

Meeting New York State Requirements for Clinical Laboratory Science Licensure at a Liberal Arts College

Abstract

Clinical Laboratory Science (CLS) programs are most students' sources of guidance for entry level curricular content areas and their related coverage on the American Society for Clinical Pathology Board of Certification exams. However, in states that offer Clinical Laboratory Science licensure such as New York, licensure eligibility requirements may not align with board exam eligibility requirements. The differences can include curricular expectations that may exceed the entry level curriculum, and a minimum number of hours of supervised clinical experience. This article will detail the licensure eligibility requirements for Clinical Laboratory Science programs in New York, and explore how those requirements impacted the design of the Clinical Laboratory Science program at Nazareth College. Nazareth College's program opened in the fall of 2014 with goals of meeting students' educational needs, preparing students for certification exams, and meeting all requirements for licensure eligibility. Utilizing a multi-faceted approach to provide comprehensive didactic, laboratory, and clinical learning, the program met these goals within its initial four years.

Abbreviations

MLT - Medical Laboratory Technician, MLS - Medical Laboratory Scientist, CLS - Clinical Laboratory Scientist, NAACLS - National Accrediting Agency for the Clinical Laboratory Scientist, ASCP BOC - American Society for Clinical Pathology Board of Certification, NYS New York State, A&P - Anatomy and Physiology

Index Terms

Curriculum; Education; Licensure; New York

Introduction

Professional licensure has been the subject of debate for clinical laboratorians for decades, bringing into contrast the needs to prioritize patient care and safety against the potential negative effects imposed by increased regulatory burdens and ability for potential laboratorians to access the profession. Licensure of clinical laboratory scientists can help ensure that only appropriately qualified personnel are performing medical testing, ensuring the completion of proper training for complex testing and instrumentation, as well as enhancing a laboratory's capacity to detect and resolve pre-analytical, post-analytical, and analytical errors¹. Licensure itself also acts as a property right, an authoritative right and privilege to perform clinical laboratory testing that cannot be revoked without just cause. Currently, there are eleven states, as well as the territory of Puerto Rico, that offer licensure (California, Florida, Georgia, Hawaii, Louisiana, Montana, Nevada, New York, North Dakota, Tennessee, and West Virginia)².

One of the more significant concerns about the impact of clinical licensure is how state licensing laws can place additional educational burdens that limit the pool of clinical laboratorians³. Licensing requirements often include completion of an appropriate national certification exam, hours of clinical practice, and continuing medical education requirements. Less commonly, including in New York, clinical scientists must also meet specific curricular requirements in excess of those commonly expected with NAACLS accredited programs⁴. While clinical laboratory science programs in New York typically train their students to meet both national certification exam requirements as well as state licensure requirements, certified clinical laboratorians from outside New York sometimes encounter a situation where a missing educational requirement makes them ineligible for licensure despite their certification.

In 2014, Nazareth College of Rochester opened a new clinical laboratory sciences program after receiving approval from the New York State Office of the Professions review program. The purpose of this article is to discuss the creation of this program in the context of meeting the requirements of New York licensure. We hope that in doing so, clinical laboratorians, educators, and advisors can better prepare themselves and their programs to meet these requirements.

Clinical Laboratory Scientist License Requirements in New York

New York introduced licensure with the Clinical Laboratory Technology Practice Act which passed in 2004 and laid forth Article 165 in Title VII of the state law⁵. The law further includes Commissioner's regulations that specify the curricular expectations and the categories of licensure, including clinical laboratory technologists, technicians, cytotechnologists, histologic technicians, and clinical laboratory supervisors and directors⁴. In the law's original application, the standard pathway to licensure was accompanied by grandfathering and transition pathways. These additional pathways became unavailable in 2009 and 2013, respectively. New York's standard licensure requirements have both similarities and differences to licensure requirements in different states. Most licensing states, including New York, recognize and require passage of

a national certification exam such as the ASCP BOC MLS or MLT exams. Likewise, licensing states typically require an appropriate baccalaureate degree either in clinical laboratory sciences or a related scientific discipline. New York's standard pathway requires either a specific baccalaureate degree in clinical laboratory science or a baccalaureate degree in the sciences followed by an advanced certificate program in clinical laboratory science⁵. New York also requires that such baccalaureate or advanced certificate programs be deemed "licensure qualifying", which requires meeting additional requirements (also thereby extending these requirements to all licensure candidates). This status requires new programs to submit an application to the Office of the Professions review program for approval, as described above.

