

# State Licensure of Laboratory Personnel

(Policy Number 05-02)

## Policy Statement

The American Society for Clinical Pathology (ASCP) believes that states should license laboratory personnel, and that state licensure legislation should ensure that laboratory personnel possess appropriate academic and clinical training, pass competency-based examinations conducted by an approved national certifying organization, and participate in continuing education programs.

## Background and Rationale

### I. Introduction

Due to the complexity of laboratory medicine and its importance in quality patient care, it is imperative that medical laboratory personnel possess the qualifications necessary to ensure their professional competence. Licensure and certification programs not only set minimum standards for medical laboratory personnel working in clinical laboratories; they also help ensure quality laboratory testing and proper patient care.

In this document ASCP outlines its view that licensure, when combined with certification, can help improve laboratory test quality and maintain laboratory personnel performance and competency. Review of the literature has not revealed any studies that have directly examined the question of whether licensure of laboratory practitioners improves test quality; however, there are studies that provide support for the idea that education, training and/or experience, and certification of laboratory personnel are linked to higher quality testing and performance. For these reasons, ASCP believes that when licensure includes these essential elements, overall test quality will improve.

ASCP supports personnel standards that incorporate certification, licensure, and practice requirements. These personnel standards must include the following essential elements: an appropriate academic degree, acceptable clinical training or work experience; passage of an examination offered by an approved national certification organization; appropriate continuing competency standards; and recognition of ASCP's professional terminology for laboratory personnel titles.<sup>1</sup>

### II. Occupational Regulation

Licensure and certification are two forms of occupational regulation. While licensure is generally well understood, certification is not, in part because this term is sometimes used interchangeably with licensure. Certification by governmental entities is also sometimes confused with certification by nongovernmental (private) organizations. The following section compares the differences between certification and licensure.

#### A. Certification

Certification is a less restrictive form of occupational regulation than licensure. A government or private entity can provide certification. Certification by a governmental entity is often referred to as "title protection." In general, governmental certification does not deal with the quality of work performed or the competence of persons performing a certain activity; it does not prevent noncertified personnel from performing the same services as "certified" personnel; it simply restricts the right to use a professional or occupational title.<sup>2</sup>



Laboratory professionals may be most familiar with certification as it relates to professional organizations or non-governmental agencies, such as the ASCP Board of Certification. In this instance, certification is a voluntary process by which the ASCP Board of Certification grants recognition of competency to persons who have satisfied predetermined qualifications, i.e., education, training and/or experience, and passage of a certifying examination.<sup>3</sup> Health care personnel can be certified without being “licensed,” as is the case with many clinical laboratory personnel.<sup>4</sup>

## **B. Licensure**

The most well known type of occupational regulation is licensure. Licensure refers to the right bestowed by a governmental agency or entity to engage in a legally defined occupational scope of practice.<sup>2</sup> With specified exceptions, this form of occupational regulation prohibits non-licensed individuals from providing certain services. Its intent is to “assure the public that practitioners have met the qualifications and minimum competencies required for practice.”<sup>5</sup> Licensure can address the maintenance of a licensee’s skill through continuing education and/or competency requirements. It can also “provide a universal benchmark for entry-level personnel.”<sup>6</sup>

State governments “license” hundreds of professions. One estimate indicates that more than 800 occupations are licensed by one or more states.<sup>7</sup> Among the healthcare occupations and professions licensed by states are physicians, nurses, midwives, physician assistants, radiologic technicians, chiropractors, physical therapists, and pharmacists. Among the non-health care related occupations regulated by the states are painters, general contractors, school bus drivers, barbers, bartenders, dogcatchers, septic system installers, and insurance agents.

It is clear that laboratory operations, including testing, have a major role in assessing and managing patient health; nevertheless, most states do not license laboratory practitioners. As of November 2009, 11 states and one territory license laboratory personnel.<sup>4</sup> These include: California, Florida, Hawaii, Louisiana, Montana, Nevada, New York, North Dakota, Rhode Island, Tennessee, West Virginia, and Puerto Rico. The state of Georgia does not license laboratory personnel but does specify personnel requirements that are more stringent than those required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Certification is utilized by every state that licenses laboratory personnel to assess the initial competency of licensure candidates.

## **C. Complementary Aspects of Licensure and Certification**

A careful examination of certification and licensure suggests that these regulations reinforce and complement one another rather than duplicate or compete with each another. Licensure provides the mechanism to accept and extend the concept of certification over time so that continued personnel competency is assured through periodic self-assessment, competency evaluation, and continuing laboratory education skills. Therefore, licensure can be the process through which laboratory personnel competency is continually maintained.

