



American Society for Clinical Pathology

THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY
POLICY STATEMENT

STATE LICENSURE OF LABORATORY PERSONNEL (POLICY NUMBER 05-02)

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POLICY STATEMENT:

Because the important work performed by laboratory professionals affects the health, safety and welfare of the public, the American Society for Clinical Pathology (ASCP) believes that states should license laboratory personnel. Licensure legislation would 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: appropriate academic education and clinical training; 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.¹

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 non-certified personnel from performing the same services as "certified" personnel; it simply restricts the right to use a professional or occupational title.²

Laboratory professionals may be most familiar with certification as it relates to professional organizations or non-governmental agencies, such as the ASCP Board of Registry (BOR), the National Credentialing Agency for Laboratory Personnel (NCA), and the American Medical Technologists (AMT). In this instance, certification is a voluntary process by which the ASCP BOR, NCA, and AMT grant recognition of competency to persons who have satisfied predetermined qualifications, i.e., education, training and/or experience, and passage of a certifying examination.³ Health care personnel can be certified without being "licensed," as is the case with many clinical laboratory personnel.⁴

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.² 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."⁵ 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."⁶

State governments "license" hundreds of professions. One estimate indicates that more than 800 occupations are licensed by one or more states.⁷ 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 June 2005, 10 states and one territory license laboratory personnel.⁴ These include: California, Florida, Hawaii, Louisiana, Montana, Nevada, North Dakota, Rhode Island, Tennessee, West Virginia, and Puerto Rico. 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

a. 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 the Clinical Laboratory Improvement Amendments of 1988 (CLIA).⁸ 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.⁹ 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.¹⁰
- **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.¹¹

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.”¹² CLIA does not require continuing education except when remediation is necessary after PT failure.⁶

b. 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.¹³ 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.¹³ 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.

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.¹⁴ State licensure can address these CLIA weaknesses by requiring adequate training and certification of laboratory personnel in all laboratories.

c. 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,^{15, 16, 17} 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.¹⁵ Significant differences were found to exist among POLs, POLs using licensed 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 certification¹⁶ found that laboratories that employ only certified medical technologists produce significantly more accurate results on proficiency tests than laboratories that employ only non-certified technologists. They also found that in laboratories employing both certified and non-certified technologists, a greater proportion of certified medical technologists 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).¹⁷ 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 HCFA indicates the staffs of alternative testing sites are less likely to include a laboratory professional with training in personnel standards, quality control and assurance programs, or be directed by a physician exposed to quality laboratory practice principles during training than hospital and independent laboratories.

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.”¹³ Without adequate training of laboratory personnel, the likelihood of inaccurate test results increases.¹⁸ A study of problems in laboratory testing in primary care estimates that more than 16 percent of incorrect test results affect patient care.¹⁹ The U.S. Health Care and Financing Administration (now the Centers for Medicare and Medicaid Services) 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.¹⁸

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.^{20, 21} Both CMS and laboratory accrediting agencies have also encountered serious problems in recent years at laboratories across the United States.^{13, 14, 20, 21, 22}

d. Preparedness for Bioterrorism and Pandemic Threats

Federal and state public health agencies have an important role in preparing laboratories for bioterrorism and pandemic threats. The licensure of qualified laboratory practitioners can provide a mechanism to ensure adequate performance of laboratory personnel in dealing with bioterrorism and a pandemic infectious disease outbreak. In the event of a bioterrorist event:

*clinicians will rely heavily upon laboratory tests for diagnostic clues as to the etiologic agent. Pathologists and laboratory personnel are most likely to first receive patient specimens for etiologic agents that may be used in bioterrorism and toxins that may be used as chemical weapons. Laboratory professionals must provide prompt and accurate test results so that a potential outbreak can be detected, provide support for hospitals and clinics caring for affected patients and assist in the development of an integrated epidemic network. Laboratory professionals must be trained to recognize microbial pathogens likely to be used for bioterrorism; to safely collect, transport and process specimens containing biological agents associated with bioterrorist acts; to follow chain of custody and other legal requirements; and to understand the role of mass disaster support services.*²³

ASCP’s policy statement “Bioterrorism, the Role of Clinical Laboratories and the Laboratory Workforce”²⁴ calls on the federal government to enhance the role of the clinical laboratory and

the workforce. In particular, the statement focuses on strategic recommendations to better prepare clinical laboratories in the event of a bioterror attack. These recommendations can only be achieved with a qualified laboratory workforce. In our opinion licensure can help ensure that the laboratory workforce possesses the necessary training, skills, and expertise to handle these threats effectively.

e. 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, technologists,ⁱ and technicians.

