

Inspection Checklist for Records (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
CFR: Section 17(a)	An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include:				
CFR: Section 17(a)(1)	An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:				
CFR: Section 17(a)(1)(i)	The name and characteristics (e.g., strain designation, GenBank Accession number, etc.)				
CFR: Section 17(a)(1)(ii)	The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source				
CFR: Section 17(a)(1)(iii)	Where stored (e.g., building, room, and freezer), <i>[Specify in Comments]</i>				
CFR: Section 17(a)(1)(iv)	When moved from storage and by whom and when returned to storage and by whom				

Entity Name:		Inspection Date:			
Reference	Statement	Yes	No	N/A	Comments
CFR: Section 17(a)(1)(v)	The select agent used and purpose of use				
CFR: Section 17(a)(1)(vi)	Records created under § 331.16, 121.16 and 73.16, (Transfers)				
CFR: Section 17(a)(1)(vii)	For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent, the quantity transferred, the date of transfer, the sender, and the recipient				
CFR: Section 17(a)(1)(viii)	Records created under § 331.19, 121.19 and 73.19 (Notification of theft, loss, or release)				
CFR: Section 17(a)(2)	An accurate, current accounting of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition)				
CFR: Section 17(a)(3)	Accurate, current inventory for each toxin held, including:				
CFR: Section 17(a)(3)(i)	- The name and characteristics				
CFR: Section 17(a)(3)(ii)	- The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source				
CFR: Section 17(a)(3)(iii)	- The initial and current quantity amount (e.g., milligrams, milliliters, grams, etc.)				
CFR: Section 17(a)(3)(iv)	- The toxin used and purpose of use, quantity, date(s) of the use and by whom				
CFR: Section 17(a)(3)(v)	- Where stored (e.g., building, room, and freezer) <i>[Specify in Comments]</i>				
CFR: Section 17(a)(3)(vi)	- When moved from storage and by whom and when returned to storage and by whom including quantity amount				

Entity Name:		Inspection Date:			
Reference	Statement	Yes	No	N/A	Comments
CFR: Section 17(a)(3)(vii)	- Records created under § 331.16, 121.16 and 73.16 (Transfers)				
CFR: Section 17(a)(3)(viii)	- For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the toxin, the quantity transferred, the date of transfer, the sender, and the recipient				
CFR: Section 17(a)(3)(ix)	- Records created under § 331.19, 121.19 and 73.19 (Notification of theft, loss, or release)				
CFR: Section 17(a)(3)(x)	- If destroyed, the quantity of toxin destroyed, the date of such action, and by whom				
42 CFR 73: Section 16(l)(i)	A registered individual or entity transferring an amount of a HHS toxin otherwise excluded under the provisions of section 73.3(d) of this part must: transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (i.e., reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins.				
42 CFR: Section 16(l)(ii)	A registered individual or entity transferring an amount of a HHS toxin otherwise excluded under the provisions of section 73.3(d) of this part must: report to CDC if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to a toxin listed in section of this part.				
CFR: Section 17(a)(4)	A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator				
CFR: Section 17(a)(5)	Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and date and time of entry				
CFR: Section 17(a)(6)	Accurate, current records created under:				
	- Section 9 (Responsible Official)				
	- Section 11 (Security)				

Entity Name:		Inspection Date:			
Reference	Statement	Yes	No	N/A	Comments
	- Section 12 (Biosafety/Biocontainment)				
	- Section 14 (Incident response)				
	- Section 15 (Training)				
CFR: Section 17(a)(7)	A written explanation of any discrepancies.				
CFR: Section 17(b)	The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate, have controlled access, and that their authenticity may be verified.				
CFR: Section 17(c)	All records created under this part must be maintained for three years and promptly produced upon request.				

Comments continued:

Inspector summary and comments:

Lead inspector:

Date:

Other inspectors present:

Date:

Lead inspector signature: _____

Date: _____