. Such "downtime" processes and procedures need to be documented and should be practiced periodically.

5.7.6 Requests for Information

The organization or service needs to establish and document processes and procedures for the handling and filling of requests for patient information in accordance with governmental, organization, and other requirements.

5.8 QSE: Occurrence Management

The table below summarizes the major requirements for QSE: Occurrence Management.

Policy	Processes	Procedures and Forms/Records
State intent and direction for:	*Describe activities that transform the intent into action.*	*Document instructions for:*
• identification, documentation, and investigation of nonconforming events, including complaints • classification, analysis, and trending the data and information they represent • identification of need for root cause analysis and process improvement	• Establish a standardized reporting mechanism for any aspect of service that does not conform to established policies, processes, or procedures, including complaints. • Establish a mechanism to manage recalls of materials, equipment, or software. • Establish a mechanism for receiving, reviewing, classifying, analyzing the information in, and filing the reports. • Review data and information from the reports at regular intervals to detect trends and initiate corrective action. • Define a mechanism for referral to process improvement for root cause analysis and corrective action.	• identifying and reporting deviations, nonconformances, unusual occurrences, unexpected outcomes, recalls, and complaints—to include remedial action • classifying occurrences • analyzing occurrence data and information using statistical tools • tracking and trending information • scheduled reporting of analysis findings to management • identifying and referring opportunities for performance improvement

The purpose of an occurrence management program is to capture and analyze information from nonconforming events to identify systematic problems and gain management's commitment to removing the cause. Occurrence management is linked to the healthcare organization's risk management program, because it provides information on systematic service problems that could pose legal or financial risk issues for the organization. Each organization needs to have a process for detecting and documenting

occurrences (nonconformances), classifying them for analysis, and correcting the problems they represent.

Identifying, investigating, and classifying occurrences early in the implementation of the quality management system leads to rapid identification of:

- lack of a documented process, procedure, or instructions;
- documented processes or procedures not being followed; and
- which QSE or work operations process(es) is/are causing the most problems.

5.8.1 Capturing Information

The organization or service needs to maintain processes and procedures to be implemented when it detects any aspect of its operations that does not conform to its own procedures, requirements of the quality management system, or the agreed-upon requirements of its customers. The organization or service needs to develop an internal system to capture and report any and all occurrences (nonconformances) when a process or procedure does not have the expected outcome. Reporting also includes a nonconforming event that was caught and corrected before any harm occurred (i.e., a "near miss").

Some examples of occurrences include:

- reporting of occasions when other services did not follow established policy, process, or procedure therefore affecting the service's ability to meet its customers' expectations;
- all occasions of verbal or written customer complaints;
- communications failures within the organization or service and to outside customers;
- mistakes and problems in work operations; and
- events that could have or have had adverse implications for patients, employees, or visitors.

5.8.2 Occurrence Report Form

An occurrence report form should minimally include space for the tracking number, date/time of occurrence, description, remedial action taken, and any follow-up or investigation. Appendix I provides an example of a quality management system-oriented occurrence report form.

5.8.3 Immediate Action and Investigation

The employee who discovers the problem should take steps necessary to resolve the immediate issue (remedial action) and document the action taken on the occurrence report form. The form is given to the designated person who logs the occurrence; the investigation then begins. The investigation needs to assess the impact of the occurrence and whether other customers were affected; where appropriate, remedial actions for all affected parties need to be taken. Appendix J provides an example that could be used as a paper form, spreadsheet, or database. However, the use of an electronic spreadsheet or database greatly facilitates sorting, tracking, and trending. Commercially available occurrence-tracking software commonly used in business and industry is easily adapted for use in healthcare organizations or services.

5.8.4 Occurrence Analysis

Analysis of occurrence information should be performed to identify trends or patterns that highlight a need for root cause analysis and corrective action. The occurrences can be sorted according to their classifications, and the sorted information can be presented in pie charts or Pareto charts. Occurrence data are also meaningful when presented as a ratio of numerator (number of occurrences) to denominator (e.g., number of tests, number of patients, number of billed procedures).

The information contained in the occurrence log should be analyzed for trends and patterns of recurring problems. When it is determined that the same type of problem will or has continued to recur, activities to identify, document, and eliminate the root cause need to be initiated.

5.8.5 Corrective Action

Awareness of a problem carries the responsibility that something will be done to remove its cause and prevent recurrence. A plan of corrective action should be devised, implemented, and documented; the corrective action should be appropriate to the magnitude of the problem and commensurate with the risks encountered. The method for assessing the effectiveness of the corrective action needs to be included in the plan. See Section 5.10 for a discussion of process improvement.

5.9 QSE: Assessments—External and Internal

The table below summarizes the major requirements for QSE: Assessments—External and Internal.

Policy	Processes	Procedures and Forms/Records
State intent and direction for:	*Describe activities that transform the intent into action.*	*Document instructions for:*
• external quality management or accreditation assessment (e.g., peer reviews) • external quality assessment (e.g., proficiency testing) • quality indicators for work processes • internal audits • benchmarking and other comparisons • preparation of a quality report for management review	• Establish a mechanism for the organization or service to participate in external assessments (e.g., accreditation assessments). • Establish a mechanism for participating in external quality assessment (i.e., proficiency testing), where needed. • Identify and implement quality indicators (e.g., turnaround time, outcome measurements) to systematically monitor the organization or service's contribution to patient care. • Develop an internal audit program. • Establish a mechanism to benchmark to outside and/or best practices. • Identify opportunities for improvement (OFI) (i.e., preventive action) and refer for process improvement. • Develop a mechanism to ensure periodic reporting to the organization's management and quality function.	• staff conduct during external assessments or internal audits • developing indicators to measure aspects of the quality of the service's operations in the path of workflow • collecting and analyzing data for quality indicators • conducting internal audits • benchmarking to other quality indicators and best practices • reviewing external and internal assessment information to identify OFI • preparing the organization or service's quality reports for management review

Assessment of quality is integral to achieving it. It is the means to determine the *effectiveness* of the quality management system. Each organization or service unit needs to periodically assess the effectiveness of its quality management system by comparing the QSEs against external and internal benchmarks to ensure that it is effectively meeting the intent of its stated requirements.

5.9.1 External Assessments

External assessments are activities to evaluate the quality management system, conducted by sources outside the organization or service.

External assessments include:

- peer inspections or assessments for the purpose of accreditation or licensure;
- interservice comparison of methods and results (e.g., proficiency testing); and
- benchmarking performance measurements to external sources.

5.9.1.1 Accreditation Assessment

Organizations should participate whenever possible in accreditation programs, based on national or regional requirements. Specific program requirements can be obtained from the accreditation organization.

The organization or service should have a documented process for handling external accreditation assessments conducted by governmental and accrediting organizations.

The process should include the responsibilities and activities for:

- scheduling;
- preassessment paperwork;
- receiving assessors;
- conducting the assessment;
- closing summary;
- follow-up response; and
- corrective action.

5.9.1.2 External Quality Assessment (e.g., Proficiency Testing)

Service units that perform diagnostic testing (e.g. medical laboratories, blood gas testing, point-of-care testing) need to participate in programs of external quality assessment. Specific program requirements can be obtained from the organization providing the external assessment materials.

5.9.1.3 Benchmarking

Benchmarking is the activity of comparing the organization or service's performance to services of like kind or the "best in class" of a similar type of service. This activity provides knowledge of how the organization or service measures up to its peers or world-class organizations. While benchmarking may

not be required for all healthcare organizations or services at this time, the trend is moving in that direction.[b]

5.9.2 Internal Assessments

Internal assessments are activities conducted by the organization or service itself that answer the questions, "How well are we doing?" and "Are we in compliance with requirements?"

5.9.2.1 Quality Indicators

Quality indicators are those observations, statistics, or data that typify the performance of a given work process. Quality indicators need to be identified and monitored for all operations across the organization or service's path of workflow. There is no one set of indicators that has been required, recommended, or suggested for each healthcare organization or service. On the contrary, organizations or services have been encouraged to identify their own high-risk, high-cost, and problematic issues that link to their quality goals and objectives. These issues then identify potential quality indicators for assessment.

Selected indicators should measure critical aspects of the organization or service's path of workflow—in preservice, service, and postservice activities that affect the organization or service's ability to meet its customers' needs. Action is to be taken when the information from indicators demonstrates unacceptable performance or trending in that direction. When information from indicators demonstrates continued accepted performance, different indicators should be monitored.

Some examples of healthcare service indicators include:

- presence of patient identification (e.g., wristband) at the time of service delivery;
- acceptability of samples for testing;
- turnaround time of service provision to key customers;
- number of medication errors, by type of error;
- number of missing medical images, when needed; and
- number of corrections to verified reports.

Appendix K is an example of a quality indicator development form.

5.9.2.2 Internal Audit Program

A quality audit reviews the organization or service's quality management system including work operations. The audit assesses compliance with internal policies, processes, and procedures, as well as any applicable regulations and requirements for both the QSEs and the service's path of workflow.

5.9.2.2.1 Quality Audit Methods

The auditor assesses the implementation of the organization or service's quality management system by reviewing the documented quality management system and conducting personal observations. The purpose is to verify that the quality management system is being followed.

[b] Healthcare organizations accredited by the Joint Commission on Accreditation of Healthcare Organizations are required to participate in benchmarking activities.

To evaluate implementation, the auditor examines whether or not the facility has defined its processes and procedures, and communicated them adequately to its employees. The auditor examines the organization or service's records, assessments, satisfaction survey results, and occurrence reports to see whether or not the services produced from the stated processes and procedures meet the stated intent, any applicable regulations or requirements, and the customers' needs. The auditor also determines whether employees are following established processes and procedures.

5.9.2.2.2 Auditors

Any employee or contractor can perform quality management system audits, but need to receive special training in the audit function. To avoid conflicts, auditors are not to audit any activity for which they have direct responsibility.

5.9.2.2.3 Audit Report

At the conclusion of the audit, the auditor issues a report to management in a timely manner that describes any discrepancies between the documented quality management system and what the auditor found in the records reviews, interviews, and observations. The report is written in a way to help management understand the impact of the discrepancies on the quality of its services to its customers.

5.9.3 Periodic Reporting

The organization or service needs to periodically report its findings from external and internal assessments to the organization's quality function and executive management for review.

