Inspection Checklist for Records (7 CFR 331.17; 9 CFR 121.17; 42 CFR 73.17)

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	
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:**				
Section 17(a)(1)	Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and recombinant 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:				
Section 17(a)(1)(i)	The name and characteristics (e.g., strain designation, GenBank Accession number, etc.)				
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				
Section 17(a)(1)(iii)	Where stored (e.g., building, room, and freezer), *[Specify in Comments]*				
Section 17(a)(1)(iv)	When moved from storage and by whom and when returned to storage and by whom				
Section 17(a)(1)(v)	The select agent used and purpose of use				
Section 17(a)(1)(vi)	Records created under § 331.16, 121.16 and 73.16, (Transfers)				
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				
Section 17(a)(1)(viii)	Records created under § 331.19, 121.19 and 73.19 (Notification of theft, loss, or release)				
Section 17(a)(2)	Accurate, current inventory for each toxin held, including:				
Section 17(a)(2)(i)	- The name and characteristics				
Section 17(a)(2)(ii)	- The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source				
Section 17(a)(2)(iii)	- The initial and current quantity amount (e.g., milligrams, milliliters, grams, etc.)				
Section 17(a)(2)(iv)	- The toxin used and purpose of use, quantity, date(s) of the use and by whom				
Section 17(a)(2)(v)	- Where stored (e.g., building, room, and freezer) *[Specify in Comments]*				
Section 17(a)(2)(vi)	- When moved from storage and by whom and when returned to storage and by whom including quantity amount				
Section 17(a)(2)(vii)	- Records created under § 331.16, 121.16 and 73.16 (Transfers)				

Reference	Statement	Response			Comments
		Yes	No	N/A	
Section 17(a)(2)(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				
Section 17(a)(2)(ix)	- Records created under § 331.19, 121.19 and 73.19 (Notification of theft, loss, or release)				
Section 17(a)(2)(x)	- If destroyed, the quantity of toxin destroyed, the date of such action, and by whom				
Section 17(a)(3)	A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator				
Section 17(a)(4)	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				
Section 17(a)(5)	**Accurate, current records created under:**				
	- Section 9 (Responsible Official)				
	- Section 11 (Security)				
	- Section 12 (Biosafety)				
	- Section 14 (Incident response)				
	- Section 15 (Training)				
Section 17(a)(6)	A written explanation of any discrepancies.				
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.				
Section 17(c)	All records created under this part must be maintained for three years and promptly produced upon request.				
Section 9(a)(5)	The Responsible Official must ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.				

Inspector summary and comments:	
Recommendations:	
Inspector completing checklist:	**Date:**
Other inspectors present:	**Date:**