

National Select Agent Workshop

Select Agent Forms

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**Select Agent Program
Workshop Series**



Purpose

To discuss specific form changes and how we plan to implement the changes through training



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Why the Changes?

- To adhere to the Office of Management and Budget forms process when making changes
- To streamline the collection of information
- To respond to audit recommendations and public comments



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APHIS/CDC

Form Numbers

APHIS/CDC Form

Form Title

- | | |
|---|--|
| 1 | Registration For Possession , Use, and Transfer of Select Agents and Toxins |
| 2 | Request to Transfer Select Agents and Toxins |
| 3 | Report of Theft, Loss, or Release of Select Agents and Toxins |
| 4 | Report of The Identification of a Select Agent or Toxin |
| 5 | Request for Exemption of Select Agents and Toxins for Public Health or Agricultural Emergency or Investigational Product |



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**Registration for the Possession, Use and Transfer
of Select Agents and Toxins
APHIS/CDC Form 1**



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APHIS/CDC Form 1

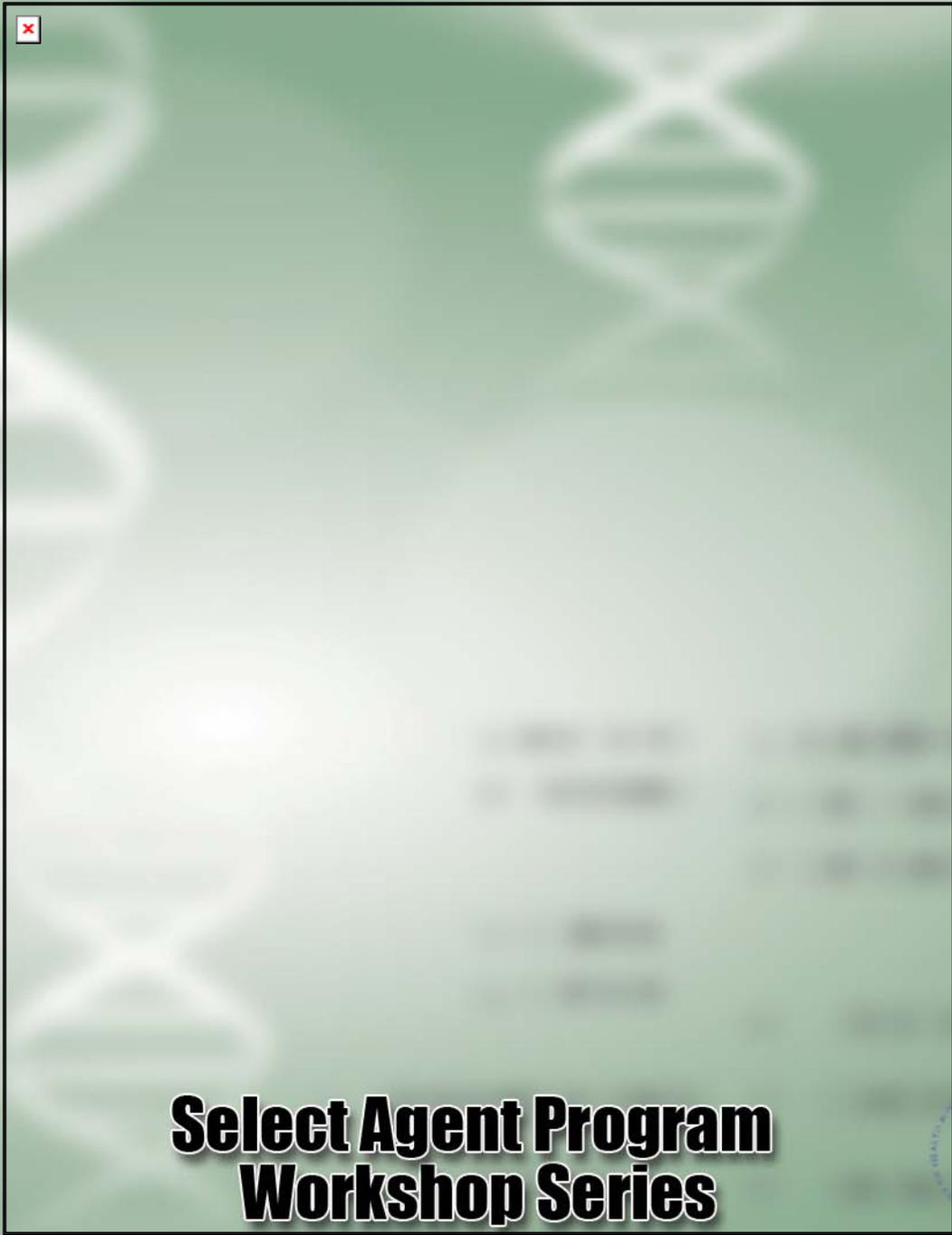
Section Changes

- Section 1 (1B, 1C) – Emergency contact information
- Section 3 – PI focus
- Section 4 – DOJ Unique Identifier Number
- Section 5 – Requirements of the regulations (“unchanging” information)
- Section 6 – Biosafety and Laboratory Information (i.e. objective of work, maximum quantities, work related questions)



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This application is: <input type="checkbox"/> A new registration <input type="checkbox"/> An amendment to an existing registration <input type="checkbox"/> Update to Amendment #: _____	Date
Entity name:	Entity registration number (e.g., A00000000-0000):

SECTION 5 – ENTITY’S SELECT AGENT REQUIREMENTS (TO BE COMPLETED BY RO)

This section should be completed by the RO during the initial request for a certificate registration and any time there is a change in the entity’s procedures noted in Section 5. For information on completing this section, refer to page 3 (B)(6) of the guidance document.

