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Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition

This guideline considers continuous quality improvement (CQI) as five integrated quality system components, which include Quality Planning, Quality Teamwork, Quality Monitoring, Quality Improvement, and Quality Review.

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

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Abstract

Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition (NCCLS document GP22-A2) addresses clinical service directors, managers, and supervisory personnel in both the public and private sectors, in any clinical service setting—from the point-of-care to the largest multidisciplinary clinical facility. Continuous quality improvement (CQI) promotes efficient and effective quality improvement of all clinical service managerial and operational functions. This guideline defines CQI and explains how to implement CQI through important quality system management approaches. To achieve CQI, the clinical service needs to synchronize five quality system components including Quality Planning, Quality Teamwork, Quality Monitoring, Quality Improvement, and Quality Review.

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Introduction to the NCCLS Quality System Management Guideline Series

NCCLS document GP22—*Continuous Quality Improvement: Integrating Five Key Quality System Components* is one of a series of NCCLS documents focused specifically on healthcare clinical service quality system management. These specialized documents are designed for any healthcare service manager who wishes to improve the processes involved in creating customer satisfaction by implementing proven standardized quality system concepts. NCCLS intends these guidelines to be useful as a set of complementary references for any service creating a new quality system management program or enhancing one already established.

The quality system approach endorsed in this series of quality management documents stems directly from the model presented in NCCLS document HS1—*A Quality Management System Model for Health Care*. HS1 provides fundamental guidance for clinical service quality management within an internal, infrastructural quality system matrix of core policies, processes, and procedures. HS1 serves as a manager's guide to quality system implementation and management.

A healthcare clinical service is any private or public sector organization that provides clinical health care to any kind of patient. The service may be of any physical size, economy of scale, or organizational complexity. For example, it could be a single, stand-alone entity (e.g., an independent medical laboratory, diagnostic imaging service, or outpatient medical or surgical clinic) or it might be an entire hospital or medical center. At the opposite end of the spectrum, it could be a subsidiary department within a multi-departmental hospital or medical center (e.g., a clinical laboratory, diagnostic imaging clinic, respiratory care clinic, pharmacy, or medical or surgical department).

Whatever its size or complexity, a healthcare service remains an organizational entity and, as such, operates within a quality system matrix of policies, processes, and procedures. Such a managerial infrastructure does not so much underlie the healthcare service operations, but rather, it pervades interstitially throughout the service operations. In fact, any healthcare service is bound to serve within two forms of infrastructural matrices, an external system and an internal system.

On one hand, there is usually some form of an *external* infrastructural matrix, a system of extrinsic guidance derived from one or more local, state, federal government, and/or parent company administrative-level policies, processes, and procedures. Simultaneously, the same healthcare service operates within its own *internal* matrix of intrinsic quality system managerial-level policies, processes, and procedures.

The quality system matrix of a healthcare service at one level should fit with the quality system matrix of the service at the next level—one organization level's quality system merging with the other organizational level's quality system. There needs to be a fit, one service level's quality system dovetailing with the next. Each quality system will consist of the same standard components—or quality system essentials—of policies, processes, and procedures.

The core array of policies, processes, and procedures of a quality system forms a grouping of 12 quality system essentials (QSEs). These 12 QSEs are the most fundamental managerial activities that are universally important for supporting any healthcare service operational path of workflow. The QSEs form the infrastructural framework necessary for the delivery of any type of product or service—they incorporate all managerial resources by which any healthcare service performs its operational work. The 12 QSEs are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Service & Satisfaction
Personnel	Process Control	Assessment	Facilities & Safety

Table 1 diagrams these QSEs. NCCLS uses this diagram throughout its quality management series to map out specific QSEs that are relevant to the respective guideline under discussion.

Table 1. The 12 Quality System Essentials Matrix

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety

Adapted from NCCLS document HS1—*A Quality Management System Model for Health Care.*

Each healthcare service also needs to integrate its managerial quality system with its operational path of workflow—matching unique managerial resources with unique operational processes. NCCLS has produced guidelines for several clinical services, each document describing how the quality system essentials meld with the respective service's path of workflow, including the following guidelines:

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

The NCCLS model of quality system design presented in NCCLS guideline HS1 and used as the central focus for this quality management reference series is consistent with that described in the International Organization for Standardization (ISO) 9000 series of standards for quality management. Table 2 compares the 12 QSEs of the NCCLS quality system with key clauses of ISO 9001:2000 and ISO 15189:2003.

Table 2 demonstrates how the NCCLS quality system management guidelines correlate to the International Organization for Standardization document ISO 15189: *Medical laboratories: Particular requirements for quality and competence*. ISO 15189 is an international standard for the requirements of a quality system for the clinical laboratory. It is consistent with its other, more generic international standards such as the ISO 9000 series and ISO/IEC 17025:1999: *General requirements for the competence of calibration and testing laboratories* (formerly *ISO/IEC Guide 25*).

Table 2. A Comparison of NCCLS Quality System Essentials to ISO 9001:2000 and ISO 15189:2003 Clauses

NCCLS Quality System Essential*	ISO 9001:2000 Clauses†	ISO 15189:2003‡
Organization	4.1 General requirements 5.1 Management commitment 5.3 Quality policy 5.4 Planning 5.5 Responsibility, authority, and communication 5.6 Management review 6.1 Provision of resources	4.1 Organization and management 4.2 Quality management system 4.15 Management review Annex C.1 General ethics Annex C.2 General principles Annex C.10 Financial arrangements
Personnel	6.2 Human resources	5.1 Personnel
Equipment	7.6 Control of measuring and monitoring devices	5.1 Laboratory equipment 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 4.7 Advisory services
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 procedures 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 5.9 Alterations and amendments of reports Annex C.7 Storage/retention of medical records
Information Management	8.4 Analysis of data	Annex B Lab Info System 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 non-conforming product	4.8 Resolution of complaints 4.9 Identification and control of nonconformities
Assessment	8.1 General 8.2 Monitoring and measurement	4.14 Internal audits
Process Improvement	8.5 Improvement	4.10 Continual improvement 4.11 Corrective action 4.12 Preventive action
Customer Service and Satisfaction	5.2 Customer focus	
Facilities and Safety	6.3 Infrastructure 6.4 Work environment	5.2 Accommodation and environmental conditions

* NCCLS guideline HS1—*A Quality Management System Model for Health Care.* Wayne, PA: NCCLS; 2004.

† ISO 9001:2000. *Quality management systems—Requirements.* Milwaukee, WI: American Society for Quality Press; 2000.

‡ ISO 15189:2003. *Medical laboratories—Particular requirements for quality and competence*. Geneva: International Organization for Standardization; 2003.

The International Organization for Standardization Technical Committee 212 (ISO/TC 212) developed ISO 15189. NCCLS holds the secretariat role for that ISO committee, making NCCLS responsible for harmonizing ISO concepts within healthcare services at the international level. Accordingly, all NCCLS healthcare services documents strive to meet the same generic ISO standards. NCCLS guidelines are no longer limited to medical laboratory standards.

We hope that the NCCLS series of quality management guidelines will be a useful set of tools for all healthcare services managers. We welcome your comments on the content of this document and its relationship to its companion NCCLS quality management guidelines.

Foreword

Every clinical service needs ongoing quality improvement. The practicing of continuous quality improvement (CQI) maximizes operational efficiency, effectiveness, and adaptability. These managerial goals are especially important for the following reasons:

- National and local governments and peer organizations continue to scrutinize the management of quality in the process of licensing and accrediting clinical services of all sizes. These regulatory and accreditation mandates spotlight the importance of customer-oriented strategic planning; team-oriented decision making; and ongoing monitoring, improvement, and reviewing of quality to enhance operational processes.

- The demands of managed health care in a constrained economy compel clinical services to handle more volume with fewer resources. Still, quality must not suffer in this economic tug-of-war. Economic forces are continually changing clinical service organizational structures and customer relationships. Achieving CQI softens the impact of these changes through enhanced internal and external customer satisfaction.

- Changing trends in illness, medical practice, and demographics call for clinical services to adapt and meet new customer needs. Examples of these pattern shifts include: the rising prominence of geriatric illness; domestic-social violence; substance abuse; new, expanding, or reemerging infectious diseases, such as HIV/AIDS, tuberculosis, SARS, and West Nile virus; new alternative healthcare approaches; and terrorist biochemical and other mass destructive activities. Responding to these changes requires anticipatory management approaches, often with relatively short—even emergency—timelines. With healthcare reform aimed at increasing patient access and cost effectiveness, there is even more interest in preventive health care with earlier detection and treatment of disease. All of these trends demand a systematic, process-oriented, multidisciplined, team-centered quality improvement effort as exemplified by the practice of CQI.

Consequently, a clinical service should focus on *systematic continuous quality improvement as measured by customer satisfaction*, including profitability. NCCLS document GP22 presents such managerial skills and outlines the importance of the synergistic combination of Quality Planning, Quality Teamwork, Quality Monitoring, Quality Improvement, and Quality Review—all functioning within the whole integrated quality system. This document presents general managerial concepts that apply to any kind of clinical service—although the guideline often uses the clinical laboratory as an operational model.

GP22 describes CQI as the integration of four QSEs as mapped out in Table 3. QSE: Organization contributes two CQI components, while each of the other QSEs contributes one component.

Table 3. The Relationship of the Four QSEs of CQI to the Entire Quality System

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
	X	X						X	X		

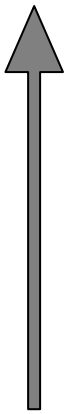
Adapted from NCCLS document HS1—*A Quality Management System Model for Health Care.*

The four QSEs and their five CQI components function sequentially, as follows:

- QSE: Organization: Quality Planning component;
- QSE: Personnel: Quality Teamwork component;
- QSE: Assessment: Quality Monitoring component;
- QSE: Process Improvement: Quality Improvement component; and
- QSE: Organization: Quality Review component.

The Organizational Hierarchy of Quality Administration

The philosophy and processes of CQI provide a means by which a clinical service can reach the highest level of operational distinction. Emulating Abraham Maslow's model of the hierarchy of individual needs, Figure 1 presents the relationship between CQI and other organizational levels of quality administration.[1] As stated in NCCLS document HS1, *"The baseline of a quality system, with operations under control, provides a platform for continuous improvement and further movement up the quality hierarchy."*



Hierarchical Level	Activities Performed
Total Quality Management	An organization-wide managerial approach centered on ongoing quality improvement as evidenced by total customer satisfaction and minimal cost of maximized quality.
Quality Cost Management[2]	An executive level managerial activity to identify, measure, and control the cost of quality.
Quality System Management	An executive level managerial implementation of the twelve quality system essentials in support of all operational path of workflow functions.
Continuous Quality Improvement	**A subset of the quality system by which executive-intermediate management integrates Quality Planning, Quality Teamwork, Quality Monitoring, Quality Improvement, and Quality Review to achieve sustained improvement.**
Quality Assurance	Intermediate managerial level activities for measuring effectiveness of the clinical service through indicators of the quality of process performance.
Quality Control	Operational level techniques for measuring the effectiveness of the clinical service through indicators of the quality of procedural performance.

Adapted from NCCLS document HS1—*A Quality Management System Model for Health Care*.

Figure 1. The Organizational Hierarchy of Quality Administration

Figure 1 demonstrates that a clinical service practices a hierarchy of progressively more complex levels of quality administration. These levels are:

- *quality control (QC)* is practiced at the operational point of care, at-the-bench, level—measuring actual operative procedural performance through indicators, such as precision and accuracy.

- *quality assurance (QA)* is practiced at the next higher, intermediate management level—measuring effectiveness of clinical service processes in regard to their respective path of workflow through indicators, such as turnaround time, and reporting error.

- ***continuous quality improvement (CQI)*** is practiced at the executive and intermediate management levels, facilitating systematic improvement through the sequential exercising of five components of the quality system essentials, including:

  - Quality Planning: a component of QSE: Organization;
  - Quality Teamwork: a component of QSE: Personnel;
  - Quality Monitoring: a component of QSE: Assessment;
  - Quality Improvement: a component of QSE: Process Improvement; and
  - Quality Review: a component of QSE: Organization.

- *quality system management (QSM)* is practiced at the executive management level—synchronizing all 12 infrastructural quality system essentials in support of all operational activities.

- *quality cost management (QCM)* is practiced at the executive management level—formally measuring the costs of poor quality, such as rework and waste, against the cost of good quality, such as monitoring and improvement activities.

- *total quality management (TQM)* is practiced organization-wide—realizing totally satisfied employees serving totally satisfied customers for every operational product or service provided.

In summary, a clinical service can achieve CQI by integrating five key quality system components. Practicing this managerial approach provides the organizational philosophy and processes, which are the baseline for the entire quality system. GP22 is a manager's guide to implementing and sustaining continuous process improvement.

We offer this guideline to clinical service directors, managers, and supervisors to assist them in their ongoing quest for excellence. By using this CQI approach, clinical service leaders should be able to better cope with an ever-changing healthcare environment.

