| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| **Applicability** | **N/A** | | | **73.0** |
| *Effective dates for new listings* | N/A | No provision in the current rule. | All individuals and entities that possess SARS-CoV, Lujo virus, or Chapare virus must provide notice to CDC regarding their possession of SARS-CoV, Lujo virus, or Chapare virus on or before November 4, 2012. Currently registered individuals and entities possessing SARS-CoV, Lujo virus, or Chapare virus must meet all the requirements of this part by December 4, 2012. All previously unregistered individuals and entities possessing SARS-CoV, Lujo virus, or Chapare virus must meet all of the requirements of this part by April 3, 2013. | 73.0 |
| **Definitions** | **73.1** | | | **73.1** |
| *Added definitions* | N/A | These definitions are not in the current rule. | Conotoxins means short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7, whereas:<br>(1) C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges;<br>(2) The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB<br>(3) X1 = any amino acid(s) or Des-X;<br>(4) X2 = Asparagine or Histidine;<br>(5) P = Proline;<br>(6) A = Alanine;<br>(7) G = Glycine;<br>(8) X3 = Arginine or Lysine;<br>(9) X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan;<br>(10) X5 = Tyrosine, Phenylalanine, or Tryptophan;<br>(11) X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine;<br>(12) X7 = Any amino acid(s) or Des X and;<br>(13) "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.<br>* * * * *<br>Information security means protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide—<br>(1) Integrity, which means guarding against improper information modification or destruction, and includes ensuring information authenticity;<br>(2) Confidentiality, which means preserving authorized | 73.1 |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| | | | restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and (3) Availability, which means ensuring timely and reliable access to and use of information.<br>* * * * *<br>Occupational exposure means any reasonably anticipated skin, eye, mucous membrane, parenteral contact, or respiratory aerosol exposure to select agents or toxins that may result from the performance of an employee's duties.<br>* * * * *<br>Recombinant nucleic acids means: (1) Molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell or (2) Molecules that result from the replication of those described in paragraph (1) of this definition.<br>* * * * *<br>Security barrier means a physical structure that is designed to prevent entry by unauthorized persons.<br>* * * * *<br>Synthetic nucleic acids means: (1) Molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids) or (2) Molecules that result from the replication of those described in paragraph (1) of this definition. | |
| **HHS/Overlap Select Agents** | **73.3<br>73.4** | | | **73.3<br>73.4** |
| *Use of asterisk for Tier 1* | 73.3(a)<br>73.4(a) | 73.3(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety.<br><br>73.4(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. | 73.3(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety. The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.<br><br>73.4(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional | 73.3(a)<br>73.4(a) |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| | | | requirements as listed in this part. | |
| *Revisions to list of HHS select agents and toxins* | 73.3(b) | Abrin<br>Botulinum neurotoxins<br>Botulinum neurotoxin producing species of *Clostridium*<br>Cercopithecine herpesvirus 1 (Herpes B virus)<br>*Clostridium perfringens* epsilon toxin<br>*Coccidioides posadasii/Coccidioides immitis*<br>Conotoxins<br>*Coxiella burnetii*<br>Crimean-Congo haemorrhagic fever virus<br>Diacetoxyscirpenol<br>Eastern Equine Encephalitis virus<br>Ebola viruses<br>*Francisella tularensis*<br>Lassa fever virus<br>Marburg virus<br>Monkeypox virus<br>Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)<br>Ricin<br>*Rickettsia prowazekii*<br>*Rickettsia rickettsii*<br>Saxitoxin<br>Shiga-like ribosome inactivating proteins<br>Shigatoxin<br>South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)<br>Staphylococcal enterotoxins<br>T-2 toxin<br>Tetrodotoxin<br>Tick-borne encephalitis complex (flavi) viruses (Central European tick-borne encephalitis, Far Eastern Tick-borne encephalitis [Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever])<br>Variola major virus (Smallpox virus) and Variola minor virus (Alastrim)<br>*Yersinia pestis* | Abrin<br>Botulinum neurotoxins*<br>Botulinum neurotoxin producing species of *Clostridium**<br>Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)<br>*Coxiella burnetii*<br>Crimean-Congo haemorrhagic fever virus<br>Diacetoxyscirpenol<br>Eastern Equine Encephalitis virus<br>Ebola virus*<br>*Francisella tularensis**<br>Lassa fever virus<br>Lujo virus<br>Marburg virus*<br>Monkeypox virus<br>Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)<br>Ricin<br>*Rickettsia prowazekii*<br>SARS-associated coronavirus (SARS-CoV)<br>Saxitoxin<br>South American Haemorrhagic Fever viruses:<br>Chapare<br>Guanarito<br>Junin<br>Machupo<br>Sabia<br>Staphylococcal enterotoxins (subtypes A-E)<br>T-2 toxin<br>Tetrodotoxin<br>Tick-borne encephalitis virus<br>Far Eastern subtype<br>Siberian subtype<br>Kyasanur Forest disease virus<br>Omsk haemorrhagic fever virus<br>Variola major virus (Smallpox virus) *<br>Variola minor virus (Alastrim) *<br>*Yersinia pestis** | 73.3(b) |
