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CENTERS for MEDICARE & MEDICAID SERVICES

Office of Clinical Standards and Quality/ Survey & Certification Group

Ref: S&C: 12-03-CLIA

DATE: **November 4, 2011**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Initial Plans and Policy Implementation for Clinical and Laboratory Standards Institute (CLSI) Evaluation Protocol-23 (EP), 'Laboratory Quality Control Based on Risk Management', as Clinical Laboratory Improvement Amendment (CLIA) Quality Control (QC) Policy

Memorandum Summary

- **Formal announcement: CMS' adoption of EP-23 for CLIA QC as a QC option.**
- **EP-23 is the product of the CLSI and CLIA partnership:** The CLSI standards document development utilizes a consensus process among affected constituencies to engender technical and scientific validity and credibility.
- **CMS will announce the date in 2012 on which laboratories may begin to implement EP-23:** After that date, laboratories may implement EP-23, or continue to follow those existing QC policies and procedures that are currently allowed, until the end of the education and transition period.
- **EP-23 will be voluntary**: As with all new CLIA requirements, laboratories will be provided ample time and education to adopt EP-23 policies. It will also be voluntary for accrediting organizations (AO) and exempt States (ES).
- **Default QC requirement will be 42 CFR 493.1256(d)(3):** The minimum regulatory requirement is two levels of external QC per each day of patient testing, if EP-23 is not used.
- **CLSI and CMS will provide webinars, workshops, educational tools and materials to facilitate EP-23 understanding**: This educational outreach will occur throughout the period of implementation and will facilitate compliance.
- **Equivalent Quality Control (EQC) will be phased out:** The existing EQC protocol, as stated in the 2004 Interpretive Guidelines (IG), will be replaced by EP-23 as official QC policy, based on 42 CFR 493.1250. Laboratories using EQC may continue its use during the EP-23 education and transition period (minimum 2 years).
- **CLSI will provide EP-23 training for ROs on Dec. 6, 2011 in Baltimore, with SA training to follow later**: The CLSI one-day training is mandatory for RO technical staff and will include major EP concepts, risk assessment principles and practical examples; the following two days, December 7-8, 2011, will consist of CO/Regional Office (RO) planning for State Agency (SA) training and implementation.

A. Background

Following publication of the CLIA Final Quality Systems regulations in 2003, CMS and the Centers for Disease Control and Prevention (CDC) developed an alternative QC plan, Equivalent Quality Control (EQC), to reduce the regulatory QC requirements for certain types of robust test systems. This reduction was permitted as long as the laboratory could meet certain conditions, but many types of tests were precluded from using this option due to quality concerns.

The protocol for EQC was placed in the IG per the new, 2003 regulatory provision at 42 CFR 492.1250 which allows HHS to include QC policy, as long as it provided 'equivalent quality' to the regulatory standard.

Subsequent to a comment period on the IG and the release of EQC, subject matter experts and organizations questioned why CMS and CDC offered QC procedures that did not adequately assure scientific validity or statistical accuracy. Many laboratories still adopted EQC and supported it, because it facilitated reduced costs and resources and still provided quality since some QC was required.

Due to these concerns, CMS collaborated with CLSI to convene a meeting of stakeholders in 2005 which included representatives from laboratories, professional organizations, industry, and government agencies to solicit ideas for "QC for the Future". The two major conclusions of that meeting were the following:

1. 'One-size-fits-all QC' was not appropriate any longer due to the new technologies now available for laboratories.
2. Stakeholders were concerned that manufacturers do not provide laboratories with sufficient information about what problems/limitations exist in their test system and how to mitigate them.

B. Discussion

After the 2005 consensus meeting, CLSI and CMS conferred and proceeded to initiate the development of the EP-23 document utilizing a consensus process and experts from all CLSI constituencies. The document is based on International Standards Organization (ISO) risk management principles and guides laboratories to design, implement and monitor a customized QC plan (QCP) based on the environment, personnel, clinical use, patient population, and test systems they employ. Many existing good laboratory practices were assembled to develop this quality protocol which contains direction for the design of an appropriate and effective QCP for each laboratory and each specific test; that is, the "Right" QC!

Surveyors and laboratories will soon discover that many of the processes outlined in EP-23 consist of things they already do, but are not formally documented and organized in a comprehensive, structured and standardized fashion. Since this protocol offers more flexibility and choices in varying circumstances, additional professional judgment is required to achieve an excellent QCP and to assess compliance. Consistency in the application of EP-23 concepts for laboratories and surveyors will be a challenge, but with proper training, focus and tools it can be accomplished.

