Inspection Checklist for Registration and Restricted Experiments (7 CFR 331, 9 CFR 121, 42 CFR 73; BMBL 6th 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
3(d)(1) 4(d)(1)	Select agents or toxins that meet any of the following criteria are excluded from the requirements of this part: Any select agent or toxin that is in its naturally occurring environment, provided the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.	To meet exclusion requirements, select agents remain in their naturally occurring environment and have not been intentionally introduced, cultivated, collected, or otherwise extracted from the natural source.	o No o Yes o N/A	
3(d)(2) 4(d)(2)	Select agents or toxins that meet any of the following criteria are excluded from the requirements of this part: Nonviable select agents or nontoxic toxins.	To meet exclusion requirements, select agents or toxins are non-viable or nontoxic.	o No o Yes o N/A	
3(d)(3) 4(d)(3)	Select agents or toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or toxin that has been subjected to decontamination or a destruction procedure when intended for waste disposal.	To meet exclusion requirements, select agents or toxins have been subjected to decontamination or destruction procedures when intended for waste disposal.	o No o Yes o N/A	
3(d)(4) 4(d)(4)	Select agents or toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactiavtion procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.	To meet exclusion requirements, select agents or regulated nucleic acids have been subjected to validated inactivation procedures confirmed through viability testing protocols.	o No o Yes o N/A	
3(d)(4)	HHS select agents and toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactiavtion procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.	To exclude chemically-treated strains of B. cereus Biovar anthracis (vegetative or spore preparations), the entity developed and implemented a chemical inactivation method with the appropriate concentration and contact time to inactivate 100% of the organisms within the sample.	o No o Yes o N/A	

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3(d)(4)	HHS select agents and toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactiavtion procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.	To exclude chemically-treated strains of B. cereus Biovar anthracis (vegetative or spore preparations), the entity used a validated inactivation method including safety margins for subsequent sample inactivations.	o No o Yes o N/A	
3(d)(4)	HHS select agents and toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactiavtion procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.	To exclude chemically-treated strains of B. cereus Biovar anthracis (vegetative or spore preparations), the entity has determined that residual chemical or antimicrobial activity from the inactivation method does not interfere with the viability test. If the residual chemical or antimicrobial activity interferes with the viability test, the entity uses neutralization methods initially validated using 100% of the sample.	o No o Yes o N/A	
3(d)(4)	HHS select agents and toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactiavtion procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.	To exclude chemically-treated strains of B. cereus Biovar anthracis (vegetative or spore preparations), following initial chemical validation, the entity's subsequent viability testing protocol meets or exceeds the following: 1) Sample volumes: the tested material consists of at least 10% of the sample or production lot inoculated into a broth medium. For large volume cultures, can use a 0.22 µm filter to filter 10% of the inactivated material and culture the filter. 2) Culture conditions: The broth culture is incubated for at least 7 days at 35°±2°C and then at least 100 µL of the broth culture is spread on approprate agar plate medium. The agar plate is incubated at 35°±2°C for at least 7 days, and no colonies are observed at the end of the incubation period.	o No o Yes o N/A	

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3(d)(4)	HHS select agents and toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactiavtion procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.	To exclude chemically-treated whole tissue specimens containing strains of B. cereus Biovar anthracis, the entity developed and implemented an inactivation method as described for chemically-treated vegetative cells and spore preparations, and validated it initially to the exact conditions to be used for subsequent inactivation.	o No o Yes o N/A	
3(d)(4)	HHS select agents and toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactiavtion procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.	To exclude heat-treated (autoclaved) strains of B. cereus Biovar anthracis (vegetative or spore preparations) for future use, the entity meets all of the following: 1) Use of an inactivation method initially developed to determine an appropriate autoclave time to inactivate 100% of the organisms within the sample, 2) Use of a validated autoclave temperature and time that includes a safety margin for subsequent inactivation of samples, 3) For subsequent inactivation of samples, use of a viability testing protocol that includes the use of an approprate Bacillus species spore-based indicator under conditions that accurately represent the types of material that are treated, and shows no growth of Bacillus species.	o No o Yes o N/A	
3(d)(5) 4(d)(5)	Select agents or toxins that meet any of the following criteria are excluded from the requirements of this part: Material containing a select agent that is subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent.	To meet exclusion requirements, material containing select agents or toxins has been subjected to a procedure for removal of viable select agents cells, spores, or virus particles and this removal subsequently confirmed through viability testing protocol.	o No o Yes o N/A	

