Inspection Checklist for Records (7 CFR 331, 9 CFR 121, 42 CFR 73; BMBL 5th Edition)

Entity Name: **Inspection Date:**

Building/Rooms: **Inspectors:**

When information is entered in this form, the form is to be considered "Sensitive Select Agent Information."

Section	Regulation Text	Observation	Status	Comments
17(a)	An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part.	An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part.	o No o Yes o N/A	
17(a)(1)	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials).	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials).	o No o Yes o N/A	
17(a)(1)(i)	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 the name and characteristics (e.g., strain designation, GenBank Accession number, etc.).	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 the name and characteristics (e.g., strain designation, GenBank Accession number, etc.).	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
17(a)(1)(ii)	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 the quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source.	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 the quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source.	o No o Yes o N/A	
17(a)(1)(iii)	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 where stored (e.g., building, room, and freezer or other storage container).	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 where stored (e.g., building, room, and freezer or other storage container).	o No o Yes o N/A	
17(a)(1)(iv)	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 when moved from storage and by whom and when returned to storage and by whom.	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 when moved from storage and by whom and when returned to storage and by whom.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
17(a)(1)(v)	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 the select agent used, purpose of use, and, when applicable, final disposition.	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 the select agent used, purpose of use, and, when applicable, final disposition.	o No o Yes o N/A	
17(a)(1)(vi)	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 records created under §73.16 and 9 CFR 121.16 (Transfers).	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 records created under §73.16 and 9 CFR 121.16 (Transfers).	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
17(a)(1)(vii)	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 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.	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 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.	o No o Yes o N/A	
17(a)(1)(viii)	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 records created under §73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release).	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: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) 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 records created under §73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release).	o No o Yes o N/A	
17(a)(2)	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: 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).	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: 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).	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
17(a)(3)	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: Accurate, current inventory for each toxin held.	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: Accurate, current inventory for each toxin held.	o No o Yes o N/A	
17(a)(3)(i)	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: Accurate, current inventory for each toxin held, including the name and characteristics.	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: Accurate, current inventory for each toxin held, including the name and characteristics.	o No o Yes o N/A	
17(a)(3)(ii)	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: Accurate, current inventory for each toxin held, including the quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source.	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: Accurate, current inventory for each toxin held, including the quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source.	o No o Yes o N/A	
17(a)(3)(iii)	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: Accurate, current inventory for each toxin held, including the initial and current quantity amount (e.g., milligrams, milliliters, grams, etc.).	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: Accurate, current inventory for each toxin held, including the initial and current quantity amount (e.g., milligrams, milliliters, grams, etc.).	o No o Yes o N/A	
17(a)(3)(iv)	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: Accurate, current inventory for each toxin held, including the toxin used and purpose of use, quantity, date(s) of the use and by whom.	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: Accurate, current inventory for each toxin held, including the toxin used and purpose of use, quantity, date(s) of the use and by whom.	o No o Yes o N/A	
17(a)(3)(ix)	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: Accurate, current inventory for each toxin held, including records created under §73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release).	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: Accurate, current inventory for each toxin held, including records created under §73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release).	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
17(a)(3)(v)	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: Accurate, current inventory for each toxin held, including where stored (e.g., building, room, and freezer or other storage container).	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: Accurate, current inventory for each toxin held, including where stored (e.g., building, room, and freezer or other storage container).	o No o Yes o N/A	
17(a)(3)(vi)	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: Accurate, current inventory for each toxin held, including when moved from storage and by whom and when returned to storage and by whom including quantity amount.	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: Accurate, current inventory for each toxin held, including when moved from storage and by whom and when returned to storage and by whom including quantity amount.	o No o Yes o N/A	
17(a)(3)(vii)	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: Accurate, current inventory for each toxin held, including records created under §73.16 and 9 CFR part 121.16 (Transfers).	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: Accurate, current inventory for each toxin held, including records created under §73.16 and 9 CFR part 121.16 (Transfers).	o No o Yes o N/A	
17(a)(3)(viii)	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: Accurate, current inventory for each toxin held, including 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.	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: Accurate, current inventory for each toxin held, including 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.	o No o Yes o N/A	
17(a)(3)(x)	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: Accurate, current inventory for each toxin held, including if destroyed, the quantity of toxin destroyed, the date of such action, and by whom.	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: Accurate, current inventory for each toxin held, including if destroyed, the quantity of toxin destroyed, the date of such action, and by whom.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
17(a)(4)	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: A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator.	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: A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator.	o No o Yes o N/A	
17(a)(5)	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: 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.	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: 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.	o No o Yes o N/A	
17(a)(6)	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: Accurate, current records created under §73.9 and 9 CFR part 121.9 (Responsible Official), §73.11 and 9 CFR part 121.11 (Security), §73.12 and 9 CFR part 121.12 (Biosafety), §73.14 and 9 CFR part 121. 14 (Incident response), and §73.15 and 9 CFR part 121.15 (Training).	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: Accurate, current records created under §73.9 and 9 CFR part 121.9 (Responsible Official), §73.11 and 9 CFR part 121.11 (Security), §73.12 and 9 CFR part 121.12 (Biosafety), §73.14 and 9 CFR part 121. 14 (Incident response), and §73.15 and 9 CFR part 121.15 (Training).	o No o Yes o N/A	
17(a)(7)	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: A written explanation of any discrepancies.	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: A written explanation of any discrepancies.	o No o Yes o N/A	
17(a)(8)	Required records created for select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or procedure for removal of viable select agent are complete.	Required records created for select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or procedure for removal of viable select agent are complete.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
17(a)(8)(i)	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, a written description of the validated inactivation procedure or viable select agent removal method used, including validation data.	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, a written description of the validated inactivation procedure or viable select agent removal method used, including validation data.	o No o Yes o N/A	
17(a)(8)(ii)	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, a written description of the viability testing protocol used.	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, a written description of the viability testing protocol used.	o No o Yes o N/A	
17(a)(8)(iii)	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, a written description of the investigation conducted by the entity Responsible Official involving an inactivation or viable select agent removal failure and the corrective actions taken.	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, a written description of the investigation conducted by the entity Responsible Official involving an inactivation or viable select agent removal failure and the corrective actions taken.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
17(a)(8)(iv)	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, the name of each individual performing the validated inactivation or viable select agent removal method.	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, the name of each individual performing the validated inactivation or viable select agent removal method.	o No o Yes o N/A	
17(a)(8)(v)	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, the date(s) the validated inactivation or viable select agent removal method was completed.	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, the date(s) the validated inactivation or viable select agent removal method was completed.	o No o Yes o N/A	
17(a)(8)(vi)	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, the location where the validated inactivation or viable select agent removal method was performed.	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, the location where the validated inactivation or viable select agent removal method was performed.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
17(a)(8)(vii)	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, a certificate, signed by the Principal Investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the Principal Investigator. A copy of the certificate must accompany any transfer of inactivated or select agent removed material.	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: For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent, a certificate, signed by the Principal Investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the Principal Investigator. A copy of the certificate must accompany any transfer of inactivated or select agent removed material.	o No o Yes o N/A	
17(b)	The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate and legible, have controlled access, and authenticity may be verified.	The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate and legible, have controlled access, and authenticity may be verified.	o No o Yes o N/A	
17(c)	The individual or entity must promptly produce upon request any information that is related to the requirements of this part but is not otherwise contained in a record required to be kept by this section. The location of such information may include, but is not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.	The individual or entity must promptly produce upon request any information that is related to the requirements of this part but is not otherwise contained in a record required to be kept by this section. The location of such information may include, but is not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.	o No o Yes o N/A	