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Medical Laboratory Advisory Committee:

We would like to converse about the Nevada State Pathologists' Assistant (PA) License, and the regulations for it. To introduce ourselves, the American Association of Pathologists' Assistants (AAPA) is a not-for-profit volunteer organization of allied health practitioners. We are the premier professional association for Pathologists' Assistants, supporting the individual practitioners as they serve patients, pathologists, and the profession. While we are greatly appreciative of the efforts that have been put forth to recognize the PA profession by establishing licensure for us in Nevada, we believe that the requirements for obtaining this license are ready to be revised to be more in line with the rigorous training PA's complete to be a fully practicing allied health professional. The state license is a way of protecting the public's health, safety, and welfare through indicating the successful passing of this rigorous training by the licensee. However, the current requirements to obtain the license do not guarantee that this training has been completed, as outlined below.

The current Nevada State Pathologists' Assistant License regulations, outlined in Chapter 652 of the Nevada Administrative Code, include two options for eligibility:

Option 1: Completing a NAACLS-accredited PA training program approved by the AAPA

Option 2: Obtaining a baccalaureate degree with a major or minor in a biological science or allied health field AND at least 3 years of combined experience in surgical pathology and autopsy pathology, which is verified with a signed/dated letter on letterhead from the laboratory(s) where the experience is obtained

These requirement options were inclusive and sufficient for the initial implementation of the PA license, and we are appreciative of your recognition. At this time, the AAPA is hopeful that you will consider adjusting the requirements to further protect and strengthen the PA profession in Nevada which will also have a positive impact on public health. The pathologists' assistant profession has followed the same steps as other licensed professionals such as nurse practitioners and physician associates, by developing National Accrediting Agency for Clinical Laboratory Science (NAACLS) accredited programs, then establishing a national board of certification through the American Society for Clinical Pathology (ASCP). Since 2010, the only pathway to PA certification through the ASCP is to complete an accredited PA program and obtain a passing score on the national board certification examination. In the past, the PA programs were split between bachelor's and master's degrees; however, all of the accredited PA programs have been converted or established as Master of Science programs. In light of the educational standardization of the PA field, we urge you to revise the state standards and educational requirements for obtaining a PA license in your state.

Our proposed new eligibility requirement is, as follows:

1. Completing a NAACLS-accredited Pathologists' Assistant training program, AND obtaining a passing score on the Pathologists' Assistant certification exam of the American Society for Clinical Pathology Board of Certification (ASCP-BOC) **OR**
2. Have previously qualified and obtained PA certification through ASCP prior to 2010 and maintained certification via the ASCP's certificate maintenance program OR
3. Have previously been licensed by the state of WV prior to [*effective date of changes*].

PA's who became ASCP-certified before 2010 when the PA program requirement went into effect, providing appropriate documentation of said certification should be seen as equivalent and suffice for licensure. A sunset period may be necessary, to allow for currently licensed laboratory personnel to retain their positions based on the original state requirements or become compliant with the new standards over a period of a few years.

Amending the Nevada license eligibility requirements to what the AAPA has proposed above is the natural next step to echo the current ASCP certification requirements. This amendment would not only provide more accurate verification of practicing PA's but also ensure the quality of patient care provided by Nevada PA's is being held to the highest standards of the profession. The AAPA believes New York is the best representation of our stance on requirements for licensure. We have linked the current licensing requirements in New York, for your information.

(<https://www.op.nysed.gov/professions/pathologists-assistant/license-requirements>). We have also included copies of our scope of practice, how licensure support document, AAPA tenants on licensure, the ASCP position on licensure and AAPA position on non-pathologist grossing personnel for your review and support.

We are truly appreciative of the efforts that have been put forth to provide a source of verification and legitimacy for PA's practicing in Nevada through the current licensure. Now, we call upon you once again to join in our vision of professional improvement by amending the licensure requirements to protect the hard work being done by the ASCP-certified PA's in Nevada. Thank you for your time and consideration. Please reach out to the AAPA if you have any questions. We would be happy to attend a MLAC committee meeting to further discuss this proposal.

Sincerely,



Jennifer Perez, Board of Trustee Chair, AAPA



Jennifer Hudson, legislative chair, AAPA



Arianna Rubinetti, legislative vice chair, AAPA

Introduction to the Pathologists' Assistant Scope of Practice

Definition

A Pathologists' Assistant is a highly trained, certified allied healthcare professional who is qualified by academic and practical training to provide various services in anatomic pathology under the direction and supervision of a licensed, Board Certified or Board Eligible Anatomic Pathologist. Pathologists' Assistants are academically and practically trained to provide accurate and timely processing of a variety of laboratory specimens, including comprehensive macroscopic examination and evaluation of all surgical pathological specimens. Pathologists' Assistants also perform postmortem examinations including prosection, assisting the Pathologist with rendering the provisional anatomic diagnosis, composing the clinical history, recording the macroscopic anatomic findings, and submitting tissue sections for microscopic examination. Pathologists' Assistants play a critical role in the delivery of healthcare services in both surgical pathology and autopsy pathology. They are key partners in assisting the Pathologist to arrive at a pathologic diagnosis, but it is the sole responsibility of the Pathologist to render a diagnosis.

Pathologists' Assistants often are responsible for the organization and operational management of the surgical pathology suite and the anatomic pathology service. This may comprise personnel management including supervising accessioners, lab aides, grossing technicians, and transcriptionists in the surgical pathology suite and autopsy technicians/morgue assistants in the autopsy room; writing and reviewing surgical pathology and autopsy procedures; inventory control; laboratory operations such as quality assurance, quality control, accreditation inspection preparation, and budgeting; and in the academic setting, supervision of learners (e.g., Pathologists' Assistant students, medical students, post-sophomore fellows, and residents) and providing shadowing experiences to prospective Pathologists' Assistant students, and college or high school students interested in healthcare.

A Pathologists' Assistant need not provide all the services listed in the Scope of Practice in the performance of their duties; however, it is expected that the Pathologists' Assistant will have received appropriate academic and practical training to provide these services.

Education and Certification

Pathologists' Assistants currently prepare for their roles as advanced practice practitioners in anatomic pathology by successfully completing a NAACLS accredited Pathologists' Assistant training program and by attaining certification as a Pathologists' Assistant from the American Society for Clinical Pathology Board of Certification (ASCP BOC). Prior to 2010, Pathologists' Assistants who had received on-the-job training (via a 3-year supervised internship) and had successfully attained certification as a Pathologists' Assistant from the American Society for Clinical Pathology Board of Certification have the same qualifications as NAACLS program-trained individuals and are capable as advanced practice practitioners in anatomic pathology.

Both NAACLS program-trained and grandfathered on-the-job trained Pathologists' Assistants who pass the ASCP BOC Pathologists' Assistant Certification Examination use the credentials PA(ASCP) and are qualified as competent mid-level practitioners in anatomic pathology. To maintain a level of expertise and awareness of changes and advances in practice and maintain certification, the Pathologists' Assistant

must complete approved Credential Maintenance Program (CMP) requirements in three-year cycles, as defined by the American Society for Clinical Pathology Board of Certification. Following completion of the CMP program, the CM superscript designation is appropriate; PA(ASCP)^{CM}.

Pathologists' Assistant Scope of Practice (updated 3/28/2023)

A Pathologists' Assistant is qualified by formal academic and practical training to perform the following tasks under the direction and supervision of a licensed, Board Certified or Board Eligible Anatomic Pathologist:

(Comment: this scope of practice is not meant to be utilized as a job description)

Surgical Pathology

Preamalytical Tasks

- Assure proper specimen collection and submission prior to accessioning.
- Assist clinicians with specimen collection questions, triage of limited samples, and esoteric testing.
- Assure appropriate specimen accessioning and/or verification of unique patient identifiers.
- Assure proper specimen handling and fixation prior to processing.
- Obtain and review pertinent clinical information and history, including imaging studies, laboratory results, and operative records.
- Discuss cases and history with surgeons, clinicians, and pathologists.