An example of a systematic quality management surveillance report can be found in Appendix L.

5.10 QSE: Process Improvement

The table below summarizes the major requirements for QSE: Process Improvement.

Policy	Processes	Procedures and Forms/Records
State intent and direction for:	*Describe activities that transform the intent into action.*	*Document instructions for:*
• participation in quality improvement activities that deal with relevant areas and outcomes of patient care • systematic review of all processes to identify potential sources of nonconformances for preventive action • corrective action of recognized process problems • use of a defined improvement process • evaluation of effectiveness of improvement actions taken	• Establish a mechanism to identify opportunities for improvement. • Develop a mechanism to change processes when indicated to prevent recurrence. • Use a defined strategy or program for process improvement. • Establish a process for approving, implementing, and monitoring necessary improvements. • Develop a mechanism to assess if corrective and preventive actions were effective.	• reviewing data from − satisfaction surveys − occurrence management reports − quality indicators − complaints − internal audits, and − assessments • applying the approved problem resolution process • planning the proposed/ suggested improvement • obtaining approval to implement proposed/ suggested improvement • measuring effectiveness of corrective and preventive actions • preparing reports of corrective and preventive actions and improvement activities for management review

5.10.1 Identifying Opportunities for Improvement

The need for improvement exists inherently in all processes. It does not necessarily come in response to a problem but can come from several sources. Healthcare organizations or services can access a wealth of information that identifies needed improvements. The information should be obtained from as many sources as possible, including all of the following:

- feedback from employees;
- feedback from patients, physicians, and others;
- feedback from external customers (e.g., referring laboratories or other healthcare services);
- performance on external assessments (governmental, accreditation, or other);

- performance on quality indicators;
- performance on internal quality audits;
- benchmarking information;
- analyses of occurrences, including trends;
- reports from other areas in the organization;
- literature reviews; and
- any other source that suggests the difference between customer needs and organization output.

Employees need to understand that they have an important and ethical responsibility to raise the issue and submit suggestions for process improvements, especially when the suggestion leads to increased patient safety.

5.10.2 Preventive and Corrective Action

Information derived from quality indicator data may show trends and patterns that, if continued, may result in eventual nonconformances. These opportunities for improvement (OFI) allow the organization or service to take action to *prevent* a nonconformance or untoward event. Such *preventive action* is proactive—that is, taken to ward off a nonconformance.

External assessments and quality audits will bring to light identified nonconformances that require corrective action. *Corrective action* is reactive—that is, action taken to remove the cause of an identified problem to prevent recurrence.

Preventive and corrective actions need to be documented and implemented, and evaluated for effectiveness with follow-up assessments, indicators, or audits.

5.10.3 Problem Resolution Process

The organization or service needs to use a problem resolution process and quality improvement tools to resolve problems and improve the quality of its services to its customers.

Quality improvement programs minimally include the basic activities of:

- problem identification, prioritization, and selection;
- analysis of the current process and collection of data;
- determination of the problem's root cause;
- generation of ideas for solutions and selection of one or more solutions;
- implementing the chosen solution; and
- monitoring the effects of the chosen solution.

The organization or service should apply the problem resolution process to all quality improvement efforts undertaken. An overview of the standard "Plan-Do-Check-Act" (PDCA) process for problem resolution is provided in Appendix M.

5.10.4 The Team Approach

When the need for improvement is identified, a team approach to the resolution may be more appropriate, depending on the character of the problem, the frequency of occurrence, and the scope of involvement (i.e., which areas of the organization are involved). In general, a team approach to problem solving increases the potential for creative problem resolution and acceptance of the recommended change. When problems develop across functional boundaries, teams should include representation from all involved areas.

5.10.5 Quality Improvement Tools

Quality improvement tools are useful in the team approach to problem resolution. Some of these tools include:

- brainstorming;
- flowcharting;
- cause-and-effect diagrams; and
- the statistical tools mentioned in Section 5.6.4.1.

Additional guidance for continuous quality improvement can be found in the current edition of NCCLS document GP22—*Continuous Quality Improvement: Integrating Five Key Quality System Components.*

5.10.6 Periodic Reporting

The organization or service needs to report its quality improvement activities, progress, and findings at predefined intervals. Individual healthcare organizations or services may need to periodically report to the larger organization. Information from process improvement activities can be made part of the quality report that is prepared for management review, discussed in Section 5.9.3.

5.11 QSE: Customer Service

The table below summarizes the major requirements for QSE: Customer Service.

Policy	Processes	Procedures and Forms/Records
State intent and direction for:	*Describe activities that transform the intent into action.*	*Document instructions for:*
• identification of the organization or service's customers • identification of customer needs and expectations • determination of internal and external customer satisfaction • determination of customer feedback mechanisms • documentation and management of complaints • referral to process improvement where needed	• Develop a mechanism for determining customer needs for new processes or programs. • Develop a means to record and resolve complaints and other feedback received (see QSE: Occurrence Management). • Develop a mechanism for measuring satisfaction with services provided. • Establish a method for analysis and reporting of information obtained from surveys, including referral to process improvement, if needed.	• receiving and responding to customer complaints (see QSE: Occurrence Management) • obtaining approval for satisfaction surveys • creating satisfaction surveys • conducting satisfaction surveys • analyzing satisfaction survey results • preparing reports for management review

One aspect whereby a healthcare organization or service's effectiveness can be measured is customer service and satisfaction. The organization or service needs to:

- identify its customers to include internal and external groups;
- determine these customers' respective needs;
- structure its work operations processes and procedures to meet these needs to the customers' satisfaction; and
- actively seek customer feedback to determine if the needs are being met.

The organization or service needs to develop mechanisms to measure the satisfaction of the different customer groups, survey the customers, and analyze the results of the survey efforts. When feedback indicates the need for improvement, the organization or service needs to undertake process improvement actions.

5.12 QSE: Facilities and Safety

The table below summarizes the major requirements for QSE: Facilities and Safety.

Policy	Processes	Procedures and Forms/Records
State intent and direction for:	*Describe activities that transform the intent into action.*	*Document instructions for:*
• space and facilities allocation • facility design and renovation in accordance with requirements • facilities use and maintenance • creation of an environment that is − ergonomic − efficient, and − safe • required safety programs	• Design, construct, and renovate the facility to optimize efficiency, minimize risk of injury and occupational illness, and protect from recognized hazards. • Design communications systems for the size and complexity of service and efficient transfer of messages. • Establish programs to ensure that governmental and/or industry standards for facilities, safety, and environmental conditions are met. • Establish a process for routine maintenance to keep the facility in functional, reliable, and safe condition. • Provide for storage of dangerous goods and safe disposal of hazardous waste. • Identify activities to maintain clean work areas and good housekeeping.	• reporting unsafe work conditions • responding to unexpected unsafe work conditions • resolving identified unsafe work conditions • cleaning of work areas • storing dangerous materials • disposing of hazardous waste • obtaining employee health assistance • submitting employee suggestions for improving the work environment

Each healthcare organization or service needs to establish and maintain an environment that provides safety for all, in compliance with requirements and standards. This would include the environment in which care, treatment, and services are delivered to patients as well as nonpatient work areas.

The organization or service's allocated space needs to be such that its workload can be performed without compromising the quality of work and the safety of personnel or patient care services. The organization or service needs to be designed for the efficiency of its operation, to optimize the comfort of its occupants, and to minimize the risk of injury and occupational illness. Patients, employees, and visitors need to be protected from recognized hazards. Work areas need to be clean and well maintained with appropriate storage and disposal of dangerous materials.

Adherence to safety requirements is an individual responsibility. Also, the organization or service must show that it has provided the correct opportunities for each employee to comply, including documentation of appropriate training and provision of any required personal protective devices. Requirements of regional and local public health authorities may also apply.

At the international level, a safety standard has been published. ISO 15190 includes guidance for safety management in medical laboratories.[15] NCCLS document GP17—*Clinical Laboratory Safety* also provides important information and guidance.

6 Establishing the Quality Management System

Implementing a quality management system in a healthcare organization means that the organization has identified important processes in its management infrastructure (i.e., the QSEs) and has clearly communicated which departments or functions are responsible for which actions. This section provides information for planning and implementing a quality management system.

6.1 Planning for the Quality Management System

6.1.1 Document Gap Analysis

The organization should first perform a "gap analysis" by comparing its current documents to the suggested policies, processes, and procedures for the quality system essentials shown in the previous tables and described in this guideline. Where the organization already has adequate policies, processes, and/or procedures in place, no document gap exists. The document gaps are the areas for which no *written* information can be located. In many organizations, the quality processes (the QSE activities followed by managers to accomplish the institutional needs) and the procedures (the step-by-step instructions for an individual employee's actions) are not documented. The process of developing one set of quality policies for the quality system essentials and describing them in one quality manual unifies and clarifies the quality message for all employees.

Where specific elements of quality policy, process, or procedure are incomplete, missing, or unclear, the organization or service is encouraged to "close the gap" by completing, developing, clarifying, or unifying these documents.

6.2 Phases of Implementation

6.2.1 How to Begin

The quality system essentials do not have to be implemented in the order in which they are presented. Some QSEs should be among those started first, while others may proceed thereafter. The order suggested below facilitates policy setting, process development, and procedure writing.

6.2.2 Initial Phases of Implementation

Confirmation of leadership commitment is paramount to the success of quality management system implementation. QSE: Organization needs to be one of the first QSEs implemented.

The following activities set the foundation and direction for implementing the quality management system and based on the gap analysis, can be implemented in the order that best suits the particular requirements of the organization or service:

- development of the quality manual documents (QSE: Documents and Records);

- development of the program for occurrence management (QSE: Occurrence Management);
- development of processes for controlling documents and records (QSE: Documents and Records);
- analysis and validation or verification of work processes, with development of procedures and instructions (QSE: Process Control); and
- implementation of process controls (QSE: Process Control).

Usually, a management-appointed steering group is charged with developing and implementing or overseeing the initial phases of the quality management system. Managers and supervisors of various work processes are included in these activities as needed. The appointed quality manager should be a member of the steering group.