| *Revisions to list of overlap select* | 73.4(b) | *Bacillus anthracis*<br>*Brucella abortus* | *Bacillus anthracis**;<br>*Bacillus anthracis* (Pasteur strain); | 73.4(b) |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| *agents and toxins* | | *Brucella melitensis*<br>*Brucella suis*<br>*Burkholderia mallei (*formerly *Pseudomonas mallei)*<br>*Burkholderia pseudomallei (*formerly *Pseudomonas pseudomallei)*<br>Hendra virus<br>Nipah virus<br>Rift Valley fever virus<br>Venezuelan Equine Encephalitis virus | *Brucella abortus;*<br>*Brucella melitensis;*<br>*Brucella suis;*<br>*Burkholderia mallei*;*<br>*Burkholderia pseudomallei**;<br>Hendra virus;<br>Nipah virus;<br>Rift Valley fever virus;<br>Venezuelan equine encephalitis virus | |
| *Synthetic nucleic acids or organisms* | 73.3(c)<br>73.4(c) | 73.3(c) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:<br>(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.<br>(2) Recombinant nucleic acids that encode for the functional form(s)of any of the toxins listed in paragraph (b) of this section if the nucleic acids:<br><br>73.4(c) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:<br>(1) Nucleic acids that can produce infectious forms of any of the overlap select agent viruses listed in paragraph (b) of this section.<br>(2) Recombinant nucleic acids that encode for the functional form(s) of any of the overlap toxins listed in paragraph (b) of this section if the nucleic acids: | 73.3(c) Genetic Elements, Recombinant and/or Synthetic Nucleic Acids, and Recombinant and/or Synthetic Organisms:<br>(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.<br>(2) Recombinant and/or synthetic nucleic acids that encode for the functional form(s) of any of the toxins listed in paragraph (b) of this section if the nucleic acids:<br><br>73.4(c) Genetic Elements, Recombinant and/or Synthetic Nucleic Acids, and Recombinant and/or Synthetic Organisms:<br>(1) Nucleic acids that can produce infectious forms of any of the overlap select agent viruses listed in paragraph (b) of this section.<br>(2) Recombinant and/or synthetic nucleic acids that encode for the functional form(s) of any of the overlap toxins listed in paragraph (b) of this section if the nucleic acids: | 73.3(c)<br>73.4(c) |
| *Additional excluded HHS select agents and toxins* | 73.3(d)(3)<br>73.3(d)(4)<br>73.3(d)(5) | (d)(3) HHS toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts: 100 mg of Abrin; 0.5 mg of Botulinum neurotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of Conotoxins; 1,000 mg of Diacetoxyscirpenol; 100 mg of Ricin; 100 mg of Saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; 100 mg of Shigatoxin; 5 mg of Staphylococcal enterotoxins; 1,000 mg of T-2 toxin; or 100 mg of Tetrodotoxin.<br><br>Paragraphs (d)(3)(i), (d)(3)(ii), (d)(4), and (d)(5) are not in the current rule. | (d)(3) Except as required in 73.16(l), the aggregate amount of the 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: 100 mg of Abrin; 0.5 mg of Botulinum neurotoxins; 100 mg of Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$); 1,000 mg of Diacetoxyscirpenol; 100 mg of Ricin; 100 mg of Saxitoxin; 5 mg of Staphylococcal enterotoxins (subtypes A-E); 1,000 mg of T-2 toxin; or 100 mg of Tetrodotoxin.<br>(i) The amounts are transferred only after the transferor uses due diligence and documents that the recipient has a legitimate need (i.e., reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. Notwithstanding the provisions of paragraph (d) | 73.3(d)(3)<br>73.3(d)(4)<br>73.3(d)(5) |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| | | | of this section, the HHS Secretary retains the authority to, without prior notification, inspect and copy or request the submission of the due diligence documentation to the CDC.<br>(ii) Reports to CDC if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to a toxin listed in this part.<br><br>(d)(4) An animal inoculated with or exposed to an HHS select toxin.<br><br>(d)(5) Any South American genotypes of Eastern Equine Encephalitis Virus and any West African Clade of Monkeypox virus will be excluded provided that the individual or entity can verify that the agent is within the exclusion category. | |
| *Additional excluded overlap select agents and toxins* | N/A | Paragraph 73.4(d)(3) is not in the current rule. | (d)(3) Any 1D and 1E serotypes of Venezuelan equine encephalitis virus provided that the individual or entity can verify that the agent is within the exclusion category. | 73.4(d)(3) |
