

## Inspection Checklist for Highly Pathogenic Avian Influenza (HPAIV) Laboratories (9 CFR 121 and 42 CFR 73)

Inspection Date:
Entity Name:
Responsible Official:
SAP Inspector(s):
Principal Investigator (P.I.):
Laboratory Location - Street Address:
Building:
Room number(s):
Agent(s)/Toxin(s):

**When information is entered in this form, the form is to be considered "Sensitive Select Agent Information."**

Reference	Statement	Response			Comments
		Yes	No	N/A	
<b>Due to the potential economic impact of HPAIV on poultry morbidity and mortality, and the trade implications of the disease, APHIS requires the following enhancements beyond BSL-2, BSL-3/ABSL-3 for work with HPAIV in the laboratory or vivarium.</b>					
<b>Section A</b>	<b>For <i>in-vitro</i> Diagnostics</b> [for diagnostic laboratories where there is use of PCR or other <i>in-vitro</i> diagnostic methods (but where there is no virus propagation), and/or storage of virus isolates or diagnostic materials known to be infected with HPAIV]: <b><u>BSL2 checklist plus the following enhancements:</u></b>				
APHIS/VS Standard: A(1)	Clothing change prior to entering the laboratory and leaving the facility; or				
APHIS/VS Standard: A(2)	Full body Tyvek jumpsuits; or				
APHIS/VS Standard: A(3)	Disposable wrap-around smock, arm covers, shoe covers; and				
APHIS/VS Standard: A(4)	Confirmation of a written personnel quarantine or restriction policy.*				
<b>Section B</b>	<b>For <i>in-vitro</i> laboratory work</b> [where there is <b>virus propagation</b> in eggs and/or cell/tissue culture, etc.]: <b><u>BSL3 checklist plus the following enhancements:</u></b>				
APHIS/VS Standard: B(1)	When leaving the facility, employees shower out of the facility. A shower room at the non-containment/containment boundary;				
APHIS/VS Standard: B(2)	Confirmation of a written personnel quarantine or restriction policy;*				
APHIS/VS Standard: B(3)	Liquid effluents originating from the laboratory (+/- liquid effluent from the shower areas), are collected and heat or chemically treated for sterility prior to exiting the facility or entering a public sewage system;				
APHIS/VS Standard: B(4)	HEPA filtration of all exhaust air derived from the containment area.				

<b>Section C</b>	<b>For <i>in-vivo</i> work</b> [where animals are contained in isolator units; the room is NOT serving as the primary barrier]: <b><u>ABSL3 checklist plus the following enhancements:</u></b>			
<b>APHIS/VS Standard: C(1)</b>	When leaving the facility, all personnel shower out of the facility. A shower room at the non-containment/containment boundary;			
<b>APHIS/VS Standard: C(2)</b>	Confirmation of a written personnel quarantine or restriction policy;*			
<b>APHIS/VS Standard: C(3)</b>	Liquid effluents originating from the laboratory (+/- liquid effluent from the shower areas), are collected and heat or chemically treated for sterility prior to exiting the facility or entering a public sewage system;			
<b>APHIS/VS Standard: C(4)</b>	Solid animal wastes and tissues are <u>heat</u> treated prior to leaving the containment area;			
<b>APHIS/VS Standard: C(5)</b>	Bio-isolators are HEPA-filtered out; and			
<b>APHIS/VS Standard: C(6)</b>	HEPA filtration of all exhaust air derived from the containment area.			
<b>Section D</b>	<b>For <i>in-vivo</i> work</b> [where the <b>room serves as the primary containment barrier</b> . Animals are loosely housed on the floor or in laboratory animal cages. Note: "Animals" are considered to be any research animal, not just livestock or poultry.]: <b><u>BSL-3Ag checklist plus the following enhancements:</u></b>			
<b>APHIS/VS Standard: D(1)</b>	Confirmation of a written personnel quarantine or restriction policy.*			
<b>*Personnel Quarantine Policy</b>				
<b>APHIS/VS Standard A(4), B(2), C(2) and D(1).</b>	For work [in vitro, as well as in vivo] with HPAIV, APHIS requires entities to implement a personnel quarantine policy for visitors and staff. Entities must have, in place, a written policy prohibiting laboratory staff and visitors from having contact with susceptible avian species for a minimum of 5 days after the last possible contact with the HPAIV virus in BSL2 and BSL3/ABSL3 laboratories. The prohibition on contact with susceptible avian species includes, but is not limited to, contact with any pet birds, backyard poultry flocks, birds at county/state fairs, commercial poultry operations, zoological collections (i.e. zoos), and wild birds (e.g., ducks, geese). Entity's policy must require that employees and visitors read the policy, and acknowledge, by signature, their agreement to comply with that policy. Additionally, laboratories working with HPAIV should not be in close proximity to avian colonies. There should be no commercial poultry flocks within 1/2 mile of the facility, or any other avian colonies (e.g. backyard flock, aviary, zoo) within 100 meters of the facility.			