6.2.3 Remaining Phases of Implementation

Based on the results of the gap analysis, the remaining phases of implementing the quality system essentials include development of:

- personnel programs (QSE: Personnel);
- equipment management plans (QSE: Equipment);
- purchasing and inventory programs (QSE: Purchasing and Inventory);
- information management program (QSE: Information Management);
- internal quality indicators and audit program (QSE: Assessments: External and Internal);
- process improvement program (QSE: Process Improvement);
- service and satisfaction program (QSE: Customer Service); and
- facilities and safety plans (QSE: Facilities and Safety).

Teams may be used to develop the processes and procedures for the remaining phases. The use of teams allows these phases to progress simultaneously.

7 Applying Quality Management Systems to a Healthcare Organization's Operations: The Companion Documents

In healthcare organizations, there are multiple service units providing various services. Each of these services can apply the larger organization's quality management system to its operational activities, or an individual service may choose to implement its own quality management system without waiting for full participation from the larger organization. The QSEs are applicable to any type or size of organization or service. However, each organization or service has its own unique activities and these activities can be "mapped" into its respective path of workflow to accomplish the assigned tasks.

7.1 The Path of Workflow

The path of workflow describes the operational aspects that define how a particular service is provided. ISO 9001[13] describes this concept as the "process model." It represents the sequence of activities from the initiation of a request for a healthcare organization's services through the provision of those services, and any necessary follow-up. The activities may cross functional (e.g., departmental) boundaries. For example, an order for a laboratory test, imaging procedure, or medication is usually initiated by a physician but is communicated to the service through another activity that may not be under the service's direct control, such as the entry of an order into a computer, the preparation of a requisition, or a telephone call. Each organization or service needs to identify the activities in its respective path of workflow. Collections of sequential, related activities are grouped together as processes.

Each healthcare service area across the continuum of care, such as emergency services, nursing, laboratory, imaging, respiratory care, medical records, accounting, home health care, outpatient services, etc., needs to define its path of workflow and understand that these paths may extend beyond their immediate operations to other services, customers, and stakeholders. Service interface responsibilities need to be defined and allocated between the involved services to assure continuity of patient care.

Each service within a healthcare organization should use the same quality management system structure to manage its specific path of workflow. It is then possible to have a quality management system integrated across an entire healthcare organization (see Figure 3 below). This figure illustrates that the patient needs to be considered at both the beginning and the end of the service's path of workflow. The clinician makes an assessment of the patient's situation before ordering a test or service. The order proceeds through the service's path of workflow operations (which is supported by the processes and procedures of the QSEs). The clinician then uses the service's output (diagnoses, results, medications, images, etc.) in the care of the patient to achieve the best possible patient outcome.

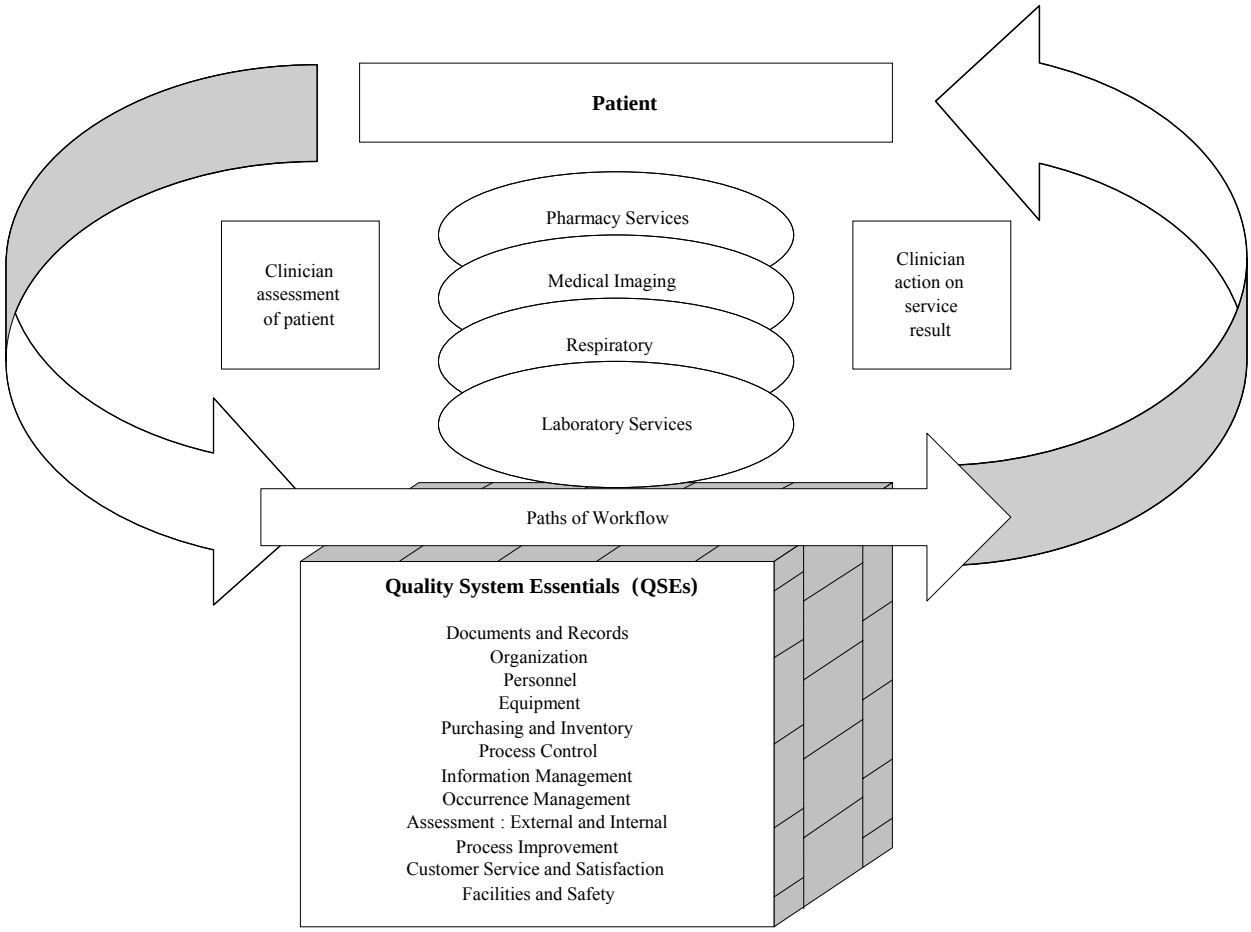


Figure 3. The Quality Management System Model. The clinician's assessment of the patient generates an order for a healthcare service. The service realizes the order through its path of workflow. The clinician uses the services output (e.g., results, image, diagnosis) to make diagnostic and treatment decisions for the patient. The 12 QSEs are the necessary infrastructure that supports any healthcare organization or service's path of workflow.

7.2 Companion Documents

Discipline-specific NCCLS companion documents have been created for application in healthcare services and illustrate the use of the quality system essentials in the specific path of workflow defined for the service. The following NCCLS documents provide this information:

GP26—*Application of a Quality System Management Model for Laboratory Services*;
HS4—*Application of a Quality System Model for Respiratory Services*;
HS5—*Application of a Quality System Model for Medical Imaging Services*; and
HS10—*Application of a Quality System Model for Inpatient Medication Use*.

8 Conclusion

Health care must expand its view of quality beyond the departmentalized quality assurance activities to keep pace with the growing role of total quality management in today's competitive environment. Quality management systems are being used successfully in the world's manufacturing and service sectors. These systems can be applied to benefit healthcare organizations and services to improve patient safety.

Each healthcare organization or service can use the same quality system essentials to manage its specific path of workflow. The healthcare organization's management can develop one universal set of policies, processes, and procedures for the quality system essentials that apply to all the services in the entire organization. Every standard that has ever been written for healthcare organizations or services, or will ever be written, can be linked to one of the QSEs.

Uniform processes and procedures for implementing the quality policies within the organization reduce medical errors and reduce opportunities for costly discrepancies, conflicts, and competition for limited resources among the organization's services. Using the same quality system essentials for each healthcare service integrates the quality management system across the entire organization.

This guideline presents a working model that will enable champions for change to take the first steps in improving quality management in healthcare organizations.

References

[1] Cianfrani CA, Tsiakals JJ, West JE. *The ASQ ISO 9000:2000 Handbook*. Milwaukee, WI: American Society for Quality; 2002.

[2] Deming WE. *Out of the Crisis*. Cambridge, MA: MIT Press; 1986.

[3] Juran JM. *Juran on Quality by Design: The New Steps for Planning Quality into Goods and Services.* New York, NY: Free Press; 1992.

[4] Maslow AH. A theory of human motivation. *Psych Rev.* 1943:50;370-396.

[5] Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System.* Washington, D.C.: National Academy Press; 2003.

[6] Wachter RM, Shojania K. *Internal Bleeding: The Truth Behind America's Terrifying Epidemic of Medical Mistakes.* New York, NY: Rugged Land; 2004.

[7] ISO. *Quality management systems—Fundamentals and vocabulary.* ISO 9000. Geneva: International Organization for Standardization; 2000.

[8] ISO. *International Vocabulary of Basic and General Terms in Metrology*. Geneva: International Organization for Standardization; 1993.

[9] ISO. *Statistics - Vocabulary and symbols - Part 2: Statistical quality control.* ISO3534:2. Geneva: International Organization for Standardization; 1993.

[10] American Association of Blood Banks. *Standards for Blood Banks and Transfusion Services.* 22nd ed. Bethesda, MD: AABB; 2003.

[11] Joint Commission on Accreditation of Healthcare Organizations. *Comprehensive Accreditation Manual for Pathology and Laboratory Services.* Oakbrook Terrace, IL: JCAHO. Published annually.

[12] ISO. *Medical laboratories—Particular requirements for quality and competence*. EN/ISO 15189. Geneva: International Organization for Standardization; 2003.

[13] ISO. *Quality Management Systems—Requirements*. ISO 9001. Geneva: International Organization for Standardization; 2000.

[14] Centers for Medicare and Medicaid Services. Department of Health and Human Services. Part 493—*Laboratory Requirements: Clinical Laboratory Improvement Amendments of 1988*. Code of Federal Regulations, Title 42, Parts 430 to end. U.S. Government Printing Office. Published annually.

