NEW YORK STATE | Department of Health | Wadsworth Center

Clinical Laboratory Evaluation Program Updates

SED PathA Board Meeting
January 26, 2023

Supervision in Histopathology

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Authorized Supervisors in Histopathology

- Licensed pathologist
- Licensed pathology assistant with either 4 or 6 yrs exp, depending on degree
- Licensed cytotechnologist with 4 yrs exp.
- Licensed clinical laboratory technologist with 6 yrs exp.

Regulatory Amendments

- 58-1 of 10NYCRR, sections 1 thru 5, proposed amendments published Sep 2022

- Additional revisions being proposed, awaiting approval to post for additional 45-day comment period.

Regulatory Amendments

- Section 58-1.3 – Clinical Laboratory and Blood Bank Supervision
- Proposes remote supervision of testing personnel provided that:
  1. A supervisor is on-site at least 8 hours per week.
  2. A supervisor is available via telephone or 2-way audio-visual communication; ‘on-call’ hours must be defined for each supervisor if more then one.
  3. Remote vs. in-person responsibilities are documented.
  4. The laboratory is in good standing with CLEP (e.g., no patterns of noncompliance or PT failures)

- EO 4 and continuing orders allows remote supervision, currently expiring Jan 23, 2023

Regulatory Amendments

- Section 58-1.4 – Qualifications of laboratory supervisor
  - Proposal reduces exp threshold for clinical laboratory technologists

- Section 58-1.5 – Duties and qualification of clinical laboratory personnel
  - Proposal recognizes histological technicians – new revisions will align terminology with new SED law; change to histotechnicians.

Regulatory Amendments

- New title histotechnologists under SED, effective early 2024
  - Additional revisions to 58-1.5 planned. Need to discuss supervisor quals with SED Clinical Laboratory Board

Histopathology Specimens

Standards relevant to specimen tracking

Specimen Processing Standard of Practice 1 (SP S1): Specimen Submission Instructions – requires specimen to be labeled with 2 unique identifiers.

- Note that this applies to the original specimen received.

Specimen Processing Standard of Practice 5 (SP S5): Accession Procedure and Documentation – requires unique laboratory identifier (e.g., accession number) and patient identifier.

Standards relevant to specimen tracking

Specimen Processing Standard of Practice 7 (SP S7): Portion or Aliquot Identification and Integrity:

Specimen portions or aliquots must be traceable to the original specimen. Standard operating procedures for the preparation and handling of specimen portions or aliquots must describe measures to prevent the cross-contamination of primary and specimen portions…

Revisions to CLEP Standards 2020

- All CLEP standards were reviewed/revised in 2019 and 2020.
- Revised standards were proposed/adopted in 2020.
- There were no significant changes to the histopathology standards.