

Why I believe licensure of Clinical Laboratory Professionals is necessary

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I believe licensure of Clinical Laboratory Professional is necessary for several reasons:

- Without a licensure law hospitals, clinics, and providers doing moderately or highly complex laboratory testing will not need to hire certified personnel, only personnel with the necessary education and “demonstrated competency” to perform the testing requested. The pertinent excerpt of the CLIA law follows:

§ 493.1487 Condition: Laboratories performing high complexity testing; testing personnel. The laboratory has a sufficient number of individuals who meet the qualification requirements of § 493.1489 of this subpart to perform the functions specified in § 493.1495 of this subpart for the volume and complexity of testing performed. § 493.1489 Standard; Testing personnel qualifications. Each individual performing high complexity testing must—(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) Meet one of the following requirements: (1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (2) (i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or—(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either—(1) 24 semester hours of medical laboratory technology courses; or (2) 24 semester hours of science courses that include—(i) Six semester hours of chemistry; (ii) Six semester hours of biology; and (iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (B) Have laboratory training that includes either of the following: (1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (3) Have previously qualified or could have qualified as a technologist under § 493.1491 on or before February 28, 1992; (4) On or before April 24, 1995 be a high school graduate or equivalent and have either—(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (5) (i) Until September 1, 1997—(A) Have earned a high school diploma or equivalent; and (B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has—(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (2) The skills required for implementing all standard laboratory procedures; (3) The skills required for performing each test method and for proper instrument use; (4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (5) A working knowledge of reagent stability and storage; (6) The skills required to implement the quality control policies and procedures of the laboratory; (7) An

awareness of the factors that influence test results; and(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and(ii) As of September 1, 1997, be qualified under § 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995;(6) For blood gas analysis—(i) Be qualified under § 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5);(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or(7) For histopathology, meet the qualifications of § 493.1449 (b) or (l) to perform tissue examinations. [57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20050, Apr. 24, 1995]

There are a few problems with this scenario. First, when personnel are hired and trained for specified tasks they have no prior *specific* education or training to do, situations may pop up, especially in small rural facilities that they are totally unequipped to handle. Ideally they would be under the supervision of certified people, but in these rural places, their supervisors may be tens or hundreds of miles away. Yes, some problems can be solved over the phone, but many cannot. How do you describe the difference between a monocyte and a hypogranular neutrophil over the phone? Second, how does one determine competency? Is someone competent to perform a WBC differential after doing 1?, 10? 100? Is there a certain acceptable rate of error? Who is the judge when the differential consists of 100 cells counted out of a possible 20,000 or more? Obviously the bar is different for different people. When a facility is under pressure to put a person on their own there may be pressure to lower the bar as far as possible and deem a person “competent” who is borderline at best. Third, nowhere in the CLIA description of education and training of laboratory personnel does it say anything about the person being able correlate the laboratory result with other results obtained in that person’s current condition, that panel of test results, or, in fact, life itself. I think that is a pretty important quality in a Laboratory Professional.

- One of the reasons I have heard for the review of the CLS license is that Laboratory Professionals are under Pathologists or other Medical Directors. Yes, but these directors in many instances visit the laboratories under their review once a month or less. I work in a large laboratory with 3 pathologists on staff and I don’t think a pathologist visits the lab section I work in that often. Pathologists or directors are responsible for reviewing policies and procedures in place in the laboratory to be sure that they are medically sound, but they don’t review our day to day results and many thousands of results go to patient records without review by the pathologists.
- Without the licensure law as written, facilities that hire certified personnel will not be assured that these people have maintained their certifications. Persons certified prior to 2004 have never been required to maintain certification, their certification was for life. In the rapidly developing world of health sciences, decades old knowledge and methods

just isn't good enough. We need to require better of the people caring for our patients in all of the allied health sciences.

