

Select Agent Rule - A Satellite Broadcast

June 22, 2000
1:00 - 3:00 pm Central Time

Study Booklet

FACULTY

Jonathan Y. Richmond, Ph.D. Director Office of Health and Safety Office of the Director, CDC	Mark L. Hemphill, M.S. Acting Chief Select Agent Program Office of Health and Safety Office of the Director, CDC
Bill Howard Chief Facility Support Office of Health and Safety Office of the Director, CDC	Henry Mathews, Ph.D. Chief Laboratory Operations Section Office of Health and Safety Office of the Director, CDC
Robert H. Hill, Jr., Ph.D. Chief Environmental Health and Safety Branch Office of Health and Safety Office of the Director, CDC	Richard C. Knudsen, Ph.D. Chief Laboratory Safety Branch Office of Health and Safety Office of the Director, CDC

Content Developers

Loretta Gaschler, M.A., M.T. (ASCP)
Training Advisor
Southeastern Office
National Laboratory Training Network

Marguerite Oates, M.P.A.
Regional Coordinator
Pacific Office
National Laboratory Training Network

Production and Broadcast

Michael Smith
Director Video Communications
Alabama Department of Public Health

Mack Carmack
Producer and Moderator
Director of Broadcast Communications
UAB School of Public Health

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Association of Public Health Laboratories

Sponsors

Centers for Disease and Control and Prevention (CDC), Office of Health and Safety and National Laboratory Training Network.

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PROGRAM DESCRIPTION

The Department of Health and Human Services has published regulations regarding access, use and transfer of select agents for research purposes. These regulations are designed to (1) Ensure that these infectious agents and toxins are shipped only to institutions or individuals equipped to handle them appropriately; (2) Transfer of these agents is to those who have legitimate reasons to use them, and, (3) A system is implemented whereby scientists and researchers involved in legitimate research may continue transferring these agents without undue burdens.

The program will include information about the registration process, how to document the transfer of select agents, verification procedures and agent disposal requirements, as well as research and clinical exemptions.

TARGET AUDIENCE

This program will be of interest to individuals responsible for laboratory research or safety in the following types of facilities: biotech firms, universities or other teaching institutions, veterinary institutions, pharmaceutical firms, or other laboratories working with or transferring any microorganisms or toxins classified as "select agents."

LEARNING OBJECTIVES

Upon completion of the program, participants will be able to:

- Summarize the rationale for regulating the movement of biological agents.
- Discuss the general requirements of the Select Agent Rule.
- Determine whether their facility must register to comply with the regulations.
- Complete an application packet.
- Describe the components of a self assessment in both BSL-2 and BSL-3 facilities and laboratories working with toxins.
- Review the registration and inspection process.
- Complete the forms and package select agents necessary for transfer.

INTRODUCTION TO THE SELECT AGENT RULE

Overview: The Department of Health and Human Services has published regulations regarding access, use and transfer of select agents for research purposes. These regulations are designed to (1) Ensure that these infectious agents and toxins are shipped only to institutions or individuals equipped to handle them appropriately; (2) Transfer of these agents is to those who have legitimate reasons to use them, and, (3) A system is implemented whereby scientists and researchers involved in legitimate research may continue transferring these agents without undue burdens.

The Regulation: Title 42 CRF Part 72.6 (Additional Requirements for Facilities Transferring or Receiving Select Agents) stems from the "Antiterrorism and Effective Death Penalty Act of 1996" which requires the Secretary of Health and Human Services to regulate the transfer of certain biological agents ("select agents") harmful to humans. The Centers for Disease Control and Prevention (CDC) is responsible for the implementation of this regulation.

The regulation includes six fundamental components:

1. A list of biological agents ("select agents") that have the potential to pose a severe threat to public health and safety.
 - Approximately 40 viruses, bacteria, rickettsia, fungi, and toxins are on the list of select agents. The transfer of these agents is controlled in the United States.
2. Registration of facilities prior to the transfer of select agents:
 - Registration requires that facilities submit information to the CDC that demonstrates that the facility is equipped and capable of safely handling the select agent. This application for registration must be sent to the CDC, Office of Health and Safety, Laboratory Registration/Select Agent Transfer (LR/SAT) Program. The LR/SAT Program is responsible for registration and on site inspections.
3. Transfer requirements:
 - Prior to transfer, both the shipper and the receiver must be registered with the LR/SAT Program or meet the requirements for exemption. Registered facilities are issued a unique registration number which must be used in the transfer process of these agents from one facility to another. Transfers of select agents are documented using a special form which includes information on both facilities, the agent being transferred, and the proposed use of the agent.
4. Verification procedures including audit, quality control, and accountability mechanisms:
 - Each facility shipping or receiving a select agent must have a "responsible facility official." This official must sign each request, certifying that the requestor of the agent is officially affiliated with the facility and that the laboratory meets guidelines for working with the requested agent. The "responsible facility official" sending the agent is required to verify that the receiving facility holds a currently valid registration number and that they are registered with the CDC for the specific agent being requested from them.

