CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

CLSI POCT07-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.

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

POCT07-A
Vol. 30 No. 20
ISBN 1-56238-734-0 Replaces POCT07-P
ISSN 0273-3099 Vol. 29 No. 18

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

Volume 30 Number 20

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.

Clinical and Laboratory Standards Institute (CLSI). *Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*. CLSI document POCT07-A (ISBN 1-56238-734-0). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2010.

Suggested Citation

CLSI. *Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline.* CLSI document POCT07-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

Previous Edition:
August 2009

Reaffirmed:
January 2018

Archived:
May 2025

ISBN 1-56238-734-0
ISSN 0273-3099

Contents

Foreword

Point-of-care testing (POCT) is defined as performance of diagnostic testing occurring at or near the site of the patient.[1]

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.[2] Of note, there is a paucity of evidence supporting the current use of POCT and improved patient outcome.[3] 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.[4]

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).[5] 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[6] and HS01,[7] 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.[8]

Key Words

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

4 Terminology

4.1 A Note on Terminology

CLSI, 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. CLSI 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 CLSI, International Organization for Standardization (ISO), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI's consensus process for development and revision of standards and guidelines focuses on harmonization of terms to facilitate the global application of standards and guidelines.

In POCT07-A, the terms *analyte* and *uncertainty* were aligned with that of the global community. The term examination replaced the term analysis. In addition, the term *analytical measurement range* was inserted parenthetically with the term *measuring interval.*

4.2 Definitions

analyte – component represented in the name of a measurable quantity (ISO 17511)[11]; see the definition for **measurand.**

blood glucose meter – component of a blood-glucose monitoring system that converts the result of a chemical reaction into the glucose concentration of the sample (ISO 15197).[12]

cartridge – one type of unit-use device containing the components necessary to perform a test, including sensors, reagents, and calibration materials. A cartridge typically requires a meter to read signals and report results.

central laboratory – for this document, a term chosen to conceptualize what is meant by the *central, core,* or *main clinical laboratory setting* to differentiate it from the *point-of-care setting;* **NOTE:** See **clinical laboratory.**

clinical laboratory – laboratory for the biological, microbiological, immunological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation, including the interpretation of results and advice on further appropriate investigation (ISO 15189)[13]; **NOTE 1:** These examinations also include procedures for determining, measuring, or otherwise describing the presence or absence of various substances or microorganisms. Facilities that only collect or prepare specimens, or act as a mailing or distribution center, are not considered to be medical or clinical laboratories, although they may be part of a larger laboratory network or system (ISO 15189)[13]; **NOTE 2:** Outside the United States, the term *medical laboratory* is used.

coagulation meter – device to assess the clotting time.

component – raw material, substance, piece, part, software, firmware, labeling, or assembly that is intended to be included as part of the finished, packaged, and labeled IVD medical device (ISO 18113-1).[14]

corrective action – action to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000)[15]; **NOTE 1:** There can be more than one cause for a nonconformity; **NOTE 2:** Corrective action is taken to prevent recurrence, whereas preventive action is taken to prevent occurrence; **NOTE 3:** There is a distinction between correction and corrective action; a correction removes a nonconformity, whereas a corrective action removes the cause of the nonconformity (ISO 9000).[15]

critical control point – a point or step in an analytical procedure that is susceptible to an error; **NOTE:** With the implementation of the right quality control, an error can be mitigated to an acceptable level.

critical failure – a failure that can initiate a hazard.

critical limit – a criterion that separates acceptability from unacceptability.

customer – organization or person who receives a product or service (revised from ISO 9000)[15]; **NOTE:** For POCT, the patient would be considered a customer, and the doctor, POCT operator, and so on may be regarded as internal customers (revised from ISO 9000).[15]

device – a measuring system that gives analytical answers as a result of electrical or mechanical measurements on an element, compound, solution, etc.; **NOTE:** In POCT, the term represents a range of diagnostic systems that may include, but are not limited to, small portable or semiportable systems, benchtop analyzers, handheld devices, cassettes, and single-use test kits having built-in readers as part of the consumable.

dry chemistry analysis – analysis that uses a test strip or reaction cartridge with no liquid reagent requirement and no liquid waste.

electronic medical record – a computerized patient medical history; **NOTE:** Hospitals are converting older paper copies of records with handwritten physician and nursing notes to computerized records that can store and transfer data in a standardized fashion.

environmental factors – conditions that may affect the analysis that include, but are not limited to, temperature, airflow, humidity, vibration, and altitude.

