Equivalent Quality Control

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The Clinical Laboratory Improvement Amendments of 1988 (CLIA) were passed overwhelmingly by Congress in 1988 in response to public and media concerns about the quality of laboratory testing. There were media stories about misread PAP smears, inaccurate cholesterol testing, and concerns about unregulated laboratories' performance. The original legislation was generally worded and declared the intent that testing would be reliable and accurate regardless of where it was performed. The Centers for Medicare and Medicaid Services (CMS), then known as the Health Care Financing Agency (HCFA) was authorized to write regulations to administer the law. Because of many concerns and comments about provisions of the first draft of proposed regulations, the first final rule, containing most of the provisions that we still practice under today, was published on February 28, 1992. Additional changes and extensions to deadlines or phase-in periods were published in final rules on December 6, 1994, May 12, 1997, October 14, 1998, and December 29, 2000.

On January 24, 2003, CMS published revisions to the Final Rule that included substantive changes in quality control practices, among other changes. (The final Rule may be accessed at www.phppo.cdc.gov/clia/regs/toc.aspx.) This necessitated a revision of the interpretive guidelines in the State Operations Manual (SOM), used by laboratories to prepare for inspections and by state department of health surveyors to perform inspections. That revision was published on January 12, 2004, and can be found at www.cms.gov/clia/appendc.asp.

The revised CLIA regulation published on January 24, 2003, states in section 493.1256 (d) "Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing, the laboratory must…" followed by a list of requirements including two levels of QC per day of testing for most quantitative tests, and positive and negative controls for most qualitative tests. The newly published revisions to the State Operations Manual address new procedures for equivalent quality control (EQC).

Organizations with deemed status to perform inspections for CMS must have standards that are equivalent to, or more stringent than, those required by CLIA. This means that the College of American Pathologists (CAP), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and other deemed status organizations, must decide whether to adopt the newly published EQC provisions.

EQC addresses the special circumstances presented when using unit-use devices, usually for point-of-care testing, that may incorporate internal QC measures. The National Committee for Clinical Laboratory Standards (NCCLS) provides a document EP-18A, *Quality Systems for Unit-Use Testing* that addresses the need for alternative approaches for these systems. EQC also may apply to more traditional laboratory test systems, as long as the CLIA regulations for specialties and subspecialties do not specifically supercede the new provisions.

There are three categories of testing addressed in the EQC provisions:

Option 1: For a test system that uses internal/procedural controls that monitor all of its analytic components, the laboratory may run internal QC (according to manufacturer's instructions) and external QC (two levels per day) for ten consecutive days of testing. If all results are satisfactory, the frequency of external QC may be reduced to two levels once per month. Unsatisfactory QC must be repeated and if it is still not acceptable, the process must begin over from the beginning.

Option 2: For a test system that uses internal controls that monitor a portion of the analytic process, the procedure is similar to Option 1, except that the evaluation period is 30 consecutive days, and after successful evaluation, external QC may be reduced to two levels once per week.

Washington Beat is intended to provide a timely synopsis of activity in the nation's capitol of importance to clinical laboratory practitioners. This section is coordinated jointly by Kathy Hansen, Chair of the ASCLS Government Affairs Committee, and Don Lavanty, ASCLS Legislative Counsel. Direct all inquiries to ASCLS (301) 657-2768 extension 3022; (301) 657-2909 (fax); or mail to ASCLS, 6701 Democracy Blvd., Suite 300, Bethesda MD 20814, Attention: Washington Beat.

Option 3: For a test system that uses external QC, the evaluation period is 60 consecutive days of testing using two levels of external QC. All personnel who perform the test must participate in the evaluation. After 60 days of successful evaluation, the QC frequency may be reduced to two levels of external QC once per week.

In all cases, the options are only permissible if allowed by the manufacturer's instructions. Once the reduced frequency of QC testing has been implemented, any out of range value that is not satisfactory upon repeat (defined as a QC failure) triggers a new evaluation period, as well as a more extensive evaluation of patient test results. The guidelines state, "The director must consider the laboratory's clinical and legal responsibility for providing accurate and reliable patient test results versus the cost implications of reducing the quality control testing frequency."

The last sentence is what laboratorians will need to consider when deciding whether to adopt EQC, which has already sparked much discussion.

Will manufacturers hurry to recommend EQC as a competitive advantage for their products?

Will it be clear to laboratories which test systems qualify for option 1 vs option 2? CMS has stated that they do not intend to make this determination; it will be between the laboratory and the vendor.

Will the accrediting bodies with deemed status adopt EQC as part of their standards? Is there scientific data to support the decreased QC testing frequency under EQC? Even with permission, will laboratories adopt EQC for more than point-of-care unit-use testing? Will they be under budget pressure to do so, even if they are not comfortable with EQC? Is EQC compatible with heightened concerns about patient safety and Six Sigma quality?

Dr James Westgard, internationally recognized expert and author on quality systems, advises laboratories not to use the new EQC options. His opinions may be found on his Website, www.westgard.com.

What do YOU think? EQC is an issue that we should all think about and on which we should be prepared to articulate our position.