

Clinical Laboratory Improvement Advisory Committee
From: American Board of Bioanalysis (ABB)
RE: Doctorate of Clinical Laboratory Science (DCLS) Degree

Dear CLIAC Committee Members:

One or more individuals have represented to CMS and the CLIAC Personnel Regulations Workgroup that a Doctorate of Clinical Laboratory Science (DCLS) is a “new” degree (as of 2018). Based, at least partly, on these representations, the CLIA Personnel Regulations Workgroup decided to recommend to CLIAC that the DCLS be included as an acceptable doctoral degree for high complexity laboratory directors in the Interpretive Guidelines for Section 493.1443(b)(3) of the CLIA '88 regulations.

A little over a year ago, on January 30, 2018, ABB was contacted by CMS about this supposed “new” DCLS degree.

ABB responded that the Doctorate in Clinical Laboratory Science (DCLS), as approved by NAACLS, was reviewed by CMS’s CLIA program **nearly 12 years ago**, in July 2007. Janet Perryman-Butler from the CMS/CLIA office and CLIA Program Director Judy Yost determined that a “clinical doctorate” degree is not equivalent to a Ph.D. degree and therefore a clinical doctorate degree, like the DCLS degree, does not meet CLIA’s requirement for high complexity clinical laboratory directors in Section 493.1443(b)(3).

After reviewing ABB’s prior correspondence with CLIA headquarters about the DCLS degree, CMS informed ABB on February 1, 2018, that “CLIA will stand by the previously stated position from Janet Perryman-Butler and Judy Yost on July 10, 2007, that a clinical doctorate degree, like the DCLS, is not equivalent to a Ph.D.” Attached is some of the correspondence between the CLIA headquarters office and ABB regarding this issue.

The CLIAC Personnel Regulations Workgroup is now recommending that a DCLS **is** equivalent to a Ph.D. degree and therefore meets the “earned doctoral degree” requirement under Section 493.1443(b)(3). We suspect that most members of CLIAC’s Personnel Regulations Workgroup were unaware of the CLIA program’s multiple reviews of this degree.

ABB is therefore requesting that CLIAC’s Personnel Regulations Workgroup explain what information and documentation it reviewed that persuaded it to recommend that the CLIA headquarter’s decisions regarding the non-acceptability of the DCLS degree be reversed.

Did the Workgroup review the course curriculum of the universities granting the DCLS degree? If so, what in that curriculum caused them to recommend that CMS’s determination be reversed? Do the DCLS graduates actually *perform* laboratory testing as the basis for an independent research project? (Our understanding is that they do not).

ABB has received a number of applications for HCLD certification from individuals with similar types of degrees. Most of these degrees are clinical doctorates in which the research does not include “in-laboratory” independent research performed by the doctoral candidate. ABB does

not believe this type of research is equivalent to that required for a Ph.D. degree with a major in a laboratory science.

However, one such degree submitted to ABB did include traditional laboratory-based research similar to that for a Ph.D. degree. ABB feels that this degree is acceptable, and recommends that all degrees of this type be reviewed at the time the recipient applies to a CLIA-approved Certifying Board to determine whether the degree curriculum includes an "in-laboratory" based research dissertation. Blanket approval of the DCLS and similar degrees without an appropriate review to determine whether the degree required a research dissertation based on "in-laboratory" research performed by the doctoral candidate is counter to previous CMS/CLIA precedent and guidance about clinical doctorate degrees.

Colleges/universities that develop a DCLS degree, or a degree with a similar name, should be informed that a research dissertation that is based on management/administrative/clinical practicums, rather than "in-laboratory" research performed by the doctoral candidate, does not satisfy the "earned doctoral degree" requirement of Section 493.1443(b)(3).

This is one of the reasons ABB requested, at the November 7-8, 2018, CLIAC meeting, that CLIA-approved Certifying Boards for High Complexity Clinical Laboratory Directors be allowed to review and assess the acceptability of these types of degrees.

ABB is disappointed that, although CLIAC received numerous public comments regarding ABB's proposal, the issue was not addressed by the CLIAC Personnel Regulations Workgroup.

