**CLIA Corner**
State Hygienic Laboratory at the University of Iowa

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**REVISIONS TO APPENDIX C**

Have you every left a CLIA exit conference asking yourself, “What is that surveyor talking about?” or “Where did the surveyor get his/her information?” The answer is likely: Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, otherwise known as the CLIA Regulations and Interpretive Guidelines.

On January 9, 2015, CMS published the Survey and Certification Letter: 15-17-CLIA. This letter details the latest revisions to Appendix C (CLIA Regulations and Interpretive Guidelines). A few highlights of these changes and updates include:

- Removal of the Clinical Laboratory Standards Institute (CLSI) standards and guidance documents;
- Patient Access regulatory changes and guidance on Patient Access to Test Reports;
- Proficiency testing regulatory changes and definitions;
- New D-tags for surveyors [$493.1291(l)$]; and
- New name for the American Board of Medical Genetics (ABMG).

Want more information? Go to the CLIA website www.cms.gov/clia, and then click on the Interpretive Guidelines for Laboratories link on the left hand side of the screen. All changes and updates made in **red** for easy identification.

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**UPDATE IN WAIVED TESTING REQUIREMENTS**

Laboratories eligible for a certificate of waiver must follow manufacturer’s instructions for performing waived testing. Previously this included following all manufacturer requirements; it was considered good laboratory practice to follow manufacturer’s recommendations. The new interpretive guidelines state the following:

“As with all laboratories, laboratories holding a Certificate of Waiver must follow the current manufacturer’s instructions for using the waived test systems that are used in patient testing. As a part of meeting the waived testing regulatory requirements, these laboratories must comply with the manufacturer’s recommendations and requirements for testing. As such, these laboratories may only use the specimen types that were approved by the Food and Drug Administration (FDA) for use with the
In order for a laboratory to be in compliance with the CLIA regulations for waived testing, the laboratory must follow ALL RECOMMENDATIONS AND REQUIREMENTS as detailed in the manufacturer instructions and/or operating guides. It is never acceptable to modify the manufacturer’s instructions for a waived test system (e.g., change sample type or incubation periods.) Any changes to a waived test system will result in a test that is no longer categorized as waived. The test will be considered modified from the Food and Drug Administration (FDA) approval process and, therefore, considered high complexity testing. The laboratory will then be subject to routine inspections and will be expected to follow the CLIA requirements for high complexity testing. In summary, laboratories performing waived testing must follow the manufacturer’s instructions (recommendations and requirements) in their entirety and without variation.

**INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) WORKBOOK RELEASED BY CENTERS FOR MEDICARE & MEDICAID SERVICES/CENTERS FOR DISEASE CONTROL (CMS/CDC)**

The CDC has published a workbook designed to assist laboratories in developing an IQCP for all eligible testing systems. This workbook uses example scenarios to guide the laboratory through the step-by-step process in developing an IQCP. This includes evaluating your laboratory’s current quality activities and developing an IQCP worksheet which, when completed, can serve as your IQCP document.

For an electronic copy of the IQCP workbook use the following link:

Laboratories may request a hardcopy of the workbook by emailing: iqcpworkbook@cdc.gov

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**IQCP WEBCAST**

Still have a few questions regarding IQCP?
Plan to attend the CMS webinar to discuss the newly released IQCP workbook.

**WEDNESDAY, JULY 15TH**
**12:30 – 2:30 P.M. CST**

Registered attendees will be able to obtain continuing education (CE) credit for attending the webinar. You MUST register for the webinar to get the link containing the call, PowerPoint and to obtain the CE credit.

**TO REGISTER:**
Go to //www.eventsvc.com/blhtechnologies
Click on the green register box located next to the course titled: IQCP for CLIA Laboratory Nonwaived Testing: Workbook Tool — Webcast.

A written transcript of the webinar will be available afterwards for those who are not able to attend.