The title of the previous edition (GP22-A—*Continuous Quality Improvement: Essential Management Approaches; Approved Guideline)* has been changed to reflect the intended use of the document in interrelating quality system essentials with continuous quality improvement.

Key Words

Continuous quality improvement (CQI); Quality Improvement; Quality Monitoring; Quality Planning; Quality Review; Quality Teamwork

Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition

1 Scope

This guideline provides the user with definitions, concepts, and methods to achieve continuous managerial and operational improvement, using five essential, interrelated quality system components:

- quality planning — a component of the planning element of QSE: Organization;
- quality teamwork — a component of the orientation and ongoing training element of QSE: Personnel;
- quality monitoring — a component of the measurement and assessment element of QSE: Assessment;
- quality improvement — a component of the improvement element of QSE: Process Improvement; and
- quality review — a component of the management review element of QSE: Organization.

This guideline includes written and graphic descriptions that clarify these five key, integrated managerial approaches to CQI.

This guideline is intended for use by all individuals involved in any clinical service including physicians, nurses, and allied health professionals, as well as laboratory, clinical, and support staff.

2 Introduction

This guideline provides basic definitions and management approaches to achieve clinical service continuous quality improvement (CQI) as evidenced by customer satisfaction. It outlines how to implement team-focused quality planning and ongoing quality monitoring, improvement, and review. Using such a systematic management approach, a clinical service of any size can become more effective and efficient despite increasing regulatory requirements, changing customer needs, and constraints in quality management resources.

3 Definitions

Action personnel – The personnel responsible for and having the authority and resources to lead or coordinate the implementation of a plan.

Audit – Systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled (ISO 9000, 3.9.1).[3]

Continuous quality improvement (CQI) – A managerial concept that is both an organizational philosophy and a systematic process.

- Philosophy – The membership of an organization, including its leaders, is committed to quality planning, teamwork, monitoring, improvement, and review that will result in ongoing quality improvement to satisfy customer needs. This philosophy includes not only resolving problems that need immediate attention, but also in seeking out opportunities for improvement where problems are

currently not symptomatic. In either case, improvement will minimize cost, waste, and injury; enhance resource and process management; and facilitate customer satisfaction in an anticipatory manner.

- Process – A systematic approach that facilitates ongoing quality improvement as evidenced by enhanced customer satisfaction. This incorporates the integrated processes of quality planning, quality teamwork, quality monitoring, quality improvement, and quality review.

Corrective action – Action to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000, 3.6.5).[3]

CQI interface – The important interchange of information between all five functionally interrelated CQI components of quality planning, quality teamwork, quality monitoring, quality improvement, and quality review; **NOTE:** By utilizing the quality review component of the QSE: Organization, this interface facilitates the synchronization of all five CQI components.

Goal – A first-level action-planning element that most broadly delineates how to accomplish a specific strategy or policy at the multiprocess level.

Milestone – An action-planning element that delineates by what date an action plan step is to be accomplished and by what criteria of success that step should be measured.

Mission – An element of the organization-wide direction phase of plans management that delineates a broad strategy to meet the paramount current customer needs with the managerial and operational resources of today.

Objective – A second-level planning element that delineates more specifically how to accomplish a specific goal at the process level.

Opportunity for improvement (OFI) – A condition, which if improved, will result in significant enhancement of organizational effectiveness and customer satisfaction.

- Symptomatic OFI – An obvious opportunity that is evidenced by preestablished surveillance indicators, their thresholds, and related observational data over a reasonable time period—usually 90 to 180 days.

- Asymptomatic OFI – An opportunity that is not clearly evidenced by preestablished surveillance indicators. However, if that condition is improved, in spite of its being “asymptomatic,” customer satisfaction is significantly enhanced. The usual instance is when elements of the Improvement Management Program, itself, need improvement.

Path of workflow – A unique series or sequence of processes and procedures necessary to produce a specific service or end product.

Policy – A definite course or method of action selected from among alternatives and in light of given conditions to guide and determine present and future decisions; a high-level, overall plan embracing the general goals and acceptable procedures of the organization; an overall, prime strategy; a statement of intent and direction.

Preventive action – Action to eliminate the cause of a potential nonconformity or other undesirable potential situation (ISO 9000, 3.6.4).[3]

Procedure – Specified way to carry out an activity or a process (ISO 9000, 3.4.5).[3]

Process – Set of interrelated or interacting activities which transform inputs into outputs (ISO 9000, 3.4.1).[3]

Quality – Degree to which a set of inherent characteristics fulfills requirements (ISO 9000, 3.1.1).[3]

Quality assurance – Part of quality management focused on providing confidence that quality requirements will be fulfilled (ISO 9000, 3.2.11).[3]

Quality control – Part of quality management focused on fulfilling quality requirements (ISO 9000, 3.2.10).[3]

Quality improvement – Part of quality management focused on increasing the ability to fulfill quality requirements (ISO 9000, 3.2.12).[3]

Quality management – Coordinated activities to direct and control an organization with regard to quality (ISO 9000, 3.2.8).[3]

Quality management system – Management system to direct and control an organization with regard to quality (ISO 9000, 3.2.3).[3]

Quality monitoring – An ongoing quality assessment process that establishes the most important monitoring targets to ensure the organization's ability to provide optimal customer satisfaction.

Quality planning – Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfill the quality objectives (ISO 9000, 3.2.9).[3]

Quality teamwork – A quality system-based teamwork process that focuses on the most effective and efficient organization-wide, anticipatory decision making.

Review – Activity undertaken to determine the suitability, adequacy, and effectiveness of the subject matter to achieve established objectives (ISO 9000, 3.8.7).[3]

Strategy – **1)** A key element of the strategic prioritization phase of plans management that most broadly delineates how a clinical service organization can best satisfy a specific customer need. A strategy can be time-phased as short-, medium-, or long-range and might require staging for research, development, and/or implementation; **2)** A policy.

Task – A third-level action-planning element that delineates the specific “who, how, and when” to accomplish a specific objective.

Value – An element of the organizational-wide direction phase of plans management that delineates a professional principle, ethic, or belief that is important to satisfying customer needs, including quality expectations.

Vision – An element of the organizational-wide direction phase of plans management that delineates a broad strategy to meet the paramount future customer needs with the managerial and operational resources of tomorrow.

4 Principle

Over several decades, the philosophy and process of continuous quality improvement have evolved through the pioneering efforts of quality management leaders such as Deming, Juran, and many others. These pioneers based their outcome enhancement concepts on organization-wide commitment to statistically based quality control, conformance to design specifications, and customer satisfaction.[4,5]

CQI is a general managerial model that enhances the outcome of patient care. It concerns identifying and understanding customer requirements and then focusing on meeting and exceeding those requirements. It is an approach to managing constrained healthcare resources as well as dealing with management paradigm shifts. An organization can achieve CQI through a system of five quality management activities that:

- identify and plan for current and foreseeable customer needs;
- generate effective, team-based decision making;
- sustain ongoing monitoring of operational process and customer satisfaction identifying process problems;
- implement appropriate process improvement; and
- practice ongoing quality review.

When a clinical service synchronizes these five quality system components, it supports the CQI philosophy of process enhancement, improved outcome, and customer satisfaction. The five CQI components are described as follows:

- **Quality Planning** is a component of the planning element of QSE: Organization. Quality planning has also been known as strategic planning and quality anticipation.[6]
- **Quality Teamwork** is a component of the orientation and ongoing training elements of QSE: Personnel. Quality teamwork has also been known as organizational effectiveness and quality actualization.[6]
- **Quality Monitoring** is a component of the measurement and assessment elements of QSE: Assessment.
- **Quality Improvement** is a component of the improvement element of QSE: Process Improvement.
- **Quality Review** is a component of the management review element of QSE: Organization. Quality review has also been known as annual review, quality program review, quality program assessment, and management review.

Before quality system concepts began to take shape, the latter three components (monitoring, improvement, and review) were not well understood and were grouped together under various other labels. They have been known collectively as quality surveillance, quality assurance (QA), quality assessment and improvement (QI), and improving organizational performance (PI).[6]

Too often, the older style practices of QA, QI, and PI have been focused on problem finding with too little emphasis on identifying opportunities for preventing problems through improving processes. Using the earlier quality management paradigm, we spend too much time reacting to unanticipated events and

putting out fires in a knee-jerk fashion—the theme being: find a problem, fix a problem—and ignore the systemic cause.

CQI optimizes resource management and customer satisfaction. By using an integrated CQI approach, it is possible to anticipate, prevent, and control quality problems. By practicing CQI, it is possible to anticipate, prevent, and control risk—instead of "managing" it.

5 Quality Planning

The overall aim of Quality Planning is that the clinical service achieves continuous improvement of organizational processes through *anticipatory planning*—rather than reactively responding to problems as they arise. The clinical service establishes managerial and operational strategies, goals, objectives, and tasks through a review of the service's current and foreseeable performance balanced against current and foreseeable market forces.

Quality Planning is supported by NCCLS document HS1—*A Quality Management System Model for Health Care* under QSE: Organization as follows:

- Policy: to embed quality throughout the organization.

- Process: performance of ongoing strategic planning that centers on quality.

5.1 Designating Quality Planning Teams

The clinical service should designate a specific quality planning team at the executive management level to conduct and coordinate the service's quality planning activities. The team members should include the service's executive management (e.g., senior clinical service managers) and key supervisors, along with appropriate internal and external customer representatives. The service should designate other coordinating and action teams at appropriate managerial levels whenever necessary.

5.2 Establishing a Quality Planning Program

To achieve the QSE policy and process prescribed above in support of planning, the clinical service can develop a Quality Planning program that consists of four general phases. These phases are diagrammed in Figure 2.

- **Phase I. Organizational Direction** – to research, analyze, and establish the clinical service's overall organizational direction. This collective pathway is based on the needs of the service's customers and the service's general capabilities. This general assessment explains the process of "How we do business" and is summarized in the service's mission and vision statements.

- **Phase II. Strategic Prioritization** – to develop prioritized and staged strategies that will enhance customer satisfaction using the managerial and operational resources available to meet current and anticipated customers' needs by improving work processes.

- **Phase III. Action Planning** – to translate the prioritized strategies into process improvement-oriented goals, objectives, and tasks.

- **Phase IV. Action Follow-up** – to evaluate the effectiveness of the strategic plans and improvement actions as measured by process performance and customer satisfaction. This phase prepares the clinical service for its next review and planning cycle.

A clinical service can develop its Quality Planning program by following the four phases described in this section. These phases provide a structure by which the service can continuously develop, implement, review, and modify plans for short-, medium-, and long-range improvement.

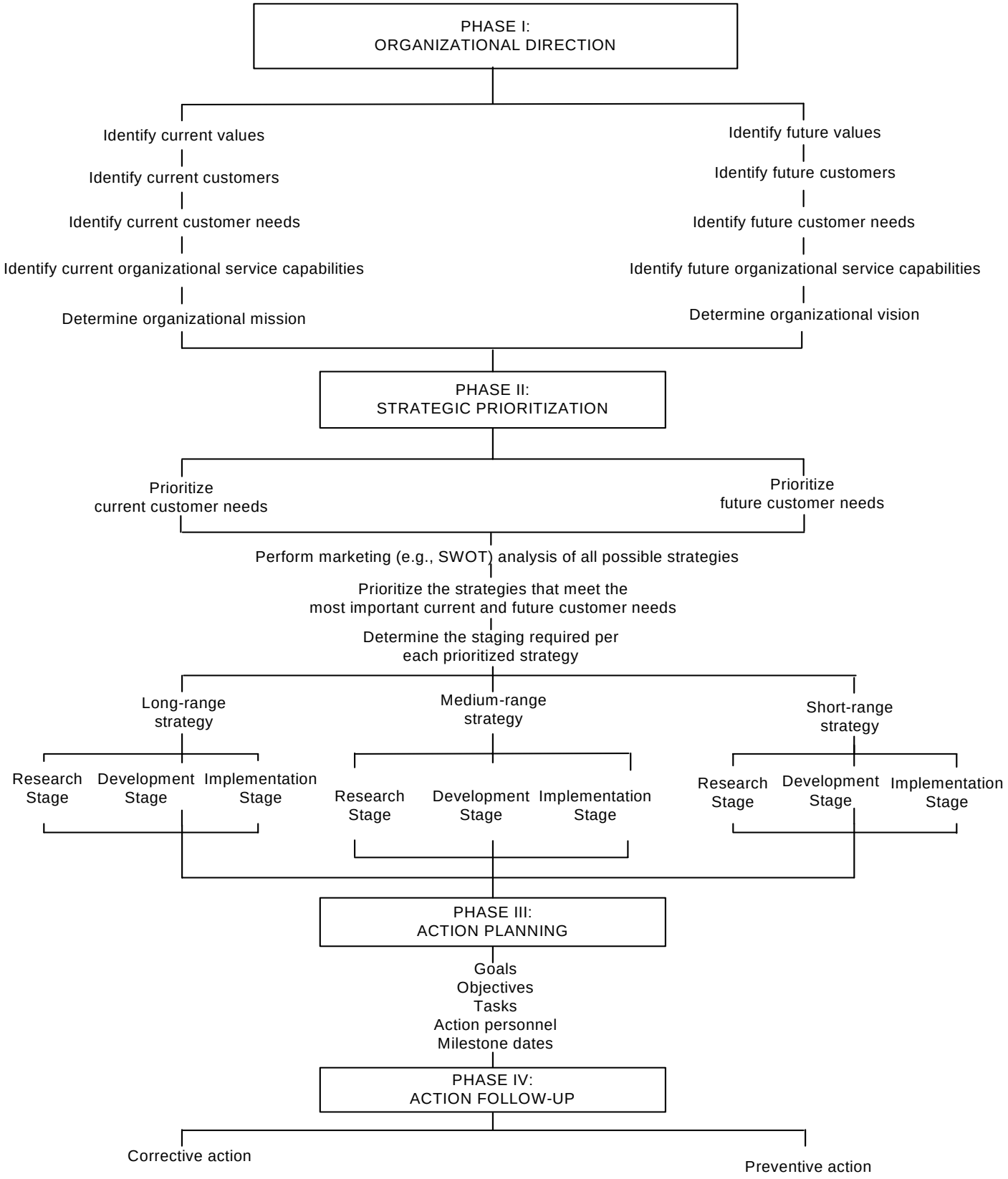


Figure 2. An Example Outline of a Quality Planning Program[6]

5.3 Phase I: Organizational Direction

The clinical service can determine its general organizational direction through the following planning activities:

- identifying basic organizational values;
- identifying internal and external customers;
- identifying customer needs;
- identifying managerial and operational resources and capabilities;
- prioritizing customer needs; and
- developing the clinical service's mission and vision.

