NEW YORK STATE DEPARTMENT OF HEALTH
CLINICAL LABORATORY EVALUATION PROGRAM

COMMENTS and RESPONSES to PROPOSED REPORTING STANDARDS

The Proposed Standards in the area of Reporting were circulated for comment on October 30, 2025. The announcement was sent to NYS-permitted facilities that held or were in application for a permit. This distribution was by e-mail to the facility, the Director's e-mail address, and the laboratory contact person's e-mail address. The documents were posted to the CLEP website.

The comment period ended December 29, 2025. Nine (9) comments were received.

The standards are considered to be accepted and will be adopted and effective as of February 12, 2026.

Proposed Standard	*Proposed Guidance*
Reporting Standard of Practice 1 (REP S1): Authorized Release of Test Results No change to existing standard	Supervisor qualified staff must verify that approved protocols are routinely followed by testing personnel who have been authorized to release results. Electronic signatures must be password protected. Personnel working remotely, in accordance with the current CLEP Remote Activities Policy, must be licensed in both the state where they are performing such work and in the state where the laboratory is located, where licensure is required.

Comment 1:

The proposed standard in green below is not appropriate for out of New York state labs in which no licensure is required from the state of physical location. For example, our lab is located in Missouri, and we have remote employees in other states. Neither Missouri nor the states where the employees reside require licensure. Thank you.

Personnel working remotely, in accordance with the current CLEP Remote Activities Policy, must be licensed in both the state where they are performing such work and in the state where the laboratory is located, where licensure is required.

Response 1:

The guidance states '…where licensure is required." If neither the state where the remote activities are taking place nor the state where the laboratory is located require licensure than remote personnel would not be expected to be licensed.

Comment 2 :

The CLEP Remote Activities Policy dated October 28, 2025, specifies in its final bullet that "personnel performing remote work must meet the licensing requirements of the state in which the primary laboratory is located".

By contrast, Reporting Standard (REP S1) Proposed Guidance references compliance with the current CLEP Remote Activities Policy, but states that personnel working remotely "must be licensed in both the state where they are performing such work and, in the state where the laboratory is located, where licensure is required".

We are seeking clarification regarding the licensing requirements for Reporting Standard (REP S1) Proposed Guidance.

Response 2:

Personnel performing remote activities must be licensed in the state where the work is being performed '…where licensure is required.' and as stated in the CLEP Remote Activities Policy dated October 28, 2025, must meet the licensing requirements of the state in which the primary laboratory is located. It is the laboratory's responsibility to ensure no individual employed by the laboratory is practicing a profession without holding the required license to perform such work.

Comment 3:

a. Will there be an implementation timeline for seeing licensure for Pathologists in both the state they are located in and the state the lab is located in?

b. The proposed update to REP S1 is unclear if the licensure requirements for remote personnel only applies to the role of Pathologist or if it is intended to apply to any additional roles.

Response 3:

a. Individuals must be licensed prior to performing the remote work.

b. The license requirements apply to all personnel working remotely; '…where licensure is required.'

Comment 4:

Can you clarify in the addition in the Proposed guidance for REP S1 is for cytopathology and histopathology?

Response 4:

The CLEP Remote Activities Policy dated October 28, 2025, does apply to histopathology and cytopathology currently.

Effective March 23, 2026, it does not apply to cytopathology. The following statement will be added to guidance: 'Remote review of cytology digital slides is not permitted.' This is also stated in the CLEP Remote Activities Policy dated October 28, 2025.

Comment 5:

Specific to the Proposed Guideline "Personnel working remotely, in accordance with the current CLEP Remote Activities Policy, must be licensed in both the state where they are performing such work and in the state where the laboratory is located, where licensure is required."

Complying with New York State (NYS) pathology licensure is not feasible for any [name redacted] labs managing global clinical trials because the requirements for US certification are incompatible with international regulatory systems.

The argument presented within is based on the below three main points:

- Global Reach: Global clinical trials depend on a large network of international experts, many of whom are located outside the United States.
- Regulatory Mismatch: International medical training and regulatory systems are fundamentally different and highly restrictive compared to US and NYS certification processes.
- Impracticality: It is therefore not practical for international assessors to obtain the necessary US and NYS credentials to review samples originating from New York State.

Response 5:

All laboratories that hold a New York State Permit regardless of location or testing performed must meet the requirement. Personnel performing remote activities must be licensed in the state where the work is being performed '…where licensure is required.' and as stated in the CLEP Remote Activities Policy dated October 28, 2025, must meet the licensing requirements of the state in which the primary laboratory is located. It is the laboratory's responsibility to ensure no individual employed by the laboratory is practicing a profession without holding the required license to perform such work.

Comment 6:

The Department's October 2025 draft of the General Standards for Clinical Laboratories includes the following language under Reporting Standard of Practice 1 (REP S1):

"Personnel working remotely, in accordance with the current CLEP Remote Activities Policy, must be licensed in both the state where they are performing such work and in the state where the laboratory is located, where licensure is required."