SECTION 5A – SECURITY

1. Each laboratory has a site-specific written security plan: Yes No
 - a. Plan designed according to a site-specific risk assessment and provides graded protection in accordance with the risk of select agent or toxin: Yes No
 - b. Plan contains all information as required by the Select Agent Regulations: Yes No
 - c. The plan is reviewed annually and revised as necessary: Yes No
 - d. Drills or exercises are conducted to validate or test the effectiveness of the plan: Yes No

2. Physical Security (check all that apply):
 - a. Means to limit access to buildings with select agents and toxins:
 - Guard station at the building entrance
 - Locks
 - Card access system
 - Biometric system
 - Intrusion detection system
 - Other (describe): _____
 - b. Means to limit access to rooms with select agents and toxins:
 - Locks
 - Card access system
 - Biometric system
 - Intrusion detection system
 - Other (describe): _____
 - c. Means to limit access to select agents and toxins inside the room:
 - Locked incubators, refrigerators, freezers, etc.
 - Locked box inside incubators, refrigerators, freezers, etc.
 - Biometric system
 - Card access system
 - Intrusion detection system
 - Other (describe): _____
 - d. Means to monitor access to areas where select agents and toxins are used or stored:
 - Electronic logs of access
 - Manual sign in logs
 - Video camera surveillance
 - Other (describe): _____
 - e. Access to select agents and toxins is restricted to individuals that have access approval from the APHIS Administrator or HHS Secretary: Yes No
 - f. Are individuals, not approved for access from the APHIS Administrator or HHS Secretary, allowed access to an area with select agents and toxins without escort by approved individual? Yes No
 - g. The laboratory is secured when no one is present during regular working hours: Yes No

3. Suspicious packages are inspected prior to entry or removal from an area where select agents and toxins are used or stored: Yes No

4. Select agents and toxins are transferred within the entity (intra-entity transfers): Yes No
 - a. Intra-entity transfer is only under the supervision of an individual with access approval from APHIS Administrator or HHS Secretary: Yes No



- b. Chain-of-custody documents are used for intra-entity transfers: Yes No
5. Select agents and toxins are transferred from an individual approved to have access to select agents and toxins directly to a licensed commercial courier services or from a licensed commercial courier service: Yes No

Note: The transfer must be from the approved person to the courier or vice versa not between the courier and the shipping area.

SECTION 5B – BIOSAFETY AND INCIDENT RESPONSE

6. Each laboratory has a written agent-specific, site-specific biosafety plan: Yes No
- a. The plan is commensurate with the risk of the select agent and toxin and contains all information as required by the Select Agent Regulations: Yes No
- b. The plan is reviewed annually and revised as necessary: Yes No
- c. Drills or exercises are conducted to validate or test the effectiveness of the plan: Yes No
7. Personal protective equipment (PPE) recommended for the agents and the work performed is required: Yes No
8. A medical surveillance system is in place for personnel using the select agents and toxins: Yes No
9. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the Responsible Official: Yes No
10. There are policies for the handling of sharps: Yes No
11. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with select agents and toxins at this facility? Yes No N/A
- If yes, has the IBC approved the work proposed in this application: Yes No
- If no, please attach an explanation.
12. The facility has been inspected by USDA, HHS, CLIA, DoE, DoD or others: Yes No
- If yes, please add attachment listing inspection organization/agency name and date of last inspection.
13. Each laboratory has a written incident response plan: Yes No
- a. The plan is commensurate with the hazards of the select agent and toxin and contains all information required by the Select Agent Regulations: Yes No
- b. The plan is reviewed annually and revised as necessary: Yes No
- c. Drills or exercises are conducted to validate or test the effectiveness of the plan: Yes No

SECTION 5C – TRAINING

14. Training:
- a. Security and biosafety training is provided prior to individual's access to areas where select agents and toxins are handled or stored: Yes No
- b. Training addresses the needs of the individual, the work being performed, and risks posed by select agents and toxins: Yes No
- c. Refresher training is provided: Annually Biannually Other (specify frequency): _____
- d. Written records of individuals trained are maintained: Yes No
- e. Personnel are required to demonstrate proficiency in laboratory procedures prior to working with select agents and toxins: Yes No
- f. Provide a brief description of what is included in the training program:
- Biosafety: _____
- Incident Response: _____
- Security: _____
- Other: _____



g. Describe the means used to verify that individuals understood the training (add additional sheets as necessary):

SECTION 5D – RECORDS AND INFORMATION SYSTEMS CONTROL

15. Records specified in Section 17 of the Select Agent Regulations are maintained and current: Yes No

16. Provide a brief explanation of the system in place that ensures records and databases are accurate, their authenticity may be verified, and explains any discrepancies:

17. Describe the means to control access to manual records that would allow for access to select agents and toxins (check all that apply):

- Locks
- Locked filing cabinet, drawer, cabinet, etc.
- Card access system
- Other: _____

18. Describe the means to control access to electronic records and database that would allow access to select agents and toxins (check all that apply):

- Locks
- Card access system
- Password protected
- Firewall protection
- Antivirus protection
- Other: _____
- Network System [inter/intranet]
- Not connected to a network (stand alone system)

19. Name(s) of Individual(s) responsible for inventory of select agent(s) and toxin(s): _____

a. Inventory record is reconciled: Annually Biannually Other (specify frequency): _____

b. Inventory tracking includes the following information (list): _____

This application is: <input type="checkbox"/> A new registration <input type="checkbox"/> An amendment to an existing registration <input type="checkbox"/> Update to Amendment # _____	Date _____
Entity name: _____	Entity registration number (e.g., A00000000-0000): _____

SECTION 6 – BIOSAFETY AND LABORATORY INFORMATION ON SELECT AGENTS AND TOXINS

Make additional copies of this section of the form as needed for *each* PI at your entity. Each PI should complete the appropriate section for laboratories under his/her control where select agents are used or stored. For information on completing this section, refer to page 3 (B)(7) of the guidance document.

SECTION 6A – TO BE COMPLETED BY ALL ENTITIES FOR EACH PRINCIPAL INVESTIGATOR

Provide the following information on a **separate line** for each laboratory safety level: the select agent or toxin; the strain designation of the select agent or toxin, the building and room number(s) where each select agent or toxin will be used and stored, and laboratory safety level for each PI (or Chief Scientist). For entities only **storing** and not actively working with select agents or toxins, do not complete "laboratory area" column. For information on completing this section, refer to page 3 (B)(7) of the guidance document.

Select Agent/Toxin	Strain Designation (list "N/A" if not applicable or "TBA" if to be acquired)	Laboratory Area		Storage Area		Laboratory Safety Level*	Principal Investigator
		Bldg	Room	Bldg	Room		

*Biosafety Level 2=BSL2 Animal Biosafety Level 2=ABSL2 rDNA BSL2=NIHBL2 rDNA Large Animal BSL2=NIH BL2N rDNA Large Scale BSL2=NIH BL2-LS
 Biosafety Level 3=BSL3 Animal Biosafety Level 3=ABSL3 rDNA BSL3=NIHBL3 rDNA Large Animal BSL3=NIH BL3N rDNA Large Scale BSL3=NIH BL3-LS
 Biosafety Level 4=BSL4 Animal Biosafety Level 4=ABSL4 rDNA BSL4=NIHBL4 rDNA Large Animal BSL4=NIH BL4N rDNA Large Scale BSL4=NIH BL4-LS
 Plant=BSL2 Plant=BSL3 Biosafety Level 3 Agriculture=BSL3ag Toxin= 29 CFR 1910.1450, 29 CFR 1910.1200 and BMBL



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This application is: <input type="checkbox"/> A new registration <input type="checkbox"/> An amendment to an existing registration	Date
<input type="checkbox"/> Update to Amendment #:	
Entity name:	Entity registration number (e.g., A00000000-0000):

SECTION 6B – TO BE COMPLETED FOR EACH PRINCIPAL INVESTIGATOR WORKING WITH SELECT AGENTS/TOXINS

1. Provide the objectives of the work for each select agent or toxin listed in Section 6A, including a description of the methodologies or laboratory procedures that will be used. Each PI should also complete each sub-section as appropriate for this work. If no work is being performed on select agent or toxin, indicate storage only. For information on completing this section, refer to page 4 of the guidance document. Attach additional sheets if needed:

2. Additional PIs performing the same objective of work: Yes No
If yes, list _____

3. Provide an estimate of the maximum quantities (e.g., number of petri dishes or total volume of liquid media) and concentration of each organism grown at a given time (e.g., 2 - 250 ml flasks of 10⁷ cfu/ml). If select agent will not be propagated, then indicate "no propagation of agent". Attach additional sheets if needed:

a. Agent/Toxin: _____ Maximum Quantities: _____

b. Agent/Toxin: _____ Maximum Quantities: _____

c. Agent/Toxin: _____ Maximum Quantities: _____

d. Agent/Toxin: _____ Maximum Quantities: _____

4. All cultures, stock and other regulated wastes are decontaminated before removal from the containment area: Yes No

If yes, describe method:

Autoclaved (temperature, time, and psi): _____

Chemical (disinfectant, concentration, and time): _____

Irradiation: _____

Other: _____

SECTION 6C –WORK WITH TOXINS

5. Will work be performed with toxins or with agents that produce regulated amounts of toxins? Yes No
If yes, complete questions 6 – 10.

