October 10, 2012

Ann E. Snyder MT (ASCP)
Medical Technologist
CMS/CCSQ/SCG
Division of Laboratory Services
7500 Security Blvd
Mail Stop C2-21-16
Baltimore, MD 21244

Dear Ms. Snyder:

The American Association for Clinical Chemistry (AACC) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) draft Individualized Quality Control Plan (IQCP) that will replace the Equivalent Quality Control (EQC) section of the interpretive guidelines. AACC supports your efforts to develop a new risk-based assessment tool to give clinical laboratories an alternative method for complying with the CLIA'88 quality requirements.

AACC is pleased with a number of aspects of the IQCP, such as its emphasis on the responsibility of the laboratory director for overall laboratory operations, permitting laboratories the flexibility to adapt the IQCP to their specific circumstances and stressing that laboratories consider the entire testing process when assuring quality testing. Although we believe this is a good start, there are a number of issues that need to be addressed before this document is finalized, such as:

- Making clearer distinctions between when a clinical laboratory must follow the manufacturer's instructions for QC procedures, in particular frequency, and when it is appropriate to develop and implement an IQCP with a different QC frequency;
- Taking into account the clinical context of how the test result is going to be used for patient care; and
- Identifying and incorporating the scientific data that justifies a reduction in QC frequency.

Given the short time frame we are unable to propose alternative language to address these concerns but are willing to work with CMS on alternative language if that would be helpful. Our specific comments follow.

General Considerations
CMS references "laboratories must always follow the manufacturer's instructions" without specifying the situations when an IQCP can be developed and implemented in place of those requirements. AACC suggests that CMS clarify that proviso. (Page one, paragraph two)

Laboratory Director Responsibilities
The IQCP states that "if a laboratory's risk assessment allows for quality control testing at a number and frequency less than the control procedure requirements that are eligible for IQCP…" The document is vague regarding how a risk assessment can lead to an IQCP for reduced frequency for QC sample testing. We request that CMS include an explanatory sentence that describes the intent of this statement and specific language to clarify when reduced QC frequency is an option. (Page two, paragraph two)

Risk Assessment
CMS states that Risk Assessments must include an evaluation of five components, including "environment." In this draft, "environment" does not include the type of patients and acuity of care as part of the environment of testing. In EP23, the environment of care and the acuity of patients were important considerations in developing a risk assessment. We recommend that CMS include these concepts in this document. (Page five, bullet two)

Probe one asks "does the laboratory have data to support its frequency of testing quality control samples? AACC recommends that the laboratory describe its basis for why it selected "its frequency of testing quality control samples." (Page six, probe one)

Quality Control Plan
The document states "the QCP must at least include requirements for the number, type, and frequency of testing control materials, a well as criteria for acceptable control results." We suggest that CMS modify this statement to require the laboratory to describe its rationale for why it selected the "number, type, and frequency of testing control materials." (Page ten, paragraph two)

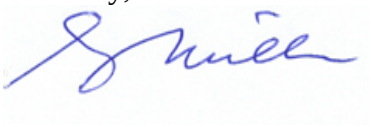
The fourth probe asks: "Does the QCP require that the laboratory will perform QC at least as frequently as specified by the manufacturer's instructions? If performing less QC than required by the manufacturer, use D5411 or D5445 as appropriate."

D5411 states that "the testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's state performance specifications for each test system as determined under 493.1253." This D link seems to contradict the direction given in the probe. We request that you clarify this discrepancy. (Page ten, probe three)

D5445 appears to be the same conditions used previously to justify reduced frequency of QC under the EQC model. Unfortunately those conditions were not based on any objective scientific data. We are concerned that retaining the lack of scientific justification will compromise this risk-based IQCP approach and make it less valuable to the laboratory community.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care. If you have any questions, please call me at (804) 828-0375, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,



Greg Miller, PhD
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