DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-07-33

DATE: **August 24, 2007**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Continuation and Revision of the Components of the Clinical Laboratory Improvement Amendments (CLIA) Educational Period Regarding Certain Quality Control (QC) Requirements. (Refer to S&C-03-30, S&C-04-16, S&C-05-39)--- **ACTION REQUIRED**

Memorandum Summary

- Announces the continuation of the educational period for the implementation of certain final CLIA QC regulations at 42 CFR 493.1256 and provides updated information about the specific requirements that are not included in this continuation.
- Clarifies the Equivalent QC (EQC) issues identified at the 2006 CLIA State Agency (SA) Surveyor training and provides an update on the status of revised QC policies.
- Presents revisions to the educational "Dear Laboratory Director" letters that are used for laboratories not meeting the CLIA QC provisions.
- Includes a revised list of "excluded" D-tags for inclusion in the QC letters and submission to CMS Central office (CO), an EQC Fact Sheet, and a QC Decision tool.

Background and Update on CLIA QC Policies

In this memorandum we provide official notification to the SAs and Centers for Medicare & Medicaid Services (CMS) Regional Offices (ROs) of the continued extension of the educational period for implementation of certain QC requirements at 42 CFR 493.1256 in the CLIA Final regulations, CMS-2226F. Due to various technological changes related to QC, we are collaborating with the Clinical and Laboratory Standards Institute (CLSI) and our partners in laboratories, industry, and other government agencies to develop revised QC protocols addressing current technology that would ultimately be incorporated into our surveyor Interpretive Guidelines.

Currently, there are two CLSI documents under development that will:

1) Provide guidance to manufacturers, using International Standards Organization (ISO) risk management concepts, to encourage them to provide enough appropriate information to laboratory directors to facilitate the laboratory's ability to design its QC procedures; and

2) Offer further guidance to laboratories for designing a customized QC protocol based on the test systems the laboratory employs and its own unique circumstances (i.e., the testing personnel's expertise, patient population served, and environmental factors, etc.).

The ultimate goal of these documents and CMS is that the laboratory should be able to follow the manufacturer's QC instructions and only be required to conduct additional QC for those test system limitations, if any, which the manufacturer is unable to mitigate otherwise. We will keep you apprised of the status of these projects as they progress.

Change in Excluded D-tags (Attachment 1)

Effective December 31, 2007, the following specific requirements are no longer included in the educational period. Therefore, they will be formally in effect. Laboratories have been educated by the States and have had sufficient opportunity and time to understand these requirements and to comply with them. These include:

- 42 CFR 493.1253, Establishment and verification of performance specifications;
- 42 CFR 493.1254, Maintenance and function checks; and
- 42 CFR 493.1255, Calibration and calibration verification procedures.

On or after December 31, 2007, when the RO/SA surveyor finds any of these requirements unmet in the course of a CLIA laboratory survey, **the unmet requirements should be cited on the CMS-2567, statement of deficiencies,** per standard operating procedures. A revised listing of excluded D-tags (i.e., those tags used to document non-compliance as part of the educational process but not the formal enforcement process) is included with this memo.

Because these may be considered new deficiency citations for some laboratories, it is imperative that the SA provide clarification to the laboratory of these requirements and resources to which the laboratory can avail itself, if necessary, in order to achieve compliance. CLIA brochures are also available on the CMS/CLIA Web site at: www.cms.hhs.gov/clia for Verification of Performance Specifications, Quality Control/EQC and Calibration/Calibration Verification.

We are also communicating this information to the approved accrediting organizations, exempt States, and professional organizations and will place a notice on the CMS/CLIA Web site.

Modification to "Dear Laboratory Director" Letter from July 14, 2005 (Attachment 2)

Attachment 2 provides a letter with revised language, to be used in place of the 2005 version of the "Dear Laboratory" QC letter. SAs must begin to use this new letter on December 31, 2007. The language comprising the attached letter **must remain as it is written,** except where prompted for State-specific contact information, the inclusion of applicable D-tags, and to indicate that the letter is accompanying a CMS-2567 (statement of deficiencies—if one is warranted), as described further in this memo.