[15] ISO. *Medical laboratories—Requirements for safety*. ISO 15190. Geneva: International Organization for Standardization; 2003.

Helpful Websites

American National Standards Institute (ANSI) Distributor of ISO Standards in America	http://www.ansi.org
International Organization for Standardization Developer and distributor of ISO standards	http://www.iso.ch
American Society for Quality Publishes extensively on various aspects of quality management and quality tools	http://www.asq.org
NCCLS Secretariat for ISO/TC 212 and publisher of numerous guidelines and standards for clinical laboratories and healthcare services	http://www.nccls.org

Appendix A. Example of a Quality Manual Table of Contents

XYZ Service Quality Manual

Appendix B. QSE Policy: Documents and Records

QSE Policy: Documents and Records
Effective Date:
Document #/version #

QSE Policy: Documents and Records

Policy

The management of [facility name/function] ensures that documents and records are managed from creation or receipt to archive or destruction according to established processes that reflect the organization's commitment to quality, as well as meet legal requirements.

Purpose

This policy provides guidance for the processes and procedures to be used in controlling the service's documents and records.

Responsibility

The [responsible function name] is responsible for establishing and maintaining the document control system.

Managers and supervisors are responsible for:

- following approved processes for receiving incoming documents and records;
- creating and gaining approval for all necessary documents and forms;
- ensuring that staff have immediate access to current copies of the documents they need to perform their work;
- overseeing the accurate and complete creation of records;
- prompt removal of obsolete documents from the workplace;
- ensuring destruction when appropriate; and
- storage and retrievability of all required documents and records.

Document Creation

Standardized formats are used for creating all types of documents to ensure consistent and effective representation of all requirements.

Review and Approval

- Staff who are familiar with the subject matter of a given document are assigned to review new documents before they are implemented.
- Staff members who are familiar with the original document review and approve changes to a document.
- Approval is obtained before implementation.

Continued on next page

Appendix B. (Continued)

QSE Policy: Documents and Records
Effective Date:
Document #/version #

Document Availability and Storage	Controlled copies of documents are: • available to staff as required; • maintained, stored, and retrievable; and • retained for periods specified in the approved retention schedule.
Document Master List and Numbering System	• The [responsible function name here] maintains a master list of current versions and effective dates of documents in this quality management system, so staff knows if they are using the correct document. • Each document is uniquely identified to ensure traceability throughout the document life cycle.
Review and Issue	Controlled documents are reviewed on a scheduled basis and reissued after significant changes are made.
Records: Reviews, Retention, Storage, and Retrieval	• Managers and supervisors review records according to established schedules. • Records are retained for periods mandated by government regulations, accreditation requirements, and the organization's policies. • Records are stored in a manner that maintains integrity, prevents damage or destruction, and facilitates retrieval.
Supporting Documents	The following processes support this quality management system essential: • New Document Creation, Review, and Approval Process • Document Change Control Process • Document Master File and Index Maintenance Process • Record Review Process • Record Change Control Process • Record Retention, Storage, Retrieval, and Destruction Process

End

Facility name/location Page 2 of 2
Filename and path

Appendix C. QSE Processes

QSE Policies	Processes to Implement QSEs
Documents and Records	• Document Creation, Review, and Approval Process • Document Change Control Process • Document Master File and Archive Process • Record Review Process • Records Change Control Process • Record Retention, Storage, and Retrieval Process
Organization	• Organization Chart Development and Maintenance Process • Strategic Planning Process • Quality Planning Process • Resource Allocation Process (e.g., budgeting) • Management Review Process
Personnel	• Job Description Development Process • Orientation Process • Training Process and Programs • Competence Assessment Process • Continuing Education Program • Professional Development Program
Equipment	• Equipment Selection Process • Equipment Installation and Identification Process • Calibration Process • Maintenance Process • Troubleshooting, Service, and Repair Process • Equipment Decommission Process
Purchasing and Inventory	• Vendor Selection Process • Purchasing Process • Receiving and Inspection Process • Inventory Management Process • Vendor Evaluation Process
Process Control	• Process Design Process • Process Validation Process • Process Verification Process • Process Change Process • Quality Control Program, where applicable

continued on next page

Appendix C. (Continued)

QSE Policies	Processes to Implement QSEs
Information Management	• Privacy and Confidentiality of Patient-Related Information Process • Data Transmission Process • Data Security and Integrity Process • Downtime and Recovery Process • Billing Compliance Process
Occurrence Management	• Occurrence Detection, Documentation, and Remedial Action Process • Occurrence Investigation and Analysis Process
Internal and External Assessment	• Accreditation Assessment Process • External Quality Assessment (Proficiency Testing) Process • Quality Indicator Process • Internal Audit Process • Benchmarking Process (where applicable) • Quality Reporting Process
Process Improvement	• Corrective Action Process • Preventive Action Process • Project Management Process
Customer Service	• Customer Needs Assessment Process • Customer Satisfaction Assessment Process
Facilities and Safety	• Facility Design and Modification Process • Facility Communications Program • Facility Maintenance and Housekeeping Process • Safety Surveillance Process • Hazardous Waste Disposal Process

Appendix D. Document Change Request Form

QSE: Documents and Records
Document #/version #

Effective Date: mm/dd/yy

Change #:_____

Document Change Request Form

Document Name:	
Document Number:	Requestor:
Version Number	Date:

Check one: ☐ **New Document** ☐ **Changed Document**

Description of Document:

Rationale for new or changed document:

Are any related documents affected? **_____Yes** **_____No**
If yes, list here. Also, prepare additional Document Change Request Forms, if needed.

Is process validation affected? **_____Yes** **_____No**
Why or why not?

Signature Approval

	Signature	**Date**
Document Author		
Supervisor		
Director		
	Issue Date for Training	
	Effective Date for Lab Use	

Annual Review

Designee	**Signature**	**Date**

Anytown Hospital Laboratory, Anytown, USA 12345
[filename and path]
Page 1 of 1

Appendix E. Sample Master Document Index

Master Index			
Document Identification	**Document Name**	**Effective Date**	**Location(s)**

End

Document number/version Facility Name/Location Page 1 of 1
Effective Date

Appendix F. Orientation Program

Orientation Program	Suggested Contents

Organization orientation	• Organization's mission statement and quality policy
	• General orientation
	• Conditions of employment (employee handbook)
	• Employee benefits
	• Facility tour
	• General safety
	  − hazard communication - general
	  − fire preparedness
	  − disaster preparedness
	• Communication system (telephone, pagers, e-mail, etc.)

Service (departmental) orientation	• Departmental mission, vision, and quality policy • Area tour • Departmental terminology • Departmental rules and policies • Dress requirements • Work schedule

Appendix G. Training Program

Component	Contents

Quality training	• Code of ethics
	• Organization's/service's quality management system
	• Organization's problem-solving approach
	• Service's quality assurance program
	• Service's quality control program
	• Employee's expected roles in each of the above to include:
	  − receiving training
	  − maintaining competence
	  − following procedures as written
	  − reporting complaints and nonconformances
	  − practicing good customer service skills
	  − collecting data for quality indicators and monitoring, and
	  − participating in quality improvement teams

Safety training	• Organization's general safety
	  − hazard communication - general
	  − fire preparedness
	  − disaster preparedness
	  − accident reporting system
	
	• Department-specific safety
	  − infection control (handling of blood-borne pathogens)
	  − disposal of hazardous waste
	  − personal protective equipment
	  − chemical hygiene plan
	  − radiation safety
	  − bioterrorism preparedness

Computer training	• Organization-wide computer system (e.g., hospital information system) • Departmental computer system (e.g., laboratory, pharmacy, imaging) • Office services system (scheduling, e-mail, word processing, spreadsheets, etc,)
Job-related training	• Work processes and related procedures (work instructions)

Appendix H. Sample Outline for a Validation Protocol

I. Purpose of Validation

II. Description of the System to Be Validated

III. Responsibilities

A. Installation qualification
    1. Performed by
    2. Reviewed by
B. Maintenance and calibration
C. Support services provided by
D. Validation
    1. Performed by
    2. Reviewed by

IV. Validation Protocol

A. Requirements
    1. Procedures to be used
    2. Personnel to perform
    3. Equipment needed
    4. Material to be used
B. Test samples required
C. Testing conditions to be used
D. Data to be collected
E. Acceptance criteria
F. Protocol
    1. Prepared by
    2. Reviewed by
    3. Approved by

V. Conclusion

A. Validation results
B. Comments/actions
C. Signatures
    1. Performed by
    2. Approved by
    3. Director review
    4. Quality function review
D. Results acceptable?
    1. Yes or no
    2. Comments

Appendix I. Sample Occurrence Management Form

Department of Laboratory Medicine and Pathology **[Facility Name]**
Laboratory Occurrence Management Form Laboratory Quality Manual
Effective Date: mm/dd/yy [Document number]
[Version number]

OM Database # _____

Step A: Fill out the following data completely: **PLEASE PRINT LEGIBLY**

Site of occurrence: Hospital OP LAB Other:_____ Occurrence time (hr): _____ Occurrence Date _____ (day/month/year)

Report Initiated by: _____ Lab Dept (initiating the report): _____ Date of report: _____

Problem Identified by: (Circle) LAB NURSING PHYSICIAN Other: _____ Patient Location: _____ (if applicable)

Step B : Indicate the problem and attach pertinent information if required (e.g., copy of requisition, report)

Preanalytical (before testing) - circle UNIT or LAB as applicable	***Analytical (testing phase)***	***Postanalytical (after testing)***	***Other***
☐ Specimen mislabeled/unlabeled by UNIT/LAB (computer codes here:) ☐ Specimen mix up/aliquoting or labeling error (computer codes here:) ☐ Wrong tube type/container (computer codes here:) ☐ Delay in transport to laboratory (e.g., courier) ☐ Tests missed at REI/wrong test ordered (computer codes here:) ☐ Req missing UNIT/LAB ☐ Specimen lost (computer codes here:) ☐ Specimen not handled/processed correctly (computer codes here:) ☐ Wrong episode selected at accessioning	☐ Result discrepancies involving investigation ☐ Delay in testing/resulting (computer codes here:) ☐ Incomplete test run (circle one) REAGENT/ INSTRUMENT/ METHOD problem ☐ Invalid test run (QC failure)	☐ Critical result not phoned when required ☐ Patient Report sent to incorrect location/physician (e.g., copy to physician, ordering physician, FAX problems) ***Corrected Reports*** ☐ Corrected report required (complete Corrected Report Section below) ***Corrected Report Classification*** (circle one): **A** - Reporting error - issued outside laboratory **B** - Reporting error - corrected before release (near miss) **C** - Minor report problem – e.g., revised format	☐ LIS or IS problem ☐ Equipment ☐ Purchasing ☐ Receiving/Delivery ☐ Vendor ☐ Waste Management ☐ Environmental issue/ Housekeeping ☐ Complaint - record name, phone # & complaint for follow up in Step C. ☐ Patient injury/incident

Corrected Reports - TO BE COMPLETED WHEN CORRECTED REPORT IS ISSUED
***Attach a copy of the ORIGINAL patient report (before correction) and REVISED REPORT with corrected statement.**

Error Identified by _____ Date/Time _____

Signature of person making correction _____ Signature of original person resulting (if different) _____

Brief explanation of how error was discovered: _____
_____

Appendix I. (Continued)

Step C: IMMEDIATE ACTION (Describe what happened and what was done)

Name of person providing immediate action _____
(Investigation on reverse side)

Step D: Supervisor/Manager Investigation and Comments (optional): (How did this happen? Why did this happen? If appropriate, what changes have been made to prevent recurrence? Note: Have the necessary staff member review and sign.)

