

Licensing Toolkit



For Chemists Working in Public Health Laboratories

Background

The Clinical Laboratory Improvement Amendments governs all laboratory testing (except research) performed on humans in the United States. Regional CLIA (or CAP) inspectors regularly ensure that public health laboratories meet CLIA requirements (or state requirements, if they are more stringent).

Traditionally biomonitoring (measuring chemicals in clinical samples) did not fall under CLIA due to its lack of connection with diagnosis and treatment.¹ During the last decade, though, the interpretation of CLIA moved away from only covering diagnostic tests to also include any tests done on clinical samples.

Until 2011, some CLIA inspectors *did* cover the chemical part of public health laboratories, while other inspectors *did not* (due to the absence of actual clinical sample testing). In 2010, CMS agreed with CDC and APHL's request to offer CLIA certification for all chemical testing laboratories, regardless of whether they met the CLIA definition for testing human samples.

Issue

Recently, APHL heard from states with more stringent licensure requirements that CLIA expressed concern regarding unlicensed chemists in the public health laboratory.

Potential Solutions

Existing Solutions

An informal survey asked other licensure states how they addressed this issue:

- **New York** has a licensure exemption built into the law for the two public health laboratories in the state, allowing the option for utilizing unlicensed staff.
- **Hawaii** has a loophole in their state licensure rules that allows for results from unlicensed analysts with a certain degree of training to be sent out under the signature of a licensed analyst who has done a thorough review of the analytical process.

Recommendations

APHL recommends that laboratories not in compliance with state laws, consider requesting a temporary waiver from their licensure board until the chemists have time to find an appropriate licensing body (see below), prepare for, take and pass the exam. Laboratories should then:

- look closely at their state requirements,

¹ The major exception being blood lead testing.

- consider any training that the employee already completed, and
- seek certifications (see below) that would both meet state needs and which would involve the least 'stretch' for that employee.

Given available funding, APHL may be able to help cover costs associated with training materials for chemists to use while preparing for the exam (contact megan.latshaw@aphl.org).

In the long-term, laboratories might consider requiring a license within a certain amount of time after the date of hire. Other options include:

- rotating non-licensed chemists through other aspects of clinical testing (i.e. microbiology, parasitology, molecular)
- providing training on coursework related to the licensure exam
- approaching a Clinical Laboratory Scientist program to see if they would rotate their candidates through the public health chemistry laboratory.²

Potential Licenses for Chemists

Below are some examples of organizations that might meet state licensing requirements.³ APHL does not endorse any of these, nor is the list meant to be exhaustive.

American Association of Bioanalysts (AAB)

- http://www.aab.org/aab/AAB_Board_of_Registry.asp
- Categories include: Medical Technologist, Medical Laboratory Technician
- Example of the minimum criteria an individual must meet:
 - Completion of a clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) (formerly CAHEA), or other accrediting agencies approved by HHS. (This includes individuals who have earned an associate degree from an accredited community college with a major in medical technology.)
 - ~OR~
 - At least three (3) months of documented laboratory training in each specialty in which the individual performs high complexity testing. (This training may be included in the 60 semester hours of college credit constituting the equivalent of an associate degree.)
 - N.B. Individuals who have documented the required education but who lack the necessary training listed above may still challenge the MT(AAB) examinations. Upon passing the examinations, these individuals will be designated Medical Technologist-Provisional [MT-P(AAB)] until they complete the training in the applicable disciplines, at which time the provisional status will be removed.

² Another option is setting up an MOU or MOA with a local hospital to rotate staff through there.

³ Note that passing an examination may not be the only requirement for licensure; individuals may also need to meet their state's educational, training, experience, and continuing education requirements. Check with your clinical laboratory personnel licensing agency.

American Board of Applied Toxicology (ABAT)

- http://www.clintox.org/ABAT_Main.cfm
- Individuals must meet the following criteria: “A graduate of a college or university with an earned doctoral degree in a biomedical discipline. Applicants without doctoral degrees must possess a baccalaureate degree in a health science discipline, such as pharmacy or nursing, followed by a minimum of five years of full-time professional experience in applied clinical toxicology. Scholastic coursework is not considered to be professional experience.”

American Board of Toxicology (ABT)

- <http://www.abtox.org/HomePage.aspx>
- Individuals must possess the following: “an earned Bachelor's degree in an appropriate field and have at least ten years of full-time professional post-baccalaureate experience in toxicology or part-time equivalent of at least 10 years. In addition, the potential Diplomate must have principal involvement in the practice of toxicology within the year immediately prior to the date of application. Experience in the practice of toxicology should include such factors as research, testing, teaching, hazard assessment, safety evaluation, management, or clinical toxicology in animals or humans.”

American Medical Technologists (AMT)

- <http://www.americanmedtech.org/default.aspx>
- Categories include: Medical Technologists, Medical Laboratory Technicians, Medical Lab Assistants
- Example of the minimum criteria an individual must meet:
 - Graduated from, or scheduled to graduate from, an academic course (or combined courses) of study that is a minimum of 200 didactic clock hours in duration AND a minimum of 120 clock hours of documented, satisfactory clinical laboratory experience. Of the 200 didactic clock hours, a minimum of 100 hours must have been devoted to the study of fundamental laboratory technology.
 - Satisfactorily completed a minimum of 1,040 hours of documented work experience within the past three years in which laboratory technology was the primary focus. While all experiential hours must have been gained in a health care setting, a minimum of 520 hours must have been devoted specifically to the performance of clinical laboratory duties.

American Society for Clinical Pathology (ASCP)

- <http://www.ascp.org>
- Categories include: Technologist & Specialist in Chemistry
- An example of the minimum criteria an individual must meet: “Baccalaureate degree from a regionally accredited college/university, with a major in biological science or chemistry, or baccalaureate degree from a regionally accredited college/university with a combination of 30 semester hours (45 quarter hours) of biology, chemistry and/or medical sciences, AND one year full time acceptable clinical laboratory experience in chemistry in the U.S., Canada or an accredited laboratory within the last ten years”

National Registry of Certified Chemists (NRCC)

- Used by **American Association for Clinical Chemistry (AACC)** among others
- <http://www.nrcc6.org/>

- Categories include: Chemical Hygiene Officer, Clinical Chemist, Clinical Chemistry Technologist, Environmental Analytical Chemist, Environmental Analytical Technician, Toxicological Chemist
- Example of the minimum criteria an individual must meet: Academic training (no degree) with at least 10 semester hours (15 quarter hours) in chemical, physical, biological, industrial hygiene, environmental, or health and safety sciences from an institution acceptable to the Board and at least 5 years of employment experience relevant to environmental analytical chemistry.

Helping Others

As laboratories address these issues in their own jurisdiction, please consider submitting resources to APHL's Member Resource Center (<http://www.aphl.org/MRC/>). Resources might include lessons learned, MOUs, trainings, study guides, letters to licensure boards, et al.

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