5. Agent disposal requirements:

- Facilities must have in place procedures for the appropriate disposal of select agents. Upon termination of the use of a select agent, the agent must be transferred to another registered facility or destroyed on site. Consumed or destroyed agents must be reported to CDC.

6. Research and clinical exemptions:

- Specific attenuated vaccine strains and toxins used for biomedical research purposes are exempt. Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 that utilize these select agents for diagnostic, reference, verification or proficiency testing purposes are exempt. The transfer of clinical specimens for diagnostic, reference, or verification purposes is also exempt.

THE LIST OF SELECT AGENTS

Appendix A to 42 CFR 72.6

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses
4. Equine Morbillivirus (Hendra virus)
5. Lassa fever virus
6. Marburg virus
7. Rift Valley fever virus
8. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
9. Tick-borne encephalitis complex viruses
10. Variola major virus (Smallpox virus)
11. Venezuelan Equine Encephalitis virus
12. Viruses causing hantavirus pulmonary syndrome
13. Yellow fever virus

Bacteria

1. *Bacillus anthracis*
2. *Brucella abortus*, *B. melitensis*, *B. suis*
3. *Burkholderia (Pseudomonas) mallei*
4. *Burkholderia (Pseudomonas) pseudomallei*
5. *Clostridium botulinum*
6. *Francisella tularensis*
7. *Yersinia pestis*

Rickettsiae

1. *Coxiella burnetii*
2. *Rickettsia prowazekii*
3. *Rickettsia rickettsii*

Fungi

1. *Coccidioides immitis*

Toxins

1. Abrin
2. Aflatoxins
3. Botulinum toxins
4. *Clostridium perfringens* epsilon toxin
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin
8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

BSL RECOMMENDATIONS FOR SELECT AGENTS

Supplement to CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*, 4th ed. (BMBL).
Summary of biosafety level (BSL) recommendations for Select Agent Bacteria, Viruses, Rickettsiae and Fungi
listed in Appendix A to Part 72* (vacc=vaccine required)

Select Agent	Biosafety Level			Immuno- prophylaxis
	Clinical Specimens / Propagation / Animal Work			
Viruses				
Crimean-Congo hemorrhagic fever virus	4	4	4	
Eastern Equine Encephalitis virus	2	2-3	3 + vacc	vaccine (IND) ^A
Ebola viruses	4	4	4	
Equine Morbillivirus (Hendra virus)	3-4	4	4	
Lassa fever	4	4	4	
Marburg virus	4	4	4	
Rift Valley fever virus ^B	3 + HEPA	3 + HEPA	3 + HEPA	vaccine (IND)
South American hemorrhagic fever viruses				
Junin	3+vacc+HEPA	3+vacc+HEPA	3+vacc+HEPA	vaccine (IND)
Machupo	4	4	4	
Sabia	4	4	4	
Flexal	3	3	3	
Guanarito	4	4	4	
Tick-borne encephalitis complex viruses				
Absettarov ^C	3 + vacc	3 + vacc	3 + vacc	vaccine (IND)
Hanzalova ^C	3 + vacc	3 + vacc	3 + vacc	vaccine (IND)
Hypr ^C	3 + vacc	3 + vacc	3 + vacc	vaccine (IND)
Kumlinge ^C	3 + vacc	3 + vacc	3 + vacc	vaccine (IND)
Kyasanur Forest disease	4	4	4	
Omsk hemorrhagic fever	4	4	4	
Russian Spring-Summer encephalitis	4	4	4	
Venezuelan Equine Encephalitis virus	3 + HEPA	3 + HEPA	3 + HEPA	vaccine (IND)
Variola major virus (Smallpox virus)	4	4	4	vaccine
Viruses causing hantavirus pulmonary syndrome				
	3	3-4	3-4	
Yellow fever virus	3 + HEPA	3 + HEPA	3 + HEPA	vaccine
Bacteria				
<i>Bacillus anthracis</i>	2	2-3	2-3	vaccine
<i>Brucella abortus</i> , <i>B. melitensis</i> , <i>B. suis</i>	2	3	3	
<i>Burkholderia (Pseudomonas) mallei</i>	2	2-3	3	
<i>Burkholderia (Pseudomonas) pseudomallei</i>	2	2-3	3	
<i>Clostridium botulinum</i>	2	2-3	2-3	toxoid (IND)
<i>Francisella tularensis</i>	2	3	3	vaccine (IND)
<i>Yersinia pestis</i>	2	2-3	2-3	vaccine
Rickettsiae				
<i>Coxiella burnetii</i>	2	3	3	vaccine (IND)
<i>Rickettsia prowazekii</i>	2	3	2-3	
<i>Rickettsia rickettsii</i>	2	3	2-3	
Fungi				
<i>Coccidioides immitis</i>	2	3	2-3	

