

Supporting Statement A

Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73)

(OMB Control No. 0920-0576)

Expiration 12/31/2018

Revision

Centers for Disease Control and Prevention  
Office of Public Health Preparedness and Response  
Division of Select Agents and Toxins

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## Supporting Statement A

- The goal of the study is to support the Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 and ensure select agents or toxins are managed appropriately to prevent any threats to human health or safety.
- The intended use of the study is to fulfill the requirements promulgated by Health and Human Services under this part and also subject to corresponding regulations promulgated by the United States Department of Agriculture at 9 CFR Part 121 and 7 CFR Part 331.
- The method used to collect data/information is an electronic data collection system that uses electronic forms, which are available on the Federal Select Agent Program website at <http://www.selectagents.gov/forms.html> in a pdf-fillable format for electronic submission.
- The subpopulation to be studied are those individuals or entities reporting the theft, loss or release of a select agent or toxin.
- This collection of information does not employ statistical methods. The data collection is mandated by 42 CFR 73.

### **A. Justification**

This request reflects revisions only to the Report of Theft, Loss, or Release of Select Agent or Toxin (United States Department of Agriculture (USDA) – Animal and Plant Health Inspection Service (APHIS)/Centers for Disease Control and Prevention (CDC) Form 3) (42 CFR 73.19(a) (b)) that the Office of Management and Budget (OMB)’s approved until December 31, 2018 (OMB Control No. 0920-0576). The reporting requirements for Form 3 are required under 42 CFR Part 73 (**Attachment 1**). In summer 2015, the CDC Director, Dr. Tom Frieden, ordered an internal 90-day review of CDC’s select agent and toxin regulatory program overseen by DSAT. A CDC Internal Review Workgroup was established to examine the Federal Select Agent Program and make recommendations to improve CDC’s responsibilities within FSAP. Based on this review, the Workgroup made a recommendation regarding the Form 3 to make the “reporting more informative about the actual and potential risk of reported incidents. DSAT, with AgSAS, shall complete a review to update the APHIS/CDC Form 3, to include subcategories of “release” and “loss” and additional fields to more consistently categorize an incident with regard to such matters as the type of release (e.g., potential release, spill within secondary containment, occupational exposure, possible breach of facility containment, etc.), type of exposure (e.g., none, intact personal protective equipment (PPE), skin, mucosal, waste water, etc.), and the understanding of safety and security risk levels relative to human illness. Input shall be solicited from the regulated community and interested stakeholders before the new form is put into practice.” Therefore, the revisions to the APHIS/CDC Form 3 are made in response the recommendation by CDC Workgroup and to are to further clarify what needs to be reported as a “release” and “loss” and additional fields to assist with categorizing the type of release (e.g., spill within secondary containment, occupational exposure, possible breach of facility containment, etc.), type of exposure, and the understanding of safety and security risk levels relative to human illness and to include a guidance document to assist respondents with completing APHIS/CDC Form 3. The CDC is requesting to revise the currently approved

APHIS/CDC Form 3 that expires on December 31, 2018. No other changes are being requested for the other forms listed under OMB Control No. 0920-0576: Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73). Guidance Documents and Templates have been added to assist with the completion of select forms described below.

## **1. Circumstances Making the Collection of Information Necessary**

Subtitle A of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, (42 U.S.C. 262a), requires the United States Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to public health and safety (select agents and toxins). Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which may be cited as the Agricultural Bioterrorism Protection Act of 2002), (7 U.S.C. 8401), requires the USDA to regulate the possession, use, and transfer of biological agents or toxins that have the potential to pose a severe threat to animal or plant health, or animal or plant products (select agents and toxins). Accordingly, the Department of Health and Human Services (HHS) and USDA have promulgated regulations requiring individuals or entities that possess, use, or transfer select agents and toxins to register with the CDC or APHIS. See 42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121 (the select agent regulations). The Federal Select Agent Program (FSAP) is the collaboration of the CDC, Division of Select Agents and Toxins (DSAT) and the APHIS Agriculture Select Agent Services (AgSAS) to administer the select agent regulations in a manner to minimize the administrative burden on persons subject to the select agent regulations. The FSAP administers the select agent regulations in close coordination with the Federal Bureau of Investigation's Criminal Justice Information Services (CJIS). Accordingly, CDC and APHIS have adopted an identical system to collect information for the possession, use, and transfer of select agents and toxins.

## **2. Purpose and Use of Information Collection**

The agents and toxins subject to the HHS data collection are those that pose a serious threat to public health and safety. These agents and toxins are further identified as non-overlap or overlap agents or toxins. These agents and toxins are subject to requirements promulgated by HHS under this part and also subject to corresponding regulations promulgated by USDA at 9 CFR Part 121 and 7 CFR Part 331. This information will assist with meeting the goals of the Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 and ensure select agents or toxins are managed appropriately to prevent any threats to human health or safety. Since the previous revision request in 2015, the CDC Director, Dr. Tom Frieden ordered an internal 90-day review of CDC's select agent and toxin regulatory program overseen by DSAT in the summer of 2015. A CDC Internal Review Workgroup was established to examine the Federal Select Agent Program and make recommendations to improve CDC's responsibilities within FSAP. Based on this review, the Workgroup made a recommendation regarding the Form 3 to make the "reporting more informative about the actual and potential risk of reported incidents. DSAT, with AgSAS, shall complete a review to update the APHIS/CDC Form 3, to include

subcategories of “release” and “loss” and additional fields to more consistently categorize an incident with regard to such matters as the type of release (e.g., potential release, spill within secondary containment, occupational exposure, possible breach of facility containment, etc.), type of exposure (e.g., none, intact personal protective equipment (PPE), skin, mucosal, waste water, etc.), and the understanding of safety and security risk levels relative to human illness. Input shall be solicited from the regulated community and interested stakeholders before the new form is put into practice.” Therefore, the revisions to the APHIS/CDC Form 3 are made in response to the recommendation by CDC Workgroup and to further clarify what needs to be reported as a “release” and “loss” and additional fields to assist with categorizing the type of release (e.g., spill within secondary containment, occupational exposure, possible breach of facility containment, etc.), type of exposure, and the understanding of safety and security risk levels relative to human illness and to include a guidance document to assist respondents with completing APHIS/CDC Form 3. There were no other recommendations or other changes being requested for the other forms listed under OMB Control No. 0920-0576: Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73). Therefore, there are no changes being requested for the other forms listed under OMB Control No. 0920-0576: Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73). The below outlines how the information is being used:

The Application for Registration (APHIS/CDC Form 1) (42 CFR, 73.7(d)) (**Attachment 5**) is used by entities to register with FSAP. The Application for Registration requests facility information; a list of select agents or toxins in use, possession, or for transfer by the entity; characterization of the select agent or toxin; and laboratory information. This form is also used by the entity to amend their registration (42 CFR, 73.7(h) (1)) if any changes occur in the information submitted. When applying for an amendment to a certificate of registration, an entity must obtain the relevant portion of the application package and submit the information requested in the package to FSAP (**Attachment 5**). The Application for Registration (APHIS/CDC Form 1) Guidance Document (**Attachment 5a**) has been added to assist respondents with completion of this form.

The Request to Transfer Select Agent or Toxin (APHIS/CDC Form 2) (42 CFR 73.16) (**Attachment 6**) is used by entities requesting pre-authorization from FSAP to receive or send a select agent or toxin. The Transfer (APHIS/CDC Form 2) Guidance Document (**Attachment 6a**) has been added to assist respondents with completion of this form.

The Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3) (42 CFR 73.19(a) (b)) (**Attachment 4**) is completed by entities whenever there is theft, loss, or release of a select agent or toxin. The entity is required to provide immediate notification and then required to submit the APHIS/CDC Form 3 within 7 days of incident.

CDC proposes the following changes to clarify the intent and meaning of the following questions on APHIS/CDC Form 3:

| Form                                | Current Item  | Requested Change  | Justification   |
|-------------------------------------|---|---|---|
| APHIS/CDC Form 3, Sections 1 and 2  | “SECTION 1 – TO BE COMPLETED BY ALL ENTITIES & SECTION 2 – TO BE COMPLETED BY ALL ENTITIES”                         | Split “SECTION 1 – TO BE COMPLETED BY ALL ENTITIES” into 2 sections and title “SECTION A – ENTITY INFORMATION” and “SECTION B – INCIDENT INFORMATION.” For section A, include blocks 4-13 and 21. For section B, blocks 1-3, 14, 17, 19, and 22-24.   | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, blocks 1 and 16   | “1. Date of Incident:” & “16. Time incident occurred:”  | Combined blocks and put under Section B, block 1 “1. Date and Time of Incident:”  | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 10          | “10. Responsible Official (registered) or Name of Laboratory Supervisor (non-registered):”                          | “7. Name of Responsible Official or Laboratory Supervisor:”   | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 11          | “11. Telephone #:”  | “9. Telephone Number:”  | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 12          | “12. Fax #:”  | “10. Fax Number:”   | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, blocks 14a and 25 | For blocks 14a “Theft” and information requested for block 25 regarding theft, created different section and block. | Block “8. Type of Incident:<br><input type="checkbox"/> Theft (After completing Section B. Go to Section C)´<br><input type="checkbox"/> Loss (After completing Section B. Go to Section D) ´<br><input type="checkbox"/> Release/ Potential Exposure (After completing Section B. Go to Section E) ´<br>Note: Please complete Appendix A, event timeline, to provide details on the theft/loss/release incident.” and “SECTION C – REPORT OF THEFT 1. Type of Theft:<br><input type="checkbox"/> Forced Entry<br><input type="checkbox"/> Insider/Insider-assisted access<br><input type="checkbox"/> Unauthorized access<br>2. Has Local Law Enforcement been Notified: (If yes, complete sections C3-C5)<br><input type="checkbox"/> Yes <input type="checkbox"/> No<br>3. Local Law Enforcement Agency:<br>4. Local Law Enforcement Agent Name:<br>First: _____ MI: _____ Last: _____<br>5. Local Law Enforcement Contact Information:<br>6. Has the FBI been Notified:<br>(If yes, fill out #s C7-8):<br><input type="checkbox"/> Yes <input type="checkbox"/> No<br>7. FBI Agent Name: (First M. Last)<br>8. FBI Agent Contact Information: | This change clarifies the meaning/intent of the question. |

| Form                                | Current Item  | Requested Change  | Justification   |
|-------------------------------------|---|---|---|
|                                     |   | 9. Was the stolen BSAT material recovered: 0 Yes<br>0 No<br>10. Was there a potential exposure: (If yes, go to section E- Q: 5-11)<br>0 Yes<br>0 No<br>0 Unsure”  |   |
| APHIS/CDC Form 3, blocks 14a and 25 | For blocks 14a “Loss” and information requested for block 25 regarding loss, created different section and block. | Block “8. Type of Incident:<br>0 Theft (After completing Section B. Go to Section C)<br>0 Loss (After completing Section B. Go to Section D) `<br>0 Release/ Potential Exposure (After completing Section B. Go to Section E) `<br>Note: Please complete Appendix A, event timeline, to provide details on the theft/loss/release incident.” and “SECTION D-REPORT OF LOSS”<br>1. Type of Loss:<br>0 Inventory/Recordkeeping error<br>0 Sample lost/discarded at entity<br>0 Sample lost in transit (Go to Appendix B to enter add'l info)<br>0 Other: _____<br>2. Has Local Law Enforcement been Notified: (If yes, fill out #s D3-D5)<br>0 Yes<br>0 No<br>3. Local Law Enforcement Agency:<br>4. Local Law Enforcement Agent Name:<br>First: M: Last:<br>5. Local Law Enforcement Contact Information: (phone/email)<br>6. Was the FBI Notified: (If yes, fill out #s D7-D8)<br>0 Yes<br>0 No<br>7. FBI Agent Name:<br>First: M: Last:<br>8. FBI Agent Contact Information:<br>9. Was the lost BSAT material found?<br>0 Yes<br>0 No<br>10. How long was the BSAT material missing?<br>Date recovered:<br>Duration of loss (hrs/days):<br>11. Give the date of the last inventory/audit performed, which meets the FSAP regulatory requirement: | This change clarifies the meaning/intent of the question. |