## **III. Justification for Licensure of Laboratory Personnel**

### *Are the Clinical Laboratory Improvement Amendments’ Personnel Requirements Sufficient?*

The Federal Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing (except research) performed on patients in the United States through CLIA.<sup>8</sup> CLIA provides a number of important patient protections, such as laboratory personnel standards, proficiency testing (PT), quality assessment and control requirements, and cytology testing standards.

The level of personnel skill and training required by the CLIA regulations depends on the complexity level of the testing performed.<sup>9</sup> Complexity levels include waived, moderate and high complexity. In order to perform laboratory testing of waived, moderate or high complexity tests, laboratory personnel must satisfy minimum standards for the level of testing they perform.

The CLIA personnel qualifications for the three categories of tests are:

- Waived Testing: Standards: None.
- Moderate Complexity Testing: Standards: Minimum requirement is a high school diploma or equivalent and documented training for the testing performed.<sup>10</sup>
- High Complexity Testing: Standards: Minimum requirement is an Associate degree, including 24 semester hours in science, and completion of either: (1) an accredited or approved clinical laboratory training program, or (2) three months laboratory training in the specialty(ies) in which the individual performs high complexity testing.<sup>11</sup>

The personnel standards required by CLIA address only the minimal requirements, and ASCP believes these are insufficient to fully protect patient and public health. For example, CLIA requires only an Associate degree and minimal laboratory training to perform tests of high complexity. Furthermore, the complexity of new test requirements, especially for genetic and molecular testing, is increasing and renders these standards insufficient. State licensure laws can and should provide higher standards. The adoption of higher standards will ensure that patient and public health are better protected.

Another factor that underscores the need for strong personnel standards is the requirement that laboratories must have the appropriate CLIA accreditation, including PT requirements. PT is an important educational and quality assurance tool used “to assist laboratories to identify and solve problems, evaluate personnel, and improve test results.”<sup>12</sup> CLIA does not require continuing education except when remediation is necessary after PT failure.<sup>6</sup>

#### **A. Waived Testing Laboratory Issue**

CLIA does not have any personnel requirements for waived testing. Furthermore, CLIA does not require direct oversight of waived testing personnel.<sup>13</sup> Individuals who perform waived testing may not be properly trained in specimen collection, preparation techniques, and the laboratory testing process.

A 2001 CMS study of facilities that performed waived testing and provider performed microscopy found widespread problems.<sup>13</sup> Registered nurses, licensed practical nurses, practicing physicians, and medical assistants performed most of the testing at these facilities; medical laboratory professionals rarely staff these facilities. The documented problematic findings included: (a) 64 percent failed to have and/or follow current manufacturer’s instructions for proper test performance; (b) 32 percent did not perform quality control as required by the manufacturer or the Centers for Disease Control and Prevention; and (c) 7 percent failed to perform required calibration according to the manufacturer’s recommendations. Moreover, 23 percent of waived testing laboratories surveyed did not have valid or appropriate CLIA certificates; 19 percent had inadequately trained or evaluated personnel; 9 percent did not follow the manufacturer’s storage and handling instructions; and 6 percent used expired reagents/test kits. Subsequent studies by CMS provide further evidence of quality problems at waived testing laboratories.

ASCP believes these findings raise concern about the quality of testing performed in these laboratories and the adequacy of CLIA requirements to safeguard public health. A survey of waived testing laboratories conducted by the Department of Health and Human Services Office of Inspector General also found similar problems, including misunderstanding CLIA requirements, untrained staff, and failure to identify incorrect results.<sup>14</sup> State licensure can address these CLIA weaknesses by requiring adequate training and certification of laboratory personnel in all laboratories. Alternatively, CLIA could be revised to require waived testing personnel to meet specific personnel requirements, such as specific training, assessments of competency by a qualified laboratory director, and competency assessment by examination.



## **B. Patient Safety and the Quality of Laboratory Testing**

### *(1) The Benefit of Higher Quality Testing Standards*

The justification for “licensure” is to protect the public from significant harm caused by incompetent or poorly trained members of an “occupational group.” Since laboratory tests form the basis for most medical diagnosis and therapy, the potential exists for serious harm from laboratory testing errors. Documenting quality in health care and the impact of personnel standards is often a difficult task, partly due to problems of measuring quality and isolating the independent effect of variables of interest. Quantifying quality has been an issue for the laboratory industry, which for years has been searching for additional indicators to monitor quality.

It appears that only a few studies have considered the relationship between laboratory test quality and laboratory personnel. These studies,<sup>15, 16, 17</sup> which examine PT data, lend support to the notion that test quality is influenced by the same requirements that are the foundation of personnel licensure, namely academic education, clinical training and/or work experience, and a competency assessment examination.