This proposed guidance statement introduces ambiguity that could be interpreted as requiring dual licensure for remote personnel performing digital review for New York-permitted laboratories—even though such a requirement does not appear in existing New York law, CLEP policy, or federal regulations. If applied as written, the guidance would create significant operational barriers, delay critical interpretations, and reduce

access to subspecialty expertise—particularly for underserved communities in New York State. *The laboratory* recognizes the Department's intent to maintain strong quality assurance for remote review activities. Fortunately, New York State already has a well-established statutory and regulatory framework, supported by policy statements that govern laboratory personnel qualifications and remote review practices. This framework clearly delineates responsibilities between the Department of Health and the New York State Education Department (NYSED), reinforced by current DOH regulations and federal CLIA standards. Together, these authorities provide robust oversight without requiring dual licensure—a structure that ensures patient access to specialized expertise. For example:

- Laboratory Personnel Licensure under Education Law Article 165: NYSED governs licensure for clinical laboratory technologists, cytotechnologists, and histotechnologists under Education Law Article 165. The statute expressly limits licensure to individuals practicing '*in this state*' (N.Y. Educ. Law § 8602). This means licensure applies when a person physically practices in New York—not when they perform remote digital review from another jurisdiction. Requiring a second New York license for personnel who never enter the state would go beyond statutory authority and duplicate qualifications already vetted by the reviewer's home jurisdiction.
- Department of Health operational authority under Public Health Law § 576(3): The Department's authority under Public Health Law § 576(3) is operationally focused and prescribes standards for laboratory management and the examination of specimens, including validation, reporting, and quality controls. It does not redefine professional licensure requirements, which remain under NYSED's jurisdiction, a fact recognized in the Department's internal regulation, 10 NYCRR § 58-1.5(b), which includes multiple deferential references to Article 165 and NYSED.
- Existing Department regulation respecting in-state vs. out-of-state practice: Department regulation 10 NYCRR § 58-1.5 requires NYSED licensure for technologists practicing in New York and recognizes equivalent licensure or specified education and experience for those practicing in laboratories outside New York. The regulation accommodates interstate practice and modern remote workflows without imposing dual licensure.
- Federal CLIA guidance and best practices: Federal policy reinforces this approach. CMS permits remote review under the primary laboratory's CLIA certificate, provided personnel are listed on *Form CMS-209*, secure access is maintained, and report location coding is clear. CLIA does not require duplicative state licensures for remote reviewers; instead, the policy emphasizes accountability through disclosure and laboratory certification.

To ensure clarity and alignment with existing policy, the proposed guidance sentence for *Reporting Standard of Practice 1 (REP S1),* should be revised to read:

"Personnel working remotely, in accordance with the current CLEP Remote Activities Policy, must be licensed in the jurisdiction where they are performing such work and must perform the work under the CLIA certificate or New York State clinical laboratory permit of the primary laboratory, as applicable, covering the applicable specialties and subspecialties."

This language is consistent with the Revised Clinical Laboratory Improvement Amendments of 1988 (CLIA) Post-Public Health Emergency (PHE) Guidance (revised Sept. 23, 2025) and accommodates quality assurance while maintaining patient access to medical expertise and efficient testing results.

If the Department seeks additional transparency, the Department's October 2025 CLEP Remote Activities Policy (*Revised October 28, 2025*) provides a strong and practical model. The Department's October policy revision already states that *"[t]he primary laboratory location must maintain a list of all personnel performing remote work, to include name, tasks qualified to perform, and the address of the remote location including any code being used to identify the location on test reports. This list must be made available to the Department upon request*."

Importantly, Federal CLIA policy reinforces the Department's approach to remote personnel disclosure by requiring laboratories to maintain a roster of personnel on *Form CMS-209* and ensuring secure access and proper reporting for remote review. Together, the New York State policy and CMS requirements already provide robust oversight without imposing a duplicative licensure burden.

In light of the potential unintended consequences of the proposed language, *the laboratory* respectfully urges the Department to clarify that the guidance does not impose dual licensure for remote reviewers and to adopt *the laboratory*'s recommended guidance language in order to preserve access to specialized expertise in New York and ensure consistency with New York law and federal standards.

Imposing dual licensure would risk reducing the pool of qualified experts available for remote review, ultimately limiting timely access to advanced diagnostic services for New York patients.

To that end, *the laboratory* respectfully requests the Department to:

a. 1) Clarify that dual licensure is not required for remote reviewers.

b. 2) Adopt *the laboratory*'s recommended language in Section III to align with existing state and federal policy.

c. 3) Maintain current oversight mechanisms that already safeguard quality and transparency.

Response 6:

a. To meet the requirement, 'Personnel working remotely, in accordance with the current CLEP Remote Activities Policy, must be licensed in both the state where they are performing such work and in the state where the laboratory is located, where licensure is required'; individuals would require dual licensure if the state in which they are working and the state the laboratory is located both have licensure requirements.

b. The location of the laboratory holding the permit is considered the location where services are delivered. Precedent has been set in telehealth where licensure is required for the state where services are delivered; individuals are considered to be practicing within the state (where services are delivered) regardless of physical location. The proposed guidance as written will stand.

c. The Clinical Laboratory Reference System (CLRS) will continue to meet the following objectives as stated in the CLEP Program Guide: (i) to monitor, improve, and broaden the clinical capabilities of participating laboratories and blood banks, (ii) to provide guidelines, quality control standards and procedures to be used by permit-holding clinical facilities, and (iii) to provide continuing education opportunities for technical personnel involved in the operation of clinical laboratories through training and remediation programs.