| *Exclusion of an inactivated toxin* | 73.3(e)(1) and (e)(2)<br><br>73.4(e)(1) and (e)(2) | 73.3(e) An attenuated strain of a HHS select agent or toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain does not pose a severe threat to public health and safety.<br>1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be published periodically in the notice section of the Federal Register and will be listed on the CDC Web site at http://www.cdc.gov/.<br>(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent or toxin will be subject to the requirements of this part.<br><br>73.4(e) An attenuated strain of an overlap select agent or toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain does not pose a severe threat to public health and safety, to animal health, or to animal products.<br>(1) To apply for an exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. | 73.3(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the HHS Secretary that the attenuated strain or inactivated toxin does not pose a severe threat to public health and safety.<br>(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry website at http://www.selectagents.gov/.<br>(2) If an excluded attenuated strain or inactivated 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.<br><br>73.4(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the HHS Secretary or Administrator that the attenuated strain or inactivated toxin does not pose a severe threat to public health and safety, to animal health, or to animal products.<br>(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. | 73.3(e)(1) and (e)(2)<br><br>73.4(e)(1) and (e)(2) |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| | | Exclusions will be published periodically in the notice section of the Federal Register and will be listed on the CDC Web site at http://www.cdc.gov/.<br>(2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent or toxin will be subject to the requirements of this part. | An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry website at http://www.selectagents.gov/.<br>(2) If an excluded attenuated strain or inactivated 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. | |
| *HHS select agents and toxins whose seizure must be reported within 24 hours* | 73.3(f)(3) | (i) The seizure of Botulinum neurotoxins, Ebola viruses, *Francisella tularensis*, Lassa fever virus, Marburg virus, South American Haemorrhagic Fever virus (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis* must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin. | (i) The seizure of Botulinum neurotoxin producing species of *Clostridium*, Botulinum neurotoxins, Ebola viruses, *Francisella tularensis*, Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis* must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin. | 73.3(f)(3) |
| *Overlap select agents and toxins whose seizure must be reported within 24 hours* | 73.4(f)(3) | (i) The seizure of *Bacillus anthracis*, *Brucella melitensis*, Hendra virus, Nipah virus, Rift Valley fever virus, or Venezuelan equine encephalitis virus must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin. | (i) The seizure of *Bacillus anthracis*, *Burkholderia mallei*, or *Burkholderia pseudomallei* must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin | 73.4(f)(3) |
| **Exemptions** | **73.5**<br>**73.6** | | | **73.5**<br>**73.6** |
| *HHS select agents and toxins that require immediate reporting* | 73.5(a)(3) | (i) The identification of any of the following HHS select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: Botulinum neurotoxins, Ebola viruses, *Francisella tularensis*, Lassa fever virus, Marburg virus, South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), or Yersinia pestis. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification. | (i) The identification of any of the following HHS select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: Botulinum neurotoxin producing species of *Clostridium*, Botulinum neurotoxins, Ebola viruses, *Francisella tularensis*, Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis* This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification. | 73.5(a)(3) |
| *Overlap select agents and toxins that require immediate reporting* | 73.6(a)(3) | (i) The identification of any of the following overlap select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis*, *Brucella melitensis*, Hendra virus, Nipah virus, Rift Valley fever virus, or Venezuelan equine encephalitis virus. This report must be followed by | (i) The identification of any of the following overlap select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis*, *Burkholderia mallei*, or *Burkholderia pseudomallei*. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days | 73.6 (a)(3) |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| | | submission of APHIS/CDC Form 4 within seven calendar days after identification. | after identification. | |
