NEW YORK STATE | Department of Health | Wadsworth Center

Regulatory Update

Clinical Laboratory Evaluation Program

Beverly Rauch
Director

Clinical Laboratory Evaluation Program (CLEP)

Oversight of clinical laboratories performing testing on specimens originating from New York State.

Elements of oversight:

- Laboratory survey
- Monitor proficiency testing performance
- Review of laboratory developed tests (LDT)

Regulatory Revisions – Subpart 58-1

Section 58-1.1 Permits

- Defines the permitting process – including provisional permits
  - Provisional permits allowed when physical inspection cannot be performed (e.g., public health emergency, etc.)
- Establishes criteria for permit denial
- Removes the outdated listing of permit categories
- Clarifies conditions to be met to stay permit void
- Codifies a process to grant patient-specific or test-specific single use permits to otherwise unpermitted laboratories.

Section 58-1.2 Laboratory Director

- Codifies the title ‘sole assistant director’
  - Essentially equivalent to a ‘technical consultant’ under CLIA
- Expands directorship limit from 2 to 5 labs
  - This includes both NY permitted and non-permitted, CLIA certificate holding labs
- Establishes criteria for onsite presence of director
- Requires notification of director resignation, termination, death or physical/mental incapacitation within 60 days – or permit is void

Public Comments

- Directors:
  - Definition of regular part time hours and need for flexibility
    - A process exists to request presence of less than ‘regular part time hours’
    - Note that a supervisor, who is not the director, must be present at least 8 hours per week, per section 58-1.3.

Section 58-1.3 Supervision

- Remote supervision!
  - 8 hrs per week on site min
  - Supervision of 5 labs max
  - Immediate accessibility via phone, text, FaceTime, etc.

- SED clarification: provisional permit holders require full-time direct supervision, by legal definition they are not licensed clinical laboratory practitioners.

Public Comments

- Is explicit DOH approval for remote supervisions required?
- Can the required 8 hours per week be divided between more than 1 one person?
- Are directors / assistant directors required to be on-site 8 hours per week?

Section 58-1.4 Supervisor Quals

- Reduced experience required
  - Certificate of Qualification holder
  - MD/DO and qualifies as CLT + 1 year exp
  - Licensed MS/MA degree with 2 yrs exp
  - Licensed BS/BA degree with 4 yrs exp
  - Licensed cytotech with 4 yrs exp
  - Resp Therapy Technologist with 4 yrs exp (blood gas only)

Public Comments

- Would like to see years of experience reduced further to only 2 years with a baccalaureate degree

Section 58-1.5 Technical Personnel

- Licensure required for personnel employed by laboratories located in New York
- Executive Order 4.1 and continuing: modifies 8602 and 8603 of education law and 58-1.5 of 10 NYCRR
  - "perform any clinical laboratory test on any specimen, including for the detection of SARS-CoV-2 and influenza, provided such individual is under appropriate supervision and meets the federal requirements for testing personnel appropriate to the assay or device authorized by the FDA or the New York State Department of Health"

Survey Window

- August 2022 policy change

- Surveys will be performed within 18 – 24 months after the last routine survey

TOP TEN SURVEY FINDINGS CY 2021

1	**REP S2**	**Reporting Standard of Practice 2 (REP S2): Test Report Content**	**116 (22%)**
• **Reference laboratory name and/or address is incorrect or missing** • **Reference range is missing or inconsistent with SOP** • **Laboratory name and/or address on report no consistent with name/address on permit** • **Report date not indicated on report**			
2	**DC S1**	**Document Control Standard of Practice 1 (DC S1): Availability**	**116 (22%)**
• **SOP not current and/or accurate** • **SOP missing for one or a few procedures**			

TOP TEN SURVEY FINDINGS CY 2021

3	**TPC S1**	**Test Procedure Content Standard of Practice 1 (TPC S1): Test Procedure Content**	**103 (20%)**
• **Required elements missing (reference range, QC requirements or materials, etc.)** • **No SOP available for procedure**			
4	**DR S2**	**Director Standard of Practice 2 (DR S2): Health Commerce System**	**100 (20%)**
• **No SOP for HCS**			

TOP TEN SURVEY FINDINGS CY 2021

5	**QMS S3**	**Quality Management System Standard of Practice 3 (QMS S3): Quality Indicators**	**94 (19%)**
One or more (usually more or all) of the required quality indicators were not established.			
6	**HR S8**	**Human Resources Standard of Practice 8 (HR S8): Competency Assessment – Testing Personnel**	**90 (18%)**
• **Six months competencies not performed for new hires.** • **Direct observation not performed.** • **Comp assessment not performed for one or more assigned tasks/procedures.** • **Comp assessments not signed by supervisor/manager/director.**			

TOP TEN SURVEY FINDINGS CY 2021

7	**DC S2**	**Document Control Standard of Practice 2 (DC S2): Compliance**	**83 (16%)**
SOP was not followed or the SOP is not current; therefore practice does not match SOP.			
8	**RGM S1**	**Reagent and Media Standard of Practice 1 (RGM S1): Reagent and Media Records**	**75 (15%)**
Required reagent data (date received, date in use, date verified, etc.) not recorded.			

TOP TEN SURVEY FINDINGS CY 2021

9	**PT S10**	**Proficiency Testing Standard of Practice 10 (PT S10): Performance Review – All Results**	**59 (12%)**
• **No documentation of director or designee review of PT results.** • **Director or designee review not documented within 2 weeks of PT result release.**			
10	**LEI S3**	**Laboratory Equipment and Instrument Standard of Practice 3 (LEI S3): Function Checks and Performance Verification of Instruments, Equipment and Test Systems**	**55 (11%)**
• **Speed checks for fuges not documented** • **Weekly maintenance not performed according to schedule.** • **Calibration/performance verifications not performed according to schedule.** • **Most common equipment cited were centrifuges, timers and thermometers.**			

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Questions?
clep@health.ny.gov