INTERPRETIVE GUIDANCE FOR OVERSIGHT OF CLINICAL LABORATORIES

May 2024

Background

Over the last several months, the Department of Health Bureau of Laboratories (BOL) has undertaken a review of its interpretation of regulations that provide for the oversight and supervision of clinical laboratories operating under a BOL-issued permit. Historically BOL has aligned its interpretations with those published by the Centers for Medicare & Medicaid Services (CMS) in the Clinical Laboratory Improvement Amendments (CLIA) State Operations Manual (SOM). However, given current challenges in recruiting and hiring staff in Pennsylvania laboratories, BOL is providing updated interpretive guidance that will benefit the regulated community in several ways, including:

1. Aligning with CLIA regulations where possible to reduce administrative burdens on laboratories that must comply with both state and federal standards.
2. Providing broader interpretations tailored to the complexity of the testing performed by the laboratory rather than a one-size-fits-all approach.
3. Giving laboratories broader discretion to determine qualifications of supervisory personnel based on the individual laboratory's scope of testing and patient population.

While this interpretive guidance will afford greater staffing flexibility to clinical laboratories, laboratories will continue to be expected to have appropriate oversight and quality control mechanisms in place to ensure the reliability and accuracy of patient test results.

General Oversight Requirements

All laboratories must have adequate supervision of the laboratory's activities. The Clinical Laboratory Act requires all laboratories to be under the "direct and personal supervision" of a laboratory director meeting the statutory qualifications.[1] The duties of the laboratory director include employing qualified personnel; ensuring the proper performance of all tests; directing and supervising all tests and work of subordinates; and continuous application of quality control procedures.[2] While the laboratory director is ultimately responsible for these duties, the regulations allow functions to be delegated to qualified supervisors.

The Clinical Laboratory Act regulations define a supervisor as "[a] properly qualified individual, who, under the direction of an authorized director, may supervise the general activities of a clinical laboratory, or a properly qualified individual who under the direction of an authorized director, may supervise the technical work in a laboratory category."[3]

The laboratory director may allow a supervisor to supervise the general activities of a clinical laboratory, but they are not required to do so and could perform those functions themselves in accordance with Sections 5.22 and 5.23 of the regulations. Regardless of the manner in which a laboratory chooses to establish its supervisory structure, qualified supervisory

[1] 35 P.S. § 2153.
[2] 28 Pa. Code § 5.22.
[3] 28 Pa. Code § 5.1.

personnel must be on-site during all normal scheduled working hours in which tests are being performed.[4]

Regulations Subject to Interpretive Guidance

Section 5.21 of the Clinical Laboratory Act regulations states, in relevant part:

> (a) No person shall be a director of a clinical laboratory unless he conforms with one of the following requirements:
>
> > (1) [They] shall hold a doctor of science degree or its equivalent in the basic sciences of chemistry, biology or microbiology or a doctoral degree in public health, medicine, osteopathy, pharmacy, dentistry or veterinary medicine from a college or university recognized by the National Committee of Regional Accrediting Agencies or the Department of Education of the Commonwealth of Pennsylvania, and who has had 2 years' experience in a laboratory acceptable to the Department or is certified by the American Board of Pathology, American Osteopathic Board of Pathology, American Board of Microbiology, American Board of Bioanalysis. American Board of Clinical Chemistry, or other national accrediting board in laboratory specialties acceptable to the Department.
> >
> > ***
> >
> > 28 Pa. Code § 5.21 (a)(1).

Section 5.23 states:

> (a) No person shall be a supervisor in a clinical laboratory unless he conforms with one of the following requirements:
>
> > (1) [They] shall have an earned doctoral degree from an accredited institution and shall have gained at least 2 years' experience acceptable to the Department in one or more of the applicable categories in the clinical laboratory.
> >
> > (2) [They] shall hold a M.A. or M.S. degree from an accredited institution with a major in medical technology or one of the biological, physical or chemical sciences and shall have had at least 4 years' experience acceptable to the Department in one or more of the applicable categories in the clinical laboratory.
> >
> > (3) [They] shall hold a B.S. or A.B. degree from an accredited institution with a major in medical technology or one of the biological, physical or chemical sciences and shall have had at least 6 years' experience acceptable to the Department in one or more of the applicable categories in the clinical laboratory.
> >
> > 28 Pa. Code § 5.23(a)(1)-(3).

Acceptable Experience for Laboratory Directors and General Supervisors

[4] 28 Pa. Code § 5.23 (b)(1).

Effective immediately, BOL will interpret the phrase "experience in a laboratory acceptable to the Department" from section 5.21 and the phrase "experience acceptable to the Department" from section 5.23 as set forth below. **The education degree types and number of years' experience required by regulation will continue to apply.**

CERTIFICATE OF WAIVER

- Laboratory director: Experience in a laboratory acceptable to the Department shall include experience directing, supervising, or performing waived tests **– or –** experience ordering and reading waived test results.
- General supervisor: Experience acceptable to the Department shall include performing waived testing **– or –** other experience as determined and documented by the laboratory director to be acceptable.

PPMP CERTIFICATE

- Laboratory director: Experience in a laboratory acceptable to the Department shall include experience directing, supervising, or performing waived tests or PPM procedures **– or –** experience ordering and reading waived or PPMP test results.
- General supervisor: Experience acceptable to the Department shall include performing waived testing or PPM procedures **– or –** other experience as determined and documented by the laboratory director to be acceptable.

MODERATE COMPLEXITY

- Laboratory director: Experience in a laboratory acceptable to the Department shall include:
    - One (1) year directing or supervising non-waived tests -**and**- one (1) year of laboratory training; experience in laboratory management; laboratory science coursework; laboratory experience obtained during residency; teaching experience related to clinical laboratory science program; research experience obtained while performing testing on human specimens.

      – or –

    - Twenty (20) Continuing Medical Education (CME) hours in laboratory practice -**and**- two (2) years of laboratory training; experience in laboratory management; laboratory science coursework; laboratory experience obtained during residency; teaching experience related to clinical laboratory science program; research experience obtained while performing testing on human specimens.
- General supervisor: Experience acceptable to the Department shall include performing non-waived testing **– or –** other experience as determined and documented by the laboratory director to be acceptable.

HIGH COMPLEXITY

- Laboratory director: Experience in a laboratory acceptable to the Department shall include one (1) year laboratory training **-and-** one (1) year experience directing or supervising high complexity testing– **or –** two (2) years' experience directing or supervising high-complexity testing.

- General supervisor: Experience acceptable to the Department shall include one (1) year of training or experience in high complexity testing **-and-** additional other experience as determined and documented by the laboratory director to be acceptable.

Demonstrating Compliance

Laboratory owners and directors will continue to be responsible for the employment of personnel that meet the qualifications specified in regulation as interpreted in this guidance. The types of experience acceptable for the director and supervisor positions, as applicable, shall be documented and made available to BOL upon request. Laboratories will be expected to maintain documentation of personnel credentials evidencing they meet the qualifications for the position for which they are employed or contracted. Curriculum vitae (CVs) will not be acceptable to demonstrate qualifications.

Other Information

Nothing in this guidance should be construed as affecting or interpreting any Federal or State law or regulation outside of the Department's jurisdiction that may impose additional qualifications or limitations on employment of certain personnel in a clinical laboratory setting.