6. A Chemical Hygiene Plan is available for the laboratory using toxins: Yes No

7. The toxin is produced by viable agent at the entity: Yes No
If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____

8. Dilution procedures and other manipulations of the concentrated toxins are performed: Yes No

a. If yes, conducted in: Fume hood Biological safety cabinet

b. If a fume hood or biosafety cabinet is used, certification is conducted:
 Annually Biannually Other (describe): _____

c. Work is conducted with two knowledgeable people present: Yes No

9. A hazard sign is posted on the door when toxins are in use: Yes No

10. All cultures, stock and other regulated wastes are decontaminated before removal from the containment area: Yes No

If yes, describe method:

Autoclaved (temperature, time, and psi): _____

Chemical (disinfectant, concentration, and time): _____

Irradiation: _____

Other: _____



SECTION 6D –WORK WITH GENETIC ELEMENTS, RECOMBINANT NUCLEIC ACIDS, OR RECOMBINANT ORGANISMS

11. Will work be performed with genetic elements, recombinant nucleic acids, recombinant organisms, or antibiotic resistant select agents? Yes No
 Yes No
 Yes No
 Yes No
 If yes, complete questions 12 – 16.
12. Will you be possessing, using or transferring the following:
- a. Nucleic acids that can produce infectious forms of any of the select agent viruses. Yes No
- b. Recombinant nucleic acids that encode for the functional form(s) of any select toxins if the nucleic acids:
- 1) can be expressed in vivo or in vitro. Yes No
- 2) are in a vector or recombinant host genome and can be expressed in vivo or in vitro. Yes No
- c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. Yes No
13. Provide a brief description of the recombinant constructs and any associated expression control elements, including what the recombinant DNA encodes for, if known: _____
14. Give an estimate of range of length of recombinant DNA to be used: _____
15. Are you intending to conduct experiments that introduce antibiotic resistance markers/traits into select agents/toxins? Yes No
- If yes, provide the agent/toxin and antibiotic being used:
- a. Select Agent/Toxin: _____ Antibiotic: _____
- b. Select Agent/Toxin: _____ Antibiotic: _____
- c. Select Agent/Toxin: _____ Antibiotic: _____
16. Will experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD₅₀ < 100 ng/kg body weight? Yes No
- If yes, list toxin and provide a brief description of the restricted experiment: _____

Note: An individual or entity may not conduct a restricted experiment as defined under 7 CFR 331.13, 9 CFR 121.13, and 42 CFR 73.13 unless approved by the APHIS Administrator and HHS Secretary.

SECTION 6E – WORK WITH ANIMALS

17. Will work be performed with animals? Yes No
 If yes, complete questions 18 – 22.
18. Provide the agent/toxin and animal being used:
- a. Select Agent/Toxin: _____ Species of Animal: _____ Route of Administration: _____
- b. Select Agent/Toxin: _____ Species of Animal: _____ Route of Administration: _____
- c. Select Agent/Toxin: _____ Species of Animal: _____ Route of Administration: _____
19. How are animal waste and animal carcasses treated prior to disposal (e.g., carcasses, sewage, bedding, etc.) by an approved method:
- Not treated
- Autoclaved (temperature, time, and psi): _____
- Chemical (disinfectant, concentration, and time): _____
- Irradiation: _____
- Other: _____
20. The entity requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this entity. Yes No
- If yes, the proposed work with select agents and toxins in animals has been approved by the IACUC: Yes No
21. The laboratory is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC): Yes No
- If yes, give accreditation date: _____
22. Is there a system in place for recording the number of animals received and the number of animals disposed of and are the records reviewed frequently? Yes No
- If yes, please describe: _____



SECTION 6F – WORK WITH PLANTS

23. Will work be performed with plants? Yes No
 If yes, complete questions 24 – 36.
24. Provide the agent/toxin and plant being used:
- a. Select Agent/Toxin: _____ Species of Plant: _____ Route of Administration: _____
 b. Select Agent/Toxin: _____ Species of Plant: _____ Route of Administration: _____
 c. Select Agent/Toxin: _____ Species of Plant: _____ Route of Administration: _____
25. Work will be done in a glass or greenhouse: Yes No
 If yes, provide a description of the glass or greenhouse:
 Laminated Glass Tempered Glass Polycarbonate Other (describe): _____
26. Structure is reinforced: Yes No
27. Floor is concrete: Yes No
28. Vents into facility: Yes No
29. Floor drains: Yes No
30. Waste water collection and treatment, prior to release into sanitary sewer system: Yes No
31. Greenhouse HVAC supply and exhaust:
- a. Negative air pressure is maintained inside greenhouse: Yes No
 b. Greenhouse exhaust air is re-circulated to other areas of the facility: Yes No
 If yes, HEPA filtration of all exhaust air is in place: Yes No
32. Vectors present: Yes No
 If yes, vectors are restricted to cages: Yes No
33. Work will be done in growth chambers: Yes No
- a. If yes, the growth chamber is integrated into the laboratory building structure: Yes No
 b. If yes, the growth chamber is stand alone: Yes No
 c. Manufacture name: _____ Model number: _____
34. Growth chamber has floor drains: Yes No
 If yes, waste water is collected and treated prior to release into sanitary sewer system: Yes No
35. Growth chamber HVAC supply and exhaust:
- a. Negative air pressure is maintained inside the growth chamber: Yes No
 b. Growth chamber exhaust air is re-circulated to other areas of the facility: Yes No
 If yes, HEPA filtration of all exhaust air is in place: Yes No
36. Plant waste is treated prior to disposal (e.g., soil, plant material, etc.) by an approved method:
- Not treated
 Autoclaved (temperature, time, and psi): _____
 Chemical (disinfectant, concentration, and time): _____
 Irradiation: _____
 Other: _____

SECTION 6G –LABORATORY INFORMATION

This section should be completed for each laboratory safety level listed in Section 6A under the control of the PI.