CONTENTS OF APPLICATION FOR REGISTRATION

Laboratory Registration and Select Agent Transfer Tracking System

Instructions and forms may be downloaded separately (PDF format) from:
<http://www.cdc.gov/od/ohs/lrsat%20tracking%20ll.htm>

TITLE	CLICK TO DOWNLOAD	DATE MODIFIED
(1) Overview	249 KB	12/3/98
(2) Instructions	220 KB	12/3/98
(3) Background Information/Certification and Signature Forms	220 KB	12/3/98
(4) Information on Select agents		
Information on Select Agent Viruses, Bacteria, Rickettsiae and Fungi	173 KB	12/3/98
Information on Select Agents Containing Recombinant DNA	228 KB	12/3/98
Information on Select Agent Toxins	228 KB	12/3/98
(5) Laboratory Assessment Instruments		
<i>CDC/NIH Biosafety in Microbiological and Biomedical Laboratories</i>		
Biosafety Level 2	181 KB	12/3/98
Biosafety Level 3	243 KB	12/3/98
Biosafety Level 4	255 KB	12/3/98
Animal Biosafety Level 2	178 KB	12/3/98
Animal Biosafety Level 3	187 KB	12/3/98
Animal Biosafety Level 4	250 KB	12/3/98
<i>NIH Guidelines for Research Involving Recombinant DNA Molecules</i>		
Biosafety Level 2	174 KB	12/3/98
Biosafety Level 3	184 KB	12/3/98
Biosafety Level 4	191 KB	12/3/98
Biosafety Level 1 (large animals)	161 KB	12/3/98
Biosafety Level 2 (large animals)	177 KB	12/3/98
Biosafety Level 3 (large animals)	193 KB	12/3/98
Biosafety Level 4 (large animals)	209 KB	12/3/98
Biosafety Level 1 (large scale)	164 KB	12/3/98
Biosafety Level 2 (large scale)	170 KB	12/3/98
Biosafety Level 3 (large scale)	185 KB	12/3/98
<i>29 CFR 1910.1450 - Occupational Exposure to Hazardous Chemicals in Laboratories</i>	205 KB	12/3/98
(6) Supplement to the CDC/NIH, "Biosafety in Microbiological and Biomedical Laboratories," 3 rd Ed.	210 KB	12/3/98
(7) Table of Select Agent Toxins- LD ₅₀ for Mice	294 KB	12/3/98

TRANSFERRING SELECT AGENTS - USING FORM EA-101

Procedure for transfer of a select agent

The purpose of the CDC EA-101 form is to provide a method for the documentation of the transfer of a select agent. An EA-101 form must be completed for each transfer of a select agent. A copy of each EA-101 must be kept by the responsible facility official (RFO) for five years.

Prior to transferring a select agent

Before a select agent is transferred, both sender (transferor) and receiver (requestor) facilities must be registered with the CDC. The requestor fills out blocks 1 and 2 of the EA-101 form and submits it, with a copy of the requesting facility's registration certificate, to the transferor. The transferor's responsible facility official (RFO) must verify with the requestor's RFO, and if appropriate, with the CDC, that the requesting facility: (1) retains a valid, current registration for the select agent being requested; (2) the person requesting the select agent is an employee of the requesting facility; and, (3) that the proposed use of the agent by the requestor is correctly indicated on CDC Form EA-101. For biosecurity reasons, CDC recognizes that the select agent registration certificate does not have information regarding which specific select agent(s) a facility is registered for with the CDC. If the transferor cannot verify the registration status of the requestor, there is suspicion that the agent may not be used for the requested purpose, or there are any other concerns, then the transferor should consult with the CDC.