IV. Impacts of Licensure on Laboratory Personnel Wages and Labor Force

Licensure has been an often-debated topic within the laboratory community for years, if not decades. Two issues often cited by those opposed to licensure are that licensure will increase wages and adversely affect the labor supply. To examine these issues, ASCP staff reviewed wage and labor supply data for “medical and clinical laboratory technologists and technicians” collected by the Health Resources and Services Administration (HRSA) as part of the agency’s State Health Workforce Profiles. Analysis of the HRSA data reveals a mean of 109.73 laboratory practitioners per 100,000 residents in “licensing” states^{ii, iii, 25} versus 103.97 for “non-licensing” states; however, these figures are not statistically different. A statistical analysis of wages reveals a mean hourly wage for licensing states of \$15.35 and a mean hourly wage of \$15.06 for non-licensing states; however, these differences are not statistically significant, even when cost of living and median income are considered.

ASCP staff also examined data from ASCP’s 2002 wage and vacancy survey.²⁵ Again, no statistically meaningful differences were found in the wages of licensing and non-licensing states for medical technologists, medical technologist supervisors, medical technologist managers, cytotechnologists, cytotechnologist supervisors, histotechnologists, histotechnologist supervisors, medical laboratory technicians, and histotechnicians.

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

ⁱⁱ For purposes of this examination, the state of Georgia was included. Georgia does not license technologist- or technician-level personnel but does specify education and training/experience requirements for them.

ⁱⁱⁱ For the purposes of this examination, California was excluded because it does not license medical laboratory technicians. This does not alter the conclusion that there is no statistical difference between licensing and non-licensing states in terms of wages and labor market size.

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 2004.²⁶ That policy states that a 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 BOR, NCA, or AMT.

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.¹³ Licensure will help protect the laboratory professionals' scope of practice by guaranteeing that only qualified individuals do testing in all laboratory areas.⁶

ASCP in its policy statement "Scope of Practice Issues Affecting Pathology and Laboratory Medicine"²⁷ 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 both 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 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.*²⁸

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.*²⁸

VI. ASCP Survey on State Licensure

To better understand the views of its members, ASCP conducted a membership survey on the licensure of medical laboratory personnel. Development of the survey took place over several months and underwent extensive review by ASCP leadership and staff. Special care was taken to ensure that the survey did not bias members in favor or against licensure. The survey was officially launched in October 2004 and was completed the following December. Over 68,000 ASCP members, including 7,766 pathologists, were asked to participate in an Internet-based survey. More than 10,000 members, including 544 pathologists, completed the survey. The response rate among the overall membership was 15 percent and slightly more than 7 percent for pathologists. To our knowledge, it is the most comprehensive and detailed survey on the issue of laboratory personnel licensure.²⁹

ASCP members received from ASCP a letter explaining the survey and informing them of the licensure criteria on which ASCP sought their opinions. The letter outlined that for the survey, the licensure standards for medical technologists and other technologists should be understood as requiring a bachelor's degree, work experience/training, and certification. For medical laboratory technicians, an Associate degree, successful completion of a medical laboratory training program, and certification would be required.

Support for licensure was clear and unequivocal; approximately 72 percent of all respondents indicated support while only 18 percent indicated opposition (10 percent expressed no opinion). The ratio of support to opposition was approximately 4:1. Support for licensure among pathologists, was more than 2:1; 62 percent supported licensure while 26 percent were opposed (12 percent expressed no opinion).

When ASCP compared the data from members in licensure and non-licensure states, it found that licensure was strongly supported in both groups. In licensure states, overall support for licensure was 90 percent, with 10 percent opposed. In non-licensure states, overall support was 77 percent, with opposition at 23 percent. Pathologists surveyed in both licensure and non-licensure states supported licensure by a ratio of more than 2:1 in both types of states.

VII. 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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