| Form                                | Current Item  | Requested Change  | Justification   |
|-------------------------------------|---|---|---|
|                                     |   | 12. Was there a potential exposure: (If yes, complete Section E- Q: 5-11)<br><input type="checkbox"/> Yes<br><input type="checkbox"/> No  |   |
| APHIS/CDC Form 3, blocks 14a and 25 | For blocks 14a “Release” “Unintended Animal Infection, Unintended Plant agent Release Other” and information requested for block 25 regarding release, created different section and block. | Block “8. Type of Incident:<br><input type="checkbox"/> Theft (After completing Section B. Go to Section C)<br><input type="checkbox"/> Loss (After completing Section B. Go to Section D)<br><input type="checkbox"/> Release/ Potential Exposure (After completing Section B. Go to Section E)<br>Note: Please complete Appendix A, event timeline, to provide details on the theft/loss/release incident.” and “SECTION E- REPORT OF RELEASE” Block “1. Type of Potential Exposure/Release:<br><input type="checkbox"/> Animal bite/scratch <input type="checkbox"/><br>Equipment/mechanical failure<br><input type="checkbox"/> PPE failure <input type="checkbox"/> Package damaged in transit (fill out Appendix B)<br><input type="checkbox"/> Spill <input type="checkbox"/> Unintended Animal Infection<br><input type="checkbox"/> Needle stick/Sharps <input type="checkbox"/> Unintended Plant Pathogen Release<br><input type="checkbox"/> Decontamination failure <input type="checkbox"/> Work performed on an open bench<br><input type="checkbox"/> Inactivation failure <input type="checkbox"/><br>Other _____<br>_____” | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 15          | 15. Did the release result in a potential exposure? Yes No N/A (If Yes, explain in Blocks 28 or 30)   | “SECTION E- REPORT OF RELEASE” Block “4. Did the release result in potential exposure(s)?<br><input type="checkbox"/> Yes<br>If yes, how many individuals/animals/plants were exposed? _____<br><input type="checkbox"/> No   | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 15          | 15. Did the release result in a laboratory-acquired infection? Yes No N/A (If Yes, explain in Blocks 28 or 30)  | “SECTION E- REPORT OF RELEASE” Block “5. Did the release result in a laboratory acquired infection or an infection/outbreak in agriculture or in the environment?<br><input type="checkbox"/> Yes<br><input type="checkbox"/> No<br><input type="checkbox"/> Not currently known”   | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 15          | 15. If yes, has medical surveillance been initiated? Yes No N/A (If   | “SECTION E- REPORT OF RELEASE” Block “6. Has medical surveillance been initiated?<br><input type="checkbox"/> Yes   | This change clarifies the meaning/intent                  |



| Form                             | Current Item  | Requested Change   | Justification   |
|----------------------------------|---|--|---|
|                                  | Yes, explain in Blocks 28 or 30)  | 0 No”  | of the question.  |
| APHIS/CDC Form 3, block 14b      | 14b, Transfer:<br>0 Transfer incident (complete Sections 1 and 2 and Appendix B   | 2 blocks created in “SECTION B – INCIDENT INFORMATION 11. Is this incident associated with an APHIS/CDC Form 2 (Transfer):<br>0 Yes (Fill out Appendix B, if incident occurred during transfer.)<br>0 No<br>APHIS/CDC Form 2 transfer #:<br>_____<br>12. Is this incident associated with an APHIS/CDC Form 4 (Identification):<br>0 Yes<br>0 No<br>APHIS/CDC Form 4 clinical ID#:<br>_____” | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, blocks 17 & 18 | 17. Location of incident (building and room#) 18. Location of incident within room (e.g., freezer, incubator, centrifuge:   | Merge into one block in “SECTION B – INCIDENT INFORMATION “4. Location of Incident (bldg., room, equipment, etc.):   | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 19       | Biosafety Level:  | Move to “SECTION B – INCIDENT INFORMATION” to block 10 and question revised to “What Biosafety Level did the incident occur?”  | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 20       | 20. Date of last inventory (for reporting loss only:)   | Move to SECTION D- REPORT OF LOSS to block 11 and question revised to “Give the date of the last inventory/audit performed, which meets the FSAP regulatory requirement:”  | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 23       | Characterization of Agent (e.g., strain, ATCC#)   | Move to “SECTION B – INCIDENT INFORMATION” to block 6 and revised to “Strain designation of Select Agent or Toxin:”  | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 24       | Quantity/Amount   | Move to “SECTION B – INCIDENT INFORMATION” to block 7 and revised to “Quantity (Unit (vial, plates, etc.))”  | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 25       | 25. Provide a detailed summary of events including a timeline of what occurred. Whenever possible, conduct a risk assessment of the event and determine if the root cause can be identified. State specifically what personal protective equipment was worn and what, if any, medical | Move to Appendix A and revised to “Provide a detailed summary of events including a timeline of what occurred.”  | This change clarifies the meaning/intent of the question. |