The guidance on these requirements broadly directs programs to ensure pre-analytical, analytical, and post-analytical topics are covered, but more specifically outlines class and curricular requirements. These requirements are outlined in **Table 1** for the technologist and technician levels. The classroom requirements indicate topic areas requiring both didactic and laboratory classwork, the latter of which can potentially represent a challenge for licensees coming from out-of-state programs without such requirements and for programs trying to control faculty workload and major credit loads. The curricular requirements do not come with particularly precise expectations; it is clear that programs must cover these topics but they are afforded latitude in how they choose to do so. The final requirement specifies that students must complete 720 hours of clinical rotations. Unlike many of the other licensing states, New York does not require periodic submissions of documentation showing continuing education for license renewal.

Restricted Licenses and Provisional Permits

New York additionally offers some licensing options for specific situations. Restricted licenses are available, requiring specific training programs, in areas adjacent to the main body of clinical laboratory practice, for example cytogenetics, histocompatibility, or stem cell work. The state has offered limited licenses in the past, intended as temporary solutions for those with out of state licenses and/or CLS credentials but a gap in meeting the state's education requirements. These limited licenses will stop being renewed and are being phased out as of August 2018, a change brought about with the recent passage and signing of a bill that establishes a provisional permit to achieve similar ends (this bill amends the Clinical Laboratory Technology Practice Act)⁶. These permits last for a year with the option to renew a single time for a second year. This legislative fix creates a permanent solution for this problem, as the previous limited license provision was intended to sunset, yet received regular extensions allowing those who did not complete their final educational requirements to continue without earning full licensure.

Solutions from a Small Liberal Arts College

Nazareth College is a primarily undergraduate institution with a student body of around 2,900 (around 2,000 undergraduates), with a focus on the liberal arts but also including some professional and graduate programs, primarily in education and health and human services. Given this setting for the college, several guiding principles emerged for the design of the new clinical laboratory sciences program, which would be housed within the Department of Chemistry and Biochemistry. Foremost was the need to differentiate what coursework required new development directly by the clinical laboratory sciences program. Likewise, it was important to identify where existing coursework housed in the departments of chemistry, biology, or mathematics could serve CLS students and meet their licensing requirements. Additionally, New York's curricular requirements (those that did not meet the classroom requirement level) needed to be clearly met, especially in situations where no specific course would directly fulfill a particular requirement. Throughout all of this loomed the challenge of keeping the credit load of the program manageable. The liberal arts core at Nazareth comprises 41 credits with relatively little overlap with programmatic needs, where a combination of CLS coursework, NYS requirements, and clinical experience result in a large credit load.

New or Existing Courses?

It became clear that the program would need to create new coursework for most of the main content areas covered by NAACLS accredited programs and directly represented on the ASCP board exam. There was one happy exception in the area of molecular diagnostics; a combined course in the biochemistry of nucleic acids and molecular biology already existed, with a clinical focus. This course could be easily adapted to the CLS program's needs, without compromising the content offered to students in other majors. These courses found themselves sequenced in the last 2 years of the program, while many of the other state-required topics naturally fit in the foundational coursework of the first two years of the program.