To assess trends for planning purposes, the clinical service needs to consider the above issues in terms of the past, present, and the foreseeable future. This information provides a minimum of three points needed to graph or map the organization's options for planning current and future operational process improvements. Actually, all improvements are future actions.

Past clinical service values, customers, their needs, and managerial-operational capabilities are those that have existed previously.

Present clinical service values, customers, their needs, and managerial-operational capabilities are those that exist currently.

Future clinical service values, customers, their needs, and managerial-operational capabilities are those that will exist in the foreseeable future. How far into the future a clinical service can plan depends on how well the team is able to prognosticate. A clinical service's success in future planning depends on its ability to confidently anticipate customers' future needs as well as future organizational capabilities. In the course of performing this prognostication, the clinical service needs to consider the future stability of the organization and the services provided.

5.3.1 Identifying Basic Organizational Values

To determine its general organizational direction, the clinical service should first review all information reflecting clinical service *values*. This information should include the professional and business principles, ethics, and beliefs that are essential for meeting customer needs. Quality is built upon organization-wide and individual member values.

Every organization, including any clinical service, consists of individual members, each having an individual personality and value set. The combination of all individual personalities and values creates an organizational personality and value system. Ultimately, the clinical service needs to identify its most basic organizational values in some way (e.g., by group discussion and survey). There needs to be an organization-wide consensus agreement on what those basic values are or should be.

5.3.2 Identifying External and Internal Customers

The clinical service needs to identify its external and internal customers, including healthcare customers, partners, suppliers, and employees. A customer is anyone who depends on another person or part of a

clinical service for a product or information. This is usually clear when referring to external customers, the most obvious being the patient or client, or the physician ordering the service. Internally, it is sometimes overlooked that staff performing preexamination functions are providing a service to those performing examinations, who are in effect their customers. Any time there is a handoff from one area to another, there is a customer/provider relationship. The service should also consider both current and future customers.

5.3.3 Identifying Customer Needs

The clinical service should identify the current and future needs and expectations of the customers identified above, including objective outcome measurements of current customer satisfaction.

5.3.4 Identifying Organizational Resources

The clinical service needs to review its data and information on the current and future status of clinical service *organizational capabilities* necessary to satisfy its customer needs.

As used here, the terms "organizational resources" or "capabilities" refer to clinical service *managerial* and *operational* resources and capabilities. It is essential that these capabilities include all the managerial and operational resources necessary to satisfy internal as well as external customer needs. These resources would include supportive policies, processes, and procedures—as well as personnel, information management, equipment, supplies, and time.

All the information needed to identify values, customers, customer needs, and resources should be available through the management review component of QSE: Organization. This is discussed in greater detail in Section 9.

5.3.5 Prioritizing Customer Needs

After identifying values, customers, their needs, and available resources, the planning team needs to realistically prioritize those customer needs against managerial and operational resource capabilities—including quality management resources. The service should prioritize customer needs in terms of:

- ethical propriety, including managerial accountability;
- clinical importance; and
- resource availability.

5.3.6 Developing the Clinical Service's Mission and Vision

As the final step in this first planning phase, the clinical service delineates its general, organization-wide direction by developing its mission and vision statements.

- The **mission** statement should very briefly state how current clinical service managerial and operational resources can best meet prioritized customer needs of *today*.
- The **vision** statement should very briefly state how future clinical service managerial and operational capabilities should best meet paramount customer needs of *tomorrow*.

The clinical service should state its mission and vision as precisely and concisely as possible. These statements should be effective as planning guidelines and employee motivators *for today* and *toward tomorrow*—keeping the clinical service positively poised for present contingencies and future changes.

5.4 Phase II: Strategic Prioritization

In this second phase of planning, the clinical service determines broad-scoped strategies in answer to the customer needs that have been prioritized in Phase I. To prepare for identifying and prioritizing such strategies, the clinical service needs to perform a marketing analysis.

The clinical service bases its strategic prioritization on the following planning activities:

- performing a market analysis;
- establishing strategies for customer needs; and
- staging the strategies.

5.4.1 Performing a Market Analysis

The market analysis should include a review of internal organizational:

- **S**trengths; and
- **W**eaknesses.

Strengths and weaknesses are driven by internal organizational factors, such as the state of policies, finances, personnel, and facilities.

The market analysis should also include a review of the external market:

- **O**pportunities; and
- **T**hreats.

Opportunities and threats are driven by external environmental factors, such as regulations, technologies, competitor activities, and demographic changes.

Using the initials of the four issues of interest, this method of market assessment and prioritization is popularly called a “SWOT” analysis.

In preparing for the SWOT analysis, the clinical service should gather available internal and external data and information regarding the service’s managerial, operational, and marketing status. This information should be available through the management review component of QSE: Organization, as is discussed in greater detail in Section 9.

The data and information must be as objective as possible. Assumptions can be important—especially for future planning—but they should be kept to an absolute minimum. The service should use subjective information only when it is absolutely essential to the planning process.

Once the SWOT analysis information has been compiled, some of the pertinent strategy-making decisions to consider are:

- Does the clinical service have specific internal strengths or core competencies that a strategy should focus on?
- Are there any weaknesses that need to be corrected before pursuing new opportunities?

- Which opportunities are realistically achievable?

- What threats should be of greatest concern?

5.4.2 Establishing Strategies

Next, the clinical service should use the SWOT analysis to *develop* and *prioritize* broad-scoped planning strategies that will satisfy the highest priority customer and their highest priority needs—both present and future. The purpose of these prioritized strategies is *to best satisfy and anticipate* the most important customer needs *by providing* the most timely, up-to-date, appropriate improvement of the clinical service's operational policies, processes, and procedures, *while expending* the fewest clinical service resources.

5.4.3 Staging Strategies

The clinical service can time phase any given strategy in terms of the length of time required for its completion. Time phasing depends on the overall complexity and degree of emergency of the related customer need as matched to the clinical service's immediate capability to satisfy that need. Thus, a strategy can be considered as:

- long-range (e.g., two to three years);

- medium-range (e.g., one year); or

- short-range (e.g., three to six months).

The examples of length of time used above are arbitrary and can vary. Medium-range and, particularly, long-range strategies often require additional interim or stopgap measures to sustain reasonable quality service performance.

Also, the clinical service can stage any given strategy phasing (i.e., long-, medium-, or short-range) in terms of the service's degree of preparedness. This preparedness depends on the extent of tried and true resources that are immediately at hand for the service to accomplish the strategy. Three possible stages include research, development, and implementation.

5.4.3.1 Research Stage

There may be a complete lack of immediately available information or adequately tested clinical service capability to fully meet a customer need and resolve a process problem. Thus, resolving the solution of the ultimate strategy will require preliminary investigative research by thorough study of the customer's need and all possible technical, market, and service resource options available to improve the related organizational process. In such a situation, the clinical service needs to ascertain what interim solutions are required to maintain customer satisfaction while meeting the longer-range staging plan.

EXAMPLE: A clinical laboratory has identified an unprecedented, new customer need for state-of-the-art blood chemical analysis requiring the laboratory to create a brand new service capability. To accomplish this, the laboratory must perform a cost-benefit analysis and market analysis of all existing options, including experimental. In the interim, the laboratory may have to select an outside testing source. Development and implementation stages are likely to follow.

5.4.3.2 Development Stage

The means to achieve a customer need (i.e., solving a clinical service's process problem) may be already supported by adequate preliminary information or an untried capability, possibly based on an earlier research stage. However, there still is a need for intermediate, developmental study and, particularly, trial exercising or testing of the most likely successful problem-solving options. Such preliminary testing might involve on- or off-site trials to develop and choose the best final option. In such a situation, the clinical service should ascertain what interim solutions are required to maintain customer satisfaction during this medium-range staging plan. An implementation stage is likely to follow.

EXAMPLE: A clinical laboratory has identified a customer need for a higher volume, broader spectrum blood chemical analyzer. If not already accomplished in a research stage, the laboratory must accomplish cost-benefit analysis, market analysis, and field visits. Most importantly, this stage involves operational trials of optional devices. Final instrument selection with planning for space renovation, installation, and staff training would follow. In the interim, the laboratory can continue using currently available instrumentation or use an outside testing source for the selective tests or certain types of specimens that will be ultimately served by the new instrument. As usual, there should be an emergency plan for backup in case the currently available instrumentation breaks down.

5.4.3.3 Implementation Stage

There may be an immediately available, first-choice, adequately tested capability that will satisfy the customer need by improving the clinical service's process problem. Although very possibly based on earlier research or developmental staging, this solution may be so readily available as to preclude any need for preliminary research, intermediate development, or even interim stopgap measures to maintain customer satisfaction.

EXAMPLE: A clinical laboratory has identified an internal, operational need to replace its aging blood chemical analyzer with a new one having similar technical characteristics. The external customer need remains unchanged. There is no need for any extensive cost-benefit analysis, market analysis, field visits, instrument selection, space renovation, or staff training—only pricing, purchasing, and replacement installation. There is no need for interim backup. However, there is a need for the usual contingency backup plan if the current instrument breaks down and cannot be repaired before being replaced.

Whereas the clinical laboratory is the example used above in the three planning stages, any clinical service can easily generate its own examples, such as:

- introducing a new diagnostic imaging technique;
- adding a new mode of respiratory therapy; or
- choosing between automated versus manual dispensing of medications.

It may be necessary to plan varying combinations of these three stages to achieve any given strategy. Whereas employing all three stages in succession may be necessary to meet one overall strategy, only one or two stages may be needed to achieve other strategies.

Staging is critically important for ensuring customer satisfaction, especially when research or development staging is necessary. In these cases, it is often required to plan and improvise interim solutions to maintain customer satisfaction during the time that the ultimate strategic resolution is being accomplished.

5.5 Phase III: Action Planning

During this third phase, the clinical service translates the general strategies from the second phase into the traditional actions of very broad goals, more specific objectives, and individual tasks.

- Goal – an overall, most broadly stated action needed to accomplish a specific strategy in the research, development, or implementation stage. A goal is a general, broad-based, single QSE, possibly multi-process improvement that requires relatively prolonged effort necessary to achieve a customer need strategy. One or more goals may be necessary to meet a strategy.

- Objective – a more specific action needed to accomplish a specific goal. An objective is focused on improving a single process and is more tangible and quickly attainable than a goal. One or more objectives may be necessary to meet a goal.

- Task – an action needed to accomplish a specific objective. A task is aimed at improving a process at the procedural level; it focuses on improving a procedure. A single task often can be broken down into specific procedural steps. One or more tasks may be necessary to meet an objective.

The accomplishment of strategies, goals, objectives, and tasks usually requires that the clinical service assign responsibilities to specific staff members at appropriate organizational managerial levels. These individuals will establish, coordinate, and monitor target dates for the accomplishment of the respective strategy, goal, objective, or task.

For each strategy, goal, objective, and task, the clinical service should determine appropriate milestones, including outcome measurements and target dates for completion. These milestones should address the following questions:

- *Which* specific processes or procedures need implementation or change?

- *Who* should plan, implement, and follow-up the subject process or procedure improvement?

- *What* clinical service resources are required to accomplish the task?

- *When* should the action team accomplish the implementation or change of process or procedure to meet the customer need in a timely fashion? *What* sequence of accomplishments should fit into a timeline?

- *What* are the specific performance indicators that will measure the result of the action taken?

Table 4 shows the relationships between the respective levels of the major Quality System Essential (QSE) and Quality Planning activities.

