

<b>TITLE:</b>	<b>IBC11-Institutional Biosafety Committee Laboratory Inspection Process</b>
<b>OVERVIEW:</b>	<p>A laboratory inspection is performed to comply with regulations contained in the <i>NIH Guidelines for Research</i>. This inspection is designed to ensure that laboratory standards are followed according to the <i>Guidelines</i> and to provide technical advice to principal investigators and other laboratory scientists on research safety and biosecurity issues.</p> <p>NOTE: All laboratories listed as ABSL-3 and BSL-3 containment must undergo an ANNUAL inspection (as described in this procedure) and an ANNUAL re-commissioning process (as described in Policy #IBC20, Laboratory Commissioning and Re-Commissioning for BSL-3 and ABSL-3 Containment) to verify that the secondary barriers and engineering controls within the laboratory are functioning according to specifications.</p>
<b>APPLIES TO:</b>	All laboratories designated as biosafety level 1 (BSL-1), biosafety level 2 (BSL-2) and biosafety level 3 (BSL-3).
<b>DEFINITIONS:</b>	<p><i>Risk Group 2 (RG-2)</i> - biological agent associated with disease which is rarely serious [moderate individual and low community risk].</p> <p><i>Risk Group 3 (RG-3)</i> - biological agent associated with serious or lethal disease [high individual and moderate community risk].</p>
<b>PROCEDURES:</b>	<p>All BSL-1 and BSL-2 research laboratories on campus undergo an ANNUAL <b>Safety Inspection</b> (conducted by Safety Department personnel) and an <b>Infection Control Compliance</b> audit (conducted by Infection Control Department personnel). A part of the Safety/Infection Control inspections will include an evaluation of basic biosafety issues such as:</p> <ol style="list-style-type: none"> <li>1] proper utilization of sharps containers;</li> <li>2] availability of hand washing sinks, PPE, and eyewash/showers;</li> <li>3] proper use of centrifuge, microwave ovens, refrigerators;</li> <li>4] proper handling of biohazardous waste;</li> <li>5] proper storage of food;</li> <li>6] laboratory security; and</li> <li>7] overall cleanliness of the laboratory.</li> </ol> <p>In addition, all BSL-2 and ABSL-2 research laboratories on campus will undergo a <b>Biosafety Inspection</b> (conducted by the Biosafety Officer [BSL-2 labs] and Comparative Medicine personnel [ABSL-2 labs], respectively) at the time of setting up a new IBC protocol. As a part of an on-going audit, these laboratories will also undergo a Biosafety Inspection every THREE years while the IBC protocol</p>

remains active.

All BSL-3 and ABSL-3 research laboratories will undergo a **Biosafety Inspection** at the time of setting up a new IBC protocol (conducted by the Biosafety Officer [BSL-3 and ABSL-3 labs] and Comparative Medicine personnel [ABSL-3 labs], respectively) with ANNUAL inspections while the IBC protocol remains active.

Inspections may also be periodically unannounced as they relate to a reported incident or when potential unsafe laboratory practices are reported.

### **For new IBC protocols**

1. The Biosafety Officer will be notified of IBC protocols requiring BSL-2 or BSL-3 containment through the IBC review process.
2. During the review process, the Biosafety Officer will arrange with the Principal Investigator for the laboratory inspection.
3. The Laboratory Biosafety Compliance Checklist for BSL-2 (**IBC11-Form 1**) with the addition of the Checklist for BSL-3 (**IBC11-Form 2**) when appropriate, will be followed.

As a part of the inspection process, the Primary Investigator or designee will be given information to be shared with other personnel who are directly or indirectly involved in experiments using a biohazardous agent as a means to enhance standard practices and training. This information may include:

**a] IBC Biological Spill Clean-up Policy (IBC04)**

(Describes the procedure to follow if an accident contaminates personnel and/or the environment.)

**b] Infectious Disease MSDS Sheet on the organism(s) used**

(To be used in the training of personnel so they understand the biology of the organism(s) used in the experiments so that the potential biohazards can be understood and appreciated. In cases where multiple biohazardous agents are used, reference to the Health Canada website to access this information will be given.)

**c] Access information to the UNMC IBC website**

(This site gives information pertaining to laboratory practices through links to the *NIH Guidelines*, the *BMBL Manual*, and to the *UNMC Biosafety Manual*. Additionally, policies pertaining to general laboratory practices and safety are also included.)

4. Following completion of the inspection, the Biosafety Officer will compile a memorandum to the PI indicating either that: (1) the laboratory complies with mandated *Guidelines* or (2) the laboratory does not comply with mandated *Guidelines* for the following reason(s): [reason(s) will be listed]. Recommendations for improvement of laboratory practices may also be included in this correspondence.

5. All laboratories that do not comply with mandated *NIH Guidelines* will be required to make the necessary changes prior to approval of the IBC protocol. A follow-up inspection by the Biosafety Officer may be conducted for a laboratory not approved in the initial inspection.

### **For re-review of IBC protocols**

(All BSL-2/ABSL-2 laboratories require an inspection **every three years** while BSL-3 laboratories require **an annual** inspection. The inspection will occur in conjunction with the annual IBC protocol re-review process.)

1. The Biosafety Officer will contact the principal investigator during the re-review process of the IBC protocol to arrange a time for the inspection.

2. The inspection process and reporting will be done as indicated for new protocols.

3. Any investigator with a previously approved IBC protocol whose laboratory is found to not be in compliance with the *NIH Guidelines* by the Biosafety Officer must correct the problem before re-approval of the IBC protocol is granted.

If the Biosafety Officer determines a personnel or environmental exposure risk exists, the IBC protocol will be placed on an Inactive Status and the experiments will be halted until such time that the noncompliance is corrected.

When non-compliance is identified, the Biosafety Officer will consult with the IBC Chair and the Associate Vice Chancellor for Academic Affairs, Regulatory Compliance, to determine the best course of action (consultation with IBC members may also be requested). The IBC Chair or the Biosafety Officer (when the Chair is not available) will contact the principal investigator to indicate that the laboratory is not compliant with the University and *NIH Guidelines* and that the IBC protocol will be placed on an inactive status and that corrective action must occur before experiments can be continued. A follow-up inspection will be conducted to determine compliance.

<b>RECORD KEEPING:</b>	A copy of the inspection report and the results will be sent to the Principal Investigator and kept on file in the Biosafety Office.
<b>OTHER INFORMATION:</b>	Laboratory inspection checklists for both BSL-2 and BSL-3 containment are available in the "Forms" section on the IBC website ( <a href="http://www.unmc.edu/ibc">www.unmc.edu/ibc</a> ).
<b>REFERENCE:</b>	<i>NIH Guidelines</i> , Section IV-B-3-c-(2), (the Biosafety Officer is to perform) periodic inspections to ensure that laboratory standards are rigorously followed.  CDC/NIH, BMBL, 5th edition, 2007
<b>STATUS:</b>	Updated: July 7, 2015