Supervisor Name: _____ Date: _____
Staff member reviewed (signature): _____ Date: _____

Step E: Quality Office Comments (optional):

Name: _____ Date: _____

Step F: Occurrence Management Database Entry

Entered into database by: _____ Date: _____

Side 2 of 2

This example was contributed by the Department of Laboratory Medicine and Pathology of the University of Alberta Hospital, Edmonton, Alberta, Canada.

Appendix J. Sample Occurrence Log

Occurrence Number	Reported By	Occurrence Type	Operations Process Involved	Occurrence Source	Corrective Action Completed Date	Corrective Action Verified (Yes or No)	Finalized and Closed Out (date)

Appendix K. Indicator Form

Quality Indicator Development Form

Instructions: Complete Parts I - III. Attach charts and graphs.

Part I: Identification of an Indicator

1. What key quality characteristic (KQC), process, or outcome does this indicator measure? (Key measure of output quality. Quality as defined or judged by the customer. Reflect aspects the customer cares most about.)

2. What is the rationale for this indicator?
(Why has this indicator been selected? What is the purpose of the indicator? Are there external/internal stakeholders who have influenced the selection?)

3. What is the specific name of this indicator?

4. List the organizational unit(s), department(s)/function(s), or teams(s) to which the indicator applies:

5. This indicator will satisfy the following core strategies:

- ☐ Customer Focus
- ☐ Quality
- ☐ Professional Development
- ☐ Responsibility
- ☐ Learning
- ☐ Research & Education
- ☐ Shared Knowledge
- ☐ Mutual Respect
- ☐ Teamwork

6. The indicator is designed to measure the following dimension(s) of excellence:

Appropriateness	_____	Financial viability	_____
Availability/access	_____	Growth/market share	_____
Continuity	_____	Respect/caring	_____
Effectiveness	_____	Timeliness	_____
Efficiency	_____	Patient safety	_____
	_____	Other (specify)	_____

Appendix K. (Continued)

Quality Indicator Development Form, continued

7. Are there literature references for this indicator? _____Yes _____No
   If yes, specify source, date, etc.:

   Date: _____ Source:

Part II: Indicator Development and Data Collection

8. Operational definition:
   (A description, in quantifiable terms, of what to measure and the steps to measure it consistently. Be clear and unambiguous in your operational definition.)

   Define the specific data collection method to be used, including:
   - Specification of the measurement method and any special equipment to be used (computers, logs, etc.).
   - Specific criteria for all data to be collected.
   - Identification of the numerator and denominator if applicable.

9. Describe the data collection plan:
   - Person(s) responsible for collecting the data.
   - Collection frequency.
   - Data sources (be specific).
   - Method.

10. Does the data collection require sampling? _____Yes _____No

    If yes, describe the sampling plan:

11. Are there current baseline data for this indicator? _____Yes _____No
    (Baseline data are the current actual measure of the indicator.)

    If yes, what is the time period from which the baseline is obtained?

    What is the actual baseline measurement?

Appendix K. (Continued)

Quality Indicator Development Form, continued

12. Is there a target or goal for this indicator? _____Yes _____No

If yes, what type of target or goal is it?

- External target or goal?

  (Specify the number, rate, or volume, etc., as well as the source of the target/goal.)

- Internal target or goal?

  (Developed internally or recommended by others? Specify the number, rate, or volume, etc., as well as the source/rationale of the target/goal.)

Part III: Indicator Analysis and Interpretation

13. Describe the analysis plan:

- What descriptive statistics will be used?

• Mean	_____	• Minimum	_____	• Standard deviation	_____
• Median	_____	• Maximum	_____	• Tabular analysis	_____
• Mode	_____	• Range	_____	• Other, specify:	_____
• Percentage	_____				

- What graphs will be used?

• Bar chart	_____	• Line chart	_____	• Pareto diagram	_____
• Histogram	_____	• Run chart	_____	• Other, specify:	_____
• Pie chart	_____	• Control chart	_____		

14. Describe the data-reporting plan:

Who will receive the results? (List all.)

How often will they receive the results? (List all.)

Document number/version Facility Name/Location Page 3 of 3
Effective Date

This example was contributed by the Mayo Department of Laboratory Medicine and Pathology, Rochester, Minnesota. It was adapted from guidance provided by Raymond G. Carey, PhD, and Robert C. Lloyd, PhD, in their presentation at the 12th National Forum on Quality Improvement in Health Care, San Francisco, California, December 2000.

Appendix L. Quality Report Form

QUALITY REPORT by Quality System Essential

Work unit:_____

Date of Report: _____

Review signature/
Date: _____

CONFIDENTIAL

Confidential-Review Organization Data. This information is confidential and protected from disclosure to third parties by statute. The statute also provides that this information may be rereleased internally only to the extent necessary to carry out the purposes of this review.

- Summarize the QSE data for your work unit using the sections outlined below.
- When applicable, import charts, graphs or tables into this document.

Organization

Staff Changes

- Number of new allied health employees
- Number of new supervisors/assistant supervisors
- Number of new consultants
- Number of new supplemental employees
- Number of employees who transferred from the work unit
- Number of employees who terminated from the work unit
- Number of employees who retired
- Reorganization changes
- Organization chart changes

Personnel

Orientation of New Employees

- Employees who attended the HR orientation this quarter.
- Employees who attended department orientation this quarter.

Training

- New employee training accomplished this quarter.
- Training to new or revised procedures this quarter.

Competency Assessments

- Competency assessments performed.

Performance Appraisals

- Performance appraisals completed

Appendix L. (Continued)

QUALITY REPORT by Quality System Essential, continued

Purchasing and Inventory

Supplier Qualification

- Reagents and supplies that were damaged, not received, or received later than agreed to

Change in Suppliers or Product

Product recalls

Process Control

New Tests Implemented
Significant Process Changes
Method Validations Performed
Test Delays
QC Failed/Failed Runs

Event Management

Summary of Reported Events
Customer Complaints

Assessments

Quality Indicator (Charts)
Proficiency Testing
Comparability Studies
Internal Audits
External Assessments/Audits
Computer-generated Patient Results Audit

Process Improvement

Process Improvement Activities

Documents and Records

New or Revised Documents
Record Review Findings

Document number/version Facility Name/Location Page 2 of 3
Effective Date

Appendix L. (Continued)

QUALITY REPORT by Quality System Essential, continued

Equipment
- New Equipment Validation
- Retired Equipment
- Major Repairs/Maintenance Issues
- Unplanned Computer Outages

Customer Service
- Customer Surveys Conducted
- Customer Comments
- Employee Surveys
- Tours Conducted

Facilities and Safety
- Employee/Patient Incidents
- Safety Audits
- Other Safety Issues
- Facility Issues (remodeling, unplanned outages, etc.)

Document number/version Facility Name/Location Page 3 of 3
Effective Date

This example was contributed by the Division of Transfusion Medicine, Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, Minnesota.

Appendix M. Plan-Do-Check-Act

PDCA
Plan: A mission-consistent, customer-oriented action plan
• Identify opportunities for improvement from data sources • Prioritize improvement activities • Develop an action plan for the selected activity - initiating a new process - improving an existing process • Identify - customer needs - participants - time frames - outcome measurements - success criteria
Do: Put the plan into action
• Implement the action plan - pilot project first - broaden only after success • Collect performance data
Check: Has the planned and implemented change created intended improvement?
• Analyze collected data • Compare performance data to established success targets and original performance data to determine if improvement was achieved • Identify any unexpected peripheral benefits • Identify unanticipated problems in other areas
Act: Decide what to do next
• Determine if customer needs were met • Take action based on the results: - *Success:* - revise the processes for further improvements (optional), and - assess again to determine if improvement is maintained -if a pilot project, standardize to the bigger group -*Lack of success* – revise the action plan and repeat

Source: Modified from: McCloskey LA, Collet DN. TQM: A Primer Guide to Total Quality Management. Methuen, MA: GOAL/QPC; 1993. Reprinted with permission of GOAL/QPC, Salem, NH; www.goalqpc.com.

NCCLS consensus procedures include an appeals process that is described in detail in Section 8 of the Administrative Procedures. For further information, contact the Executive Offices or visit our website at www.nccls.org.

Summary of Consensus/Delegate Comments and Working Group Responses

HS1-A2: *A Quality Management System Model for Health Care; Approved Guideline—Second Edition*

General

1. A comprehensive document and an interesting comparison with Australian standard ISO-IEC 17025 used in Australian laboratories (mandatory compliance).

- **ISO-IEC Standard 17025 was used as a basis for developing the laboratory-specific requirements contained in ISO Standard 15189: *Medical laboratories—Particular requirements for quality and competence.* NCCLS document HS1-A2—*A Quality Management System Model for Health Care* can be used to implement the requirements of ISO 17025 in any kind of measurement service or the requirements of ISO 15189 in a medical laboratory service.**

2. Very thorough with many good ideas. I would like to see more statistical data. With the advent of Six Sigma, many laboratories are now using this as a measure.

