Inspection Checklist for Responsible Official (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
9(a)(1)	The Responsible Official must be approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General.	The Responsible Official must be approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General.	o No o Yes o N/A	
9(a)(2)	The Responsible Official must be familiar with the requirements of this part.	The Responsible Official must be familiar with the requirements of this part.	o No o Yes o N/A	
9(a)(3)	The Responsible Official must have authority and responsibility to act on behalf of the entity.	The Responsible Official must have authority and responsibility to act on behalf of the entity.	o No o Yes o N/A	
9(a)(4)	The Responsible Official must ensure compliance with the requirements of this part.	The Responsible Official must ensure compliance with the requirements of this part.	o No o Yes o N/A	
9(a)(5)	The Responsible Official must have a physical (and not merely a telephonic or audio/visual) presence at the registered entity to ensure that the entity is in compliance with the select agent regulations and be able to respond in a timely manner to onsite incidents involving select agents and toxins in accordance with the entity's incident response plan.	The Responsible Official must have a physical (and not merely a telephonic or audio/visual) presence at the registered entity to ensure that the entity is in compliance with the select agent regulations and be able to respond in a timely manner to onsite incidents involving select agents and toxins in accordance with the entity's incident response plan.	o No o Yes o N/A	
9(a)(6)	The Responsible Official must ensure that annual inspections are conducted for each registered space 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 and the corrections documented.	The Responsible Official must ensure that annual inspections are conducted for each registered space 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 and the corrections documented.	o No o Yes o N/A	
9(a)(7)	The Responsible Official must ensure that individuals are provided the contact information for the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any biosafety or security concerns related to select agents and toxins.	The Responsible Official must ensure that individuals are provided the contact information for the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any biosafety or security concerns related to select agents and toxins.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
9(a)(8)	The Responsible Official must investigate to determine the reason for any failure of a validated inactivation procedure or any failure to remove viable select agent from material. If the Responsible Official is unable to determine the cause of a deviation from a validated inactivation procedure or a viable select agent removal method; or receives a report of any inactivation failure after the movement of material to another location, the Responsible Official must report immediately by telephone or email the inactivation or viable agent removal method failure to CDC or APHIS.	The Responsible Official must investigate to determine the reason for any failure of a validated inactivation procedure or any failure to remove viable select agent from material. If the Responsible Official is unable to determine the cause of a deviation from a validated inactivation procedure or a viable select agent removal method; or receives a report of any inactivation failure after the movement of material to another location, the Responsible Official must report immediately by telephone or email the inactivation or viable agent removal method failure to CDC or APHIS.	o No o Yes o N/A	
9(a)(9)	The Responsible Official must review, and revise as necessary, each of the entity's validated inactivation procedures or viable select agent removal methods. The review must be conducted annually or after any change in Principal Investigator, change in the validated inactivation procedure or viable select agent removal method, or failure of the validated inactivation procedure or viable select agent removal method. The review must be documented and training must be conducted if there are any changes to the validated inactivation procedure, viable select agent removal method, or viability testing protocol.	The Responsible Official must review, and revise as necessary, each of the entity's validated inactivation procedures or viable select agent removal methods. The review must be conducted annually or after any change in Principal Investigator, change in the validated inactivation procedure or viable select agent removal method, or failure of the validated inactivation procedure or viable select agent removal method. The review must be documented and training must be conducted if there are any changes to the validated inactivation procedure, viable select agent removal method, or viability testing protocol.	o No o Yes o N/A	
9(b)	An entity may designate one or more individuals to serve as an alternate Responsible Official, who acts for the Responsible Official in his/her absence. These individuals must have the authority and control to ensure compliance with the regulations when acting as the Responsible Official.	An entity may designate one or more individuals to serve as an alternate Responsible Official, who acts for the Responsible Official in his/her absence. These individuals must have the authority and control to ensure compliance with the regulations when acting as the Responsible Official.	o No o Yes o N/A	

Section	Regulation Text	Observation	Status	Comments
9(c)(1)	The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: Bacillus anthracis,, Bacillus cereus Biovar anthracis," Botulinum neurotoxins, Botulinum neurotoxin producing species of Clostridium, Burkholderia mallei, Burkholderia pseudomallei Francisella tularensis, Ebola viruses, , Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), or Yersinia pestis. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within seven calendar days after identification. A copy of the completed form must be maintained for three years.	The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: Bacillus anthracis,, Bacillus cereus Biovar anthracis," Botulinum neurotoxins, Botulinum neurotoxin producing species of Clostridium, Burkholderia mallei, Burkholderia pseudomallei Francisella tularensis, Ebola viruses, , Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), or Yersinia pestis. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within seven calendar days after identification. A copy of the completed form must be maintained for three years.	o No o Yes o N/A	
9(c)(2)	To report the identification and final disposition of any other select agent or toxin, APHIS/CDC Form 4 must be submitted within seven calendar days after identification. A copy of the completed form must be maintained for three years.	To report the identification and final disposition of any other select agent or toxin, APHIS/CDC Form 4 must be submitted within seven calendar days after identification. A copy of the completed form must be maintained for three years.	o No o Yes o N/A	
9(c)(3)	Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.	Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.	o No o Yes o N/A	
9(d)	The Responsible Official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. To report the identification and final disposition of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for three years.	The Responsible Official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. To report the identification and final disposition of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for three years.	o No o Yes o N/A	