| Form                       | Current Item  | Requested Change   | Justification   |
|----------------------------|---|--|---|
|                            | surveillance was provided or planned. If incident involves a non-human primate, please state species. For discovery of select agents and toxins in unregistered locations, include your entity's plan of action to assure no future discoveries, how discovered agents were found and disposition of the discovered agents, inventory reconciliation and assurance that the discovered material was safeguarded against unauthorized access, theft, loss, or release. |  |   |
| APHIS/CDC Form 3, block 26 | 26. An internal review of laboratory procedures and policies has been initiated to lessen the likelihood of recurrences of theft, loss or release of select agents and toxins at this entity. No<br>Yes If yes, please provide additional details.  | Move to SECTION E- REPORT OF RELEASE to "8. Has an internal review of laboratory procedures and policies been initiated to lessen the likelihood of recurrences of incident involving the select agents and toxins at this entity? 0 Yes (If yes, please provide additional details.) 0 No   | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 27 | 27. What were the hazards posed to humans by the extent of the release or occupational exposure?  | Move to SECTION E- REPORT OF RELEASE to "2. Was there a release outside containment barriers? (choose all that apply)<br>0 Release outside primary containment (e.g. biosafety cabinet, storage vial within storage unit, etc...)<br>0 Release beyond secondary containment (e.g. PPE, laboratory)<br>0 Release outside all containment barriers of the facility (e.g. resulting in possible agricultural/environmental/public health threat)" | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 28 | 28. What is the estimated extent of the release or exposure in relation to the proximity of susceptible humans, animals, and plants?  | Move to SECTION E- REPORT OF RELEASE to "3. What PPE was worn at the time of the incident?<br>0 Hand Protection (gloves) 0 Foot Protection (booties, shoe covers, etc...)<br>0 Head Protectors/Covers 0 Eye/Face Protection (goggles, face shield, etc.)<br>0 Body Protection 0 Respiratory Protection: Type_____  | This change clarifies the meaning/intent of the question. |

| Form                         | Current Item   | Requested Change   | Justification   |
|------------------------------|--|--|---|
|                              |  | 0 Other: " " " "   |   |
| APHIS/CDC Form 3, block 29   | 29. Provide a brief summary of how the laboratory and work surfaces were decontaminated after the release.   | Move to SECTION E- REPORT OF RELEASE to "10. Provide a brief summary of how the laboratory and work surfaces were decontaminated after the incident."  | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, block 30   | 30. In select agents and toxins posing a risk to humans, please state how many laboratorians were potentially exposed and provide a brief summary of the medical surveillance provided (do not provide names or confidential information). | Move to SECTION E- REPORT OF RELEASE to "7. Has prophylaxis or treatment been provided?<br>0 Yes<br>0 No<br>9. Other than a potential for occupational illness, what other hazards have been identified as a result of this incident?<br>11. Provide a brief summary of the medical surveillance conducted (do not provide names or confidential information). | This change clarifies the meaning/intent of the question. |
| APHIS/CDC Form 3, Appendix B | APPENDIX B IF THE INCIDENT OCCURRED DURING TRANSFER, COMPLETE SECTIONS 1 AND 2 OF FORM 3 AND PROVIDE THE FOLLOWING INFORMATION (INCLUDE A COPY OF THE RELEVANT APHIS/CDC FORM 2)   | APPENDIX B IF THE INCIDENT OCCURRED DURING TRANSFER, COMPLETE SECTIONS A AND B OF FORM 3 AND PROVIDE THE FOLLOWING INFORMATION (INCLUDE A COPY OF THE RELEVANT APHIS/CDC FORM 2)   | This change clarifies the meaning/intent of the question. |

In addition, CDC has developed a guidance document for entities to use to assist with completing the APHIS/CDC Form 3 - APHIS/CDC Guidance Document for Reporting Potential Theft, Loss, Release, or Occupational Exposure (**Attachment 4a**).

The Report of Identification of Select Agent or Toxin from a Clinical/Diagnostic Specimen (APHIS/CDC Form 4A) (42 CFR 73.5(a) and 73.6(a)) (**Attachment 7A**) is used by clinical or diagnostic laboratories and other entities to notify FSAP that a select agent or toxin identified as the result of diagnosis or proficiency testing have been disposed of in a proper manner.

The Report of Identification of Select Agent or Toxin from a proficiency testing (APHIS/CDC Form 4B) (42 CFR 73.5(b) and 73.6(b)) (**Attachment 7B**) is used by clinical or diagnostic laboratories and other entities to notify FSAP that a select agent or toxin identified as the result of proficiency testing have been disposed of in a proper manner.

The Report of Identification of Select Agent or Toxin from a Federal law enforcement agency that seizes a select agent or toxin (APHIS/CDC Form 4c) (42 CFR 73.3(f) and 73.4(f))

(**Attachment 7C**) is used a Federal law enforcement agency used to report the seizure of a select agent or toxin.

The Report of Identification of Select Agents and Toxins (APHIS/CDC Form 4) Guidance (Attachment 7i) has been added to assist respondents with Forms 4A, 4B, and 4C (**Attachments -7A, B, C**).

The Request for Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5) (42 CFR 73.5(d)(e) and 73.6(d)(e)) (**Attachment 8**) is used by entities that are using an investigational product that are, bear, or contain select agents or toxins. The Request for Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5) Guidance (**Attachment 8a**) has been added to assist respondents with this form.

In addition to the standardized forms listed above, CDC has not developed standardized forms to use in the below situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

Request for Exclusion (**Attachment 9**): 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 (42 CFR 73.3 and 4 (e)). The Request for Exclusion Guidance (**Attachment 9a**) has been added to assist respondents with this form.

Documentation of Self-Inspection (**Attachment 10**): Prior to issuance of a certificate of registration, CDC inspects entities to ensure compliance with this regulation (42 CFR 73.18). As part of the inspection process, the entity may need to respond to written requests from CDC. CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

Request for Expedited Review (**Attachment 11**): An entity may apply to the HHS Secretary for an expedited review of an individual by the Attorney General (42 CFR 73.10(e)). To apply for this expedited review, an entity must submit a request in writing to the HHS Secretary establishing the need for such action. CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

Security Plan (**Attachment 12**): An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release (42 CFR 73.11(a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation. The Security Plan Guidance (**Attachment 12a**) has been added to assist respondents with this information collection.

Biosafety Plan (Attachment 13): 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 (42 CFR 73.12(a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation. CDC has added a guidance document, Biosafety Plan Guidance (**Attachment 13a**) to provide information to the registered entities on how to develop a biosafety plan and template (**Attachment 13b**) to use as outline for the entities to develop a biosafety plan.

Request Regarding a Restricted Experiment (**Attachment 14**): 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 HHS Secretary:

- (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.
- (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<sub>50</sub> < 100 ng/kg body weight (42 CFR 73.13 (a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation. The Request Regarding a Restricted Experiment Guidance (**Attachment 14a**) has been added to assist respondents with this form.

