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Centers for Disease Control and Prevention
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RE: Virtual Comments for April 10, 2024 Spring Virtual Clinical Laboratory Improvement Advisory Committee Meeting, the Applicability of CLIA Personnel Requirements to Preanalytic Testing

The National Society for Histotechnlogy appreciates the opportunity to provide comments concerning the Applicability of CLIA Personnel Requirements to Preanalytic Testing on behalf of its membership. The National Society for Histotechnology is a non-profit member organization that supports histotechnicians and histotechnologists worldwide through education, collaboration and innovation.

When CMS last revisited the CLIA regulations in 1992, it excluded from oversight many histological pre-analytic, analytical and post-analytical processes because they were deemed relatively simple, minimal risk procedures that did not require a Histotechnologist to produce an independent result. However much has changed in the last 30 years. The field of histotechnology has witnessed unprecedented technical advances including innovative approaches, methodologies, and automation in traditional areas as well as in the fields of immunohistochemistry, in situ hybridization, molecular diagnostics, and computer-assisted digital image analysis, all of which are critical to patient diagnosis and treatment. For example, loading slides on an immunohistochemistry instrument is not a simple task. Loading an instrument requires the selection of proper reagents, insuring appropriate controls are in place, programing the instrument and reviewing results. Multiple individuals may be involved at any time throughout the work shift in this process and all must be capable of executing the entire task for a successful test. In addition, many laboratories have a varied menu of pre-diluted reagents and concentrates as well as other reagents for special stains requiring the ability to do complex dilutions and calculations. Histologists also manipulate specimens. Grossing is the most obvious but processing, embedding, sectioning and staining all change the specimen in ways that can influence diagnosis. Histologists also reject specimens for a variety of reasons including if a specimen cannot be embedded as required, sectioned as indicated or if tissue falls of a slide or a stain is not working. Histologists must use their experience to determine if the specimen is adequate for further processing. This occurs at multiple points throughout the sample workflow. In addition, when test systems fail, there is a critical need for an individual with high complexity skills to troubleshoot the problem and bring the test system back on line. As noted, histology procedures and methods have become highly complex, and with personalized medicine becoming the standard of care, the entire test system is critical to deliver high quality patient care. There is sufficient evidence that quality outcomes depend on the quality of input and as such, preanalytical steps should be considered part of the high complexity *Total Test* approach (1).

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NSH strongly believes that the definition of a "test," specifically as it relates to histology, needs reexamination. The complexity designation should include the pre analytical and analytical phase steps of the total test approach.

Essential to providing quality patient healthcare in today's complex medical laboratory environment are educated, trained, professional histotechnicians and histotechnologists. The NSH strongly believes that histologists should have post-secondary education that confers a degree and training culminating in national certification or licensure to demonstrate competency and meet CLIA's high complexity personal requirements, consistent with the American Society of Clinical Pathology Board of Certification credential requirements. Given the complexity of contemporary histology laboratories, we strongly feel that the current level of education required in CFR 42 §492.20 does not adequately provide the education and expertise necessary to provide high quality patient care and outcomes.

The National Society for Histotechnology advocates that the CLIA recommendations be amended to include Histotechnicians and Histotechnologists under CLIA's oversight therefore requiring histology laboratory personnel to meet CLIA's high complexity personal requirements.

The National Society for Histotechnology strongly believes that CLIA should increase its oversight of histology laboratories by requiring those facilities or entities that perform histologic processing of anatomic tissues to be classified as CLIA-certified high complexity laboratories. In this way, the procedures are performed in an appropriately accredited CLIA laboratory and by personnel who meet CLIA personnel requirements in order to provide high quality personalized care, today and in the future.

The National Society for Histotechnology is the largest a non-profit member organization, representing histotechnicians and histotechnologists worldwide. NSH is the leading provider of histotechnology education designed to demonstrate continuing competence in an increasingly complex laboratory-testing environment. We look forward to CLIAC's response to these issues and continued discussion in order to advance the histotechnology profession and provide the highest quality care to the patients we serve. We thank the committee for the prior work, ongoing efforts, and consideration.

1. Taylor, C.R., *Quality assurance and standardization in immunohistochemistry. A proposal for the annual meeting of the Biological Stain Commission, June, 1991.* Biotech Histochem, 1992. **67**(2): p. 110-7.