| *Public health emergency* | 73.5(e)<br>73.6(e) | (e) The HHS Secretary may temporarily exempt an individual or entity from the requirements of this part based on a determination that the exemption is necessary to provide for the timely participation of the individual or entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 calendar days, except that one extension of an additional 30 calendar days may be granted. To apply for an exemption or an extension of an exemption, an individual or entity must submit a completed APHIS/CDC Form 5 establishing the need to provide for the timely participation of the individual or entity in a response to a domestic or foreign public health emergency. A written decision granting or denying the request will be issued. | (e) The HHS Secretary may temporarily exempt an individual or entity from the requirements of this part based on a determination that the exemption is necessary to provide for the timely participation of the individual or entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 calendar days, except that one extension of an additional 30 calendar days may be granted. | 73.5(e)<br>73.6(e) |
| **Responsible Official** | **73.9** | | | **73.9** |
| *Physical presence* | N/A | This provision is not in the current rule. Current paragraph (a)(5) will be redesignated as paragraph (a)(6). | (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 | 73.9(a)(5) |
| *Alternate Responsible Official* | 73.9(b) | (b) An entity may designate one or more individuals to be an alternate Responsible Official, who may act 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. | (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. | 73.9(b) |
| *Select agents and toxins that require immediate reporting* | 73.9(c)(1) | (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, *Brucella melitensis*, *Francisella tularensis*, Ebola viruses, Hendra virus, Marburg virus, Lassa fever virus, Nipah virus, Rift Valley fever virus, South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito), Variola major virus (Smallpox virus), Variola minor (Alastrim), Venezuelan equine encephalitis virus, 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. | (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 neurotoxin producing species of *Clostridium*, Botulinum neurotoxins, *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. | 73.9(c)(1) |
| **Restricted access** | **73.10** | | | **73.10** |
| *Providing* | N/A | This provision is not in the current rule. Current paragraph (e) | (e) A person with a valid approval from the HHS Secretary or | 73.10(e) |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| *approved access status to another* | | will be redesignated as paragraph (f). | Administrator to have access to select agents and toxins may request, through his or her Responsible Official, that the HHS Secretary or Administrator provide their approved access status to another registered individual or entity for a specified period of time. | |
| *Length of access approval validity* | 73.10(i) | (i) Access approval is valid for a maximum of five years. | (j) Access approval is valid for a maximum of three years | 73.10(j) |
| **Security** | **73.11** | | | **73.11** |
| *Submission of Security Plan* | 73.11(b) | (b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. The security plan must be submitted upon request. | (b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. A current security plan must be submitted for initial registration, renewal of registration, or when requested. | 73.11(b) |
| *Requirement for control of access in the Security Plan* | 73.11(c)(2) | (c)(2) Contain provisions for the control of access to select agents and toxins | (c)(2) Contain provisions for the control of access to select agents and toxins, including the safeguarding of animals, including arthropods, or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release. | 73.11(c)(2) |
| *Additional requirements for provisions in the Security Plan* | N/A | Paragraphs (c)(8), (c)(9), and (c)(10) are not in the current rule. | (c)(8) Describe procedures for how the Responsible Official will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins; and describe procedures for how the entity will notify the appropriate federal, state, or local law enforcement agencies of such activity.<br>(c)(9) Contain provisions for information security that:<br>(i) Ensure that all external connections to systems which manage security for the registered space are isolated or have controls that permit only authorized and authenticated users;<br>(ii) Ensure that authorized and authenticated users are only granted access to select agent and toxin related information, files, equipment (e.g., servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities, and that access is modified when the user's roles and responsibilities change or when their access to select agents and toxins is suspended or revoked;<br>(iii) Ensure that controls are in place that are designed to prevent malicious code (such as, but not limited to, computer virus, worms, spyware) from compromising the confidentiality, integrity, or availability of information systems which manage access to registered spaces in §73.11 of this part or records in §73.17 of this part;<br>(iv) Establish a robust configuration management practice for information systems to include regular patching and updates | 73.11(c)(8)<br>(c)(9)<br>(c)(10) |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| | | | made to operating systems and individual applications; and<br>(v) Establish procedures that provide backup security measures in the event that access control systems, surveillance devices, and/or systems that manage the requirements of section 17 of this part are rendered inoperable.<br>(c)(10) Contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including documented procedures for receiving, monitoring, and shipping of all select agents and toxins. These provisions must provide that an entity will properly secure containers on site and have a written contingency plan for unexpected shipments. | |