Analytical Tasks

Macroscopic Description and Dissection

- Perform the macroscopic description and dissection of all surgical specimens ranging from simple to complex cases including pertinent macroscopic information for the staging of complex cancer cases.

Tissue Sampling

- Prepare and submit tissue sections for light microscopy.
- Obtain samples for ancillary studies including, but not limited to:
 - Tumor triage
 - Lymphoma protocol
 - Flow cytometric analysis
 - Immunofluorescence
 - Immunohistochemistry
 - Microbial cultivation
 - Molecular microbiology
 - Cytogenetic analysis
 - Electron microscopy
 - Tissue banking and clinical trials
 - Research

- Microarray
- Institutional tumor registries

Perform Surgical Pathology Special Procedures including, but not limited to:

- Decalcification
- Frozen section (tissue selection, dissection, embedding, mounting, cutting/staining, cover-slipping)
- Intraoperative consultation for evaluation of macroscopic specimen adequacy and margins
- Muscle biopsy preparation
- Assessment of renal biopsy specimens for adequacy by evaluation of the presence of glomeruli
- Nerve biopsy orientation and preparation
- Heart and other transplant biopsy preparation
- Bone marrow aspirate and biopsy preparation
- Touch preparations/imprints/squash preparations
- Tumor mapping
- Bone saw operation

Imaging

- Specimen photomacrography
- Photomicrography
- Specimen radiography
- Slide scanning

Postanalytical Tasks

- Review of macroscopic description transcription.
- Microscopic triage of surgical pathology cases for quality control and quality assurance purposes.
- Coding
 - Verify the accuracy and editing of CPT codes.
 - Assign, review, and edit SNOMED codes.
- Store and properly dispose of specimens.
- Assist in the organization and coordination of surgical pathology conferences.
- Assure proper maintenance of equipment and provision of adequate supplies.

Autopsy Pathology

Prosection of adult, neonatal/perinatal, pediatric, forensic, or infectious autopsies

Preanalytical Tasks

- Assure proper autopsy authorization, permission, and release of body documents.
- Review the patient's medical record including imaging studies and laboratory results, etc.
- Discuss with the attending Pathologist(s) to identify any special techniques and procedures to be utilized in the completion of the postmortem examination (e.g., tissue for microbial cultivation, histochemistry, molecular analysis, microarray, PCR analysis, immunofluorescence, toxicological, viral, or electron microscopic studies, etc.), and notify all personnel directly involved.
- Notify decedent's physician, the funeral home, and all other appropriate authorities prior to the commencement of the autopsy; and coordinate any requests for special specimen sampling (e.g., organ and tissue procurement for transplantation, research, etc.).

Analytical Tasks

Autopsy Performance

- Perform postmortem examinations including:
 - External examination
 - In situ organ inspection
 - Evisceration
 - Dissection and dictation or recording of data including organ weights, measurements, presence and quantitation of body fluids, and macroscopic anatomic findings

Tissue Sampling

- Select, prepare, and submit appropriate and ample tissue samples for the following:
 - Frozen section
 - Permanent section
 - Immunofluorescence
 - Electron microscopy
 - Microbial cultivation
 - Tissue banking or research
 - Cytogenetic analysis
 - Toxicology
 - Decalcification
 - Microarray
 - Metabolic studies

Autopsy Special Procedures

- Perform Autopsy special procedures including:
 - Obtaining blood/body fluids for clinical pathologic testing
 - Cut and stain frozen sections
 - Bone marrow sampling
 - Spinal cord removal

- Long bone removal
- Coronary artery perfusion
- Central nervous system perfusion
- Corneal removal and/or orbital enucleation
- Temporal bone removal
- Sample collection for research

Imaging

- Photomacrography of the body, internal organs, lesions, and other pertinent findings and external or internal identification markings
- Photomicrography
- Image analysis
- Radiography

Preparation of Reports

- Clinical history
- Assist with preparation of the provisional anatomic diagnosis (PAD)
- Macroscopic (gross) description
- Assist with preparation of the final summary/clinical pathologic correlation

Postanalytical Tasks

- Reconstruct and prepare the body for release and maintain HIPAA criteria for the release of the body to the appropriate mortuary or funeral home representative.
- Assure accurate completion of a microscopic section log.
- Perform duties related to completion and finalization of the autopsy procedure and report including administrative maintenance of anatomic pathology protocols; photomacrography and photomicrography images; assignment, review, and editing of SNOMED codes; and compliance with laboratory accreditation criteria.
- Assist in the organization and coordination of anatomic pathology conferences.
- Assure proper maintenance of equipment and provision of adequate supplies.

Laboratory Operations

Regulatory

- Prepare for laboratory accreditation inspection.
- Write, maintain, and update policy and procedure manuals.
- Monitor compliance with regulatory agencies (e.g., The Joint Commission, College of American Pathologists [CAP], state and local accrediting agencies).

Quality Improvement

- Prepare and maintain quality assurance monitors (e.g., frozen section/permanent section concordance/discordance, turn-around-time reports).
- Participate in quality assurance/process improvement activities.
- Participate in general problem solving and troubleshooting in pathology technical issues.
- Review of microscopic slides for section adequacy (*not diagnostic interpretation*).

Safety

- Apply laboratory safety governmental regulations and standards as practical to anatomic pathology.
 - Monitor compliance with safety regulatory agencies (e.g., OSHA).
- Implement appropriate safety procedures in relation to specific biohazards (e.g., TB, CJD, COVID-19)
- Participate in safety training (e.g., chemical hygiene, infection control), avoid biological hazards, and practice proper use of personal protective equipment.
- Maintain the cleanliness of the surgical and autopsy pathology suites, gross station, and instruments with daily disinfection.

Management Activities

- Perform laboratory administration activities including surgical pathology workflow and scheduling.
 - Record and evaluate workflow and personnel metrics.
- Prepare laboratory budgets and purchase equipment.
 - Order supplies/perform inventory control.
- Perform personnel management activities including hiring, disciplinary action, job description creation, supervision, and performance evaluations.
- Attend and prepare for conferences (e.g., tumor board, grand rounds, journal club, and morbidity and mortality conferences).
- Develop, implement, and evaluate a competency testing program encompassing ACGME guidelines where appropriate.
- Provide guidance in new laboratory design and construction.

Education

- Educate and train pathology residents, new employees, students, and technical staff.
- Participate in the development of a didactic curriculum for educational processes.
- Perform formal evaluation of residents, Pathologists' Assistant students, and medical students.

- Educate nursing and hospital staff on best practices in pathology including proper specimen collection procedures and triage.
- Present at academic conferences.
- Community outreach educating colleagues and the public about laboratory medicine.
- Participate in professional organizations.

Laboratory Information Systems

- Responsibilities may involve analysis, design and implementation including:
 - Data gathering and analysis of methods and procedures
 - Design recommendations in the form of user proposals
 - Operational instructions
 - Computer program specifications
 - Implementation and support involving systems testing
 - User training
 - Telepathology systems

Research

- Develop Institutional Review Board (IRB) proposals.
- Coordinate and manage tissue banking activities (e.g., obtain consents, appropriate tissue collection, tissue storage, release of tissues, review of protocols).

Ancillary duties (may include):

- Maintain equipment (e.g., calibration, performance checks, identification of malfunctions).
- Assess new technology for possible implementation.
- Validate new tests or instruments.
- Quality control (e.g., stain check, temperature check).
- Comply with regulatory requirements for specimen storage and disposal.
- Service on institutional committees.
- Participate in faculty recruitment.