Incident Response Plan (**Attachment 15**): 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 (42 CFR 73.14 (a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation. The Incident Response Plan Guidance and Template (**Attachment 15a**) have been added to assist respondents with this information collection.

Training (**Attachment 16**): 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 (42 CFR 73.16(d)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation. The Training Guidance (**Attachment 16a**) has been added to assist respondents with this information collection.

Records (**Attachment 17**): An individual or entity required to register under this part must maintain complete records relating to the activities covered by the select agent regulations (42 CFR 73.17 (a)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation. The Guidance on the Inventory of Select Agents (**Attachment 17a**) has been added

to assist respondents with this information collection.

Administrative Review (**Attachment 19**): 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. 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. (42 CFR 73.20 (a) and (b)). CDC has not developed standardized forms to use in the above situation. Rather, the entity should provide the information as requested in the appropriate section of the regulation.

### **3. Use of Improved Technology and Burden Reduction**

CDC/DSAT has implemented an electronic data collection system that uses electronic forms, which are available on the Federal Select Agent Program website at <http://www.selectagents.gov/forms.html> in a pdf-fillable format for electronic submission. The use of a pdf-fillable format, allows respondents to save the document to their local drive, complete the form, and then upload the form to FSAP. The entity can retain an electronic copy of their submission, which will make it easier for the entity to amend any future submissions.

The FSAP is also committed and pursuing to a single shared web-based system that will allow the regulated community to conduct transactions electronically with either agency. By providing the regulated community a single web portal, FSAP will be able to interact efficiently, effectively, while reducing the burden on the public. This environment will provide for the electronic exchange of information for reports of theft, loss, or release of a select agent or toxin.

### **4. Efforts to Identify Duplication and Use of Similar Information**

The FSAP continues to working closely to identify duplication of the proposed data collection. DSAT has established relationships with the following federal agencies: Department of Homeland Security (DHS), the Department of Defense; Department of Army Inspector General (DoD, DAIG) and the Department Veterans Affairs. Each of these agencies shares a similar interest in the possession, use, transfers of select agents and toxins, and has participated in joint inspections.

The Public Health Safety and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107) required the development of a common registration system for the purpose of verifying the credentials, licenses, accreditations, and hospital privileges of such professionals during public health emergencies. There is no similar database available to identify individuals or entities registered to possess, use and transfer select agents and toxins.

### **5. Impact on Small Businesses or Other Small Entities**

CDC recognizes that a small number of entities affected by the data collection requirements of this regulation may be small businesses. For this reason, the information needed in the data collection has been kept to a minimum.

## **6. Consequences of Collecting the Information Less Frequently**

There are legal obstacles to reducing the burden by collecting this information less frequently. The purpose of this information collection is to meet mandated regulatory requirements. If this information were collected less frequently, it would not be possible for DSAT to carry out its commitments to protect the public health as mandated by these regulations.

## **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This request fully complies with the regulation in 5 CFR 1320.5.

## **8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

**A8A.** A “**60 Day Federal Register Notice**” was published in the Federal Register on Friday, December 30, 2016, Vol. 81, No. 251, Pages 96456-96457. CDC received one comment that the term “laboratory supervisor” should be removed, all communication should be through the Responsible Official (RO) and not a laboratory manager. The commenter stated that this would ensure that the RO is apprised of all situations in the laboratory as they are occurring. CDC made no changes based on this comment as the term “laboratory supervisor” is used for entities not registered with FSAP. The same commenter recommended revising the block that list the type of personal protective equipment (PPE) worn during the incident because the commenter stated the examples were very generic. CDC made no changes based on this comment because CDC only wants to confirm that PPE was used during the incident. The same commenter recommended to modify the question to ask if an internal incident investigation has been initiated to identify the root cause versus only a review of procedures and policies. CDC agreed with the commenter and revised the form and guidance document accordingly.

### **A8B. Consultation Outside the Agency**

FSAP began revising the proposed data collection instruments in the fall of 2015. The following representatives from AgSAS assisted with the development of the data collection instruments:

Cassie Armiger  
Animal Plant Health and Inspection Service  
U.S. Department of Agriculture  
4700 River Road, Unit 40  
Riverdale, MD 20737-1231

Phone: (301) 851-2052  
[cassie.c.armiger@aphis.usda.gov](mailto:cassie.c.armiger@aphis.usda.gov)

Kimberly A. Hardy  
Animal Plant Health and Inspection Service  
U.S. Department of Agriculture  
4700 River Rd., Unit 123  
Riverdale, MD 20737  
Phone: (301) 851-2727  
[kimberly.a.hardy@aphis.usda.gov](mailto:kimberly.a.hardy@aphis.usda.gov)

## **9. Explanation of Any Payment or Gift to Respondents**

Respondents will not receive any payment or gift.

## **10. Protection of the Privacy and Confidentiality of Information Provided by Respondents**

The Privacy Act applies to this information collection request.

To comply with the Office of Management and Budget (OMB) Memoranda (M) 07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information, a Federal Register notice Vol. 76, No. 16, Tuesday, January 25, 2011 was published to alter the System of Records, 09-20-0170 (**Attachment 2**), National Select Agent Registry (NSAR)/Select Agent Transfer and Entity Registration Information System (SATERIS), HHS/CDC/COTPER. The System of Records is currently being revised because the information system is being modified from “NSAR” to “Electronic Federal Select Agent Program portal (eFSAP portal)/Electronic Import Permit Program portal (eIPP portal) (**Attachment 2**).”

The following special safeguards are provided to protect the records from inadvertent disclosure:

**Authorized Users:** A database security package is implemented on CDC computers to control unauthorized access to the system. Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Individuals who have routine access to these records are limited to Select Agent Program staff (DSAT Full Time Employees) and contractors) who have responsibility for conducting regulatory oversight of individuals and entities that possess, use, or transfer select agents and toxins.

