

CLIA Corner

State Hygienic Laboratory at the University of Iowa

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IMPORTANT UPDATE: Waived Testing Interpretative Guidelines Final Revision

Remember in the last issue of the CLIA Corner we wrote that laboratories performing waived testing must follow ALL of the manufacturer's instructions, including any recommendations or suggestions. **NEWS FLASH** – the Centers for Medicare & Medicaid Services (CMS) revised the Interpretive Guidelines (IG) again in May 2015. We apologize for the confusion - unfortunately we did not receive notification of the revision until after we released the Third Quarter 2015 issue.

The excerpt below is from the May-June 2015 issue of the CLIA Network Newsletter.

After further review and legal discussions with CMS Office of General Counsel (OGC), a change has been made in the waived testing Interpretative Guidelines (IG) at §493.15(e). The initial version, published in 01/09/2015, stated that *“As part of meeting the waived testing regulatory requirements, these laboratories must comply with the manufacturer's recommendations and requirements for testing.”*

Per Division of Laboratory Services (DLS) discussion with CMS OGC, there is no legal basis for holding laboratories to manufacturer's recommendation. In the **final version** of the IGs published on 5/29/2015, §493.15(e) (D1000) now states, *“To meet the waived testing regulatory requirements, these laboratories must comply with the manufacturer's requirements. We encourage laboratories to comply with the manufacturer's recommendations for testing.”* Therefore, if the manufacturer's instructions require something, it is required. If the manufacturer's instructions recommend something, or use words such as “should”, it is good laboratory practice but not mandatory.

This IG can be located in Appendix C – Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, otherwise known as the CLIA Regulations and Interpretive Guidelines. Go to the CLIA website www.cms.gov/clia, then click on the Interpretive Guidelines for Laboratories link on the left had side of the screen. All changes and updates were made in red for easy identification.

Laboratory Personnel Qualifications

Foreign Education Equivalency Evaluation

Is your laboratory planning to hire an individual who has been educated and earned his/her degree outside the United States? The CLIA regulations for laboratory personnel qualifications require the individual to have earned their degree “**from an accredited institution.**”

As defined at §493.2, “**accredited institution**” means a school or program which--

- (a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;
- (b) Is legally authorized within the State to provide a program of education beyond secondary education;
- (c) Provides an educational program for which it awards a bachelor’s degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master’s or doctoral degree;
- (d) Is accredited by a nationally recognized accrediting agency or association.**

This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.

Interpretive Guidelines §493.2

Individuals who have degrees from foreign institutions must have an evaluation of their credentials to determine the equivalency of their education to an education obtained in the United States (U.S.). The equivalency evaluations should be on a course-by-course basis and may be performed by a nationally recognized organization. These may include such organizations as the National Association Credential Evaluation Services, Inc. (NACES) (<http://www.naces.org>) and the Association of International Credential Evaluators, Inc. (AICE) (<http://www.aice-eval.org>).

What this means for the laboratory is that individuals who have degrees from foreign institutions must have an evaluation of their credentials to determine equivalency of their education to an education obtained in the United States. Either the laboratory or the individual must obtain this equivalency evaluation prior to reporting patient test results. As with all records, the laboratory must maintain documentation along with their personnel records.

Contact Information:

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Say “NO” to Agency Evaluations (excluding foreign credentials)

Laboratory surveyors have guidelines we must follow to determine whether individuals in prescribed positions (e.g. laboratory director, testing personnel, etc.) meet the CLIA personnel qualifications stated in 42 CFR Part 493. Subpart M. These guidelines are located in the CMS Survey and Certification Letter, Ref: S&C-10-07-CLIA, on “Consolidation of Personnel Policies for Individuals Directing or Performing Non-waived Tests under the Clinical Laboratory Improvement Amendments (CLIA)” issued November 6, 2009.

In the General Surveyor Guidance section, one of the criteria states: **“Agency evaluations, except foreign credentials, are not acceptable to determine if an individual’s qualifications meet CLIA.”** This means that if your institution uses an outside agency to evaluate an individual’s education and experience, the agency evaluation does not comply with the CLIA regulations.

Microbiology IQCP Examples

- On October 6, 2016, Alere, Inc. hosted a webinar titled: **“Creating Your IQCP for Microbiology: Real-Life Examples.”** The webinar can be viewed at www.whitehatcom.com/alere.
- The American Society for Microbiology (ASM), College of American Pathologists (CAP) and Clinical Laboratory Standards Institute (CLSI) have collaborated to develop Individualized Quality Control Plans (IQCPs) for antimicrobial susceptibility testing (AST), exempt media and microbial identification systems. To see these examples go to <http://clinmicro.asm.org/iqcp>.