Table of Contents

1. Regulations: An Overview	not separt 1
2. Proficiency Testing	15
3. Procedure Manual 4. Method Verification, Calibration & Calibration Verification	51 65
6.Individualized Quality Control Plans (IQCPs)	111 ALIO
7. Quality (Assurance) Assessment	137
8. Personnel	165
9. Preparing for Inspection	201
10. Point of Care Testing	219
Index	255

What's new in the 2019 Edition

In early 2019, the CMS unveiled a set of proposed changes to CLIA proficiency testing criteria, the first update since those specifications were originally released in 1992. While these new proposals are not ratified yet, now is the time to consider the impact of tightened proficiency testing criteria on laboratory operations. We also discuss the final FDA guidelines for glucose meters as well as the continuing frustration of using them on "critically ill" patients. These are just a few of the significant changes in regulations that today's laboratories must confront. Of course, the accreditation organizations, The Joint Commission (TJC), the College of American Pathologists (CAP), and COLA have issued updated requirements. All this and more is covered in the 2019 edition of the *Poor Lab's Guide*.