Table 4. A Comparison of QSE Activities to Quality Planning Activities

QSE Activities	Quality Planning Activities
Policy	Developing the strategy necessary to meet a given customer need
Process	Developing goals and objectives to meet the set strategy
Procedure	Developing tasks that support the implementation or improvement of a process to meet the set goals and objectives

5.6 Phase IV: Action Follow-up

At all strategy, goal, objective, and task-planning and action levels, the clinical service needs to periodically monitor and assess the effectiveness of its improvement efforts in a timely fashion, including adherence to timelines, deadlines, and performance indicators.

The planning and action teams evaluate the performance measurements to determine the success of overall accomplishment and the necessity for any follow-up action. The teams periodically report their findings and actions to the appropriate supervisory level in a timely fashion.

At its highest planning level, the clinical service needs to regularly assess the effectiveness of all planning and action for each clinical service strategy, asking:

- How well have the implementers complied with the clinical service's mission, vision, and strategic prioritization in formulating their action-planning activities?

- Is there measurable evidence of improvement of the managerial and operational processes and customer satisfaction?

- Do the mission, vision, strategy, goals, objectives, or tasks, including milestones, require preventive or corrective action?

Figure 3 is a diagram that provides an example of plans management for a clinical laboratory section. Compared to Figure 2, for the sake of brevity, each strategy time phasing (e.g., short-, medium-, or long-range) is matched to only one staging example (e.g., implementation, development, or research). However, because of the time factor, strategic phasing and staging quite often will coincide as shown in Figure 3.

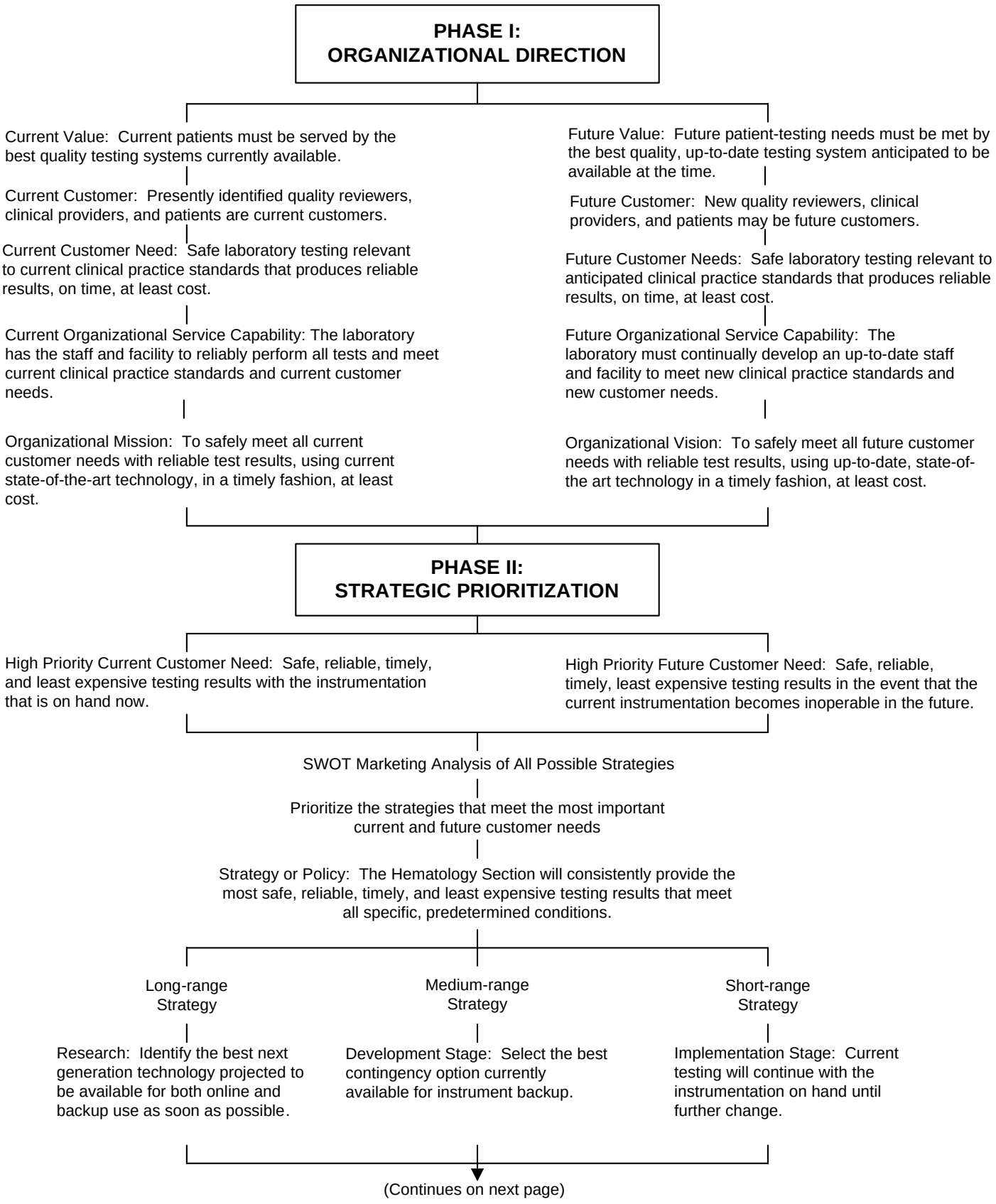


Figure 3. An Example Outline of a Quality Planning Program in a Clinical Laboratory Hematology Section[6]

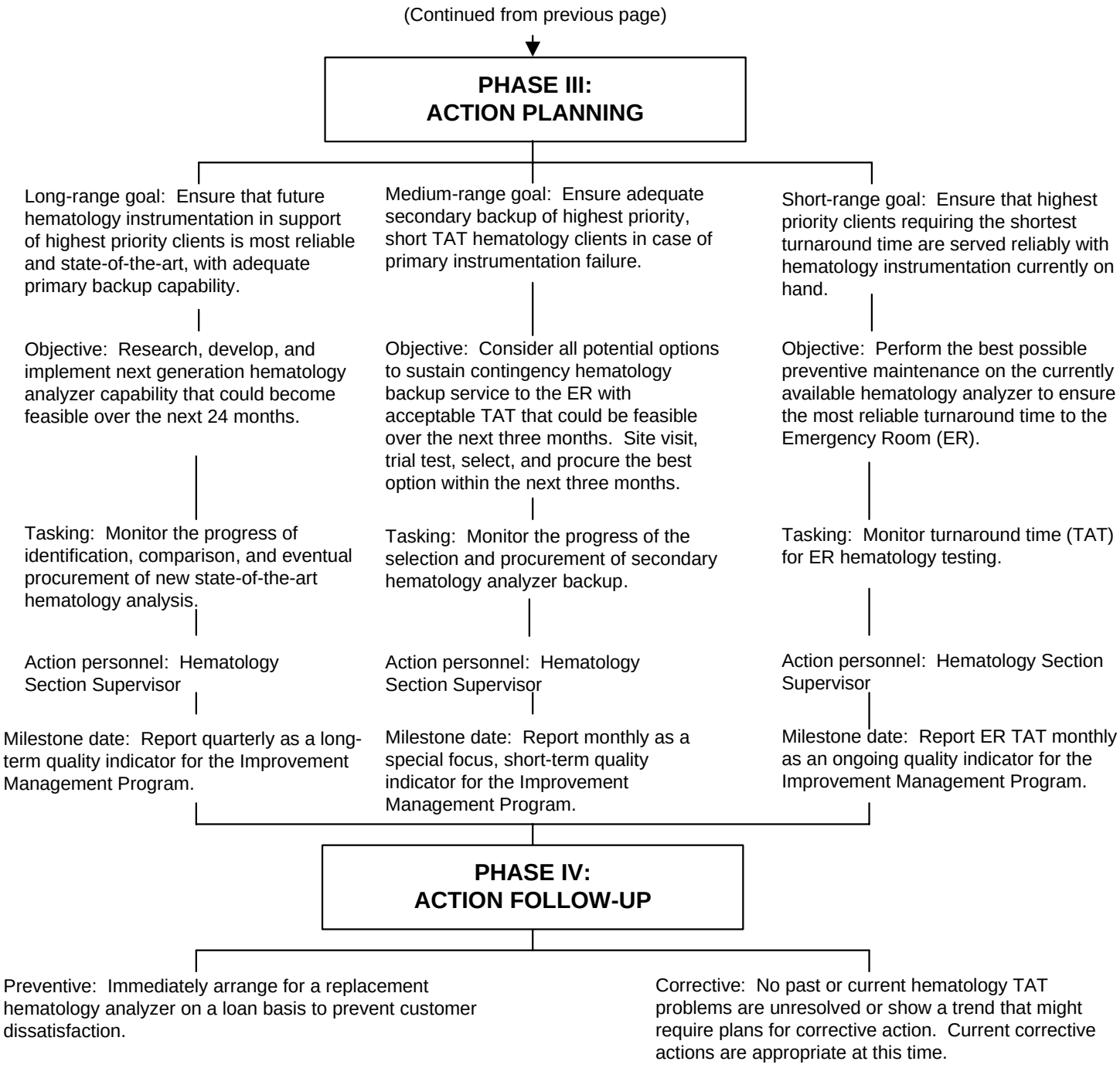


Figure 3. (Continued)

5.7 Reviewing Quality Planning

The clinical service should periodically review its mission, vision, and strategic planning to ensure ongoing validity. It is particularly important to routinely review the status of action plans in a timely fashion to ensure successful completion. Planning and action teams can utilize planning milestones as quality indicators for the Quality Monitoring and Improvement components of CQI. The latter two CQI components are described in greater detail in Sections 7 and 8. Also, the status of various quality planning activities should be a part of the clinical service's quality report in the Quality Review component, which is discussed in greater detail in Section 9.

6 Quality Teamwork

The overall aim of Quality Teamwork is that the clinical service achieves continuous managerial and operational process improvement through effective *team-based quality decision making.* This activity enhances managerial and operational process improvement by exercising leadership, empowerment, cooperation, and analytical skills.

A team-based organization founded on quality system concepts avoids automatically pointing the finger at an individual employee as the cause of customer dissatisfaction. Instead, a quality team seeks out and improves the managerial or operational process that is faulty.

Quality Teamwork is supported by NCCLS document HS1—*A Quality Management System Model for Health Care* under QSE: Personnel as follows.

- Policy: to prepare and retain personnel who are best skilled to provide the best quality decision making for optimal continuous process improvement in times of constant change.

- Processes:

  - use of team-based quality decision making to practice systematic process improvement;

  - provision of orientation and ongoing training of all personnel in quality system principles, teamwork, appropriate decision making, and timely process improvement; and

  - assessment of individual and organization-wide teamwork and quality-oriented decision making.

To achieve the policy and processes prescribed above, the clinical service can develop a Quality Teamwork program that consists of three general elements, including:

- **Establishing Guidelines for Quality Teamwork**—to develop and practice specific standards of expected performance for team-based quality decision making;

- **Establishing Guidelines for Quality Teamwork Training**—to develop and practice specific standards of expected performance for quality team training; and

- **Establishing Guidelines for Assessing Quality Teamwork**—to assess current quality team capabilities. This assessment should include quality team ability to make appropriate and timely decisions at all organizational levels, as well as management's support of employee quality teamwork.

6.1 Establishing Guidelines for Quality Teamwork

The clinical service should establish specific guidelines for quality teamwork aimed at enhancing decision making and process improvement organization-wide. To accomplish this, all clinical service personnel should understand the following teamwork essentials:

- the definition, structure, and use of teams;
- individual and organization-wide behavior;
- opportunity finding and analytical problem-solving skills; and
- prioritized process improvement.

6.1.1 Defining a Quality Team

A quality team is an organizational unit that is expected to perform specific managerial or operational functions. These assignments may be either routine or specially assigned (i.e., ad hoc).

A clinical service can apply the principles of quality team management to any work group, regardless of the service's size or structure. The service can be very large (e.g., a metropolitan hospital clinical service) or it can be extremely small (e.g., a physician's office). Likewise, a quality team can consist of any of the following sizes:

- an entire clinical service (e.g., a diagnostic imaging service);
- a smaller group within that organization (e.g., a mammography screening unit); or
- an individual staff employee (e.g., a diagnostic imaging secretary).

The general structure of a quality team can take on many forms. Examples include a committee, panel, task force, quality team, or quality circle. These team forms provide a varying array of leadership styles, team member roles, and modes of group decision making.

There are various possibilities of quality team composition or membership, depending on the extent and nature of the problem or opportunity for improvement at hand. For example, improvement projects confined to the clinical service may require only staff members involved in the managerial or operational process in question. On the other hand, quality problems that cross service boundaries (e.g., laboratory-nursing, radiology-surgery, pharmacy-medical) usually require representatives of all involved activities. Team membership also may require the participation of higher-level executive management.

