

<p><b>TITLE:</b></p>	<p><b>IBC20- Laboratory Commissioning and Re-Commissioning for BSL-3 and ABSL-3 Containment</b></p>
<p><b>OVERVIEW:</b></p>	<p>Prior to occupation, all laboratories designed as biosafety level-3 (BSL-3) and animal biosafety level-3 (ABSL-3) must undergo an initial commissioning process. This process is part of the initial certification process as an orderly advancement from state of static completion to a functioning facility in accordance with the design intent. Additionally, these facilities must also undergo an annual re-commissioning process to ensure that the secondary and engineering controls for the facility continue to operate as originally specified.</p> <p>NOTE: This document does not specifically address the commissioning process conducted by an outside company during construction of a new building or restoration of an old building. This process is completed prior to a final commissioning conducted by the Biosafety Officer as described in this policy.</p>
<p><b>APPLIES TO:</b></p>	<p>All laboratories that will be used to manipulate risk group 3 biohazardous agents.</p>
<p><b>DEFINITIONS:</b></p>	<p><i>Certification</i> - verification that the facility meets requirements for design and use.</p> <p><i>Re-certification</i> - ongoing verification that the secondary barriers and engineering controls within the facility are functioning according to original specifications.</p> <p><i>BSL-3 containment</i> - applicable for work with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.</p> <p><i>ABSL-3 containment</i> - practices suitable for work with animals infected with risk group 3 agents.</p> <p><i>Risk Group 3 (RG3) agent</i> - biological agent that is associated with a serious or lethal disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).</p>
<p><b>PROCEDURES:</b></p>	<p>The commissioning process for the initial certification of a laboratory is performed to address the <i>facility design</i>.</p> <p>All core ABSL-3 and BSL-3 facilities must undergo an initial biosafety laboratory inspection to address <i>standard practices</i> utilized, <i>safety</i> issues, and any <i>special practices</i> needed in the function of the laboratory.</p> <p>The final commissioning process for the BSL-3/ABSL-3 laboratory is completed by the Biosafety Officer.</p>

	<p>Facility design commissioning verifies the following (see <b>IBC20- Form 1</b> for a pre-occupancy commissioning checklist and <b>IBC20- Form 2</b> for a re-commissioning checklist):</p> <ol style="list-style-type: none"> <li><b>1. Room integrity</b></li> <li><b>2. Equipment Installation and Certification</b></li> <li><b>3. Access Control and Security</b></li> <li><b>4. General Laboratory Design</b></li> <li><b>5. Air Handling System</b></li> <li><b>6. Additional Facility Needs for ABSL-3</b></li> </ol> <p>Any failure noted during the pre-occupancy commissioning process must be corrected prior to certification of the containment laboratory.</p> <p>Any failure noted during the re-commissioning process will require a risk assessment in consultation among the facility Director, Safety and Security Manager, Biosafety Officer, and other individuals as appropriate to determine what action needs to be considered for continued operation of the laboratory.</p> <p>All deficiencies identified during the inspection process must be corrected.</p>
<b>RECORD KEEPING:</b>	Copies of both the pre-occupancy commissioning checklist and the annual re-commissioning checklists are given to the Director of each containment suite to verify that the commissioning process has been completed and that the laboratory meets certification requirements. These documents are kept on file in the Standard Operating Procedures Manual of the laboratory.
<b>OTHER INFORMATION:</b>	The commissioning process must begin at the design or re-design phase of construction and must be ongoing during the construction phase. The final act of commissioning is completed just prior to “activation” of the laboratory.
<b>REFERENCES:</b>	Biosafety in Microbiological and Biomedical Laboratories, 5 <sup>th</sup> Edition, 2007.
<b>STATUS:</b>	Updated: July 7, 2015