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3(d)(5) 4(d)(5)	HHS select agents and toxins that meet any of the following criteria are excluded from the requirements of this part: Material containing a select agent that is subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent.	To exclude extracts (e.g., nucleic acids, antigens, lysates, etc.) from regulated strains of B. cereus Biovar anthracis or material where viable agent is removed, the entity developed and implemented a procedure involving filtration through a 0.22 µm or smaller pore filter size. Following filtration, the material shows no growth after using a viability testing protocol that meets or exceeds the following: 1) Sample volumes: The tested material consists of 10% of the sample or production lot of inactivated material inoculated into a broth medium. For large volume cultures, can use a 0.22 µm filter to filter 10% of the inactivated material and culture the 0.22 µm filter. 2) Culture conditions: The broth culture is incubated for at least 48 hours at 35°±2°C, and then at least 100 µL of the broth culture is spread on an agar plate medium that is incubated at 35°±2°C for at least 48 hours and no colonies are observed at the end of the incubation period.	o No o Yes o N/A	
3(d)(6) 4(d)(6)	Select agents and toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the Administrator to be effectively inactivated or effectively removed. To apply for a determination an individual or entity must submit a written request and supporting scientific information to APHIS/HHS. A written decision granting or denying the request will be issued.	To meet exclusion requirements, entity received written determination from Administrator that material does not require validated inactivation or removal method.	o No o Yes o N/A	
3(d)(7)	HHS select agents and toxins that meet any of the following criteria are excluded from the requirements of this part: Except as required in Â§73.16(l), the aggregate amount of toxin under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor does not, at any time, exceed the following amounts: 1000 mg of Abrin; 1 mg of Botulinum neurotoxins; 100 mg of Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7); 10,000 mg of Diacetoxyscirpenol; 1000 mg of Ricin; 500 mg of Saxitoxin; 100 mg of Staphylococcal enterotoxins (subtypes A-E); 10,000 mg of T-2 toxin; or 500 mg of Tetrodotoxin.	The aggregate amount of each toxin under the control of an unregistered principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor does not exceed the exclusion amount for that toxin.		

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3(d)(9)	HHS select agents and toxins that meet any of the following criteria are excluded from the requirements of this part: An HHS select toxin identified in an original food sample or clinical sample.	To meet exclusion requirements, HHS toxins remain in original food or clinical samples.		
3(d)(10)	HHS select agents and toxins that meet any of the following criteria are excluded from the requirements of this part: For those laboratories that are not exempt under §5(a) and §6(a), Botulinum neurotoxin that is produced as a byproduct in the study of Botulinum neurotoxin producing species of Clostridium so long as the toxin has not been intentionally cultivated, collected, purified, or otherwise extracted, and the material containing the toxin is rendered non-toxic and disposed of within 30 days of the initiation of the culture.	To meet exclusion requirements, the entity renders nontoxic, and disposes of, any Botulinum neurotoxin produced as a byproduct in the study of Botulinum neurotoxin producing species of Clostridium within 30 days of the initiation of the culture. The toxin is not intentionally cultivated, collected, purified, or otherwise extracted.		
3(d)(8) 3(d)11) 4(d)(8)	Select agents and toxins that meet any of the following criteria are excluded from the requirements of this part: Waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent, where that waste is decontaminated or transferred for destruction by complying with State and Federal regulations within 7 calendar days of the conclusion of patient care.	To meet exclusion requirements, if select agents are contained in waste generated during delivery of patient care, the waste is decontaminated or transferred for destruction within 7 calendar days of conclusion of patient care.	o No o Yes o N/A	
3(e)(2) 4(e)(2)	An attenuated strain of a select agent or a select toxin modified to be less potent or toxic may be excluded from the requirements of this part based upon a determination by the HHS Secretary that the attenuated strain or modified toxin does not pose a severe threat to public health and safety. If an excluded attenuated strain or modified toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.	To maintain exclusion requirements, the entity does not restore or enhance virulence or toxic activities to otherwise excluded or attenuated strains of HHS select agents or toxins.		
4(d)(4)	Overlap select agents or toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactiavtion procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.	To exclude chemically-treated strains of B. anthracis or B. anthracis Pasteur (vegetative or spore preparations), the entity developed and implemented a chemical inactivation method with the appropriate concentration and contact time to inactivate 100% of the organisms within the sample.	o No o Yes o N/A	

