CLIA Final Rules for Quality Systems: Quality Assessment Issues and Answers. James O. Westgard, Sharon S. Ehrmeyer, and Teresa P. Darcy. Madison, WI: Westgard QC, Inc., 2004, 225 pp., softcover, $60.00 ($50.00 AACC members). ISBN 1-886958-20-3.

Laboratories in the United States were first regulated at the federal level in 1967 under the Medicare Act and the Clinical Laboratory Improvement Act of 1967 (CLIA'67). Government agencies have modified the regulations to these statutes in an attempt to adapt to changes in testing sites (increase in near-patient testing), technologic advances, and evolving approaches to maintaining quality systems. The last revision, published in the *Federal Register* on January 24, 2003, does not change the scope or intent for achieving quality in laboratories, but it does contain important changes in the prescriptive aspects of the regulation, e.g., verification of method performance and frequency of performing quality control (QC).

The authors provide a practical, informative roadmap for interpretation and insight from their long experiences with CLIA. There are also helpful discussions of where College of American Pathologists (CAP) accreditation and CLIA requirements might differ. References to source material, such as the CMS State Operations Manual and the CAP checklist, enable the reader to access the sources directly. When opinions are offered, they are stated clearly so that the reader understands where there might be uncertainty in an auditor's interpretation. Most valuable are sections at the end of each chapter listing "DOs" and "DON'Ts".

Readers should be warned that QC is only part of an effective quality system. The authors put too much reliance on the ability of QC to detect errors when, in fact, for stable systems the "unexpected" blunder or mistake will not be detected by any reasonable sampling technique (for destructive testing). The QC techniques emphasize only quantitative test methods, when qualitative testing is growing more rapidly in the near-patient environment (where help would be most beneficial). For method comparison, the authors state that a statistical comparison might be all that is needed to satisfy the inspector (risky), but that "few people know the secrets, . . . that is why [it] is often done so poorly." This is not very helpful advice to meet the needs of the users of the test results.

Imprecise terminology is demonstrated by the inappropriate equating of error with variability without regard to the effect on the clinical use of the result, i.e., how much difference is an error? In addition, the reader should be cautious of the authors' casual use of "validation", when the commonly used term in CLIA is "establish and verify". Process and design validations are different tools from verification; they can be used together or independently, but they are not identical.

Practical information pertains to QC, but the discussions around quality assurance strategies are far less satisfying. The authors demean the ability of the CLIA regulation to achieve its goal, with their theme that meeting requirements achieves "only" compliance, but not quality. They underplay the fact that all currently used quality systems place responsibility and accountability on senior management for assuring that adequate processes and personnel are in place to meet a facility's quality policy.

CLIA has been criticized for being both too prescriptive and too lax. Government agencies have said consistently that it is not possible to have a "one size fits all" approach, particularly with changing needs. The authors suggest other approaches, but the discussion is limited and misleading. For example, understanding user needs is mentioned, but there are no clear suggestions as to how to obtain and to use information on these needs to establish acceptance criteria—an opportunity lost. Six Sigma is discussed (and not adequately cited) only in statistical process control terms, when it is much more: a comprehensive process for achieving quality that uses many other tools that can lead to additional benefits. There appears to be higher regard for ISO quality systems than for CLIA, but the fundamental principles of ISO 15189, *Medical Laboratories — Particular Requirements for Quality and Competence*, were developed to parallel (harmonize) the CLIA regulation, with substantial contribution from US representatives from government, industry, and the clinical laboratory. The cynicism and lack of understanding of the quality systems that affect medical device manufacturers is illustrated with an admonition that "FDA [US Food and Drug Administration] doesn't require a claim for quality." I doubt that either the FDA or manufacturers that have entertained FDA auditors would agree! Compliance to the Quality System Regulation (21CFR820), which was developed to harmonize with ISO 9000:1996, provides high assurance for delivery of quality medical devices.

In conclusion, this book is useful and practical for understanding the latest changes to CLIA. Sections dealing with quality systems raise unfounded concerns without providing guidance. Laboratories need to be alert to opportunities to improve a generally good system, but this book

will not help address most of these opportunities.