Various CQI-oriented team approaches are available that are designed to stimulate leadership, participatory management, and employee empowerment down to the lowest organizational level. For example, a team has a choice of reaching consensus through brainstorming, nominal, majority rule, Delphi, or benchmarking techniques.[5,6]

6.1.2 Understanding Individual and Organization-Wide Behavior

Consistent with Maslow's behavioral theory of the hierarchy of needs, a clinical service actualizes CQI by improving the satisfaction of customer needs. To accomplish this, the service must be attentive to a variety of external and internal customers, their needs, and their behavior.[1]

In health care, the primary *external* customer is the patient. However, the clinical service needs to design its processes to meet the needs of many other primary requestors who make direct use of the service's products or services to ultimately provide the patient's primary care. These other external customers include physicians, nurses, and other external clients directly linked in the chain of primary care. Each external customer has unique professional and behavioral needs that they often bring to the clinical service's quality team structure.

Naturally, the primary *internal* customer is the clinical service employee. The internal customer is of central importance to quality teamwork.

Whether an external or internal customer, each quality team member brings personal values, beliefs, needs, expectations, and aspirations to the organization—to all aspects of managerial and operational work. The total sum of these individual employee characteristics meld to form the service's unique set of organizational or group values, beliefs, needs, expectations, and aspirations. Quality teamwork is challenged by these individual and organizational personality characteristics and needs, and they must be understood to maximize the productive power and minimize the weaknesses of group dynamics.

Borrowing from Maslow's theory of the hierarchy of needs, through the ongoing practice of quality team skills, the clinical service works toward actualizing its highest organization-wide aspirations. Up-to-date, well-honed quality team skills result in the continuous improvement of employee decision making. This synergistic capability, in turn, enhances the continuous improvement of external and internal customer satisfaction. Consequently, quality decisions become the clinical service's most important customer product.

6.1.3 Understanding Opportunity Finding and Analytical Problem Solving

A clinical service should be capable of team-based finding of opportunities for improvement. Generally, these opportunities are of two types: symptomatic and asymptomatic.

Symptomatic opportunities for improvement are those problems due to dysfunctional managerial and operational processes or procedures. These activities become symptomatic when their objectively measured quality indicator data exceed threshold limits. Team-based skills in process and statistical analysis are important in identifying these out-of-control processes or procedures that need corrective action. Symptomatic opportunities need corrective action.

Asymptomatic opportunities are associated with processes or procedures that are not blatantly or overtly problematic. That is, these improvement-rich functions are *not* objectively evidenced by indicator data that exceed their threshold limits. However, upon close scrutiny of operational trends and customer reports, these activities still warrant some improvement through preventive action.

These "asymptomatic" processes or procedures are of such high priority that their improvement (although nothing appears "broken") will significantly enhance managerial or operational effectiveness and customer satisfaction and prevent impending failure. Team-based skills in anticipatory opportunity finding are important for detecting the need for preventive action.

Aided by synergistic group dynamics, a clinical service quality team can use various improvement processes to facilitate a consistent and logical approach to opportunity finding, decision making, and process improvement. Any improvement cycle or analytical process can be tailored to suit the individual clinical service and the improvement project at hand.

It is important to remember that it is not usually feasible to strive for absolutely perfect, error-free process performance. Usually, there is an optimal level of quality for which the clinical service can strive beyond, for which the cost of any further quality management is not feasible, and the cost of error is imperceptible

to the customer. The identification of process problems and opportunities for improvement through analytical skills is discussed in greater detail in Section 8, which addresses the Quality Improvement component of CQI.

6.2 Establishing Guidelines for Quality Teamwork Training

As a quality team, every clinical service is a learning organization. All team members should be continually learning through ongoing instruction and the practical solving of problems. Accomplishing this requires various team skills for which there is a need for scheduled training.

A specified team should be responsible for designing, training, and maintaining a team skills training curriculum and schedule. This training program should build and sustain the organization's ability to make decisions at the team level, no matter what size that team might be.

The curriculum should include the following basic concepts:

- individual and organizational values;
- behavioral awareness;
- conflict prevention and resolution;
- cooperation;
- negotiation;
- following;
- leadership;
- empowerment;
- process and problem analysis;
- alternative option finding and decision making;
- action skills;
- follow-up assessment; and
- organizational communication.

Table 5 describes such a curriculum.

Table 5. An Outline of a Basic Team Skill Training Curriculum for the Development of Quality Decision Making[6]

DESIRABLE SKILLS	SKILL CONTENT
Skills that meld individual values with group values:	How to identify individual and organizational values that are fundamentally important to form a cohesive team that can make good decisions
Skills that develop behavioral awareness:	How to understand the decision-making behavior of other individuals
	How to understand how we send and receive signals and interrelate with other people
	How to understand personality and interpersonal dynamics, including individual and organizational behavioral and decision-making traits
	How to develop interpersonal awareness skills using Jungian-based theory, e.g., the Myers Briggs Type Indicator (MBTI)[7] and Freudian-based theory, e.g., transactional analysis (TA)[8]
Conflict prevention and resolution skills:	How to be professional and not take team decisions personally
Cooperation skills:	How to form partnerships in the team environment
Negotiation skills:	How to reach a consensus
Membership skills:	How to share responsibilities and follow responsible leadership
Leadership skills:	How to achieve team motivation and commitment
Empowerment skills:	How to delegate authority and share power
Problem-opportunity identification and analysis skills:	How to determine strengths, weaknesses, opportunities, and threats
Alternative-finding and decision-making skills:	How to determine the best options for action
Action skills:	How to reach closure and achieve established goals and objectives
Assessment skills:	How to perform follow-up evaluation of quality improvement and improve the team building process
Communication skills:	How to most effectively communicate quality improvements and lessons learned

6.3 Establishing Guidelines for Assessing Quality Teamwork

This section provides guidance for assessing quality teamwork capability and determining the status of the clinical service members' team skills needed to make appropriate and timely decisions.

6.3.1 Assessing Clinical Service Teamwork Capability

The clinical service should assess the quality of clinical service team capability. This includes measuring the caliber of:

- employee morale;
- work attitude;
- commitment to quality;
- decision-making skills; and
- team-based process improvement.

This appraisal should address *all* clinical service employees, organization-wide, from the service's highest to lowest organizational levels.

How does a clinical service elicit and document the above-listed workforce team characteristics? The two easiest ways to achieve this assessment are to observe and ask. This information is obtained by "walking the walk and talking the talk"—an old managerial saying, which still remains very true in this high-tech and potentially low-touch working environment.

The supervisor, manager, and senior administration should regularly visit the clinical service's managerial and operational workforce to observe, ask questions, and document findings. This is not an effort to ferret out individual malfeasance or negligence. It is an effort to gauge organization-wide morale, work attitude, and other barriers to quality decision making.

Also, the clinical service should derive this information from:

- employee survey questionnaires;
- written employee comments;
- employee quality training records;
- employee job performance records; and
- quality improvement records, including timeliness of planning action achievements.

From this information, the clinical service can determine if its personnel are:

- capable of performing team-based quality management;
- skilled enough in their quality management tasks, as well as their operational clinical work, to cope with change; and/or

- supported with adequate resources.

The clinical service should obtain the above information as part of the Quality Report as is discussed in greater detail in Section 9.

6.3.2 Assessing the Status of Team Skills

The second element of team assessment is to regularly determine quality team skill needs. This assessment should point to managerial and operational resources required to optimize team decision making. Thus, the clinical service should ascertain and provide the necessary managerial and operational resource support needed to build and maintain employee morale, work attitude, commitment to quality teamwork, quality decision making, and process improvement—including the continued teaching of quality team skills and feedback of quality teamwork and improvement results.

6.3.2.1 Management's Responsibilities in Support of Quality Teamwork

One special aspect of this recurrent appraisal is assessing the caliber of the clinical service's managerial support of the service's employees and their quality teamwork.

How does a clinical service supervisor, manager, or administrator—especially a top executive—gauge the effectiveness of his or her own quality team involvement? Again, the simplest solution is to ask by obtaining candid, honest, documented employee opinion through regularly scheduled employee questionnaires and spontaneous employee comments—always guaranteeing employee anonymity. In addition, the service can gauge management's support for quality improvement by review of the managers' own quality training records and performance appraisals.

From this information, the clinical service can determine if its management is:

- philosophically ready to lead in times of change;
- trained and capable to identify any need for and to facilitate change; and
- trained and capable to participate in team-based quality improvement.

Managers should lead by example, using quality system-based, team-building principles in their daily work. Managers should delegate decision-making authority to as wide a range of personnel as possible, including those who are closest to the work and to the primary customer. As they delegate their authority throughout the organization, leaders must provide their employees with adequate quality management resources such as sufficient time, data processing, and clerical support.

The employee's role and needs in achieving CQI should be paramount to the clinical service's management. It is the responsibility of the clinical service leadership to ensure that all employees have sufficient education, training, quality management resources, and empowerment for the clinical service to achieve CQI.

Even when the clinical service employees are adept at the skills of team-based CQI, they may NOT readily participate if they perceive that the clinical service management:

- tells them to just take orders and not question authority;
- is not helping them to do their best job;
- denies them empowerment to make any improvements;

- does not listen to any employee suggestions for improvement;
- will not recognize or reward them for making improvements;
- practices favoritism;
- tolerates incompetence;
- is untruthful, that is, the leaders talk about practicing CQI but, in fact, are not really committed to putting it into practice; or
- is punitive, that is, when employees encounter a blatant problem versus an asymptomatic opportunity for improvement, they will solve the obvious problem to protect themselves first and resolve the less obvious, but nonetheless important, opportunity later—if ever.

6.3.2.2 Employees' Responsibilities in Support of Quality Teamwork

If afforded true empowerment, clinical service employees must recognize that they should take an active role in the CQI process. In a truly proactive environment, employees will much more likely be willing to take the initiative and work with each other to anticipate and solve quality process problems.

6.4 Reporting Quality Teamwork Activities

The clinical service should establish specific guidelines for the timely monitoring and assessment of the effectiveness of the Quality Teamwork program. Data and information derived from the Quality Teamwork program should be a part of the clinical service's Quality Report. These reports should include the various quality team activities, including team skills training. The Quality Report is discussed in greater detail in Section 9.

7 Quality Monitoring

The overall aim of Quality Monitoring (QM) is that the clinical service achieves an objective, evidence-based assessment of continuous improvement of customer satisfaction based on a set of measurable quality indicators. These indicators should characterize the most important managerial and operational path of workflow processes on a prioritized, cost-effective basis.

Quality Monitoring is supported by NCCLS document HS1—*A Quality Management System Model for Health Care* under QSE: Assessment as follows:

- Policy: to monitor and document achieved levels of quality as determined through systematic internal assessment and external peer review.
- Processes:
  - practice of a systematic internal assessment program based on the timely and regularly scheduled monitoring of quality indicators that measure the performance of highest priority managerial and operational path of workflow processes;
  - practice of an internal auditing program, based on standard criteria and training of auditors;
  - participation in an external peer review program;

- participation in an externally identified benchmark program, comparing the clinical service's performance to best practices recognized industry-wide; and

- submission of a report to the clinical service's executive management through the Quality Review component of CQI.

To achieve the QSE policy and processes prescribed above, the clinical service can develop a general approach to Quality Monitoring consisting of the five major internal and external assessment activities, including:

- establishing an internal quality indicator surveillance program;
- establishing an internal auditing program;
- establishing an external peer assessment program;
- establishing an external benchmarking program; and
- generating a report of Quality Monitoring activities.

7.1 Designating Quality Monitoring Teams

The clinical service should designate a specific Quality Monitoring team at the executive management level to conduct and coordinate the service's Quality Monitoring activities. The QM team members should include the service's executive management and key supervisors along with appropriate internal and external customer representatives. The service should designate other monitoring teams at appropriate managerial levels whenever necessary.

7.2 Establishing an Internal Quality Indicator Surveillance Program

As described in NCCLS document HS1—*A Quality Management System Model for Health Care*, internal quality indicator surveillance consists of:

- identifying the service's path of workflow; and
- selecting and monitoring quality indicators that measure the performance of the processes in that path of workflow.

7.2.1 Identifying the Path of Workflow

The clinical service should identify operational processes in its path of workflow that are key to meeting customer needs. The path of workflow includes three segments as follows:

- preservice segment (e.g., laboratory preanalytic activities);
- service segment (e.g., laboratory analytic activities); and
- postservice segment (e.g., laboratory postanalytic activities).

Table 6 directs readers of this guideline to the respective path of workflow identified for four major hospital clinical services.

Table 6. Path of Workflow for Four Major Hospital Clinical Services

Clinical Service	Path of Workflow as Depicted in NCCLS Guideline[a]
Laboratory Service	GP26—*Application of a Quality System Model for Laboratory Services*
Respiratory Service	HS4—*Application of a Quality System Model for Respiratory Services*
Medical Imaging Service	HS5—*Application of a Quality System Model for Medical Imaging Services*
Inpatient Medication Use	HS10—*Application of a Quality System Model for Inpatient Medication Use*

The above-named NCCLS guidelines describe paths of workflow that are generic to any size or scope of its respective clinical service, and should serve as useful models for the service's Quality Planning and Quality Teamwork programs that this document discusses.