| *Additional security requirements* | N/A | New paragraphs (e) and (f) are not in the current rule. Current paragraphs (e) and (f) will be redesignated as paragraphs (g) and (h). | (e) Entities must conduct complete inventory audits of all affected select agents and toxins in long-term storage when any of the following occur:<br>(1) Upon the physical relocation of a collection or inventory of select agents or toxins for those select agents or toxins in the collection or inventory;<br>(2) Upon the departure or arrival of a principal investigator for those select agents and toxins under the control of that principal investigator; or<br>(3) In the event of a theft or loss of a select agent or toxin, all select agents and toxins under the control of that principal investigator.<br>(f) In addition to the requirements contained in paragraphs (c) and (d) of this section, the security plan for an individual or entity possessing a Tier 1 select agent or toxin must also:<br>(1) Describe procedures for conducting a pre-access suitability assessment of persons who will have access to a Tier 1 select agent or toxin;<br>(2) Describe procedures for how an entity's Responsible Official will coordinate their efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents and toxins and share, as appropriate, relevant information; and<br>(3) Describe procedures for the ongoing assessment of the suitability of personnel with access to a Tier 1 select agent or toxin. The procedures must include:<br>(i) Self- and peer-reporting of incidents or conditions that could affect an individual's ability to safely have access to or work with select agents and toxins, or to safeguard select agents and toxins from theft, loss, or release;<br>(ii) The training of employees with access to Tier 1 select agents and toxins on entity policies and procedures for reporting, evaluation, and corrective actions concerning the assessment of personnel suitability; and | 73.11(e)<br>73.11(f) |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| | | | (iii) The ongoing suitability monitoring of individuals with access to Tier 1 select agents and toxins.<br>(4) Entities with Tier 1 select agents and toxins must prescribe the following security enhancements:<br>(i) Procedures that will limit access to a Tier 1 select agent or toxin to only those individuals who are approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General, have had an entity-conducted pre-access suitability assessment, and are subject to the entity's procedures for ongoing suitability assessment;<br>(ii) Procedures that limit access to laboratory and storage facilities outside of normal business hours to only those specifically approved by the Responsible Official or designee;<br>(iii) Procedures for allowing visitors, their property, and vehicles at the entry and exit points to the registered space, or at other designated points of entry to the building, facility, or compound that are based on the entity's site-specific risk assessment;<br>(iv) A minimum of three security barriers where each security barrier adds to the delay in reaching secured areas where select agents and toxins are used or stored. One of the security barriers must be monitored in such a way as to detect intentional and unintentional circumventing of established access control measures under all conditions (day/night, severe weather, etc.) The final barrier must limit access to the select agent or toxin to personnel approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General.<br>(v) All registered space or areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS) unless physically occupied;<br>(vi) Personnel monitoring the IDS must be capable of evaluating and interpreting the alarm and alerting the designated security response force or law enforcement;<br>(vii) For powered access control systems, describe procedures to ensure that security is maintained in the event of the failure of access control systems due to power disruption affecting registered space;<br>(viii) The entity must:<br>(A) Determine that the response time for security forces or local police will not exceed 15 minutes or<br>(B) Provide security barriers that are sufficient to delay unauthorized access until the response force arrives in order to safeguard the select agents and toxins from theft, intentional | |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| | | | release, or unauthorized access. The response time is measured from the time of an intrusion alarm, or report of a security incident, to the arrival of the responders at the first security barrier.