ABB, once again, asks CLIAC to favorably consider ABB's request made on November 7, 2018.

Furthermore, according to Rutgers University (Rutgers claims it is the first university to award a DCLS degree), the DCLS degree is designed to prepare medical technologists (MTs, CLSs, MLSs) for "advanced practice roles as health care practitioners... through consultation as members of interprofessional healthcare teams..."

According to Rutgers, "advanced practice medical laboratory scientists" would be involved in Patient Care Intervention (PCI), Diagnostic Management Intervention (DMI), and Consultation With Patients regarding laboratory test selection and test result interpretation.

While these are laudatory goals, ABB is concerned that:

- a) at least some of the duties/functions Rutgers ascribes to a DCLS are not encompassed in the responsibilities of high complexity clinical laboratory directors enumerated in Section 493.1445 of the CLIA regulations, and
- b) at least some of the duties/functions Rutgers ascribes to a DCLS may not comport with state medical practice acts.

In 1992, when the CLIA '88 regulations were first published, the consultative duties of a high complexity clinical laboratory director who also qualified as a Clinical Consultant were limited to being available to the laboratory's "clients," which were almost entirely attending physicians. The licensed physicians, not the HCLD laboratory director, was expected to consult with the patient about the interpretation of the patient's laboratory test results, as required under state medical practice acts.

We are especially concerned by statements made by DCLS proponents that the DCLS degree will allow medical technologists to "replace pathologists." Non-physician high complexity laboratory directors certified by ABB are not licensed to practice medicine, and even though the performance of most clinical laboratory tests (as opposed to anatomical pathology tests) is not the practice of medicine, providing an interpretation of test results directly to the patient may crossover into the practice of medicine. ABB urges CLIAC to carefully consider these issues when evaluating the claims of some proponents of the DCLS degree.

Sincerely Yours,

A handwritten signature in blue ink that reads "Mark S. Birenbaum". The signature is fluid and cursive, with a long horizontal flourish at the end.

Mark S. Birenbaum, Ph.D.
Administrator

Attachments

1. NAACLS Newsletter, Volume 94, Fall 2006 "NAACLS Approves Standards for the Clinical Doctorate"
2. Correspondence with Kathleen Steed (February 1, 2018)
3. Correspondence with Janet Perryman-Butler (July 10, 2007)
4. ABB public statement to CLIA, November 7, 2018

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.

Tina Huelsing

From: Perryman-Butler, Janet R. (CMS/CMSO) <janet.perrymanbutler@cms.hhs.gov>
Sent: Tuesday, July 10, 2007 9:53 AM
To: englands@birenbaum.org
Cc: Yost, Judith A. (CMS/CMSO); Anderson, Nancy L. (CDC/CCID/NCPDCID)
Subject: RE: Clinical Doctorate in Clinical Laboratory Science -- RESENT DISCARD ALL OTHER COPIES.

Sensitivity: Confidential

Greetings Sara / Dr. Birenbaum:

Currently, the requirement that the Ph.D. and board certification is the main degree referenced at §493.1443(b)(3)(i) for the new laboratory directors after 2/24/2003. The other doctoral degrees with board certification that have been acceptable are those referenced within the interpretive guidelines (D.Sc., D.D.S. D.V.M., & Masters in P.H.) using previously approved board requirements for the acceptability of any new individuals with those degrees to test for those boards listed under §493.1443.

If the board was going to change what had previously been approved, the certifying (board) organization would have to formally submit its changes in its requirements to HHS (via CDC/CMS) for a "new" approval.

Consequently, your assessment that the "clinical doctorate degree" (as described within the NAACLS news article that you supplied) is not equivocal to a Ph.D. would be correct at this point.

If I find out differently, DLS will be contacting you and/or Dr. Birenbaum directly in the mean time.

