

Inspection Checklist for Security (7 CFR 331; 9 CFR 121; 42 CFR 73)					
Entity Name:	0	Insp. Date:	January 0, 2000		
Street Address:	, ,				
City, State, Zip:	, ,	Responsible Official (RO):	0		
Lead Inspector:	0	Alternate RO(s):			
Other Inspectors:					
Building/Room(s):					
PI(s):					
HHS Agents:					
Overlap Agents:					
USDA Agents (incl. PPQ):					
<b>When information is entered in this form, the form is to be considered "Sensitive Select Agent Information."</b>					
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Reference	Statement	Response			Comments
		Yes	No	N/A	
CFR: Section 11(a)	An individual or entity required to register under this part must develop and implement a written security plan.				
CFR: Section 11(a)	The security plan must be sufficient to safeguard the select agent or toxin against:				
	- unauthorized access				
	- theft				
	- loss				
	- release				
CFR: Section 11(b)	The security plan must be designed according to a site-specific risk assessment.				
CFR: Section 11(b)	Graded protection is in accordance with the risk of the select agent or toxin, given its intended use. The security plan must be submitted upon request. <i>[APHIS requires that the security plan be submitted with the entity's registration application.]</i>				

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<b>CFR: Section 11(c)</b>	<b>The security plan must:</b>				
<b>CFR: Section 11(c)(1)</b>	Describe procedures for:				
	- physical security				
	- inventory control				
	- information systems control				
<b>CFR: Section 11(c)(2)</b>	Contain provisions for the control of access to select agents and toxins				
<b>CFR: Section 11(c)(3)</b>	Contain provision for:				
	- routine cleaning				
	- maintenance				
	- repairs				
<b>CFR: Section 11(c)(4)</b>	Establish procedures for removing unauthorized or suspicious persons				
<b>CFR: Section 11(c)(5)</b>	Describe procedures for addressing loss or compromise of: <i>[Specify in Comments]</i>				
	- keys				
	- passwords				
	- combinations				
	- protocols for changing access numbers or locks following staff changes				
<b>CFR: Section 11(c)(6)</b>	Contain procedures for: <i>[Specify in Comments]</i>				
	- reporting unauthorized or suspicious persons or activities				
	- loss or theft of select agents or toxins				

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	- release of select agents or toxins				
	- alteration of inventory records				
CFR: Section 11(c)(7)	Contain provisions for ensuring that all individuals with access approval from the HHS Secretary or APHIS Administrator understand and comply with the security procedures				
<b>CFR: Section 11(d)</b>	<b>An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security:</b>				
CFR: Section 11(d)(1)	Allow access only to individuals with access approval from the HHS Secretary or APHIS Administrator				
CFR: Section 11(d)(2)	Allow individuals not approved for access from the HHS Secretary or APHIS Administrator, once select agents are secured, to conduct:				
	- routine cleaning				
	- maintenance				
	- repairs				
	- other activities not related to select agents or toxins only when continuously escorted by an approved individual				
CFR: Section 11(d)(3)	Provide for the control of select agents and toxins by requiring security (e.g. card access system, lockboxes, etc.) against unauthorized access to: <i>[Specify in Comments]</i>				
	- freezers				
	- refrigerators				
	- cabinets				
	- other containers where select agents or toxins are stored				
CFR: Section 11(d)(4)	Inspect all suspicious packages before they are brought into or removed from the area where select agents or toxins are used or stored				
CFR: Section 11(d)(5)	Establish a protocol for intra-entity transfers:				

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	- under the supervision of an individual with access approval from the HHS Secretary or APHIS Administrator				
	- including chain-of-custody documents and provisions for safeguarding against:				
	- theft				
	- loss				
	- release				
CFR: Section 11(d)(6)	Require that individuals with access approval from the HHS Secretary or APHIS Administrator refrain from sharing with any other person their unique means of accessing a select agent or toxin (e.g., keycards or passwords)				
CFR: Section 11(d)(7)	<b>Require that individuals with access approval from the HHS Secretary or APHIS Administrator immediately report any of the following to the Responsible Official:</b>				
CFR: Section 11(d) (7)(i)	Any loss or compromise of keys, passwords, combination, etc.				
CFR: Section 11(d) (7)(ii)	Any suspicious persons or activities				
CFR: Section 11(d) (7)(iii)	Any loss or theft of select agents or toxins				
CFR: Section 11(d) (7)(iv)	Any release of a select agent or toxin				
CFR: Section 11(d) (7)(v)	Any sign that inventory or use records for select agents or toxins have been altered or otherwise compromised				
CFR: Section 11(d) (8)	Separate areas where select agents and toxins are stored or used from the public areas of the building.				
CFR: Section 11(e)	In developing a security plan, an entity or individual should consider, the document entitled "Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents. Morbidity and Mortality Weekly Report December 6, 2002; 51:RR-19:1-6." The document is available on the Internet at: <a href="http://www.cdc.gov/mmwr">http://www.cdc.gov/mmwr</a> .				

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CFR: Section 11(f)	The plan must be reviewed annually and revised as necessary.				
CFR: Section 11(f)	Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan.				
CFR: Section 11(f)	The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.				

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<b>Inspector summary and comments:</b>					
<b>Recommendations:</b>					
<b>Inspector completing checklist:</b>					<b>Date:</b>
<b>Other inspectors present:</b>					<b>Date:</b>