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EP23-A™

Laboratory Quality Control Based on Risk Management; Approved Guideline

This document provides guidance based on risk management for laboratories to develop quality control plans tailored to the particular 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 document EP23-A—*Laboratory Quality Control Based on Risk Management; Approved Guideline* provides guidance to laboratories on the development of quality control plans for measuring systems. Regulatory requirements, information provided by the manufacturer, information pertaining to the laboratory environment, and medical requirements for the test results are evaluated, using risk management principles, to develop a quality control plan tailored to the particular combination of measuring system, laboratory environment, and clinical application. The effectiveness of the laboratory quality control plan is monitored to detect trends, identify corrective actions, and provide continuous quality improvement. The advantages and limitations of various quality control processes are considered.

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Foreword

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Although the manufacturer is responsible for quality in design of its measuring system and reagents, the laboratory and, ultimately, the laboratory director are accountable for the quality of test results. **To establish effective quality control (QC), laboratories should process an array of information** (regulatory requirements, manufacturer-provided information, the laboratory’s environment, and the medical applications of tests performed) through a risk assessment process.

This process identifies potential weaknesses in the measuring system and 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 in consideration of the clinical use of a laboratory result. This document provides guidance to laboratories for establishing a quality control plan (QCP). Once developed, the QCP is monitored for effectiveness and modified as unanticipated failure modes or underestimated risks of error are discovered or as particular control procedures are no longer required once sufficient objective data demonstrating reliable performance have been established. The advantages and limitations of a variety of QC measures are discussed to help the laboratory develop a QCP that is appropriate for its particular measuring system, laboratory, and clinical environment.

Compliance with EP23 may not satisfy the requirements of all regulatory, accreditation, or certification bodies. Laboratories need to comply with all applicable requirements in the development of their QCPs.

KEY WORDS

Quality Control
 Risk Assessment
 Risk Management

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Chapter 1

Introduction

In this document, you will learn how to **create a quality control plan (QCP) that is customized for your institution, facility, and laboratory**, so that you can **run your tests in an effective and efficient manner**, improving patient care.

You will learn:

- ▶ How to compile information into a QCP
- ▶ The many types of tools in the QC toolbox, and which are most effective for your situation
- ▶ How to detect potential errors
- ▶ How to determine if potential errors can cause harm
- ▶ How to help prevent errors from occurring
- ▶ How to ensure your QCP is effective



Laboratory Quality Control Based on Risk Management; Approved Guideline

1 Scope

NOTE:

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This document may not satisfy the requirements of all regulatory, accreditation, or certification bodies.

LABORATORIES NEED TO COMPLY WITH ALL APPLICABLE REQUIREMENTS

in the development of their QCPs.

This document describes good laboratory practice for developing and maintaining a 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 manufacturer and identified by the laboratory, applicable regulatory and accreditation requirements, and the individual health care and laboratory setting are considered in development of the QCP. This document is intended to guide laboratories in determining QC procedures that are both appropriate and effective for the test being performed.

This document may not satisfy the requirements of all regulatory, accreditation, or certification bodies. Laboratories need to comply with all applicable requirements in the development of their QCPs.

2 Introduction

2.1 Quality Control Plan

Health care providers need test results that are relevant, accurate, and reliable for patient care. A number of factors can adversely affect the quality of test results and present a risk of harm to the patient, from failures of the measuring system, to operator errors, to environmental conditions. Failure is used in this document in the context of risk management and means, in the broadest sense, a case when the system does not meet the user's expectation. Failure includes the inability of a measurement process to perform its intended functions satisfactorily or within specified performance limits, errors of a measuring system that may produce an incorrect result, and incorrect use of a measuring system that may cause an incorrect result. Risk management is the systematic application of management policies, procedures, and practices to the tasks