37. Laboratory(ies) is/are currently operational: Yes No
 If no, indicate on floor plan which laboratory/laboratories are not operational and the date of anticipated certification/commission of laboratory.
38. Include a floor plan for each laboratory under the control of the PI where select agents or toxins listed in Section 6A are to be used or stored (for all laboratory safety levels). Floor plan(s) for all laboratory safety levels include: entry into laboratory and locations of equipment (e.g., sink, eyewash, biological safety cabinets (BSC), fume hoods, freezer, refrigerator, incubator, centrifuges, autoclave, and incinerator), HVAC supply and exhaust, and cage washing area (if applicable).



39. A facility risk assessment was performed to determine biosafety level: Yes No
 a. If yes, what was the determination:
 BSL2 BSL3 BSL4 ABSL2 ABSL3 BSL3 Ag ABSL4
 Other: _____
 b. List the resources/references used: _____

40. Define certification period for BSC located in laboratory: Annual Biannual Other (explain): _____
41. Laboratory exhaust is re-circulated to other areas of the facility: Yes No
42. The laboratory is maintained at negative air pressure to provide directional air into the laboratory: Yes No
43. Laboratory is separated from open and unrestricted areas: Yes No
44. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the laboratory: Yes No
45. An alarm system is provided to warn laboratory personnel of exhaust system failure: Yes No
46. HEPA filtration of all exhaust air is in place: Yes No

SECTION 6H – BSL3 AG LABORATORIES

47. Will work with animals be performed in BSL-3 Ag Laboratory? Yes No
 If yes, complete questions 48 – 59.
48. Describe where infected animals will be housed during and after experiments:

49. Personnel assigned to work with infected animals work in pairs: Yes No
50. Aerosol experiments are conducted in this BSL-3 Ag laboratory: Yes No
51. There is a mandatory daily inspection of the containment parameters for the BSL-3 Ag laboratory area(s) and critical life support systems: Yes No
52. Supplies, material and equipment enter BSL-3 Ag space only through an airlock, fumigation chamber, and interlocked and double-door autoclave or shower. Yes No
53. All walls are constructed slab-to-slab and walls, floors, and ceilings of the BSL-3 Ag laboratory rooms are sealed. All penetrations into the laboratory are sealed airtight to prevent escape of contained agents and to allow gaseous fumigations for biological decontamination: Yes No
54. Bench tops are seamless or sealed surfaces that are impervious to water and resistant to moderate heat and organic solvents, acids, alkalis, and other decontaminant chemicals: Yes No
55. Laboratory furniture is capable of supporting anticipated loads and uses and is covered with a non-fabric material that can be easily decontaminated: Yes No
56. Differential pressures/directional airflow are monitored and alarmed (visually and audibly) to indicate system failure: Yes No
57. There is HEPA filtration of all supply and exhaust air from the room(s), inner change room(s), and anteroom(s): Yes No
 If yes, all HEPA filters are tested and certified annually: Yes No
58. Appropriate communication systems are provided between the laboratory and external personnel (intercom, phone, fax, and computer): Yes No
59. All drains in the cabinet room(s), inner change room(s), and autoclave chambers connect directly to an appropriate liquid waste decontamination system: Yes No
 If yes, describe method utilized for decontamination of BSL-3 Ag area(s):



