

# POCTo7-A

## Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline

This document presents the core infrastructure for a standardized error tracking system with the primary goals of reducing risk and increasing quality of point-of-care testing, while accumulating standardized data for benchmarking use.

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A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Clinical and Laboratory Standards Institute  
950 West Valley Road, Suite 2500  
Wayne, PA 19087 USA  
P: +1.610.688.0100  
F: +1.610.688.0700  
[www.clsi.org](http://www.clsi.org)  
[standard@clsi.org](mailto:standard@clsi.org)

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## Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline

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Lou Ann Wyer, MS, MT(ASCP)  
Diane Burford, MT(ASCP) QPOCTE  
Ronda D. Elliott, ASQ, CQM  
Cheryl Hackett, MT(ASCP)  
Abdel-Baset Halim, PharmD, PhD, DABCC  
Ellis Jacobs, PhD, DABCC, FACB  
Kenneth C. Jensen, PhD

Valerie L. Ng, PhD, MD  
Wadid Sadek, PhD  
Halcyon St. Hill, EdD, MS, MT(ASCP)  
Megan E. Sawchuk, MT(ASCP)  
Kathy Scruggs, MT(ASCP)  
Sally Skrlin, MT(ASCP)  
Monica Thomas, MPA, MT(ASCP)

### Abstract

This document presents the core infrastructure for a risk management and standardized error tracking system for reducing risk at the point of care, as well as for benchmarking purposes. Clinical and Laboratory Standards Institute document POCT07-A—*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline* proposes a set of indicators for each analytical process for incorporation into a point-of-care quality program. It also presents the user with predefined common causes of error and respective error prevention mechanisms for a more standardized reporting mechanism. POCT07-A encourages institutions to define their own additional indicators based on industry risk management procedures presented in this document. An error tracking system can also offer possibilities for benchmarking and improvement of point-of-care processes.

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## Foreword

Point-of-care testing (POCT) is defined as performance of diagnostic testing occurring at or near the site of the patient.<sup>1</sup>

During the entire history of laboratory testing, there has always been concern about the reliability of results. The recognition for and implementation of quality management systems necessary for reliable and accurate laboratory results influenced the trend toward centralized, highly controlled clinical laboratories, where high-volume complex testing was reliable and cost effective. Lost in this trend was the ability to quickly and easily make medical decisions, a process previously possible with POCT because of few pre- or postexamination issues (eg, specimen transport, specimen accessioning and processing, laboratory result or information transfer from laboratory to ordering provider). The decision of whether to perform testing in central laboratories vs POCT was and remains a complex decision, with recognition that overall better patient outcome is the key factor for consideration.<sup>2</sup> Of note, there is a paucity of evidence supporting the current use of POCT and improved patient outcome.<sup>3</sup> Subsequent studies have demonstrated that performance of these tests, many of which continue to be performed as POCT, often do not adhere to manufacturers' recommendations.<sup>4</sup>

In the United States in the late 1980s, the perceived variable quality of laboratory results was of such public concern that regulatory processes were implemented to ensure minimum expectations and performance levels, regardless of where such testing occurred (the Clinical Laboratory Improvement Amendments of 1988, or CLIA '88).<sup>5</sup> At this time, laboratory tests commonly performed as POCT included dipstick urinalysis, fecal occult blood, urine pregnancy, whole blood glucose, and whole blood hemoglobin. Performance of these tests had minimal requirements—simply that of following the manufacturer's recommendations.

There has been and will continue to be an ever-increasing growth in the development of point-of-care tests for measurands not previously available in a POCT format. This growth is continuously fostered by new technological advances melding miniaturization, engineering, and laboratory testing (eg, nucleic acid microarrays, nanotechnology). Devices under development for clinical use may obviate the need for obtaining a specimen for testing (eg, indwelling sensors for blood gas determination; transcutaneous devices for glucose, bilirubin, or other chemical measurands). Regardless of these technological advances and whether the test is performed in the clinical laboratory or as POCT, the need for and adherence to quality systems continues to ensure accurate and reliable laboratory results for optimal patient care.