One study of California clinical laboratories investigated PT results in physician’s office laboratories (POLs) during calendar year 1996, the first year after the California legislature reduced the previously stringent laboratory testing standards.<sup>15</sup> Significant differences were found to exist among POLs, POLs using licensed medical laboratory scientists (formerly known as medical technologists), and non-POL laboratories. It was concluded that the failure rates for PT tests were significantly lower in POLs that included licensed laboratory professionals as part of the laboratory team.

Another study examining the relationship between the accuracy of laboratory PT results and certification<sup>16</sup> found that laboratories that employ only certified medical laboratory scientists produce significantly more accurate results on proficiency tests than laboratories that employ only noncertified scientists. They also found that in laboratories employing both certified and non-certified scientists, a greater proportion of certified medical laboratory scientists positively affects the accuracy of PT results.

A Centers for Disease Control and Prevention study in 1994 (the first year of compulsory participation under CLIA) analyzed PT performance by type of testing facility: hospital and independent laboratories (HI) and all other testing sites (AOT).<sup>17</sup> The aggregate rate of satisfactory performance for all regulated analytes, tests, and specialties was 97 percent for the HI group and 91 percent for the AOT group. The unsatisfactory performance by the AOT sites on three commonly utilized medical tests [glucose (15 percent), hemoglobin (9.1 percent) and bacteriology (7.2 percent)] was considered particularly notable. The study comments that the U.S. Health Care and Financing Administration (now the Centers for Medicare and Medicaid Services) indicates the staffs of alternative testing sites are less likely than hospital and independent laboratories to include a laboratory professional with training in personnel standards, quality control and quality assurance programs or be directed by a physician exposed to quality laboratory practice principles during training.

That study concluded that “the laboratory and health care community at large must work together to assure all individuals involved in the performance of clinical laboratory testing have the requisite knowledge and experience to provide optimally accurate and reliable test results.” Because state personnel licensure requirements require academic and clinical training as well certification, ASCP believes licensure should enhance laboratory test quality.



*(2) Impact of Laboratory Testing Error on Patient Health*

Medical diagnosis and therapy greatly depend on laboratory test results, and test result errors expose patients to a significantly higher risk of inaccurate diagnosis and improper treatment. A CMS study of waived testing laboratories indicates that incidents of failure to follow manufacturers' instructions may occur in as many as 60,000 laboratories and that this may "potentially harm patients."<sup>13</sup> Without adequate training of laboratory personnel, the likelihood of inaccurate test results increases.<sup>18</sup> A study of problems in laboratory testing in primary care estimates that more than 16 percent of incorrect test results affect patient care.<sup>19</sup> HCFA suggests that these patient care impacts include delays in receiving appropriate care and the possibility that inappropriate or harmful diagnoses or treatments could result in injury or death.<sup>18</sup>

Several well-publicized instances of problems in clinical laboratories in the past few years illustrate how errors in the testing process adversely affected patient health and well being.<sup>20, 21</sup> Both CMS and laboratory accrediting agencies have also encountered serious problems in recent years at laboratories across the United States.<sup>13, 14, 20, 21, 22</sup>

**C. Professional Recognition**

State licensure of laboratory personnel is an opportunity to increase professional recognition for the individuals who work in our nation's laboratories. This professional recognition could increase the recruitment of new individuals into laboratory medicine and promote the retention of current laboratory professionals. Licensure can promote a positive image beyond the walls of the laboratory to educate other health care providers, the public, and legislators about the value of laboratory tests in facilitating medical diagnosis and therapy and about the essential role of the entire laboratory team, e.g., pathologists, clinical scientists and other graduate level personnel, medical laboratory scientists, technologists\*, and technicians.

**IV. Regulatory Burdens and Lessons Learned**

While ASCP believes that licensure of laboratory personnel can improve quality testing, ASCP is simultaneously concerned about the potential for some state laws to create inappropriate or unnecessary burdens on the licensure process. Saddling potential licensees, training programs and clinical laboratories with extraneous requirements that have little or no relation to quality can create artificial personnel shortages and cause the closure of accredited academic and clinical training programs. Such requirements can adversely affect patient care, clinical laboratories and laboratory personnel.

When New York established licensure for laboratory personnel, the state imposed a number of extraordinary burdens that have made licensure difficult or impossible for a number of qualified potential licensees and clinical training programs\*\* These requirements have also hampered clinical laboratories in their efforts to appropriately staff their facilities with skilled personnel. Among these burdens was a requirement that accredited academic and clinical training institutions granting degrees or certificates to potential licensee undergo a rigorous state approval process before the state would recognize the academic degrees or clinical training earned at these programs. Moreover, New York's approval process was not consistent with accreditation requirements. The result was that potential licensees were caught in limbo in disputes between the state, accrediting agencies, and training programs.