Transfer:

(a) Shipment of the select agent to the requestor

- After the transferor has verified the information in blocks 1 and 2 of the EA-101, then the transferor ships the material to the receiver. The transferor fills out Section 3 and the shipping information in Section 4, including the date the agent was shipped. Select agents must be packaged, labeled, and shipped in accordance with all federal (e.g., 42 CFR 72 and 49 CFR 100-180) and international (IATA) regulations. It is highly recommended that the transferor utilize a mechanism for tracking the movement of select agents shipped. Return receipt is required by law for some select agents listed in 42 CFR part 72.3(f).¹

(b) Receipt of the select agent by the requestor

- The RFO from the receiver's facility must acknowledge receipt of the agent to the transferor by telephone or otherwise electronically within 36 hours of receipt. The receiver's RFO is also required to provide a paper copy or facsimile transmission of receipt to the transferor within three business days of receipt of the agent.

¹*Coccidioides immitis*; Ebola virus; *Francisella tularensis*; Viruses causing HPS; CCHF; Junin Virus; Machupo virus; Lassa virus; Marburg virus; *Burkholderia mallei*; *Burkholderia pseudomallei*; Tick-borne encephalitis virus complex; Variola major virus; *Yersinia pestis*

(c) Transmittal of the EA-101 form to the CDC

- After telephonic acknowledgment of receipt of the agent, the transferor writes in the date the agent was received in Section 4 of the EA-101 form. The transferor is required to provide a completed paper copy or facsimile transmission of the EA-101 form within 24 hours to the CDC. In addition, we recommend that a completed copy of the CDC Form EA-101 be sent to the receiver as well at the same time. This not only provides the receiver with a courtesy copy of the completed form, but assists the receiver if and when they need to complete Section 5 in the future (below).

Destruction or depletion of a select agent

When a select agent from a transfer is depleted or destroyed, the RFO of the facility must complete Section 5 of the CDC Form. A copy or FAX of the EA-101 form must be sent to the CDC.

Table 1. Steps in transferring a select agent

Requestor RFO	Transferor RFO
1. Completes agent description (Block 1)	
2. Completes requestor information (Block 2)	
3. Faxes form EA-101 and registration certificate to transferor	
	4. Verifies registration information
	5. Completes transferor information
	6. Completes shipping information
	7. Oversees packaging and shipment of agent to requestor. Sends shipment.
8. Receives agent	
9. Requestor RFO notifies transferor RFO of receipt of agent via facsimile or telephone within 36 hours (or provides paper copy to the transferor RFO within 3 days)	

Requestor RFO	Transferor RFO
	10. Transferor enters date agent received in block 4
	11. Transferor faxes completed form EA-101 to CDC within 24 hours
12. Retains paper record for 5 yr, or retains record 5 yr after agent consumed or destroyed, whichever is longer	12. Retains paper record for 5 yr, or retains record 5 yr after agent consumed or destroyed, whichever is longer

TRANSFER PROCESS FOR EXEMPTED CLIA-CERTIFIED LABORATORIES

The rule (42 CFR 72.6) specifically exempts clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) that utilize select agents for diagnostic, reference, verification, or proficiency testing purposes. In addition, the rule provides procedures for facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory. No additional paperwork on behalf of CLIA laboratories is required by this final rule. CDC will accept a CLIA certification number on CDC Form EA-101 in lieu of the required institutional registration number, as stipulated in this final rule.

This exemption is found in 42 CFR 72.6 (h) (2) and the transfer procedure for sending a select agent from a registered facility to a CLIA laboratory are found in 42 CFR 72.6 (h) (3); both are repeated here for your convenience:

(2) Exemption of CLIA certified laboratories: Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, (42 U.S.C. 263a) (CLIA), that utilize these select agents for diagnostic, reference, verification, or proficiency testing purposes are exempt from the provisions of Sec. 72.6.

(3) Procedures for facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory: Facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory must comply with the following provisions. (No additional paperwork on behalf of CLIA laboratories is required by this section.)

(i) Prior to transferring a select agent subject to this part to a CLIA laboratory for diagnostic, reference, verification, or proficiency testing purposes, the transferor must:

(A) Provide the following information on CDC Form EA-101:

- (1) The name of the requestor and requesting facility;*
- (2) The name of the transferor and transferring facility;*
- (3) The name of the transferor's responsible facility official;*
- (4) The requesting facility's CLIA certification number (which the transferor must verify as valid and current with the registering entity);*
- (5) The transferring facility's registration number;*
- (6) The name of the agent(s) being shipped;*
- (7) The proposed use of the agent(s); and*
- (8) The quantity (number of containers and amount per container) of the agent(s) being shipped.*