Fred D. Lasky

Genzyme Diagnostics
Regulatory Affairs
Cambridge, MA 02139

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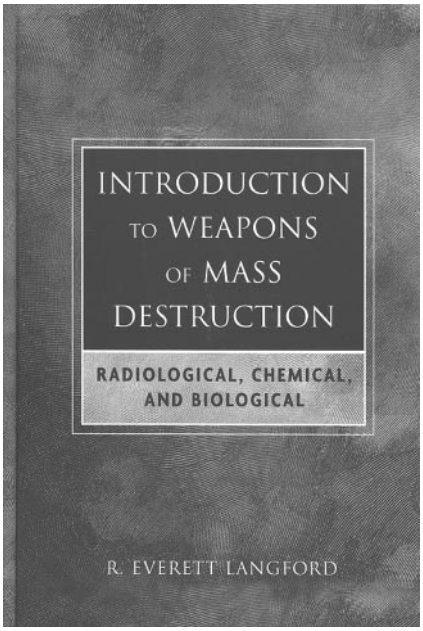
Introduction to Weapons of Mass Destruction: Radiological, Chemical, and Biological. R. Everett Langford. Hoboken, NJ: Wiley-Interscience; John Wiley & Sons, Inc., 2004, 410 pp., $89.95, hardcover. ISBN 0-471-46560-7.



This book was intended to develop a badly needed resource for the first-responder community. The purpose, as stated in the preface, is to "be both a textbook for those new to the subject as well as a summary reference to the more experienced practitioner. The goal is to provide clear, technically accurate, concise information to the public, industrial hygiene and other safety professionals, first responders, and writers in the news media." The book is divided into three sections dealing with three different weapon types: nuclear, biological, and chemical warfare agents. The text is intended to provide both a basic reference for the general public and a summary for the experienced practitioner. Information is presented in basic language interspersed with technical presentation and little translation for newcomers to the field.

This review began with great expectations that were quickly quenched. A concise reference providing the aforementioned information is a worthy undertaking. Unfortunately, this book does not accomplish its objectives. Conflicting statements occur early and often in the text, and although the preface mentions the use of general and unconfirmed references, the author must be responsible for the accuracy and consistency of his text. The book would also benefit greatly from solid technical references tied directly to statements made.

One might excuse typographical or translational errors, such as 200 meters equated to 65 feet; however, conflicting statements are harder to accept. Errors abound; on pages 91 and 92, two different dates are given for the same event, and on pages 63 and 101, conflicting information is provided regarding underwater nuclear detonations. The discussion of the well-publicized mailed anthrax attacks in the United States in the autumn of 2001 omits some key details and contains factual errors.

The text also contains misleading statements on treatment. Contrary to statements on page 157, high-dose intravenous antibiotics have been used successfully and have cured people when therapy was initiated after the onset of anthrax symptoms. If antibiotic therapy has been initiated after a possible exposure to anthrax spores and the patient remains asymptomatic, vaccination is recommended before discontinuing antibiotic therapy. If a patient with anthrax symptoms (disease) has been successfully treated with antibiotics, vaccination is neither necessary nor recommended.

Inconsistencies and inaccuracies occur with sufficient frequency throughout the text to limit the confidence with which the reader can use the information contained therein for decisions that include public health and safety. Because of these problems and others, I do not feel that this text fulfills the stated purpose and cannot recommend it.

Jim Pearson

Division of Consolidated
Laboratory Services
Richmond, VA 23219

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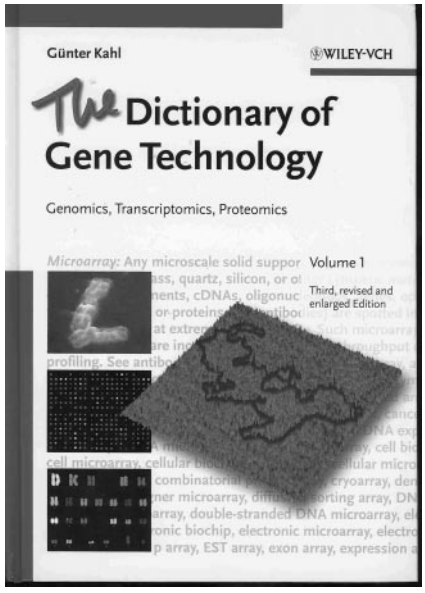
The Dictionary of Gene Technology: Genomics, Transcriptomics, Proteomics, Third, Revised and Enlarged Edition, Volumes 1 and 2. Günter Kahl. Weinheim, Federal Republic of Germany: Wiley-VCH Verlag GmbH & Co. KGaA, 2004, 1292 pp., $230.00, cloth. ISBN 3527307656.



This is a comprehensive dictionary containing a total of 9000 technical terms commonly used in molecular biology, genetics, genomics, proteomics, biotechnology, and other modern life sciences. With 2500 more entries more than its previous edi-