



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 systems, laboratory setting, and class of application of the tests.

A guideline for guidelines developed through the CLSI® and laboratory standards committee process

Ep23 A Laboratory Quality Control Based On Risk 339132

George S. Cembrowski, R. Neill Carey



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Laboratory Quality Control Based on Risk Management: Approved Guideline James H Nichols, Jr, 2011-10-01

Quality Control in the Age of Risk Management, an Issue of Clinics in Laboratory Medicine James O.

Westgard, Sten Westgard, 2013-01-28 In October of 2011 CLSI published a new guideline EP23A on Laboratory Quality Control Based on Risk Management In March 2012 CMS announced its intention to incorporate key concepts from EP23A into its Interpretative Guidelines and QC policy for Individualized Quality Control Plans Thus begins a new era of Quality Control in the Age of Risk Management This issue is intended to help laboratories with the transition between traditional QC practices and the new risk management approach Laboratories face a steep learning curve to apply risk analysis for identifying and prioritizing failure modes developing and implementing control mechanisms to detect those failure modes and assessing the acceptability of the residual risks that exist after implementation of a QC Plan One of the main benefits of the new risk analysis based QC Plans should be an integration of all the control mechanisms that are needed to monitor the total testing process including pre analytic analytic and post analytic controls One of the main risks of the new approach is an expectation that Statistical QC is no longer important even though SQC still remains the most useful and flexible approach for monitoring the quality of the analytic process The key to the future is the successful integration of all these control mechanisms to provide a cost effective quality system that monitors all phases of the total testing process This issue should help laboratories understand the evolution of QC practices to include risk management but also to recognize the need to maintain traditional techniques such as Statistical QC especially during the transition to well designed and carefully validated QC Plans Risk analysis may be risky business unless laboratories proceed carefully and cautiously **Laboratory quality control and patient safety** Jeremie M. Gras, 2017-03-06 Every clinical laboratory devotes considerable resources to Quality Control Recently the advent of concepts such as Analytical Goals Biological Variation Six Sigma and Risk Management has generated a renewed interest in the way to perform QC However laboratory QC practices remain highly non standardized and a lot of QC questions are left unanswered The objective of this book is to propose a roadmap for the application of an integrated QC protocol that ensures the safety of patient results in the everyday lab routine Risk, Error and Uncertainty: Laboratory Quality Management in the Age of Metrology. An Issue of the Clinics in Laboratory Medicine James O. Westgard, David Armbruster, Sten Westgard, 2017-02-06 This issue of Clinics in Laboratory Medicine entitled Risk Error and Uncertainty Laboratory Quality Management in the Age of Metrology will be guest edited by Sten Westgard James Westgard and David Armbruster The issue will cover a broad range of topics related to management in the laboratory including but not limited to Metrology Perspectives Biologic Variation Approach to Daily Laboratory Clinical Outcome Approach to Goal Setting Six Sigma Quality Management System Traceability and Comparability MU Risk and Sigma metrics at Sunway and Quality Indicators for the Total Testing Process among others *Quality Control in Laboratory* Gaffar

Zaman,2018-08-22 The book presents a qualitative and quantitative approach to understand manage and enforce the integration of statistical concepts into quality control and quality assurance methods Utilizing a sound theoretical and practical foundation and illustrating procedural techniques through scientific examples this book bridges the gap between statistical quality control quality assurance and quality management Detailed procedures have been omitted because of the variety of equipment and commercial kits used in today s clinical laboratories Instrument manuals and kit package inserts are the most reliable reference for detailed instructions on current analytical procedures **Laboratory Quality**

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Ratliff,2005-02-25 Both the 17025 1999 standard and especially ANSI ISO ASQ 9001 2000 standard require that a laboratory document its procedures for obtaining reliable results The Laboratory Quality Assurance Manual details to the user how to a prepare a new laboratory quality assurance manual which will be appropriate to use as a procedures manual for a particular laboratory a sales tool to attract potential customers a document that can be to answer regulatory questions and ultimately a tool to become a registered ISO 9001 2000 Lab and gain related certifications based on the standard The Laboratory Quality Assurance Manual Incorporates changes to ANSI ISO ASQ 9001 2000 pertaining to laboratories Provides blank forms used in preparing a quality manual Provides information on the interrelationship of ANSI ISO 17025 1999 and ANSI ISO ASQ 9001 2000 Basic Quality Assurance and Quality Control in the Clinical Laboratory A. Wayne Bruce,1984-01-01 1E Includes co

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