Another reality of the small college setting is that the CLS program would generally need to adapt current course offerings where possible. Given the size of departments and the student body, it was not practical to create CLS specific versions of all courses. An example of this situation was the immunology course, already offered in a strong biology course that extensively covered the topic, with two caveats. The immunology course did not have an extensive clinical focus and did not offer a laboratory. Resolving the first challenge required communication with the Biology department to negotiate the inclusion of clinical content and to explain CLS curricular needs. Creation of a new laboratory course, however, was ultimately not feasible, and so the CLS program identified specific classes and activities elsewhere in the program where serology, immunoassays, and other clinical applications of immunology could be discussed and performed.

Foundational Sciences

The simplest challenges to resolve were generally the foundational math and science courses which would not benefit from a CLS specific focus, including inorganic chemistry (covered in general chemistry), analytical chemistry, and statistics, where existing coursework easily sufficed. However, coverage of physiology and organic chemistry shared a common problem. To what extent should the program cover these topics, especially when the content of existing courses may exceed what is needed and risk adding credits to an already large burden? Likewise, are courses that cover these topics at a level appropriate for allied health programs suitable, or should the courses approach the material as they would for biology or chemistry majors?

For organic chemistry, the choice was between a two semester sequence for chemistry and biochemistry majors, or a combined organic and biochemistry course for allied health professions. In this case, the combined course serves the students in the program well, ensuring coverage of needed topics but leaving students flexibility for completing other requirements. The choice for anatomy and physiology (A&P) looked similar, either choosing between a two semester sequence in human physiology (including work in a cadaver lab) or a single semester course in animal physiology. The two semester A&P sequences had a relatively heavy anatomic focus as the courses also supported the allied health professions. After evaluation of the syllabus it became clear that the physiologic systems of the body were well represented. The A&P courses also gave students contact with fixing of tissues and histology, an added benefit.

Curricular Requirements

The remaining curricular material (see **Table 1**) was primarily integrated from existing college educational opportunities. Nazareth College's science departments had both an extant laboratory safety training course as well as a separate bloodborne pathogen course, the latter administered by campus safety as an online module. While nearly all laboratory courses began with safety discussions, the program requested the safety training course incorporate the bloodborne pathogen training into one combined, required course, which lets the program prove students have received this training. The maintenance of equipment and records occurs primarily in the clinical rotations, where students observe the clinical laboratories directly. Finally, while ethics was intended to be present throughout the curriculum, specific units in an introductory laboratory medicine course and in a laboratory management course allow the program to clearly indicate where students were introduced and could show mastery of the material.

Arranging the Clinical Experience

During early planning for the clinical laboratory science program, the decision was made to model the program as a 2+2 program that would pursue NAACLS accreditation. Given that the college would hold the accreditation, the program needed to contact potential clinical sites. Generally, clinical sites were eager to have students, keenly aware of the benefit of participating

in their education, and the potential future benefit to attracting these students to open positions. A general concern of potential clinical affiliates was the coordination of scheduling and timing given their own work and staffing. The fall semester in the senior year was revealed as an effective time for Nazareth students and the clinical sites, who needed to manage their schedules and prior agreements with other CLS programs. However, Nazareth College operates on a fifteen week semester, meaning that at a rate of 40 hours per week, students would accumulate a maximum of only 600 hours, and this number would not include time missed for holidays. In addition to classes cancelled by Nazareth as part of the Labor Day and Thanksgiving holidays, the clinical affiliates also indicated that staffing shortages tended to occur on Columbus Day due to public school closure.

The program needed to ensure that we met and exceeded the 720 hour requirement, giving students the chance to miss a reasonable amount of time for illness or family emergency and still meet their hours. The solution lay in the fact that the specific language of the requirements, indicating the need for “a supervised clinical experience of at least 30 hours per week for at least 24 weeks or its equivalent as determined by the department...” We followed the example of other programs that included laboratory coursework in CLS topics to allow students to acquire the additional hours. The program used on-campus laboratory courses in clinical chemistry, hematology, microbiology, transfusion service, and urinalysis/body fluids to meet an additional 200 hours of training, with each lab offering approximately 40 hours of training.

