

Date Submitted: October 24, 2018

**ABB Written Comments Regarding CLIA Personnel Requirements Under Section 493.1443(b)(3)
Clinical Laboratory Improvement Advisory Committee (CLIAC) Meeting
November 7-8, 2018
Atlanta, Georgia**

Dear CLIAC Members:

The American Board of Bioanalysis (ABB) is a CLIA-approved Board for clinical laboratory directors under the CLIA '67 regulations (1974-1992) and for high complexity clinical laboratory directors under the CLIA '88 regulations (1992-present).

ABB wishes to comment on the current CLIA regulation found in Section 493.1443(b)(3) that states that the laboratory director (for high complexity testing) must:

(b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and –

(b)(3)(i) Be certified and continue to be certified by a board approved by HHS;

CLIA's Interpretive Guidelines for Section 493.1443(b)(3) state that

“An acceptable doctoral degree is a Doctor of Philosophy – Ph.D., Doctor of Science – D.Sc. If acceptable to the (CLIA-approved certifying) board, a Doctor of Dental Surgery – D.D.S., Doctor of Veterinary Medicine – D.V.M., Doctor of Public Health – Dr.P.H.”

Note that the Interpretive Guidelines delegate to CLIA-approved certifying boards discretion regarding D.D.S., D.V.M., and Dr.P.H. degrees, but not for Ph.D. and D.Sc. degrees.

That the acceptability of Ph.D. and D.Sc. degrees is determined by CMS, and not a CLIA-approved certifying board, was explained by CMS to ABB on May 24, 2017, as follows:

“The degree requirement mentioned at 42 CFR §493.1443(b)(3) (“Hold an earned doctoral degree in chemical, physical, biological, or clinical laboratory science from an accredited institution”) is distinct from the board certification requirement mentioned under 42 CFR §493.1443(b)(3)(i) (“Be certified and continue to be certified by a board approved by HHS”). In the past, CMS has given guidance on whether certain degrees qualify as a chemical, physical, biological, or clinical laboratory science degree under the CLIA regulations. As the aforementioned educational and certification requirements continue to be distinct, and as the latter is determined based on the board's own testing and certification criteria, we continue to believe that the boards themselves are the appropriate bodies to determine whether an individual should be allowed to sit for a board certification examination and, ultimately, whether an individual should receive that board's certification. As such, CMS will continue to limit its evaluation of an individual's qualifications to be a laboratory director to the information available at the time that we evaluate a laboratory's compliance with the applicable personnel requirements.”

CMS provided additional clarification to ABB on May 31, 2017, as follows:

“You (ABB) are correct in that becoming board certified by ABB or any of the approved Boards is not a guarantee that an individual will qualify for an HCLD in a CLIA laboratory as the requirements for a doctoral degree is distinct from board certification requirements. CMS will continue to limit its evaluation of an individual’s qualifications to be a laboratory director to the information provided at the time that a laboratory’s compliance with applicable personnel requirements is evaluated.”

CMS has standard processes for the implementation of the personnel requirements in the regulations. There has been no change in that regard. CLIA does not evaluate hypothetical situations or pre-qualify personnel for laboratory positions. The regulations are applied equally to all individuals. The role of the Boards continue to be certifying individuals that meet their requirements to be board certified, and continue to be board certified; and CMS’s role continues to be evaluating personnel qualifications based on CLIA regulations.”

ABB believes the CMS policy described above presents several issues:

1. Leaving the decision about the acceptability of a Ph.D. or D.Sc. degree to a CLIA surveyor “at the time that a laboratory’s compliance with applicable personnel requirements is evaluated” introduces the possibility that –
 - a. Judgments by different surveyors will be inconsistent and arbitrary, and
 - b. Decisions made only after the degree is earned and after the individual is employed by the laboratory will create confusion, uncertainty and disruption for individual laboratory directors and their laboratories.

Under this policy, individuals who are certified by a CLIA-approved Board may discover that after they have attained board certification and employment as laboratory directors, they are not CLIA-qualified to direct high complexity testing because a CLIA surveyor subsequently determines their Ph.D. or D.Sc. degrees do not satisfy CLIA’s “earned doctoral degree” requirement in Section 493.1443(b)(3).

ABB receives applications from individuals who have degrees that may not meet the intent of 42 CFR 493.1443(b)(3). For example, individuals who have Ph.Ds in public administration, management, epidemiology, bioengineering, informatics, chemical engineering, environmental sciences and other disciplines apply to ABB for HCLD certification.

Some of these degrees are clearly not acceptable because the individuals holding them do not have enough courses in core laboratory sciences and/or their doctoral theses are not laboratory-based research. But others document a significant number of courses in core laboratory sciences and have doctoral theses that are traditional laboratory-based independent research.

Because CMS’s Interpretive Guidelines allow CLIA-approved Boards to determine the acceptability of D.D.S., D.V.M., and Dr.P.H. degrees, ABB recommends that CLIA-approved Boards also be allowed to determine the acceptability of Ph.D. and D.Sc. degrees.

AAB recommends this be accomplished by amending CLIA’s Interpretive Guidelines for Section 493.1443(b) as follows:

“An acceptable doctoral degree is a Doctor of Philosophy – Ph.D., Doctor of Science – D.Sc., Doctor of Dental Surgery – D.D.S., Doctor of Veterinary Medicine – D.V.M., or Doctor of Public Health – Dr.P.H. acceptable to a CLIA-approved certifying board for a director of high complexity testing.”

An alternative and preferred solution is to amend Section 493.1443(b) of the CLIA regulations as follows:

“Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution **that is acceptable to a certifying board approved by HHS.**”

ABB believes CLIA-approved certifying boards should be allowed to use reasonable criteria that prioritize the relevant course work and laboratory-relatedness of the thesis over the title or name of the degree in determining the acceptability of a Ph.D. or D.Sc. degree.

If CLIAC feels that the process for determining the acceptability of a particular Ph.D. or D.Sc. degree should have broader input beyond a CLIA-approved certifying board, then ABB recommends that the matter be referred to a CLIAC working group that, at a minimum, includes representatives from CDC, ABB, and APHL.

In any case, decisions should be made far enough in advance that individuals, their degree granting universities/colleges, and their clinical employment laboratories know whether or not the Ph.D. or D.Sc. degree will meet CLIA’s requirements. And if not, why not.

Such a system will allow individuals, if they wish, to adjust their curricula and training to satisfy CLIA’s earned doctoral degree requirement.

We thank you for allowing ABB to present this issue for discussion, and we are willing to answer questions or provide additional information.