The information in the revised "Dear Laboratory Director" letter contains essentially the same concepts as previous versions; that is, the laboratory may or may not be meeting requirements published in the 1992 CLIA final regulations, but is definitely not meeting certain new QC requirements at 493.1256 that were effective April 24, 2003. As noted above, a CMS-2567 is to be issued if:

a) the laboratory is not meeting other previously existing regulations (1992 Regulations);
b) the laboratory is not meeting 493.1253, 493.1254, or 493.1255 (listed earlier in this memo); or
c) there is real or potential harm to patients due to improper QC practices in the laboratory or the surveyor finds, in his/her judgment, that they have serious concerns regarding the lab's QC practices and therefore, the results of that laboratory's testing with regard to 493.1256.

To facilitate decision-making during this interim period, we have included a Decision Table, (**Attachment 4**), for each of the QC circumstances the surveyor may encounter on surveys.

This "Dear Laboratory Director" letter serves as the communication of non-compliance, but does not represent a formal deficiency citation due to our having identified new technologies and acquiring additional information that may warrant changes to current guidance. The letter permits the laboratory director to make an informed compliance decision regarding the laboratory's QC program.

The letter explains that no deficiency citation (CMS-2567) or letter is issued if the laboratory director finds the manufacturer's instructions for QC acceptable, the laboratory follows the manufacturer's instructions and, the instructions meet CLIA QC requirements described in the 2003 regulation.

Laboratories that meet the QC regulations at 42 CFR 493.1256(d)(3) or perform the CMS EQC protocol correctly, as written in the Surveyors' Interpretive Guidelines, will be determined to be in compliance with CLIA QC procedures and will not receive a letter or CMS-2567 indicating non-compliance.

If the manufacturer's instructions are followed, but are less stringent than CLIA QC, the appropriate D-tags are cited in the QC letter and routinely reported to CMS as previously directed.

Continuation of Special Data Reporting

We will continue to collect monthly submissions of the applicable QC D-tags in the ASPEN system as part of the survey kit. Timely receipt of this information from ROs/SAs is extremely important as it informs CMS of national QC activities, laboratory issues, and may also be used for developing future policies, procedures, and training materials.

Equivalent Quality Control (EQC) Fact Sheet (Attachment 3)

Lastly, an EQC Fact Sheet is included that covers key points about EQC and addresses questions from the September, 2006 CLIA SA surveyor training session.

If you require further information, please contact Judy Yost at (410) 786-3407 or via email at Judith.yost@cms.hhs.gov.

Effective Date: **December 31, 2007**. The SA should disseminate this information within 30 days of the date of issuance of the memorandum.

Training: This information should be shared with all appropriate Survey and certification Staff, their managers, QIES coordinators, and the SA/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management
RO Laboratory Consultants

Attachments:
Attachment 1 – Revised Listing of Excluded D-Tags
Attachment 2 – Dear Laboratory Director Letter
Attachment 3 – Equivalent Quality Control Fact Sheet
Attachment 4 – QC Decision Table

Attachment 1

CLIA Excluded D-tags for Reporting to CO
(Please continue to report monthly to Kathy Todd)

D5441
D5445
D5447
D5449
D5451
D5453
D5455
D5457
D5459
D5461
D5463
D5465
D5467
D5469
D5471
D5473
D5475
D5477
D5479
D5481
D5485

Attachment 2

Dear Laboratory Director:

Representative(s) of the **(State Agency)** surveyed your laboratory on **(Date)** for Clinical Laboratory Improvement Amendment (CLIA) purposes. The surveyor(s) identified certain quality control (QC) requirement(s) contained in the final regulations published on January 24, 2003, and effective on April 24, 2003, that were not met.

Findings and Observations Under Revised CLIA Rules

During the exit interview of your laboratory's survey, the **(State Agency)** representative(s) discussed certain QC provisions contained in the 2003 revisions of the regulations. At present, the Centers for Medicare & Medicaid Services (CMS) is educating laboratory directors about CLIA QC regulatory requirements. Below are the requirements that were identified as not being met. We are issuing this non-compliance notice as a letter, rather than a formal enforcement action, as part of this educational effort. CMS anticipates that this educational process will allow laboratories to become more knowledgeable about QC requirements in order to make informed compliance decisions. All other applicable unmet CLIA requirements will be cited on the CMS-2567, deficiency report, and must be corrected timely.

Additionally, since the publication of the 2003 CLIA final regulations and accompanying interpretive guidelines in 2004, CMS has identified innovations in technology and received input from technical experts that may lead to further modifications of CLIA QC policies in these guidelines. CMS is currently working with the Clinical and Laboratory Standards Institute (CLSI) and experts from laboratories, industry, and government to acquire input relative to QC and technological advances so that our policies will ultimately reflect this new information. We will continue the educational process until any merited changes are incorporated into our guidelines.