**Physical Safeguards:** Paper records are maintained in locked cabinets in locked rooms in a restricted access location that is controlled by a cardkey system, and security guard service provides personnel screening of visitors. Electronic data files are password protected and stored in a restricted access location. The computer room is protected by an automatic sprinkler system, numerous automatic sensors (e.g., water, heat, smoke, etc.) are installed, and a proper mix of portable fire extinguishers is located throughout the computer room. The system is backed up on a nightly basis with copies of the files stored off site in a secure location. Computer workstations, lockable personal computers, and automated records are located in secured areas.



Procedural Safeguards: Protection for computerized records includes programmed verification of valid user identification code and password prior to logging on to the system; mandatory password changes, limited log-ins, virus protection, and user rights/file attribute restrictions. Password protection imposes user name and password log-in requirements to prevent unauthorized access. Each user name is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily backup procedures and secure off-site storage is available for backup files.

Knowledge of individual tape passwords is required to access tapes, and access to the system is limited to users obtaining prior supervisory approval. To avoid inadvertent data disclosure, a special additional procedure is performed to ensure that all Privacy Act data are removed from computer tapes and/or other magnetic media. When possible, a backup copy of data is stored at an offsite location and a log kept of all changes to each file and all persons reviewing the file. Additional safeguards may also be built into the program by the system analyst as warranted by the sensitivity of the data set.

CDC/DSAT and contractor employees who maintain records are instructed in specific procedures to protect the security of records, and are to check with the system manager prior to making disclosure of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel. Appropriate Privacy Act provisions are included in contracts and the CDC/DSAT Project Director, contract officers, and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to CDC/DSAT or destroyed, as specified by the contract.

The USDA/APHIS/AgSAS maintains similarly stringent safeguards that are discussed within that agency's Select Agent system of records notice.

Implementation Guidelines: The safeguards outlined above are in accordance with the HHS Information Security Program Policy and FIPS Pub 200, "Minimum Security Requirements for Federal Information and Information Systems." Data maintained on CDC's Mainframe and the OPHPR Local Area Network is in compliance with OMB Circular A-130, Appendix III. Security is provided for information collection, processing, transmission, storage, and dissemination in general support systems and major applications.

Because of the national security sensitivity of the information in this database, CDC has determined that making this information available through a public database would compromise one of the primary purposes of the legislation. Therefore, CDC will not create a publicly available database of information. Disclosure of any registration or transfer documentation by the federal government is prohibited by P.L. 107-188.

#### Institutional Review Board

Institutional Review Board approval is not required. (**Attachment 21**)

## 11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board

Institutional Review Board approval is not required. (Attachment 21)

Justification for Sensitive Questions

There are no sensitive questions in this data collection.

## 12. Estimates of Annualized Burden Hours and Costs

Estimated Annualized Burden Hours

Annualized burden hours and cost were calculated based on data obtained from 2016 Annual Report of the Federal Select Agent Program for submissions to FSAP for 2016. The estimated annualized burden for the 2015 submission was 8,527 hours. Burden has been reduced to 8,408 hours due to the decrease in the number of Respondents.

For the changes reflected for the APHIS/CDC Form 3, the estimated annualized burden is 307.5 and is a reduction of 122.5 from the 2015 submission, which was 430. The burden includes the addition of the questions noted above and the revised guidance document that accounts for addition of 30 minutes to complete the form.

Estimated Annualized Burden Hours

| Attachment | Section  | Form Name   | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours |
|------------|----------|---|-----------------------|------------------------------------|--|--------------------|
| 5          | 73.7     | Application for Registration (APHIS/CDC Form 1)   | 1                     | 1                                  | 4                                      | 4                  |
| 5          | 73.7     | Amendment to a Certificate of Registration  | 238                   | 7                                  | 1                                      | 1,666              |
| 5a         | 73.7     | Application for Registration (APHIS/CDC Form 1) Guidance  | 1                     | 1                                  | 1                                      | 1                  |
| 6          | 73.16    | Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2)   | 188                   | 1                                  | 1                                      | 188                |
| 6a         | 73.16    | Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2) Guidance                                    | 188                   | 1                                  | 30/60                                  | 94                 |
| 4          | 73.19    | Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3)                               | 205                   | 1                                  | 1.5                                    | 308                |
| 4a         | 73.19    | Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3) Guidance                      | 205                   | 1                                  | 30/60                                  | 103                |
| 7A         | 73.5 & 6 | Report of Identification of a Select Agent or Toxin from a Clinical/Diagnostic Specimen (APHIS/CDC Form 4A) | 1030                  | 1                                  | 30/60                                  | 515                |
| 7B         | 73.5 & 6 | Report of Identification of a Select Agent or Toxin from a Proficiency Test (APHIS/CDC Form 4B)             | 10                    | 1                                  | 30/60                                  | 5                  |
| 7C         | 73.5 & 6 | Federal Law Enforcement Reporting Seizure of Select Agent or Toxin (APHIS/CDC Form 4C)                      | 1                     | 1                                  | 30/60                                  | 1                  |
| 7i         | 73.5 & 6 | Report of Identification of a Select Agent or Toxin (APHIS/CDC Form 4) Guidance                             | 1030                  | 1                                  | 30/60                                  | 515                |

