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Sommario/riassunto

A much-needed guide on how to use numerical methods to solve practical engineering problems Bridging the gap between mathematics and engineering, Numerical Analysis with Applications in Mechanics and Engineering arms readers with powerful tools for solving real-world problems in mechanics, physics, and civil and mechanical engineering. Unlike most books on numerical analysis, this outstanding work links theory and application, explains the mathematics in simple engineering terms, and clearly demonstrates how to use numerical methods to obtain solutions and interpret results

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Cover -- Title Page -- Copyright Page -- Dedication Page -- Contents -- Foreword -- Preface -- Acknowledgments -- About the Author -- List of Abbreviations -- Part I Getting Started: Regulatory Oversight and Laboratory Accreditation -- Chapter 1 Clinical Laboratory Improvement Amendments (CLIA) and Regulatory Oversight -- How is "clinical laboratory" defined? -- What is CLIA? -- What is the Code of Federal Regulations (CFR)? -- What roles do the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the U.S. Food and Drug Administration (FDA) play in regulating clinical laboratories? -- What is an FDA-cleared or FDA-approved test? -- What is a laboratory developed test (LDT)? -- What does the FDA final rule mean for my laboratory? -- FDA Requirements -- Implementation Stages and Compliance Start Dates -- LDT Categories -- Targeted Enforcement Discretion -- Legal Challenges to the FDA Final Rule -- What is Emergency Use Authorization (EUA)? -- What is test complexity? -- Is there a list of tests categorized by complexity? -- References -- Chapter 2 Clinical Laboratory Improvement Amendments (CLIA) Certificates -- Which laboratories need a CLIA certificate? -- Which laboratories are NOT required to obtain a CLIA certificate? -- What are the types of CLIA certificates? -- What procedures are categorized as provider-performed microscopy (PPM) procedures? -- How does a laboratory obtain a CLIA certificate? -- How many laboratories can be on one CLIA certificate? -- Can one location have multiple CLIA certificates? -- How many CLIA certificates can one laboratory director have? -- How long is a CLIA certificate effective, and how does a laboratory renew a CLIA certificate? -- What are the laboratory specialties and subspecialties? -- Which states have CLIA-exempt laboratory programs? -- When can a laboratory begin testing? -- Who should be notified if there are changes in the laboratory, and when? -- What happens if a laboratory is out of compliance with CLIA requirements? -- References -- Chapter 3 Waived Testing -- What are waived tests? -- Is there a list of tests that are waived? -- Is my laboratory subject to inspection if we perform waived testing? -- What are the personnel qualifications for performing waived testing in clinical laboratories? -- Are there compliance exemptions for laboratories performing waived testing? -- References -- Chapter 4 Laboratory Accreditation -- What is laboratory accreditation? -- What are the current CMS-approved accrediting agencies? -- How can my laboratory become accredited? -- How does my laboratory maintain accreditation? -- What happens during a laboratory inspection? -- How does a laboratory respond when cited for deficiencies? -- How is laboratory noncompliance addressed by CMS? -- Can I become a laboratory inspector? -- What is "ISO certification/accreditation" and does my laboratory need it? -- I need some help with terms! -- References -- Part II Going Live: Verification and Validation of Test Systems -- Chapter 5 Verification and Validation -- What are verification and validation? -- When should a laboratory perform a verification or validation study? -- What is a test system? -- What counts as a modification to a test system? -- Who is responsible for designing and implementing a verification or validation study? -- Can the company who made the instrument perform the verification study? -- What performance characteristics should be assessed for a verification study? -- What performance characteristics should be assessed for a validation study? -- Is verification/validation

necessary for point of care and other CLIA-waived assays?.

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Sommario/riassunto

"Laboratory accreditation is a vital and necessary process for clinical laboratories, and the requirements coming from the oversight bodies, CAP, CLIA, and FDA. And although information are freely accessible, they are often confusing and difficult to execute in the lab. Every clinical microbiology laboratory director, manager, and supervisor must interpret the requirements and work to keep the laboratory in compliance while responding to novel microbe outbreaks in addition to the regular workflow of testing. This resource gathers information from many different sources into one place and addresses the "how-tos" of implementing regulations around laboratory activities"--