CMS CO staff, an RO representative, as well as the CDC CLIA personnel have actively participated in the ongoing development of EP-23 and recently received CLSIs EP-23 training on the document's significant concepts to ensure a clear and consistent understanding. Based on that extensive experience and history, CMS CO-CLIA has determined that it will adopt the CLSI protocol for 'Laboratory Quality Control Based on Risk Management' Guideline for its QC policies. CMS CO will no longer allow the use of EQC to meet CLIA requirements once the EP-23 education and transition period of at least 2 years is concluded. See policy and timeline sections of this memo for further information.

CLSI published the EP-23 document on October 25, 2011, along with a workbook that guides the user through a scenario and allows them to apply the concepts of the risk management process, QCP development, and QCP monitoring. Copies of these materials will be provided to RO staff before the December training. We ask that you read them in advance of the training to maximize the training session's benefits. These materials are copyrighted and are being used for educational purposes, but cannot be shared elsewhere.

An EP-23 Training and Planning Workshop for RO and CO staff will be conducted on December 6-8, 2011 in Baltimore. The CLSI one-day training on Dec. 6 will include major EP concepts, risk management principles and practical examples. The following two days, December 7-8, 2011, will consist of CO/RO planning for SA training, identification of educational needs, concerns and additional policy determinations and implementation. Attendance is required for RO CLIA technical staff. A draft agenda for this training and meeting was provided for RO travel planning. A more updated one will be provided at a later date.

The EP-23 concepts are most easily applied when organized into these modules:

- Information gathering;
- Process mapping;
- Risk assessment;
- QC Plan development; and
- Monitoring, corrective action(s), and QA.

The RO's active participation in all related activities is vital to the success of the implementation process. This process will require a second RO/CO planning meeting to finalize the development of the SA training in the usual mode including:

- Requirements;
- Policy statement;
- Process to assess compliance/provide technical assistance to laboratories;
- What to expect and see in the laboratory/minimum compliance determination;
- Citations; and
- Enforcement recommendations.

To facilitate SA, RO, CO and laboratories' understanding and application of EP-23 principles, both CLSI and CMS will produce workshops, webinars, tools, educational materials and brochures throughout the implementation process. Additionally CO has developed a list of

helpful FAQs which will be periodically updated and a summary of the benefits and advantages of EP-23. The FAQs will accompany this memo.

C. Related EP-23 Policies

To avoid the practice of co-existing inconsistent QC protocols, CMS is phasing out EQC, but will allow laboratories which use it currently to retain its use until the education and transition period for EP-23 has concluded. Existing EQC policies will remain in place until that time.

After the SA training has been conducted, CMS will announce a date when the education and transition period starts and laboratories can start to implement EP-23. EP-23 will remain educational for the first survey cycle. It will be voluntary for laboratories and AOs and ESs.

Until the conclusion of the education and transition period, which we expect to last a minimum of two years, laboratories may continue to follow those existing QC policies and procedures that are allowed under current policy. At a later time, CMS will announce the conclusion date of the education and transition period.

During the phasing out period for EQC and the education and transition period for EP-23, laboratories will be transitioning to their chosen QCP.

Revised IG, developed by CO and ROs, reflecting EP-23 related information will be available for the SA training in 2012. This will provide CMS the authority to use the IG in lieu of QC regulatory requirements.

EP-23 is not intended to necessarily reduce QC requirements as did EQC, but it is intended to ensure a much more effective QCP for each laboratory and the tests it performs.

Laboratories that do not wish to use EP-23 and/or those which are ceasing EQC must meet the default QC regulation at 493.1256(d)(3) or manufacturer's instructions if equal to or more stringent.

All specialties will be eligible for EP-23, except Pathology.

