Personnel Regulations Workgroup

Report to CLIAC

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Lee H. Hilborne, MD, MPH, DLM(ASCP)^{CM}

Workgroup Chair

A Big “Thank You” Workgroup Members

- **Chair:**
  Lee Hilborne, MD, MPH, DLM(ASCP)^{CM}
- **Members:**
  Nicole Colby, MLS(ASCP)^{CM}, SBB^{CM}, SC^{CM}
  Denise K. Driscoll, MS, MT(ASCP)
  Brandy Gonsolus, DCLS, MLS(ASCP)^{CM}
  Susan M. Harrington, PhD, D(ABMM), MLS(ASCP)^{CM}
  Bradley S. Karon, MD, PhD
  Paul Kimsey, PhD
  Beverly Rauch, MS
  Bonnie D. Rubin, CLS(ASCP), MBA, MHA
  David L. Smalley, PhD, BCLD/PHLD(ABB)
  Clare J. Thornton, HTL(ASCP)^{CM}, QIHC
  Susan Walker, MA(HEd), MT(ASCP)
  Cynthia E. Wilkerson, MT(ASCP)

And A Huge “Thank You” To our HHS Workgroup Colleagues and Subject Matter Experts

- **Designated Federal Officer:**
  Heather Stang, MS, MT(AMT)
- **Ex Officio Members:**
  Nancy Anderson, MMSc, MT(ASCP)
  Sarah Bennett, MT(ASCP)
- **Agency Staff Subject Matter Experts:**
  Marie Earley, PhD
  Cindy Flacks, MPH, MT(ASCP)
  Theresia Snelling, MBA, MPM

Personnel Regulations Workgroup Charge

The workgroup is charged with providing advice to CLIAC for consideration in making recommendations to the Department of Health and Human Services (HHS) on revising the CLIA personnel regulations.

The workgroup will specifically advise on questions asked by the Centers for Medicare & Medicaid Services (CMS) during the November 2018 CLIAC meeting.

Discussion Question #1: Educational Background

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?

Workgroup agreement:

- A physical science degree should not be an acceptable degree under CLIA.
- Acceptable degrees should include chemical, biological, or medical technology/clinical laboratory science.
- The base requirement is that for individuals to qualify as laboratory personnel under CLIA, the must have the necessary coursework to provide a foundation on which to function effectively in the laboratory.
- The acceptable degrees referenced here are acceptable because the course of study includes the relevant coursework and therefore serve as a "surrogate" for that coursework.

Discussion Question #1: Educational Background (cont.)

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?

Workgroup discussion:

- Because degree titles have evolved, it is challenging to determine acceptability based solely on degree name.
- Examining transcripts to evaluate degree content is labor intensive and course names can be misinterpreted.
- Minimum required semester hours in the appropriate sciences is only included for high complexity testing personnel. [493.1489(b)(2)(ii)]
- Individuals with nontraditional degrees should be considered when they have the required, appropriate science coursework relevant to the laboratory position sought.
- An consistent approach to evaluate education is needed by CMS, accrediting organizations, exempt states, and the DoD.
- Personnel requirements should graduate as roles and responsibilities increase.
- Minimum educational requirements are necessary but not sufficient. Relevant training and experience must follow and build on the education base.
- Evaluate educational requirements across certifying agencies to assess consistency.
- Consider whether personnel requirements should be added for histotechnologists, histotechnicians, pathology assistants, and bioinformaticians.

Discussion Question #2: Training, Experience, Supervision

2a. What should be considered appropriate:

- **Laboratory training and/or experience for testing personnel and technical consultants?**
- **Supervisory experience for laboratory directors and technical supervisors?**

Workgroup agreement: All personnel should have experience and training in the responsibilities listed for their CLIA positions at the appropriate test complexity.

Workgroup discussion:

- Training and experience should be in a CLIA-certified laboratory.
- Training should be from an accredited institution or organization.
- Training and experience obtained in DoD and VA laboratories need to be recognized.
- Ordering diagnostic tests does not qualify as laboratory training or experience.

- Personnel must be trained to be competent for the testing they perform.
- When moving to a higher level position, previous experience should provide an individual with the knowledge and ability to apply for the new position.

