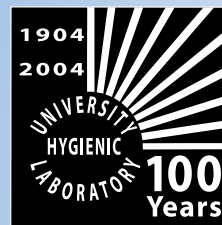


CLIA Corner

The University of Iowa Hygienic Laboratory

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Mandatory Training Equals Mandatory Citations

CLIA surveyors attended mandatory training entitled, "CLIA Laboratory Surveyor Update Training" October 29-November 2, 2007 in Dallas, Texas. The goal of this training was to establish consistency in regulatory practices between each state and between individual surveyors. One of the topics that the surveyors received clarification on was the practice of mandatory citations. There are four types of mandatory citations where condition level deficiencies will automatically be cited: proficiency testing referral, proficiency testing non-enrollment, unsuccessful proficiency testing participation, and personnel qualifications.

Proficiency Testing Referral:

Proficiency testing referral occurs when a laboratory intentionally refers proficiency testing material to another laboratory for analysis and then submits the other laboratory's results as its own. Proficiency testing referral will result in a mandatory citation. Immediate jeopardy will automatically be determined, and the laboratory's CLIA certificate will be revoked for a minimum of one year. In addition, the owner/operator of the referring laboratory and the director of the laboratory will be suspended from owning, operating and directing a laboratory for a minimum of two years. *For laboratories that retain previously tested proficiency testing samples for other purposes (e.g.*

*competency, training, etc.), the laboratory should wait until **AFTER** the proficiency testing program sends the graded results back to the laboratory before using the proficiency testing specimens.*

Proficiency Testing Non-Enrollment:

Non-waived laboratories must enroll in a CMS approved proficiency testing program for all regulated analytes, specialties, and subspecialties listed in Subpart I* of the CLIA regulations for which the laboratory seeks certification. Failure to enroll in proficiency testing will result in a mandatory condition level citation. *Reminder: For all unregulated analytes (analytes not listed in Subpart I*) the laboratory must verify the accuracy at least twice annually.*

**To reference Subpart I, go to www.cms.hhs.gov/clia, click on CLIA Regulations and Federal Register Documents, then click on CLIA Regulations Part 493 (CDC site).*

Unsuccessful Proficiency Testing Participation:

Unsuccessful proficiency testing performance is defined as unsatisfactory performance in two consecutive or two out of three events for a specialty, subspecialty, or analyte. Unsuccessful proficiency testing participation is a mandatory condition level citation, and the sanctions taken will depend of the laboratory's history, and whether this is an initial or non-initial unsuccessful participation.

Personnel Qualifications:

For laboratories performing moderate complexity testing, each laboratory must have a qualified director, clinical consultant, technical consultant, and testing personnel. For laboratories performing high complexity testing, each laboratory must have a qualified director, clinical consultant, technical supervisor, general supervisor, and testing personnel. For all laboratories performing non-waived testing, testing personnel are qualified based on their highest level of education. CLIA uses diplomas, transcripts, HEW exam certificates, and GED certificates to qualify testing personnel (**Nursing or other allied health licensures are not acceptable.**) If the laboratory does not have the necessary documentation, the personnel will be considered unqualified and a mandatory condition level deficiency will be cited.

Other News and Clarifications

Educational Period Ends for Some New Regulations

Effective December 31, 2007, the following requirements will no longer be included in the new regulation educational period:

- 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.

Starting January 1, 2008 if the surveyor finds a laboratory not meeting these requirements, the laboratory will be cited on the CMS-2567 statement of deficiencies form. CLIA brochures are available on the CMS website (www.cms.hhs.gov/clia), for those laboratories needing further information on these topics.

Clarification of Manufacturer's Package Inserts Requirements:

- For waived tests, if the manufacturer's package insert uses words such as "must or shall,"

the laboratory is required to follow these guidelines. If the laboratory uses words such as "recommends or suggests," it is considered good laboratory practice to follow these guidelines.

- For non-waived tests, if the manufacturer's package insert uses words such as "must, shall, should, recommends, good laboratory practice," the laboratory is required to follow **all** of these guidelines.
- For non-waived tests, if the manufacturer's package inserts state for instrument ABC, the laboratory must use ABC reagents/controls and there are other brands of reagents and controls that can be used on the instrument, the laboratory is not required to use the specific ABC reagents/controls. However, it is the laboratory's responsibility to perform and document studies to ensure that the use of another brand of reagents and controls does not affect patient testing.
- For non-waived tests, if the manufacturer's requirements are more stringent than the CLIA regulations, the laboratory is required to follow the manufacturer's requirements.

Contact Information:
If you want to be added to our e-mailing list, need a change of address, or have a question or topic suggestion for the CLIA Corner you can contact either Kristi Rotzoll at krotzoll@uhl.uiowa.edu or Nancy Grove at ngrove@uhl.uiowa.edu.