

## Inspection Checklist for Security (7 CFR 331; 9 CFR 121; 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
<b>CFR: Section 11(a)</b>	An individual or entity required to register under this part must develop and implement a written security plan.				
<b>CFR: Section 11(a)</b>	<b>The security plan must be sufficient to safeguard the select agent or toxin against:</b>				
	unauthorized access,				
	theft,				
	loss, or				
	release.				
<b>CFR: Section 11(b)</b>	The security plan must be designed according to a site-specific risk assessment and				

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<b>CFR: Section 11(b)</b>	must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use.				
<b>CFR: Section 11(b)</b>	A current security plan must be submitted for initial registration, renewal of registration, or when requested.				
<b>CFR: Section 11(c)</b>	<b>The security plan must:</b>				
<b>CFR: Section 11(c)(1)</b>	<b>Describe procedures for:</b>				
	physical security,				
	inventory control, and				
	information systems control,				
<b>CFR: Section 11(c)(2)</b>	Contain provisions for the control of access to select agents and toxins including the safeguarding of animals, [including arthropods, 7 CFR 331, 42 CFR 73 only] or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release.				
<b>CFR: Section 11(c)(3)</b>	<b>Contain provisions for:</b>				
	routine cleaning,				
	maintenance, and				
	repairs,				
<b>CFR: Section 11(c)(4)</b>	Establish procedures for removing unauthorized or suspicious persons,				

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<b>CFR: Section 11(c)(5)</b>	<b>Describe procedures for addressing loss or compromise of:</b> <i>[Specify in Comments]</i>				
	keys,				
	passwords,				
	combinations, etc. and protocols for changing access numbers or locks following staff changes,				
<b>CFR: Section 11(c)(6)</b>	<b>Contain procedures for:</b> <i>[Specify in Comments]</i>				
	reporting unauthorized or suspicious persons or activities,				
	loss or theft of select agents or toxins,				
	release of select agents or toxins, or alteration of inventory records, and				
<b>CFR: Section 11(c)(7)</b>	Contain provisions for ensuring that all individuals with access approval from the HHS Secretary or Administrator understand and comply with the security procedures.				
<b>CFR: Section 11(c)(8)</b>	<b>Describe procedures for how the Responsible Official will be informed of suspicious activity that may be criminal in nature and related to:</b>				
	the entity,				

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	its personnel, or				
	its select agents or toxins; and				
	describe procedures for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of such activity.				
<b>CFR: Section 11(c) (9)</b>	<b>Contain provisions for information security that:</b>				
<b>CFR: Section 11(c) (9)(i)</b>	<b>Ensure that all external connections to systems which manage security for the registered space are:</b>				
	isolated or				
	have controls that permit only authorized and authenticated users;				
<b>CFR: Section 11(c) (9)(ii)</b>	Ensure that authorized and authenticated users are only granted access to select agent and toxin related information, files, equipment (e.g., servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities, and that access is modified when the user's roles and responsibilities change or when their access to select agents and toxins is suspended or revoked;				
<b>CFR Section 11(c)(9)(iii)</b>	Ensure that controls are in place that are designed to prevent malicious code (such as, but not limited to, computer virus, worms, spyware) from compromising the confidentiality, integrity, or availability of information systems which manage access to registered spaces in §11 or records in §17;				
<b>CFR Section 11(c)(9)(iv)</b>	Establish a robust configuration management practice for information systems to include regular patching and updates made to operating systems and individual applications; and				
<b>CFR Section 11(c)(9)(v)</b>	Establish procedures that provide backup security measures in the event that access control systems, surveillance devices, and/or systems that manage the requirements of section 17 of this part are rendered inoperable.				

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CFR: Section 11(c) (10)	<b>Contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including:</b>				
	documented procedures for receiving, monitoring, and shipping of all select agents and toxins.				
	These provisions must provide that an entity will properly secure containers on site and				
	have a written contingency plan for unexpected shipments.				
CFR: Section 11(d)	<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 Administrator,				
CFR: Section 11(d)(2)	<b>Allow individuals not approved for access from the HHS Secretary or Administrator to conduct:</b>				
	routine cleaning,				
	maintenance,				
	repairs, or				
	other activities not related to select agents or toxins only when continuously escorted by an approved individual,				

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CFR: Section 11(d)(3)	Provide for the control of select agents and toxins by requiring <i>[Specify in Comments]</i>				
	freezers,				
	refrigerators,				
	cabinets, and				
	other containers where select agents or toxins are stored to be secured against unauthorized access (e.g., card access system, lock boxes),				
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)	<b>Establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the HHS Secretary or Administrator, including:</b>				
	chain-of-custody documents and				
	provisions for safeguarding against theft, loss, or release,				
CFR: Section 11(d)(6)	Require that individuals with access approval from the HHS Secretary or 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 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,				