<br>(5) Entities that possess Variola major virus and Variola minor virus must have the following additional security requirements:<br>(i) Require personnel with independent unescorted access to Variola major or Variola minor virus to have a Top Secret security clearance;<br>(ii) Require Variola major or Variola minor virus storage locations be under the surveillance of closed circuit television that is monitored;<br>(iii) After-hours access procedures for Variola major or Variola minor virus must require notification of the entity's security staff prior to entry into the Variola laboratory and upon exit;<br>(iv) Require that observation zones be maintained in outdoor areas adjacent to the physical barrier at the perimeter of the entity and be large enough to permit observation of the activities of people at that barrier in the event of its penetration;<br>(v) Provide for a minimum of four barriers for the protection of the Variola major or Variola minor virus, one of which must be a perimeter fence;<br>(vi) Require a numbered picture badge identification subsystem to be used for all individuals who are authorized to access Variola major or Variola minor without escort;<br>(vii) Require the use, at all times, of properly trained, and equipped security force personnel able to interdict threats identified in the site specific risk assessment;<br>(viii) Identify security force personnel designated to strengthen onsite response capabilities, and that will be onsite and available at all times to carry out their assigned response duties;<br>(ix) Provide for security patrols to periodically check external areas of the registered areas to include physical barriers and building entrances;<br>(x) Require that all on-duty security force personnel shall be capable of maintaining continuous communication with support and response assets by way of security operations center;<br>(xi) Require that Variola major and Variola minor material in long term storage be stored in tamper-evident systems;<br>(xii) Require that all spaces containing working or permanent Variola major or Variola minor stocks be locked and protected | |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| | | | by an intrusion alarm system that will alarm upon the unauthorized entry of a person anywhere into the area;<br>(xiii) Require that alarms required pursuant to this section annunciate in a continuously manned security operations center located within the facility; and<br>(xiv) Require that the security operations center shall be located within a building so that the interior is not visible from the perimeter of the protected area. | |
| *Document that should be considered in developing a security plan* | 73.11(e) | (e) In developing a security plan, an entity or individual should consider, the document entitled "Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents. Morbidity and Mortality Weekly Report December 6, 2002; 51The document is available on the Internet at: http://www.cdc.gov/mmwr. | (g) In developing a security plan, an individual or entity should consider the document entitled, "Security guide for select agent or toxin facilities." The document is available on the National Select Agent Registry website at http://www.selectagents.gov/. | 73.11(g) |
| **Biosafety** | **73.12** | | | **73.12** |
| *Biosafety plan requirement* | 73.12(a) | (a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures. | (a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. | 73.12(a) |
| *Documents to consider* | 73.12(c) | (c) In developing a biosafety plan, an individual or entity should consider:<br>(1) The CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories", including all appendices. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Post Office Box 371954, Pittsburgh, Pennsylvania, 75250-7954 or from the CDC Web site at http://www.cdc.gov/. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia.<br>(2) The Occupational Safety and Health Administration (OSHA) regulations in 29 CFR parts 1910.1200 and 1910.1450.<br>(3) The "NIH Guidelines for Research Involving Recombinant DNA Molecules," (NIH Guidelines). Copies may be obtained from the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia, 30333 or from the CDC Web site at http://www.cdc.gov/. Copies may be inspected at the Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-79, Atlanta, Georgia. | (c) In developing a biosafety plan, an individual or entity should consider:<br>(1) The CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories." This document is available on the National Select Agent Registry website at http://www.selectagents.gov.<br>(2) The Occupational Safety and Health Administration (OSHA) regulations in 29 CFR parts 1910.1200 and 1910.1450. This document is available on the National Select Agent Registry website at http://www.selectagents.gov.<br>(3) The "NIH Guidelines for Research Involving Recombinant DNA Molecules," (NIH Guidelines). This document is available on the National Select Agent Registry website at http://www.selectagents.gov. | 73.12(c) |