- (B) Verify receipt of the agent with the CLIA laboratory and note such receipt on CDC Form EA-101;*
 - (C) Transmit a copy of the form, signed by the transferrer and the responsible facility official representing the transferring facility, to the registering entity holding the transferring facility's registration; and*
 - (D) Retain a copy of CDC Form EA-101 in accordance with Sec. 72.6(d)(3) and Sec. 72.6(d)(4).*
- (ii) Prior to receiving a select agent listed in Appendix A of this part from a CLIA laboratory, the requestor must be registered in accordance with Sec. 72.6(a) and comply with the following requirements:*
- (A) Provide the following information on the CDC Form EA-101:*
 - (1) The name of the requestor and requesting facility;*
 - (2) The name of the transferor and transferring facility;*
 - (3) The name of the requestor's responsible facility official;*
 - (4) The transferring facility's CLIA certification number;*
 - (5) The requesting facility's registration number;*
 - (6) The name of the agent(s) being shipped;*
 - (7) The proposed use of the agent(s); and*
 - (8) The quantity (number of containers and amount per container) of the agent(s) being shipped.*
 - (B) Upon receiving the agent, note such receipt on CDC Form EA-101;*
 - (C) Transmit a copy of CDC Form EA-101, signed by the requestor and the responsible facility official representing the requesting facility, to the registering entity holding the requesting facility's registration;*
 - (D) Retain a copy of the CDC Form EA-101 in accordance with Secs. 72.6(d)(3) and 72.6(d)(4);*
 - (E) Comply with the disposal requirements of Sec. 72.6(i) and all other sections of this part when subsequently transferring the agent.*

Since CLIA-certified laboratories that are using select agents for exempt purposes are not required to register with CDC, our office cannot verify that a CLIA laboratory is authorized to receive, or is capable of handling, a select agent. When a registered facility receives a request from a CLIA-certified laboratory for a select agent, we recommend that the CLIA laboratory provide you with a copy of their current CLIA certificate, and a signed statement that their facility is capable of safely handling this select agent, and that it will only be used for the purposes that are exempt from this regulation.

FOR MORE INFORMATION

Laboratory Registration and Select Agent Transfer Program

Office of Health and Safety
Centers for Disease Control and Prevention
1600 Clifton Rd. MS A-13
Atlanta, Georgia 30333
Tel: (404) 639-4418
FAX: (404) 639-0880
E-mail: Irsat@cdc.gov
Website: www.cdc.gov/od/ohs/Irsat.htm

**LABORATORY REGISTRATION /
SELECT AGENT TRANSFER
PROGRAM**

Mark L. Hemphill, M.S.
External Activities
Office of Health and Safety
Centers for Disease Control
and Prevention

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OUTLINE

- What is the rule?
- What are Select Agents?
- Who needs to register?
- Registration process & requirements
 - Application
 - Inspections
- Do I need to register? - Exemptions

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WHAT IS THE RULE?

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Antiterrorism and Effective Death Penalty Act of 1996
Sec. 511. Enhanced Penalties and Control of Biologic Agents
Public Law 104-132; April 24, 1996

The Secretary of HHS shall, through regulation:

- Maintain a list of biological agents that have the potential to pose a severe threat to public health and safety.
- Establish procedures for the transfer of the listed biological agents, including measures to ensure:
 - Proper training and appropriate skills to handle agents.
 - Proper laboratory facilities to contain and dispose of agents.

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Antiterrorism and Effective Death Penalty Act of 1996
(continued)

- Provide safeguards to prevent access to agents for criminal purpose.
- Establish procedures to protect public safety in the event of a transfer of an agent in violation of safety procedures.
- Provide availability of agents for legitimate purposes.

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FINAL RULE

42 CFR Part 72.6
“Additional requirements for facilities transferring or receiving select agents”

Federal Register, Oct. 24, 1996
Effective date: April 15, 1997

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TITLE 42 PART 72 - INTERSTATE SHIPMENT OF ETIOLOGIC AGENTS

- Sec.
 - 72.1 Definitions.
 - 72.2 Transportation of diagnostic specimens, biological products, and other materials; minimum packaging requirements.
 - 72.3 Transportation of materials containing certain etiologic agents; minimum packaging requirements.
 - 72.4 Notice of delivery; failure to receive.
 - 72.5 Requirements; variations.
 - 72.6 Additional requirements for facilities transferring or receiving select agents.**
 - 72.7 Penalties.**
- Appendix A to Part 72 - Select Agents**

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PURPOSE OF THE REGULATION

Rule was designed to:

- Establish a system of safeguards to be followed when specific agents are transported;
- Collect and provide information on the location where certain potentially hazardous agents are transferred;
- Track the acquisition and transfer of these agents;
- Establish a process for alerting authorities if an unauthorized attempt is made to acquire these agents.

