

New York State Committee for Pathologists' Assistants
1411 Broadway
10th floor
New York, NY 11018

To whom it may concern:

The AAPA respectfully requests the opportunity to engage in discussion regarding the New York State requirements for performing macroscopic examinations (or grossing) for licensed clinical laboratory personnel, specifically Histotechnology professionals, and their associated regulations, particularly as they compare to and intersect with the licensure and scope of practice of Pathologists' Assistants.

The American Association of Pathologists' Assistants (AAPA) is a not-for-profit volunteer organization representing allied health practitioners in anatomic pathology. AAPA is the premier professional association for pathologists' assistants (PAs), supporting the individual practitioners as they serve patients, pathologists, and the broader healthcare system. We are greatly appreciative of New York State's efforts to formally recognize the PA profession through licensure and commend the state's commitment to protecting public health and safety.

We are writing to express concern that the current regulatory framework does not sufficiently distinguish between levels of grossing complexity permitted for licensed histotechnologists, versus licensed pathologists' assistants. While state licensure appropriately signals that an individual has met defined educational and competency standards, the existing scope of practice for histotechnologists does not ensure that licensees have completed the rigorous, pathology-specific training required to safely perform gross examination of complex specimens.

According to the New York State Education Department State Board for Clinical Laboratory Technology, a **histotechnologists' education requires:**

"A histotechnology program leading to a bachelor's or higher degree or post-baccalaureate advanced certificate, the combination of which shall:

1. *include coursework, which may include a laboratory component, in each of the following subject areas or their equivalent as determined by the department:*
 - a. *anatomy and physiology;*
 - b. *inorganic and organic chemistry;*
 - c. *histology;*
 - d. *histological techniques, including but not limited to; (i) specimen accessioning, grossing, fixation, processing, embedding, sectioning (including microtomy), and staining techniques; (ii) immunohistochemistry procedures; and (iii) molecular and cytology preparation techniques;*

- e. *laboratory operations relevant to histology services, including, but not limited to, quality control, quality assurance, equipment maintenance, record keeping, laboratory procedures, and safety; and*
2. *include a supervised clinical experience of at least 500 clock hours of histotechnologist practice”*

By comparison, NYS regulation 8601 requires that licensure as a **pathologists’ assistant** be predicated upon completion of *"a bachelor’s or higher degree in a pathologists’ assistant program registered by the Department, or the substantial equivalent of such a program as determined by the Department, or have a bachelor’s or higher degree in a National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) accredited pathologists’ assistant program."*

These programs are fundamentally different in scope and focus. Histotechnology programs emphasize specimen preparation such as accessioning, embedding, microtomy, and staining, while PA programs provide in-depth education in gross morphology, pathology, anatomy and tumor staging with extensive hands-on training in macroscopic examination (grossing). PA programs prepare practitioners to safely and accurately handle the full spectrum of specimen types, including complex oncologic resections that require detailed knowledge of cancer staging protocols critical to diagnosis and treatment.

Currently, NYS regulation 8601 defines a histotechnologist as:

"a clinical laboratory practitioner who pursuant to established and approved protocols of the department of health performs slide based histological assays, tests, and procedures and any other such tests conducted by a clinical histology laboratory, including maintaining equipment and records and performing quality assurance activities relating to procedure performance on histological testing of human tissues, and which requires the exercise of independent judgment and responsibility as determined by the department."

Notably, this definition restricts HTL practice to slide-based testing and does not include gross examination of specimens. Gross examination is however, explicitly authorized within the PA licensure scope of practice. It is entirely absent from the histotechnologist scope of practice, and appears only within the histotechnologist training requirements, an inconsistency that creates an apparent loophole that has resulted in the inappropriate expansion of histotechnologist duties beyond those explicitly permitted by law. Furthermore, in the Histotechnician FAQ page a question is asked “What are the regulatory requirements to perform gross examination” and the answer is: *“Grossing personnel must possess a license, such as, but not limited to, a physician or clinical laboratory technology practitioner license, or be otherwise authorized in statute or regulation to engage in the grossing process.”* This FAQ response provides conflicting information about which practitioners are permitted to perform gross examinations, while not defining what gross examinations are or if they are limited for any non-PA licensed professionals further supporting the loophole allowing any clinical laboratory practitioner to gross any specimen without requiring specific knowledge and training as set forth by law in the PA license requirements.

The AAPA has been made aware of licensed histotechnologists reportedly being trained and permitted to gross highly complex pathology specimens, including cancer staging cases. Failure to clearly regulate grossing responsibilities jeopardizes patient outcomes, as pathologic diagnoses depend on the accuracy of gross descriptions, the ability to recognize subtle abnormalities, assess tumor invasion, and perform selective tissue sampling. Allowing individuals to gross specimens beyond their authorized scope of practice increases the likelihood of misdiagnoses, inadequate staging, unnecessary or inappropriate surgical interventions, costly repeat procedures, and improper treatment. Additionally, the absence of clearly delineated grossing tiers between histotechnologists and PAs creates the potential for professional encroachment and undermines the licensure framework that New York State has so carefully implemented.

Given these reports, AAPA respectfully requests additional information and dialogue regarding the statutory or regulatory interpretations that allow licensed histotechnologists to perform gross examinations of highly complex cancer specimens. AAPA supports non-PA grossing personnel performing gross examination of specimens which are entirely submitted and does not seek to prohibit HTL staff from grossing altogether. Rather, we advocate for clearly defined limitations on the types and complexity of specimens handled by non-PA personnel, reflecting the significant differences in education and training.

We remain grateful for the state's leadership in recognizing and licensing pathologists' assistants, and now respectfully request your partnership in further clarifying and, if necessary, amending licensure definitions and scopes of practice to clearly define what non-PA personnel may gross and what limitations should apply. Such action would further New York State's commitment to patient safety, diagnostic accuracy, and high-quality care. Thank you for your time and consideration, and we welcome the opportunity for continued dialogue on this important issue. Please reach out to the AAPA for additional information.

Sincerely,

A handwritten signature in cursive script, appearing to read "E Paulsen".

Erika Paulsen, MS, PA(ASCP)
Board of Trustees Chair
American Association of Pathologists' Assistants

Attachments:

(1) AAPA Scope of Practice, (2) AAPA Position on Utilization of Non-Pathologist Grossing Personnel