Janet Perryman-Butler
Staffer within the Division of Laboratory Services (DLS)
CMS/CMSO/SCG
Telephone: 410) 786-3368, fax: 410) 786-1224
janet.perrymanbutler@cms.hhs.gov

Helen Russo

From: American Board of Bioanalysis <abb@abbcert.org>
Sent: Thursday, February 01, 2018 12:11 PM
To: russoh@birenbaum.org
Subject: FW: Doctorate in Clinical Laboratory Science

From: Steed, Kathleen E. (CMS/CCSQ) [mailto:Kathleen.Steed@cms.hhs.gov]
Sent: Thursday, February 01, 2018 11:20 AM
To: American Board of Bioanalysis <abb@abbcert.org>
Subject: RE: Doctorate in Clinical Laboratory Science

Dr. Birenbaum:

Thank you for your extremely informative email. CLIA will stand by the previously stated position from Janet Perryman-Butler and Judy Yost. I appreciate your recall of the previous discussion.

Kathleen Steed BS, MT, (ASCP)

Health Insurance Specialist
CMS/CCSQ/QSOG/DCLIQ
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From: American Board of Bioanalysis [mailto:abb@abbcert.org]
Sent: Thursday, February 1, 2018 11:45 AM
To: Steed, Kathleen E. (CMS/CCSQ) <Kathleen.Steed@cms.hhs.gov>
Subject: Doctorate in Clinical Laboratory Science

Dear Ms. Steed:

Reply is made to your email dated 30 January 2018.

The degree referenced in your email is not new, as we have been approached about it before. The DCLS is a "clinical doctorate" degree, not a Ph.D. research-based degree.

When individuals approached ABB with this type of degree over 10 years ago, we asked CMS/CLIA whether a clinical doctorate degree satisfies the doctoral degree requirement for high complexity clinical laboratory directors as specified in Section 493.1443(b)(3), and included a [July 2006 NAACLS news article](#) that discusses clinical doctorate degrees. The 2006 NAACLS article makes it clear that a clinical doctorate degree is not the same as a Ph.D. degree. In addition, NAACLS states that the individual holding the DCLS degree will function in Patient Care Management, Education, Research, and Health Care Policy Development and Services Delivery. NAACLS does not claim that the DCLS qualifies individuals to be high complexity clinical laboratory directors.

On 10 July 2007 Janet Perryman-Butler, from the CMS/CLIA office, informed us that " your [ABB's] assessment that the 'clinical doctorate degree' (as described within the NAACLS news article that you [ABB] supplied) is not equivocal to a Ph.D. would be correct at this point." Ms. Perryman-Butler said that her email was approved by her supervisor, Judy

Yost. Based on the 10 July 2007 email from CMS, ABB does not accept clinical doctorates in "health sciences" or "clinical laboratory sciences" for HCLD certification.

The article you forwarded implies that one of the responsibilities of a DCLS is "providing interpretation of test results to other health care professionals as well as patients..." You should be aware that the American Medical Association (AMA) and the College of American Pathologists (CAP) consider the interpretation of laboratory tests to be the practice of medicine. A DCLS who interprets laboratory tests may find themselves accused of practicing medicine under current AMA/CAP policies.

Sincerely yours,

Mark S. Birenbaum, Ph.D.
Administrator

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MSB:hr

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News

NAACLS Approves Standards for the Clinical Doctorate

By David D. Gale, PhD, Chair, NAACLS Graduate Task Force

NAACLS, a non-profit organization, is committed to being the premier agency for accreditation and approval of educational programs in the clinical laboratory sciences and related healthcare disciplines through the involvement of expert volunteers and its dedication to public service.

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**Volume 94
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At the September 30, 2006 meeting of the NAACLS Board of Directors, the *Standards of Accredited Educational Programs for the Clinical Doctorate in Clinical Laboratory Sciences* were approved. This effort was the culmination of more than six years of study and planning on the part of NAACLS in cooperation with NAACLS stakeholder organizations.

What began with discussions at a Futures Conference in September 2000 developed into a formal study of graduate level entry for CLS. A second Futures Conference in October 2004 resulted in the appointment of a Graduate Task Force (GTF), whose charge began with a bibliographic review of patient and laboratory needs, as well as planning steps to develop Standards for a new profession in the clinical laboratory at the doctoral level. Please see NAACLS News, Volume 92, Spring 2006 Special Edition, for a list of Graduate Task Force members.