|     |             |   |     |   |       |       |
|-----|-------------|---|-----|---|-------|-------|
| 8   | 73.5 & 73.6 | Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5)          | 1   | 1 | 30/60 | 1     |
| 8a  | 73.5 & 73.6 | Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5) Guidance | 1   | 1 | 30/60 | 1     |
| 9   | 73.3 & 73.4 | Request for Exclusions  | 3   | 1 | 30/60 | 2     |
| 9a  | 73.3 & 73.4 | Request for Exclusions Guidance   | 3   | 1 | 30/60 | 2     |
| 10  | 73.9        | Documentation of Self-inspection  | 238 | 1 | 1     | 238   |
| 11  | 73.1        | Request for Expedited Review  | 1   | 1 | 15/60 | 1     |
| 12  | 73.11       | Security Plan   | 238 | 1 | 5     | 1,190 |
| 12a | 73.11       | Security Plan Guidance  | 238 | 1 | 30/60 | 119   |
| 12b | 73.11       | Security Plan Template  | 238 | 1 | 30/60 | 119   |
| 13  | 73.12       | Biosafety Plan  | 238 | 1 | 5     | 1,190 |
| 13a | 73.12       | Biosafety Plan Guidance   | 238 | 1 | 30/60 | 119   |
| 13b | 73.12       | Biosafety Plan Template   | 238 | 1 | 30/60 | 119   |
| 14  | 73.13       | Request Regarding a Restricted Experiment   | 1   | 1 | 30/60 | 1     |
| 14a | 73.13       | Request Regarding a Restricted Experiment Guidance  | 1   | 1 | 30/60 | 1     |
| 15  | 73.14       | Incident Response Plan  | 238 | 1 | 5     | 1,190 |
| 15a | 73.14       | Incident Response Plan Guidance   | 238 | 1 | 30/60 | 119   |
| 15b | 73.14       | Incident Response Plan Template   | 238 | 1 | 30/60 | 119   |
| 16  | 73.15       | Training  | 238 | 1 | 30/60 | 119   |
| 16a | 73.15       | Training Guidance   | 238 | 1 | 30/60 | 119   |
| 17  | 73.17       | Records   | 238 | 1 | 30/60 | 119   |
| 17a | 73.17       | Guidance on the Inventory of Select Agents  | 238 | 1 | 30/60 | 119   |
| 19  | 73.20       | Administrative Review   | 1   | 1 | 1     | 1     |
|     |             |   |     |   |       |       |
|     | Total       |   |     |   |       | 8,407 |
|     |             |   |     |   |       |       |

### Estimated Annualized Burden Costs

| Section | Form Name  | Number of Respondents | Number of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours | Hourly Wage Rate | Total Respondent Cost |
|---------|--|-----------------------|------------------------------------|--|--------------------|------------------|-----------------------|
| 73.7    | Application for Registration (APHIS/CDC Form 1)          | 1                     | 1                                  | 4                                      | 4                  | \$35.12          | \$140.48              |
| 73.7    | Amendment to a Certificate of Registration               | 238                   | 7                                  | 1                                      | 1,666              | \$35.12          | \$58,509.92           |
| 73.7    | Application for Registration (APHIS/CDC Form 1) Guidance | 1                     | 1                                  | 1                                      | 1                  | \$35.12          | \$35.12               |
| 73.16   | Request to Transfer Select                               | 188                   | 1                                  | 1                                      | 94                 | \$35.12          | \$6,602.56            |

|             |   |      |   |       |     |         |             |
|-------------|---|------|---|-------|-----|---------|-------------|
|             | Agents and Toxins (APHIS/CDC Form 2)  |      |   |       |     |         |             |
| 73.16       | Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2) Guidance                                    | 188  | 1 | 30/60 | 94  | \$35.12 | \$3,301.28  |
| 73.19       | Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3)                               | 205  | 1 | 1.5   | 205 | \$35.12 | \$10,816.96 |
| 73.19       | Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3) Guidance                      | 205  | 1 | 30/60 | 103 | \$35.12 | \$3,617.36  |
| 73.5 & 6    | Report of Identification of a Select Agent or Toxin from a Clinical/Diagnostic Specimen (APHIS/CDC Form 4A) | 1030 | 1 | 30/60 | 515 | \$35.12 | \$18,086.80 |
| 73.5 & 6    | Report of Identification of a Select Agent or Toxin from a Proficiency Test (APHIS/CDC Form 4B)             | 10   | 1 | 30/60 | 5   | \$35.12 | \$175.60    |
| 73.5 & 6    | Federal Law Enforcement Reporting Seizure of Select Agent or Toxin (APHIS/CDC Form 4C)                      | 1    | 1 | 30/60 | 1   | \$35.12 | \$35.12     |
| 73.5 & 6    | Report of Identification of a Select Agent or Toxin (APHIS/CDC Form 4) Guidance                             | 1030 | 1 | 30/60 | 515 | \$35.12 | \$18,086.80 |
| 73.5 & 73.6 | Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5)          | 1    | 1 | 30/60 | 1   | \$35.12 | \$35.12     |
| 73.5 & 73.6 | Request of Exemption of Select Agents and Toxins for an Investigational Product                             | 1    | 1 | 30/60 | 1   | \$35.12 | \$35.12     |

|             |  |     |   |       |      |         |              |
|-------------|--|-----|---|-------|------|---------|--------------|
|             | (APHIS/CDC Form 5) Guidance                        |     |   |       |      |         |              |
| 73.3 & 73.4 | Request for Exclusions                             | 3   | 1 | 30/60 | 2    | \$35.12 | \$70.24      |
| 73.3 & 73.4 | Request for Exclusions Guidance                    | 3   | 1 | 30/60 | 2    | \$35.12 | \$70.24      |
| 73.9        | Documentation of Self-inspection                   | 238 | 1 | 1     | 238  | \$35.12 | \$8,358.56   |
| 73.1        | Request for Expedited Review                       | 1   | 1 | 15/60 | 1    | \$35.12 | \$35.12      |
| 73.11       | Security Plan                                      | 238 | 1 | 5     | 1190 | \$35.12 | \$41,192.80  |
| 73.11       | Security Plan Guidance                             | 238 | 1 | 30/60 | 119  | \$35.12 | \$4,179.28   |
| 73.11       | Security Plan Template                             | 238 | 1 | 30/60 | 119  | \$35.12 | \$4,179.28   |
| 73.12       | Biosafety Plan                                     | 238 | 1 | 5     | 1190 | \$35.12 | \$41,792.80  |
| 73.12       | Biosafety Plan Guidance                            | 238 | 1 | 30/60 | 119  | \$35.12 | \$4,179.28   |
| 73.12       | Biosafety Plan Template                            | 238 | 1 | 30/60 | 119  | \$35.12 | \$4,179.28   |
| 73.13       | Request Regarding a Restricted Experiment          | 1   | 1 | 30/60 | 1    | \$35.12 | \$35.12      |
| 73.13       | Request Regarding a Restricted Experiment Guidance | 1   | 1 | 30/60 | 1    | \$35.12 | \$35.12      |
| 73.14       | Incident Response Plan                             | 238 | 1 | 5     | 1190 | \$35.12 | \$41,792.80  |
| 73.14       | Incident Response Plan Guidance                    | 238 | 1 | 30/60 | 119  | \$35.12 | \$4,179.28   |
| 73.14       | Incident Response Plan Template                    | 238 | 1 | 30/60 | 119  | \$35.12 | \$4,179.28   |
| 73.15       | Training   | 238 | 1 | 30/60 | 119  | \$35.12 | \$4,179.28   |
| 73.15       | Training Guidance                                  | 238 | 1 | 30/60 | 119  | \$35.12 | \$4,179.28   |
| 73.17       | Records  | 238 | 1 | 30/60 | 119  | \$35.12 | \$4,179.28   |
| 73.17       | Guidance on the Inventory of Select Agents         | 238 | 1 | 30/60 | 119  | \$35.12 | \$4,179.28   |
| 73.2        | Administrative Review                              | 1   | 1 | 1     | 1    | \$35.12 | \$35.12      |
|             |  |     |   |       |      |         | \$295,359.20 |
|             |  |     |   |       |      |         |              |

