By Ronald H. Laessig, PhD, and Sharon S. Ehrmeyer, PhD

On Jan. 24, 2003, the Centers for Medicare and Medicaid Services (CMS) released the latest version of the Clinical Laboratory Improvement Amendments (CLIA), termed the “Final Rules.” In section §493.1256 of Subpart K, CMS quietly introduced a new quality-control (QC) concept — equivalent quality control (EQC). The Jan. 12, 2004, CMS Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services (Appendix C in the State Operations Manual [SOM]) provides detailed implementation procedures for EQC, which include three evaluation options. To implement EQC for daily use, test sites first must demonstrate that a method's internal checks are as effective as traditional, external QC materials in monitoring the analytic process. If these internal checks are found to be “equivalent,” the required frequency of analyzing external QC can be reduced by 97% (once per month) or 86% (once per week). CMS places the decision to implement EQC, along with any potential liability resulting from its use, squarely on laboratory directors. Directors alone — not regulators and not manufacturers — must decide to adopt or eschew EQC in their testing environment.

What is EQC?

Conceptually, EQC is simple. It empowers manufacturers to design instruments with internal quality-assessment systems. These systems utilize internal and/or procedural controls to evaluate analytical quality, independent of the operator. If the laboratory director decides that an instrument's means of monitoring the analytical process is “equivalent” to that achieved with traditional, external liquid controls, EQC can be implemented. This reduces the frequency of analyzing CLIA-mandated external controls from a daily basis to a weekly or monthly basis.

For the equivalency evaluation, the laboratory director must first decide if the instrument's internal quality-assurance system monitors the “entire,” “a portion,” or “none” of the analytical process. CMS offers no protocol for making this decision but suggests that the director, consulting with the manufacturer, make the decision. For test systems that monitor the entire analytic process, the test site's evaluation is based on EQC option one — data is collected and compared from external QC and the internal (system's) controls over a 10-day period. Test systems that monitor only a portion of the analytic process need to follow EQC option two, which requires data collection and evaluation over 30 days. When the instrument has no internal quality checks, a 60-day evaluation (EQC option three) is followed to demonstrate instrument stability. By CMS directive, option three is not available to the specialties of chemistry and hematology, but (apparently) may be used under certain circumstances for some microbiological tests.

The decision process is equally “simple.” During the 10-, 30- or 60-day evaluation period, the test site uses the instrument's internal quality-control system and traditional, external QC materials to produce parallel quality-assessment data. If the data is (appears to be) equivalent, the laboratory director may choose to adopt EQC. Thereafter, the test site is required to run external controls only every seven or 30 days, depending on the EQC evaluation option selected. CMS has made it very clear that the selection of options is strictly between the manufacturer (whose product information describes the capabilities of the instrument's internal quality system) and the laboratory director who makes the final choice. The inspector and CMS are not involved in the decision.

Is EQC able to assure quality?

With the CLIA 2003 revisions, CMS identified three purposes of QC:

- to monitor the accuracy and precision of the complete analytical process;
- to detect immediate errors that occur due to test-system failure, adverse environmental conditions, and operator performance; and
- to monitor over time the accuracy and precision of test performance that may be influenced by changes in test-system performance and environmental conditions, and variance in operator performance.

The SOM states that the traditional, concurrent analysis of external QC material along with patient samples, as well as EQC, meets these purposes.

Quality test results are always a concern, especially at point of care (POC) where test results are acted upon immediately. Consequently, the laboratory director must decide whether EQC meets patients' needs and, as well, satisfies CMS' QC requirements. In making the decision, the laboratory director must be aware of several pitfalls inherent in the EQC.
concept. The director must decide whether the comparison of internal and external QC data, in the words of CLIA 2003, “is acceptable.” CMS offers no criteria to define what is acceptable — the decision is left to the director. Ascertaining acceptability is difficult when only limited external data are evaluated and when the instrument’s quality-assessment algorithm is not fully disclosed, described, or evaluated, and its ability to detect error is not documented in the literature.

The laboratory director also must realize that in the event of any external QC (performed every seven or 30 days) failure, CMS mandates specific responses. With the initial failure, the external control is rerun. If this result is within limits, testing continues under the EQC rubric with no ramifications for patient test results. If the control fails again, the test site must identify and correct the problem, plus evaluate all patient test results since the last acceptable external control run either seven or 30 days ago. This becomes, particularly at POC, an impossible — though mandated — activity; the specimens are gone and the patient results have been acted upon.