Reporting Standard of Practice 2 (REP S2): Test Report Content Test results must be available in a timely manner to the authorized ordering source or client. Laboratories must be capable of producing a ~~hard~~ copy of a laboratory	A "copy" of a laboratory report may be either electronic or hardcopy.

report that meets the below requirements. Report information, whether required or discretionary, must be accurate. Test results, whether transmitted electronically or by hard copy, must include all required report information, including: a) patient name or other identification; b) the name and address under which the reporting laboratory has been issued a permit, unless the laboratory has reported to the Department an alternative name (e.g., "doing business as"); c) the date, and hour if required, when the specimen was collected; d) the test report date; e) specimen type and/or source (i.e., anatomic location), when appropriate; f) the test(s) performed g) test results, and if applicable, units of measure, reference ranges, or a similar method for identifying abnormal values; i. Alternative mechanisms to provide reference ranges, etc. to clients may be approved by the Department; h) signature of the qualified person who reviewed, approved and/or diagnosed the case, as required under Reporting Standard of Practice 1; or i. a record of the cytotechnologist releasing the report is required for negative gynecological cytopathology reports; and i) a statement on the report if compromised specimens are tested, the nature of the problem and, if applicable, any impact on result interpretation; j) if applicable, the name and address of the reference or contract laboratory and the date the specimen was tested or the date the result was reported; k) any disclaimers or limitations to testing where required by the Department for an approved laboratory developed test (LDT); l) any additional information required for the interpretation of results; and	j) The address of a remote location performing review of digital results under a laboratory's permit may be indicated on the final report by a code. The testing laboratory is responsible for maintaining a 'key' to correlate codes to addresses. l) Examples include: disclosure of the specific equation used for eGFR for physician awareness, limitations stated by the manufacturer prohibiting testing, or limitations stated by the manufacturer affecting results in certain patient population.

m) any other information as required in any part of the New York State Clinical Laboratory Standards of Practice. *Regulatory authority: 10 NYCRR paragraph 58-1.11(b)(2)*	

Comment 1:

a. If a 'key' is acceptable for identifying remote locations performing analysis activities as proposed in REP S2, it would be valuable to have examples of what is acceptable.

b. For remote reporting activities it would be valuable for the proposed update to REP S2 to include guidance on how to address any hybrid employees performing remote reporting activities for what NYSDOH would expect to see.

Response 1:

a. Codes may be numerical, alphabetical, abbreviations or any other format deemed acceptable by the Laboratory Director. The laboratory must be able to determine the address at which the remote work was performed based on their internal key for the code used on the report. (i.e., if 'a' is the code for the remote location where the work was performed; the key would identify 'a' is 123 Tree Ave. Albany, NY 14223)

b. The expectation is the report will indicate where the work was actually performed. If the employee is performing work at a remote location, the address of the remote location or a code must be on the report. If the employee is performing work on-site at the laboratory, the address of the laboratory must be on the report. It is the laboratory's responsibility to ensure the correct location is on the report.

Comment 2:

Question: Practice 2 Proposed Guidance j) – if a digital review of results occurs while traveling to different locations does there need to be a code for each location?

- Different Lab
- Home
- Airport

Or can there be one code indicating the person reviewing with their normal location indicating they are traveling?

Response 2:

New York State requires the address, or a code be on the report for each remote location where remote activities are being performed. In addition, the following requirement must be met: 'Personnel performing remote activities must be licensed in the state where the work is being performed '…where licensure is required.' and as stated in the CLEP Remote Activities Policy dated October 28, 2025, must meet the licensing requirements of the state in which the primary laboratory is located.'

Performing remote work at a 'Different Lab' is not allowed. If performing remote work on-site at a 'Different Lab' the employee is, consider to be working at that laboratory. The laboratory must hold a New York State permit with the applicable category. The name and address of that laboratory must be on the report as the performing location.

Comment 3:

The *organization* recommends the addition of "*Examples include: disclosure of the specific equation used for estimated Glomerular Filtration Fate (eGFR) for clinician awareness, limitations stated by the manufacturer prohibiting testing, or limitations stated by the manufacturer affecting results in certain patient population*" to the Proposed Guidance for "l) any additional information required for the interpretation of results." Calculated test results may differ based on the equation used. When the source equation is not readily available to clinicians it may impact results assessment and/or comparison across laboratories, healthcare delivery settings, and patient populations.

Response 3:

CLEP agrees with the recommendation. The guidance for 'l) any additional information required for the interpretation of results' will be changed to 'Examples include: disclosure of the specific equation used for estimated Glomerular Filtration Rate (eGFR) for clinician awareness, limitations stated by the manufacturer prohibiting testing, or limitations stated by the manufacturer affecting results in certain patient populations.'