

Background, Personnel Questions for CLIAC, November 2018

General

- 1. What should be considered as appropriate educational background (e.g., degree, curriculum) in order to meet CLIA personnel requirements under a chemical, physical, or biological science degree?**
 - Should CMS consider using degree and/or relevant course works as an algorithm for qualifications for non-chemical/biological and non-traditional degrees?
 - CMS does not intend to evaluate and approve curricula.
 - An example of a nontraditional degree is a Regents Bachelor of Arts (RBA) which is a baccalaureate degree program designed for adult students which does not include a designation of a major. The basic principle is that credit is awarded for what students know regardless of how that knowledge was obtained. In other words, students may earn college-equivalent credit for work and life experiences that can be equated to college courses. It is designed to provide students with a comprehensive general education. Many times, no specific courses are required for graduation, allowing students to design their own programs of study. This degree is usually awarded by a Board of Regents.

- 2. What should be considered appropriate laboratory training and/or experience for testing personnel and technical consultants? Supervisory experience for laboratory directors and technical supervisors? What is appropriate documentation to verify these training, experience and supervisory activities?**
 - No additional background information needed

- 3. Should the definition of midlevel practitioner be expanded? If so, how?**
 - Currently “midlevel practitioners means nurse midwives, nurse practitioner, or physician assistant licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.”
 - Advanced Practice Nurse (APN) is a general category for master’s level nurses which includes specialized types of nurses, specifically nurse midwives, nurse practitioners, nurse anesthetists, clinical nurse specialists. It is a general classifications for nurses who have obtained a masters direct and who provide primary and specialty healthcare. CLIA current midlevel practitioner includes two of the four categories.

Laboratory Director

- 4. What should “possessing qualifications that are equivalent to board certification” mean?**
 - Currently this is interpreted to mean that an individual is eligible to sit for a specific Board, and must produce documentation from the Board of eligibility.

- 5. Should 20 continuing education hours (e.g., CMEs, CEUs) be required for individuals, regardless of degree, prior to qualifying as both moderate and high complexity laboratory directors?**
 - 20 CME is currently a mode of qualifying for moderate complexity (MC) laboratory director (LD) at 42 CFR §493.05(b)(2)(ii)(B). These 20 CME should include laboratory practice that is commensurate with the CLIA director responsibilities.
 - Moderate and high complexity laboratory director citations continue to be 2 of the 10 top cited condition-level deficiencies.
 - We are asking if this should be a requirement for all LDs, regardless of qualifying degree. These CMEs would be required as part of the qualification process for both moderate and high complexity LDs (i.e., prior to qualifying).

6. How often should a laboratory director be required to be on-site at a laboratory?

- Moderate and high complexity laboratory director citations continue to be 2 of the 10 top cited condition-level deficiencies.
- Current regulations allow a LD to be accessible to the laboratory to provide onsite, telephone or electronic consultation, as needed. 42 CFR §§493.1407(c), 1445(c)

7. In addition to already required Board certification for doctoral degree laboratory directors, what other clinical laboratory experience should be required?

- Current regulations at 42 CFR §§493.1443(b)(3)(i) requires an applicable doctoral degree and board certification.
- High complexity laboratory director citations continue to be 1 of the 10 top cited condition-level deficiencies.

Technical Consultant

8. What, if any, modifications should be made to the education qualifications (e.g., associate's degree) for technical consultant?

- The high complexity personnel regulations (Subpart M) include lab director (LD), technical supervisor (TS), clinical consultant (CC), general supervisor (GS) and testing personnel (TP).
- The moderate complexity personnel regulations (Subpart M) include lab director, technical consultant (TC), clinical consultant, and testing personnel.
- The moderate complexity personnel regulation do not have a general supervisor position, therefore moderate complexity LD and TC responsibilities cannot be delegated to a to a general supervisor because the GS is only found in the high complexity personnel regulations.
- The lowest level degree with which a GS may qualify is an associate's degree, whereas the lowest level degree with which a TC can qualify is a bachelor's degree.
- In order to perform competency on moderate complexity personnel, a person must be able to meet the CLIA regulatory requirements to qualify as a technical consultant. Competency Assessment (CA) for high complexity testing is the responsibility of the Technical Supervisor (TS), but can be delegated, in writing to the General Supervisor (GS).
- In a laboratory performing both moderate and high complexity testing, an individual must meet TC requirement in order to perform competency assessment. A GS may perform CA on the moderate complexity testing as long as they meet the TC qualifications. However, a GS with only an associate's may not perform competency assessment on moderate complexity testing
- This is problematic in laboratories performing both moderate and high complexity testing.

Histopathology

9. What timeframe should be considered appropriate for a pathologist to review the gross examination performed by an individual who is not a pathologist?

- No additional background information