REFERENCES:

- 1) AAPA Bylaws, Scope of Practice. www.pathassist.org
- 2) American Society for Clinical Pathology Board of Certification Task Analysis
- 3) Vitale J, Brooks R, Sovocool M, Rader WR. Value-Added Benefits and Utilization of Pathologists' Assistants. *Arch Pathol Lab Med.* 2012;136:1565-1570.
- 4) Grzybicki DM, Reilly TL, Hart AR, et al. National Practice Characteristics and Utilization of Pathologists' Assistants. *Arch Pathol Lab Med.* 2001;125:905-912.
- 5) Changes in Healthcare Professions' Scope of Practice: Legislative Considerations. http://www.ncbn.org/ScopeofPractice_09.pdf. Published October 2009. Accessed October 1, 2017.



AAPA Tenets on State Licensure

The American Association of Pathologists' Assistants (AAPA) asserts that both NAACLS program-trained Pathologists' Assistants and those who were grandfathered through on-the-job training prior to 2010—who successfully pass the ASCP-BOC Pathologists' Assistant Certification Examination—are qualified as competent mid-level practitioners in anatomic pathology.

The AAPA advocates for state licensure to ensure that anatomic pathology services are performed with an adequate level of professional competence. This licensure should establish appropriate entry-level qualifications for Pathologists' Assistants, including training, experience, and certification that confirm their capability to perform essential functions.

The AAPA recommends that minimum requirements for licensure include:

- Graduation from a NAACLS-accredited Pathologists' Assistant training program, or, for those trained prior to 2010, on-the-job training
- Successful passage of the ASCP-BOC Pathologists' Assistant Certification Examination by both NAACLS-accredited program graduates and grandfathered on-the-job trained Pathologists' Assistants prior to 2010.
- Earning 60 continuing education credits every three years (an increase from 45 credits effective January 1, 2022) to maintain certification as required by the ASCP-BOC Credential Maintenance Program.

The AAPA believes that establishing appropriately stringent competency requirements through licensure will enhance the health and safety of patients. Additionally, state licensure provides a crucial legal framework to restrict incompetent practitioners from delivering anatomic pathology services to the public.

It is essential to define Pathologists' Assistant qualifications, certification, and scope of practice within state statutes to exclude those who have not met the necessary requisites for licensure. Furthermore, the AAPA advocates that licensure renewal should require documentation of continuing education as a means to demonstrate ongoing competence.

The AAPA calls for the implementation of these licensure requirements to ensure the integrity of the profession and the safety of the public

AAPA Position on Utilization of Non-Pathologist Grossing Personnel in the Anatomic Pathology Laboratory

College of American Pathology (CAP) Qualifications for Gross Examination by Non-Pathologist

If individuals other than a pathologist or pathology resident assist in gross examinations, such individuals qualify as high complexity testing personnel.

(Reference: CAP Anatomic Pathology Checklist item ANP.11610 Gross Examination – High Complexity Testing Qualifications, 06/04/2020)

NOTE: Grossing involves examining tissue that requires anatomical knowledge and judgment. This process includes specimen dissection, tissue selection, and a detailed examination that may involve describing characteristics such as color, weight, and measurements. The laboratory director may delegate specimen dissection to qualified non-pathologist personnel who meet the CLIA regulations for high complexity testing. Minimum training and experience required under CLIA '88 for these personnel include:

- Associate degree in a chemical or biological science, or medical laboratory technology from an accredited institution; **OR**
- Education or training equivalent to the above that includes at least 60 semester hours (or equivalent) from an accredited institution, with a minimum of 24 semester hours in medical laboratory technology courses. **OR**
- 24 semester hours of science courses that include 6 semester hours each of chemistry and biology, and 12 semester hours of chemistry, biology, or medical laboratory technology in any combination;

AND

- Laboratory training must include completion of a clinical laboratory program accredited by ABHES, NAACLS, or another HHS-recognized organization, which may count toward the required 60 semester hours. **OR**
- At least three months of documented laboratory training in each specialty where the individual performs high complexity testing
- Possess a current license issued by the state in which the laboratory is located, if such licensing is required.

Definition of Terms

- Non-pathologist grossing personnel
 - **Pathologists' Assistant:** A Pathologists' Assistant (PA) is a certified allied healthcare professional, qualified by academic and practical training to provide services in anatomic pathology. Under the supervision of a licensed, Board Certified, or Board Eligible anatomic pathologist, PAs conduct comprehensive macroscopic evaluations of complex surgical specimens, perform postmortem examinations and submit tissue sections for microscopic examination. Pathologists' Assistants serve as physician extenders to pathologists, analogous to physician assistants or nurse practitioners.
 - **Histologist:** Histotechnicians (HTs) and histotechnologists (HTLs) are members of a laboratory team who employ histologic technology to diagnose diseases, conduct research, or instruct others in the science. Histology is the study of the microscopic structure of tissues.
 - ◆ **Histotechnician:** A clinical laboratory technician that uses specific reagents, chemicals, and dyes, to prepare tissue slides for microscopic examination by the surgical pathologist.
 - ◆ **Histotechnologist:** A histotechnologist is a specialized medical lab professional. Similarly to histotechnicians, they prepare tissue slides for microscopic examination by the surgical pathologist using specific reagents, chemicals, and dyes. With advanced education and training, a histotechnologist possesses the qualifications necessary for HTL certification.
 - **Cytotechnologist:** Cytotechnologists analyze fluid and tissue specimens for microscopic cellular abnormalities, such as bacterial and viral infections, cancer, meningitis, and other diseases.
 - **Grossing Technician:** An anatomic laboratory technician that examines low-complexity specimens, including small routine biopsies or specimens submitted in their entirety for microscopic examination by a pathologist. They must meet the minimum education requirements outlined in the CAP Anatomic Pathology Checklist item ANP.1161 for Gross Examination – High Complexity Testing Qualifications.

- Tissue submission
 - **Selective sampling:** Sampling a specimen to demonstrate specific pathology that requires in-depth knowledge of anatomy, pathology, and sectioning principles. This process involves selecting and preparing tissue samples to accurately represent pathological features. A thorough understanding of tissue relationships and principles of sectioning are essential for obtaining high-quality samples that support accurate diagnosis and effective treatment planning.
 - **Representative submission:** Careful selection of representative areas ensures that the sample accurately reflects the overall characteristics of the pathology being investigated. This process requires knowledge of anatomy, pathology, and sectioning principles to facilitate an accurate diagnosis.
 - **Entire submission:** The specimen is entirely submitted with or without sectioning for microscopic examination by a pathologist.
 - **In toto submission:** The specimen is entirely submitted without manipulation or sectioning for microscopic examination by a pathologist.
- Direct vs. indirect supervision
 - **Direct supervision:** The supervising physician (or appropriate designee) is present in the vicinity of the laboratory subspecialty area and available for consultation and direction.
 - **Indirect supervision:**
 - ◆ **Direct Supervision Immediately Available** - The supervising physician (or appropriate designee) is physically present within the hospital or other site of patient care and is immediately available to provide direct supervision. **OR**
 - ◆ **Direct Supervision Available** - The supervising physician (or designee) is not physically present at the hospital or patient care site but is immediately accessible via telephone or electronic means for direct supervision.

AAPA Position on Basic Qualifications for Macroscopic Examination of Specimens Requiring Selective Sampling

For those who perform macroscopic examinations on specimens that require *selective or representative sampling*, the AAPA maintains the following standard qualifications be met:

- Be a board certified, licensed anatomic pathologist, pathology fellow, or pathology resident, **OR**
- Be an ASCP certified Pathologists' Assistant, **AND**
- Possess a current license issued by the state in which the laboratory is located, if such licensing is required.