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COMPONENTS OF THE REGULATION

Fundamental components:

1. A comprehensive list of select agents
2. Registration of facilities transferring these agents
3. Transfer requirements
4. Verification procedures including audit, quality control, and accountability mechanisms
5. Agent disposal requirements
6. Research and clinical exemptions

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WHAT ARE SELECT AGENTS?

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APPENDIX A TO PART 72 - SELECT AGENTS

- 13 Viruses
- 9 Bacteria
- 3 Rickettsiae
- 1 Fungi
- 12 Toxins

Genetically modified / genetic elements

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APPENDIX A TO PART 72 - SELECT AGENTS

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

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APPENDIX A TO PART 72 - SELECT AGENTS

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

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APPENDIX A TO PART 72 - SELECT AGENTS

- **Rickettsiae**
 - *Coxiella burnetii*
 - *Rickettsia prowazekii*
 - *Rickettsia rickettsii*
- **Fungi**
 - *Coccidioides immitis*

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APPENDIX A TO PART 72 - SELECT AGENTS

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

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APPENDIX A TO PART 72 - SELECT AGENTS

- 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.

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WHO NEEDS TO REGISTER?

- Government Agencies
- Universities
- Research Institutions
- Commercial Entities
- Manufacturers & Suppliers

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TITLE 42 CFR 72.6 APPLIES IF YOU:

Import into the U.S.
or
Transfer within the U.S.
an item on the Select Agent list

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REGISTRATION PROCESS AND REQUIREMENTS

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APPLICATION FOR REGISTRATION

- Designate Responsible Facility Official
 - Safety/Senior Management
- Provide information on facility and procedures
- Perform self-assessment based on requirements for handling select agents

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REQUIREMENTS FOR HANDLING SELECT AGENTS

- For BSL 2-4 select agents:
 - Biosafety in Microbiological and Biomedical Laboratories, Third edition, May 1993.
- For toxin select agents:
 - 29 CFR 1910.1450 Occupational Exposure to Hazardous Chemicals in Laboratories.
- For recombinant select agents:
 - Guidelines for research involving recombinant DNA molecules (NIH Guidelines).

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APPLICATION

Laboratory Registration and Select Agent Transfer Tracking System

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FORMS TO BE COMPLETED

- Background Information/Certification & Signature
- Information on Select Agent (Section 1 & 2)
 - Viruses, Bacteria, Rickettsiae & Fungi
 - Recombinant DNA
 - Toxins
- Laboratory Assessment Instrument (Section 3)
 - CDC/NIH Biosafety in Microbiological and Biomedical Laboratories
 - NIH Guidelines for Research Involving Recombinant DNA Molecules
 - 29 CFR 1910.1450 – Occupational Exposure to Hazardous Chemicals in Laboratories

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BACKGROUND INFORMATION/CERTIFICATION AND SIGNATURE

- Identify:
 - Facility
 - Responsible facility official (RFO)
 - Select agents
- Signature of RFO

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**INFORMATION ON SELECT AGENT
Section 1**

- Select appropriate form based on agent
- List select agent(s)
- Location
- Assessment
 - Diagnostic work/CLIA registration?
 - Small animal/Large Animal?
 - Large Scale?
 - Select requirements (BMBL, NIH Guidelines, or 29 CFR 1910.1450)

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**INFORMATION ON SELECT AGENT
Section 2**

- Individual responsible for laboratory
- Work that will be done
- Practices & Procedures:
 - Security
 - Training
 - Storage & Disposal
 - Spill & exposure management
- Facility Containment:
 - Sketch/floor plan
 - Air handling system
 - Biosafety cabinet/fume hood

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**LABORATORY ASSESSMENT INSTRUMENT
Section 3**

- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories
 - BSL 2-4
 - ABSL 2-4
- NIH Guidelines for Research Involving Recombinant DNA Molecules
 - BSL 2-4
 - Large Animal BSL 1-4
 - Large Scale BSL 1-3
- 29 CFR 1910.1450 – Occupational Exposure to Hazardous Chemicals in Laboratories

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REGISTRATION AND TRACKING

- Issued unique registration number
- Issued registration certificate
 - Valid for 3 years
- Issued EA-101 tracking form
 - Track shipments between facilities
- Inspection to verify registration / tracking information
 - Prior to registration, or
 - During the 3 year registration period

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REGISTRATION MAY BE DENIED OR WITHDRAWN

- Facility not or is no longer capable of handling agents at appropriate BSL.
- Facility has handled covered agents in a manner in contravention of the BMBL.
- Facility has or intends to use agents in a manner harmful to human health.
- Facility does not comply with provisions of the regulation.