| *Occupational* | N/A | New paragraph (d) is not in the current rule. Current paragraph | (d) The biosafety plan must include an occupational health | 73.12(d) |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| *health program* | | (d) will be redesignated as paragraph (e). | program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program. | |
| **Restricted experiments** | **73.13** | | | **73.13** |
| *Prohibition on possessing products from restricted experiments* | 73.13(a) | (a) An individual or entity may not conduct a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary. In addition, an individual or entity may not conduct a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary, after consultation with Administrator. | (a) An individual or entity may not conduct, or possess products (i.e., select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from, a restricted experiment with a HHS select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary. In addition, an individual or entity may not conduct, or possess products (i.e., select agents that are not known to acquire the resistance naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture, or recombinant and/or synthetic DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight) resulting from, a restricted experiment with an overlap select agent or toxin unless approved by and conducted in accordance with any conditions prescribed by the HHS Secretary, after consultation with Administrator. | 73.13(a) |
| *Restricted experiments defined* | 73.13(b) | (b) Restricted experiments:<br>(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.<br>(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] < 100 ng/kg body weight. | (b) Restricted experiments:<br>(1) 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.<br>(2) 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. | 73.13(b) |
| **Incident Response** | **73.14** | | | **73.14** |
| *Requirement for incident response plan* | 73.14(a) | (a) An individual or entity required to register under this part must develop and implement a written incident response plan. The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review. | (a) An individual or entity required to register under this part must develop and implement a written incident response plan based upon a site specific risk assessment. The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review. | 73.14(a) |
| *Response procedures in the* | 73.14(b) | (b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent | (b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select | 73.14(b)<br>73.14(c) |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| *incident response plan* | | or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent and toxin and appropriate actions to contain such select agent or toxin. | agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, and other natural and man-made events.<br>(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. | |
| *Additional requirements for Tier 1* | N/A | New paragraph (e) is not in the current rule. Current paragraphs (c) and (d) will be redesignated as paragraphs (d) and (f). | (e) Entities with Tier 1 select agents and toxins must have the following additional incident response policies or procedures:<br>(1) The incident response plan must fully describe the entity's response procedures for failure of intrusion detection or alarm system; and<br>(2) The incident response plan must describe procedures for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins. | 73.14(e) |
| **Training** | **73.15** | | | **73.15** |
| *Required training* | 73.15(a) | (a) An individual or entity required to register under this part must provide information and training on biosafety and security to each individual with access approval from the HHS Secretary or Administrator before he/she has such access.[1] In addition, an individual or entity must provide information and training on biosafety and security to each individual not approved for access from the HHS Secretary or Administrator before he/she works in or visits areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, etc.). The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. | (a) An individual or entity required to register under this part must provide information and training on biosafety, security (including security awareness), and incident response to:<br>(1) Each individual with access approval from the HHS Secretary or Administrator before that individual has such access to select agents and toxins. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins; and<br>(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. | 73.15(a) |
| *Requirements for Tier 1* | N/A | New paragraph (b) is not in the current rule. Current paragraphs (b) and (c) will be redesignated as paragraphs (c) and (d). | (b) Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors. | 73.15(b) |

[1] The training need not duplicate training provided under the OSHA Bloodborne Pathogen Standard set forth at *29 CFR 1910.1030*.

