



ASU Guidelines for Receiving Samples Potentially Containing Highly Pathogenic Agents

Lapses in inactivation protocols at other institutions have resulted in the transfer of samples containing highly pathogenic agents from BSL-3 and BSL-4 containment laboratories to BSL-2 laboratories. In one instance, material from an Ebola virus experiment was transferred from a select agent-approved BSL-4 laboratory to a BSL-2 laboratory with potentially live virus in the samples¹. Similar instances of samples containing live *Bacillus anthracis* and live H5N1 influenza virus occurred in mid 2014^{2,3}.

Active BSL-4 agents are not permitted at ASU. Active BSL-3 agents must be used and maintained in BSL-3 containment laboratories. BSL-3 and BSL-4 agents that have been inactivated are permitted for use within BSL-2 laboratories if at least one of the following conditions have been met:

1. **Sample Inactivation by Provider.** A validated method for inactivation must be employed. This will include either: 1) testing a fraction of the samples to ensure sterility of the samples to be shipped; or 2) including a vial containing a sentinel aliquot of the listed infectious agent. After the inactivation process, this sentinel vial will be cultured to ensure sterility is achieved. Documentation describing the validation method used, the date performed, and a point of contact for the process, must be included with the sample and provided to the IBC.
2. **Irradiation of Sample at ASU.** If sample inactivation is not possible from the shipping site, sample inactivation may be accomplished at ASU using either a Gamma Cell irradiator or CRT Irradiator along with a sentinel virus to ensure sterility. Documentation describing the irradiation method used, the date performed, and a point of contact for the process, must be provided to the IBC.
3. **Site-Specific Risk Assessment.** If irradiation at ASU is not feasible, or if sample inactivation cannot be validated, a site-specific risk assessment will be performed to determine the procedures, engineering controls, and appropriate personal protective equipment (PPE) necessary to work safely with the samples. The determination of whether the work can be safely performed at ASU will be made by EH&S Biosafety/Biosecurity in collaboration with the Institutional Biosafety Committee (IBC).

Questions regarding the inactivation of highly infectious agents may be directed to the ASU Biological Safety Officer at 480.965.5389 or via email at biosafety@asu.edu.

Note: Any Material being transferred to or from ASU must be linked to an approved and executed Material Transfer Agreement (MTA) or sponsored research agreement that includes provisions related to the transfer of materials. The MTA process ensures that Materials have been approved for transfer and provides an alert to relevant departments with regard to the nature and associated risks of the Materials. Investigators should contact the Office of Industry Research and Collaboration to initiate a request for transfer.

¹ <http://www.cdc.gov/media/releases/2015/s0204-ebola-lab.html>

² <http://www.cdc.gov/media/releases/2014/s0619-anthrax.html>

³ <http://www.cdc.gov/flu/news/h5n1-influenza-shipment.htm>