Application

Laboratory Registration
and
Select Agent Transfer Tracking System

42 CFR 72.6

Additional Requirements for Facilities Transferring or Receiving Select Agents

16 MARCH 2001

Office of Health and Safety
Office of the Director
Centers for Disease Control and Prevention
Atlanta, GA 30333

OMB 0920-0199

Laboratory Registration and Select Agent Transfer Tracking System

Contents of Application Package

Attachments (Attachments include the regulation and several update/clarification documents. All applicants should review these before attempting to complete the application forms)

1. 42 CFR Part 72.6 Additional requirements for facilities transferring or receiving select agents; Final Rule. Federal Register, Oct. 24, 1996.
2. Site Registration Fee Schedule and Related Matters for Facilities Transferring or Receiving Select Agents; Notice. Federal Register, April 14, 1997.
3. Table of Select Agent Toxins - LD_{50} for Mice.
4. Suspension of Site Registration Fee for Facilities Transferring or Receiving Select Agents; Notice. Federal Register, November 27, 1998.
5. Supplement to CDC/NIH Biosafety in Microbiological and Biomedical Laboratories.
6. EA-101 instructions
7. Importation of Select Agents

Application for Laboratory Registration Overview

This application package is for facilities required to register to transfer or receive select agents under Public Law 104-132 and its implementing regulation (42 CFR 72.6 - *Additional Requirements for Facilities Transferring or Receiving Select Agents*). Oversight of facility registration and tracking of select agent transfers required by the regulation has been delegated by the Department of Health and Human Services to the Centers for Disease Control and Prevention (CDC).

The regulation requires that a responsible facility official (RFO) be identified, that the facility demonstrate its ability to work safely with select agent(s), and that registered facilities keep records of select agents transferred to and from their facilities. The purpose of the RFO is to ensure management oversight of the transfer process. He or she will be the designated individual responsible for all activities related to the handling or transfer of select agents under the regulation. 42 CFR 72.6 (j) defines the "responsible facility official" as the official authorized to transfer and receive select agents on behalf of the transferor and/or requestor's facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility. The responsible facility official must review and sign the "Background Information/Certification and Signature" form, and will be the person contacted if CDC has questions concerning the application or other matters related to the regulation. The RFO should consult with others (e.g., engineering support services, principal investigators) as necessary to obtain the information required for this application. The RFO may designate an alternate responsible facility official in cases where extended absences or other circumstances warrant, however the RFO is ultimately responsible for ensuring that the facility is meeting the requirements of 42 CFR 72.6. The RFO is also responsible for notifying CDC of any changes to the registration, such as modifications to currently registered laboratories, or changes in protocols from what was originally submitted.

Facilities wishing to register must submit an application to CDC for review. A copy of 42 CFR 72.6 and subsequent Federal Register Notices are included as attachments to this application package. Please read these documents carefully to determine whether your facility is required to register before you complete this application. Note that there are some exemptions to the registration requirement (see 42 CFR 72.6 subsection (h)). The RFO will also perform a facility risk assessment, based on the requirements for handling that agent, to ensure that the facility meets those requirements. If information supplied in the application package indicates that the facility is properly equipped and capable of handling and transferring select agents, CDC will issue a registration certificate to the facility. The registration is valid for three years. All facilities will be subject to inspection during the three year registration period. If a facility's application fails to document that the facility is properly equipped and capable of work with select agents, or if the application is incomplete, the facility will not be registered. CDC will inform the facility of the problems with the facility and/or the application by contacting the designated RFO. When these problems are resolved by the facility, the facility may again seek registration. Allow at least 8 weeks for processing. Submission of an incomplete application will result in a significant delay in processing your application.

The information you provide on this application will not be routinely shared with other government agencies or other entities. However, information will be provided on request to federal law enforcement agencies, and to other entities as required under the Freedom of Information Act (5 USC 552).

Contents of this application package

Please note that this application has been revised. This application package is also available on the CDC internet website: http://www.cdc.gov/od/ohs/lrsat.htm

Instructions for Registration of Facility

Forms required to be completed by all applicants

(1) "Background Information/Certification and Signature" form (Section 2). This form must be signed by the responsible facility official for your institution. Indicate the select agents your facility works with and intends to receive or transfer under this regulation. Facilities registering for nonviable material or genetic elements only should indicate this to the side of the applicable select agent listed on the form.

(2) Information about Select Agents facility intends to work with or transfer. All facilities are required to complete Section 3A (Table on page 3-2), and Section 3B. Complete Sections 3C through 3G as appropriate for your facility.

Facility Risk Assessments and Safety Levels; Requirements for Handling Select Agents

All Select Agent facilities must base their facility risk assessments on the applicable sections of the most recent edition of the BMBL, NIH Guidelines, 29 CFR 1910.1450 or other required assessment materials.

- Laboratories working with live select agent viruses, bacteria, fungi or rickettsiae will base their facility risk assessments on the most current edition of the CDC/NIH BMBL. Use the BMBL and the BMBL supplement (Attachment 5) to determine the appropriate Biosafety Level (BSL) for the various types of work you will do with each of the select agents you have listed in Section 3A.
- Laboratories working with recombinant DNA, genetic elements, or inactivated agents may refer to either the appropriate BMBL-based requirements, and/or those of the *NIH Guidelines for Research Involving Recombinant DNA* to determine the recommended Biosafety Level (BSL) for the various types of work you will do with each of the select agents you have listed in Section 3A. The responsible facility official may determine this based on which document is used for that institution's policies and procedures for work with those select agents. Institutions using recombinant DNA for large animal studies or in large scale production should base their facility risk assessments on the *NIH Guidelines*, as there are no corresponding sections in the BMBL.
- Laboratories working with select agent toxins must meet the requirements of 29 CFR 1910.1450 and the toxin guidelines contained in the appendix of the current edition of the BMBL. If the facility is also working with intact toxin-producing organisms or recombinant DNA encoding for select agent toxins, the laboratory should base its facility risk assessments on the BMBL and/or *NIH Guidelines* in addition to 29 CFR 1910.1450. Certain uses of the select agent toxins are exempt from the requirements of this regulation (see 42 CFR 72.6 subsection (h).

Send the completed application package to:

Centers for Disease Control and Prevention
Office of Health and Safety
Laboratory Registration/Select Agent Transfer Program
1600 Clifton Road, NE., Mail Stop A13
Atlanta, GA 30333

Additional materials you may need

(1) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). The BMBL is available on the internet at http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm, or you may obtain a single copy of this document by faxing a request to CDC, Office of Health and Safety. The fax number is 404-639-0880. An errata sheet for the most current edition of the BMBL is available at the internet website: http://www.cdc.gov/od/ohs/biosfty/bmbl4/toc.htm . Please note that some corrections are applicable to Select Agent transfers.

(2) *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines),* March 1996 or more recent edition. The *NIH Guidelines* are available on the internet at http://www4.od.nih.gov/oba/guidelines.html, or contact NIH (phone 301-496-9838).

(3) 29 CFR 1910.1450 - *Occupational Exposure to Hazardous Chemicals in the Laboratory.* Available on the Internet at http://www.osha.gov/ or from the U.S. Government Printing Office (phone 202-512-1800).
(4) Additional information and clarification is available through the CDC Laboratory Registration/Select Agent Transfer Program website: www.cdc.gov/od/ohs/lrsat.htm.

How to amend your registration
To add, delete or change information on your registration, complete Section 3A (Table on page 3-2), Section 3B, and Sections 3C through 3G as appropriate, to include any new information not currently on file with CDC. In addition, the RFO must complete and sign the Certification and Signature form for each new amendment request (Section 2). These forms are available on the internet at http://www.cdc.gov/od/ohs/lrsat.htm, or may be requested from our office (404-639-4418).

To designate a different or an alternate RFO, the current RFO must send or fax to our office a signed statement on official facility letterhead requesting such changes. We remind you that when you designate an alternate RFO that your designated alternate must also meet the requirements set forth in section "(j) Definitions" for Responsible facility official. That definition is reprinted below for your convenience.

> "Responsible facility official means an official authorized to transfer and receive select agents covered by this part on behalf of the transferor's and/or requestor's facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility."

Obtaining extra copies of the forms in this package
One copy of each form is included in this packet. Photocopy the originals contained in this application package if additional copies are needed. This application package is also available on the internet at the CDC Laboratory Registration/Select Agent Transfer program website (http://www.cdc.gov/od/ohs/lrsat.htm).

How the information in this application package will be used
Each section of the application package is designed to obtain certain information required under 42 CFR 72.6: (1) The "Background Information/Certification and Signature" form will provide us with the information required under 42 CFR 72.6(c)(2)(i); (2) The "Information on Select Agents" forms will: (A) Help determine whether your laboratory is equipped to work safely with the select agent(s) in question, so that you may take appropriate action if necessary before applying for registration under this regulation, and; (B) Assist CDC in determining whether your laboratory meets the requirements of 42 CFR 72.6(a)(2)(ii).

Public reporting burden
Public reporting burden of this collection of information is estimated to average 120 minutes for completion of the **Background Information/Certification and Signature, Information about Select Agents facility intends to work with or transfer** forms, including the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed 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 (0920-0199)

OMB Control Number 0920-0199
Forms approved
Expiration date 6/30/03

LR/SAT Application for Laboratory Registration — Section 2

Background Information/Certification and Signature

Name of facility
Address
Address
City State Zip

Name of designated Responsible Facility Official (RFO)
Title of Responsible Facility Official (e.g., biosafety officer)
Address
Address
City State Zip
Telephone
FAX
E-mail

Name of alternate Responsible Facility Official
Address (if different from above)
Telephone
FAX
E-mail

Mark an x in the ( ) to the left of each select agent for which your facility wishes to register its laboratories (If you are registering only for inactivated agents or genomic materials please indicate this next to the appropriate agent).

Viruses

( ) Crimean-Congo haemorrhagic fever virus
( ) Eastern Equine Encephalitis virus
( ) Ebola viruses
( ) Equine Morbillivirus (Hendra virus)
( ) Lassa fever virus
( ) Marburg virus
( ) Rift Valley fever virus
( ) South American haemorrhagic fever viruses
  ( ) Junin
  ( ) Machupo
  ( ) Sabia
  ( ) Flexal
  ( ) Guanarito
( )Tick-borne encephalitis complex viruses
( ) Variola major virus (Smallpox virus)
( ) Venezuelan Equine Encephalitis virus
( ) Viruses causing hantavirus pulmonary syndrome
( )Yellow fever virus

Bacteria

( ) *Bacillus anthracis*
( ) *Brucella abortus, B. melitensis, B. suis*
( ) *Burkholderia (Pseudomonas) mallei*
( ) *Burkholderia (Pseudomonas) pseudomallei*
( ) *Clostridium botulinum*
( ) *Francisella tularensis*
( ) *Yersinia pestis*

Rickettsiae

( ) *Coxiella burnetii*
( ) *Rickettsia prowazekii*
( ) *Rickettsia rickettsii*

Fungi

( ) *Coccidioides immitis*

Toxins

( ) Abrin
( ) Aflatoxins
( ) Botulinum toxins
( ) *Clostridium perfringens* epsilon toxin
( ) Conotoxins
( ) Diacetoxyscirpenol
( ) Ricin
( ) Saxitoxin
( ) Shigatoxin
( ) Staphylococcal enterotoxins
( ) Tetrodotoxin
( ) T-2 toxin

Recombinant organisms/molecules

( ) Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.
( ) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.

~~*Calculation of Registration Fee*~~ *

~~Refer to Federal Register Notice - *Notice of Site Registration Fee Schedule...* (included as an attachment to this Application Package) for information on user fees and for definitions of small, medium and large facilities.~~

~~This application is for (mark one):~~
~~( ) a small facility ($13,000)~~
~~( ) a medium facility ($14,000)~~
~~( ) a large facility ($15,000)~~

~~Additional charges (mark all that apply):~~
~~( ) facility includes one or more BSL4 laboratories ($2,000)~~
~~( ) facility expects to do >50 select agent transfers per year ($1,000)~~

~~Total registration fee for this facility: $_____~~
~~This fee is for the three year registration period.~~
~~Payment is to be made to Centers for Disease Control and Prevention.~~
~~Payment must accompany Application Package.~~

* Currently, the "Site Registration Fee for Facilities Transferring or Receiving Select Agents" is suspended. At this time there is no fee required to register facilities under this regulation (see Attachment 4).

Certification and Signature

I hereby certify that I have been designated as the Responsible Facility Official for the institution/organization listed above, that I am authorized to bind the institution/organization, and that the information supplied in this registration package is to the best of my knowledge accurate and truthful. The institution/organization listed above meets the requirements specified in 42 CFR 72.6 (a)(5), is equipped and capable of safely handling the agent(s), and will use/transfer these agents solely for purposes authorized by 42 CFR 72.6. I understand that a false statement on any part of this agreement or failure to comply with the provisions of 42 CFR 72.6 will result in immediate revocation of this institution's/organization's registration as described in 42 CFR 72.6(a)(4) and could result in a fine of up to $500,000 or imprisonment for up to five years, or both for each violation (42 U.S.C. §§ 264, 271; 18 U.S.C. § 1001; 18 U.S.C. §§ 3559, 3571).

_____ _____
(Signature) (Date)

42 CFR 72.7 - Penalties
Individuals in violation of this part are subject to a fine of no more than $250,000 or one year in jail, or both. Violations by organizations are subject to a fine of no more than $500,000 per event. A false, fictitious or fraudulent statement or representation on the government forms required in the part for registration of facilities or for transfers of select agents is subject to a fine or imprisonment for not more than five years, or both for an individual; and a fine for an organization.

Send completed application package to: Centers for Disease Control and Prevention, Office of Health and Safety, Laboratory Registration/Select Agent Transfer Program, 1600 Clifton Road, NE., Mail Stop A13, Atlanta, GA 30333

Information about Select Agents facility intends to work with or transfer

Section 3A

All applicants must complete the Table on page 3-2. For each of the select agents you plan to use, list the following information on a separate line: the select agent(s); the characteristics of each select agent you plan to use (e.g., viable, nonviable, purified genomic, recombinant material, use in small or large animals, or large scale), the building and room number(s) where select agent(s) will be worked with and stored; and, the facility risk assessment based on the requirements for the type of activities done in each of the rooms.

Example 1. A facility needs to register one principal investigator: Dr. Jane Doe will be working with viable *Bacillus anthracis* in Bldg A, Room 2 at BSL-2; genetic elements from *Bacillus anthracis* in Bldg A, Room 5 at BSL2, and *Bacillus anthracis* in small mammals in Bldg B, Room 200 at ABSL2. Storage of the agents will be in the same locations where the work will be done.

	TYPE OF WORK TO BE PERFORMED AT FACILITY													
			Purified Genomic	Recombinant	Small	Large	Large		Laboratory Area		Storage Area			Principal
	Viable	Nonviable	material	DNA	Animal	Animal	Scale	Toxin	Bldg	Room	Bldg	Room	Safety Level	Investigator
SELECT AGENT	INDICATE WITH AN "X" FOR EACH AGENT AS APPROPRIATE													
Bacillus anthracis	X								A	2	A	2	BSL2	Dr. Jane Doe
Bacillus anthracis			X						A	5	A	5	BSL2	Dr. Jane Doe
Bacillus anthracis					X				B	200	B	200	ABSL2	Dr. Jane Doe

EXAMPLE ONLY

Example 2. A facility needs to register three principal investigators: Dr. John Smith will be working with recombinant Ebola in Bldg 15, Room 100 at NIHBSL-2; Dr. Mary Johnson will be working with botulinum toxins in Bldg 3A, Room 1000 under 29 CFR 1910.1450 conditions; and Dr. Tony Small will be working with viable *Francisella tularensis* in Bldg 4, Room 300 at BSL3 and recombinant *F. tularensis* under NIHBSL3 in the same room. Storage of the agents will be in the same locations where the work will be done.

	TYPE OF WORK TO BE PERFORMED AT FACILITY													
			Purified Genomic	Recombinant	Small	Large	Large		Laboratory Area		Storage Area			Principal
	Viable	Nonviable	material	DNA	Animal	Animal	Scale	Toxin	Bldg	Room	Bldg	Room	Safety Level	Investigator
SELECT AGENT	INDICATE WITH AN "X" FOR EACH AGENT AS APPROPRIATE													
Ebola virus				X					15	100	15	100	NIHBL2	Dr. John Smith
Botulinum toxin								X	3A	1000	3A	1000	29 CFR	Dr. Mary Johnson
F. tularensis	X								4	300	4	300	BSL3	Dr. Tony Small
F. tularensis				X					4	300	4	300	NIHBL3	Dr. Tony Small

EXAMPLE ONLY

Legend for Safety Levels

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

Toxin= 29 CFR

Information on Select Agents

Table – All applicants must complete this table. Each select agent used at different risk levels should be listed separately. Failure to complete this table in detail will delay processing of your application.

	TYPE OF WORK TO BE PERFORMED AT FACILITY													
			Purified Genomic	Recombinant	Small	Large	Large		Laboratory Area		Storage Area			Principal
	Viable	Nonviable	material	DNA	Animal	Animal	Scale	Toxin	Bldg	Room	Bldg	Room	Safety Level*	Investigator
SELECT AGENT	INDICATE WITH AN "X" FOR EACH AGENT AS APPROPRIATE													

*Legend for Safety Levels

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
Toxin= 29 CFR

Descriptions of laboratories and procedures for work with select agents at your facility

Provide the following information on a separate sheet for each principal investigator (PI). Lack of sufficient detail will result in a delay processing your application.

Section 3B
To be completed by all applicants

1. State the name of the individual responsible for the laboratory (e.g., principal investigator or laboratory supervisor). Include a current resume or Curriculum Vitae from the principal investigators for our files.
2. Briefly state (paragraph in length) the objectives of the work that will be done with the select agent(s), including a description of the types of methodologies or laboratory procedures that will be used. State if you will be working with any host-vector systems. If you will be working with live agent as well as recombinant DNA and/or nonviable DNA, then include these procedures in your description.
3. Include a diagram of the floor plan (preferably not blueprints) showing the layout and rough dimensions of the laboratory(s) where select agents will be handled or stored. Clearly indicate on your diagram the following: entry and exit ways; air supply and exhaust vents; incubators; freezers; autoclaves; sinks; eyewash and emergency shower stations; biosafety cabinets (BSCs), fume hoods, centrifuges, and any other major laboratory equipment present in the laboratory.
4. Describe the operation of the air-handling system in the laboratory where the work will be performed; specifically state if the air is single pass (dedicated exhaust or connected to building exhaust system) or recirculated within the laboratory. Indicate methods of maintaining air balance in the laboratory (i.e., variable air volume versus constant air volume, redundant exhaust fans, and emergency backup power systems). If applicable, include the type of supply and/or exhaust filtration utilized, and how airflow is visually monitored by laboratorians (e.g., pressure differential gauges, or other monitoring systems).
5. State whether a Biosafety Cabinet (BSC) will be used. If yes, then describe the procedures to be done in the BSC. State what type of BSC will be used (e.g., Class II, Type B2). Describe if the BSCs are recirculating, or directly exhausted. If the BSC exhaust is connected to the building exhaust system, provide details of exhaust ductwork (hard-ducted or thimble connection). State how often the BSCs are inspected and certified.
6. State whether a chemical fume hood will be used. If yes, then describe the procedures to be performed in the chemical fume hood. State what type of filters, if any, are utilized with the chemical fume hood. Is there a visual method to verify inward airflow? State how often the fume hood is certified and the filters, if present, are changed.
7. Describe how your facility limits access to the laboratories where select agents are being manipulated and stored to only authorized and qualified persons (e.g., is there a guard at the entrance? card key access? door keys or combination-locked?)
   (A) Describe the policy in place to limit further access to this laboratory and/or storage area when a temporary employee (e.g., students, post-doctoral fellows, etc.) leaves the facility.
   (B) Are only personnel working with the select agents allowed in the specified laboratory? If not, who else is allowed? Are guests escorted in the laboratory at all times? Are maintenance personnel allowed in the laboratory? How many people have access to the laboratory where select agents are handled or stored?
   (C) Is the laboratory secured when no one is present during regular working hours?
8. Does an Institutional Biosafety Committee (IBC) review and approve protocols prior to working with select agents at this facility? If yes, then has the IBC approved the work proposed in this application?
9. Is the facility inspected by USDA, FDA, CLIA, DoE, DoD or others? If yes, then give date of last inspection(s).

Section 3C
To be completed by applicants working with infectious select agents

10. Provide a brief summary regarding the strains of organisms that will be used. Provide an estimate of the maximum quantities (e.g., number of petri dishes or flasks) and concentration of organisms grown at a given time.

Section 3D
To be completed by applicants working with select agent genomic DNA or nonviable organisms

11. We strongly recommend that your facility request written verification that material has been rendered nonviable from each of the facilities for which you receive select agent DNA or nonviable organisms. These recommendations are made in the interest of the health and safety of the laboratorians in your facility that will be working with the select agent material, and is particularly critical due to the severe illnesses that many of these agents cause. Provide a concise assurance on the following points regarding inactivation of live agent:
    (A) A procedure is in place for inactivating live agent.
    (B) The procedures employed for inactivating live agent have been verified.

Section 3E
To be completed by applicants working with recombinant DNA

12. Give an estimate of the range in length (in bp's) of the recombinant select agent DNA material and what it encodes for.
13. What type of host-vector system(s) will be used?

Section 3F
To be completed by applicants working with small animals (ABSL2 – ABSL4)

14. What route of infection will be used with the select agent(s)?
15. Facilities for laboratory animal studies should be physically separate from areas with other activities, such as clinical laboratories and those that provide patient care. Include with your sketch of the floor plan (question number 3 above), another sketch that shows the animal rooms to be used and rooms adjacent to them. Indicate what type(s) of activities are conducted in areas adjacent to the animal rooms.
16. Does the facility require that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this facility? If yes, has the proposed work with select agents in small animals been approved by the IACUC?
17. Is the laboratory space described in this application AAALAC accredited? If yes, when was the date of the last inspection for these rooms?

Section 3G
To be completed by applicants working with select agent toxins

18. Clearly state the form(s) of the toxin that will be used (e.g., are the toxins received in liquid or dry form?). If the toxin is received in dry form, describe decontamination procedures prior to removing material from the chemical fume hood.
19. What concentration of toxins will be handled? What volume of toxins are you working with or storing?
20. Are dilution procedures and other manipulations of the concentrated toxins conducted in a fume hood or biosafety cabinet with two knowledgeable people present? Is there a hazard sign on the door when toxins are present?
21. If toxins are to be produced from live agent, then briefly describe procedures used for doing so. Include in your summary an estimate of the maximum quantities (e.g., number of plates) grown at a given time.