Due to the variability and complexity of macroscopic examination of anatomic specimens the potential exists for serious harm from errors made by unqualified personnel. Pathology plays a crucial behind-the-scenes role in healthcare, as no other hospital staff can proceed without the information we provide. The macroscopic examination of surgical specimens forms the basis for accurate medical diagnoses and treatment. Pathologists rely on the skills of PAs, and inadequate examination or tissue submission can severely compromise patient diagnoses and treatment options. Consequently, the AAPA believes that the CLIA '88 regulations regarding minimal educational requirements for performing high complexity testing are inadequate and outdated (42 CFR493.1489 and 1491). The CLIA '88 regulations for minimum personnel requirements do not adequately address the liability and potential impact on patient safety associated with examining tissue specimens. Additionally, these requirements fail to specify the essential elements that must be mastered during didactic and practical training. Such elements are crucial for understanding fundamental pathology, developing observational skills, and acquiring the dexterity and judgment needed for effective tissue specimen handling in an anatomic pathology setting.

Since 2005, completion of a NAACLS-accredited Pathologists' Assistant program has been required to take the ASCP BOC Pathologists' Assistant certification exam. Before 2010, individuals with a bachelor's degree in a basic science and three years of supervised internship could also qualify. To maintain certification, the AAPA and ASCP BOC require participation in the Credentialing Maintenance Program (CMP), which includes completing 60 continuing education (CE) credits every three years. This consists of 15 advanced anatomic pathology credits, 20 anatomic pathology credits, 23 general pathology credits, one laboratory safety credit, and one medical ethics credit.. The AAPA believes that these requirements adequately qualify individuals as competent mid-level practitioners in anatomic pathology, enabling them to perform anatomic pathology services with a sufficient level of professional competence. This framework ensures that pathologists' assistants are well-prepared to contribute effectively to patient care and diagnostic processes.

AAPA Position on Basic Qualifications for Macroscopic Examination of Specimens NOT Requiring Selective Sampling

The American Association of Pathologists' Assistants (AAPA) asserts that all anatomic pathology specimens should be examined by certified Pathologists' Assistants. However, grossing technicians, histologists, and cytotechnologists can play a useful role, but their involvement should be limited to the gross examination of specific specimen types and conducted under direct supervision.

- The scope of work should be limited to the macroscopic examination of low-complexity specimens requiring entire tissue submission for microscopic analysis without selective sampling. Due to the lack of adequate education and training, entire specimen submission is crucial to prevent oversight and ensure the pathologist does not miss critical diagnostic information.
- Grossing technicians, histologists, and cytotechnologists may be trained to examine limited specimen types and work under the direct supervision of a certified pathologists' assistant or pathologist.
- Complex specimens requiring knowledge of pertinent pathology and anatomy are excluded from the scope of work (e.g., gallbladder, breast lumpectomy).
- There shall be no increase in the complexity of specimens handled by grossing technicians, histologists, or cytotechnologists. To advance, these personnel must complete advanced didactic and clinical training through a NAACLS-accredited pathologists' assistant program or an ACGME-accredited pathology residency program.

A detailed list of appropriate specimen types for macroscopic examination by non-pathologist grossing personnel is provided in the delineation of privileges by specimen and procedure type template.

To assist in the macroscopic examination of routine biopsy specimens which are entirely submitted for microscopic examination, it is the AAPA's position that personnel must meet the following:

- Be a certified pathologists' assistant **OR**
- Have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological, or clinical laboratory science, medical technology, histotechnology, or cytotechnology from an accredited institution, **AND**
- Have at least three months of recorded laboratory training in anatomic pathology.

Grossing Technicians

The use of grossing technicians, biopsy technicians, and other minimally trained personnel (e.g., histotechnicians and cytotechnologists) is common and valuable in high-volume anatomic pathology laboratories for macroscopic examination of routine, low-complexity specimens. While larger specimens and complex resections demand extensive anatomical and pathological knowledge, routine biopsy specimens are crucial for initial disease diagnoses, including cancer. Additional testing on biopsy material can further characterize malignancies, identify predictive markers, and guide treatment. Despite their technical simplicity, these specimens carry significant responsibility and liability.

Low-complexity specimens include small routine biopsies or those submitted entirely for microscopic examination by a pathologist. These require counting fragments, measuring the material, and additional simple quantifications, then transferring the entire specimen to a cassette without sectioning or manipulation. Careful handling is essential to maintain accurate patient identification and avoid cross-contamination. Ensuring patient safety depends on meticulous specimen management, proper laboratory techniques, and organization to prevent errors, destruction or loss. Adequate education and training are crucial for performing these tasks effectively and safely.

Routine specimen types such as hernia sacs, appendices, gallbladders, and soft tissue lesions require more than basic measurement and sampling skills; they necessitate a solid understanding of anatomy, medical terminology, clinical correlation, associated diseases, and sectioning techniques. Recognizing uncommon lesions that may require additional sampling is also crucial for patient care.

The absence of guidelines and structured training for grossing technicians raises significant concerns when handling specimens needing selective sampling. On-the-job training, topics covered, and competency measures vary widely and often remain unclear. Proper handling of all specimen types in the anatomic pathology laboratory demands qualified and well-trained personnel.

Comment on Cytotechnologist Training

The Commission on Accreditation of Allied Health Education Programs (CAAHEP), Standards and Guidelines for the Accreditation of Educational Programs in Cytotechnology does not list the macroscopic examination of surgical specimens in the Curriculum in Cytotechnology for Entry-level Competencies. The ASCP Board of Certification examination for cytotechnologist does not include a macroscopic examination of surgical specimen assessment.

Grossing Histologists

With the increasing volume of biopsies and cost containment concerns, histotechnicians and histotechnologists are being utilized more extensively in anatomic pathology laboratories. When adequately trained, histologists can effectively examine select specimen types, including gynecological, gastrointestinal, urinary bladder biopsies, needle biopsies (such as prostate, kidney, bone marrow, breast, and lymph node), as well as muscle and nerve biopsies. According to the National Accrediting Agency for Clinical Laboratory Science (NAACLS) Unique Standards, histotechnicians (HT) and histotechnologists (HTL) assist with and perform macroscopic examinations and frozen section procedures in histopathology, as well as prepare cytology specimens. However, the ASCP BOC examination for HTL does not assess macroscopic examination of surgical specimens. While some histology students may receive selective training in macroscopic examination focused on simple specimen types (e.g., dermatology specimens), any formal training typically provides only a general overview of the entire process, from accessioning to gross room maintenance. Histologists, experienced in embedding and microtomy, can visualize and anticipate how a small sample will behave after macroscopic examination, ensuring that the most diagnostically valuable parts appear on the slide. Practical training in macroscopic examination for histologists is often limited to non-complex specimen types and should focus on examining biopsies and small specimens as defined by institutional policy.

Summary

A survey of 450 certified pathologists' assistants regarding the use of grossing technicians and histologists in surgical pathology revealed strong support for employing grossing technicians, provided there are specific limitations on the specimen types they examine. A significant majority emphasized that oversight and supervision of grossing technicians are critical for patient care and safety. Most participants noted that using grossing technicians for routine biopsy specimens allowed them to dedicate more time to complex cases. The macroscopic examination of surgical specimens requiring dissection and selective sampling should be conducted only by professionally trained and qualified individuals, including board-certified anatomic pathologists, pathology fellows, residents, and certified pathologists' assistants. To ensure patient safety, these personnel are the only ones qualified to handle such specimens due to their rigorous formal training and established requirements.

The Accreditation Council for Graduate Medical Education (ACGME) outlines elements of pathology residency programs, including a patient care section with detailed milestones for macroscopic examination throughout the four-year training. ACGME requires pathology residents to assess at least 2,000 surgical specimens, a standard supported by the Association of Pathology Chairs to ensure competency. PGY-1 residents must be directly supervised while performing macroscopic examinations of three consecutive surgical specimens from each organ system before they can examine these specimen types under indirect supervision. Qualified supervisors include pathologists' assistants, senior residents, pathology fellows, or attending pathologists.