- **This guideline is not meant to be a statistical reference, but rather a model for implementing a quality management system in any healthcare service; as such, it is especially applicable to implementation of a quality management system in a medical laboratory. Statistical tools and models have an important role to play in the measurement and improvement aspects of a quality management system but must not be considered as replacements for a quality management system.**

3. I think it would be difficult to know which document to order/access between GP22-A2 and GP26-A3 and HS1-A2. Will people bother with HS when they have a GP? I think there should be one or two documents at the most on Quality Management or Improvement, or whatever today's buzz word is.

- **The HS1-A2 guideline is meant to be an "umbrella" document that provides generic guidance for a quality management system for any healthcare service. GP26-A3 is a companion document that supplements the HS1 guideline specifically for laboratory services. (NOTE: NCCLS also has supplemental companion documents for respiratory services, diagnostic imaging, and inpatient medication services.) GP22-A2 provides in-depth detail about the important relationships between five of the 12 quality system essentials (QSEs). NCCLS is in the process of linking each current and future standard and guideline to its respective QSE. Information on the "Quality System Approach" and "Path of Workflow" is currently located at the back of each updated version or new document. The template maps each document to its place in the quality management system.**

4. NCCLS Administrative Procedures (page 12) indicate that any discussion of price, costs, inventories, or changes in such, are forbidden topics of discussion at NCCLS meetings and conference calls. NCCLS HS1-A2 looks into price, costs, and inventories. Page 26, Section 5.5, QSE: Purchasing and Inventory indicates: "Efficient and cost-effective operations need the uninterrupted availability of reagents, supplies, and services." Page 27, Section 5.5.1.3, Contract Review indicates: "Contracts to obtain critical supplies, materials, referral, and other needed services are to be reviewed to ensure that each party's expectations are defined...Contracts to provide critical supplies, materials, referral, and other needed services to other organizations are to be developed and reviewed to ensure that each party's expectations are defined." Page 40, Section 5.9.2.1, Quality Indicators indicates: "On the contrary, organizations or services have been encouraged to identify their own high-risk, high-cost, and problematic issues that link to their quality goals and objectives." The above guidelines refer to "cost-effectiveness," "contract review," and "high-cost issues." If an accrediting organization adopts these NCCLS standards, will they review contracts for cost-effectiveness and high-cost issues? It would be appropriate for an outside accrediting organization to review contracts to ensure continuous supply of reagents and supplies. However, it may not be appropriate to discuss costs and cost-effectiveness. Perhaps "cost-effective" should be deleted from Section 5.5.

- **The Working Group believes the intent of the specified requirement in NCCLS's Administrative Procedures is to preclude committee discussion of specific monetary, competitive, or other commercial topics, not to preclude general considerations of such topics as in the case of this document.**

  HS1-A2 is not a standard that dictates requirements for an accreditation program; it is offered as guidance for how to implement a quality management system in a healthcare organization or service. Because it is a guideline that

provides expert advice on how to implement requirements, it is appropriate to emphasize the need for an organization or service to conduct its operations in a cost-effective manner.

The HS1-A2 guideline is based on the requirements in published international standards ISO 9001 and ISO 15189. An accrediting organization should adopt the original published standard(s) as the basis for its accreditation program. Cost effectiveness would therefore not be an assessment activity of the accrediting organization.

Foreword

5. Accreditation is about professional competence. Organizations get certified to quality management standards. The word "accreditation" in the last sentence should be replaced with "certification" or to obtain accreditation to relevant ISO competence standard.

- **The word "accreditation" has been replaced with the word "certification."**

Section 3, Definitions

6. VIM (ref. 8) is currently under a progressed revision. Depending on the foreseen date of publication, I suggest citing the new definitions from the new version of VIM.

- **NCCLS, as a global leader in standardization, is firmly committed to achieving global harmonization in terminology wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences in terms while taking steps to achieve worldwide uniformity. NCCLS recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in NCCLS, ISO, and CEN documents; and that legally required use of terms, regional usage, and different consensus timelines are all obstacles to harmonization. In light of this, NCCLS recognizes that harmonization of terms facilitates the global application of standards and deserves immediate attention and has developed a relational database based upon the hierarchy of preferred terms and definitions as follows: VIM, ISO, CEN, NCCLS, and/or other approved authoritative terminology documents to facilitate the process of harmonization.**

  In accordance with this policy, NCCLS documents do not cite definitions from draft terminology documents.

Section 4.2.3.1, Policies for the QSEs

7. As described in Section 4.2.3.2, the procedures describe what we do. Policies describe the goal and intentions of an organization. Change the question in lines one and two: What do we intend to do?

- **The word "intentions" already appears in the sentence. The second sentence includes the word "intent" emphasized in italics. The committee believes there is there no need to change the question.**

Section 4.2.3.3, Procedures

8. There should be procedures (instructions) for the critical activities in ~~the~~ each QSE.

- **This editorial correction has been made.**

Section 5.1.1.2, Identification of Documents

9. Effective date is an absolute necessity and may not be replaced by edition, revision, or revision number. Change the text to read: edition, revision, or revision number and an effective date.

- **The text has been changed to read, "edition or revision number and effective date."**

Section 5.1.1.6, Master Index of Documents (Document Log)

10. The sentence should read, "Control of the master index should reside with a single person and be in a single secure site."

- **This editorial correction has been made.**

Section 5.2, QSE: Organization

11. In order to ensure quality, the Quality Manager should report to top management. Top management should be involved in quality work and delegate authority to the Quality Manager. Add a bullet point in the middle of the section: "Processes"

parallel to the second bullet point in the left section ("The organization structure to ensure quality"): Nominate a Quality Manager reporting to top management. Delegate authority to Quality Manager.

- **A new 6th bullet has been added. It reads, "Appoint a quality manager who reports to top management and has authority to manage the quality system."**

Section 5.3.3, Training

12. Employees need to be aware of relevant standards and literature. Add to the points in "need to have training in the following areas:" Normative standards and relevant literature.

- **The four points in this area represent distinct training programs. The requirements stated in the normative standards and relevant literature need to be built into the processes and procedures in each of the four training programs. A new sentence has been added: "Training programs need to include reference to relevant standards and applicable literature."**

Section 5.4.3, Equipment Maintenance, Calibration, and Use

13. The organization needs to evaluate which equipment needs calibration and in which uncertainty. The evaluation should be based on the equipment's role in the decision-making process. In other words, it should be determined which equipment affects patient well being. The organization should develop policies regarding use of calibration results (i.e., correct the results or adjust the equipment) and design of calibration programs accordingly (analysis of calibration results and intermediate checks results). Add the following at the beginning of 5.4.3:

    The organization should develop criteria, based on implications to patient well being, for which equipment should be calibrated. The policy should include considerations of required calibration uncertainty.
    Following the first sentence, add: The organization should develop policy and procedures regarding the design on calibration plan (evidence based) and use of calibration results.

    The calibration plan should take into account frequency and ways of use of equipment, environmental conditions, manufacturers' instructions, and all other factors affecting the equipment state of calibrations.

- **The first paragraph in Section 5.4.3 has been modified to reflect the commenter's suggestion. It reads as follows:**

  "The organization or service needs to identify equipment that affects patient safety, such as that used in patient care or treatment, or making decisions regarding patient care or treatment, or used to generate results of any examinations. The organization or service also needs to develop calibration plans for this equipment that include:

  - **the schedule for calibrations and intermediate calibration checks;**
  - **the analysis of the results of calibrations or intermediate calibration checks; and**
  - **actions to be taken on the results."**

Section 5.4.4, Troubleshooting, Service, and Repair

14. The equipment record should contain analyses of data calibration and intermediate obtained by checks. Add a bullet point: Analyses of data obtained by calibrations and intermediate checks.

- **Section 5.4.5 has been modified to reflect the commenter's suggestion. The seventh bullet now reads, "maintenance records, to include follow-up actions of unexpected or outlying results." A new eighth bullet has been added and reads, "calibration records, to include analysis of data obtained by calibrations and intermediate calibration checks, and any follow-up actions taken."**

Section 5.6.2, Process Validation or Verification

15. The standard refers to the healthcare system whereas this clause refers to the laboratory only. There are other processes, which need validation in the healthcare system such as patient treatment, point of care testing, operations, computer systems, and others. This subclause belongs to GP26—*Application of a Quality System Model for Laboratory Services*. The organization should develop a policy regarding process validation. The policy should consider:

    — Which processes need to be validated?
    — How is a process validation performed?
    — Indicators, which should be proven by the validation process.
    — Designation of authorized personnel to design and improve validation protocol.
    — Analysis of validation reports.

— Authorization of a new process.

- **This section has been modified to reflect the commenter's suggestion.**

Section 5.7.1, Focus of Information Management

16. A computer system includes software. All software, including patient records, must be validated. Add at the end: Each software and hardware system including patient records should be validated to prove fitness for purpose.

- **For the purposes of this guideline, computer hardware and software are considered to be equipment. This comment has been addressed in Section 5.4.2, Equipment Validation.**

Related NCCLS Publications*

GP2-A4 **Clinical Laboratory Technical Procedure Manuals; Approved Guideline—Fourth Edition (2002).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the laboratory testing community.

GP6-A **Inventory Control Systems for Laboratory Supplies; Approved Guideline (1994).** This document contains recommendations for inventory control systems to ensure availability of reagents and supplies in the laboratory.

GP17-A2 **Clinical Laboratory Safety; Approved Guideline—Second Edition (2004).** This document contains general guidelines for implementing a high-quality laboratory safety program. The framework is adaptable to any laboratory.

GP21-A2 **Training and Competence Assessment; Approved Guideline—Second Edition (2004).** This document provides background and recommended processes for the development of training and competence assessment programs that meet quality regulatory objectives.

GP22-A2 **Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition (2004).** This guideline considers continuous quality improvement (CQI) as integrated quality system components, which include Quality Planning, Quality Teamwork, Quality Monitoring, Quality Improvement, and Quality Review.

GP26-A3 **Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition (2004).** This guideline describes the clinical laboratory's path of workflow and provides information for laboratory operations that will assist the laboratory in improving its processes and meeting government and accreditation requirements.

