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2nd Edition

EP23™

Laboratory Quality Control Based on Risk Management

This guideline provides recommendations based on risk management for laboratories to develop quality control plans tailored to the combination of measuring system, laboratory setting, and clinical application of the test.

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

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Abstract

Clinical and Laboratory Standards Institute guideline EP23—*Laboratory Quality Control Based on Risk Management* provides recommendations based on risk management for laboratories to develop quality control plans (QCPs) tailored to the combination of measuring system, laboratory setting, and clinical application of the test. Regulatory requirements, information provided by the developer, information pertaining to the laboratory environment, and medical requirements for the test results are evaluated, using risk-management principles, to develop a QCP tailored to the combination of measuring system, laboratory environment, and clinical application. The effectiveness of the laboratory QCP is monitored to detect trends, identify corrective actions, and provide continual quality improvement opportunities. The advantages and limitations of various QC processes are discussed.

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Foreword

This guideline presumes that the type of measuring system, testing personnel, and location where the test will be performed were all considered before the measuring system was selected. Although the developer is responsible for design quality of its measuring system and reagents, the laboratory and, ultimately, the laboratory director are accountable for the quality of test results. To establish effective QC, laboratories should gather and analyze an array of information (regulatory and accreditation requirements, developer-provided information, the laboratory's environment, and the medical applications of tests performed) through a risk-assessment (RA) process. This process identifies potential weaknesses in the measuring system and test environment that are weighed against the probability for error, the effectiveness of control processes built into the measuring system, and the laboratory's assessment of risk when the clinical use of a laboratory result is considered. This guideline provides recommendations to laboratories for establishing a quality control plan (QCP). Once developed, the QCP is monitored for effectiveness. It is modified when a laboratory process or procedure is revised per regulatory or accreditation requirements and when unanticipated failure modes or underestimated risks of error are discovered. When sufficient objective data demonstrate reliable performance, some control procedures might no longer be needed. The advantages and limitations of a variety of QC measures are discussed to help the laboratory develop a QCP that is appropriate for its measuring system and clinical environment.

This guideline supports the development of an individualized quality control plan (IQCP) under Clinical Laboratory Improvement Amendments requirements¹ and provides guidance for implementing risk management. Compliance with EP23 might not satisfy the requirements of all regulatory, accreditation, or certification organizations. Laboratories need to comply with all applicable regulatory and accreditation requirements when developing QCPs.

Overview of Changes

This guideline replaces the previous edition of the approved guideline, EP23-A, published in 2011. Several changes were made in this edition, including:

- Aligning EP23 with international standards^{2,3} and an ICCP
- Incorporating detectability in the RA
- Replacing the hypothetical “glucose concentration measurement on an automated measuring system” example with a real-world example of a QCP for a noninstrumented single-use device, instrumented single-use device, and exempt microbiological media

NOTE: The content of this guideline is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

analyte

individualized quality control
plan

measurand

quality assessment

quality control

quality control plan

risk assessment

risk management

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Chapter ①

Introduction

Laboratory Quality Control Based on Risk Management

1 Introduction

1.1 Scope

This guideline is intended for global use in laboratories to help determine QC procedures that are appropriate and effective for the test being performed. Developers will also find it useful for understanding laboratory QC requirements and how they will be assessed. The use of risk management is broadly applicable to all processes in the laboratory and can be used beyond the focus of QC. This guideline describes good laboratory practice for developing and maintaining a quality control plan (QCP) for medical laboratory testing using internationally recognized risk-management principles. An individual QCP should be established, maintained, and modified as needed for each measuring system. The QCP is based on the performance required for the intended medical application of the test results. Risk mitigation information obtained from the developer and identified by the laboratory, applicable regulatory and accreditation requirements, and the individual health care and laboratory setting are considered in the development of a QCP.

This guideline supports the development of an individualized quality control plan (IQCP) under Clinical Laboratory Improvement Amendments requirements¹ and provides guidance for implementing risk management. This guideline might not satisfy the requirements of all regulatory, accreditation, or certification organizations. Laboratories need to comply with all applicable requirements when developing QCPs.

1.2 Background

Regular performance of intralaboratory QC has been invaluable in ensuring that measuring systems are performing as expected. Existing highly reliable measuring systems, however, demonstrated that conventional intralaboratory QC practices were seemingly excessive (eg, exempt microbiology media, automated systems for microbiology organism identification, or antimicrobial susceptibility testing). The evolution and availability of unit-use test devices (eg, single-use device and/or cassette that contains reagent necessary for performing one test), some with an accompanying measuring system containing integrated controls, measuring system function checks, and/or electronic system and calibration checks additionally identified the need for a different QC process; by design, these unit-use devices did not permit simultaneous testing of intralaboratory control(s) and a patient sample. A risk-assessment (RA) approach incorporates the unique features and performance of each of these measuring systems in individual laboratories, formulated into IQCPs, with the original goal of conventional QC (ie, ensuring reliable and accurate results).

1.3 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 bloodborne pathogens. Published guidelines are available that discuss the daily operations of diagnostic medicine in humans and animals while encouraging a culture of safety in the laboratory.⁴ 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 diseases, refer to CLSI document M29.⁵