

**April 13-14, 2016 Clinical Laboratory Improvement Advisory Committee (CLIAC) Biosafety Recommendation
Update as of March 1, 2018**

Recommendation	Status Update
<p>CLIAC considers the matter of biosafety in clinical laboratories as an urgent unmet national need. We therefore recommend that CDC convene a multidisciplinary task force to develop a biosafety strategy for clinical laboratories that:</p> <ul style="list-style-type: none"> - Includes stakeholders from all areas of clinical laboratories (including professional societies), diagnostic instrumentation industry, other relevant Federal agencies, and patient/clinician representatives. 	<p>CDC Division of Laboratory Systems (DLS) has assembled an overarching Steering Committee to oversee multiple biosafety projects that have been initiated in response to this recommendation. Work on individual projects is conducted by internal and external multidisciplinary teams comprised of clinical, public health, private and reference laboratory professionals, and representatives from academia, private industry, equipment manufacturers, federal agencies, medical institutions, and laboratory professional organizations.</p>
<ul style="list-style-type: none"> - Recommends areas requiring further research in clinical laboratory safety. 	<p>CDC DLS has secured funding and initiated a laboratory research project to address the potential for generation of infectious droplets or aerosols during routine operation of diagnostic laboratory equipment. Data from this research will provide scientifically based evidence to inform safe operation, maintenance, and repair of laboratory equipment. In addition, results will be presented to the FDA and instrument manufacturers to influence future requirements for the design and approval of safe laboratory equipment and instrumentation.</p>
<ul style="list-style-type: none"> - Develops tools, templates, and guidelines for risk assessment in all areas of the clinical laboratories, both for routine operations and for emerging infectious diseases. 	<p>Biosafety guidance from CDC positively impacts all laboratories. CDC DLS has developed multiple on-line laboratory biosafety courses that will be released publicly for use both nationally and globally. CDC is updating and editing the CDC/NIH publication, "Biosafety in Microbiology and Biomedical Laboratories (BMBL)," which provides guidance on risk assessment and safe work practices. Included in the next edition of the BMBL will be a new chapter that specifically focuses on "clinical laboratory biosafety." CDC DLS has several representatives who serve on a national Biosafety and Biosecurity Committee to develop guidance, checklists, job aids, and templates for clinical and public health laboratories.</p>
<ul style="list-style-type: none"> - Publishes interim materials and progress reports broadly, and specifically to CLIAC, to inform and to solicit input from the clinical laboratory and broader medical communities. 	<p>CDC DLS provides guidance nationally and globally in response to inquiries on laboratory issues and preventing laboratory-acquired infections. CDC DLS has reactivated the Laboratory Outreach Communications System (LOCS) to distribute information to clinical laboratory organizations, public health laboratories, and private reference laboratories to facilitate information exchange between CDC and the laboratory community. CDC DLS initiated the development of a new Clinical and Laboratory Standards Institute (CLSI) Guideline Document on "Decontamination of Laboratory Equipment and Instrumentation" based on data obtained from research studies conducted at CDC. This guidance will be intended for any personnel involved in handling, repair, servicing, relocation, transport, shipping, or disposal of common diagnostic equipment used to process or test clinical specimens containing potentially infectious materials.</p>

<p>- Describes cultural, regulatory, measurement, and evaluation strategies for goal achievement in biosafety.</p>	<p>CDC DLS continues to promote a risk-based management approach to assessing and mitigating biological risks in facilities that store and handle biological materials. A new chapter in the next edition of the BMBL, written by DLS staff, addresses risks unique to clinical laboratories, including how to assess and mitigate risks when the infectious agent is unknown.</p>
<p>- Develops a framework for implementation of good clinical practices that also addresses transparent evaluation and monitoring of biosafety practices.</p>	<p>The risk management methodology supported by CDC DLS relies on performance and evaluation of the process in order to ensure continuous improvement of biosafety practices and reduce risks, injury, illness, and infection from occupational exposure to infectious materials.</p>