When estimating the annualized burden costs, CDC assumes that the hourly burden would be evenly split between managerial staff and clerical staff. We are using an average hourly respondent labor rate of \$55.81 for managerial staff and \$ 14.42 for clerical staff. To calculate the mean hourly rate, we averaged these two figures for an hourly wage rate of \$35.12. These rates were obtained from the Bureau of Labor Statistics, from the 2013 Occupational Employment Statistics Survey by Occupation (<http://www.bls.gov/oes/>).

**13. Estimates of Other Total Annual Cost Burden to Respondents or Record keepers**

Respondents incur no capital or maintenance costs. The only costs incurred to respondents are those associated with telephone calls, mailing, and fax transmissions. All of these costs are part of normal business expenses.

**14. Annualized Cost to the Government**

The total cost for implementing these regulatory activities budgeted for Fiscal Year 2016 is \$20,210,121 and includes FTE's and contracts.

|  |              |
|--|--------------|
| Compensation summary                                     | \$6,571,707  |
| Personnel benefits                                       | 2,372,450    |
| Travel & transportation: Inspectors                      | 840,771      |
| Transportation: Shipping                                 | 9,000        |
| Rent, telecommunication, other communication & utilities | 92,000       |
| Printing & reproduction                                  | 8,000        |
| Consulting and other services                            | 10,165,257   |
| Supplies & materials                                     | 50,000       |
| Equipment  | 31,984       |
| Grand Total:   | \$20,210,121 |

**15. Explanation for Program Changes or Adjustments**

There was no change in program changes or adjustments.

**16. Plans for Tabulation and Publication and Project Time Schedule**

There are no plans for tabulation and publication of these data.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The display of the OMB expiration date is appropriate.

**18. Exceptions to Certification for Paperwork Reduction Act Submission**

There are no exceptions to the certification.

***List of Attachments:***

|                                   |   |
|-----------------------------------|---|
| Attachment 1                      | Possession, Use and Transfer of Select Agents and Toxins (42 CFR Part 73) – Final Rule                      |
| Attachment 2                      | 60-Day Federal Register Notice  |
| Attachment 2a                     | 60-Day Federal Register Notice Comments   |
| Attachment 3                      | System of Record Notice   |
| Attachment 4<br>Form 3)           | Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3)                               |
| Attachment 4a<br>Form 3) Guidance | Report of Theft, Loss, or Release of Select Agent or Toxin (APHIS/CDC Form 3) Guidance                      |
| Attachment 5a                     | Application for Registration (APHIS/CDC Form 1)   |
| Attachment 5b                     | Application for Registration (APHIS/CDC Form 1) Guidance  |
| Attachment 6                      | Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2)   |
| Attachment 6a                     | Request to Transfer Select Agents and Toxins (APHIS/CDC Form 2) Guidance                                    |
| Attachment 7A                     | Report of Identification of a Select Agent or Toxin from a Clinical/Diagnostic Specimen (APHIS/CDC Form 4A) |
| Attachment 7B                     | Report of Identification of a Select Agent or Toxin from a Proficiency Test (APHIS/CDC Form 4B)             |
| Attachment 7C                     | Federal Law Enforcement Reporting Seizure of Select Agent or Toxin (APHIS/CDC Form 4C)                      |
| Attachment 7i                     | Report of Identification of a Select Agent or Toxin (APHIS/CDC Form 4) Guidance                             |
| Attachment 8                      | Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5)          |
| Attachment 8a                     | Request of Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5) Guidance |
| Attachment 9                      | Request for Exclusions  |

|                |  |
|----------------|--|
| Attachment 9a  | Request for Exclusions Guidance                              |
| Attachment 10  | Documentation of Self-inspection                             |
| Attachment 11  | Request for Expedited Review                                 |
| Attachment 12  | Security Plan  |
| Attachment 12  | Security Plan Guidance                                       |
| Attachment 12  | Security Plan Guidance and Template                          |
| Attachment 13  | Biosafety Plan   |
| Attachment 13a | Biosafety Plan Guidance and Template                         |
| Attachment 13b | Biosafety Plan Template                                      |
| Attachment 14  | Request Regarding a Restricted Experiment                    |
| Attachment 14a | Request Regarding a Restricted Experiment Guidance           |
| Attachment 15  | Incident Response Plan                                       |
| Attachment 15a | Incident Response Plan Guidance and Template                 |
| Attachment 16  | Training   |
| Attachment 16a | Training Guidance  |
| Attachment 17  | Records  |
| Attachment 17a | Guidance on the Inventory of Select Agents                   |
| Attachment 18  | Administrative Review  |
| Attachment 19  | Amendment to Certificate of Registration                     |
| Attachment 20  | Determination of Applicability of Human Subjects Regulations |