- Laboratory directors should have experience directing personnel in a CLIA-certified laboratory.
- Laboratory training varies – general training required for board certification vs. specialized training in a laboratory specialty.
- Clinical laboratory experience is implicit in the requirements for obtaining board certification in laboratory medicine specialties.

Discussion Question #2: Training, Experience, Supervision

2b. What is appropriate documentation to verify these training, experience, and supervisory activities?

Workgroup Discussion:

- CMS acceptable documentation includes transcripts, a diploma, letters from laboratory directors on official letterhead that include specific experience and timeframes.
- A CV alone is insufficient documentation of training or experience
- Obtaining documentation can be challenging when hospitals or laboratories have closed.
- Templates or forms could be helpful in standardizing the process to obtain and document minimum information.
- Consider linking documentation to competency assessments.

Discussion Question #3: Laboratory Director Qualifications

What should "possessing qualifications that are equivalent to board certification" mean?

Workgroup agreement: It is not possible to evaluate qualifications as equivalent to board certification in anatomic and clinical pathology by the American Board of Pathology/American Osteopathic Board of Pathology (ABP/AOBP). Remove this option for meeting **CLIA laboratory director, technical consultant and technical supervisor** qualifications (for both moderate and high complexity testing) from the regulations.

Workgroup discussion:

- Pathologists must be certified by ABP/AOBP to meet CLIA qualifications via board certifications.
- If individuals are not ABP/AOBP certified, they can still qualify through other regulatory routes specified in CLIA.
- Consider replacing current State Operations Manual language about equivalent qualifications with "in the period of eligibility for board certification."

Discussion Question #4: Laboratory Director Continuing Education

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?

Workgroup agreement:

- The requirement for 20 continuing education hours (e.g., CMEs, CEUs) in laboratory practice commensurate with the laboratory director responsibilities should apply to all moderate and high complexity directors, except those qualifying by board certification (ABP, AOBP), or HHS-approved boards for doctoral degrees.
- HHS should ensure that current and future recognized boards include 20 hours of education and training in clinical laboratory operations, management, and supervisory duties to sit for the board.
- The requirement for one-year of laboratory training during medical residency for high complexity laboratory directors who qualify through this route should specify that it is "clinical laboratory training."

Discussion Question #4: Laboratory Director Continuing Education

Workgroup discussion:

- This requirement currently applies only to certain moderate complexity laboratory directors.
- All laboratory directors need general clinical laboratory knowledge related to their director responsibilities – the 20 hour CE content should be specific to knowledge needed to carry out these responsibilities.
- Two courses currently exist that meet this requirement; others could be created.
- Review already approved boards to ensure that they include requisite laboratory director education as a required component.

Discussion Question #5: Laboratory Director On-Site Requirements

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

Workgroup agreement:

- Laboratory directors for moderate and high complexity testing should be on-site a minimum of once every six months, with visits not less than four months and not greater than eight months apart.
- On-site tasks should include things that cannot be assessed remotely or delegated and visits should be clearly documented.

Discussion Question #5: Laboratory Director On-Site Requirements

Workgroup discussion:

- Specified in some state and accrediting agency requirements:
  - TN - requires laboratory directors to be on-site every month
  - CA – requires on-site at least once per week, no more than five laboratories
  - NY – requires minimum on-site every other week, only two laboratories
  - CAP - requires an agreement between the medical director and the laboratory director, with an on-site frequency >0
- Requiring some minimum of on-site visits may help to decrease the number of laboratory director deficiencies.
  - Adding the 20 CE credit requirement may also help resolve some recurrent laboratory director deficiencies identified on inspection.
- Need to set the minimum requirements for both moderate and high complexity testing – every 3 or 6 months, same or different depending on complexity?
  - Minimum requirements seem reasonable, many duties can be performed off-site.

Discussion Question #5: Laboratory Director On-Site Requirements

Workgroup discussion (cont.):

- Need to identify what would be done during on-site visits and how to document.
- On-site tasks should include things that cannot be assessed remotely or delegated such as:
  - Assessing physical and environmental conditions
  - Reviewing and signing documents requiring laboratory director signature
  - Assessing staffing in the laboratory
  - Verifying ongoing compliance with CLIA and other laws/regulations
  - Reviewing the effectiveness of the laboratory's quality plan
- Clear documentation and recordkeeping of the on-site visit is essential.