error – see **occurrence.**

examination – set of operations having the object of determining the value or characteristics of a property (ISO 15189)[13]; **NOTE:** *Examination* has replaced terms such as *test*, *assay*, and *analysis* in this document. Subsequently, the adjectives *preexamination* and *postexamination* have replaced the adjectives *preanalytical* and *postanalytical.*

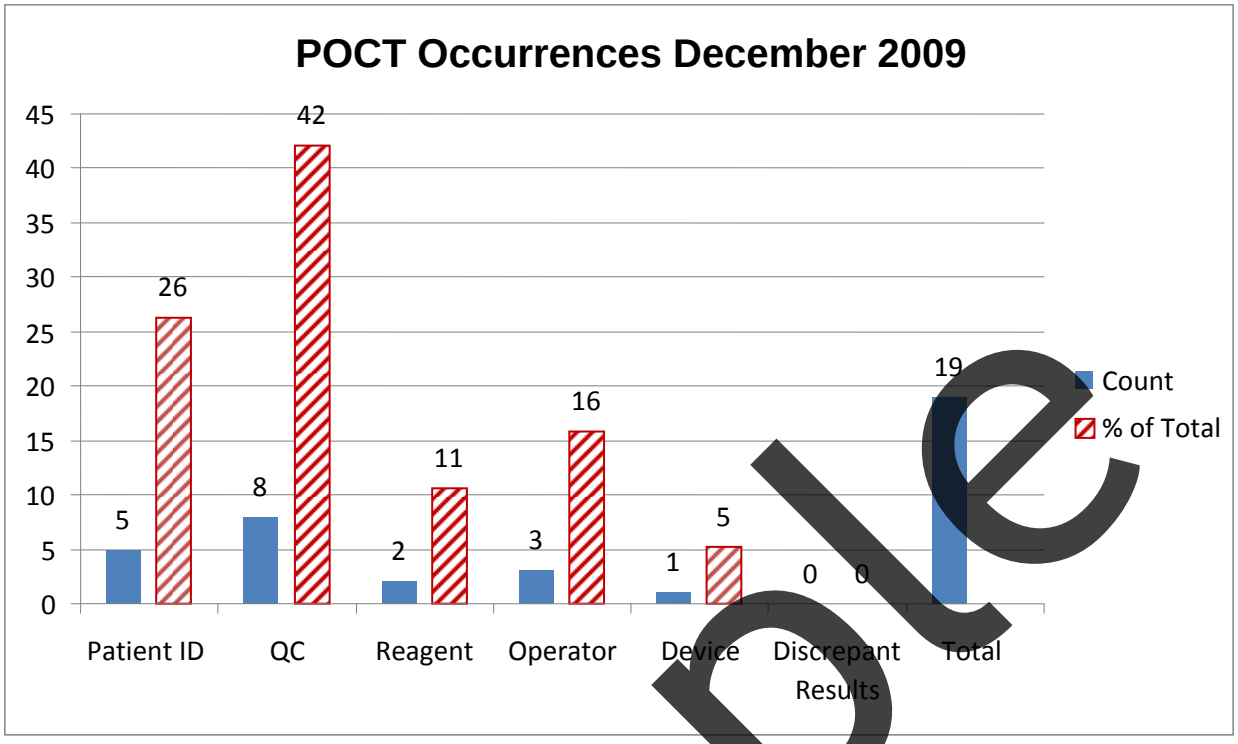
failure – in the broadest sense, a case when the system does not meet the user's expectation; **NOTE:** Errors of measurement and errors of use are subsets of failures.

failure mode – manner by which a failure is observed; generally describes the way the failure occurs and its impact on equipment operation.[16]

failure mode and effects analysis (FMEA) – systematic review of an instrument system or process that examines how failures can affect the instrument system or process, the test results, or the testing personnel; **NOTE:** See CLSI document EP18 for further information.[17]

failure reporting, analysis, and corrective action system (**FRACAS)** – a process whereby a system is tested, and failures are observed and classified by severity and frequency of occurrence; **NOTE 1:** The

Appendix C. (Continued)



The collection of information over time can be helpful to the POCC to identify the frequency of NCEs and establish prevention techniques and strategies to reduce the number of errors in each category. Ideally, one would start to work on the category of NCEs that has the highest frequency.

This chart provides for a visual display of the numbers of NCEs as compared to the total number of errors. This is called a Pareto chart. This example demonstrates the frequency of the types of patient identification errors. The wrong identification number was more frequently observed than the other sources of error. This information points to the areas that require more focused attention for performance improvement processes. For a more thorough in-depth investigation of NCEs, refer to CLSI document EP18.[1]

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

ISBN 1-56238-734-0

CLSI POCT07-A