7.2.2 Selecting Quality Indicators

Next, the clinical service should select indicators that measure the performance of processes in its path of workflow. Quality indicators are observations, statistics, or other data that typify and measure the performance of a process. It is important for the clinical service to ask, "What can be measured?" to determine if a process is functioning properly. Although NCCLS cannot require or recommend any particular set of indicators, examples of quality indicators for four clinical services are shown in Table 7.

Table 7. Examples of Quality Indicators for Four Major Hospital Clinical Services

Clinical Service	In NCCLS Guideline[a]
Laboratory Service	GP26—*Application of a Quality System Model for Laboratory Services*
Respiratory Service	HS4—*Application of a Quality System Model for Respiratory Services*
Medical Imaging Service	HS5—*Application of a Quality System Model for Medical Imaging Services*
Inpatient Medication Use	HS10—*Application of a Quality System Model for Inpatient Medication Use*

Both GP26 and HS10 include a form that shows how to design and monitor a quality indicator.

7.2.3 Monitoring Quality Indicators

The clinical service should set a schedule for the collection, analysis, and presentation of quality indicator data. The service should identify the team responsible for monitoring. The regular monitoring of indicators will determine if the process being measured is performing within acceptable limits. The team may record the indicators in many ways, such as:

- graphs in linear or block format;
- flow charts;
- cause-and-effect charts;
- check sheets; or
- computer programs.

Graphs are especially useful for identifying trends. See Section 8.4 under Quality Improvement for suggestions of other recording and analytical tools.

[a] For a complete description and the most current version of the documents mentioned in these tables, please contact the Executive Offices for a copy of the current NCCLS catalog. Telephone: 610.688.0100; Fax: 610.688.0700; E-mail: exoffice@nccls.org; Website: www.nccls.org

The service should compare its performance to predetermined thresholds and determine if any symptomatic or asymptomatic problems are present (see Section 8.1). This information may be important and trigger further investigation.

The team should keep a record of when, and by whom, the indicators are reviewed. The team should initiate appropriate action according to the outcome of the review, as follows:

- If the indicator is within defined limits, documenting the review is sufficient. An indicator may experience regular shifts while remaining within acceptable limits.

- When the indicator falls outside the defined limits, then corrective action is required.

7.3 Establishing an Internal Auditing Program

An audit is a planned, independent, and documented assessment to determine whether a clinical service is meeting agreed-upon requirements. To do this, a clinical service's internal auditing program reviews the service's quality management system and path of workflow processes on a predetermined schedule. The audit assesses whether the service has a quality management system in place and evaluates the service's ability to comply with its internal policies, processes, and procedures and with any external regulatory or contractual requirements. Auditors assess the intent, implementation, and effectiveness of the service's quality system by reviewing the quality system's documentation and comparing it to actual practice. The service submits formal reports of the results of the internal audits to executive management for their review and follow-up.[9,10]

Readers can refer to the wealth of literature available on quality auditing, selections of which are provided in this guideline.

7.4 Establishing an External Peer Assessment Program

In external assessment, representatives from a peer organization outside the clinical service assess the clinical service's conformance with a set of mandatory or voluntary process performance requirements and generate a report as to the number and type of nonconformances identified.

External assessments are often associated with the process of peer and regulatory review, including accreditation and licensure. Readers can refer to the wealth of literature available on external assessment, including that offered by JCAHO, CAP, AABB, FDA, and other accrediting and regulatory bodies.[b]

7.5 Establishing an External Benchmarking Program

Benchmarking—a particular form of external assessment—requires selecting managerial and operational activities of other clinical services that are alike or very similar in terms of operations and size and comparing characteristics and performance measurements. A clinical service could also benchmark to a nonclinical organization that provides a similar service. For example, the courier service for a laboratory outreach program might compare characteristics and performance measurements to a local or regional delivery service.

Characteristics might include the number of couriers, the frequency of scheduled pickups, and volume of transports handled. Performance measurements might include adherence to preestablished pickup times, accuracy of pickups and deliveries, and timeliness of complaint resolution.

[b] In the United States, peer organizations provide such review in support of regulatory mandate, e.g., Joint Commission on Accreditation of Healthcare Organizations (JCAHO), College of American Pathologists (CAP), and the American Association of Blood Banks (AABB).

Readers can refer to the wealth of literature available on benchmarking.[c]

7.6 Generating a Report of Quality Monitoring Activities

The clinical service should periodically compile and analyze the data and information derived from its Quality Monitoring program, covering all appropriate managerial and operational levels. The service should prepare this Quality Report at least annually; however, more frequent reports may be necessary to satisfy timeliness. Sources of these data and information should include the following:

- data and information from internal quality indicators;
- findings from internal quality audits;
- nonconformances identified in external peer assessments; and
- rankings and comparisons from benchmarking.

In addition, information derived from other QSEs should be included to provide a complete quality report. These might include:

- occurrence information, i.e., analysis, trends, and patterns (per QSE: Occurrence Management);
- customer service surveillance activities (per QSE: Customer Service and Satisfaction);
- input from the subject clinical service's staff, e.g., suggestion box (per QSE: Customer Service and Satisfaction); and
- information from other services' quality reports regarding the subject clinical service's performance.

The data, information, and analyses constituting the contents of the Quality Report should portray the status of all pertinent managerial activities and patient-related operations. Every major clinical service activity or managerial level should contribute to this report for subsequent follow-up by the clinical service through the Quality Improvement and Quality Review components of CQI. The objective of this reporting is to reveal the status of the clinical service's performance as measured against the service's established mission, vision, and quality improvement strategies, goals, objectives, and tasks.

Each respective service activity should forward the findings from this analysis to its appropriate oversight managerial level in a timely manner befitting whatever degree of urgency the findings warrant. Appendix A provides an example of a clinical service quality report.

8 Quality Improvement

The overall aim of Quality Improvement (QI) is that the clinical service proactively institutes continuous enrichment of customer satisfaction by finding the most important managerial and operational opportunities for process improvement. Such process enhancement is based on the timely, periodic, and systematic review of quality surveillance data and information with appropriate improvement of important processes and procedures of the highest priority.

[c] In the United States, benchmarking of clinical services is required by JCAHO as its "ORYX®" initiative.

Quality improvement data and information are available from the Quality Report generated by the Quality Monitoring program. The QI team uses this information to identify opportunities for process improvement, to prioritize the processes needing improvement, and to determine the improvement process necessary to resolve the problem at hand.

Compared to the more long-range, anticipatory approach of the Quality Planning program, Quality Improvement provides a more short-range, real-time fine-tuning of the clinical service's processes and strategic timeline. It is important that process improvement activities include the monitoring and improving of all twelve QSEs of the quality system.

Quality Improvement is supported by NCCLS document HS1—*A Quality Management System Model for Health Care* under QSE: Process Improvement as follows:

- Policy: to achieve continuous (i.e., timely, regularly scheduled) quality improvement of the most important (highest priority) managerial and operational processes.

- Processes:

  - utilization of a recognized mechanism for identifying and prioritizing opportunities for process improvement; and

  - utilization of a recognized mechanism for resolving a specific process problem.

8.1 General Approach to Quality Improvement

A general approach to Quality Improvement is to:

- identify and resolve any current problem in managerial or operational process performance as evidenced by objective quality indicator surveillance data that exceed their predetermined thresholds. This situation exemplifies a *symptomatic* quality problem that requires *corrective action*.

- identify and improve managerial or operational processes that require improvement to satisfy a prioritized customer need—even though there is no overt problem evidenced by objective quality indicator surveillance data. This situation exemplifies an *asymptomatic* quality problem that requires *preventive action*.

8.2 Designating Quality Improvement Teams

The clinical service should designate a specific Quality Improvement team at the executive management level to conduct and coordinate the service's QI activities. The team members should include the service's executive management and key supervisors along with appropriate internal and external customer representatives. The service should designate other quality improvement teams at appropriate managerial levels whenever necessary.[11]

8.3 Establishing a Quality Improvement Program

To achieve the QSE policy and processes prescribed above, the clinical service can develop a general program for Quality Improvement through the following approach:

- identifying processes with significant problems and prioritizing those opportunities for improvement (OFI);
- selecting the appropriate improvement process and action plan for resolving a specific OFI;
- gaining managerial approval and resources for the specific quality improvement action;

- implementing the specific quality improvement action; and
- measuring and reporting the quality improvement action outcome.

8.4 Identifying Processes with Significant Problems and Prioritizing Those Opportunities for Improvement

Various analytical tools can facilitate thorough, statistically based decision making for selecting and prioritizing problematic processes that require quality improvement. Examples of such tools include:

- process and workflow analysis;
- flow charts;
- cause-and-effect charts;
- Pareto charts;
- run charts;
- histograms;
- force field analysis;
- check sheets;
- control charts;
- scatter diagrams;
- pie charts; and
- stratification graphs.[6,11,12]

As described by Brassard, some of these analytical tools best facilitate *identification* of opportunities for improvement and some best facilitate *solution finding*, while some are equally useful for either decision-making process.[12]

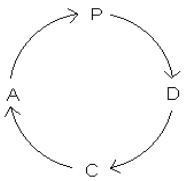
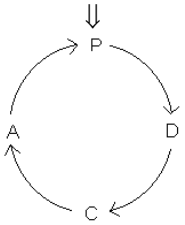
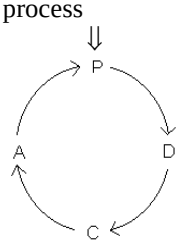
The clinical service should identify and prioritize its opportunities for improvement based on the information provided in the Quality Report. The QI team should prioritize each opportunity while considering the clinical service's quality objectives, as based on customer needs, the regulatory environment, and financial risk.

8.5 Selecting an Appropriate Improvement Process and Action Plan to Resolve a Specific OFI

A major decision in implementing an ongoing quality surveillance improvement program is selecting an appropriate improvement process. Table 8 presents various problem identification and solving formats that range from the very basic concepts of Shewhart's PDCA cycle to the more recent Six Sigma™, [d] approach.

[d] "Six Sigma" is a registered trademark and service mark of Motorola Inc.

Table 8. A Comparison of Alternative Improvement Processes[6]

Shewhart's PDCA Cycle[13]	JCAHO's Ten-Step Process[14]	Juran's Journey[5]	HCA's FOCUS-PDCA Process[14]	Joiner's Process[11]	ODI's F-A-D-E Process[14]	Six Sigma™ Process[15]
Plan	1-Responsibility 2-Scope 3-Important aspects 4-Indicators 5-Thresholds	Diagnostic phase: 1-Understand the symptom	1-Find an opportunity 2-Organize a team	1-Understand the process	1-Focus	1- Design
Do	6-Exercise and monitor the system	2-Theorize the cause	3-Clarify the process ⇓ 	2-Eliminate errors 3-Remove the slack to simplify the process	2-Analyze the process	2- Measure
Check	7-Evaluate	3-Test the theory	4-Understand causes for variation ⇓ 	4-Reduce the variation to establish control	3-Develop a plan for improvement	3- Assess
Act	8-Action 9-Assess 10-Communicate	Remedial phase: 1-Establish a remedy for improvement 2-Test the remedy 3-Establish controls	5-Select the process ⇓ 	5-Plan for continuous improvement	4-Execute	4- Improve 5- Control

NOTE: ⇓ This figure symbolizes merging a given step of HCA's FOCUS process with Shewhart's PDCA cycle.

Similarly, Appendix B provides an example of a Diagnostic Imaging Service's application of the Six Sigma™ process[16] for improving wait time.

Evaluation would include looking at staffing, the appointment-booking process, times required for patient preparation (changing into gown, etc.), time for performing procedures and postexamination time (changing back to street clothes and waiting for preliminary result). Studies reveal a lack of changing room space. The action is to request resources for more changing rooms; in the interim, extend the time for each appointment and divide the waiting area into those requiring/not requiring changing rooms. The assessment is a 30-day review of wait times.

8.5.1 Three Alternative Presentations of Opportunities for Process Improvement

Figures 4 and 5 diagram the improvement process, offering three alternative situations or scenarios by which process problems may present themselves.

- The "Stable Program" scenario depicts a quality improvement process that is revealing no new problems or opportunities for improvement at the moment. In support of this, there has been adequate indicator activity over the past 90 to 180 days that has resulted in improvement of either symptomatic or asymptomatic opportunities for improvement of some kind. Thus, the clinical service simply needs to continue the quality improvement process as designed.

- The "Symptomatic Problem" scenario depicts a quality improvement process that is revealing a problematic opportunity for improvement. The clinical service needs to react and resolve the blatant problem at hand, as evidenced by preestablished quality monitoring indicators, their thresholds, and related observation data. These QI elements demonstrate a managerial or operational process that is clearly out of control, but on the way to being resolved.

- The "Asymptomatic Problem" scenario depicts a quality improvement process that reveals a more anticipative than reactive situation. The monitoring data reveal no blatant process problems—according to preestablished surveillance indicators, their thresholds, and matching data, all processes *seem* to be in control. In fact, it is the Quality Improvement process that is the problem; it has not been sensitive enough to detect any opportunity for improvement over a reasonable period of time. Thus, the entire improvement program needs to be reassessed for effectiveness. In this case, the specificity of an indicator definition or threshold usually needs improvement. At times, it is even necessary to investigate the communicative interface between the five CQI components or scrutinize each of the CQI component programs for desired effectiveness.