Discussion Question #6: Laboratory Director Qualifying Experience

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

Workgroup agreement:

- Required experience for board-certified laboratory directors should include experience directing personnel in a CLIA-certified laboratory.
- Clinical laboratory experience is implicit in the requirements for obtaining board certification from recognized boards.

Workgroup discussion: See comments under question #2

Discussion Question #7:
Technical Consultant (Moderate complexity)

What, if any, modifications should be made to the education qualifications for technical consultant?

Workgroup agreement: Add an optional route to qualify as a technical consultant by having an associate's degree in a chemical, biological, or medical technology/clinical laboratory science and two years training or experience, or both, in moderate complexity testing.

Discussion Question #7: Technical Consultant (Moderate Complexity)

Workgroup discussion:

- Issues have surfaced because general supervisors with an associate's degree can do competency assessments for high complexity, but not moderate complexity, testing personnel.
- This occurs most frequently in physician office and blood gas/respiratory therapy labs.
- Individuals with prior military experience also may not meet the "earned bachelor's degree" specified in the regulations.
- Add an optional qualification route for technical consultants with an associate's degree similar to that included for general supervisors.
- Why are there different personnel categories for high complexity (technical supervisor and general supervisor) vs. moderate complexity (technical consultant) personnel?

Discussion Question #8: Midlevel Practitioners

Should the definition of midlevel practitioner be expanded? If so, how?

Workgroup agreement: Consider adding clinical nurse specialists and certified registered nurse anesthetists to the definition of midlevel practitioners qualified as a laboratory director and testing personnel under the provider-performed microscopy (PPM) subcategory of moderate complexity testing.

Workgroup discussion:

- The term “advanced practice nurse” refers to master’s degree specialized nurses and includes nurse midwives, nurse practitioners, nurse anesthetists, and clinical nurse specialists.
- The current definition of midlevel practitioners includes nurse midwives, nurse practitioners, and physician assistants licensed by the state in which the individual practices, if licensing is required in the state where the laboratory is located.
- Consider whether all four categories of advanced practice nurses should be eligible for the PPM category.
- DoD: Army and Navy Independent Duty Corpsmen, who have training equivalent to a physician assistant, perform PPM procedures in the military

Discussion Question #9: Histopathology

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

Workgroup agreement: The workgroup supports the comments noted by CLIAC at the November 2018 meeting that “having policies in place would be sufficient and preferable to a time-based requirement.”

Workgroup discussion:

- Laboratories should have a policy to ensure the integrity of the specimen submitted for review and the adequacy of grossing.
- Depending on the specimen and the processing, frequently there may not be anything left for review.

Other Personnel Issues Considered

Military training and experience:

- Military training on performing medical laboratory procedures was discussed as a route to meet moderate complexity testing personnel requirements.
- Military training and experience should also be recognized under high complexity personnel qualifications given laboratory professionals with military experience are a potential source for future civilian laboratory professionals.

Doctorate of clinical laboratory science (DCLS): Because DCLS is a new degree with appropriate qualifications, a DCLS should be added to the CLIA interpretive guidelines as an acceptable laboratory based doctoral degree.

Recognition of histotechnologists as laboratory personnel:

- Histopathology is a specialty under CLIA.
- Histotechnologists perform services that are closely tied to patient diagnosis and prognosis.
- Therefore, histotechnologists should be added as a personnel category similar to cytotechnologists, with histology courses being part of required education.

Similar consideration should be given to pathology assistants

Potential Topics for Future CLIAC Agendas

Given current and future technology including laboratory automation, discuss when the analytic testing process begins for the purpose of determining when personnel requirements should be applied.

- How do robotics impact the testing process?
- Systems already exist where nurses or phlebotomists collect specimens and place them in racks or transport systems that automatically load the instrument and initiate testing.

Reconsideration of CLIA complexity model:

- Many laboratory practice and technology changes have occurred since the CLIA regulations were implemented in 1992.
- In addition to looking at personnel qualifications and responsibilities, consider whether the criteria used for categorizing tests should be modified to be more relevant to evolving technology and the role of the laboratory.

Examination of current modes of communication and information exchange and how these impact laboratory testing and communication between laboratories, healthcare providers and patients.