Nazareth College lacks a direct connection with a major medical center, creating the challenge of ensuring that said laboratory courses offered a true training equivalent. This required ensuring the inclusion of content that covered pre-analytical through post-analytical issues, work with human specimens, and also importantly simulating actual laboratory function including the reporting of results, both in written and oral format. To meet this need, laboratory courses incorporated simulated “dry lab” experiences focusing on the interpretation of data, the detection of errors anywhere from sample collection to resulting, and the proper medical reporting of appropriate results.

Overall, after a recent change adding the finals week to the clinical rotations as a sixteenth week, the program offers students approximately 800 hours of clinical experience.

Conclusion

The requirements for licensure have major implications for programs and students in New York, but also for those who might one day move to the state and seek to obtain licensure. Only New York and California have class requirements in excess of what NAACLS accredited programs offer, setting the stage for frustration for certified out-of-state clinical laboratorians and the laboratories that would hire them. The new provisional permit law is meant to stabilize a mechanism for these scientists to begin working while finding a way to fill educational gaps. Hopefully, a broader discussion of the state licensure requirements will let faculty advisors and students begin conversations about whether graduates might work in New York, and for those

students to take the relevant coursework in a timely fashion during their undergraduate experience if needed.

For new or existing programs in New York trying to ensure they receive approval and licensure qualifying status, there can be flexibility in meeting the requirements. However these requirements must be met, and programs are advised to be able to precisely indicate how and where that occurs in the overall curriculum. Clinical laboratory science is a profession covering an expansive area of focus, substantially more than many other undergraduate majors, even those in the sciences. The substantial credit burden can come under pressure as students look to expand their experience with service learning or semesters abroad that undoubtedly enrich their college experiences, but can be difficult to accommodate in a credit heavy program. Administrative pressure can also apply, especially on campuses with fewer professional programs that tend to have more rigid requirements than other majors. Program directors need to effectively cover the curriculum with these pressures in mind, and particularly at smaller schools, must think carefully about how existing course offerings can meet their needs and where new course offering must be developed.

References

1. Laboratory Personnel Licensure [Internet]. American Society for Clinical Laboratory Science. 2006. Available from: <http://ascls.org/position-papers/176-laboratory-personnel-licensure>
2. Personnel Licensure [Internet]. American Society for Clinical Laboratory Science. 2017 [cited Aug 2018]. Available from: <http://ascls.org/new-graduates/163-personnel-licensure>
3. Balachandran I, Walker JW, Taylor J, Cheng M, Wheeler ME. Impact of New York State's Licensure Regulations for Laboratory Professionals on Staffing of Clinical Laboratories. *J Allied Health*. 2009 Winter;38(4):113-7.
4. N.Y. Comp. Codes R. & R. tit. 8, § 52.38 (2008). Available from: <http://www.op.nysed.gov/prof/clt/clplaw.htm>
5. Clinical Laboratory Technical Practice Act, N.Y. Educ. Law §§ 8600 to 8610 (2008)
6. Assembly Bill A9966 [Internet]. New York State Assembly. 2018. Available from: http://nyassembly.gov/leg/?default_fld=&leg_video=&bn=A09966&term=2017&Summary=Y&Text=Y

Table 1. Educational Requirements for NYS CLS Licensure

Class Requirements (Didactic and Laboratory)

Inorganic Chemistry
Analytic Chemistry and/or Biochemistry
Clinical Chemistry
Physiology, with Anatomy Content
Immunology/Serology
Immunohematology
Hematology and Hemostasis
Body Fluids*
Molecular Biology and Diagnostics
Microbiology/Clinical Microbiology**

Curricular Requirements

Organic Chemistry
Statistics
Infection Control and Universal Precautions
Maintenance of Equipment and Records
Ethics

Items in italics are only required for the Technologist level of certification

*Technician licensure requirements also specify clinical microscopy

**Microbiology includes parasitology, mycology, virology, and bacteriology

Adapted from Commissioner's Regulations