- With the licensure law in force, Human Resource departments are required to check for the presence of the license before hiring Clinical Laboratory Professionals. In these days of increasing fiscal pressures on healthcare, facilities are under pressure to spend less and get more. I can say from personal experience that not all Human Resource Departments are responsible. I'm not sure of the reason, but all of our recently hired lower level licensed personnel have ID tags identifying them as higher level personnel. They rotate into the various laboratory sections and perform the testing they prove themselves capable of. Some are not capable of testing in all sections, yet are identified as capable of working in a supervisory capacity. I absolutely shudder to think what would happen if our license law is deemed unnecessary for some inexplicable reason.
- There are only a handful of states in the U. S. requiring licensure of their Clinical Lab Professionals, but that doesn't mean that Laboratory Professionals shouldn't be licensed. I am most familiar with Minnesota where laboratory workers have been trying year to year unsuccessfully to get their state to pass a licensure law. The reason is because of objections from the Minnesota Hospital Association and Minnesota Medical Association. The hospitals are afraid a licensed workforce will cost them more (we could tell them they won't), the physicians are afraid they won't be able to perform the testing they do in their offices and clinics as readily (most of that testing is waived and unaffected by licensure). Mayo clinic wasn't able to find enough qualified personnel to hire in their labs which do highly complex specialized reference testing, so they started their own NAACLS (National Association for Accreditation of Clinical Laboratory Sciences) accredited MLS program. Altogether there are 13 MLT programs and 6 MLS programs currently in Minnesota so a workforce shortage should not be an obstacle to licensure. Yet, as far as I know, Minnesota still has uncertified people with the requisite degrees and training working in its clinical laboratories.
- Montana's Clinical Laboratory Personnel Licensure Act as written has not prohibited any even marginally qualified people from entering and working in Montana as CLS or CLT professionals. Some wishing to enter and work in Montana have been required to complete the required CE to make the initial license application, but in my mind this is not unreasonable. It may present a temporary hardship for unemployed people, but in the long run it's a small price to pay. Montana's license is reciprocal with all other states having licensure laws and accepts the three major certification agencies, all of which accept military and other alternate routes to certification. I would prefer that Montana only accept the ASCP-BOR certification, but duly certified professionals who have been certified previously by AAB or AMT would then be barred from practice, so unless a facility HR department chooses to set that qualification, the law itself should probably remain unchanged. (The difference in ASCP and other certifications is that coursework prior to certification must be current within the previous 5 years.)

The only existing study on the accuracy of laboratory test results evaluates the effect on accuracy of having ASCP-certified MTs versus non-ASCP-certified MTs in the laboratory was published in 1987.²⁶ The study compared laboratories with all ASCP-certified MTs to those with no ASCP-certified MTs, and also compared laboratories based on the proportion of ASCP-certified to non-ASCP-certified MTs. It found that laboratories with all ASCP-certified MT staff had significantly higher accuracy in their test results compared with laboratories having no ASCP-certified MTs on staff. The study also found that, among laboratories having some ASCP-certified and some non-ASCP-certified MTs, accuracy of test results was positively related to the proportion of ASCP-certified MTs on staff.

Lunz ME, Castleberry BM, James K, Stahl J. "The impact of the quality of laboratory staff on the accuracy of laboratory results." JAMA. 1987 Jul 17;258(3):361-3

Cited in ASCLS position paper on Levels of Practice, July 2009 from ASCLS website.

We as a profession no longer need to fear the entry of "high school graduates" into our laboratories trying to do our jobs, true, but we still don't want to require our laboratory professionals who have their hands full with the day to day demands of their jobs trying to fill in the gaps in knowledge of an associate's or bachelor's degree holder with courses in biology and chemistry. These graduates don't necessarily know anything about immunology, hematology, medical microbiology, etc. There are accredited programs for that purpose, yes even in Montana. Montana is educating 15 Medical Laboratory Scientists every year, with the goal of these new graduates being placed back in their home town hospitals to work. These programs have defined curricula for their students that cover every aspect of Laboratory Science and the programs are accredited by NAACLS, which in turn is recognized by CAHEA (referred to in the CLIA law excerpted above).

The point isn't necessarily that only Montana grads should work in Montana, but that only properly educated and trained individuals should be licensed to work in Clinical Laboratories to do Moderately or Highly complex laboratory testing, or to have oversight of waived testing performed in clinic and hospital laboratories. Therefore the Clinical Laboratory Practice Act should remain as it is.