

Background Information for April 13-14, 2016 CLIAC Meeting

We are providing background information and some links for topics that will be discussed during the upcoming CLIAC meeting. We recommend you review the attached information prior to attending the meeting to facilitate your engagement in the Committee Discussions. The links can serve as informational resources not only for the upcoming meeting but for CLIA and CDC information in general. Additional meeting information including the agenda and presentations can be found at <http://www.cdc.gov/cliac/>.

HHS Agency Updates

We have decreased the time allotted for agency updates. We are asking CLIAC members to review each agency presentation prior to the start of the meeting on April 13, 2016. As they become available, updates from the CDC, CMS, and FDA can be found at <http://www.cdc.gov/cliac/> under Presentations & Other Documents.

CMS Advisory Panel on Clinical Diagnostic Laboratory Tests

- <https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>

Laboratory Interoperability: ONC policies and engagement with clinical laboratories

- The Office of the National Coordinator for Health Information Technology (ONC) Fact Sheet “ONC Health IT Certification Program: Enhanced Oversight and Accountability” Proposed Rule https://www.healthit.gov/sites/default/files/2016-oversight-rule_.pdf
- Fact Sheet: Commitments from health care industry to make electronic health records work better for patients and providers https://www.healthit.gov/sites/default/files/Fact%20Sheet%20-%20Interoperability%20Commitments_2.29.16.pdf
- The Office of the National Coordinator for Health Information Technology (ONC) Report to Congress on Health IT Progress <https://www.healthit.gov/buzz-blog/from-the-onc-desk/report-to-congress-health-it-progress/>

Update on Laboratory Biosafety

- Morbidity and Mortality Weekly Report (MMWR) “Guidelines for Safe Work Practices in Human and Medical Diagnostic Laboratories: Recommendations of a CDC-convened, Biosafety Blue Ribbon Panel; January 6, 2012. <http://www.cdc.gov/mmwr/pdf/other/su6101.pdf>
- Nature “Safety Survey Reveals Lab Risks” January 2013. <http://www.nature.com/news/safety-survey-reveals-lab-risks-1.12121>

CLIA Requirements Related to Safety/Biosafety

The middle column	Description	Comments
493.1101 (a) (1)	The laboratory must be constructed, arranged, and maintained to ensure the following: (1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.	Construction and ventilation especially for BSL3 labs
493.1101 (a) (2)	The laboratory must be constructed, arranged, and maintained to ensure the following: contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized	
493.1101 (b)	The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.	Molecular Dx performed on biothreat agents (i.e. BSC)
493.1101 (c)	The laboratory must be in compliance with applicable Federal, State and local laboratory requirements.	BSL3 labs especially
493.1101 (d)	Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.	
493.1235	As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.	Must be assessed on proper use of equipment (i.e. Biosafety cabinet) and PPE to ensure personnel safety.
493.1241 (C)(8)	The lab must ensure the test requisition solicits: Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.	i.e. Travel history/suspected Biothreat agent/ suspected Ebola / information needed when a pandemic declared, etc.
493.1254 (a)(1)(2)	The lab must perform and document : (1) Maintenance as defined by the manufacturer and with the frequency specified by the manufacturer. (2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.	Equipment used for personnel safety, i.e. BSC, PAPR

493.1407 (e) (2)	The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.	
493.1407 (e) (10)	Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report tests results in accordance with the personnel responsibilities described in this subpart;	Insufficient personnel can cause overworked staff to make mistakes in safety
1407 (e) (11)	Ensure that prior to testing patient's specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;	Inexperienced personnel can make critical safety mistakes (i.e. donning/doffing PPE, incorrect use of BSC)
1407 (e) (12)	Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.	Personnel have to maintain competency on safety procedures, equipment safety, etc.
1445 (e) (2)	The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.	
1445 (e) (11)	Ensure that prior to testing patient's specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;	Inexperienced personnel can make critical safety mistakes (i.e. donning/doffing PPE, incorrect use of BSC)
1445 (e) (12)	Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and	Personnel have to maintain competency on

	postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.	safety procedures, equipment safety, etc.
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Occupational Safety & Health Administration (OSHA)

OSH Act of 1970

29 USC 654

SEC. 5. Duties

(a) Each employer --

(1) shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees;

(2) shall comply with occupational safety and health standards promulgated under this Act.

(b) Each employee shall comply with occupational safety and health standards and all rules, regulations, and orders issued pursuant to this Act which are applicable to his own actions and conduct.