Request to Transfer Select Agents and Toxins APHIS/CDC Form 2



**Select Agent Program
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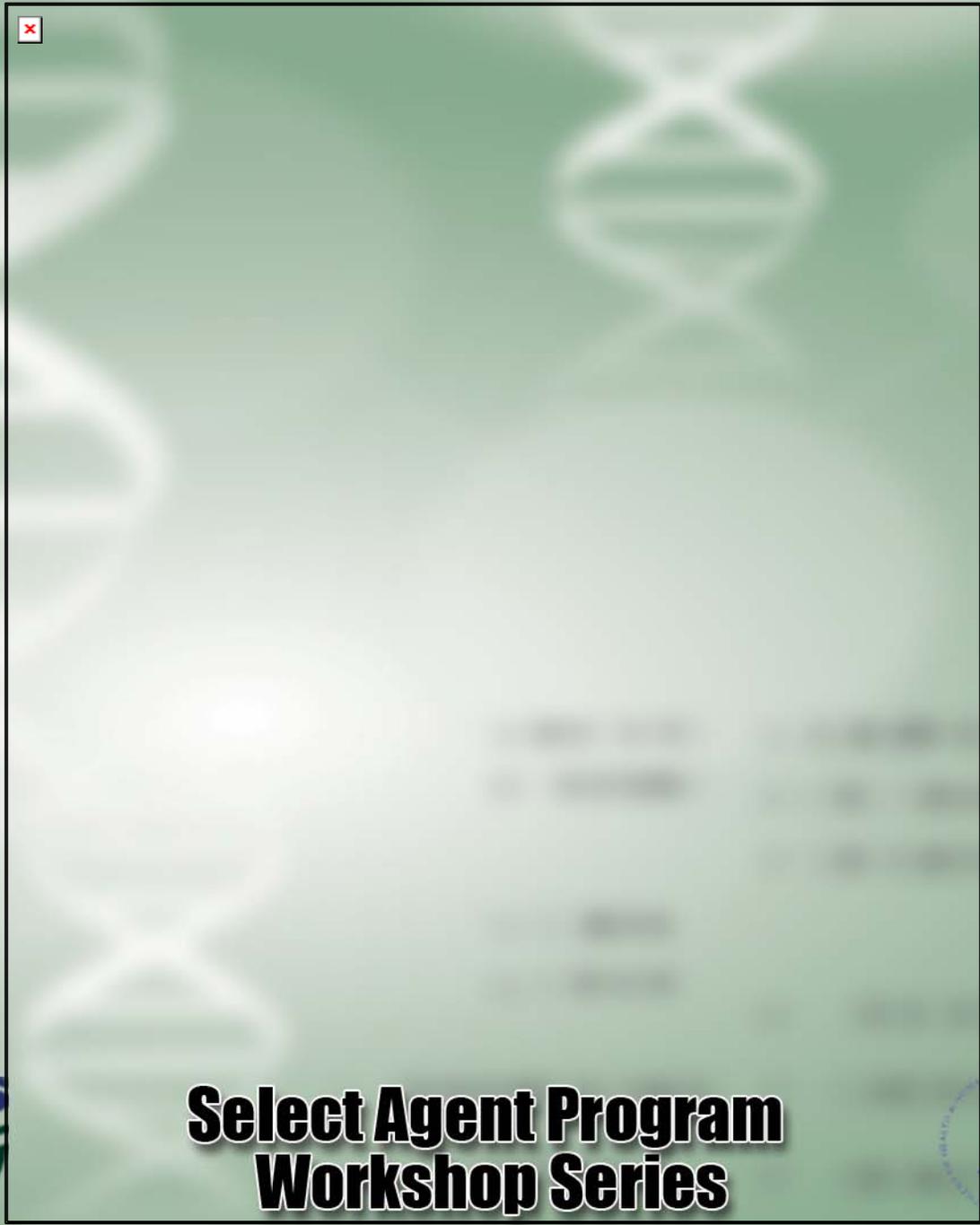
Changes to APHIS/CDC Form 2

- HHS-Office of Inspector General Audit:
 - Requiring the recipient to submit the initial request
 - Sender notified of the expected shipment date
 - Verify if the shipment did not occur
- Public Comments:
 - Illegible forms caused by multiple faxing
 - Essential information needed for the form



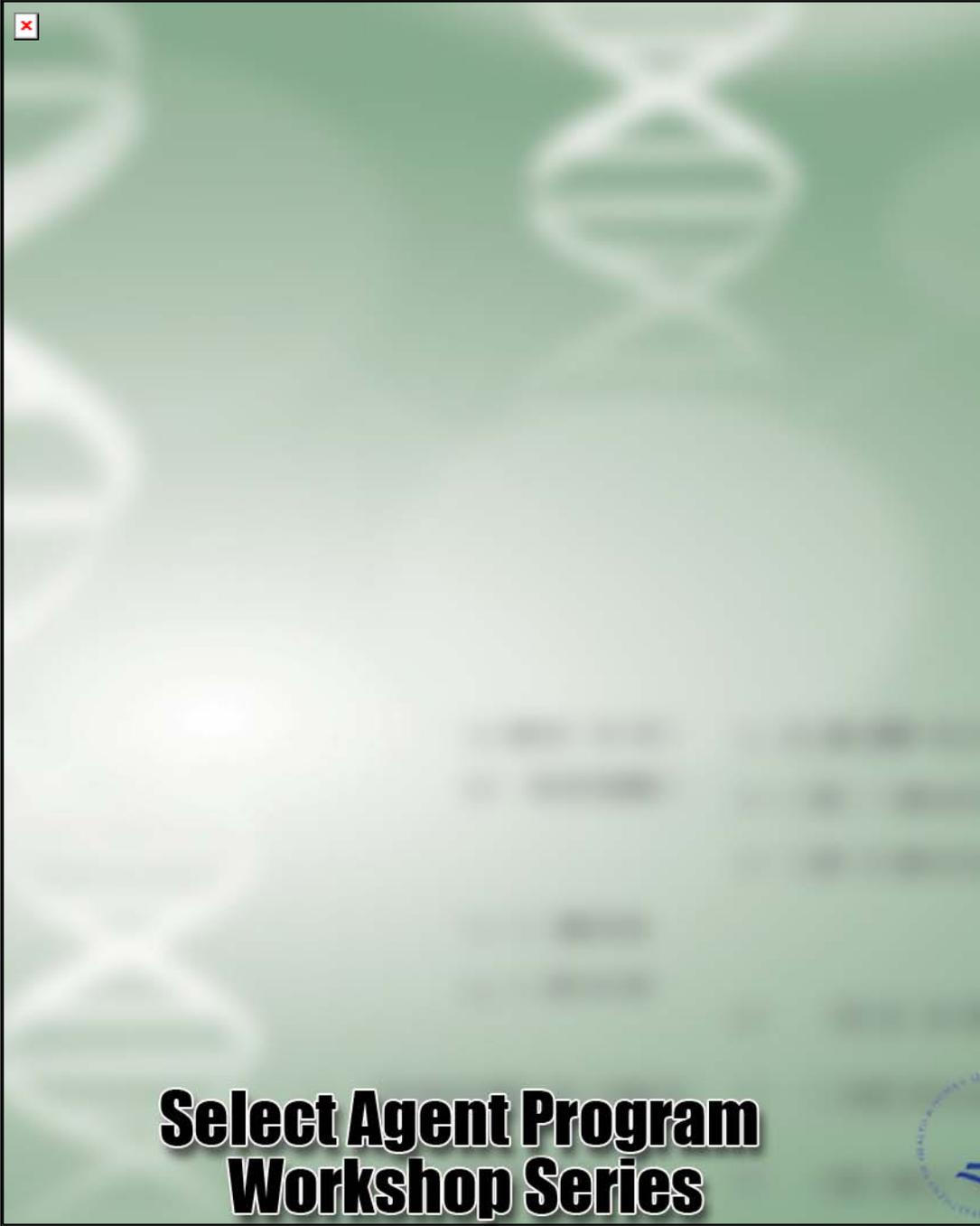
**Select Agent Program
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Select Agent Program Workshop Series



Report of The Identification of a Select Agent or Toxin

APHIS/CDC Form 4



**Select Agent Program
Workshop Series**



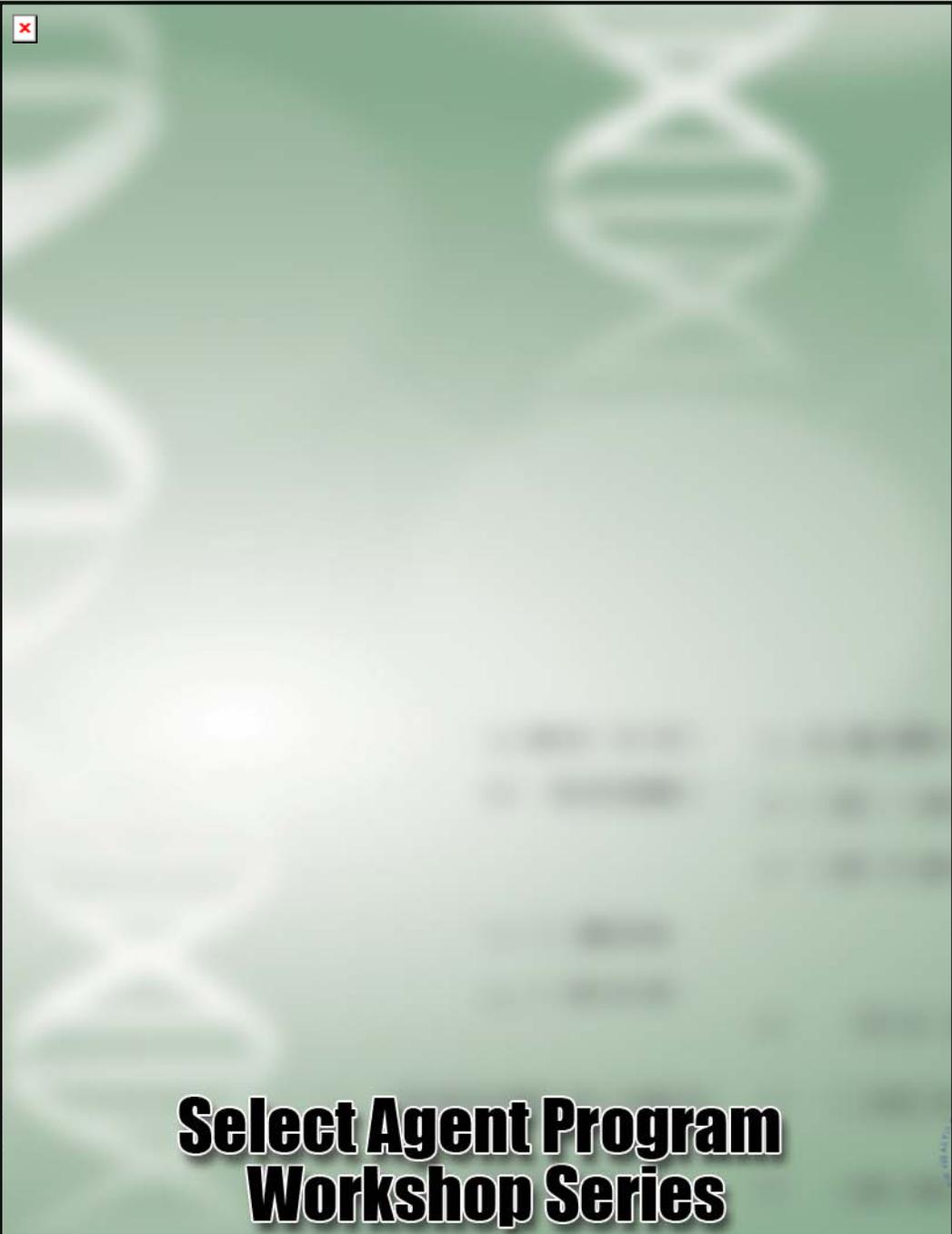
Changes to APHIS/CDC Form 4

- Separate Sections based on purpose
 - Diagnosis/Verification
 - Proficiency Testing
 - FBI Notification
- Chain of custody concept
 - The reference laboratory (laboratory that confirms the identification of the select agent) completes Section C for all entities who sent them the specimen or isolate.
- “One case one form”
 - Example: The case (e.g., patient) generates multiple specimens (e.g., tissue, fluid) and/or multiple specimen types that are cultured on various media (e.g., 15 blood agar plates) would be listed as 1 case with the information provided in block 15.



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SECTION 2 – TO BE COMPLETED BY LABORATORY THAT RECEIVED PROFICIENCY TESTING			
SECTION A – LABORATORY INFORMATION			
31. Entity name:		32. Entity registration number:	
33. Address (NOT a post office address):		34. City:	35. State: 36. Zip Code:
37. Responsible Official or Facility Director name First: MI: Last:		38. Telephone #:	
39. FAX #:		40. E-mail address:	
41. Was there a possibility of an exposure while working with this sample? <input type="checkbox"/> No <input type="checkbox"/> Yes (if Yes, please complete APHIS/CDC Form 3.)			
SECTION B – SELECT AGENTS AND TOXINS IDENTIFIED FROM PROFICIENCY TESTING			
42. Select agent and strain designation (if known) or toxin being reported:		43. Total quantity identified:	
44. Location where proficiency testing was conducted Building: Room:		45. BSL of laboratory or PPQ containment designation:	
46. Name of laboratory test that proficiency test was designed to assess:		47. Date obtained from sponsor:	
48. Sponsor/entity that you received select agent or toxin from: <input type="checkbox"/> College of American Pathologists <input type="checkbox"/> Registered entity (Entity name, APHIS or CDC registration number): _____ <input type="checkbox"/> Other (Explain): _____			
49. Disposition of select agent or toxin: <input type="checkbox"/> Transferred to a registered entity (Give entity name and APHIS/CDC registration number. Include a copy of the approved APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins"): _____ <input type="checkbox"/> Destroyed on site: <input type="checkbox"/> Autoclaving <input type="checkbox"/> Chemical (Describe: _____) <input type="checkbox"/> Incineration <input type="checkbox"/> Irradiation <input type="checkbox"/> Other: _____ Date select agent or toxin was destroyed: _____ <input type="checkbox"/> Retained and transferred via intra-entity transfer to (Give name of Principal Investigator and/or Amendment #): _____ Date select agent or toxin was transferred: _____			