\* This term includes categorical technologists as well as chemists, cytogeneticists, cytotechnologists, hematologists, histotechnologists, immunohematologists (blood bankers), immunologists, microbiologists, molecular biology technologists, and other baccalaureate-level technologists working in a medical laboratory.

\*\* At least one clinical training program is believed to have closed as a direct result of the New York Department of Education training program requirements.

New York also mandates that training programs must provide both “didactic and clinical training.” Since many, if not, most clinical laboratory training programs are not affiliated with a college or university, training at these “independent” programs, even when accredited, are not considered acceptable for purposes of licensure. Because New York has refused to recognize work experience or on-the-job training, the only route to meeting New York’s clinical training requirement appears to be completion of laboratory training at a state-approved, accredited college or university.

Moreover, when California recognized ASCP’s certification examinations, it refused to recognize certifications earned more than five years before the state recognized ASCP’s examinations. The effect has been to discourage certified personnel from seeking employment opportunities in California.

ASCP is unaware of any evidence suggesting that these mandates have any quality benefit. Such requirements needlessly interfere with the licensure process and should be avoided. To guard against unnecessary or inappropriate burdens on the licensure process, ASCP believes that states should keep licensure requirements to the minimum and where appropriate harmonize their requirements with those of recognized accrediting and certification agencies. Moreover, ASCP believes states should accept academic degrees and training credentials granted by institutions that are accredited by an agency recognized by the U.S. Department of Education or U.S. Department of Health as satisfying state academic and clinical training requirements.

Further, in recognizing certification examinations states should recognize ASCP credentials, regardless of when they were earned.

## **V. Components of Laboratory Personnel Licensure Laws**

In order to ensure that state licensure programs will set appropriate standards for excellence in laboratory medicine, certain key elements must be included in state laws or legislation to license laboratory personnel.

### **A. Academic Education and Clinical Training**

The overall competence of laboratory professionals is strongly influenced by the amount of academic education and training they possess. To recognize the importance of competence to patient outcomes, test quality, and personnel qualifications, ASCP developed and approved a policy statement on personnel standards for laboratory professionals in 2004.<sup>23</sup> That policy states that a medical laboratory scientist/technologist should “possess a baccalaureate degree and successfully complete an accredited or approved training program or specified work experience.” A technician should possess an Associate degree, successfully complete an “accredited or approved medical laboratory training program,” and be able to perform high complexity testing.

### **B. Certification**

Certification examinations offer the most reliable, cost-effective means to ensure that laboratory staff are competent. Licensure programs should require laboratory professionals to pass a competency assessment examination, such as that provided by a recognized national certification organization like the ASCP Board of Certification.

### **C. Grandfather Provisions**

To prevent disruption of the medical laboratory workforce, laboratory personnel licensure bills should include “grandfathering provisions” to allow individuals who have established careers as laboratory personnel to continue working at their current professional level. Typically, state licensure laws for laboratory personnel spell out certain criteria allowing an established laboratory practitioner to be licensed. At a minimum, grandfather provisions would need to conform to the requirements specified by CLIA for high complexity testing. This would generally require



laboratory personnel to possess an Associate degree and appropriate clinical laboratory training, but could involve lesser qualifications depending on CLIA's requirements and the amount of work experience possessed by the laboratory practitioner. Individuals licensed via grandfathering provisions should be certified, provided they are eligible for a state-approved certification examination.

**D. Continuing Education**

A continuing education requirement should be included in state licensure laws. Continuing education can help maintain the skill level of licensed laboratory personnel (especially as it relates to bioterrorism and new technologies) and is therefore a useful mechanism to ensure patient health and welfare.

**E. Scope of Practice**

State licensure laws must define the scope of practice for laboratory professionals. The passage of a state licensure law is an opportunity to reaffirm the scope of practice for laboratory professionals and to ensure adequate personnel standards and protection of patient safety and health.