HS4-A **Application of a Quality System Model for Respiratory Services; Approved Guideline (2002).** This document provides a model for providers of respiratory services that will assist with implementation and maintenance of an effective quality system.

HS5-A **Application of a Quality System Model for Medical Imaging Services; Approved Guideline (2002).** This guideline provides the necessary background information and infrastructure to develop a quality system that defines a structure for a comprehensive, systematic approach to build quality into the imaging services processes, assess its performance, and implement quality improvements. Individual service areas, such as diagnostic radiology, CT, ultrasound, interventional radiology, magnetic resonance imaging (MRI), mammography, and nuclear medicine, will benefit from applying this model to their respective operations. To provide a practical example of how a quality system is developed and implemented, suggestions for diagnostic radiology are included.

HS10-A **Application of a Quality System for Inpatient Medication Use; Approved Guideline (2004).** This document describes the path of workflow for inpatient medication use, which is defined as the sequential processes in preservice, service, and postservice activities that transform a physician's medication order into an administered medication. Pharmacy-specific information and examples for the path of workflow and quality system essentials are provided.

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

NOTES

NOTES

Active Membership
(as of 1 October 2004)

Sustaining Members

Abbott Laboratories
American Association for Clinical Chemistry
Bayer Corporation
BD
Beckman Coulter, Inc.
bioMérieux, Inc.
CLMA
College of American Pathologists
GlaxoSmithKline
Ortho-Clinical Diagnostics, Inc.
Pfizer Inc
Roche Diagnostics, Inc.

Professional Members

American Academy of Family Physicians
American Association for Clinical Chemistry
American Association for Respiratory Care
American Chemical Society
American Medical Technologists
American Society for Clinical Laboratory Science
American Society for Microbiology
American Society of Hematology
American Type Culture Collection, Inc.
Asociacion Mexicana de Bioquimica Clinica A.C.
Assn. of Public Health Laboratories
Assoc. Micro. Clinici Italiani-A.M.C.L.I.
British Society for Antimicrobial Chemotherapy
Canadian Society for Medical Laboratory Science - Société Canadienne de Science de Laboratoire Médical
Canadian Standards Association
Clinical Laboratory Management Association
COLA
College of American Pathologists
College of Medical Laboratory Technologists of Ontario
College of Physicians and Surgeons of Saskatchewan
ESCMID
International Council for Standardization in Haematology
International Federation of Biomedical Laboratory Science
International Federation of Clinical Chemistry
Italian Society of Clinical Biochemistry and Clinical Molecular Biology
Japan Society of Clinical Chemistry
Japanese Committee for Clinical Laboratory Standards
Joint Commission on Accreditation of Healthcare Organizations
National Academy of Clinical Biochemistry
National Association of Testing Authorities - Australia
National Society for Histotechnology, Inc.
New Zealand Association of Phlebotomy
Ontario Medical Association Quality Management Program-Laboratory Service
RCPA Quality Assurance Programs PTY Limited
Sociedad Espanola de Bioquimica Clinica y Patologia Molecular
Sociedade Brasileira de Analises Clinicas
Taiwanese Committee for Clinical Laboratory Standards (TCCLS)
Turkish Society of Microbiology

Government Members

Armed Forces Institute of Pathology
Association of Public Health Laboratories
BC Centre for Disease Control
Caribbean Epidemiology Centre
Centers for Disease Control and Prevention
Centers for Medicare & Medicaid Services
Centers for Medicare & Medicaid Services/CLIA Program
Chinese Committee for Clinical Laboratory Standards
Commonwealth of Pennsylvania Bureau of Laboratories
Department of Veterans Affairs
Deutsches Institut für Normung (DIN)
FDA Center for Devices and Radiological Health
FDA Center for Veterinary Medicine
FDA Division of Anti-Infective Drug Products
Iowa State Hygienic Laboratory
Massachusetts Department of Public Health Laboratories
National Center of Infectious and Parasitic Diseases (Bulgaria)
National Health Laboratory Service (South Africa)
National Institute of Standards and Technology
National Pathology Accreditation Advisory Council (Australia)
New York State Department of Health
Ontario Ministry of Health
Pennsylvania Dept. of Health
Saskatchewan Health-Provincial Laboratory
Scientific Institute of Public Health; Belgium Ministry of Social Affairs, Public Health and the Environment
Swedish Institute for Infectious Disease Control

Industry Members

AB Biodisk
Abbott Laboratories
Abbott Diabetes Care
Acrometrix Corporation
Advancis Pharmaceutical Corporation
Affymetrix, Inc.
Ammirati Regulatory Consulting
Anna Longwell, PC
A/S ROSCO
AstraZeneca Pharmaceuticals
Aventis
Axis-Shield POC AS
Bayer Corporation - Elkhart, IN
Bayer Corporation - Tarrytown, NY
Bayer Corporation - West Haven, CT
BD
BD Consumer Products
BD Diagnostic Systems
BD Thailand Ltd.
BD VACUTAINER Systems
Beckman Coulter, Inc.
Beckman Coulter K.K. (Japan)
Bio-Development SRL
Bio-Inova Life Sciences International
Biomedia Laboratories SDN BHD
bioMérieux, Inc. (MO)
Biometrology Consultants
Bio-Rad Laboratories, Inc.
Bio-Rad Laboratories, Inc. – France
Bio-Rad Laboratories, Inc. – Plano, TX
Blaine Healthcare Associates, Inc.
Bristol-Myers Squibb Company
Canadian External Quality Assessment Laboratory
Cepheid
Chen & Chen, LLC
Chiron Corporation
ChromaVision Medical Systems, Inc.
Clinical Micro Sensors
The Clinical Microbiology Institute
Cognigen
CONOSCO
Copan Diagnostics Inc.
Cosmetic Ingredient Review
Cubist Pharmaceuticals
Dade Behring Inc. - Cupertino, CA
Dade Behring Inc. - Deerfield, IL
Dade Behring Inc. - Glasgow, DE
Dade Behring Inc. - Marburg, Germany
Dade Behring Inc. - Sacramento, CA
David G. Rhoads Associates, Inc.
Diagnostic Products Corporation
Digene Corporation
Eiken Chemical Company, Ltd.
Elanco Animal Health
Electa Lab s.r.l.
Enterprise Analysis Corporation
F. Hoffman-La Roche AG
Fort Dodge Animal Health
Gen-Probe
GenVault
GlaxoSmithKline
Greiner Bio-One Inc.
Immunicon Corporation
ImmunoSite, Inc.
Instrumentation Laboratory
International Technidyne Corporation
I-STAT Corporation
Johnson and Johnson Pharmaceutical Research and Development, L.L.C.
K.C.J. Enterprises
LifeScan, Inc. (a Johnson & Johnson Company)
Machaon Diagnostics
Medical Device Consultants, Inc.
Merck & Company, Inc.
Minigrip/Zip-Pak
Nanosphere, Inc.
National Pathology Accreditation Advisory Council (Australia)
Nippon Becton Dickinson Co., Ltd.
Nissui Pharmaceutical Co., Ltd.
Norfolk Associates, Inc.
Novartis Pharmaceuticals Corporation
Olympus America, Inc.
Optimer Pharmaceuticals, Inc.
Ortho-Clinical Diagnostics, Inc. (Rochester, NY)
Ortho-McNeil Pharmaceutical (Raritan, NJ)
Oxoid Inc.
Paratek Pharmaceuticals
Pfizer Animal Health
Pfizer Inc
Pfizer Italia Srl
Powers Consulting Services
Premier Inc.
Procter & Gamble Pharmaceuticals, Inc.
QSE Consulting
Radiometer America, Inc.
Radiometer Medical A/S
Replidyne
Roche Diagnostics GmbH
Roche Diagnostics, Inc.
Roche Laboratories (Div. Hoffmann-La Roche Inc.)
Sarstedt, Inc.
Schering Corporation
Schleicher & Schuell, Inc.
Second Opinion
SFBC Anapharm
Streck Laboratories, Inc.
SYN X Pharma Inc.
Sysmex Corporation (Japan)
Sysmex Corporation (Long Grove, IL)
TheraDoc
Theravance Inc.
Thrombodyne, Inc.
THYMED GmbH
Transasia Engineers
Trek Diagnostic Systems, Inc.
Vetoquinol S.A.
Vicuron Pharmaceuticals Inc.
Vysis, Inc.
Wyeth Research
XDX, Inc.
YD Consultant
YD Diagnostics (Seoul, Korea)

Trade Associations

AdvaMed
Japan Association of Clinical Reagents Industries (Tokyo, Japan)

