CLIA Corner

State Hygienic Laboratory at The University of Iowa

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In This Issue of the CLIA Corner we adress:

- **Introduction to Individualized Quality Control Plan (IQCP);**
- **Free on-line CLIA educational courses; and**
- **Updates in Blood Bank record retention requirements.**

Introduction to Individualized Quality Control Plan (IQCP)

In November 2013, all CLIA laboratory surveyor staff from the State Agency, Regional Office, and Central Office met in Towson, MD, to receive training regarding IQCP. The IQCP Education and Transition period is effective January 1, 2014 – December 31, 2015. During this time period surveyors will educate laboratories about IQCP and the implantation of IQCP.

What exactly is IQCP?

IQCP stands for Individualized Quality Control Plan and is the alternative CLIA quality control (QC) option that will provide for equivalent quality testing to meet the CLIA regulations for nonwaived tests. IQCP will include many practices that your laboratory already engages in to ensure quality testing, not just the frequency and number of QC materials. IQCP considers the entire testing process: pre-analytic, analytic and post-analytic; thus, your laboratory will need to consider the corresponding risks in each of these phases and applicable regulatory requirements.

After the transition period, IQCP will officially replace the existing Equivalent Quality Control (EQC) options currently found in the CLIA's Appendix C-Interpretative Guidelines for Laboratories and Laboratory Surveys. The Interpretative Guidelines will be updated at the end of the educational transition period.

Benefits of IQCP:

- Customizes QC Plan for each test in its unique environment
- Optimizes use of electronic/integrated controls
- Offers laboratories flexibility in achieving QC compliance
- Incorporates other sources of Quality information
- Strengthens Manufacturer/Laboratory partnerships
- Formalizes risk management data already maintained within the laboratory
- Provides equivalent quality testing to meet the CLIA QC regulations

For more information about IQCP refer to the CLIA website: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Individualized_Quality_Control_Plan_IQCP.html

Additional concerns, thoughts and questions can be sent to the IQCP mailbox at IQCP@cms.hhs.gov, please also cc your State Agency contact.

Free On-Line CLIA Educational Courses

With the start of the New Year and with competency assessments lurking their ugly heads around the laboratory corner, here is information about two free on-line CLIA educational courses. Both courses, ***Tools for Proficiency Testing*** and ***Mission Possible: Understand Training and Competency Assessment***, were developed by the State Hygienic Laboratory at The University of Iowa (SHL) in conjunction with the Association of Public Health Laboratories (APHL).

- ***Tools for Proficiency Testing*** Course Description: This one-hour course includes details and illustrated examples of CLIA requirements for Proficiency

Testing as well as tips and forms that will assist laboratories in documenting their performance and improving PT scores.

- ***Mission Possible: Understand Training and Competency Assessment*** Course Description: In this module, the CLIA requirements for Training and Competency Assessment are explained and information is provided on how to document both. Downloadable forms and attachments are available in the one-hour course.

Both of these are basic, entry level courses; no prior knowledge of the subject is necessary to participate. They are intended for owners, laboratory personnel, technical staff, supervisors, managers and laboratory directors in both public health and other clinical laboratories. Upon the successful completion of each course, a certificate is available.

To participate in either course use the following link: http://www.shl.uiowa.edu/dcd/sentlabtrain/courses/index.xml, then click on the appropriate course under the CLIA Compliance heading.

Disclaimer: Participation in either or both courses is not a CLIA requirement. The courses are to be used solely as educational tools.

Update of Blood Bank Retention Records

The CLIA regulation for immunohematology retention requirements reads:

§493.1105 Standard: Retention requirements.

(a)(3)(ii) The laboratory must retain its records and, as applicable, slides, blocks and tissues as follow: immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d).

The FDA regulation, Current Good Manufacturing Practice for Blood and Blood Components, 21 CFR 606.160(d) states:

- **Non-transfusion** related immunohematology patient testing and quality control (QC) records, such as instrument function checks, maintenance, and temperature records, must be retained for at least 2 years.
- **Transfusion** related immunohematology patient and QC records, including but not limited to, donor processing, compatibility testing, and transfusion reaction investigations, must be retained for individual product records ***no less than 10 years*** after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date. When there is no expiration date, records shall be retained indefinitely.
    - This includes the visual inspection of whole blood and red blood cells during storage and immediately before distribution, record of reissue, including records of proper temperature maintenance, and emergency release of blood, including the signature of the requesting physician obtained before and after release.

Previously the blood bank retention record was for no less than 5 years. Be sure to update procedures and notify staff of the change in order to be in compliance with the CLIA regulations.

References

State Operations Manual, *Appendix C- Survey Procedures and Interpretative Guidelines for Laboratories and Laboratory Services*; Centers for Medicare and Medicaid Services (CMS); published January 12, 2004.

CLIA RECORD RETENTION REQUIREMENTS

(As of August 2007)

Type of Record	Specialty/Subspecialty	Retention Time
Test Requisitions & Authorizations • Including patient's chart or medical record	**All**	**2 years**
Test Procedures • Include dates of initial use and discontinuance	**All**	**2 years after procedure has been discontinued**
Analytic Systems Records • Quality control, including instrument printouts, if applicable • Patient test records, including instrument printouts, if applicable • Analytic systems activities (maintenance, temperatures, functions checks), including instrument printouts, if applicable. • Test performance specifications	**Immunohematology (Transfusion-related Only)**	As specified in FDA 21 CFR 606.160(b)(3)(ii), (b)(3)(v), & (d): ***Currently 5 years*** (After processing records have been completed, or six months after the latest expiration date whichever is the later date.)
	All Others	**2 years**
Proficiency Testing • All records, including reporting forms, test records, signed attestation statement, program test reports	**All**	**2 years**
Laboratory Quality Systems Assessment	**All**	**2 years**
Test Reports • Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports)	**Immunohematology (Transfusion-related Only)**	As specified in FDA 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), & (d): ***Currently 10 years*** (After processing records have been completed, or six months after the latest expiration date whichever is the later date.)
	Pathology Cytology & Histopathology	**10 years**
	All Others	**2 years**
Slides	**Cytology**	**5 years**
	Histopathology Oral Pathology Dermatopathology	**10 Years**
	All Others	**No requirements**
Specimen Blocks	**Pathology**	**2 years**
Tissue Remnants	**Pathology**	**Completion of diagnosis**

NOTE: If the laboratory ceases operation, the laboratory must make provisions for record retention for the specified requirements.