Certified pathologists' assistants complete a similarly structured postgraduate didactic and practical curriculum based on NAACLS Standards for Accredited Pathologists' Assistant Training Programs, which outline training elements and entry-level requirements in anatomic pathology, including the macroscopic examination of surgical specimens from all organ systems. This comprehensive training is provided through an intensive 24-month program leading to a master's degree. Graduates of NAACLS-accredited programs are eligible to sit for the ASCP BOC exam and must participate in the ASCP Credentialing Maintenance Program for continuing education. Practicing certified pathologists' assistants typically examine 10,000 to 15,000 surgical cases annually, encompassing a range from simple to complex.

In contrast, grossing technicians lack formal education in pathology, do not have a defined scope of duties, and have no established training requirements for the macroscopic examination of surgical specimens. They also lack a path to national credentials, such as ASCP certification, and have no continuing education requirements. While some institutions provide in-house training and delineate duties, the content and quality of this training varies widely and are often unknown. The title of grossing technician is generic, with no established standards beyond the minimum education requirements specified by the CAP Anatomic Pathology Checklist item ANP.1161 Gross Examination – High Complexity Testing Qualifications.

ASCP certified Histotechnicians (HT) and Histotechnologists (HTL) receive only a basic overview of macroscopic pathology techniques in their accredited training programs. This overview covers the overall process, including accessioning, organizing cases and cassettes before macroscopic examination, safety in the gross room, and

assisting PAs, residents, and pathologists during specimen examination. Some histologists may receive additional on-the-job training for specific specimen types, such as biopsy and dermatology specimens that are submitted entirely for microscopic examination. Cytotechnologists also do not receive training in macroscopic pathology techniques in their programs. Notably, the ASCP certification exams for HT, HTL, and CT do not assess macroscopic examination of surgical specimens.

Pathologists' assistants often train and oversee pathology residents and other grossing personnel. While errors by grossing technicians and histologists are largely anecdotal, it is documented that first-year pathology residents commonly make mistakes while learning to examine specimens. These errors, made by trained doctors, highlight the expertise needed to properly assess a common specimen type, which requires clinical correlation, careful examination, and selective sampling. In contrast, individuals with minimal education and training, such as grossing technicians, histologists, and cytotechnologists, are not adequately prepared or qualified to examine specimens that require dissection and selective sampling.

In many pathology departments, attending pathologists do not directly examine gross specimens and instead rely on skilled gross room personnel to accurately examine, describe, and sample these specimens. This relationship requires a high level of trust, developed and tested over time. Gross room personnel must exercise sound judgment and recognize when to involve attending pathologists, particularly for unusual or complex specimens.

The AAPA asserts that grossing technicians, histologists, and cytotechnologists are not adequately prepared for this critical role in patient care. In alignment with our vision and core values, we emphasize our position on patient safety and support for attending pathologists, who bear the ultimate responsibility for rendering accurate diagnoses. Therefore, the scope of work for grossing technicians, histologists, and cytotechnologists in surgical pathology should be limited to the macroscopic examination of small routine biopsies and low-complexity specimens that require entire tissue submission for microscopic examination without selective sampling.

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Pathologists' Assistant Professionals

If your organization doesn't currently employ a pathologists' assistant (PA), we strongly encourage you to find out more about this profession, the value of a PA, and how you can hire one for your practice. To help you, we've provided answers to the following questions:

- ▶ What is a Pathologists' Assistant?
- ▶ Why Hire a Pathologists' Assistant?
- ▶ How Do I Hire a Pathologists' Assistant?

Additional information about Pathologists' Assistants can be found on our website: pathassist.org.



Visit us at pathassist.org for employer resources including our Inspection Readiness Kit and the *AAPA Macroscopic Examination Guidelines: Utilization of the CAP Cancer Protocols at the Surgical Gross Bench, aka "Grossing Guidelines"*.

Don't forget to mark April 14th on your calendar to celebrate **Pathologists' Assistant Day!**

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The Value of an **ASCP-Certified** Pathologists' Assistant



What is a Pathologists' Assistant?

A pathologists' assistant (PA) is a highly trained, certified allied healthcare professional trained to perform surgical and autopsy pathology services under the direction and supervision of a licensed, Board Certified or Board Eligible Anatomic Pathologist. PAs can also be utilized in administrative roles such as lab managers/directors, instructors, and other such duties.

PAs become certified through the American Society for Clinical Pathology Board of Certification (ASCP BOC), and maintain certification by accruing at least 45* CE credits during a three-year certification period.

** Increasing from 45 to 60 credits for those recertifying on or after January 1, 2022.*



Why Hire a Pathologists' Assistant?

PAs play a critical role in the delivery of healthcare services in both surgical pathology and autopsy pathology. They are key partners in assisting the Pathologist to arrive at a pathologic diagnosis, but it is the sole responsibility of the Pathologist to render a diagnosis. Hiring a PA will contribute to the overall efficiency of your laboratory or practice in a cost-effective way because they are trained academically and practically. Their skills can be personalized to fit any individual laboratory's needs and requirements.

How Do I Hire a Pathologists' Assistant?

First, determine the role you wish your pathologists' assistant to assume in your laboratory. Because ASCP-certified PAs are trained to perform in various roles in a laboratory, you need to decide what this position's focus needs to be. You can then advertise your job opening through the Career Center found on the AAPA's website (careercenter.pathassist.org). Pricing starts at \$350 to have your ad published for three (3) months. Or, you may choose to browse the bank of posted resumes. Members of the AAPA who are certified or certification exam eligible are able to access the Career Center 24 hours a day.



About the AAPA

The American Association of Pathologists' Assistants (AAPA) was founded in 1972 as a not-for-profit organization dedicated to the advocacy and advancement of a then newly-emerging allied health profession. From its inception, a major goal of the AAPA was to obtain national recognition for both the profession and the individual pathologists' assistant. The AAPA is dedicated to providing comprehensive professional support for pathologists' assistants, while also being the premier provider of continuing education for pathologists' assistants.

AAPA Core Values:
Quality Patient Care :: Education
Advocacy :: Collaboration

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.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 noncertified 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 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.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 November 2009, 11 states and one territory license laboratory personnel.⁴ 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.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

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.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. 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.¹⁴ 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,^{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 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 certification¹⁶ 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).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 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."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 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.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}

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 2004.²³ 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.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"²⁴ 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.²⁵

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



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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What is a Pathologists' Assistant?

A pathologists' assistant is a certified allied health professional, qualified by academic and practical training to assist in providing services in anatomic pathology under the direction and supervision of a qualified anatomic pathologist. Pathologists' assistants are analogous to PAs, functioning as dependent practitioners with anatomic pathologists.

Definition

Pathologists' Assistants are academically and practically trained to provide accurate and timely processing of a variety of laboratory specimens, including comprehensive macroscopic examination and evaluation of all surgical pathological specimens. Pathologists' Assistants also perform postmortem examinations including prosection, assisting the Pathologist with rendering the provisional anatomic diagnosis, composing the clinical history, recording the macroscopic anatomic findings, and submitting tissue sections for microscopic examination. Pathologists' Assistants play a critical role in the delivery of healthcare services in both surgical pathology and autopsy pathology. They are key partners in assisting the Pathologist to arrive at a pathologic diagnosis, but it is the sole responsibility of the Pathologist to render a diagnosis.