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4(d)(4)	Overlap select agents or toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactiavtion procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.	To exclude chemically-treated strains of B. anthracis or B. anthracis Pasteur (vegetative or spore preparations), the entity used a validated inactivation method including safety margins for subsequent sample inactivations.	o No o Yes o N/A	
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4(d)(4)	Overlap select agents or toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactiavtion procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.	To exclude heat-treated (autoclaved) strains of B. anthracis or B. anthracis Pasteur (vegetative or spore preparations) for future use, the entity meets all of the following: 1) Use of an inactivation method initially developed to determine an appropriate autoclave time to inactivate 100% of the organisms within the sample, 2) Use of a validated autoclave temperature and time that includes a safety margin for subsequent inactivation of samples, 3) For subsequent inactivation of samples, use of a viability testing protocol that includes the use of an approprate Bacillus species spore-based indicator under conditions that accurately represent the types of material that are treated, and shows no growth of Bacillus species.	o No o Yes o N/A	
4(d)(5)	Overlap select agents or toxins that meet any of the following criteria are excluded from the requirements of this part: A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactiavtion procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.	To exclude extracts (e.g., nucleic acids, antigens, lysates, etc.) from regulated strains of B. anthracis or B. anthracis Pasteur or material where viable agent is removed, the entity developed and implemented a procedure involving filtration through a 0.22 µm or smaller pore filter size. Following filtration, the material shows no growth after using a viability testing protocol that meets or exceeds the following: 1) Sample volumes: The tested material consists of 10% of the sample or production lot of inactivated material inoculated into a broth medium. For large volume cultures, can use a 0.22 µm filter to filter 10% of the inactivated material and culture the 0.22 µm filter. 2) Culture conditions: The broth culture is incubated for at least 48 hours at 35°±2°C, and then at least 100 µL of the broth culture is spread on an agar plate medium that is incubated at 35°±2°C for at least 48 hours and no colonies are observed at the end of the incubation period.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
5(a)(1)	Diagnostic laboratories and other entities that possess, use, or transfer a select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that: Unless directed otherwise by the Administrator, within seven calendar days after identification of the select agent or toxin, the select agent or toxin is transferred in accordance with §16 or destroyed on-site by a recognized sterilization or inactivation process.	For specimens presented for diagnosis or verification, the entity transfers or destroys identified BSAT within 7 calendar days of identification, or within 30 calendar days if BSAT is Botulinum neurotoxin or Staphylococcal enterotoxin (Subtypes A-E).	o No o Yes o N/A	
5(a)(3)	Diagnostic laboratories and other entities that possess, use, or transfer a select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the speciment, provided that: Unless otherwise directed by the Administrator, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with §16 or destroyed on-site by a recognized sterilization or inactivation process within 7 calendar days after delivery of patient care by health care professionals has concluded.	Clinical and diagnostic laboratories that identify BSAT in specimens collected from patients transfer or destroy the samples within 7 calendar days of conclusion of patient care.	o No o Yes o N/A	
7(b)	As a condition of registration, each entity is required to be in compliance with the requirements of this part for select agents and toxins listed on the registration regardless of whether the entity is in actual possession of the select agent or toxin. With regard to toxins, the entity registered for possession, use or transfer of a toxin must be in compliance with the requirements of this part regardless of the amount of toxin currently in its possession.	The entity complies with all regulations for each select agent and toxin on its registration, regardless of possession status of agents and toxins or amount of toxin possessed.	o No o Yes o N/A	
7(i)(1-3)	A certificate of registration may be amended to reflect changes in circumstances (e.g., replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application. (2) The Responsible Official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of the amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.(3) No change may be made without such approval.	The entity conducts all manipulations or storage of viable select agents, regulated nucleic acids, and/or functional toxins in registered space.	o No o Yes o N/A	

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7(i)(1-3)	A certificate of registration may be amended to reflect changes in circumstances (e.g., replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application. (2) The Responsible Official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of the amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.(3) No change may be made without such approval.	Information in the entity's current APHIS/CDC Form 1 accurately reflects the select agent and toxin activities performed: Each registered principal investigator (PI) meets the regulatory definition of a principal investigator (in section 1).	o No o Yes o N/A	
7(i)(1-3)	A certificate of registration may be amended to reflect changes in circumstances (e.g., replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application. (2) The Responsible Official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of the amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.(3) No change may be made without such approval.	Accurate, comprehensive strains/serotypes of BSAT are reported in the entity's Form 1, Section 7B.	o No o Yes o N/A	
7(i)(1-3)	A certificate of registration may be amended to reflect changes in circumstances (e.g., replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application. (2) The Responsible Official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of the amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.(3) No change may be made without such approval.	Observed activities with select agents and toxins reflect the work objectives described in the Form 1, Section 7A/C and attachments.	o No o Yes o N/A	

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7(i)(1-3)	A certificate of registration may be amended to reflect changes in circumstances (e.g., replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application. (2) The Responsible Official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of the amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.(3) No change may be made without such approval.	Comprehensive maximum quantities propagated for each select agent, or quantities of select toxin held, are accurately reported on the entity's Form 1, Section 7A/C.	o No o Yes o N/A	
7(i)(1-3)	A certificate of registration may be amended to reflect changes in circumstances (e.g., replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application. (2) The Responsible Official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of the amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.(3) No change may be made without such approval.	Prior to making changes to the select agent and toxin activities performed at the entity, the Responsible Official (or designee) appropriately updated the entity's APHIS/CDC Form 1 to reflect the proposed changes. The proposed changes in select agent and toxin activities did not commence until approval by FSAP.	o No o Yes o N/A	
7(j)	An entity must immediately notify CDC or APHIS if it loses the services of its Responsible Official. In the event that an entity loses the services of its Responsible Official, an entity may continue to possess or use select agents or toxins only if it appoints as the Responsible Official another individual who has been approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General and who meets the requirements of this part.	An entity must immediately notify CDC or APHIS if it loses the services of its Responsible Official. In the event that an entity loses the services of its Responsible Official, an entity may continue to possess or use select agents or toxins only if it appoints as the Responsible Official another individual who has been approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General and who meets the requirements of this part.	o No o Yes o N/A	

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13(a)(1)	An individual or entity may not conduct, or possess products resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator: Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.	The entity has not conducted, or does not possess products resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator: Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.	o No o Yes o N/A	
13(a)(2)	An individual or entity may not conduct, or possess products resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator: Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] <100 ng/kg body weight.	The entity has not conducted, or does not possess products resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the Administrator: Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] <100 ng/kg body weight.	o No o Yes o N/A	