

Inspection Checklist for RO §9 and Registration §7 (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 9(a)	An individual or entity required to register under this part must designate an individual to be the Responsible Official. The Responsible Official must:				
CFR: Section 9(a)(1)	Be approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General.				
CFR: Section 9(a)(2)	Be familiar with the requirements of this part.				
CFR: Section 9(a)(3)	Have authority and responsibility to act on behalf of the entity.				
CFR: Section 9(a)(4)	Ensure compliance with the requirements of this part				
CFR: Section 9(a)(5)	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, and				

Entity Name:		Inspection Date:			
Reference	Statement	Yes	No	N/A	Comments
CFR: Section 9(a)(6)	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.				
CFR: Section 9(a)(6)	The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.				
CFR: Section 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.				
7 CFR 331: CFR: 9 CFR 121: Section 9(b)	These individuals must have the authority and control to ensure compliance with the regulations when acting as the Responsible Official.				
CFR: Section 9(c)	The Responsible Official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification.				
42 CFR 73: Section 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, 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.				
9 CFR 121: Section 9(c) (1)	The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: African horse sickness virus, African swine fever virus, avian influenza virus (highly pathogenic), Bacillus anthracis, Burkholderia mallei, Burkholderia pseudomallei, classical swine fever virus, foot-and-mouth disease virus, virulent Newcastle disease virus, rinderpest virus, and swine vesicular disease virus. The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within 7 calendar days after identification. A copy of the completed form must be maintained for 3 years.				
CFR: Section 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.				

Entity Name:		Inspection Date:			
Reference	Statement	Yes	No	N/A	Comments
CFR: Section 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.				
Section §7	Some Registration considerations only				
CFR: Section 7(h)(1)	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). 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.				
CFR: Section 7(i)	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.				
Section §10	Security risk assessments				
7 CFR 331: Section 10(j) 42 CFR 73 and 9 CFR 121: Section 10(k)	The Responsible Official must immediately notify CDC or APHIS when an individual's access to select agents or toxins is terminated by the entity and the reasons therefore.				

Comments continued:

Inspector summary and comments:

Lead inspector:

Date:

Other inspectors present:

Date:

Lead inspector signature: _____

Date: _____