Pathologists' Assistants often are responsible for the organization and operational management of the surgical pathology suite and the anatomic pathology service. This may comprise personnel management including supervising accessioners, lab aides, grossing technicians, and transcriptionists in the surgical pathology suite and autopsy technicians/morgue assistants in the autopsy room; writing and reviewing surgical pathology and autopsy procedures; inventory control; laboratory operations such as quality assurance, quality control, accreditation inspection preparation, and budgeting; and in the academic setting, supervision of learners (e.g., Pathologists' Assistant students, medical students, post-sophomore fellows, and residents) and providing shadowing experiences to prospective Pathologists' Assistant students, and college or high school students interested in healthcare.

A Pathologists' Assistant need not provide all the services listed in the Scope of Practice in the performance of their duties; however, it is expected that the Pathologists' Assistant will have received appropriate academic and practical training to provide these services.

Education and Certification

Pathologists' Assistants currently prepare for their roles as advanced practitioners in anatomic pathology by successfully completing a NAACLS accredited Pathologists' Assistant training program and by attaining certification as a Pathologists' Assistant from the American Society for Clinical Pathology Board of Certification (ASCP BOC). Prior to 2010, Pathologists' Assistants who had received on-the-job training (via a 3-year supervised internship) and had successfully attained certification as a Pathologists' Assistant from the American Society for Clinical Pathology Board of Certification have the same qualifications as NAACLS program-trained individuals and are capable as advanced practitioners in anatomic pathology.

Both NAACLS program-trained and grandfathered on-the-job trained Pathologists' Assistants who pass the ASCP BOC Pathologists' Assistant Certification Examination use the credentials PA(ASCP) and are qualified as competent advanced practitioners in anatomic pathology. To maintain a level of expertise and awareness of changes and advances in practice and maintain certification, the Pathologists' Assistant must complete approved Credential Maintenance Program (CMP) requirements in three-year cycles, as defined by the American Society for Clinical Pathology Board of Certification. Following completion of the CMP program, the CM superscript designation is appropriate; PA(ASCP) CM.

Scope of Practice

A Pathologists' Assistant is qualified by formal academic and practical training to perform the following tasks under the direction and supervision of a licensed, Board Certified or Board Eligible Anatomic Pathologist:

[Scope of Practice - 2024](#)

The Direct Impact Pathologists' Assistants Have on Patient Care

In every medical and surgical subspecialty, there exists a corresponding pathology counterpart. Pathology plays a vital role behind the scenes, as no healthcare professional can act without the information we provide. The primary goal of anatomic pathology is to deliver a correct and complete diagnosis to the appropriate patient in a timely manner, ensuring that the information is understandable and useful for the treating physician.

Diagnosis

Accurate diagnosis relies on gross examination, which provides crucial information about a specimen's characteristics, such as size, shape, color, and texture. Pathologists' Assistants undergo extensive training in gross morphology, oncology, pathophysiology, tumor characteristics, staging guidelines, and invasion criteria for various cancers. This expertise allows them to recognize tumor stages and invasion patterns, ensuring no critical diagnostic sections are overlooked. A thorough gross examination identifies abnormal areas for further sampling, preventing significant lesions from being missed. Failing to sample representative areas can lead to inadequate or delayed identification of serious conditions like cancer, resulting in delayed treatment and worsened outcomes. Missed critical findings may cause patients to present with more advanced disease stages, negatively affecting prognosis and treatment options.

Moreover, misinterpretations from inaccurate diagnoses or inadequate grossing can lead to unnecessary surgeries, further tests, treatments, or hospitalizations, causing both physical and emotional distress for patients and incurring additional costs for the hospital.

Treatment Guidance

Ultimately, pathology drives the management plans that clinicians use to treat patients. An untrained or unqualified PA may overlook critical details and fail to submit necessary sections for accurate diagnosis. This can lead to missed vital information and incorrect treatment, which can be fatal if cancer goes undiagnosed until it is too late to treat.

Lymph node identification is critical for effective cancer treatment, especially in breast and colorectal cancers. Studies show that complete lymph node sampling during gross examinations significantly contributes to accurate pathologic staging. PAs have been shown to retrieve more lymph nodes than pathology residents, which is vital for thorough assessment and treatment planning. Identifying more lymph nodes—even if negative for metastasis—allows for a more complete evaluation of the disease's extent, enhancing confidence in the pathologic stage and guiding tailored treatment decisions. The superior performance of PAs underscores their crucial role in enhancing patient outcomes through meticulous gross examination and sampling.

PAs also play a key role in determining treatment effectiveness. After treatment, they assess whether cancer has been fully removed or if it has spread, utilizing their training to distinguish between tumor tissue, treated tissue, and uninvolved tissue.

Importance of a Qualified Pathologists' Assistant

Effective Communication

Incomplete documentation—such as inadequate or inaccurate clinical history, specimen details, or processing steps—can impede a pathologist's ability to make informed diagnoses. This can lead to missed critical findings and incorrect diagnoses, adversely affecting patient management. Pathologists' Assistants are trained to provide clear and concise gross descriptions by knowing what information is essential and what can be omitted, ensuring pathologists can diagnose quickly and accurately.

Miscommunication with pathologists or clinical staff regarding specimen details can also result in overlooked findings. PAs are educated in common clinical procedures, terminology, and abbreviations, enabling effective communication with surgeons and pathologists. They know how specimens should appear post-procedure and how to document any issues. Accurate grossing delivers detailed specimen accounts, facilitating effective communication between pathologists and clinicians. Furthermore, poor



documentation can expose healthcare facilities to legal risks, especially if patient harm occurs. Comprehensive and precise grossing aids legal documentation, helping protect against potential malpractice claims by ensuring all findings are accurately recorded.

Adequate Specimen Processing

PAs undergo extensive training in specimen processing, including proper fixation and preparation techniques essential for maintaining tissue quality and diagnostic accuracy. Proper fixation preserves tissue morphology and integrity, enabling accurate diagnoses. PAs learn about various chemical reagents, tissue reactions, and the physiological and chemical processes involved in fixation, as well as the consequences of improper practices.

Their training includes the purpose of fixation, knowledge of common fixatives and their requirements, and guidelines for time, temperature, and volume based on tissue type. PAs also learn handling techniques to prevent degradation and identify tissues that should not be fixed. They are trained to recognize potential artifacts from fixation, which are crucial for accurate interpretation. Additionally, PAs document fixation details—including the type of fixative, fixation time, and handling instructions—to ensure consistency and reproducibility in specimen processing, along with specific handling instructions based on clinical concerns and diagnoses.

Proper technique in tissue sectioning

Errors in cutting or sectioning tissue samples can lead to the loss of critical diagnostic information. Studies show that laboratories employing only certified medical laboratory scientists produce significantly more accurate proficiency test results than those with non-certified scientists. Moreover, in labs with both certified and non-certified scientists, a higher proportion of certified professionals positively impacted result accuracy.

Certified Pathologists' Assistants receive extensive training in grossing and sectioning, including a year of didactic classes followed by a year of hands-on clinical rotations. They learn the rationale behind specific sections and the precise methods for staging tumors, determining diagnoses, and ensuring negative margins. Each disease and organ has distinct sectioning requirements and staging guidelines that PAs must comprehend. Since pathologists do not always see the specimens, they rely on PAs to accurately identify and demonstrate key features in their sections. Proper techniques minimize tissue damage, preventing artifacts that obscure important diagnostic details. By adhering to learned protocols, PAs ensure consistency across specimens, facilitating accurate interpretation by pathologists. Adequate grossing techniques lead to higher quality tissue sections, essential for microscopic examination and accurate diagnosis.

Why Licensure for Pathologists' Assistants is Essential

Ensured Competence

PAs undertake responsibilities that were previously limited to pathologists; therefore, it is logical that only licensed and competent professionals be permitted to carry out these duties. Licensure is crucial because it requires Pathologists' Assistants (PAs) to meet specific educational and training standards. This ensures they have the necessary skills and knowledge to perform their duties safely and effectively. A license issued by a governmental entity protects the public by confirming that the PA has met predetermined standards, setting minimum qualifications and competencies for safe practice.