The rising costs of health care technology, changes in reimbursement, and resulting budget cuts have driven health care institutions to restructure, downsize, and further contain costs. A rising number of medical errors present newer financial and risk management challenges to health care quality. Although errors have not been pinpointed to laboratory or POCT services, the potential exists given their extensive diagnostic and assessment value. As POCT technologies continue to expand and diversify to newer applications, the increased access to testing and more comprehensive patient assessment at the point of care further contributes to the error potential. A standardized system of indicators is needed to classify, monitor, and track errors.

As part of a total quality systems approach suggested in CLSI documents GP22<sup>6</sup> and HS01,<sup>7</sup> each organization needs to have a process for detecting and documenting occurrences (nonconformities), or errors; classifying them for analysis; and correcting the problems they represent. As a general basis, this guideline starts with the "Occurrence Management" recommendations of such a total quality systems approach. However, a key difference is an emphasis on error indicators as opposed to quality indicators.

In the end, the value of having a standardized system for tracking or reporting errors is the standardized capture of data for dissemination, benchmarking, and error prevention. Data mining and access to information can provide ample possibilities for improvement to laboratory (or point-of-care) processes.

An error reporting system facilitates learning from errors while leading to improved safety; similarly, an error tracking system can help track performance and accountability.<sup>8</sup>

**Key Words**

Benchmarking, error indicators, error tracking, point of care, process improvement, quality indicators, quality management, standardization

SAMPLE

# Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline

## 1 Scope

This document provides a basic framework or infrastructure for a standardized risk management system. Error indicators for each analytical phase are suggested for incorporation into a quality management program. This guideline serves as a complementary tool to laboratory quality management procedures.

This guideline is intended for use by laboratory directors, managers, supervisors, quality managers, point-of-care coordinators (POCCs), and other testing personnel responsible for implementing the policies, processes, procedures, activities, and records that support the quality management activities described herein. Although it is understood that point-of-care testing (POCT) is performed in a variety of settings, the structure and contents of this document focus more on hospital-based programs. The information in this document can be applied to all POCT instruments and kits. However, some parameters may be relevant only to POCT in hospital or large institutional settings.

The goal of this guideline is to improve the performance of POCT by developing different indicators that are applicable to all aspects of preexamination, examination, and postexamination phases of the testing. This document highlights the critical components of a POCT quality management program, as well as defines the critical role that central laboratories should play in the coordination of POCT quality activities.

## 2 Introduction

The rising costs of health care technology, changes in reimbursement, and resulting budget cuts have forced institutions to restructure, downsize, or reorganize so efficiency is maximized. Regardless of institutional status, POCT may contribute to efficiency of care, because unlike its laboratory counterparts, it can provide results that are more rapidly available to the physician for fast assessment, diagnosis, and treatment. However, the training and competence of persons performing POCT are important influences of reliability of patient test results. This document is designed to assist POCT sites and personnel with the information required to address challenges and approaches to quality testing at the point of care by the implementation of quality management procedures and systematic approaches to reducing risk for errors.

### 2.1 Underestimation of Risk by End User

The increasing robustness and operation simplicity that characterizes most POCT systems used today can lead to the false perception that no risk or harm to the patient is possible if the devices are not used according to instructions. Therefore, as a result of underestimation of risk, deviations could result in inaccurate test results and may cause poor patient outcomes, unnecessary costs, adverse events, or death.

### 2.2 Point-of-Care Testing: Benefits and Challenges

The cost to perform a test by POCT may be much higher than the same test in the central laboratory, but the drive for hospitals to shorten patient stays and redirect care to outpatient settings to reduce costs, and the emergence of advanced technologies combined with new patient care models are increasing the demand for POCT. Also, the availability of POCT may enhance patient management under emergency situations. In general, POCT can offer the following benefits over central laboratory testing:

1. Access to test results in shorter time frames leads to earlier implementation of treatment decisions, which may result in better patient care.

2. Specimen transport time is eliminated or minimized, leading to faster testing after acquisition and fewer concerns related to sample stability, which can be critical for some tests (eg, blood gases, lactate).
3. POCT reduces the risk of preexamination errors that may accompany traditional laboratory testing, such as the handling, transport, and labeling of samples.
4. Sampling-related blood loss is decreased, an important feature in settings like the operating room or intensive care unit (ICU), where blood conservation is key, or in pediatric testing. Some analyzers used in central laboratories have test menus that require a minimum sample size, whereas most POCT devices use smaller samples.