Associate Active Members

Academisch Ziekenhuis -VUB (Belgium)
Alfred I. duPont Hospital for Children (DE)
All Children's Hospital (FL)
Allina Health System (MN)
American University of Beirut Medical Center (NY)
Anne Arundel Medical Center (MD)
Antwerp University Hospital (Belgium)
Arkansas Department of Health
ARUP at University Hospital (UT)
Associated Regional & University Pathologists (UT)
Atlantic Health System (NJ)
Aurora Consolidated Laboratories (WI)
AZ Sint-Jan (Belgium)
Azienda Ospedale Di Lecco (Italy)
Barnes-Jewish Hospital (MO)
Baxter Regional Medical Center (AR)
Baystate Medical Center (MA)
Bbaguas Duzen Laboratories (Turkey)
BC Biomedical Laboratories (Surrey, BC, Canada)
Bermuda Hospitals Board
Brazosport Memorial Hospital (TX)
Broward General Medical Center (FL)
Cadham Provincial Laboratory (Winnipeg, MB, Canada)
Calgary Laboratory Services (Calgary, AB, Canada)
California Pacific Medical Center
Canterbury Health Laboratories (New Zealand)
Cape Breton Healthcare Complex (Nova Scotia, Canada)
Carilion Consolidated Laboratory (VA)
Carolinas Medical Center (NC)
Cathay General Hospital (Taiwan)
Central Texas Veterans Health Care System
Centro Diagnostico Italiano (Milano, Italy)
Champlain Valley Physicians Hospital (NY)
Chang Gung Memorial Hospital (Taiwan)
Changi General Hospital (Singapore)
Children's Hospital (NE)
Children's Hospital & Clinics (MN)
Children's Hospital Medical Center (Akron, OH)
Children's Medical Center of Dallas (TX)
Chinese Association of Advanced Blood Bankers (Beijing)
CHR St. Joseph Warquignies (Belgium)
Clarian Health - Methodist Hospital (IN)
CLSI Laboratories (PA)
Community Hospital of Lancaster (PA)
Community Hospital of the Monterey Peninsula (CA)
CompuNet Clinical Laboratories (OH)
Cook Children's Medical Center (TX)
Cook County Hospital (IL)
Covance Central Laboratory Services (IN)
Creighton University Medical Center (NE)
Danish Veterinary Laboratory (Denmark)
Detroit Health Department (MI)
DFS/CLIA Certification (NC)
Diagnósticos da América S/A (Brazil)
Dr. Everett Chalmers Hospital (New Brunswick, Canada)
Duke University Medical Center (NC)
Dwight David Eisenhower Army Medical Center (GA)
Eastern Health Pathology (Australia)
Emory University Hospital (GA)
Enzo Clinical Labs (NY)
Evangelical Community Hospital (PA)
Fairview-University Medical Center (MN)
Florida Hospital East Orlando
Focus Technologies (CA)
Focus Technologies (VA)
Foothills Hospital (Calgary, AB, Canada)
Franciscan Shared Laboratory (WI)
Fresno Community Hospital and Medical Center
Gamma Dynacare Medical Laboratories (Ontario, Canada)
Geisinger Medical Center (PA)
Guthrie Clinic Laboratories (PA)
Hagerstown Medical Laboratory (MD)
Harris Methodist Fort Worth (TX)
Hartford Hospital (CT)
Headwaters Health Authority (Alberta, Canada)
Health Network Lab (PA)
Health Partners Laboratories (VA)

Highlands Regional Medical Center (FL)
Hoag Memorial Hospital Presbyterian (CA)
Holy Cross Hospital (MD)
Hôpital du Sacré-Coeur de Montreal (Montreal, Quebec, Canada)
Hôpital Maisonneuve - Rosemont (Montreal, Canada)
Hôpital Saint-Luc (Montreal, Quebec, Canada)
Hospital Consolidated Laboratories (MI)
Hospital for Sick Children (Toronto, ON, Canada)
Hospital de Sousa Martins (Portugal)
Hotel Dieu Grace Hospital (Windsor, ON, Canada)
Huddinge University Hospital (Sweden)
Hunter Area Health Service (Australia)
Indiana University
Innova Fairfax Hospital (VA)
Institute of Medical and Veterinary Science (Australia)
International Health Management Associates, Inc. (IL)
Jackson Memorial Hospital (FL)
Jacobi Medical Center (NY)
John C. Lincoln Hospital (AZ)
Johns Hopkins Medical Institutions (MD)
Kadlec Medical Center (WA)
Kaiser Permanente (MD)
Kangnam St. Mary's Hospital (Korea)
Kantonsspital (Switzerland)
Kenora-Rainy River Regional Laboratory Program (Ontario, Canada)
Kimball Medical Center (NJ)
King Abdulaziz Medical City – Jeddah (Saudi Arabia)
King Faisal Specialist Hospital (Saudi Arabia)
LabCorp (NC)
Laboratoire de Santé Publique du Quebec (Canada)
Laboratorio Dr. Echevarne (Spain)
Laboratório Fleury S/C Ltda. (Brazil)
Laboratorio Manlab (Argentina)
Laboratory Corporation of America (NJ)
LAC and USC Healthcare Network (CA)
Lakeland Regional Medical Center (FL)
Landstuhl Regional Medical Center (APO AE)
LeBonheur Children's Medical Center (TN)
Lewis-Gale Medical Center (VA)
L'Hotel-Dieu de Quebec (Canada)
Libero Instituto Univ. Campus BioMedico (Italy)
Loma Linda Mercantile (CA)
Long Beach Memorial Medical Center (CA)
Louisiana State University Medical Center
Lourdes Hospital (KY)
Maimonides Medical Center (NY)
Marion County Health Department (IN)
Martin Luther King/Drew Medical Center (CA)
Massachusetts General Hospital (Microbiology Laboratory)
MDS Metro Laboratory Services (Burnaby, BC, Canada)
Medical College of Virginia Hospital
Medical University of South Carolina
Memorial Medical Center (Napoleon Avenue, New Orleans, LA)
Memorial Medical Center (Jefferson Davis Pkwy., New Orleans, LA)
Methodist Hospital (Houston, TX)
Methodist Hospital (San Antonio, TX)
Michigan Department of Community Health
Mid America Clinical Laboratories, LLC (IN)
Middlesex Hospital (CT)
Monmouth Medical Center (NJ)
Montreal Children's Hospital (Canada)
Montreal General Hospital (Canada)
National Serology Reference Laboratory (Australia)
NB Department of Health & Wellness (New Brunswick, Canada)
The Nebraska Medical Center
New Britain General Hospital (CT)
New England Fertility Institute (CT)
New England Medical Center (MA)
New York City Department of Health & Mental Hygiene
NorDx (ME)
North Carolina State Laboratory of Public Health
North Central Medical Center (TX)
North Shore - Long Island Jewish Health System Laboratories (NY)
North Shore University Hospital (NY)
Northwestern Memorial Hospital (IL)
Ochsner Clinic Foundation (LA)
O.L. Vrouwziekenhuis (Belgium)
Ordre professionnel des technologists médicaux du Québec
Orlando Regional Healthcare System (FL)
Ospedali Riuniti (Italy)
The Ottawa Hospital (Ottawa, ON, Canada)
OU Medical Center (OK)
Our Lady of the Resurrection Medical Center (IL)
Pathology and Cytology Laboratories, Inc. (KY)
Pathology Associates Medical Laboratories (WA)
Peking University Shenzhen Hospital (China)
The Permanente Medical Group (CA)
Piedmont Hospital (GA)
Pocono Medical Center (PA)
Providence Health Care (Vancouver, BC, Canada)
Provincial Laboratory for Public Health (Edmonton, AB, Canada)
Queen Elizabeth Hospital (Prince Edward Island, Canada)
Queensland Health Pathology Services (Australia)
Quest Diagnostics Incorporated (CA)
Quintiles Laboratories, Ltd. (GA)
Regions Hospital
Rex Healthcare (NC)
Rhode Island Department of Health Laboratories
Riverside Medical Center (IL)
Robert Wood Johnson University Hospital (NJ)
Royal Columbian Hospital (New Westminster, BC, Canada)
Sahlgrenska Universitetssjukhuset (Sweden)
St. Alexius Medical Center (ND)
St. Anthony Hospital (CO)
St. Anthony's Hospital (FL)
St. Barnabas Medical Center (NJ)
St. Christopher's Hospital for Children (PA)
St-Eustache Hospital (Quebec, Canada)
St. John Hospital and Medical Center (MI)
St. John's Hospital & Health Center (CA)
St. Joseph Mercy Hospital (MI)
St. Joseph's Hospital – Marshfield Clinic (WI)
St. Jude Children's Research Hospital (TN)
St. Mary of the Plains Hospital (TX)
St. Michael's Hospital (Toronto, ON, Canada)
Ste. Justine Hospital (Montreal, PQ, Canada)
Salem Clinic (OR)
San Francisco General Hospital (CA)
Santa Clara Valley Medical Center (CA)
Seoul Nat'l University Hospital (Korea)
Shands at the University of Florida
South Bend Medical Foundation (IN)
South Western Area Pathology Service (Australia)
Southern Maine Medical Center
Spartanburg Regional Medical Center (SC)
Specialty Laboratories, Inc. (CA)
State of Connecticut Dept. of Public Health
State of Washington Department of Health
Stony Brook University Hospital (NY)
Stormont-Vail Regional Medical Center (KS)
Sun Health-Boswell Hospital (AZ)
Sunnybrook Health Science Center (ON, Canada)
Sunrise Hospital and Medical Center (NV)
Swedish Medical Center - Providence Campus (WA)
Temple University Hospital (PA)
Tenet Odessa Regional Hospital (TX)
The Toledo Hospital (OH)
Touro Infirmary (LA)
Tripler Army Medical Center (HI)
Truman Medical Center (MO)
UCLA Medical Center (CA)
UCSF Medical Center (CA)
UNC Hospitals (NC)
Unidad de Patologia Clinica (Mexico)
Union Clinical Laboratory (Taiwan)
Universita Campus Bio-Medico (Italy)
University College Hospital (Galway, Ireland)
University of Alabama-Birmingham Hospital
University of Chicago Hospitals (IL)
University of Colorado Hospital
University of Debrecen Medical Health and Science Center (Hungary)
University of Illinois Medical Center
University of Maryland Medical System
University of the Ryukyus (Japan)
University of Wisconsin Hospital
The University of Texas Medical Branch
The University of the West Indies
University of Virginia Medical Center
University of Washington
USA MEDDAC-AK
US LABS, Inc. (CA)
UZ-KUL Medical Center (Belgium)
VA (Hampton) Medical Center (VA)
VA (Tuskegee) Medical Center (AL)
Valley Children's Hospital (CA)
Virginia Beach General Hospital (VA)
Virginia Department of Health
Virginia Regional Medical Center (MN)
ViroMed Laboratories (MN)
Washington Adventist Hospital (MD)
Washoe Medical Center Laboratory (NV)
Waterford Regional Hospital (Ireland)
Wellstar Health Systems (GA)
West Jefferson Medical Center (LA)
Wilford Hall Medical Center (TX)
William Beaumont Army Medical Center (TX)
William Beaumont Hospital (MI)
William Osler Health Centre (Brampton, ON, Canada)
Winn Army Community Hospital (GA)
Winnipeg Regional Health Authority (Winnipeg, Canada)
Wishard Memorial Hospital (IN)
Yonsei University College of Medicine (Korea)
York Hospital (PA)

NCCLS ▾ 940 West Valley Road ▾ Suite 1400 ▾ Wayne, PA 19087 ▾ USA ▾ PHONE 610.688.0100
FAX 610.688.0700 ▾ E-MAIL: exoffice@nccls.org ▾ WEBSITE: www.nccls.org ▾ ISBN 1-56238-554-2