The most profound implications may be at the “physician’s office” test site where long-term care decisions are made based on test results. In this case, notifying the treating physician and possibly reviewing all patient records for therapeutic decisions based on test results is a real possibility. An example is a failure in a liver function test used to monitor statin therapy. At any test site, a “dump” of all of the internal QC data, including function checks, and an assessment — perhaps with the manufacturer’s help — leading to identification of the cause would be needed. In addition, the test site must restart and successfully complete the 10-, 30-, or 60-day evaluation process before re-implementing EQC. Finally, the fundamental validity of the EQC evaluative process also must be questioned. Very simply, if the instrument’s internal QC system does not encounter a failure during the evaluation process, there is no assurance (except the manufacturer’s promise) that the internal monitoring system, in fact, is able to detect a quality-system failure.

The laboratory director’s responsibility and liability

Consistent with the original 1992 CLIA regulations, the laboratory director is responsible for the quality of test results. In §493.1256(d) of the SOM, CMS reminds laboratory directors to consider the quality of test results delivered to patients as their legal responsibility and liability: Since the purpose of control testing is to detect immediate errors and monitor performance over time, increasing the interval between control testing (i.e., weekly or monthly) will require a more extensive evaluation of patient test results when a control failure occurs (see §493.1282). The director must consider the laboratory’s clinical and legal responsibility for providing accurate and reliable patient test results vs. the cost implications of reducing the quality-control testing frequency.

The decision to implement EQC on a routine basis should not be taken lightly — the risks and the benefits must be weighed.

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Liability for a failed test that results in an adverse patient outcome lies not with CMS who created the rules nor with the manufacturer who developed the instrument’s algorithm and quality-assessment protocol, but with the laboratory director. The decision to implement EQC on a routine basis should not be taken lightly — the risks and the benefits must be weighed. The “benefits” of adopting EQC include the obvious reduction of QC materials and staff costs associated with purchasing and analyzing external liquid controls, evaluating control data, and documenting the entire process. Does the instrument’s internal quality-assessment system, along with external controls, provide the same level of confidence we derive from traditional controls? It is solely the director’s call.

**Final analysis**

In 1997, we predicted an emerging quality alliance among government, manufacturers, and laboratory professionals. We suggested that, based on innovative technologies, the alliance would develop alternative approaches to quality control and assessment. With some of today’s instruments, particularly those used at POC, our 1997 vision is consistent with the EQC concept. At POC, where analysts are focused on patient care and not the testing process, EQC creates an absolute link between quality assessment and the test result — albeit one that is primarily in the hands of the manufacturer. Once implemented, EQC assures that the instrument’s quality-assessment regimen will be followed. It may actually assure better patient results than when nonlaboratorian analysts are responsible for analyzing QC materials and interpreting the results.

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Our 1997 vision, however, did not include the CLIA 2003-specified evaluation protocol. Making an informed decision to implement EQC based on only 10, 30, or 60 days of external QC data and the limited information from the instrument’s internal quality system appears to lack scientific rigor. At a superficial level, the short duration of the evaluation protocol may never allow the instrument to encounter an out-of-control situation; hence, the response of the internal/procedural controls system is, in fact, not actually validated. To date, there is a striking absence of papers in the scientific literature describing carefully designed evaluation protocols and estimates of the power of internal quality systems to detect error. For a true assessment of EQC capabilities, the manufacturer must provide the magnitude of error that triggers a recognizable out-of-control situation. In the 1992 CLIA regulations, the government (CMS, the Centers for Disease Control and Prevention, and the Food and Drug Administration) placed the responsibility for validating and documenting the performance of in vitro diagnostic products, including their QC design, directly on the manufacturer. CLIA 2003 shifts that responsibility to the laboratory director.

In the final analysis, EQC could be viewed, in the context of the evolutionary process of today’s cutting-edge testing technologies, as a concept whose time has come. The specified regulatory approach for implementation, however, lacks credibility and is at best empirical. As of January 2005, the “CLIA-deemed” accrediting and inspection organizations — the College of American Pathologists (CAP), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and the Commission on Office Laboratory Accreditation (COLA), have adopted a “wait-and-see” attitude with respect to adopting EQC. If history serves as an example (as when CMS’ predecessor, the Health Care Financing Administration, approved “electronic” quality control for some instruments), CAP, JCAHO, and COLA may soon follow with revisions of their inspection criteria. Accordingly, test sites inspected by these organizations should not implement EQC until revised inspection guidelines are developed and published. As state-inspected test sites attempt to comply with the CLIA 2003 regulations, they should remember that EQC is a choice.

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**References**