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PENALTIES

42 CFR 72.7

- 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 or 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.

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DISPOSAL

- Disposal of select agents must be at the facility, by known effective methods, and the facility should maintain records.
- CDC must be notified of the disposal or complete consumption of a select agent by completing EA-101.

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SECURITY

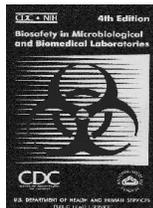
- "Prudent laboratory practices suggest storing select agents such that unauthorized and unqualified persons cannot gain access to them and such that the responsible person can account for quantities stored. Prudent practice also suggests that storage be secure, including controlled access to the storage area and storage equipment."

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BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES

4th Edition
JY Richmond & RW McKinney (eds.)
CDC/NIH, May 1999



<http://www.cdc.gov/od/ohs/biosfty/bmb14/bmb14toc.htm>

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BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES, Fourth edition, May 1999

- Incorporation into rule pending publication of new interstate shipping regulation by CDC
- Appendix F
 - Laboratory Security and Emergency Response for Microbiological and Biomedical Laboratories
- Appendix I
 - Guidelines for Work With Toxins of Biological Origin

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**DO I NEED TO REGISTER?
EXEMPTIONS**

- Attenuated vaccine strains
- CLIA certified laboratories
- Clinical specimens
- Toxins

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**EXEMPTIONS
ATTENUATED STRAINS**

- “Attenuated strains of select agents approved for human vaccination purposes by FDA or other recognized national or international organizations will be exempt. All other attenuated, avirulent, or less pathogenic strains will not be exempt at this time.”

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VIRUS VACCINE EXEMPTED STRAINS

42 CFR 72.6, subpart (h)(1)(iii)

- Rift Valley fever virus
 - Vaccine strain MP-12
- Junin
 - Vaccine strain Candid #1
- Venezuelan Equine Encephalitis virus
 - Vaccine strain TC-83
- Yellow fever virus
 - Vaccine strain 17-D

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BACTERIAL VACCINE EXEMPTED STRAINS

42 CFR 72.6, subpart (h)(1)(iii)

- FDA approved human vaccine strains
- USDA Title 9 CFR, Part 78.1
 - *Brucella abortus* 19; RB51.
- Other approved USDA vaccine strains

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“CLIA” EXEMPTION

42 CFR 72.6, subpart (h)(2)

- “Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, (42 U.S.C. 263a) (CLIA), that utilize these select agents for diagnostic, reference, verification, or proficiency testing purposes are exempt from the provisions of Sec. 72.6.”

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**“CLIA” EXEMPTION
for CLIA lab - non-CLIA lab transfers
42 CFR 72.6, subpart (h)(3)**

- CLIA lab must be using the select agent for exempt purposes
- Non-CLIA lab must be registered
- Non-CLIA lab must complete EA-101

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**“CLINICAL SPECIMEN” EXEMPTION
42 CFR 72.6, subpart (h)(1) (i)**

- “The agent is part of a clinical specimen intended for diagnostic, reference, or verification purposes. Isolates of covered agents from clinical specimens shall be disposed of in accordance with Sec. 72.6(i) after diagnostic, reference, or verification procedures have been completed;”

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**“CLINICAL SPECIMEN” EXEMPTION
42 CFR 72.6, subpart (h)(1) (i)
(continued)**

- Intent was NOT to put the regulation between the physician and the patient
- Must be directly related to the health of the human or animal

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“TOXIN” EXEMPTION
42 CFR 72.6, subpart (h)(1)(ii)

- For medical use
- National standard toxins required for biologic potency testing as described in USDA Title 9 CFR Part 113
- Preparations for biomedical research use at an LD₅₀ for vertebrates of > 100 ng/kg body weight by IP in a mouse

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REVIEW

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SELECT AGENTS

- May pose a severe threat to public health and safety
- Existing regulations used for packaging, labeling, and shipping select agents
- U.S. facilities shipping and receiving must be registered with CDC
- CDC notified of all shipments (EA-101)

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FOR MORE INFORMATION

- Laboratory Registration/Select Agent Transfer Program

- Phone 404-639-4418
- Fax 404-639-0880
- E-mail lrsat@cdc.gov
- Website <http://www.cdc.gov/od/ohs/lrsat.htm>

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BIOSAFETY LEVEL 2/3 FACILITY REQUIREMENTS

