Guidance Document for the Completion of APHIS/CDC Form 4

Clinical/Diagnostic Identification (Form 4A)
Any person or entity, including any clinical or diagnostic laboratory, having identified a select agent or toxin contained in a specimen or sample presented for diagnosis or verification is required by Federal regulations (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73) to report this identification by submitting a completed and signed **APHIS/CDC Form 4A** to either APHIS or CDC within the time proscribed by the Select Agent regulations. This requirement applies regardless of whether the person or entity is registered with the Select Agent Program.

Proficiency Testing Identification (Form 4B)
Any person or entity, including any clinical or diagnostic laboratory, having identified a select agent or toxin contained in a specimen or sample presented for proficiency testing is required by Federal regulations (9 CFR Part 121 and 42 CFR Part 73) to report this identification by submitting a completed and signed **APHIS/CDC Form 4B** to either APHIS or CDC within the time proscribed in the Select Agent regulations. This requirement applies regardless of whether the person or entity is registered with the Select Agent Program.

Federal Law Enforcement Seizure (Form 4C)
A Federal law enforcement agency that seizes a select agent or toxin is required by Federal regulations (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73) to report this seizure by submitting a completed and signed **APHIS/CDC Form 4C** to either APHIS or CDC within the time proscribed by the Select Agent regulations.

<u>Additional requirements for all persons or entities:</u>

- The identification of any of the select agents or toxins listed under 7 CFR §331.3, 9 CFR §121.5(a)(3)(i), 9 CFR §121.9(c)(1)), 42 CFR §73.5(a)(3)(i), or 42 CFR § 73.9(c)(1) must be immediately reported to APHIS or CDC by email, facsimile, or telephone.
- The identified or seized select agent or toxin must be secured against theft, loss, or release during the period between identification or seizure and final disposition.
- Unless otherwise directed by either CDC's Division of Select Agents and Toxins or the APHIS' Agriculture Select Agent Services, within 7 calendar days after identification of the select agent or toxin contained in a specimen presented for diagnosis or verification or 90 days of receipt for proficiency testing, the identified select agent or toxin must be transferred in accordance with 7 CFR §331.16, 9 CFR §121.16 or 42 CFR §73.16 or destroyed on-site by a recognized sterilization or inactivation process.
    - For select agents or toxins seized by a Federal law enforcement agency, the select agent or toxin must be destroyed or transferred to an entity eligible to receive such agent or toxin as soon as practicable.
- The select agent or toxin may be retained only if the entity is currently registered for the select agent or toxin identified.

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APHIS/CDC Form 4A – Reference Laboratory Report

Any person or laboratory which identifies or confirms a select agent or toxin presented in a specimen or sample needs to complete the Form 4A within seven calendar days after identification. Upon request, less stringent reporting may be approved based on extraordinary circumstances (e.g., agricultural emergencies, widespread outbreaks, endemic areas). Please see Frequently Asked Questions for further information.

Section A – Reference Laboratory Information

Block A1 – Name of Individual Completing the Form:

- Please provide the full legal name of the personnel at your entity that is most familiar with the case(s) being reported on the APHIS/CDC Form 4 (e.g., Principal Investigator; Microbiology Supervisor, Biosafety Officer).

Block A2 – Email Address:

- Please provide the email address for the individual listed in *Block A1*.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included. If additional space is required to include the full email address please enter it in the "Comments/Notes" section.

Block A3 – Telephone Number:

- Please provide the telephone number including the area code for the individual listed in *Block A1*; including any extension.

Block A4 – Registration Information:

- For entities registered with the APHIS or CDC Select Agent Program, please check the box labeled "Registered Entity (APHIS or CDC registration number)" and enter the registration number exactly as it appears on your entity's current certificate of registration. Please do not provide the entity's application number; provide only the thirteen digit registration number (e.g. A00000000-0000 *or* C00000000-0000).
    - If you do not know your entity's current registration number, please contact your Responsible Official.
- For entities not registered with the APHIS or CDC Select Agent Program, check the box titled "Clinical or diagnostic laboratory [non-registered entity (NRE)]" and enter your entity's NRE number. This number will be provided to your entity after the first APHIS/CDC Form 4 report is submitted.
    - If you do not know your entity's NRE number please contact APHIS or CDC to obtain the NRE number.
    - If your entity has not been assigned an NRE number please check the box and leave the field blank. An NRE number will be assigned and emailed to the individuals listed in Section A for use on future Form 4A submissions.

Block A5 – Responsible Official or Laboratory Supervisor Name:

- For entities registered with APHIS or CDC, please provide the complete name of your entity's Responsible Official (RO), exactly as it appears on the current certificate of registration. If the RO is listed in Block A1 please skip to Block A9.

- For non-registered entities, please provide the full legal name of your entity's Facility or Laboratory Supervisor or the individual who supervises the laboratory that handled or manipulated the identified select agent or toxin (e.g., Microbiology Supervisor). If this individual is listed in Block A1 please skip to block A9.
    - For the purposes of the APHIS/CDC Form 4, the term "full legal name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.
    - For the purposes of the APHIS/CDC Form 4, the term "Facility or Laboratory Supervisor" refers to the person ultimately responsible for the overall operation and administration of the laboratory and who ensures that quality standardized testing methods provide accurate and reliable results.

Block A6 – E-mail Address:

- Please provide the email address for the individual listed in *Block A5*.

Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included. If additional space is required to include the full email address please enter it in the "Comments/Notes" section.

Block A7 – Telephone #:

Please provide the telephone number including the area code for the individual listed in *Block A5*; including any extension.

Block A8 – FAX #:

- Please provide the 10-digit fax number for the entity listed in *Block A9*.

Block A9 – Entity Name:

- For entities registered with APHIS or CDC, please provide the name of your entity exactly as it appears on your entity's current certificate of registration.
    - If you do not know your entity's registration name, please contact your Responsible Official.
- For non-registered entities, please provide the complete name of your entity under which the business conducts its operations
- Please do not abbreviate the entity name (e.g., International Business Machine Corporation instead of IBM).

Blocks A10-13 – Entity's Address:

- For entities registered with APHIS or CDC, please provide your entity's complete address, exactly as it appears on your current certificate of registration.
- For non-registered entities, please provide the complete address of your entity.
- A P.O. Box address is not acceptable.
- Please provide only the five digit zip code.

Section B – Select Agents and Toxins Identified from Clinical/Diagnostic Specimens

Block B1 – Select Agent or Toxin Identified:

- List only one select agent or toxin.
  - If more than one select agent or toxin is identified please use additional APHIS/CDC Form 4s to report those agents.
- Do not abbreviate the name of a select agent or toxin.
- Use the name of the select agent or toxin exactly as it appears in the Select Agent regulations (Select Agent/Toxin List).
- Do not list an agent or toxin that is not a select agent or toxin.

Note: The following select agents and toxins identified in a specimen presented for diagnosis or verification are required to be immediately reported to APHIS or CDC by email, facsimile, or telephone.

Immediate Notification Required	
Bacillus anthracis	**Variola major virus (Smallpox virus)**
Botulinum neurotoxins	**Variola minor (Alastrim)**
Botulinum neurotoxin producing species of *Clostridium*	***Yersinia pestis***
Burkholderia mallei	
Burkholderia pseudomallei	
Ebola virus	
Foot-and-mouth disease virus	
Francisella tularensis	
Marburg virus	
Rinderpest virus	

Block B2 – Date Identified:

- Enter the date that the select agent or toxin was identified.
- Enter only one date in Block B2.

Block B3 – Case/patient ID#:

- If your entity assigns a unique, internal tracking number, specimen ID, or reference number to the specimen, enter it in Block B3.

Block B4 – Number of Samples:

- Enter the number of samples that were produced and tested for the patient or animal. If more samples are anticipated see Block B11 for more information.

Block B5 – Sample Type:

When selecting clinical/diagnostic specimen or isolate, **indicate where the sample type originated from: human, animal, or plant.** Refer to the description of the terms listed below for indicating the type of sample analyzed and select only one sample type. If more than one type of specimen or sample was analyzed, please select the **one specimen or sample type** that was used to identify the select agent or toxin.

- **Clinical/diagnostic specimen** – a sample (not the isolate) that was directly derived from an individual human, animal, or plant.

- For samples originating from an animal (nonhuman) or plant, please provide the genus and species of the organism from which the sample originated (e.g., *Capra aegagrus*, *Bos taurus*, *Zea mays*, *Triticum aestivum*).

- **Isolate** – A purified culture obtained from a specimen or sample taken from a host or the environment.
  - For samples originating from an animal (nonhuman) or plant, please provide the genus and species of the organism from which the sample originated (e.g., *Capra aegagrus*, *Bos taurus*, *Zea mays*, *Triticum aestivum*).
- **Environmental sample** – a sample that was not directly derived from a human, animal, or plant (e.g., water sample, soil sample, air sample).
- **Food sample-** a sample that was directly derived from a food source, food container or food by-product.

Block B6 – Case/Patient Origin (zip code):

- Enter the zip code from which the patient, animal or plant is located.
- If the zip code is unknown enter the city and state.

Block B7 – Type of test performed (e.g., PCR, mouse bioassay, ELISA):

- Enter the type of test that was performed to identify the select agent or toxin.
- If multiple tests were performed please list them all.

Block B8 – Disposition of Select Agent or Toxins (check all that apply)*:*

Transferred:

- Check the "Transferred" box if all *or* part of the identified select agent or toxin was transferred to another entity.
- Please provide the name of the entity, exactly as it appears on their current certificate of registration and the date that the transfer request was submitted to the APHIS or CDC for approval. If you do not know the entity's registered name, please contact their Responsible Official to obtain this information.
- To request prior authorization to transfer select agent(s) or toxin(s) identified for research purposes, APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins," must be submitted to either APHIS or CDC. To ensure that your entity receives authorization from APHIS or CDC to transfer the select agent or toxin, you need to verify that the recipient is registered for that agent or toxin.

Destroyed:

- Check the "Destroyed on site" box only if the *entire* identified select agent or toxin was destroyed on site.
- Indicate the method of destruction in the space provided. Below are the approved recognized methods that can be used:
  - Autoclave
  - Irradiation
  - Incineration
  - Chemical- Indicate the type of chemical was used.
  - Expended/Consumed

- Commercial medical waste disposal company - please note that any confirmed select agent or toxin contained within a sample needs to be destroyed on site before releasing material to the commercial medical waste disposal company.
- Other- If selected you must provide a description of the method.

- Provide the date on which the entire identified select agent or toxin was destroyed. ***Do not*** state that the identified select agent or toxin will be destroyed at a future date. If the identified select agent or toxin is to be destroyed at a future date you ***must*** check the "Retained" box and follow the procedures listed below under Retained.

Retained:

- Check the "Retained" box if all ***or*** part of the identified select agent or toxin was retained by your entity.
  - The select agent or toxin may be retained only if the entity is currently registered for the select agent and toxin identified.
- Please provide the name of the Principal Investigator who is registered for the use, storage, and disposition of the retained select agent or toxin.

Block B9 – Exposure outside Primary Containment:

- If there is any possibility that personnel handled the sample containing a select agent or toxin outside primary containment (e.g., working with culture on open bench), this box should be checked "Yes" and an APHIS/CDC Form 3 must be submitted.

Block B10 – Additional Samples Anticipated:

- If there is possibility that the case/patient will produce additional samples, this box should be checked "Yes."

Block B11 – Sample Provider Notified:

- Please select "Yes" if the facility that provided the specimen has been notified of the identification of the select agent or toxin. If the sample provider has not been notified of the identification select "No." If your facility processed the original sample select "N/A" and skip to field 17.
- If there is a sample provider for the specimen, please request sections C and D be completed and signed by each laboratory that was in possession of the specimen.

Block B12 – Sample Provider Entity Name:

- Please provide the name of the entity that provided the sample to the clinical/diagnostic or reference laboratory listed in Section A.
  - For sample providers that are registered with APHIS or CDC, please provide the name of the entity exactly as it appears on their current certificate of registration.
    - If you do not know their registered name, please contact their Responsible Official.
  - For non-registered entities, please provide the complete name of the entity under which the business conducts its operations (e.g., International Business Machine Corporation instead of IBM). Please do not abbreviate the entity name.

- In instances where the sample provider is a doctor's office or small medical clinic which does not have a laboratory section, please provide, at a minimum, the name of the treating physician, veterinarian, or botanist, as well as a direct e-mail address and a telephone number for this individual.

Block B13 – Sample Provider Point of Contact Name:

- Please provide the full legal name of the person at the sample provider entity that is the most familiar with the case(s) being reported on the APHIS/CDC Form 4 report (e.g., Principal Investigator; Microbiology Supervisor, Biosafety Officer).

Block B14 – Sample Provider E-mail Address:

- Please provide the email address for the individual listed in Block B14.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included. If additional space is required to include the full email address please enter it in the "Comments/Notes" section.

Block B15 – Sample Provider Contact Number:

- Please provide the telephone number (including the area or country code if outside the U.S.) for the individual listed in Block B14; including any extension.

Block B16 – Comments/Notes:

- Please provide any information as it relates to the case. Attach additional sheets if necessary.

Signature:

- For all entities, the individual named in Block A5 (RO, ARO, Facility Director or Laboratory Supervisor), must sign and date the signature line.

Section C – Sample Provider Information

Block C1 – Name of Individual Completing the Form:

- Please provide the full legal name of the personnel at your entity that is most familiar with the case(s) being reported on the APHIS/CDC Form 4 report (e.g., Principal Investigator; Microbiology Supervisor, Biosafety Officer).

Block C2 – Email Address:

- Please provide the email address for the individual listed in Block C1.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included. If additional space is required to include the full email address please enter it in the "Comments/Notes" section.

Block C3 – Telephone Number of Individual Completing the Form:

- Please provide the direct dial 10-digit telephone number for the individual listed in Block C1; including any extension.

Block C4 – Registration Information:

- For entities registered with the APHIS or CDC Select Agent Program, please check the box labeled "Registered Entity (APHIS or CDC registration number)" and enter

the registration number exactly as it appears on your entity's current certificate of registration. Please do not provide the entity's application number; provide only the thirteen digit registration number (e.g. A00000000-0000 *or* C00000000-0000).

  - If you do not know your entity's current registration number, please contact your Responsible Official.

- For entities not registered with the APHIS or CDC Select Agent Program, check the box titled "Clinical or diagnostic laboratory [non-registered entity (NRE)]" and enter your entity's NRE number. This number will be provided to your entity after the first APHIS/CDC Form 4 report is submitted.
  - If you do not know your entity's NRE number please contact APHIS or CDC to obtain the NRE number.

Block C5 – Responsible Official or Laboratory Supervisor Name:

- For entities registered with APHIS or CDC, please provide the complete name of your entity's Responsible Official (RO), exactly as it appears on the current certificate of registration. If the RO is listed in Block C1 please skip to Block C9.
- For non-registered entities, please provide the full legal name of your entity's Facility or Laboratory Supervisor or the individual who supervises the laboratory that handled or manipulated the identified select agent or toxin (e.g., Microbiology Supervisor).
  - For the purposes of the APHIS/CDC Form 4, the term "full legal name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.
  - For the purposes of the APHIS/CDC Form 4, the term "Facility or Laboratory Supervisor" refers to the person ultimately responsible for the overall operation and administration of the laboratory and who ensures that quality standardized testing methods provide accurate and reliable results.

Block C6 – E-mail Address:

- Please provide the email address for the individual listed in Block C5.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included. If additional space is required to include the full email address please enter it in the "Comments/Notes" section.

Block C7 – Telephone #:

Please provide the direct dial 10-digit telephone number for the individual listed in Block C5; including any extension.

Block C8 – FAX #:

Please provide the 10-digit Fax number for the entity listed in Block C9.

Block C9 – Entity Name:

- For entities registered with APHIS or CDC, please provide the name of your entity exactly as it appears on your entity's current certificate of registration.
  - If you do not know your entity's registration name, please contact your Responsible Official.

- For non-registered entities, please provide the complete name of your entity under which the business conducts its operations
- Please do not abbreviate the entity name (e.g., International Business Machine Corporation instead of IBM).

Blocks C10-13 – Entity's Address:

- For entities registered with APHIS or CDC, please provide your entity's complete address, exactly as it appears on your current certificate of registration.
- For non-registered entities, please provide the complete address of your entity.
- A P.O. Box address is not acceptable.
- Zip Code – please provide only the five digit zip code.

Section D – Specimen (s) Containing Select Agent or Toxin Provided to Reference Laboratory

Block D1 – Select Agent or Toxin Identified by Reference Laboratory:

- List only one select agent or toxin.
- Do not abbreviate the name of a select agent or toxin.
- Use the name of the select agent or toxin exactly as it appears in the Select Agent regulations (Select Agent/Toxin List).
- Do not list an agent or toxin that is not a select agent.

Block D2 – Date Notified by Reference Laboratory of the Select Agent Identification:

- Enter the date that your facility was notified about the identification of the select agent or toxin was confirmed by the reference laboratory.
- Enter only one date in *Block D6*.

Block D3 – Case/patient ID#:

- If your entity assigns a unique, internal tracking number, specimen ID, or reference number to the specimen enter it in Block D3.

Block D4 – Number of Specimen (s) Provided:

- Enter the number of samples that were produced and tested for the patient or animal. If more samples are anticipated see Block D12 for more information.

Block D5 – Sample Type:

When selecting clinical/diagnostic specimen or isolate, **indicate where the sample type originated from: human, animal, or plant.** Refer to the description of the terms listed below for indicating the type of sample analyzed and select only one sample type. If more than one type of specimen or sample was analyzed, please select the **one specimen or sample type** that was used to definitively identify the select agent or toxin.

- **Clinical/diagnostic specimen** – a sample (not the isolate) that was directly derived from an individual human, animal, or plant.
    - For samples originating from an animal (nonhuman) or plant, please provide the genus and species of the organism from which the sample originated (e.g., *Capra aegagrus*, *Bos taurus*, *Zea mays*, *Triticum aestivum*).

- **Isolate** – A purified culture obtained from a specimen or sample taken from a host or the environment.
    - For samples originating from an animal (nonhuman) or plant, please provide the genus and species of the organism from which the sample originated (e.g., *Capra aegagrus*, *Bos taurus*, *Zea mays*, *Triticum aestivum*).
- **Environmental sample** – a sample that was not directly derived from a human, animal, or plant (e.g., water sample, soil sample, air sample).
- **Food sample-** a sample that was directly derived from a food source, food container or food by-product.

Block D6 – Case/Patient/Sample Origin (Zip Code):

- Enter the zip code from which the patient, animal, or plant is located.
- If the zip code is unknown please enter the city and state.

Block D7 – Date sample(s) shipped to Reference Laboratory:

- Enter the date the samples were transferred to the reference laboratory.

Block D8 – Name of Reference Laboratory:

- Enter the name of the reference laboratory to which the samples were transferred.
- If the samples were transferred to multiple laboratories list additional laboratories in the "Comment/Notes."

Block D9 – Disposition of Select Agent or Toxin (check all that apply):

Destroyed:

- Check the "Destroyed on site" box only if the remaining identified select agent or toxin was destroyed on site.
- Indicate the method of destruction in the space provided. Below are the approved recognized methods that can be used:
    - Autoclave
    - Irradiation
    - Incineration
    - Chemical- Indicate the type of chemical was used.
    - Expended/Consumed
    - Commercial medical waste disposal company - please note that any confirmed select agent or toxin contained within a sample needs to be destroyed on site before releasing material to the commercial medical waste disposal company.
    - Other- If selected you must provide a description of the method.
- Provide the date on which the entire identified select agent or toxin was destroyed. ***Do not*** state that the identified select agent or toxin will be destroyed at a future date. If the identified select agent or toxin is to be destroyed at a future date you ***must*** check the "Retained" box and follow the procedures listed below under Retained.

Retained:

- Check the "Retained" box if all ***or*** part of the identified select agent or toxin was retained by your entity.

- The select agent or toxin may be retained only if the entity is currently registered for the select agent and toxin identified.

Please provide the name of the Principal Investigator who is registered for the use, storage, and disposition of the select agent or toxin.

Not applicable:
Check this box if the ***entire*** sample was transferred to the reference laboratory.

Block D10 – Exposure outside Primary Containment:

- If there is any possibility that personnel handled the sample containing a select agent or toxin outside primary containment (e.g., working with culture on open bench), this box should be checked "Yes" and an APHIS/CDC Form 3 must be submitted.

Block D11 – Source of the samples:

- If your entity was the source of the samples that were sent to the reference laboratory check "Yes" and skip to field 18.

Block D12 – Additional Samples Anticipated:

- If there is a possibility that the case/patient will produce additional samples, this box should be checked "Yes."
- All samples relating to the initial case (e.g., hospitalized patient during one, continuous visit) will not require an additional APHIS/CDC Form 4. Please provide the disposition of all additional samples to either APHIS or CDC along with the accession number (provided to you by APHIS or CDC).

Block D13 – Sample Provider Notified:

- Please select "Yes" if the facility that provided the specimen has been notified of the identification of the select agent or toxin. If the sample provider has not been notified of the identification select "No."
- If there is a sample provider for the specimen, please request sections C and D be completed and signed by each laboratory that was in possession of the specimen.

Block D14 – Sample Provider Entity Name:

- Please provide the name of the entity that provided the sample to the clinical/diagnostic or reference laboratory listed in Section C.
  - For sample providers that are registered with APHIS or CDC, please provide the name of the entity exactly as it appears on their current certificate of registration.
    - If you do not know their registered name, please contact their Responsible Official.
  - For non-registered entities, please provide the complete name of the entity under which the business conducts its operations (e.g., International Business Machine Corporation instead of IBM). Please do not abbreviate the entity name.
- In instances where the sample provider is a doctor's office or small medical clinic which does not have a laboratory section, please provide, at a minimum, the name of the treating physician, veterinarian, or botanist, as well as a direct e-mail address and a direct dial telephone number for this individual.

Block D15 – Sample Provider Point of Contact Name:

- Please provide the full legal name of the person at the sample provider entity that is the most familiar with the case(s) being reported on the APHIS/CDC Form 4 report (e.g., Principal Investigator; Microbiology Supervisor, Biosafety Officer).

Block D16 – Sample Provider E-mail Address:

- Please provide the email address for the individual listed in BlockD15.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included. If additional space is required to include the full email address please enter it in the "Comments/Notes" section.

Block D17 – Sample Provider Telephone Number:

- Please provide the direct telephone number (including the area or country code if outside the U.S.) for the individual listed in BlockD15; including any extension.

Block D18 – Comments/Notes:

- Please provide any information as it relates to the case. Attach additional sheets if necessary.

Signature:

- For all entities, the individual named in Block C5 (RO, ARO, Facility Director or Laboratory Supervisor), must sign and date signature line.

APHIS/CDC Form 4B – Proficiency Testing

Complete the Form 4B within 90 calendar days of receipt of samples. For registered entities, the information provided on this form should match the information submitted for the entity's certificate of registration. A select agent or toxin that is contained in a specimen or sample for proficiency testing may be transferred from a sponsor to an entity without prior authorization from APHIS or CDC provided that, at least seven calendar days prior to the transfer, the sending sponsor reports to APHIS or CDC the select agent or toxin to be transferred and the name and address of the recipient (See 7 CFR 331.16, 9 CFR 121.16 and 42 CFR 73.16).

Section A – Information for Laboratory That Received Proficiency Testing Sample(s)

Block A1 – Name of Individual Completing the Form:

- Please provide the full legal name of the personnel at your entity that is most familiar with the case(s) being reported on the APHIS/CDC Form 4 report (e.g., Principal Investigator; Microbiology Supervisor, Biosafety Officer).

Block A2 – Email Address:

- Please provide the email address for the individual listed in *Block A1*.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included. If additional space is required to include the full email address please enter it in the "Comments/Notes" section.

Block A3 – Telephone Number of Individual Completing the Form:

- Please provide the telephone number including the area code for the individual listed in *Block A1*; including any extension.

Block A4 – Registration Information:

- For entities registered with the APHIS or CDC Select Agent Program, please check the box labeled "Registered Entity (APHIS or CDC registration number)" and enter the registration number exactly as it appears on your entity's current certificate of registration. Please do not provide the entity's application number; provide only the thirteen digit registration number (e.g. A00000000-0000 *or* C00000000-0000).
    - If you do not know your entity's current registration number, please contact your Responsible Official.
- For entities not registered with the APHIS or CDC Select Agent Program check the box titled "Clinical or diagnostic laboratory [non-registered entity (NRE)]" and enter your entity's NRE number. This number will be provided to your entity after the first APHIS/CDC Form 4 report is submitted.
    - If you do not know your entity's NRE number please contact APHIS or CDC to obtain the NRE number.

Block A5 – Entity Name:

- For entities registered with APHIS or CDC, please provide the name of your entity exactly as it appears on your entity's current certificate of registration.
    - If you do not know your entity's "registration name" please contact your Responsible Official.
- For non-registered entities, please provide the complete name of your entity under which the business conducts its operations.
- Please do not abbreviate the entity name (e.g., International Business Machine Corporation instead of IBM).

Block A6 – Responsible Official or Laboratory Supervisor Name:

- For entities registered with APHIS or CDC, please provide the complete name of your entity's Responsible Official (RO), exactly as it appears on the current certificate of registration.
- For non-registered entities, please provide the full legal name of your entity's Facility or Laboratory Supervisor or the individual who supervises the laboratory that handled or manipulated the identified select agent or toxin (e.g., Microbiology Supervisor).
    - For the purposes of the APHIS/CDC Form 4, the term "full legal name" refers to an individual's first name, middle initial(s), and last name or surname, without use of nicknames.
    - For the purposes of the APHIS/CDC Form 4, the term "Facility or Laboratory Supervisor" refers to the person ultimately responsible for the overall operation and administration of the laboratory and who ensures that quality standardized testing methods provide accurate and reliable results.

Block A7 – Entity's Address:

- For entities registered with APHIS or CDC, please provide your entity's complete address, exactly as it appears on your current certificate of registration.
- For non-registered entities, please provide the complete address of your entity.

- A P.O. Box address is not acceptable.

Block A8 – Telephone #:

- Please provide the telephone number including the area code for the individual listed in *Block A6*; including any extension.

Block A9 – FAX #:

- Please provide the 10-digit Fax number for the individual listed in *Block A6*.

Blocks A10- E-mail Address:

- Please provide the email address for the individual listed in *Block A6*.
- Please print or type clearly and ensure the email domain (e.g., .org, .gov, .edu, .com, .net) is included. If additional space is required to include the full email address please enter it in the "Comments/Notes" section.

Block A11- City:

- Please provide the city where the facility is located.
  - For entities registered with APHIS or CDC, please provide your entity's city exactly as it appears on your current certificate of registration.
  - For non-registered entities, please provide your entity's city where the testing laboratory is located.

Block A12- State:

- Please provide the state where the facility is located.
  - For entities registered with APHIS or CDC, please provide your entity's state exactly as it appears on your current certificate of registration.
  - For non-registered entities, please provide your entity's state where the testing laboratory is located.

Block A13 – Zip code:

- Please provide only the five digit zip code.

Block A14 – Sponsor/Entity that You Received Select Agent or Toxin from:

- Please provide the following information for any entity that provided you with a proficiency sample for testing:
  - For entities registered with APHIS or CDC, please provide the name of their entity, their entity registration number (if known), and their entity contact information (telephone, e-mail, and address).
  - For non-registered entities, please provide the name of their entity, and their entity contact information (telephone, e-mail, and address).
  - Please do not abbreviate the entity name.

Section B – Select Agents and Toxins Identified from Proficiency Testing

Multiple select agents identified in proficiency testing samples can be entered into the table containing *Blocks B1-3*.

Block B1 – Select Agent or Toxin Identified:

- List select agent or toxin(s).

- Do not abbreviate the name of a select agent or toxin.
- Use the name of the select agent or toxin exactly as it appears in the Select Agent regulations (Select Agent/Toxin List).
- Do not list an agent or toxin that is not a select agent or toxin.
- List the strain designation for the identified select agent (if known).

Block B2 – Date Obtained from Sponsor:

- Please provide the date that the proficiency sample was received by your entity.

Block B3 – Date Identified:

- Please provide the date that the select agent or toxin within the proficiency sample was identified by your entity.

Block B4 – Disposition of Select Agents or Toxins (check all that apply)*:*

Transferred:

- Check the "Transferred" box if all ***or*** part of the identified select agent or toxin was transferred to an entity that is currently registered for the select agent or toxin identified.
- Please provide the name of the entity, exactly as it appears on their current certificate of registration and the date that the transfer request was submitted to the APHIS or CDC for approval. If you do not know the entity's registered name, please contact their Responsible Official to obtain this information.
- To request prior authorization to transfer select agent(s) or toxin(s) identified for research purposes, APHIS/CDC Form 2, "Request to Transfer Select Agents and Toxins," must be submitted to either APHIS or CDC. To ensure that your entity receives authorization from APHIS or CDC to transfer the select agent or toxin, you need to verify that the recipient is registered for that agent.

Destroyed:

- Check the "Destroyed on site" box only if the ***entire*** identified select agent or toxin was destroyed on site.
- Indicate the method of destruction in the space provided. Below are the approved recognized methods that can be used:
  - Autoclave
  - Irradiation
  - Incineration
  - Chemical- Indicate the type of chemical was used.
  - Expended/Consumed
  - Commercial medical waste disposal company - please note that any confirmed select agent or toxin contained within a sample needs to be destroyed on site before releasing material to the commercial medical waste disposal company.
  - Other- If selected you must provide a description of the method.
- Provide the date on which the entire identified select agent or toxin was destroyed. ***Do not*** state that the identified select agent or toxin will be destroyed at a future date. If the identified select agent or toxin is to be destroyed at a future date you

must check the “Retained” box and follow the procedures listed below under Retained.

Retained:

- Check the “Retained” box if all *or* part of the identified select agent or toxin was retained by your entity.
  - The select agent or toxin may be retained only if the entity is currently registered for the select agent and toxin identified.
- Please provide the name of the Principal Investigator who is registered for the use, storage, and disposition of the retained select agent or toxin.

Block B5 – Exposure Outside Primary Containment:

- If there is a possibility that personnel handled the sample containing a select agent or toxin outside primary containment (e.g., working with culture on open bench), this box should be checked “Yes” and an APHIS/CDC Form 3 must be submitted.

Signature:

- For all entities, the individual named in Block A6 (RO, ARO, Facility Director or Laboratory Supervisor), must sign and date the signature line.

APHIS/CDC Form 4C – Federal Law Enforcement Seizure Report

Form 4C is *only* for use by Federal law enforcement agencies who are reporting the seizure of a select agent or toxin. Complete this section within seven calendar days after seizure and/or final disposition of select agents or toxins. If you need assistance completing this section, please contact APHIS or CDC directly.

Document Change History

Version	Date	Summary of Changes
1.0	August 2009	Initial Release
2.0	November 2015	Updated to reflect revisions to Form 4