

Dear Sir/Madam:

RE: Response to the September 27, 2018 Federal Register notice for Public Comment on the Clinical Laboratory Improvement Advisory Committee (CUAC) regarding proposed revisions to Clinical Laboratory Improvement Amendments (CUA) PERSONNEL REQUIREMENTS.

I am writing this response as a longtime member of AAB. I have over 25 years work experience in all aspects of Assisted Reproductive Technology, obtained my undergraduate degree in Animal Science from Cornell University, hold a Master's of Science in Clinical Embryology and Andrology from Eastern Virginia Medical School (EVMS) and a certificate in Bioethics from Hofstra University. I am licensed as a CLT by New York State and TS by ABB. Currently, I am a PhD candidate in Reproductive Clinical Laboratory Science at EVMS. While my program has both a significant amount of laboratory courses and well as a doctoral thesis it is considered a "non-traditional" program. My program is rigorous demanding many hours of studying and research. When I complete my studies in May 2019, I plan on applying to take the HCLD exam through ABB. Yet, in my discussions with ABB, I have been told that once I complete my PhD, I may still not be "qualified" to take the HCLD exam because of its "non-traditional" status. They have advised me they are seeking more latitude to allow them to further scrutinize these non-traditional programs.

On several recent occasions, I have questioned the president of ABB about their position on the PhD requirements for the HCLD, so students/programs can be well prepared for the application for the HCLD exam. On both occasions their answers have been at best vague. I have asked them how they envision any "changes" being implemented. They have been unclear but told me, they don't believe the non-traditional programs are equivalent to a traditional PhD program. I am concerned by their responses and if their requested changes are approved, if their ill-defined criteria will be applied fairly between candidates. There seems to be great room for bias and discrimination by allowing such latitude. I have been told by ABB that they would like the ability to "individually evaluate" each candidate's application for the HCLD. They would specifically like to scrutinize the thesis, its topic, how it was performed and who was the advisor. When I asked for specifics on how they would "differently" evaluate from a traditional PhD, I was told they would possibly evaluate based on the following criteria: Where was my research conducted, was it at an academic or private laboratory (they may not approve research conducted at a "private", clinical or non-academic laboratories). Was my advisor "published enough"? If they did not "feel" my advisor was published "enough", they may reject my application. It was not clear that this criteria would be applied evenly to those students applying from traditional programs, since there is a perception they are "clearly" qualified, just those applying from "non-traditional" programs are not. They would not approve any dissertations based on clinical research as they believe these candidates are clearly not qualified. It seems counterintuitive that an application to take the HCLD exam to direct a clinical laboratory may be rejected because the candidate's thesis was based on "clinical" research and not "basic laboratory research."

While DVM, DDS or D.Ph. degree candidates clearly do not have the requisite coursework or thesis work to be eligible for the HCLD exam, I agree that ABB should be given latitude for these candidates to ensure their training, education, qualifications are equivalent to an earned doctoral degree in a biological, chemical, clinical or physical science. I do not agree that this should also grant them the ability to judge individual candidates who hold an earned PhD in a biological science based solely on the programs non-traditional status. Candidates with an earned doctoral degree in a biological science

regardless of the type of program should be eligible to take the HCLD exam without undo prejudice against them. Accepted dissertations should not be able to be rejected by ABB for arbitrary reasons once an earned doctoral degree is granted by an accredited US institution. In this scenario, two students holding the same degree from the same institution, one may be approved while another rejected. I do not believe ABB should have the ability to reject a candidate's dissertation once it has been accepted by a US accredited institution. This would result in an undo burden on both the student and university. Remember, the candidates still must pass this rigorous exam. I do not believe that the position put forth by ABB represents that of the majority of its members nor was there adequate discussion/debate requested from its members before their position was decided.

If ABB is allowed this latitude with the qualifications for the HCLD exam, their new guidelines need to be set for them and be very specific and not vague to avoid personal bias and/or discriminatory practices. Research has shown that non-traditional programs consist of a more diverse population than those students from traditional programs, this has increased not only gender but racial diversity in almost all programs, any additional scrutiny applied to them needs to be done so fairly. This would also allow the non-traditional programs to adjust their curriculum accordingly if needed in advance.

There is clearly an increased need for more doctorate level scientists, the non-traditional doctorate has emerged as one solution for this critical shortage and should be encouraged not discouraged.

Sincerely,



Eva Schenkman, MS, CLT (NYS), TS (ABB)

References:

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