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Continuous Quality Improvement: Essential Management Approaches; Approved Guideline

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Continuous Quality Improvement: Essential Management Approaches; Approved Guideline

Abstract

Continuous Quality Improvement: Essential Management Approaches; Approved Guideline (NCCLS document GP22-A) is primarily intended for clinical laboratory directors, managers, and supervisory personnel in both the public and private sectors, from the bedside to large multidisciplinary testing facilities. The guideline defines continuous quality improvement (CQI) and explains how to implement important quality management approaches in any healthcare laboratory setting—including clinical pathology, anatomical pathology, public health, and any other laboratory activity. CQI promotes efficient and effective quality management of all laboratory operational functions. To achieve CQI, there is need for a total quality management (TQM) system of three synchronized programs, including a Team Management Program, a Plans Management Program, and an Improvement Management Program.

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Introduction to the NCCLS Quality Series

This document is one of a series designed for healthcare managers who wish to improve their programs through quality management activities. While three of the documents in this series and several examples apply to clinical laboratory testing, two others are applicable to most healthcare settings. These guidelines were developed independently, but can be used together as a complementary set of resources for facilities beginning to build their quality programs as well as those with mature programs.

A comprehensive program of quality improvement is described in NCCLS publication GP26— *A Quality System Model for Health Care*. This document assists any healthcare organization with the description and analysis of its path of workflow according to the essential elements of each step. A *quality system* builds upon the concepts of quality control and quality assurance to design quality into the organization's product or service. NCCLS document GP26 applies concepts of quality design that are consistent with those described in the ISO 9000 series of standards for quality management.

A well-structured quality system must be managed with a focus on *continuous quality improvement* (CQI) as measured by customer satisfaction. Such management skills are illustrated in NCCLS document GP22— *Continuous Quality Improvement: Essential Management Approaches*. This NCCLS guideline outlines the importance of the synergistic combination of team building, anticipative planning, and quality surveillance. The clinical laboratory is used as the operational model in this document, but its concepts can apply to any healthcare quality system.

NCCLS document C24— *Statistical Quality Control* provides basic statistical fundamentals for the first level of quality management— *quality control* (QC). These are documented procedures to address variation in the testing processes, with a focus on those processes that the laboratory can control. Quality control is fundamental to all aspects of any quality program, and many other NCCLS standards are designed to support a facility's quality control efforts.

An important part of quality management is *external quality assessment*, or proficiency testing (PT). Externally operated programs provide comparisons with other laboratories and with established quality goals. NCCLS document GP27— *Using Proficiency Testing to Improve the Clinical Laboratory* describes one external assessment method to identify and correct significant process variation. This guideline also shows how to fit the review into the laboratory's quality control system.

The NCCLS documents can be used to develop a quality system that could lead to compliance with the draft ISO 15189— *Quality Management in the Medical Laboratory*. This is a draft standard for quality systems in the clinical laboratory, consistent with other international standards such as the ISO 9000 series and ISO 17025 (formerly *ISO/IEC Guide 25*). The draft standard was developed by International Organization for Standardization Technical Committee 212 (ISO/TC 212), for which NCCLS holds the secretariat.

We trust that these documents will prove to be a useful set of tools for quality improvement. Your comments not only on the content of this document but also on its relationship to other NCCLS quality documents are welcome.

Foreword

There is continuous need for quality improvement in the healthcare laboratory. Practicing continuous quality improvement (CQI) systematically can maximize laboratory efficiency, effectiveness, and adaptability. These goals are especially important for three reasons.

(1) National and local governments and peer organizations continue to scrutinize quality management for licensing and certifying all healthcare laboratories of all sizes. These mandates spotlight the importance of team decision making, customer-oriented strategic planning, and ongoing monitoring and enhancement of laboratory testing outcome.

(2) The demands of managed health care compel laboratories to handle more volume with fewer resources. Still, quality must not suffer in this economic tug of war. These forces are continually changing laboratory organizational structures and customer-supplier relationships. Employing CQI softens the impact of these changes through better teamwork, anticipatory planning, and quality improvement.