At a March 2006 Invitational Conference, the first draft of Standards was unveiled. Based upon comments and critiques offered at that conference, a Special Edition of the NAACLS News was distributed, articulating the rationale, history, role and function of a clinical doctorate. Based on the responses received from the Special Edition and from public input, an updated set of

Standards was developed and presented to the NAACLS Board for approval in September 2006.

The members of the GTF reflected a broad spectrum of experience and responsibility in CLS education, in graduate education as well as administration and accreditation. The members recognize that doctoral education is significantly different from undergraduate education and requires standards and processes that provide for flexibility, creativity, discovery and autonomy but culminate in a highly skilled professional.

It has become clear that the Clinical Doctorate in CLS is very much needed to bridge gaps in the health care delivery system as well as to complete the career ladder for clinical laboratory scientists. Without this new professional, much of laboratory diagnosis, test interpretation, patient education and management will fall to individuals less qualified or even untrained in the clinical laboratory sciences.

In addition to the Standards and the Special Edition, the GTF has developed numerous documents to assist the public with understanding of the new professional. These include, but are not limited to, a full bibliography, an historical

treatise, and required education and practice areas developed in cooperation with the ASCLS Professional Doctorate Task Force. Key documents are on the NAACLS web site and the others are available from NAACLS.

In addition, the GTF recommended to the Board a proposed initial accreditation process for the doctorate that differs somewhat from current NAACLS processes. It suggests achievement of Program Candidate Status, an optional focused site visit, and graduation of at least three students prior to submission of the Self-Study before a full site visit.

At the April 2007 NAACLS Board meeting, a Review Committee will be assigned to finalize processes and begin to review applications. A survey of interested graduate level CLS programs has been completed by the GTF, and there are plans to develop documents helpful to potential program directors and faculty. It is likely that workshops could be provided on issues such as development of appropriate internships/residencies, program funding, coursework requirements, etc.

Questions and comments are still being invited and readers are asked to contact any one on the Task Force, the Board or the office for assistance.



National Accrediting Agency
for Clinical Laboratory Sciences

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NAACLS independently accredits clinical laboratory scientist/medical technologist, clinical laboratory technician/medical laboratory technician, histotechnologist, histotechnician, pathologists' assistant, cytogenetic technologist and diagnostic molecular scientist education programs. NAACLS also independently approves phlebotomist and clinical assistant education programs. NAACLS News is published three times a year, and permission is required to reproduce articles.

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Coordinator
Francine F. Schwartz,
Accountant
Ever Jean Frazier,
Accounting Assistant
Mark Spence,
Program Services Assistant
Adair L. Cohoat,
Staff Assistant

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Newly Accredited and Approved Programs September 2006

Accredited CLT/MLT Program

Northland Community and
Technical College
East Grand Forks, MN
(Based on the transfer of sponsorship
from Northern Minnesota Consortium
in Bemidji, MN)

Approved Phlebotomy Program

Northcentral Technical College
Wausau, WI

NAACLS to Conduct Meetings in April 2007

The April Meeting of the NAACLS Board of Directors will be held face to face in the Chicago area. A meeting of the NAACLS Graduate Task Force will also be held during that weekend, along with a Strategic Planning Session.

NAACLS Approves AAPA Representative Position on Board

At the recent meeting of the NAACLS Board of Directors, revisions to the Bylaws were adopted to add an American Association of Pathologists' Assistants (AAPA) member to the Board, effective September 2007. In addition, it will no longer be required to have a CLT/MLT practitioner nor a second public member on the Board. With these changes the overall composition of the Board will be reduced from 13 to 12 members. In accordance with the Bylaws, these changes were approved prior to the Board meeting by NAACLS' sponsoring organizations, ASCLS and ASCP. In a separate Board action, it voted to combine the CLSPRC and the APRC into one committee, effective following the July 2007 meetings. The composition of the combined committee will include pathologists' assistants and at least one additional pathologist.