D. Implementation Milestones and Timeline

- CLSI CO EP-23 training—September 20, 2011
- CLSI publication of EP-23 and Workbook—October 25, 2011
- Mandatory CLSI RO training for surveyors and RO/CO planning meeting—December 6-8, 2011
- CLSI Webinars November 8 and 30, 2011(Consult CLSI web site, www.clsi.org, for further information.)
- Partners in Laboratory Oversight discussion of EP-23 with AOs—June 2012
- Second RO/CO Planning Meeting for SA Training—2012
- Revised IG available in draft—2012
- CMS SA/RO training—2012

- CMS/CLIA start date for EP-23 and beginning of minimum 2 year education and transition period for laboratories—2012
- CMS reviews of AO/ES proposals for EP-23 equivalency if not adopting EP-23—2012

More information and memos will be forthcoming as they become available. If you have any questions, please contact Penny Meyers at: penelope.meyers@cms.hhs.gov for project management; Ann Snyder at: ann.snyder@cms.hhs.gov for document content and CLSI educational WG; Sarah Bennett at: sarah.bennett1@cms.hhs.gov for training; or Melissa Singer at: melissa.singer@cms.hhs.gov for communication.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
Thomas E. Hamilton

Attachment: FAQs for EP-23

cc: Survey and Certification Regional Office Management

FAQs for EP-23

What is EP-23?
Evaluation Protocol - 23 is a CLSI consensus guidance document that contains innovative QC concepts, developed around many current lab quality practices, which will be used to allow a new alternative QC approach for laboratories.

What is the main concept included in EP23?
EP-23 describes good laboratory practice for developing and maintaining a quality control plan (QCP) for medical laboratory testing using internationally recognized risk management principles. An individual QCP should be established, maintained, and modified as needed for each measuring system. The QCP is based on the performance required for the intended medical application of the test results. Risk mitigation information obtained from the manufacturer and identified by the laboratory, applicable regulatory and accreditation requirements, and the individual health care and laboratory setting are considered in development of the QCP. This document is intended to guide laboratories in determining quality control (QC) procedures that are both appropriate and effective for the test being performed and the laboratory's patient population.

Is EP-23 intended to reduce the amount of quality control in laboratories?
This new QC protocol will not necessarily reduce QC requirements, but instead, will be the "right" QC for this lab, its environment, patients, personnel, test systems, etc.

How will CLIA use the EP-23 document/concepts? What will be our policy?
The concepts in EP-23 will be used to replace the existing EQC options in CLIA. It is currently envisioned that all CLIA specialties, with the exception of pathology, will be eligible for EP-23.

If EP-23 will be adopted, what happens to EQC?
EQC will be gradually phased out (would set a double inconsistent standard). EP-23 will be phased in following CO, RO and SA training and the development of the updated Interpretive Guidelines. There will be an education and transition period to allow laboratories and surveyors time to learn about and implement EP-23. Until they are notified, laboratories must continue to do what they are presently doing for QC.

The ROs are not familiar with the concepts in EP-23. Will there be training for the ROs?
RO training will occur Dec. 6-8, 2011, in Baltimore. CO will also be present. The 1st day will consist of CLSI training on EP-23 document concepts, risk management principles and laboratory examples. The subsequent 2 days will consist of beginning the process of applying the principles to labs and surveys, identifying needs and issues, and planning for SA training

Will laboratories be required to use the concepts included in EP-23?
EP-23 will be optional with 493.1256 being the default requirement for CLIA QC. EP-23 will be also optional for accrediting organizations (AOs) and exempt States (ESs).

What training will be provided to the surveyors and State agencies?
Additional tools, workshops, educational materials, brochures, etc. will be developed for surveyors and laboratories. ROs will be heavily involved in the design and development of revised Interpretive Guidelines, SA training, and on-going EP-23 implementation. RO input and participation are critical to the success of the realization of EP-23.

How do we train the surveyors effectively to ensure consistent application of this new QC policy?
Training for surveyors will be developed jointly, with CO and RO participation. RO input and expertise is essential to ensure adequate and effective training. It is anticipated that follow-up training sessions will be necessary after the initial training.

What do we tell laboratories and surveyors now if they make an inquiry?
Laboratories and surveyors can be directed to the S&C letter on the CLIA website. For the immediate future, laboratories may begin to consider EP-23, but may continue to do what they have been doing for CLIA QC until further notice. Accredited laboratories should contact their AOs for guidance and laboratories in exempt States should contact their States directly.
ROs and SAs should keep CO informed of inquiries about EP23 received from external sources.

What is the timeline for Implementing EP-23?
A timeline for SA training and implementation is under development. Surveyors and laboratories will be given an ample education and transition period.

When can we expect more information?
Communication about EP-23 implementation will be ongoing. EP-23 updates will be provided on each RO call, in the CNN, and new FAQs will be distributed as needed throughout the implementation process. A copy of EP-23 and the related workbook will be distributed to the ROs prior to the December training.