

Dear Sir/Madam,

I heard that the meeting of Clinical Laboratory Improvement Committee meeting will be held on Nov. 7th, 2018 at CDC, and among the other agenda, CLIA personnel requirement will be discussed.

Here I would like to make my comments on the issue of what constitutes an acceptable earned doctoral degree under CLIA regulation 493.1443 (b)(3).

I obtained my Ph.D. degree at The University of Alabama at Birmingham, Department of Biomedical Engineering. I worked at CLIA certified clinical laboratory for certain years, and am a member of American Board of Bioanalysis (ABB). I was trying to obtain a certificate of Technical Supervisor from ABB. However, I was told that my degree is not eligible for the certificate because my degree is not listed under CLIA regulation 493.1443 (b)(3). ABB also told me, "CMS previously advised us that a Biomedical Engineering degree does not meet the educational requirement for HCLD or TS". Because of this reason, I withdraw my application.

Based on the above facts, I would like to address my comment on the subject.

My understanding of the purpose of Clinical Laboratory Improvement Amendment is the assurance of the quality of clinical testing, which can provide same results for same specimen under different circumstances including testing site, personnel and equipment. This whole idea is same as the key concept of engineering manufacture quality control. Natural science including medical science, is basically exploring and finding out rules of nature whereas Engineering is the act of constructing system based on the rules found by the natural science. The concept of the quality control is started from industrial manufacturing to obtain uniform products from day to day production. This idea is expanded quickly for the measurement technique to obtain uniform result from same specimen. As engineering students, we learn statistical analysis and industrial control from very beginning of our career. I believe that the degree of engineering is a proof of the understanding and ability to perform quality control, that is the ability required for CLIA laboratory personnel. Therefore, the degree in Engineer should not be excluded from the qualification for the CLIA laboratory management layer.

In addition to that, recent requirement of the society for working personnel is much wider than it used be. Many classes in a college or university require the skill of computer software and programming. Also, many students learn the concept of the quality control not only in the departments of natural science but also engineering and even in humanities or economics

department. Instead of limiting the CLIA personnel eligibility based on the department conferred the degree, I would appreciate if you can qualify the personnel based on his/her type of degree and/or ability by examination.

It would be very much appreciated if my comments can be contributed for your discussions.

Sincerely yours,

A handwritten signature in blue ink, appearing to read 'Masahiko Amano', with a stylized flourish at the end.

October 1st, 2018

Masahiko Amano, Ph.D.