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<b>CFR: Section 11(d)(7)(iii)</b>	Any loss or theft of select agents or toxins,				
<b>CFR: Section 11(d)(7)(iv)</b>	Any release of a select agent or toxin, and				
<b>CFR: Section 11(d)(7)(v)</b>	Any sign that inventory or use records for select agents or toxins have been altered or otherwise compromised, and				
<b>CFR: Section 11(d)(8)</b>	Separate areas where select agents and toxins are stored or used from the public areas of the building.				
<b>CFR: Section 11(e)</b>	<b>Entities must conduct complete inventory audits of all affected select agents and toxins in long-term storage when any of the following occur:</b>				
<b>CFR: Section 11(e)(1)</b>	Upon the physical relocation of a collection or inventory of select agents or toxins for those select agents or toxins in the collection or inventory;				
<b>CFR: Section 11(e)(2)</b>	Upon the departure or arrival of a principal investigator for those select agents and toxins under the control of that principal investigator; or				
<b>CFR: Section 11(e)(3)</b>	In the event of a theft or loss of a select agent or toxin, all select agents and toxins under the control of that principal investigator.				
<b>CFR: Section 11(f)</b>	<b>In addition to the requirements contained in paragraphs (c) and (d) of this section, the security plan for an individual or entity possessing a Tier 1 select agent or toxin must also:</b>				
<b>CFR: Section 11(f)(1)</b>	Describe procedures for conducting a pre-access suitability assessment of persons who will have access to a Tier 1 select agent or toxin;				
<b>CFR: Section 11(f)(2)</b>	Describe procedures for how an entity's Responsible Official will coordinate their efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents and toxins and share, as appropriate, relevant information; and				

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<b>CFR: Section 11(f)(3)</b>	<b>Describe procedures for the ongoing assessment of the suitability of personnel with access to a Tier 1 select agent or toxin. The procedures must include:</b>				
<b>CFR: Section 11(f)(3)(i)</b>	Self- and peer-reporting of incidents or conditions that could affect an individual's ability to safely have access to or work with select agents and toxins, or to safeguard select agents and toxins from theft, loss, or release;				
<b>CFR: Section 11(f)(3)(ii)</b>	The training of employees with access to Tier 1 select agents and toxins on entity policies and procedures for reporting, evaluation, and corrective actions concerning the assessment of personnel suitability; and				
<b>CFR: Section 11(f)(3)(iii)</b>	The ongoing suitability monitoring of individuals with access to Tier 1 select agents and toxins.				
<b>CFR: Section 11(f)(4)</b>	<b>Entities with Tier 1 select agents and toxins must prescribe the following security enhancements:</b>				
<b>CFR: Section 11(f)(4)(i)</b>	Procedures that will limit access to a Tier 1 select agent or toxin to only those individuals who are approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General, have had an entity-conducted pre-access suitability assessment, and are subject to the entity's procedures for ongoing suitability assessment;				
<b>CFR: Section 11(f)(4)(ii)</b>	Procedures that limit access to laboratory and storage facilities outside of normal business hours to only those specifically approved by the Responsible Official or designee;				
<b>CFR: Section 11(f)(4)(iii)</b>	Procedures for allowing visitors, their property, and vehicles at the entry and exit points to the registered space, or at other designated points of entry to the building, facility, or compound that are based on the entity's site-specific risk assessment;				
<b>CFR: Section 11(f)(4)(iv)</b>	A minimum of three security barriers where each security barrier adds to the delay in reaching secured areas where select agents and toxins are used or stored. One of the security barriers must be monitored in such a way as to detect intentional and unintentional circumventing of established access control measures under all conditions (day/night, severe weather, etc.) The final barrier must limit access to the select agent or toxin to personnel approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General.				
<b>CFR: Section 11(f)(4)(v)</b>	All registered space or areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS) unless physically occupied;				

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<b>CFR: Section 11(f)(4)(vi)</b>	Personnel monitoring the IDS must be capable of evaluating and interpreting the alarm and alerting the designated security response force or law enforcement;				
<b>CFR: Section 11(f)(4)(vii)</b>	For powered access control systems, describe procedures to ensure that security is maintained in the event of the failure of access control systems due to power disruption affecting registered space;				
<b>CFR: Section 11(f)(4)(viii)</b>	<b>The entity must:</b>				
<b>CFR: Section 11(f)(4)(viii) (A)</b>	Determine that the response time for security forces or local police will not exceed 15 minutes [where the response time is measured from the time of an intrusion alarm, or report of a security incident, to the arrival of the responders to the first security barrier] or				
<b>CFR: Section 11(f)(4)(viii) (B)</b>	Provide security barriers that are sufficient to delay unauthorized access until the response force arrives in order to safeguard the select agents and toxins from theft, intentional release, or unauthorized access. The response time is measured from the time of an intrusion alarm, or report of a security incident, to the arrival of the responders at the first security barrier.				
<b>CFR: Section 11(g)</b>	In developing a security plan, an individual or entity should consider the document entitled, "Security Guidance for Select Agent or Toxin Facilities." The document is available on the National Select Agent Registry Web site at <a href="http://www.selectagents.gov/">http://www.selectagents.gov/</a> .				
<b>CFR: Section 11(h)</b>	The plan must be reviewed annually and revised as necessary.				
<b>CFR: Section 11(h)</b>	Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan.				
<b>CFR: Section 11(h)</b>	The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident.				

Comments continued:

Inspector summary and comments:

Lead inspector:

Date:

Other inspectors present:

Date:

Lead inspector signature: \_\_\_\_\_

Date: \_\_\_\_\_