

Inspection Checklist for Newcastle Disease Virus (vNDV) 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	
Due to the potential economic impact of vNDV on poultry morbidity and mortality, and the trade implications of the disease, APHIS requires the following enhancements beyond BSL-2/ABSL-2 for work with vNDV in the laboratory or vivarium.					
Section A	vNDV enhancements: BSL-2 checklist plus the following enhancements:				
APHIS/VS Standard: A(1)	There are no avian colonies within 1/2 mile of the facilities;				
APHIS/VS Standard: A(2)	Personnel working with vNDV are not permitted to have contact with susceptible animal species for a period of 5 days following last exposure to vNDV.				
APHIS/VS Standard: A(2)(i)	Personnel have been instructed on the proper procedures for handling vNDV.				
APHIS/VS Standard: A(3)	Access to vNDV materials and areas is restricted.				
APHIS/VS Standard: A(4)	Special/dedicated clothing for direct contact with vNDV material or areas is required.				
APHIS/VS Standard: A(5)	Facilities where work with vNDV will be conducted must have a separate air supply and exhaust system capable of containing the virus within the facility. This should include primary and secondary barriers and use of air flow.				
APHIS/VS Standard: A(5)(i)	Blueprints and legends of the facilities should specifically document the type of filters used in all rooms where work with vNDV will be conducted.				
APHIS/VS Standard: A(6)	Facility legends specify disinfectant products and procedures for use to contain routine spills and to disinfect the facilities before and after each animal study.				
APHIS/VS Standard: A(7)	All waste materials are disinfected before disposal, according to VS Memo #800.56:				

APHIS/VS Standard: A(7)(i)	<u>Incineration</u> : application of flame for a period of time sufficient to degrade all infectious organic material to a noninfectious state; or				
APHIS/VS Standard: A(7)(ii)	<u>Dry heat</u> - 160°C for at least 1/2 hour; or				
APHIS/VS Standard: A(7)(iii)	<u>Autoclaving</u> - application of live steam at a temperature of at least 120°C for for a period of time (not less than 1/2 hour) adequate to inactivate, detoxify, and/or sterilize the material involved; or				
APHIS/VS Standard: A(7)(iv)	<u>Chemical inactivation</u> - addition of formalin, phenol, cresol, beta-propiolactone, phenylmercuric nitrate, or equivalent inactivating agents at sufficient concentration for sufficient time and under proper conditions to inactivate, detoxify, and/or sterilize the material involved; or				
APHIS/VS Standard: A(7)(v)	<u>Rendering</u> - application of sufficient heat for a period of time sufficient to effectively destroy and to degrade to a noninfectious state; or				
APHIS/VS Standard: A(7)(vi)	<u>Burial</u> - of contaminated feed, manure, bedding, and other items below ground level with sufficient covering material to prevent any further dissemination of microorganisms.				
APHIS/VS Standard: A(8)	In the laboratory, employees conduct all work with the agent in a certified BSC.				
Section B	<u>vNDV enhancements: ABSL-2 checklist plus the following enhancements:</u>				
APHIS/VS Standard: B(1)	There are no avian colonies within 1/2 mile of the facilities;				
APHIS/VS Standard: B(2)	Personnel working with vNDV are not permitted to have contact with susceptible animal species for a period of 5 days following last exposure to vNDV.				
APHIS/VS Standard: B(2)(i)	Personnel have been instructed on the proper procedures for handling vNDV.				
APHIS/VS Standard: B(3)	Access to vNDV materials and areas is restricted.				
APHIS/VS Standard: B(4)	Special/dedicated clothing for direct contact with vNDV material or areas is required.				
APHIS/VS Standard: B(5)	Facilities where work with vNDV will be conducted must have a separate air supply and exhaust system capable of containing the virus within the facility. This should include primary and secondary barriers and use of air flow.				

APHIS/VS Standard: B(5)(i)	Blueprints and legends of the facilities should specifically document the type of filters used in all rooms where work with vNDV will be conducted.				
APHIS/VS Standard: B(6)	Facility legends specify disinfectant products and procedures for use to contain routine spills and to disinfect the facilities before and after each animal study.				
APHIS/VS Standard: B(7)	All waste materials are disinfected before disposal, according to VS Memo #800.56:				
APHIS/VS Standard: B(7)(i)	<u>Incineration</u> ; or				
APHIS/VS Standard: B(7)(ii)	<u>Dry heat</u> - 160°C for at least 1/2 hour; or				
APHIS/VS Standard: B(7)(iii)	<u>Autoclaving</u> - steam at 120°C for at least 1/2 hour; or				
APHIS/VS Standard: B(7)(iv)	<u>Chemical inactivation</u> - addition of formalin, phenol, cresol, beta-propiolactone, phenylmercuric nitrate, or equivalent inactivating agents at sufficient concentration for sufficient time and under proper conditions to inactivate, detoxify, and/or sterilize the material involved; or				
APHIS/VS Standard: B(7)(v)	<u>Rendering</u> - application of sufficient heat for a period of time sufficient to effectively destroy carcasses for human food purposes and to degrade to a noninfectious state; or				
APHIS/VS Standard: B(7)(vi)	<u>Burial</u> - the interment of carcasses, contaminated feed, manure, bedding, and other items below ground level with sufficient covering material to prevent any further dissemination of microorganisms.				
APHIS/VS Standard: B(8)	All carcasses are incinerated or autoclaved on site, as per VS Memo #800.56:				
APHIS/VS Standard: B(8)(i)	<u>Incineration</u> - application of flame for a period of time sufficient to degrade all infectious organic material to a noninfectious state; or				
APHIS/VS Standard: B(8)(ii)	<u>Autoclaving</u> - application of live steam at a temperature of at least 120°C for for a period of time (not less than 1/2 hour) adequate to inactivate, detoxify, and/or sterilize the material involved.				
APHIS/VS Standard: B(9)	All dead animals are transported from the animal room directly to the incinerator or autoclave in leak-proof covered containers.				
APHIS/VS Standard: B(10)	Necropsies are conducted only in areas capable of containing the virus.				

