

EP23 Laboratory QC Based on Risk Management Update

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Status Report: CLSI EP23 Guideline

Title: *Laboratory Quality Control Based on Risk Management—Proposed Guideline*

- Project authorized: February 2006
- Project re-authorized: June 2008
- Timeline for Subcommittee Vote – Fall 08

EP23 Subcommittee Members

- James H. Nichols, PhD, DABCC, FACB, Chairholder
- Greg Cooper, CLS, MHA
- Devery Howerton, PhD
- Ellis Jacobs, PhD, DABCC, FACB
- Ronald H. Laessig, PhD
- Ronalda Leneau, MS, MT(ASCP)
- W. Gregory Miller, PhD
- Robert Murray, JD, PhD
- Valerie L. Ng, PhD, MD
- Nils B. Person, PhD, FACB
- Arleen Pinkos, MT(ASCP)
- Marcia L. Zucker, PhD



Intended Users: CLSI EP23

- Document intended for users of Laboratory and POC systems with alternative control processes.
- All labs (waived and nonwaived) will find the manufacturer's test limitations and risk mitigation information useful.

Scope: CLSI EP23

- Labs will receive guidance to develop QC processes and procedures to:
 - Reduce negative impact of test system's limitation, while considering laboratory environmental/operator factors like personnel competency, temperature, storage conditions, clinical use of test results, etc.
 - Monitor immediate and extended test performance.

Scope: CLSI EP23

- Labs will receive guidance to enable them to develop effective, cost-efficient QC protocols that will ensure appropriate application of local regulatory requirements based on the technologies selected by the lab and reflective of the lab's unique environmental aspects.

Manufacturer Package Insert QC Recommendations

Moderate Complexity Device Package Insert:

“ Current good laboratory practice includes the daily use and documentation of either liquid controls or electronic (internal) controls to ensure that the calibration of the diagnostic devices is maintained within acceptable limits. ...The (external) controls are recommended for use in monitoring the performance of the cassette...The recommended frequency of use of the controls is once each time a new lot or new shipment of cassettes is received or whenever there is uncertainty about the cassettes.”

Manufacturer Package Insert QC Recommendations

What about CLIA and CAP accredited labs that mandate two levels of QC each day of testing?

Interpreting Manufacturer QC Recommendations

- What does this mean?
- How do I, as a lab director, know that the internal controls on these devices can substitute for two levels of external QC?
- Will the internal controls detect environmental exposure, deviations in operator technique, and other factors with the same frequency/sensitivity as external QC?