Despite these benefits, POCT presents the following key challenges for hospitals:

1. Standardization of testing among the various testing locations and the central laboratory.
2. Information management; ability to link all POCT data from different testing locations to each other and to the central laboratory within a medical institution.
3. Documentation of tests performed at remote locations.
4. Logistics of training and competency verification of numerous testing personnel with a diverse variety of educational backgrounds.
5. Logistics of inventory management for numerous testing locations.
6. Preexamination techniques, such as proper specimen collection and handling.

Improperly addressing these challenges not only leads to loss of POCT benefits mentioned earlier but may contribute to a poor outcome on patient management.

Although some POCT responsibilities are often delegated to workers outside the laboratory, or the POCT program is under a separate license, the laboratory is most likely still responsible for oversight of POCT and the assurance for its compliance with regulations. Challenges may increase when POCT responsibility is delegated to nonlaboratory personnel, even in the presence of a POCC. Therefore, communication is essential to ensure that reported test results are consistent with the patient's clinical picture, especially as patients move between care delivery locations within the hospital, and laboratory testing is conducted in the laboratory as well as at the bedside.

### **3 Standard Precautions**

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all known infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard and universal precaution guidelines are available from the US Centers for Disease Control and Prevention.<sup>9</sup> For specific precautions for preventing the laboratory transmission of all known infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all known infectious disease, refer to CLSI document M29.<sup>10</sup>

### The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI document HS01—*A Quality Management System Model for Health Care*. The quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any health care service’s path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The QSEs are

- Documents and Records Organization Personnel
- Equipment Purchasing and Inventory Process Control
- Information Management Occurrence Management Assessments—External and Internal
- Process Improvement Customer Service Facilities and Safety

POCT07-A addresses the QSEs indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Documents and Records	Organization	Personnel	Equipment	Purchasing and Inventory	Process Control	Information Management	Occurrence Management	Assessments—External and Internal	Process Improvement	Customer Service	Facilities and Safety
X	X	X	X		X	X	X	X	X		X
HS01	HS01	HS01	HS01	HS01	GP32 HS01	HS01	GP32 HS01	HS01	HS01	HS01	GP17 HS01 M29
			POCT9	POCT9	POCT9			POCT9			

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care*.

## Related CLSI Reference Materials\*

- EP18-A2**      **Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition (2009).** This guideline describes risk management techniques that will aid in identifying, understanding, and managing sources of failure (potential failure modes) and help to ensure correct results. Although intended primarily for *in vitro* diagnostics, this document will also serve as a reference for clinical laboratory managers and supervisors who wish to learn about risk management techniques and processes.
- GP17-A2**      **Clinical Laboratory Safety; Approved Guideline—Second Edition (2004).** This document contains general recommendations for implementing a high-quality laboratory safety program. The framework is adaptable to any laboratory. (See related publication ISO 15190.)
- GP22-A2**      **Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition (2004).** 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.
- GP32-A**      **Management of Nonconforming Laboratory Events; Approved Guideline (2007).** This guideline provides an outline and the content for developing a program to manage a health care service's nonconforming events that is based on the principles of quality management and patient safety.
- HS01-A2**      **A Quality Management System Model for Health Care; Approved Guideline—Second Edition (2004).** This document provides a model for providers of health care services that will assist with implementation and maintenance of effective quality management systems.
- K2Q**      **The Key to Quality (2007).** A high-quality, specialty portfolio, with tabs for quick references, showcases the implementation of all 12 Quality System Essentials (QSEs). This comprehensive portfolio includes Essentials, Examples, Flow Charts, Cross-References, Evaluations, and a CD-ROM. Based on the widely used Quality Management Systems documents HS01-A2, GP02-A5, GP21-A3, and the electronic toolkits; GP26-A3; and ISO 15189.
- M29-A3**      **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.
- POCT09-A**      **Selection Criteria for Point-of-Care Testing Devices; Approved Guideline (2010).** This document provides guidance on selection of point-of-care testing devices based on the patient care setting and clinical needs. It is designed as an aid to laboratory and facility management to simplify and facilitate the selection process, but also allows evaluation of devices to identify those that are optimal to the patient care setting and population served.

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P: 610.688.0100 Toll Free (US): 877.447.1888 F: 610.688.0700

E: [customerservice@clsi.org](mailto:customerservice@clsi.org) [www.clsi.org](http://www.clsi.org)

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