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.

[ASCP State Licensure Policy](#)



Improved Results

According to the ASCP, "Laboratory tests are fundamental to most medical diagnoses and treatments, which means that errors in laboratory testing can lead to serious harm." Research indicates that the quality of tests is shaped by the same foundational elements as personnel licensure, such as academic education, clinical training, work experience, and competency assessments. A study examining proficiency testing results in California physician's office laboratories (POLs) in 1996 revealed significant variations between POLs employing licensed medical laboratory scientists and ones employing non-licensed personnel. The study concluded that POLs with licensed laboratory professionals on their teams had notably lower failure rates for proficiency tests.

Protection for the Public

As a healthcare profession, Pathologists' Assistants must be regulated because the potential exists for serious harm from macroscopic tissue examination errors by unqualified personnel. Pathology is a critical behind-the-scenes field; no one else in the hospital can act without having the information we provide. The macroscopic examination of surgical specimens forms the basis for medical diagnoses and treatment. Pathologists depend on PAs eyes and hands; if PAs don't sample the right tissue, the final diagnosis affecting patient care can be severely compromised. The general public may lack sufficient information to identify unqualified providers, making them vulnerable to unsafe practices. Since patients do not typically interact with PAs, they may never know if the individual handling their specimen—who directly impacts diagnosis, treatment, and prognosis—is qualified to do their job.

Protection of Professional Titles

Licensure protects the use of professional titles. Only licensed PAs can represent themselves as such, preventing uncertified individuals or grossing technicians from using the PA title, applying for jobs, or operating within the designated scope of practice. This regulation can elevate the status of PAs to be recognized as advanced or mid-level practitioners, aligning them with the roles typically performed by physicians.

Advancing Recognition for Pathologists' Assistants

An Advanced Practice Provider is a health care provider who is not a physician but who performs medical activities typically performed by a physician. Licensure can elevate PAs by providing credible endorsement of skills and provide tangible evidence of qualifications and education when established correctly. Licensing represents the state's sanction of work and can confer legitimacy for PAs. By definition, a mid-level or advanced practitioner is a health care provider who is not a physician but who performs medical activities typically performed by a physician, which is true for pathologists' assistants. However, to be recognized as a mid-level or advanced practitioner, you also need to be a licensed healthcare professional who is legally authorized to provide healthcare. Without state recognition via licensure, it is hard to convince others to understand that we are highly trained medical professionals.

Definition of Scope of Practice

A clear scope of practice outlines the specific tasks and responsibilities that PAs are authorized to perform. This clarity helps prevent role ambiguity, ensuring that PAs, pathologists, grossing techs and other pathology team members understand their respective duties. By establishing defined roles, a scope of practice facilitates better collaboration among healthcare professionals. Instead of competing for similar work, defined roles ensure that PAs can work in tandem with histology, grossing techs and pathologists by leveraging different skill sets.

Defining the scope of practice provides legal clarity about what PAs are permitted to do and what non-PAs are not permitted to do. Florida law only defines the scope of practice for histotechs and cytotechs, which states only histology can perform frozen sections and that non-licensed personnel cannot hold administrative roles. This means that PAs are prohibited from cutting frozen sections and from becoming administrative laboratory directors because we are not licensed. Ideally, other grossing personnel such as



histotechs or grossing technicians can be distinctly defined with a separate and appropriate license or a “limited” license which restricts their scope of work to a specified set of tissue types or CPT codes. This “limited” license would include separate educational standards from those of a Pathologists’ Assistant.

Regulatory Oversight and Compliance

Licensing boards monitor and enforce compliance with established standards and practices, which helps prevent malpractice and ensures adherence to safety protocols. Many licensing requirements include ongoing education, keeping healthcare professionals updated on the latest advancements, technologies, and best practices. This commitment directly impacts patient care. Furthermore, licensing often involves assessments and examinations that ensure practitioners can deliver quality care, thereby minimizing the risk of errors that could harm patients.

Accountability and Public Trust

Licensed professionals are held accountable for their actions. If they violate standards or ethical guidelines, they can face disciplinary actions, which deters unsafe practices. This accountability fosters confidence in healthcare providers, making patients feel more secure knowing their professionals are licensed and regulated.

AAPA Tenets on State Licensure

The American Association of Pathologists’ Assistants (AAPA) asserts that both NAACLS program-trained Pathologists’ Assistants and those who were grandfathered through on-the-job training prior to 2010—who successfully pass the ASCP-BOC Pathologists’ Assistant Certification Examination—are qualified as competent mid-level practitioners in anatomic pathology.

The AAPA advocates for state licensure to ensure that anatomic pathology services are performed with an adequate level of professional competence. This licensure should establish appropriate entry-level qualifications for Pathologists’ Assistants, including training, experience, and certification that confirm their capability to perform essential functions.

The AAPA recommends that minimum requirements for licensure include:

- Graduation from a NAACLS-accredited Pathologists’ Assistant training program, or, for those trained prior to 2010, on-the-job training
- Successful passage of the ASCP-BOC Pathologists’ Assistant Certification Examination by both NAACLS-accredited program graduates and grandfathered on-the-job trained Pathologists’ Assistants prior to 2010.
- Earning 60 continuing education credits every three years (an increase from 45 credits effective January 1, 2022) to maintain certification as required by the ASCP-BOC Credential Maintenance Program.

The AAPA believes that establishing appropriately stringent competency requirements through licensure will enhance the health and safety of patients. Additionally, state licensure provides a crucial legal framework to restrict incompetent practitioners from delivering anatomic pathology services to the public. It is essential to define Pathologists’ Assistant qualifications, certification, and scope of practice within state statutes to exclude those who have not met the necessary requisites for licensure. Furthermore, the AAPA advocates that licensure renewal should require documentation of continuing education as a means to demonstrate ongoing competence.

The AAPA calls for the implementation of these licensure requirements to ensure the integrity of the profession and the safety of the public

What licensure is not

Licensure is not an encroachment on pathologists’ scope of practice

Pathologists primarily diagnose and sign out anatomic pathology cases. Regulations from CLIA, CAP, and the Joint Commission require that all surgical tissue diagnoses be made by qualified pathologists, and PAs



cannot legally perform these functions. PAs must meet state qualification requirements and operate under the supervision of a qualified pathologist, as mandated by CAP.

It's important to note that PAs do not have their own billing codes. PAs engage in technical work, along with histology, but do not perform the professional diagnostic portion of cases. Technical charges cover all activities from specimen receipt to staining, but PAs cannot undertake billable professional tasks reserved for pathologists.

According to the AAPA and relevant regulatory bodies, PAs can perform gross examinations and post-mortem examinations, but cannot render final diagnoses. Licensing would not change our established scope of practice; it would merely formalize our permitted activities.

Employing both PAs and pathologists enhances efficiency in pathology departments. While PAs can handle various tasks within their scope, they do not diagnose patients and are not physicians, therefore their salaries will always reflect this distinction and be less than that of a pathologist. With current shortages in the pathologist workforce, pathologists spend more time at the microscope and less in the gross room. Utilizing PAs for grossing and processing allows pathologists to focus on their primary diagnostic responsibilities. This collaboration allows for more cost-effective use of resources, maximizing the strengths of both pathologists and PAs.

Licensure is not a hiring impediment

Licensing will not hinder the hiring of PAs or contribute to a perceived workforce shortage. In fact, the number of accredited PA programs has doubled in the past decade, with 16 NACCLS-accredited programs graduating up to 230 students annually, plus two additional programs in the application process.