In recent years, a variety of health care practitioners, such as pharmacists, registered nurses, and midwives, have attempted to expand their scope of practice to include performing and/or interpreting laboratory tests as well as directing or owning clinical laboratories. These health care practitioners generally lack the proper training and experience to ensure quality testing. Such persons may also be performing testing without regard to federal and state laws designed to ensure quality testing.<sup>13</sup> Licensure will help protect the laboratory professionals' scope of practice by guaranteeing that only qualified individuals do testing in all laboratory areas.<sup>6</sup>

ASCP in its policy statement "Scope of Practice Issues Affecting Pathology and Laboratory Medicine"<sup>24</sup> states that:

*Every clinical laboratory, regardless of the complexity of testing it performs, should be under the overall medical supervision of a board-certified pathologist. While the pathologist must ultimately be responsible for each laboratory's medical, scientific, and technical operations, he or she may delegate the management of the laboratory's technical and administrative operations to other skilled laboratory practitioners, such as a senior certified medical technologist, cytologist, or histotechnologist. In addition, clinical laboratories should rely only on qualified laboratory personnel, i.e., certified medical and other technologists, cytotechnologists, and medical laboratory technicians, to perform laboratory tests and procedures.*

ASCP believes that medical laboratory scientists, technologists and technicians should, under the direction of the laboratory director, be able to perform waived, moderate complexity and high complexity testing. ASCP believes that scientists and technologists should be afforded the following scope of practice:

*to perform, interpret and correlate laboratory procedures requiring the broad exercise of independent judgment and responsibility with minimal technical supervision. A technologist may maintain equipment and records, establish and implement protocols, select or develop test methodology, perform quality assurance activities related to test performance.<sup>25</sup>*

Medical laboratory technicians and other technicians should be provided the following scope of practice:

*to perform laboratory procedures according to established and approved protocols that require the limited exercise of independent judgment and interpretation. The technician performs laboratory procedures across the major areas of the laboratory or concentrates activity in an area such as histology.<sup>28</sup>*



#### **F. Licensure Compact: Recognizing Out-of-State Licensure**

State licensure laws typically contain provisions requiring the licensing state to recognize licenses granted by other states as meeting state licensure requirements, provided the other state's licensure laws are equal to or more stringent than their own. Unfortunately, it appears that a number of states do not consider other state licenses to be their equal. This blocks a valuable route to licensure, particularly for individuals who have been working in laboratory medicine for years and may not be able to meet updated personnel requirements. ASCP believe that by simplifying licensure laws to rely on accredited academic education and clinical training, as proposed in this policy statement, these barriers to interstate employment can be lessened.

#### **VI. Summary**

ASCP believes that individual states should license laboratory personnel. The important work performed by clinical laboratory professionals affects the health, safety and welfare of the public. Licensure is an effective tool to encourage laboratory professionals to possess the skills and expertise needed to perform quality testing. It is the foundation that will guarantee that licensed laboratory professionals possess adequate academic and clinical training, pass competency-based examinations, and participate in continuing education programs.

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<sup>2</sup> Occupational Regulation: A Program Evaluation Report. Office of the Legislative Auditor. State of Minnesota. February 1999. p. xii.

<sup>3</sup> Procedures for Examination and Certification. ASCP Board of Registry. 2005.

<sup>4</sup> State-Mandated Licensure of Laboratory Personnel. *LabMedicine*. 2004; 35; 596.

<sup>5</sup> Health Professions Education: A Bridge to Quality. Institute of Medicine. National Academies Press. Washington, DC. P. 104.

<sup>6</sup> Elgert, P. Point-Counterpoint: State Licensure. *LabMedicine*. 2004; 35: 751-2.

<sup>7</sup> Berry, F. State Regulation of Occupations and Professions. *The Book of the States*. Council of State Governments. 1986. p. 379.

<sup>8</sup> Section 353 of the Public Health Service Act, Subpart 2, Certification of Laboratories 9 42 Code of Federal Regulations Section 493.5 Categories of tests by complexity.

<sup>10</sup> 42 Code of Federal Regulations Section 493.1423(b)(4)(ii)

<sup>11</sup> 42 Code of Federal Regulations Section 493.1489 Standard; Testing personnel qualifications (high complexity).

<sup>12</sup> Schoonmaker, M. Memo on Follow up to the Hearing on "Ensuring Accuracy and Accountability in Laboratory Testing" held May 18, 2004. Library of Congress Congressional Research Service. Washington, DC.

<sup>13</sup> Certificate of Waiver and Provider Performed Microscopy Procedures Pilot Project Overview. U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services. 2001.

<sup>14</sup> Enrollment and Certification Processes in the Clinical Laboratory Improvement Amendments Program. U.S. Department of Health and Human Services Office of Inspector General. August 2001 OEI-05-00-00251.



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- <sup>24</sup> ASCP Model Bill for State Licensure of Medical Laboratory Personnel. July 29, 1999.
- <sup>25</sup> Steward, C.A., Schulze, F.M. ASCP Survey on Laboratory Personnel State Licensure. *LabMedicine* 2005: 36. (ASCP anticipates publishing this data in the September 2005 issue)