



NEW YORK CITY DEPARTMENT OF  
HEALTH AND MENTAL HYGIENE  
Michelle Morse, MD, MPH  
Acting Health Commissioner

February 20, 2026

Gotham Center  
42-09 28th St.  
Long Island City, NY 11101

via electronic submission: [REDACTED]

**Re: Comments on New York State Proposed Rules: Certificates of Qualification for Clinical Laboratory Directors [I.D. No. HLT-51-25-00008-P] and Clinical Laboratories [I.D. No. HLT-51-25-00009-P]**

Dear Ms. Ceroalo:

The New York City Department of Health and Mental Hygiene (NYC Health Department) appreciates the opportunity to submit comments in response to the New York State Department of Health's proposed rules repealing Part 19, adding Subpart 58-6, and amending Subpart 58-1 of Title 10 of New York Codes, Rules and Regulations (N.Y.C.R.R.), which sets forth definitions, requirements, and other matters related to clinical laboratory directors and technical directors.

The NYC Health Department supports the direction and general framework of the proposed rules and recommends the following to add greater clarity and specificity:

**1. Specify in Sections 58-6.2 and 58-6.4 that an individual may simultaneously hold both a Laboratory Director Certificate of Qualifications (LDCQ) and Technical Director Certificate of Qualification (TDCQ).** This is alluded to in the paperwork section of the Regulatory Impact Statement, but this should be made explicit in the text of the rule.

**2. Clarify the requirements for an initial application for a Laboratory Director Certificate of Qualification and a renewal of a Laboratory Director Certificate of Qualification in Sections 58-6.2(b)-(c).** This proposed language is vague and leaves open the possible interpretation that a current or recent laboratory director is exempt from the board certification and laboratory training requirements altogether. To clarify that the exemption is just to the 10-year window in which said requirements must have occurred, we recommend amending the proposed rule as follows (new text is underlined; deleted text in brackets):

The applicant must demonstrate that board certification and laboratory management training occurred within the previous 10 years, [or they have served as a laboratory director in an acceptable laboratory within the previous 10 years] except that an applicant who has served as a laboratory director in an acceptable laboratory within the previous 10 years must only demonstrate completion of board certification and laboratory management training.

We further suggest subdividing paragraph (2) under subdivision (d) into subparagraphs for each requirement, as is done elsewhere in the proposed regulations, as follows:

- (2) be a physician who, within the previous 10 years, has at least:
  - (i) two years of experience supervising high complexity clinical testing;
  - and
  - (ii) at least 20 credit hours in clinical laboratory operations training to include training in the responsibilities outlined in this section; or

The NYC Health Department also recommends specifying that the 20 credit hours in clinical laboratory operations is required only for the initial application and not annually or for each subsequent renewal. This would more clearly delineate between renewing (proposed Section 58-6.2 subdivision (c)) and maintaining (subdivision (d)) a Certificate of Qualification.

- 3. Specify the permissibility of having multiple technical directors for a testing category, as well as the applicability of laboratory director experience towards a TDCQ.** Given increasing hiring and retention challenges, it is vital that laboratories plan for staffing changes to ensure there are no disruptions in essential public health laboratory services. This can be accomplished by specifying that a laboratory may have multiple technical directors for a permit category and that acting as a laboratory director for a facility that performs a testing category is applicable experience for a TDCQ.
- 4. Add board certification through ABB(HCLD) for TDCQ for Diagnostic Immunology.** The current regulations accept board certification through ABB(HCLD) for Diagnostic Immunology, and the proposed rule (§58-6.4(f)) accepts ABB(HCLD) for Bacteriology, Mycobacteriology, Mycology, Parasitology and/or Virology (paragraph (2)) but not Diagnostic Immunology (paragraph (11)).
- 5. Renumber proposed Section 58-6.2(d) to avoid two paragraphs numbered (3).**

Thank you for the opportunity to comment on this important matter.

Sincerely,



Sarah L. Braunstein, PhD MPH  
Acting Deputy Commissioner  
Division of Disease Control  
Department of Health and Mental Hygiene