Data from the AAPA Career Center shows strong demand for PAs, with over 265 job postings from October 2022 to December 2023. More than 70% of these positions were filled after the initial advertisement, indicating effective hiring. Perceived workforce shortages are more likely related to job characteristics such as location, salary, schedule, and workload.

With a shortage of pathologists, PAs are increasingly relied upon for gross examinations and autopsy pathology, enabling pathologists to focus on diagnostics. As demand for PAs grows, so does the number of training programs, resulting in more qualified professionals entering the field.

Licensure can improve the hiring process for PAs by standardizing job titles and responsibilities. Currently, job postings vary widely—using titles like pathology assistant and pathology specialist—leading to confusion and a smaller, often underqualified applicant pool. A uniform, law-protected title would streamline job searches and attract more qualified candidates.

With licensure, employers can be assured that NAACLS-accredited, program-trained PAs have received standardized training, improving the quality of applicants. Licensure also establishes clear standards and defines the scope of practice for PAs, allowing healthcare facilities to avoid creating job descriptions from scratch and ensuring consistency across the profession.

Additionally, licensure centralizes credential verification. Currently, employers must verify certification through the American Society of Clinical Pathologists, often incurring fees and delays. Once licensure is established, credentialing can be done through a state board website, enabling direct verification without added costs or waiting times.

Licensure is not just added bureaucracy

Without licensure requirements, anyone with an associate degree can perform high-complexity testing, including gross examinations on all tissue types. This allows unqualified individuals to fill Pathologists' Assistant roles, leading to several significant issues:

- **Job Security:** Grossing technicians may take positions meant for Pathologists' Assistants, undermining job security for qualified professionals.
- **Salary Averages:** Lower qualifications typically lead to lower pay, reducing the average salary in the Pathologists' Assistant field.
- **Professional Visibility:** Confusion about our role diminishes visibility among lab administrators, hospital staff, and surgeons, often grouping us with histology or clinical lab personnel.



- Exclusion from Leadership Roles: The lack of required education and licensure often results in us being overlooked for laboratory administrative positions.
- Quality of Care: Patients whose tissues are handled by less qualified personnel face a higher risk of missed significant or unexpected findings.

Role classification within medical laboratories significantly affects the recognition and functionality of specialized professions. The National Laboratory Director has stated that Veterans Affairs hospitals do not need a dedicated Pathologists' Assistant category, as grossing falls under the Histotechnologist (HTL) category. This classification excludes Pathologists' Assistants from job postings, as we are not certified as HTLs, and may lead to directors mistakenly preventing us from performing gross examinations.

Licensure will not block ASCP-certified on-the-job trained Pathologists' Assistants from employment

When states implement a new licensure for Pathologists' Assistants, they typically include a grandfathering period. This ensures that individuals currently performing PA duties are not excluded from the profession. During this initial phase, some non-certified PAs may be granted the PA license title, but this period usually lasts only 1-2 years. After this time, all new applicants must meet the full set of requirements established by state law.

It is essential for legislation to clearly outline the educational pathways for Pathologists' Assistants, including:

- ASCP-certified Pathologists' Assistants trained via the on-the-job training (OJT) route
- ASCP-certified Pathologists' Assistants from Bachelor's degree programs
- Pathologists' Assistants from Master's degree programs
- ASCP BOC certification maintenance requirements

Licensure will not prevent practice across state lines

PAs interested in travel work must be credentialed in the state where they intend to practice. Currently, licensing requirements are inconsistent and vary significantly from state to state. However, as more states begin to implement licensing, we hope that neighboring states will allow for reciprocity. Many travel agencies also cover the costs associated with licensure applications, and these applications are typically reviewed and approved promptly—sometimes within a week. Other licensed professions, such as nursing, also offer travel opportunities across states. While travel nurses must obtain a license in each state, the field continues to grow in popularity, indicating that licensure does not deter nurses from pursuing travel work. With increasing recognition and licensure across states, there is potential for mutual recognition, where one state acknowledges the licensing and verification from another.

Licensure will not eliminate grossing technicians

The licensing of Pathologists' Assistants will clearly define the role and capabilities of PAs, encompassing all levels of complexity related to grossing and autopsy tasks within our scope of practice. Other personnel, such as biopsy or grossing technicians, should be clearly defined under a separate or "limited" license that restricts their scope of work to specific tissue types or CPT codes. This limited license would entail distinct educational standards, separate from those required for Pathologists' Assistants. Grossing tasks can then be delineated at different levels to reflect varying degrees of responsibility and expertise. For instance, New York effectively differentiates the grossing responsibilities of PAs and histotechnicians, allowing for the optimal use of both skill sets.



How licensure can be implemented effectively

Lawmakers often lack a clear understanding of the role of Pathologists' Assistants and their significant impact on patient care. Effective communication is essential. Some pathologists have proactively invited lawmakers into their practices to showcase our contributions and the consequences of reimbursement cuts. Many also participate in local and national policy events to advocate for our specialty and educate legislators.

Despite these efforts, confusion persists among legislators, clinicians, and patients regarding the role of Pathologists' Assistants and our ability to provide cost-effective, quality care. To persuade lawmakers to establish licensure for PAs, compelling anecdotal evidence can be compelling.

- We can share specific cases where PAs significantly improved patient outcomes, such as thorough specimen examinations leading to early cancer detection and timely treatment.
- Highlight instances where inadequate training or oversight in specimen processing caused errors that licensed PAs could have prevented, emphasizing potential risks to patient safety.
- Describe scenarios where PAs' accurate specimen processing avoided repeat tests and unnecessary procedures, saving resources for patients and healthcare facilities.
- Share how PAs have streamlined operations in pathology labs, resulting in faster turnaround times for diagnoses, will underscore the positive impact on patient care and clinician satisfaction.

Establish essential qualifications:

Identify and recognize essential qualifications for Pathologists' Assistants (PAs) and establish clear standards for safe PA practice.

We can begin by modeling the Nurse Practice Act (NPA), which stipulates that state legislatures can enact NPAs to establish the regulatory framework for nursing within their jurisdictions.

- The NPA outlines licensure requirements and defines the scope of practice. It establishes the authority, composition, and powers of the board of nurses, specifies types of licenses and their requirements, and sets educational program standards.
- The Board of Nursing makes licensure decisions based on comprehensive evidence that a candidate meets all state qualifications, not solely on passing the board exam.

Inclusion of all pathways

When a state establishes the requirements for education and training, the language for the varying pathways must be included in legislation to allow for:

- ASCP certified Pathologists' Assistant trained via the OJT route prior to 2008.
- BS program trained ASCP certified Pathologists' Assistants.
- MS program trained Pathologists' Assistants.

AND

- Completing ASCP BOC Certification maintenance requirements.

Grandfathering allows existing practitioners to retain their ability to work without needing to meet new licensing requirements. This approach acknowledges the experience and knowledge of current professionals who may not meet updated standards.

- A grandfathering clause must be included to prevent job loss among established workers currently performing the duties of a PA
- Need to balance consumer protection without disruption to the workforce or perpetuation of outdated practices if standards are not updated regularly
- Encourage policymakers to evaluate whether existing practitioners are meeting necessary competencies and whether their continued practice aligns with current public safety needs.

Streamlining Licensing

To facilitate easier movement and travel for Pathologists' Assistants (PAs), state licensing processes can be optimized.

- Single-State Licenses: Currently, PAs receive licenses granted by individual states, authorizing them to practice within that jurisdiction. A PA licensed in one state can obtain licensure in another
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- through endorsement, which involves verification of their original license along with meeting any additional state-specific requirements.
- **Mutual Recognition:** An emerging solution is mutual recognition, which allows PAs to hold a license in their home state while practicing in other participating states. This framework enables PAs to work across state lines unless specific restrictions apply.

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