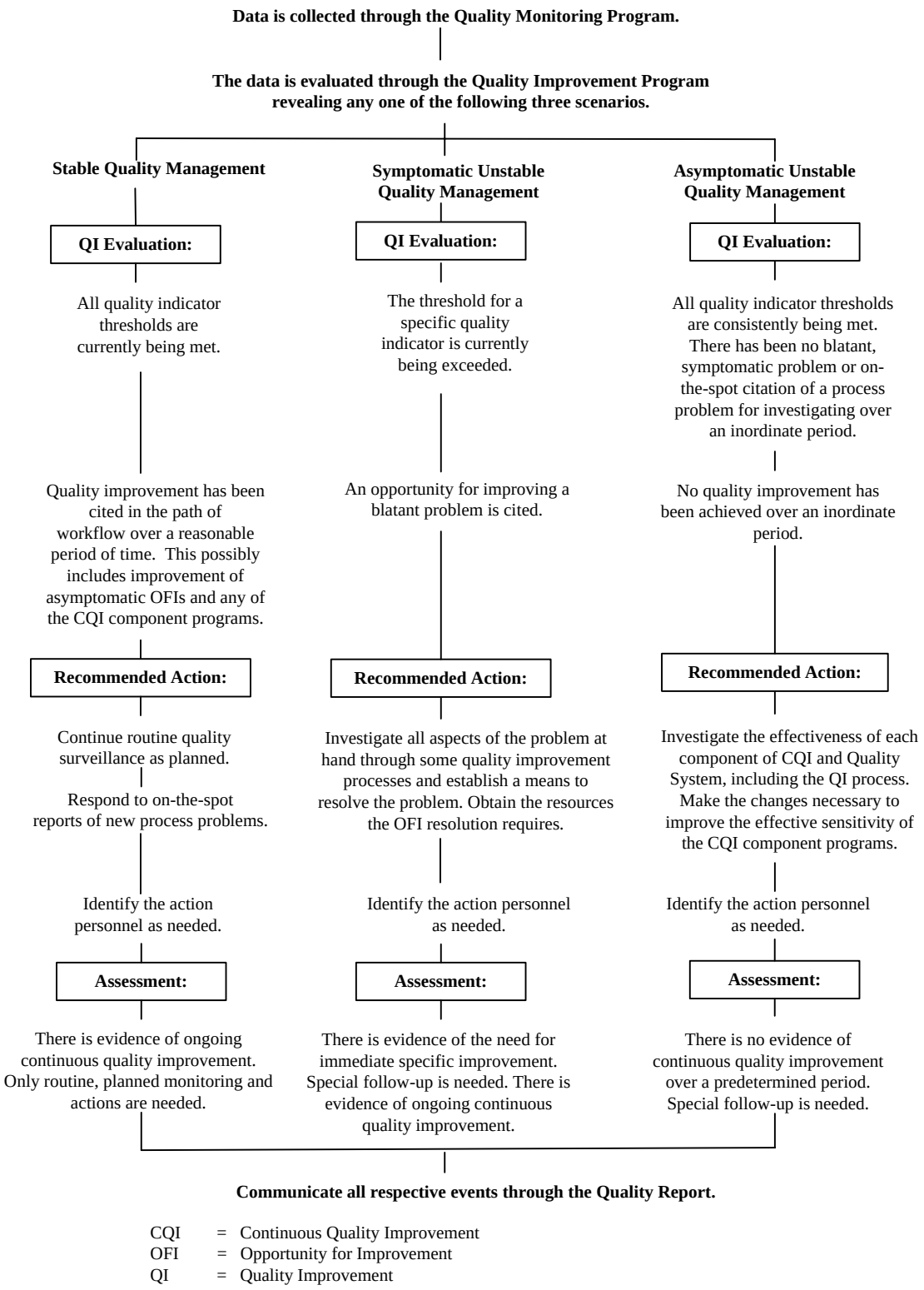


Figure 4. An Outline Showing How a QI Program Can Address the Three Quality Improvement Scenarios

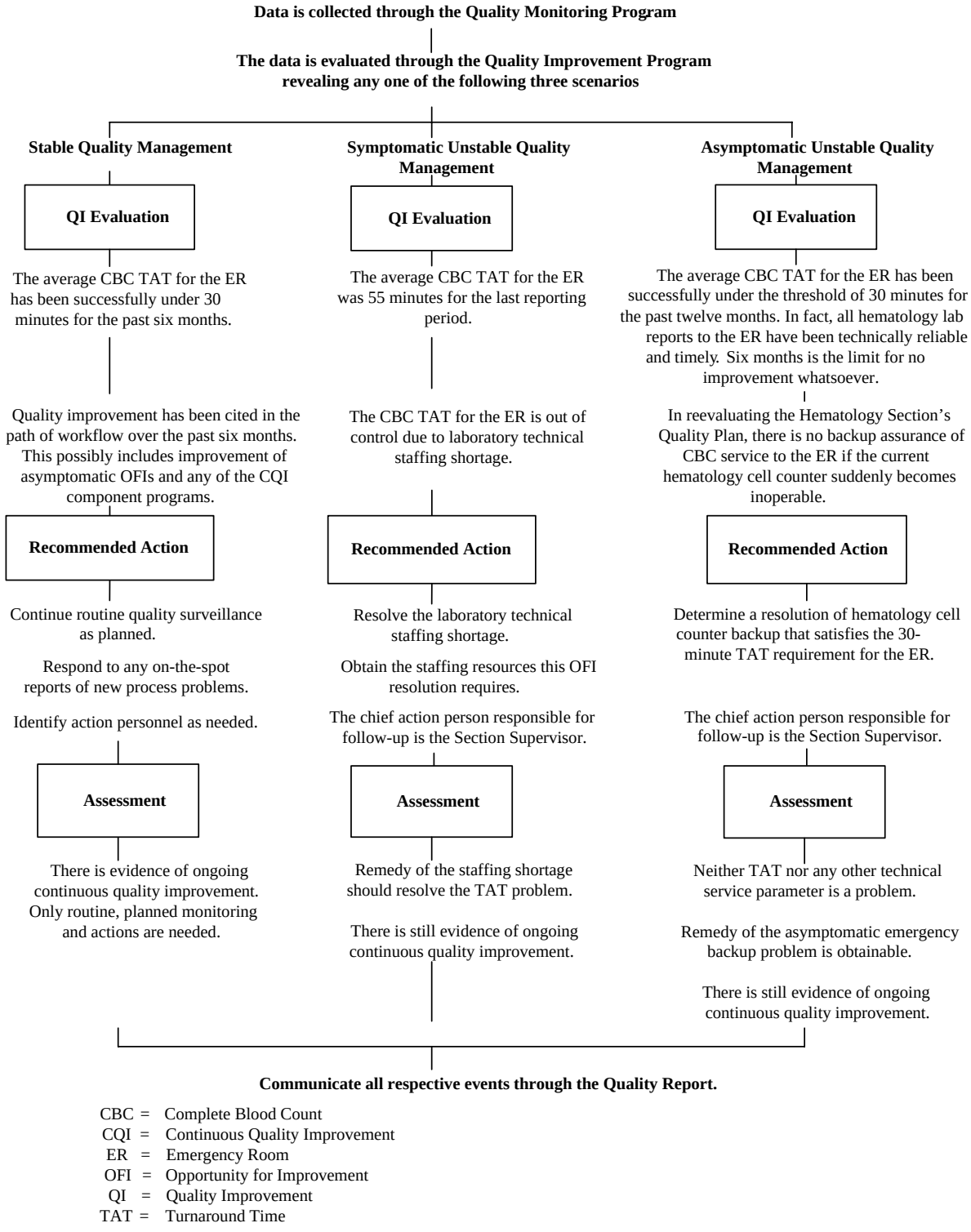


Figure 5. An Outline Showing How a Clinical Hematology Laboratory Section QI Program Can Address the Three Quality Improvement Scenarios Regarding Emergency Room Turnaround Time

8.6 Gaining Managerial Approval and Resources for the Specific Quality Improvement Action

After the clinical service has selected an improvement process, identified and prioritized a process problem, and selected a process improvement action, the involved service managerial level or operational section needs to gain managerial approval to proceed with the required action and expend the required resources before implementing the improvement action plan. The service needs to design a process by which this approval can be staffed in a timely fashion.

8.7 Implementing the Specific Quality Improvement Action Plan

Upon gaining managerial approval and resources, the clinical service can implement the Quality Improvement Action Plan. The scope of the change brought about by the implementation of the action plan will determine the implementation process. Minor changes can be implemented at the staff level and overseen by supervisors. Management need only confirm the implementation. A change of significant impact should use a project management approach to implementation, with a designated project manager. This will include a plan with milestones to monitor progress.[17]

8.8 Measuring and Reporting the Quality Improvement Action Outcome

The clinical service needs to follow the timelines, milestone completion dates, and outcomes of all Quality Improvement (QI) action plans. The service should analyze the results of that QI follow-up and determine appropriate responses.

9 Quality Review

The overall aim of the Quality Review (QR) program is that the clinical service effectively collects and conveys the important quality management data and information for improvement planning. Thus, the clinical service can monitor and support current, ongoing quality improvement activities and institute the next cycle of strategic planning for quality improvement. The QR program confirms the integrity of the organization's entire quality system and path of workflow through ongoing, periodic review of all managerial and operational information, appropriately considering all strategic plans, QSEs, resources, and quality improvement requirements.

Quality Review is supported by NCCLS document HS1—*A Quality Management System Model for Health Care* under QSE: Organization as follows:

- Policy: to embed quality throughout the organization.

- Process: the management review of the clinical service's quality system and its managerial and operational processes, facilitating the current and following cycle of quality planning for continuous quality improvement.

9.1 Designating Quality Review Teams

The clinical service should designate a specific Quality Review team at the executive management level to conduct and coordinate the service's quality review activities. The team members should include the service's executive management and key supervisors along with appropriate internal and external customer representatives. The service should designate other QR teams at appropriate managerial levels whenever necessary.

The participants in the review team will be the team leaders of the Quality Planning, Quality Teamwork, and Quality Improvement groups, together with supervisory and management staff. The composition of

the review team should serve to provide an objective look at the progress of ongoing process improvement activities. Sometimes, it may be necessary to assign priorities to process improvement activities, especially those that are resource intensive. A consensus decision process is preferable to a top down mandate. This can be achieved by bringing together representatives from all areas of the clinical service to consider the implications of resource distribution decisions.

9.2 Establishing a Quality Review Program

To achieve the prescribed QSE policy and process, establishing a Quality Review program consists of the following approach:

- reviewing the contents of the quality report;
- reviewing opportunities for improvement and improvement outcomes;
- providing guidance and marshalling resources for current, ongoing process improvement activities; and
- providing input to higher managerial level Quality Review and the strategic planning process.

The objectives of the review process are to ensure coordination of quality improvement activities, to highlight successes, and to identify opportunities for improvement and improvement outcomes.

9.3 Reviewing the Contents of the Quality Report

The clinical service should perform Quality Review (also known as Management Review) on a timely and regular schedule. Performed at least annually, ideally, it should be scheduled more frequently to ensure timely evaluation of quality data and information and up-to-date prioritization of needed improvements.

It is essential to have input from all members of the Quality Review team. The team should review the report for trends, patterns, and/or bias from the data collected. The report should show evidence of successes, opportunities for further improvements and any failures compared to the objective(s) of the program. The QR team should look for evidence of symptomatic and asymptomatic problems. The quality report should contain summary information from the CQI elements from the preceding period, including:

- Quality Planning;
- Quality Teamwork;
- Quality Monitoring; and
- Quality Improvement.

9.4 Reviewing Opportunities for Improvement and Improvement Outcomes

The quality report is used to recognize any event that may need further improvements or changes. In addition, it is used to establish in what order and urgency the events are to be addressed.

9.4.1 Prioritizing Opportunities for Improvement

The QR team should consider the following criteria for prioritizing opportunities for improvement:

- regulatory requirements (i.e., issues that compromise the service's licensure or accreditation);
- financial requirements (i.e., issues of cost of poor quality, such as waste, rework, and mistakes); and
- customer requirements (i.e., issues that cause the most customers the most problems).

9.4.2 Review of CQI Team Reports

Opportunities for improvement may exist in any of the five CQI components. For example:

- the planning process may be open to improvement based on past experience;
- teamwork may need to be the focus for improvement to ensure that the quality improvement process is producing the desired results; and
- the quality monitoring, quality review, and quality improvement processes may warrant similar attention.

It is important to note that the review at this level focuses on the process, not the actual functional activities of the quality programs. This review may result in a celebration of successes or a need to revisit one or more of the CQI processes.

9.5 Providing Guidance and Marshalling Resources for Current, Ongoing Process Improvement Activities

The Quality Review team should make recommendations to the clinical service's executive management that specify needs for quality management resources to solve the quality problems highlighted in the quality report.

