

CLIAC

Clinical Laboratory Improvement Advisory Committee

May 6, 2015

The Honorable Sylvia M. Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Madam Secretary:

I am writing on behalf of the Clinical Laboratory Improvement Advisory Committee (CLIAC) to express the Committee's recommendation pertaining to clinical laboratory biosafety, especially with regards to emerging infections in the United States (US).

BACKGROUND

CLIAC is the federal advisory committee charged with the responsibility of advising HHS on issues related to the Clinical Laboratory Improvement Amendments of 1998 (CLIA), as well as technological advances affecting general clinical laboratory quality and laboratory medicine. This includes issues of clinical laboratory safety that fall under the overarching umbrella of laboratory quality. During the November 5-6, 2014 CLIAC meeting, the Committee deliberated on laboratory biosafety in the United States. The topic of laboratory safety and quality, with lessons learned through the Ebola response, was again presented to the Committee for consideration during the April 15-16, 2015 CLIAC meeting. Background information was given from the clinical and public health laboratory perspectives, as well as a presentation on the importance of safety assessments from a NIOSH industrial hygienist. After deliberating on the issues, the Committee voted to provide the following recommendation to HHS.

RECOMMENDATION

With regard to emerging infections, HHS should:

1. Provide oversight that ensures assessment of the safety and decontamination of laboratory instrumentation by manufacturers.
2. Ensure that biosafety training and assessment is required of all CLIA-certified laboratories, including personnel responsible for the preanalytical, analytical, and postanalytical phases of testing.

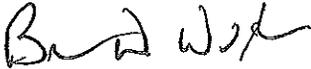
Clinical Laboratory Improvement Advisory Committee

3. Ensure oversight, input, and resources into studies evaluating the safety of all laboratory practices, instrument testing, etc., so that studies are sound, robust, evidence-based, and applicable.
4. Develop a process for investigating and reporting laboratory acquired infections.

CLIAC appreciates the significant and continuing efforts made by HHS and its operating divisions to advance laboratory safety and quality in the US. CLIAC is committed to providing HHS thoughtful advice in support of this effort. Thank you for your consideration of this recommendation.

If you have any questions regarding CLIAC's recommendation, please feel free to contact me via my personal email at burton.wilcke@med.uvm.edu or by telephone at 802-860-2925.

Sincerely,



Burton W. Wilcke, Jr., Ph.D.

Chairperson

Clinical Laboratory Improvement Advisory Committee (CLIAC)

cc:

Dr. Thomas Frieden

Director, CDC

Dr. William R. Mac Kenzie CLIAC Designated Federal Official

Deputy Director for Science, Division of Laboratory Programs, Standards, and Services

Dr. Barbara Zehnbauer, CLIAC Ex-Officio

Director (Acting), Division of Laboratory Systems, CDC

Ms. Karen Dyer, CLIAC Ex-Officio

Director (Acting), Division of Laboratory Services, CMS

Dr. Alberto Gutierrez, CLIAC Ex-Officio

Director, Office of In Vitro Diagnostic Devices, FDA



AUG 05 2015

Burton W. Wilcke Jr., Ph.D.
Chairperson
Clinical Laboratory Improvement Advisory Committee
2877 Brandywine Road
Williams Building, Floor 2, Room 2716
Atlanta, GA 30341

Dear Dr. Wilcke:

Thank you for the Clinical Laboratory Improvement Advisory Committee's (CLIAC) recommendations regarding biosafety in clinical laboratories. Secretary Burwell asked that I respond directly to you on her behalf.

The Department of Health and Human Services (HHS) recognizes the important role that the CLIAC plays in keeping HHS informed of potential issues that affect or could affect clinical laboratories, including CLIA-certified laboratories. Emerging infections such as Ebola present serious challenges to the safety of laboratory personnel, and it is important to ensure that these personnel have the oversight, resources, and training to manage potential exposures to such infections. The evaluation of the safety of current laboratory practices and the proper procedures for the decontamination of laboratory instrumentation also play extremely important roles in protecting laboratory employees.

We will carefully consider the CLIAC's recommendations regarding clinical laboratory biosafety and will welcome any additional comments or suggestions that the CLIAC may have.

Sincerely,

A handwritten signature in cursive script that reads "Mary K. Wakefield".

Mary K. Wakefield
Acting Deputy Secretary