FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 05/31/2005

GUIDANCE DOCUMENT FOR REPORTING THE IDENTIFICATION OF A SELECT AGENT OR TOXIN IN A CLINICAL OR DIAGNOSTIC LABORATORY

INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188) signed into law on June 12, 2002, requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select agents and toxins were published by HHS (42 CFR 73) and by USDA (9 CFR 121 and 7 CFR 331).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, HHS/CDC and the USDA/APHIS have developed a common reporting form for this data collection. This form is designed to assist entities in complying with this legal obligation.

Clinical or diagnostic laboratories that have identified the following select agents and toxins from diagnostic or verification testing activities are required by law (42 CFR 73.6) to contact CDC immediately: Variola major virus (Smallpox virus) and Variola minor (Alastrim), *Bacillus anthracis*, *Yersinia pestis*, Botulinum neurotoxins, *Francisella tularensis*, Ebola viruses, Marburg virus, Lassa fever virus, and South American Hemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito). CDC should be contacted by telephone at 404-498-2255, facsimile at 404-498-2265, or e-mail at lrsat@cdc.gov.

For HHS/USDA overlap agents, the applicant should contact either APHIS or CDC. For USDA agents and toxins, the applicant should contact APHIS by telephone at 301-734-5960 or facsimile at 301-734-3652. A listing of HHS select agents and toxins is available at http://www.cdc.gov/od/sap. A listing of USDA animal agents and toxins is available at http://www.aphis.usda.gov/vs/ncie/bta.html. The list of plant agents and toxins is available at http://www.aphis.usda.gov/ppq/permits.

The select agents and toxins obtained through diagnosis or verification must be destroyed or transferred to a registered entity within 7 days of identification. Select agents and toxins used for proficiency testing must be destroyed or transferred to a registered entity within 90 days after receipt. A "Report Of Transfer Of Select Agents And Toxins" form (CDC form EA-101; APHIS form 2041) must be completed in addition to this form for transferring agents. This form must be submitted to CDC or APHIS, as appropriate, within 7 days after identification of select agents or toxins.

INSTRUCTIONS

Entities that have obtained select agents and toxins through diagnosis or verification must complete sections 1, 2 or 3, and 5. Section 5 may require "Report Of Transfer Of Select Agents And Toxins" form (CDC form EA-101; APHIS form 2041) to be completed in addition to this form. Section 3 of the form allows for bi-weekly reporting by veterinary diagnostic entities that identify select agents or toxins in areas where the select agent is endemic or during outbreaks. An entity may request bi-weekly reporting by submitting a request in writing to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737 or by faxing it to 301-734-3652.

Those entities that obtained select agents and toxins for proficiency testing must complete sections 1, 4, and 5. All forms must be signed and dated.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact the CDC at (404) 498-2255 or APHIS at (301) 734-5960. This guidance document and form are also available at http://www.cdc.gov/od/sap, http://www.aphis.usda.gov/vs/ncie/bta.html and http://www.aphis.usda.gov/ppq/permits .

WHERE TO SEND THE COMPLETED FORM

For HHS agents, return completed forms to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333.

For USDA agents, return completed forms to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737.

For HHS/USDA overlap select agents, return forms to: either CDC or APHIS at the addresses provided.

This form shall not be disclosed under the Freedom of Information Act. Under Public Law 107-188, information derived from this form is also protected from release.

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REPORT OF THE IDENTIFICATION OF A SELECT AGENT OR TOXIN IN A CLINICAL OR DIAGNOSTIC LABORATORY

Read all instructions carefully before completing the form. Answer all items completely and type or print in ink. The form must be signed. For HHS agents, submit document to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333. For USDA agents, submit document to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737. For HHS/USDA overlap agents submit the form to either CDC or APHIS.

SECTION 1 – TO BE COMPLETED BY LABORATORY DIRECTOR

Legal name of entity	Entity registration number (*if applicable*) APHIS# CDC#			
Address (NOT a post office address)	City	State	Zip Code	
Name of laboratory director	Title	Telephone	FAX	E-mail
Address (NOT a post office address)	City	State	Zip Code	
Select agent being reported:	Name of laboratory supervisor (if applicable):			
Name and strain designation of select agent (if known) / toxin:				
Provide any data regarding molecular, phenotypic, or morphological characterization of select agent(s):				
Location where work with specimens was conducted: Building: Room:	Biosafety level of laboratory or PPQ containment designation:			

SECTION 2 –TO BE COMPLETED FOR SELECT AGENTS AND TOXINS FROM CLINICAL/DIAGNOSTIC TESTING

INFORMATION ON AGENT/ TOXIN

Source of select agent isolate(s):

- ☐ Clinical or diagnostic specimen (Specify from which species):
  - Specimen type: Blood Tissue Other (specify):
- ☐ Environmental sample (specify type):
- ☐ Isolate (Specify laboratory that sent isolate):
- ☐ Other (specify):

INFORMATION ON CLINICAL CASE FROM WHICH THE SELECT AGENT OR TOXIN WAS OBTAINED

Name of person most familiar with the case		Telephone
Description of the disease:		
Number of cases	Date first case observed	How diagnosis was made
Laboratory that confirmed original diagnosis	Name, address and phone of laboratory director	

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SECTION 3 –INFORMATION ON DIAGNOSTIC CASES FROM WHICH SELECT AGENTS AND TOXINS WAS OBTAINED (OUTBREAK/ENDEMIC AREAS)

Name of person most familiar with the case	Telephone

Description of the disease:

Identification date of index case	Number of cases (bi-weekly total)	How diagnosis was made

Laboratory that confirmed original diagnosis	Name, address and phone of laboratory director

SECTION 4 –TO BE COMPLETED FOR SELECT AGENTS AND TOXINS FROM PROFICIENCY TESTING

Entity that you obtained select agent from:
☐ College of American Pathologists
☐ Registered entity (Name, CDC or APHIS registration number):
☐ Other (Explain):

Date obtained

Name of laboratory test that proficiency test was designed to assess:

SECTION 5 –TO BE COMPLETED BY ALL ENTITIES

INFORMATION ON DESTRUCTION OR TRANSFER OF SELECT AGENTS AND TOXINS

Date(s) agent was isolated or toxin was detected	Amount of agent / toxin on site prior to destruction or transfer

Select agent was:
☐ Transferred to a registered entity (give name, CDC or APHIS entity registration number, date, and CDC or APHIS confirmation Number):

Note: Entities must complete "Report Of Transfer Of Select Agents And Toxins" form (CDC form EA-101; APHIS form 2041) in addition to this section

☐ Destroyed on site
If destroyed on site: Date select agent was destroyed: _ Method of destruction:
☐ Other (Provide detailed explanation):

Is this source expected to provide additional specimens? ☐ No ☐ Yes	Anticipated quantity of specimens to be received:

Anticipated time period to receive specimen (give estimated end date):

I certify that all select agents and toxins isolated by this entity have been transferred or disposed of according to all Federal, State and local regulations. 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 42 CFR 73, 9 CFR 121, or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Laboratory Director: _____ Typed or printed name:

Date: _____

Public reporting burden: Public reporting burden of providing this information is estimated to average 60 minutes 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-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

CDC 0.1318 (E) (05/31/2005); APHIS 2044 (E) (05/31/2005)
(CDC Adobe Acrobat 5.0 Electronic Version, 8/2004)

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