Time is always at a premium for senior level management. Therefore, information being presented for Quality Review at the senior or executive level must be concise and clear. The results of the initial Quality Review should be concise, highlighting only the most important facts, including:

- review of quality goals and objectives set at the previous planning session;
- successful quality outcomes in the preceding period;
- any resource issues arising from ongoing quality improvement activities; and
- summary of a current SWOT analysis.

In the true sense of CQI, executive management should always give appropriate consideration to such recommendations and allocate the necessary resources on a prioritized schedule.

10 The CQI Cycle: Integrating the Five CQI Components with the Total Quality System

In any clinical service, the five CQI component programs should operate synchronously in a repeating cycle. Ideally, the cycle should start with Quality Planning and return to renewed Quality Planning. The cycle should renew itself in a timely fashion, depending on the managerial level involved and the process improvement project at hand.

To function effectively in this cyclic manner, all CQI components must interrelate, or interface, closely with one another. The institutional glue that holds these five CQI components together is organizational communication. The efficiency and effectiveness of how well the clinical service manages and facilitates this communication relies on the following service attributes:

- organizational structure;
- documents, forms and records management; and
- information management.

Every clinical service needs to establish its formal organizational structure. All levels and lines of authority and responsibility must be straightforward and clearly outlined. The service needs to appropriately design and clearly define all managerial and operational roles.

In every clinical service, organizational communication also relies on documents, forms, and records management and information management—regardless of the degree of the service's electronic sophistication. There is need for an up-to-date means of collecting and archiving relevant licensing, certifying, and accreditation requirements. There should also be a compilation of all organizational (e.g., parent hospital and laboratory) policies, plans, procedures, forms, reports, and other pertinent records that document compliance with all regulatory and peer-level requirements. Effective documentation of quality management activities can facilitate resolution of improvement opportunities and avoid the reoccurrence of resource-demanding problems. All documents and forms can be presented in a manual or a computerized, word-processed format. The clinical service's information management system should ensure that all customers who have a need to know receive appropriate quality management information in a timely fashion.

In this modern era of high capacity electronic information processing, the transmitting and archiving of organizational communication still remains the classic "Achilles heel" for every clinical service administration. The degree to which communication management activities are computerized varies from service to service. Regardless of the degree of computerization, the critical importance of these activities never varies. If the service's organizational communication management is efficient and effective, the five CQI components should function in a reasonably integrated and cyclic fashion.

11 Integrating the Five Key Quality System Components of CQI to Perpetuate the CQI Cycle

Ideally, CQI would be methodically implemented "from scratch" to ensure the best results. First, the Quality Planning program would be planned and implemented. Second, the Quality Teamwork program would be planned and instituted organization-wide. Then, the Quality Monitoring, Improvement, and Review programs would be established, sequentially. Finally, the rest of the clinical service's managerial and operational activities would be built on top of the administrative quality system infrastructure. Starting from the very beginning, this approach would ensure the most methodical, "do it right the first time" development of the quality management system in a CQI organization.

Of course, reality rarely matches the ideal, and the ideal is rarely practical. In most clinical services, essential operations and some form of quality surveillance are already established along with some forms of planning and team building. So, how can CQI be implemented and integrated under such dynamic, preexisting conditions?

The usual approach has been incremental in nature. There has to be some starting point, so often, managers ask, "Why not start with process surveillance?" The immediate importance of established technical processes to patient care, the service's process control experience, and the readily available database make this choice attractive.

Selection of operative resource indicators often follows next, since so much resource management data are already available. Then, outcome surveillance indicators develop, because of the added time needed to establish effective communication between the service and clinician. Selection of indicators for the overall effectiveness of quality improvement as well as the quality planning and quality teamwork programs occurs last—often, this level of quality surveillance and TQM is never achieved.

Even though the initial selection of process indicators for improvement management seems to be the logical first step toward attaining TQM and CQI, such an incremental approach is often a mistake. Instead, a combined, three-pronged campaign is advisable—with initial emphasis on organizational team actualization. A clinical service organization cannot effectively plan or monitor quality organizational performance unless it has first formed an effective team process.

One suggestion for implementing all five CQI programs in balanced, synchronized fashion is as follows. First, select a leader for each of the five programs. That person is to follow up all program implementation activities—not to micromanage but to delegate, empower, facilitate, and coordinate.

Rank the five CQI programs in order of precedence and sequence of implementation, using the following formula:

- Quality Planning first;
- Quality Team Building second;
- Quality Monitoring third;
- Quality Improvement fourth; and
- Quality Review fifth.

To do otherwise is to stray from building and sustaining the necessary infrastructure that must be in place before the next step. It is critical that an appropriate team culture is in place throughout the organization in order to implement the most effective planning, teamwork, monitoring, improvement, and review components of CQI.

Second, select an appropriately trained, multidisciplined implementing team, representing all major functional sections of the clinical service and other involved organizational activities.

Third, each team writes an implementation plan for its respective program, including the initial training curriculum and schedule and specifying which personnel are to be taught and the sequence of phasing or grouping. These plans should follow the general guidelines provided above for each respective CQI component program. Each plan should dovetail with the other four—the training schedules, in particular, should meld.

12 Summary

Clinical services tend to rely solely on incremental quality monitoring and improvement, focusing simply on the quick fix of overt problems. This is the shortsighted, problem-focused, reactive approach of old-fashioned quality assurance. This approach ignores strategically oriented quality planning; team-oriented decision making; and systematic quality monitoring, improvement, and review. Such a limited approach results in incremental and incomplete—rather than cyclic and complete—quality improvement. Solely relying on problem-focused quality improvement leads to disconnected, rather than truly continuous, systemic quality management.

Instead, the clinical service should design a CQI program that integrates the five QSE components, as described in this guideline. A quality systems approach contributes to much more effective customer satisfaction.

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Appendix A. Quality Report by QSE

QUALITY REPORT BY QSE

[Insert Work Section Name Here]

Date of Report: _____

Section Director Review:

_____
(signature and date)

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

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QSE – Process Control……..

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QSE – Assessments……

QSE – Process Improvement…….

QSE – Safety and Facilities…….

QSE – Customer Service and Satisfaction……..

Appendix A. (Continued)

Quality Report by QSE Summary

[Insert work section name here]

1. Summarize the QSE data for your work section using the sections outlined below.

2. Where needed for better comprehension, import charts, graphs, or tables into this document.

QSEs:

Organization

Staff Changes

- Number of new work section employees
- Number of new supervisors/assistant supervisors
- Number of new directors, assistant directors, or consultants
- Number of new supplemental employees
- Number of employees who transferred from the work unit
- Number of employees who left the organization
- Number of employees who retired
- Reorganization changes
- Organization chart changes

Personnel

Orientation of New Employees

- Employees who attended the hospital orientation this quarter
- Employees who attended the [insert clinical service name here] orientation this quarter

Training

- Number of new employees trained this quarter
- Number of all employees trained to new or revised procedures this quarter

Competency Assessments

- Number of competency assessments performed

Performance Appraisals

- Number of performance appraisals completed

Equipment

Number and type of new equipment validations performed

Names and types of any decommissioned equipment

Types of major repairs and maintenance issues, by equipment

Purchasing and Inventory

List by supplier any reagents or supplies that were damaged, not received, or received later than agreed to.

Changes in suppliers or products

Product recalls

Appendix A. (Continued)

Quality Report by QSE Summary (Continued)

Process Control
Names of new tests implemented
Description of significant process changes
Descriptions of validation performed
Description of test delays
Number of invalid test runs (QC failed)
Number of failed test runs (instrument malfunctions, etc.)

Documents and Records
Numbers of new or revised documents
Description of record review findings

Information Management
Numbers and types of data security violations
Description of any data corruptions
Describe unplanned computer downtime

Occurrence Management
Summary of reported occurrences (insert chart)

Assessments
Performance on quality indicators (insert charts)
Performance on proficiency testing
Results of comparability studies
Findings from internal audits
Deficiencies or nonconformances on external assessments, audits, or inspections
Findings from audit of computer-generated patient results

Process Improvement
Description and results of process improvement activities

Customer Service and Satisfaction
Type and number of customer surveys conducted
Numbers and types of customer complaints or comments
Results from any employee surveys
Tours conducted or guest visits

Facilities and Safety
Employee incidents or accidents
Patient incidents or accidents
Results of any safety audits
Other safety issues
Facility issues (remodeling, unplanned outages, etc.)

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

Appendix B. Application of the Six Sigma™ Process to Improving Diagnostic Imaging Service Wait Time. (Brassard M, Finn L, Ginn D, Ritter D. *The Six Sigma Memory Jogger™ II*. Salem, NH: Goal/QPC; 2002.)

Six Sigma™ Process	General Sections	Healthcare Example
Design	• Develop the charter.	• Develop the improvement team's charter (to reduce outpatient wait time for diagnostic imaging).
	• Map the process.	• Flowchart the current diagnostic imaging process.
	• Understand the voice of the customer.	• Survey and interview outpatients as to the aspects of outpatient imaging: - that they would wish to be improved - with which they are satisfied.
Measure	• Collect baseline data on defects & possible causes.	• Collect data on [for example…] - staffing at diagnostic imaging reception - appointment scheduling - patient preparation time - wait time before procedure performance - postexamination time to verification of image adequacy.
	• Plot defect data over time and analyze for special causes.	• Prepare a control chart of more than 25 documented wait times and analyze for outliers - sign-in to DI registration - registration to imaging.
	• Create and stratify frequency plots and do Pareto analysis.	• Prepare a frequency table and histogram from the collected wait time data and prepare Pareto analysis of the reasons for the outlier wait times.
	• Calculate process sigma.	• Calculate process sigma - 2 Sigma = 66% within control limits - 3 Sigma = 99.7% within control limits - 4 Sigma = 99.99% within control limits
	• Create detailed process maps.	• Flowchart all process activities from patient arrival to beginning of procedure including decisions to be made.
Analyze	• Develop a focused problem statement.	• Describe specifically what occurs, when or under what circumstances it occurs, and what functions/job titles are involved.
	• Explore potential causes.	• Use a cause-and-effect diagram and root cause analysis tools to identify potential causes.
	• Organize potential causes.	• Stratify causes.
	• Collect data.	• Collect more data to confirm root cause(s).
	• Use statistical methods to quantify a cause-and-effect relationship.	• Use additional quality tools to quantify wait time causes and effects on patients.

Appendix B. (Continued)

Six Sigma™ Process	General Sections	Healthcare Example
Improve	• Create possible solutions for root causes	• Use brainstorm and other idea-generating techniques to reduce outpatient wait times, e.g.: - increase changing room spaces - divide waiting area into those requiring and not requiring a changing room - increase DI receiving efficiency.
	• Select solutions	• Use voting and selection tools to narrow choices.
	• Develop plans	• Use project management tools to develop the implementation plan.
	• Pilot plans	• Try out the proposed solution for 30 days to see if it reduces wait times and collect data to determine "before and after."
	• Implement plans	• Broaden the pilot across the department; prepare staff and customers for the change.
	• Measure results	• Collect and analyze more data to verify that wait times have truly been reduced.
	• Evaluate benefits	• Project the economic impact of reduced wait times on diagnostic imaging revenues and expenses.
Control	• Develop and document standard practices	• Officially document the new process flowchart and procedures (instructions).
	• Train teams	• Train imaging department staff and assess competence in the new process and procedures.
	• Monitor performance	• Identify quality indicators and data collection and reporting methods.
	• Create a process for updating procedures	• Use an established document control process to archive old documents and implement new ones.
	• Summarize and communicate findings	• Deliver a report to hospital quality function about the results, success, and lessons learned from this improvement effort.
	• Recommend future plans	• Identify the next opportunity for improvement.

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

GP22-A2: *Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition*

General

1. I'm not sure why we need a separate document for this, why not weave GP22 into HS1? It is confusing to talk of quality improvement vs. quality management and five key quality system components vs. the twelve quality system essentials discussed in other documents.

- **HS1—*A Quality Management System Model for Healthcare* is intended to provide broad practical guidance for healthcare services that are interested in building quality into their organizations. It is meant to be an "umbrella" document that provides general recommendations for integrating the twelve quality system essentials (QSEs) of a quality management system into any healthcare service. As general guidance, HS1 presents a hierarchical model that defines successive stages of quality (i.e., quality control, quality assurance, quality management system, quality cost management, and total quality management). Each level in the hierarchy incorporates the attributes of all preceding levels below it.**

  As defined in GP22-A2, continuous quality improvement is an intermediary stage between the hierarchical levels of quality assurance and quality management system, integrating five of the 12 QSEs. GP22-A2 has been designed to provide in-depth detail in how to achieve continuous quality improvement by understanding the important interrelationships between those five QSEs, whereas HS1 is too broad a guideline to provide such detail.

Related NCCLS Publications*

C24-A2 **Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline—Second Edition (1999).** This guideline provides definitions of analytical intervals; plans for quality control procedures; and guidance for quality control applications.

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.

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

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.

HS1-A2 **A Quality Management System Model for Health Care; Approved Guideline—Second Edition (2004).** This document provides a model for providers of healthcare services that will assist with implementation and maintenance of effective quality systems.

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.

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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)

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