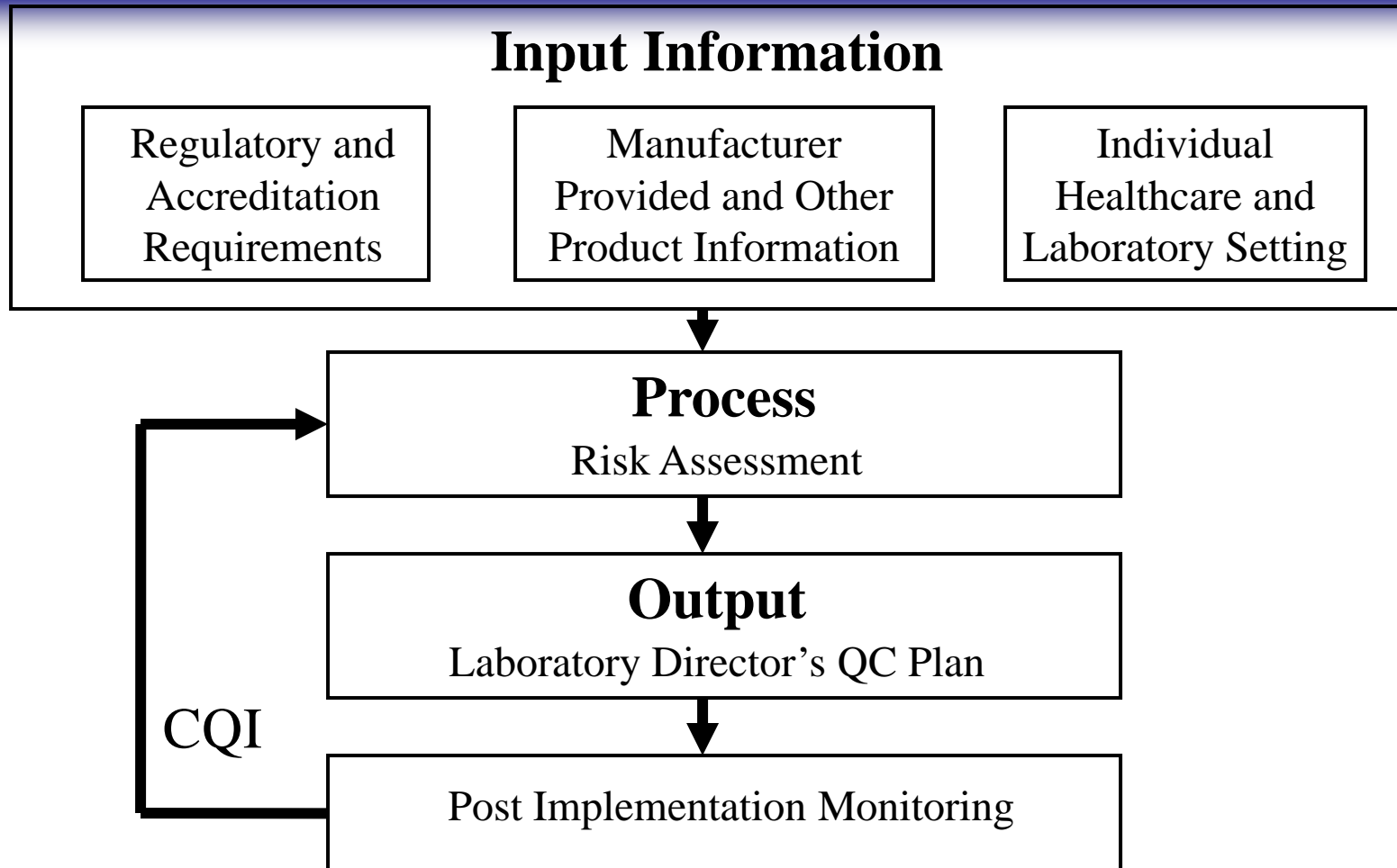
Interpreting Manufacturer QC Recommendations

- What factors did the manufacturer consider when making this recommendation and did the manufacturer place the same emphasis on certain errors that I see most frequently in my hospital and clinic settings?
- EP22 will provide the manufacturer studies and data supporting QC recommendations and EP23 will interpret those recommendations within the unique laboratory environment.

Manufacturer Risk Assessment

| Targeted Failure Mode | Device Feature or Recommended Action | How feature or action performs intended function | Known limitations of feature or action | Actions required to address known limitations | Studies to verify intended feature or action achieves intended purpose |
|-----------------------|--------------------------------------|--|--|---|--|
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EP23 Laboratory QC Based on Risk Management



Document Content: CLSI EP23

- Table of Contents
- Foreword – Shared foreword with EP18, EP22, and EP23
- Section 1 – Scope
- Section 2 – Introduction
- Section 3 – Standard Precautions
- Section 4 – Terminology
 - Definitions – Shared with EP18, EP22, and EP23
 - Abbreviations and Acronyms

Document Content: CLSI EP23

- Section 5 – Available Quality Control Tools
 - Surrogate Sample (traditional) QC protocols to Monitor or Mitigate Errors
 - Nonintegrated
 - Integrated (QC built into device)
 - Alternative QC Processes and Other Laboratory Error Identification and Avoidance Techniques
- Provide strengths and weaknesses of each QC mechanism or process

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- Section 6 – Laboratory-Specific Factors to Be Considered When Adopting or Modifying Manufacturer’s Quality Control Recommendations
- Section 7 – Development of Laboratory-Specific QC Protocols
- Section 8 – Surveillance and Follow-up

Summary

- Common FMEA example to be carried through EP18, EP22, and EP23 – Glucose on an automated analyzer
- Assist laboratories by describing the multiple factors that must be considered when developing laboratory-specific QC protocols
- Possible future spin-off product of EP23 in nontechnical terms for physician's office market and non-laboratorians

Thank You

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