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

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

A guideline for global application developed through the NCCLS consensus process.
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Global Consensus Standardization for Health Technologies

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Abstract

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


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Foreword

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 Our historic perspective of quality control and quality assurance as defining quality needs to be superseded by a more global view of internationally accepted quality activities applied to a given scope of work.

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

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

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

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

<table>
<thead>
<tr>
<th>Stage</th>
<th>Activities Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Quality Management</td>
<td>Management approach centered on sustained high quality, by focusing on long-term success through customer satisfaction.</td>
</tr>
<tr>
<td>Quality Cost Management</td>
<td>Includes the stages below and also the economic aspects of the “cost of quality.”</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>Planned and systematic activities to provide confidence that an organization fulfills requirements for quality.</td>
</tr>
<tr>
<td>Quality Control</td>
<td>Operational process control techniques to fulfill requirements for quality and governmental compliance.</td>
</tr>
</tbody>
</table>

Using a scheme similar to Maslow’s hierarchy of personal needs, an organization can best obtain the next higher stage by mastering of the preceding one.
An integrated quality management system provides an opportunity to deliver consistent, high quality, and cost-effective health care in any healthcare organization. In healthcare service areas where governmental and accreditation compliance apply, a quality management system will simplify the process.

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

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

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

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

Overview of Changes

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

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

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

A Note on Terminology

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

Key Words

Quality, quality indicators, quality management system
A Quality Management System Model for Health Care; Approved Guideline—Second Edition

1 Scope

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

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

2 Introduction

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

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

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

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

3 Definitions

**Accident** – An undesirable or unfortunate happening that occurs unintentionally.

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