APHIS/VS Standard: B(11)	In the laboratory, employees conduct all work with the agent in a certified BSC.				
APHIS/VS Standard: B(12)	Challenge tests with vNDV are conducted in an isolator capable of containing the virus during the post-challenge observation period, and isolators are decontaminated at the end of the study or test.				
APHIS/VS Standard: B(12)(i)	The facilities legends include isolator specifications such as type of filters and air flow and outline specific procedures used to ensure containment of vNDV within the isolator and to decontaminate the isolator when studies are concluded.				
Section C	<u>vNDV enhancements:</u> BSL-3/ABSL-3 checklist plus the following enhancements when applicable:				
APHIS/VS Standard: C(1)	There are no avian colonies within 1/2 mile of the facilities;				
APHIS/VS Standard: C(2)	Personnel working with vNDV are not permitted to have contact with susceptible animal species for a period of 5 days following last exposure to vNDV.				
APHIS/VS Standard: C(2)(i)	Personnel have been instructed on the proper procedures for handling vNDV.				
APHIS/VS Standard: C(3)	Access to vNDV materials and areas is restricted.				
APHIS/VS Standard: C(4)	Special/dedicated clothing for direct contact with vNDV material or areas is required.				
APHIS/VS Standard: C(5)	Facilities where work with vNDV will be conducted must have a separate air supply and exhaust system capable of containing the virus within the facility. This should include primary and secondary barriers and use of air flow.				
APHIS/VS Standard: C(5)(i)	Blueprints and legends of the facilities should specifically document the type of filters used in all rooms where work with vNDV will be conducted.				
APHIS/VS Standard: C(6)	Facility legends specify disinfectant products and procedures for use to contain routine spills and to disinfect the facilities before and after each animal study.				
APHIS/VS Standard: C(7)	All waste materials are disinfected before disposal, according to VS Memo #800.56:				
APHIS/VS Standard: C(7)(i)	<u>Incineration</u> ; or				

APHIS/VS Standard: C(7)(ii)	<u>Dry heat</u> - 160°C for at least 1/2 hour; or				
APHIS/VS Standard: C(7)(iii)	<u>Autoclaving</u> - steam at 120°C for at least 1/2 hour; or				
APHIS/VS Standard: C(7)(iv)	<u>Chemical inactivation</u> - addition of formalin, phenol, cresol, beta-propiolactone, phenylmercuric nitrate, or equivalent inactivating agents at sufficient concentration for sufficient time and under proper conditions to inactivate, detoxify, and/or sterilize the material involved; or				
APHIS/VS Standard: C(7)(v)	<u>Rendering</u> - application of sufficient heat for a period of time sufficient to effectively destroy carcasses for human food purposes and to degrade to a noninfectious state; or				
APHIS/VS Standard: C(7)(vi)	<u>Burial</u> - the interment of carcasses, contaminated feed, manure, bedding, and other items below ground level with sufficient covering material to prevent any further dissemination of microorganisms.				
APHIS/VS Standard: C(8)	All carcasses are incinerated or autoclaved on site, as per VS Memo #800.56: [ABSL-3 only] ;				
APHIS/VS Standard: C(8)(i)	<u>Incineration</u> - application of flame for a period of time sufficient to degrade all infectious organic material to a noninfectious state; or				
APHIS/VS Standard: C(8)(ii)	<u>Autoclaving</u> - application of live steam at a temperature of at least 120°C for a period of time (not less than 1/2 hour) adequate to inactivate, detoxify, and/or sterilize the material involved.				
APHIS/VS Standard: C(9)	All dead animals are transported from the animal room directly to the incinerator or autoclave in leak-proof covered containers. [ABSL-3 only]				
APHIS/VS Standard: C(10)	Necropsies are conducted only in areas capable of containing the virus. [ABSL-3 only]				
APHIS/VS Standard: C(11)	In the laboratory, employees conduct all work with the agent in a certified BSC.				
APHIS/VS Standard: C(12)	Challenge tests with vNDV are conducted in an isolator capable of containing the virus during the post-challenge observation period, and isolators are decontaminated at the end of the study or test. [ABSL-3 only] .				
APHIS/VS Standard: C(12)(i)	The facilities legends include isolator specifications such as type of filters and air flow and outline specific procedures used to ensure containment of vNDV within the isolator and to decontaminate the isolator when studies are concluded. [ABSL-3 only] .				

Recommendations:	
Inspector completing checklist:	Date:
Other inspectors present:	Date: