The Laboratory Has Entered a New Era of Uncertainty

- Today's Laboratory Manager faces a bewildering array of laws, guidelines, and standards. Are you going to be able to read all the CLIA Final Rules, EQC protocols and options, CLSI guidelines, ISO standards, Risk Management formulas, Patient Safety Goals and the accreditation and inspection checklists and procedures? If you can, congratulations. You're probably the only one.

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5Qs and 3Ss

- QC Materials
- QC Frequency
- QC Levels
- QC Limits
- QC Actions
  - Risk Management
- System
- Staff
- State-of-the-Art (Instrumentation)

Quality Control and Risk Assessment

Clinical Chemistry 54:12
2049–2054 (2008)

Assessing the Impact of the Frequency of Quality Control Testing on the Quality of Reported Patient Results

Curtis A. Parvin[1]

BACKGROUND: The traditional measure used to evaluate QC performance is the probability of rejecting an analytical run that contains a critical out-of-control error condition. The probability of rejecting an analytical run, however, is not affected by changes in QC-testing frequency. A different performance measure is necessary to assess the impact of the frequency of QC testing.

METHODS: I used a statistical model to define in-control and out-of-control processes, laboratory testing modes, and quality control strategies.

RESULTS: The expected increase in the number of unacceptable patient results reported during the presence of an undetected out-of-control error condition is a performance measure that is affected by changes in QC-

of how frequently QC testing should be performed *(1)*. The traditional approach to assessing quality control performance is based on the probability of rejecting an out-of-control analytical run, where analytical run is defined as the group of patient specimens for which a decision about control status is being made *(2)*. The probability of rejecting an analytical run depends on the QC rule that is applied, the number of QC sample results used by the rule, and the true state of the testing process—whether the process is in control or the degree to which it is out of control. The probability of rejecting an analytical run, however, does not depend on the frequency of QC testing. It only answers the question, Given that a QC rule is evaluated, what is the probability of a QC rejection?

Curtis Parvin, PhD

- Manager of Advanced Statistical Research, Quality Systems Division, Bio-Rad Laboratories, Plano, TX, USA
- Academic Positions/Employment in the field of Biostatistics and Informatics, Washington University School of Medicine, St. Louis, MO, USA
- Served on several Clinical and Laboratory Standards Institute (CLSI) subcommittees
- Patent
  - Biometric quality control process.

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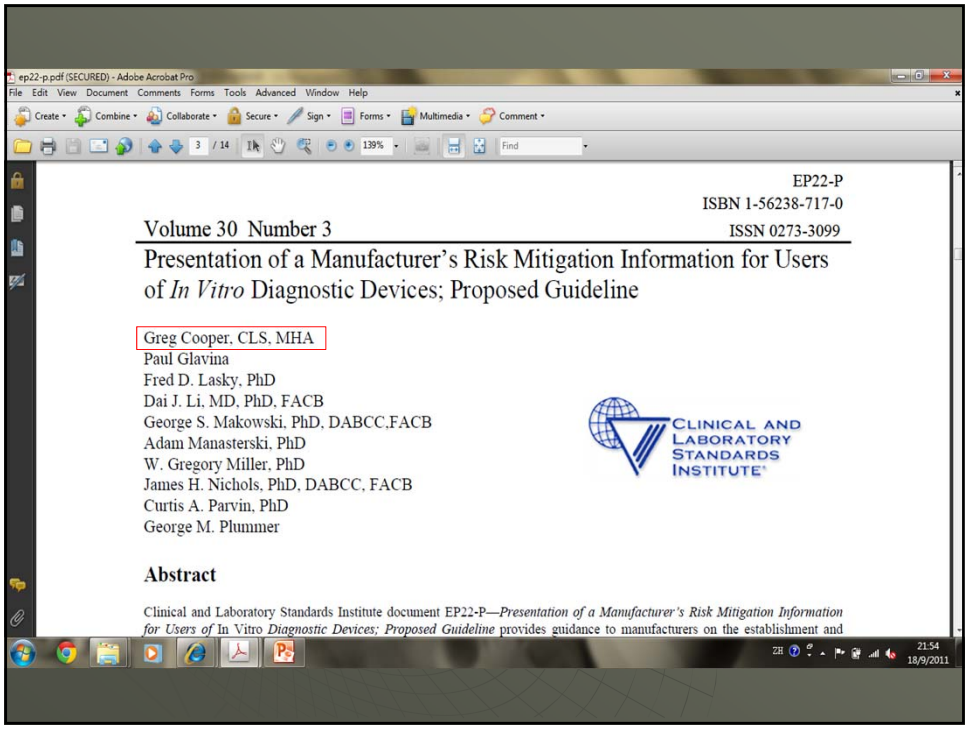

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Presentation of a Manufacturer's Risk Mitigation Information for Users of *In Vitro* Diagnostic Devices; Proposed Guideline