Laboratories will not receive a deficiency citation if, at a minimum, the laboratory director determines that manufacturers' QC instructions reasonably monitor the accuracy of their testing and the laboratory follows these instructions, but may still receive these letters.

At the time of your survey on (**Date**) your laboratory was not in compliance with the following QC provisions contained in the revised CLIA regulations:

*************List the specific D-tags from 493.1256 not met by the laboratory here. Include a description of each regulatory citation in clear language to accompany the citation and clarify it.********

Additional information regarding these items may be found on the CMS CLIA Web site at: www.cms.hhs.gov/clia in the Interpretive Guidelines and Brochures.

The (**State Agency**) representative will be available should you have any questions regarding the areas identified during the survey. You may contact (**Name**) at (**Phone No**.) if you require further assistance.

Sincerely,

CLIA Inspector
DHSS Office of Health Facilities
Licensing and Certification

Attachment 3

CLIA EQUIVALENT QUALITY CONTROL (EQC) FACT SHEET

- The QC "exclusion" letters will continue to be used to indicate noncompliance with QC procedures at 42 CFR 493.1256 until new CLSI QC consensus documents for manufacturers and laboratories are completed and pertinent information is incorporated into the Interpretive Guidelines.
- Exclusion letters are applicable to non-compliance with D tags D5441 to D5485.
- The letters CANNOT be changed except to include the specific survey citations and surveyor contact information and whether a 2567 is included..
- The letter notifies the laboratory about QC noncompliance; on site the surveyor clarifies the regulations so the laboratory can make informed compliance decisions.
- There are 3 EQC options depending on the extent and/or presence of internal QC.

  Option I—Internal QC monitors entire analytic process**.**
  Option II—Internal QC monitors a portion of the analytic process.
  Option III—NO internal QC; STABLE.
- For non-waived laboratories EQC is a *choice* to be determined by the Laboratory Director who selects the EQC option based on written manufacturer's information regarding the extent internal QC monitors the analytic process (*operator, analysis, environment*) and the laboratory's circumstances; i.e., staff competency, turnover, device stability, etc. The laboratory may use option 1 or 2 at their discretion.
- If the laboratory chooses EQC, the surveyor can provide guidance by clarifying eligibility, and explaining the protocol and evaluation process, etc.
- EQC permits the laboratory to decrease the frequency of external QC to save costs, as long as the test system is stable, eligible, the laboratory successfully completes their evaluation process, and their quality system is functioning within acceptable limits.
- If the laboratory doesn't choose EQC, it is subject to QC procedures at 493.1256(d)(3) which requires two levels of *external* QC/day & applicable specialty requirements.
- Manufacturer's instructions which are more stringent than CLIA must be met.
- Laboratories not performing any QC or with grossly incorrect results that may harm patients, will be cited on a CMS-2567. You may also cite noncompliance specific to the requirements for laboratory director, depending on the impact and scope of the problems. If immediate jeopardy exists, then follow Standard Operating Procedures.
- If the laboratory chooses EQC for a test with specialty requirements, like coagulation or blood gases, internal QC is once/day in lieu of the specialty requirements.
- For the initial evaluation process and EQC ongoing, when the lab has a QC failure, it can only repeat the QC once. If it is an obvious problem or the QC meets expected values, EQC can be continued. If the problem isn't obvious or QC is still not meeting expected values, then the laboratory must repeat the evaluation process.
- When a QC failure occurs, the laboratory must repeat all patient testing back to the last acceptable QC result.
- To continue EQC indefinitely, the lab must ensure its quality system is functioning within acceptable limits, i.e., satisfactory proficiency testing, acceptable personnel competency, and good analytic systems quality assurance.

Attachment 4

QC DECISION TABLE

Finding			
2 levels of external QC performed/day	Yes	No	
EQC performed correctly	Yes	No	
EQC done incorrectly	No	Yes	
Lab follows manufacturer's QC instructions that are ≥ EQC or 2 external QC/day	Yes	No	
Lab follows manufacturer's QC instructions that are < external QC or EQC	No	Yes	
Lab uses internal QC only - may or may not meet manufacturer's instructions	No	Yes	
Lab doesn't follow manufacturer's instructions, but does some QC	No	Yes	
Lab does no QC or there are serious concerns about test quality or there is immediate jeopardy (real or potential harm to patients)	No	No	