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GP26-A3
Vol. 24 No. 36
Replaces GP26-A2
Vol. 23 No. 3

Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition

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.

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

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NCCLS...

Global Consensus Standardization for Health Technologies

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Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition

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Abstract

NCCLS document GP26-A3—*Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition* expands on the laboratory-specific guidance presented in NCCLS document GP26-A2—*Application of a Quality System Model for Laboratory Services.* 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 governmental and accreditation requirements. In addition, information from a recently published international standard for medical laboratories has been included in this version. This document, when used with NCCLS document HS1—*A Quality Management System Model for Health Care*, can provide the means for a laboratory to implement a complete quality management system.

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Foreword

This document, GP26-A3, introduces the clinical laboratory's path of workflow—that is, the processes that transform a request for a clinical laboratory service (i.e., a laboratory that performs screening, diagnostic, or monitoring examinations for patient care) through obtaining and transporting the sample, performing the examination, interpreting the results, and providing the patient's laboratory examination report.

NCCLS document GP26-A3 is intended for use in conjunction with NCCLS document HS1—*A Quality Management System Model for Health Care*, when developing a quality management system for the clinical laboratory. Additional guidelines in the NCCLS Quality Series will also be a valuable resource for additional QSE- and clinical service-specific information.

Overview of Changes

The revisions in this version of the GP26 guideline are intended principally to include the concepts published in ISO 15189, *Medical laboratories—Particular requirements for quality and competence*.[1]

The document has been streamlined and a new "crosswalk" table has been introduced that correlates laboratory QSE information with its generic counterparts in HS1. Laboratory-specific forms and examples are also 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.

In order to align the usage of terminology in this document with that of ISO, the term *sample* has replaced the term s*pecimen* and the term *test* has replaced the term *examination.* The users of GP26-A3 should understand that the fundamental meanings of the terms are identical in many cases, and are defined in the guideline's Definitions section (see Section 3). The terms in this document are consistent with those defined in the ISO 15189 and ISO 9000 series of standards.

Key Words

Examination, path of workflow, postexamination, preexamination, processes

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Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition

1 Scope

This publication describes important activities in the path of workflow for laboratory services, including *in vitro* testing in clinical and anatomic pathology. Discipline-specific details are referenced in the Related NCCLS Publications section of this document.

This guideline is intended for use by laboratory directors, managers, supervisors, and the quality manager as a means to ensure that their laboratories have in place the policies, processes, procedures, activities, and records that support the activities described herein.

2 Introduction

This document describes the clinical laboratory's path of workflow—defined as the sequential processes in clinical laboratory activities that transform a physician's order into laboratory information. Each facility—whether large and complex, or of narrower scope such as physician's offices and point-of-care-programs— needs to understand how work flows through its particular laboratory so that processes can be designed and procedures documented that will build the required level of quality into laboratory work and reduce the potential for medical error that wastes resources and harms patients.

To establish a complete quality management system, policies, processes, and procedures for activities in the clinical laboratory's path of workflow need to be combined with policies, processes, and procedures for the Quality System Essentials (QSEs). Readers of this document are strongly encouraged to combine the activities described in both GP26-A3 and the most current version of NCCLS document HS1—*A Quality Management System Model for Health Care,* to ensure a complete infrastructure for quality management in the clinical laboratory.

This guideline presents information about the clinical laboratory's path of workflow and provides specific laboratory examples. Additional laboratory-specific information for the QSEs is also provided with relevant examples.

3 Definitions

Accreditation – Procedure by which an authoritative body gives formal recognition that an organization or person is competent to carry out specific tasks [modified from ISO/IEC 17000].[2]

Certification – Procedure by which a third party gives written assurance that a service conforms to specified requirements [modified from ISO/IEC 17000].[2]

Examination – Set of operations having the object of determining the value or characteristics of a property; **NOTES:** a) In some disciplines (e.g., microbiology), an examination is the total activity of a number of tests, observations, or measurements [ISO 15189 (3.3)][1]; b) In this document, the term "examination" replaces the term "test"; however, for the purposes of this guideline, readers can consider the terms equivalent.

Examination procedure – Set of operations, described specifically, used in the performance of examinations according to a given method [ISO 15198].[3]

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