

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

Entity Name:
 Inspection Date:
 Street Address:
 City, State, Zip:
 RO:
 ARO(s):

 Lead Inspector:
 Other Inspectors:

Building/Room(s):

 PI(s):

 HHS Agents:

 Overlap Agents:

 USDA Agents:

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

Entity Name:		Inspection Date:			
Reference	Statement	Yes	No	N/A	Comments
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.					
Section A	For <i>in-vitro</i> Diagnostics [for diagnostic laboratories where there is use of PCR or other in-vitro diagnostic methods (but where there is no virus propagation), and/or storage of virus isolates or diagnostic materials known to be infected with HPAIV]: <u>BSL2</u>				
APHIS/VS Standard: A(1)	Clothing change prior to entering the laboratory and leaving the facility; or OIE 1.1.4 OIE 2.3.4				
APHIS/VS Standard: A(2)	Full body Tyvek jumpsuits; or OIE 1.1.4 OIE 2.3.4				
APHIS/VS Standard: A(3)	Disposable wrap-around smock, arm covers, shoe covers; and OIE 1.1.4 OIE 2.3.4				
APHIS/VS Standard: A(4)	Confirmation of a written personnel quarantine or restriction policy.* VS Memo 591.46				
Section B	For <i>in-vitro</i> laboratory work [where there is virus propagation in eggs and/or cell/tissue culture, etc.]: <u>BSL3 checklist plus the following enhancements:</u>				
APHIS/VS Standard: B(1)	When leaving the facility, employees shower out of the facility. A shower room at the non-containment/containment boundary; C.F.R. 93.106(c)(2)(i)(H)				

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Reference	Statement	Yes	No	N/A	Comments
APHIS/VS Standard: B(2)	Confirmation of a written personnel quarantine or restriction policy;* VS Memo 591.46				
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; OIE 1.1.4				
APHIS/VS Standard: B(4)	HEPA filtration of all exhaust air derived from the containment area. OIE 1.1.4 OIE 2.3.4				
Section C	For <i>in-vivo</i> work [where animals are contained in isolator units; the room is NOT serving as the primary barrier]: <u>ABSL3 checklist plus the following enhancements:</u>				
APHIS/VS Standard: C(1)	When leaving the facility, all personnel shower out of the facility. A shower room at the non-containment/containment boundary; OIE 1.1.4 VS Memo 591.46				
APHIS/VS Standard: C(2)	Confirmation of a written personnel quarantine or restriction policy;* VS Memo 591.46				
APHIS/VS Standard: C(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; OIE 1.1.4				
APHIS/VS Standard: C(4)	Solid animal wastes and tissues are heat treated prior to leaving the containment area; OIE 1.1.4				
APHIS/VS Standard: C(5)	Bio-isolators are HEPA-filtered out; and OIE 1.1.4 OIE 2.3.4				
APHIS/VS Standard: C(6)	HEPA filtration of all exhaust air derived from the containment area. OIE 1.1.4 OIE 2.3.4				
Section D	For <i>in-vivo</i> work [where the room serves as the primary containment barrier. 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.]: <u>BSL-3Ag checklist</u>				
APHIS/VS Standard: D(1)	Confirmation of a written personnel quarantine or restriction policy.* VS Memo 591.46				

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*Personnel Quarantine Policy					
APHIS/VS Standard A(4), B(2), C(2) and D(1). VS Memo 591.46 C.F.R. 93.106(c)(2)(i) (B) OIE 1.1.4 OIE 2.3.4	APHIS/VS Standard A(4), B(2), C(2) and D(1). 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.				

Comments continued:

Inspector summary and comments:

Lead inspector:

Date:

Other inspectors present:

Date:

Lead inspector signature: _____

Date: _____