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, or 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Signature of Responsible Official/Facility Director: _____ Date: _____



SECTION 3 – TO BE COMPLETED BY FEDERAL LAW ENFORCEMENT AGENCY			
SECTION A – FEDERAL LAW ENFORCEMENT INFORMATION			
50. Name of federal law enforcement agent First: MI: Last:		51. Telephone #:	
52. Badge #:		53. E-mail address:	
54. Select agent and strain designation (if known) or toxin being seized:		55. Total quantity identified:	
SECTION B – ENTITY INFORMATION			
56. Disposition of select agent or toxin: <input type="checkbox"/> Transferred to a registered entity (Give entity name and APHIS/CDC registration number.): _____ <input type="checkbox"/> Destroyed on site: <input type="checkbox"/> Autoclaving <input type="checkbox"/> Chemical (Describe: _____) <input type="checkbox"/> Incineration <input type="checkbox"/> Irradiation <input type="checkbox"/> Other: _____ Date select agent or toxin was destroyed: _____			
57. Entity name:		58. Entity registration number:	
59. Address (NOT a post office address):		60. City:	61. State: 62. Zip Code:
63. Responsible Official name First: MI: Last:		64. Telephone #:	
65. FAX #:		66. E-mail address:	
67. Select agent and strain designation (if known) or toxin being seized:		68. Total quantity identified:	

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 7 CFR 331, 9 CFR 121, or 42 CFR 73 may result in civil or criminal penalties, including imprisonment.

Signature of Agent: _____ Date: _____

Public reporting burden: Public reporting burden of providing this information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

APHIS/CDC Form 4 (XX/XX/XXXX)



Discussion of Changes

- Theft, Loss or Release of Select Agent and Toxins
(APHIS/CDC Form 3)
- Request for Exemption of Select Agents and Toxins
for Public Health or Agricultural Emergency or
Investigational Product
(APHIS/CDC Form 5)



**Select Agent Program
Workshop Series**



Training



**Select Agent Program
Workshop Series**



Training on Forms and Processes

- Development of a web-based training module
- Internal and external training



**Select Agent Program
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Questions?



**Select Agent Program
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