Greg Cooper, CLS, MHA
Paul Glavina
Fred D. Lasky, PhD
Dai J. Li, MD, PhD, FACB
George S. Makowski, PhD, DABCC,FACB
Adam Manasterski, PhD
W. Gregory Miller, PhD
James H. Nichols, PhD, DABCC, FACB
Curtis A. Parvin, PhD
George M. Plummer

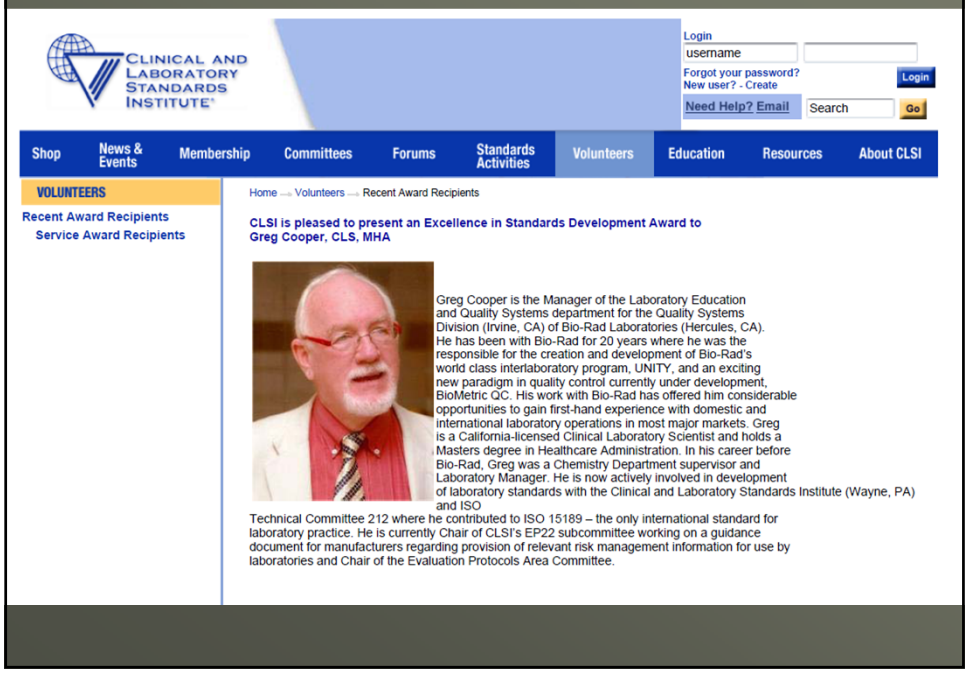
CLINICAL AND LABORATORY STANDARDS INSTITUTE

Abstract

Clinical and Laboratory Standards Institute document EP22-P—*Presentation of a Manufacturer's Risk Mitigation Information for Users of* In Vitro *Diagnostic Devices; Proposed Guideline* provides guidance to manufacturers on the establishment and

Greg Cooper, CLS, CQA, MHA

- Member Representative Clinical and Laboratory Standards Institute (Wayne, PA)
  - Served on several Clinical and Laboratory Standards Institute (CLSI) subcommittees and currently serve as a Chair of the Consensus Committee for Evaluation Protocols with responsibility for over 25 guidance documents.
- Published a text on the international quality system standard for clinical/medical laboratories, ISO 15189.
- Consultant and Manager, Scientific Affairs, Bio-Rad Laboratories.
- Laboratory Auditor for the American Association for Laboratory Accreditation (A2LA)



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Opinion Paper

Collective opinion paper on findings of the 2010 convocation of experts on laboratory quality

Greg Cooper[1], Niels DeJonge[2], Sharon Ehrmeyer[3], John Yundt-Pacheco[4], Rob Jansen[5], Carmen Ricós[6] and Mario Plebani[7,*]

[1] W. Gregory Cooper LLC, Denton, TX, USA
[2] Haga Teaching Hospital, Clinical Chemistry Hematology Laboratory, The Hague, The Netherlands
[3] University of Wisconsin School of Medicine and Public Health, Madison, WI, USA
[4] Scientific Fellow, Bio-Rad Laboratories Inc. (Hercules, CA), Quality Systems Division, Plano, TX, USA
[5] SKML, NL-NEQAS, Nijmegen, The Netherlands
[6] Biochemistry Department, Valle de Hebron General Hospital, Barcelona, Spain
[7] Department of Laboratory Medicine, University Hospital of Padova, Padova, Italy

Introduction

This collective opinion paper is intended to document the proceedings and findings from a round of discussions held May 10–12, 2010 in Bardolino-Lago di Garda (Verona), Italy on quality in laboratory medicine; in particular regarding currently debated topics. These include: a) the use of biological variation 10 years after the Stockholm Conference; b) achieving quality in point-of-care testing (POCT); c) assessing risk and controlling sources of error in the laboratory; d) determining the appropriate frequency of quality control (QC); and f) putting laboratory medicine at the core of patient care.

This was part of yearly meetings sponsored by Bio-Rad, with the aim of offering laboratory professionals from different countries and backgrounds the opportunity to share