

March 30, 2018

Attention: CLIAC Secretariat
1600 Clifton Road NE
Mailstop F-11
Atlanta, GA 300333

Submitted via CLIAC@cdc.gov

RE: ABB CLIAC Public Comment on Educational Requirements for High Complexity Laboratory Directors

The American Board of Bioanalysis (ABB) fully supports the CLIA '88 regulatory requirement that a "laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests." There is a three-step process in identifying and certifying such individuals, and it is based on three different sets of standards or criteria and is carried out by different entities.

ABB feels that this three-step process, one that: first, assures that the laboratory director candidates have the requisite scientific knowledge, as evidenced by their educational background, to direct a high complexity clinical laboratory followed by second, documenting the appropriate work experience and third, passing a certifying examination that measures the candidate's specific and applicable knowledge across a range of laboratory directing areas of responsibility, is an appropriate one.

The identification of potentially qualified laboratory directors is based first on their level and type of education and is assessed by the Centers for Medicare and Medicaid Services (CMS) and is governed by the applicable CLIA regulations that state that the laboratory director must "hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution." Since this is logically the first standard to be met, the determination of whether a candidate meets this standard should be a prerequisite to the next step in this process, which is board certification.

The certification of such identified individuals is based on the requirement to be certified by one of the certifying boards deemed acceptable by CMS. ABB requires candidates to document a certain amount of work experience/training, and then take and pass a rigorous and comprehensive certifying examination. This part of the process is governed by the applicable CLIA regulations that state that the laboratory director, in addition to meeting the educational requirements above, must "be certified and continue to be certified by a board approved by HHS."

An issue about which ABB is receiving many questions relates to the process that is used by CMS to ascertain whether an individual has an *acceptable* "earned doctoral degree in a chemical, physical, biological, or clinical laboratory science." It appears that this part of the

regulation has two components, one to decide what degree is acceptable and the second to decide what fields of study fall within the area of “chemical, physical, biological, or clinical laboratory science.” Since the language of the regulations is not restricted to degrees within a specific discipline, there seems to be some latitude as to what areas of science are acceptable. We know for example that individuals with PhDs in the fields of microbiology or immunology have been deemed acceptable. A problem exists in trying to decide what is considered “an earned doctoral degree” for the purpose of meeting this standard. Certainly, a PhD is a degree that incorporates both the educational as well as the research or scholarship components reflective of a broad understanding of a given discipline. However, the PhD degree itself is not a sufficient standard. There are other non-PhD doctoral degrees that are granted by many institutions of higher education in the fields of “chemical, physical, biological, or clinical laboratory science.” These include degrees such as the DrPH and ScD degrees. Again, the degree alone is insufficient to know whether the recipient has the educational and research or scholarship experience necessary within an acceptable discipline. So, ABB contends that the exact title of the doctorate degree is less critical than the field of study and what it includes.

With respect to the field of study, the language in the CLIA regulations is quite broad. Clearly the intent is to only allow individuals to qualify who have a high level of knowledge within the broad scientific disciplines that can be applied to high complexity testing. In addition, the term “earned doctoral degree” seems to refer to degrees that include the rigor of a PhD-type program. The challenge is in determining what should be logically incorporated into the broad description of “chemical, physical, biological, or clinical laboratory science.” The trend in higher education over the last decade or so has been to offer doctoral degrees in many new areas of medical laboratory science that are clinically relevant to high complexity testing and can serve as the basis to grant candidates the opportunity to take a board certification examination. Newly developed degrees include such courses of study as cell and molecular biology, molecular pathology, molecular genetics, comparative pathology, biomedical technology or any number of other emerging fields within the broad area of laboratory sciences. All of these degrees could well serve as the basis for the foundational scientific knowledge necessary to oversee a laboratory performing high complexity testing. Rather than trying to identify specific degrees and fields of study that are worthy of consideration, the *content* of those degrees, in terms of relevant coursework or investigatory studies, is the more logical approach. In the final analysis it is the content of the doctoral program that is most important, not the exact degree or the specific name of the discipline. Another concern is the proliferation of new formats for earning an accredited doctoral degree, e.g., online versus live classroom instruction. Individuals enrolling in these “new format” degrees or new areas for doctoral degrees will make a considerable commitment of time and money, and they deserve to know if the investment of their resources will result in an acceptable doctoral degree.

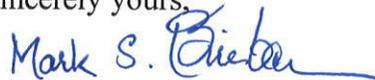
The degree, however, is not the only standard required, since the individual who is deemed educationally qualified must still document the required amount of clinical laboratory experience/training and pass a board certification examination. The examination serves as the final step in qualifying to serve in the capacity of a high complexity clinical laboratory director.

ABB, therefore, is of the firm belief that the process for determining laboratory director qualifications should be established as follows:

1. A candidate should be able to determine whether his/her doctorate is acceptable for consideration based on its academic content. [Note: ABB believes this should be the first step of the three-step process referenced above.]
2. Likewise, any academic institution granting related doctoral degrees should be able to determine if its program meets the CMS educational requirements for a high complexity laboratory director.
3. A candidate who has been deemed qualified based on his/her educational credentials should then be allowed to proceed to document his/her work experience and apply to take one of the examinations administered by an approved board.

ABB is willing to work with CLIAC, CMS, and other certifying boards to define the essential educational content for a given doctoral degree to meet the regulatory requirements under CLIA, thereby paving the way to allow potential candidates and the HHS-approved boards to complete the rest of the steps required for credentialing without the concern that a given degree or field of study could be declared unacceptable *a posteriori*.

Sincerely yours,



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Administrator

On behalf of:

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