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
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| *Refresher training* | 73.15(b) | (b) Refresher training must be provided annually. | (c) Refresher training must be provided annually for individuals with access approval from the HHS Secretary or Administrator or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans. | 73.15(c) |
| *Record of training* | 73.15(c) | (c) A record of the training provided to each individual must be maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training. | (d) The Responsible Official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (e.g., laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training. | 73.15(d) |
| **Transfers** | **73.16** | | | **73.16** |
| *Packaging by an approved individual* | N/A | New paragraph (f) is not in the current rule. Current paragraphs (f) and (g) will be redesignated as paragraphs (i) and (j). | (f) After authorization is provided by APHIS or CDC, the packaging of the select agent(s) and toxin(s) is performed by an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins and is in compliance with all applicable laws concerning packaging. | 73.16 (f) |
| *Compliance with laws on shipping* | 73.16(i) | (i) The sender must comply with all applicable laws concerning packaging and shipping. | (g) The sender must comply with all applicable laws concerning shipping. | 73.16 (g) |
| *Transportation in commerce* | N/A | New paragraph (h) is not in the current rule. Current paragraph (h) will be redesignated as paragraph (k). | (h) Transportation in commerce starts when the select agent(s) or toxin(s) are packaged for shipment and ready for receipt by a courier transporting select agent(s) or toxin(s) and ends when the package is received by the intended recipient who is an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General. | 73.16(h) |
| *Transfer of toxins otherwise excluded by 73.3(d)* | N/A | New paragraph (l) is not in the current rule. | (l) A registered individual or entity transferring an amount of a HHS toxin otherwise excluded under the provisions of section 73.3(d) of this part must:<br>(1) Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (i.e., reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins.<br>(2) Report to CDC if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to a toxin listed in section of this part. | 73.16(l) |
| **Records** | **73.17** | | | **73.17** |
| *An inventory of select agents in* | 73.17(a)(1) | (1) Accurate, current inventory for each select agent (including viral genetic elements, recombinant nucleic acids, and | (1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic | 73.17(a)(1) |

| Subject | CFR Section | Current Language | Final Rule (FR) Language | FR Section |
|---|---|---|---|---|
| *long-term storage* | | 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: | nucleic acids, and recombinant and/or synthetic 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: | |
| *An accounting of exposed animals or plants* | N/A | New paragraph (a)(2) is not in the current rule. Current paragraphs (a)(2) through (a)(6) will be redesignated as paragraphs (a)(3) through (a)(7). | (2) 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) | 73.17(a)(2) |
| **Administrative review** | **73.20** | | | **73.20** |
| | 73.20 | An individual or entity may appeal a denial, revocation, or suspension of registration under this part. An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 30 calendar days of the decision. Where the denial, revocation, or suspension of registration or the denial, limitation, or revocation of an individual's access approval is based upon an identification by the Attorney General, the request for review will be forwarded to the Attorney General. The HHS Secretary's decision constitutes final agency action. | (a) An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 30 calendar days of the decision.<br>(b) An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 180 calendar days of the decision.<br>(c) The HHS Secretary's decision constitutes final agency action. | 73.20(a)<br>73.20(b)<br>73.20(c) |