(3) Changing trends in illness, medical practice, and demographics call for healthcare laboratories to adapt and meet new customer-supplier needs. Examples of these pattern shifts include the rising prominence of geriatric illness, domestic-social violence, substance abuse, new or re-emerging infectious diseases such as HIV/AIDS and tuberculosis, and alternative healthcare approaches. Responding to these changes requires anticipatory management approaches, often with relatively short timelines. With healthcare reform aimed at increasing patient access and cost effectiveness, there is even more interest in the support of preventive health care with earlier laboratory detection of disease. All of these trends demand a multidisciplinary, clinically-oriented, team-centered quality improvement effort as generated by the practice of CQI.

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

Key Words

Continuous quality improvement (CQI), improvement management, team management, total quality management (TQM), plans management

Continuous Quality Improvement: Essential Management Approaches; Approved Guideline

1 Introduction

This guideline provides basic definitions and management approaches to achieve laboratory continuous quality improvement (CQI) as measured by customer satisfaction. It includes a skeletal outline for tailoring total quality management (TQM) programs to facilitate team-focused decision making, anticipatory planning, and ongoing quality improvement. Using such management approaches, a laboratory of any size can be more effective and efficient despite increasing regulatory requirements, changing customer needs, and constraints in quality management resources. The intended audience for this guideline includes laboratory directors, managers, and supervisors. Readers are invited to utilize the accompanying references to learn about CQI in greater depth.

2 Scope

This guideline provides the user with definitions, concepts, and methods to achieve continuous laboratory improvement, using three interrelated quality management programs: team management, plans management, and improvement management. It includes written and graphic descriptions that clarify these general approaches.

3 Definitions

Action personnel, *n* – A fourth-level action planning element of plans management that identifies the personnel responsible for and having the authority and resources to lead or coordinate the implementation of a plan.

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

- **Philosophy, *n*** - The membership of an organization, including its leaders, is committed to strategic planning and teamwork that will result in ongoing quality improvement to satisfy customer needs. This philosophy includes not only resolving problems that need immediate attention,

but also seeking opportunities for improvement where no problems currently exist. In the latter case, improvement will minimize cost, waste, and injury; enhance resource and process management; and facilitate customer satisfaction in a preventive, anticipatory manner.

- **Process, *n*** - A systematic, total management approach that facilitates ongoing quality improvement as evidenced by enhanced customer satisfaction.

Customer-supplier concept, *n* - Every internal and external customer is simultaneously receiving and supplying some service or product to or from other individuals in the system. The patient is the ultimate *external* customer-supplier; the laboratory employee is the primary *internal* customer-supplier.

Goal, *n* - A first-level action planning element that delineates how to accomplish a specific strategy or policy.

Improvement Management Program, *n* - An ongoing quality assessment and improvement process that establishes the most important monitoring targets to ensure the organization's ability to provide optimal customer satisfaction.

Milestone, *n* - 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, *n* - An element of the organizational direction phase of plans management that delineates a broad strategy to meet the paramount current customer needs with the organizational resources of today.

Objective, *n* - A second-level action planning element that delineates how to accomplish a specific goal.

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

Related NCCLS Publications*

- EP14-P** **Evaluation of Matrix Effects; Proposed Guideline (1998).** This document provides guidance for evaluating the error or bias in analyte measurements that is due to the sample matrix (physiological or artificial) when two analytical methods are compared.
- GP2-A3** **Clinical Laboratory Technical Procedure Manuals—Third Edition; Approved Guideline (1996).** This document provides guidelines that address design, preparation, maintenance, and use of technical procedure manuals in the clinical laboratory.
- GP19-A** **Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline (1995).** This document identifies important factors that designers and laboratory managers should consider when developing new software-driven systems and selecting software user interfaces. Also included are simple rules to help prepare validation protocols for assessing the functionality and dependability of software.
- GP21-A** **Training Verification for Laboratory Personnel; Approved Guideline (1995).** This document provides background and recommends an infrastructure for developing a training verification program that meets quality/regulatory objectives.
- GP26-P** **Quality System Model for Healthcare; Proposed Guideline (1998).** This document provides a model for providers of healthcare services that will assist with implementation and maintenance of effective quality systems.
- GP27-A** **Using Proficiency Testing (PT) to Improve the Clinical Laboratory; Approved Guideline (1999).** This guideline provides assistance to laboratories in using proficiency testing as a quality improvement tool.
- NRSCL8-A** **Terminology and Definitions for Use in NCCLS Documents; Approved Standard (1998).** This document provides standard definitions for use in NCCLS standards and guidelines, and for submitting candidate reference methods and materials to the National Reference System for the Clinical Laboratory (NRSCL).

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