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Laboratories Protect

- **Personnel**
Scientists, technicians, maintenance workers
Custodial workers, visitors, students
- **Products**
Samples, reagents, processes
- **Environment**
Adjacent non-laboratory areas, other laboratories
The community, exterior environment



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Laboratory Hazards

- **Chemical**
Flammables, acids, corrosives, reactive chemicals, carcinogens
Mutagens, teratogens, toxins, compressed gases
- **Radiological**
Radionuclides, equipment that produces ionizing radiation
- **Physical**
Lasers, magnet fields, moving parts, high voltage, high noise
ultraviolet light, extreme heat or cold
- **Biological**
Etiologic agents, material containing etiologic agents
Organisms with recombinant DNA, toxins, allergens

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Biocontainment Levels

- **BSL1**
Defined organisms
Not known to cause disease in healthy adults
- **BSL2**
Moderate-risk agents present in the community
Disease of varying severity
- **BSL3**
Indigenous or exotic agents, aerosol transmission
Serious and potentially lethal infection
- **BSL4**
Dangerous or exotic, high-risk agents
Life threatening disease

Basic Labs

Containment Labs

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Concept of Biocontainment

- **Primary Barriers**
BSC's, personnel protective gear, containment equipment
- **Secondary Barriers**
Room, systems
- **Tertiary Barriers**
Containment around systems

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Biosafety Level 2 Guidelines

INWARD FLOW

LAB AREAS
KNOWN POPULATION

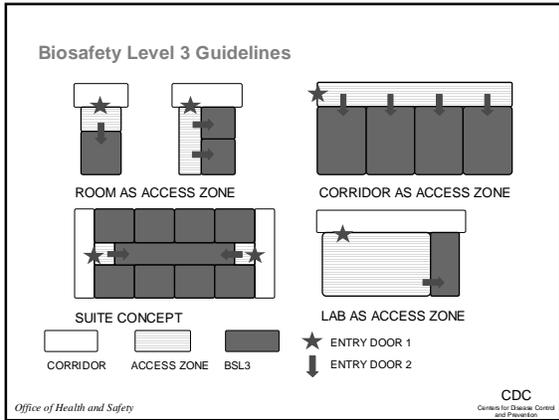
NON LAB AREAS
UNKNOWN POPULATION

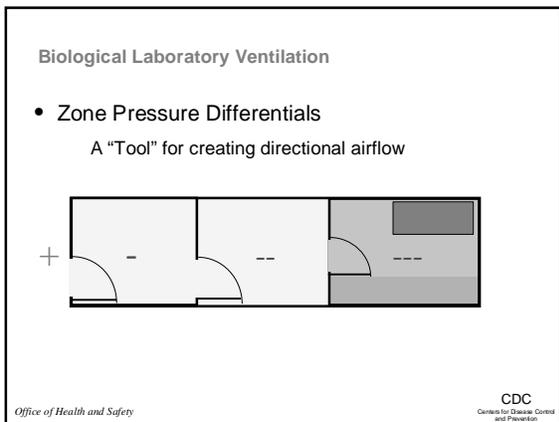
EXHAUST FUME HOODS

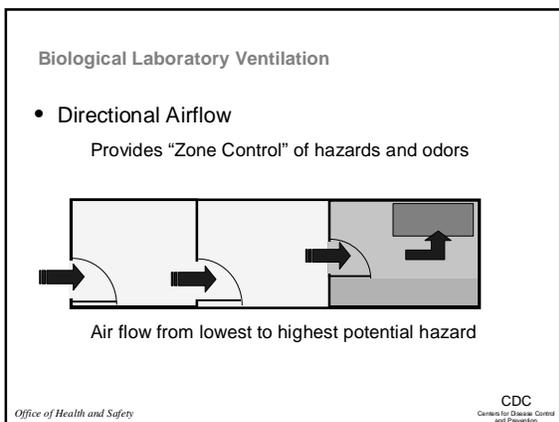
ACCEPTABLE TO RETURN AIR TO LAB AREAS

NOT RECOMMENDED TO RETURN AIR TO NON LAB AREAS

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Biological Laboratory Ventilation

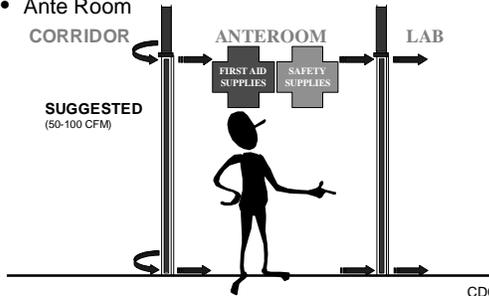
- Sealing the Barrier
 - Building Component Movement
 - Sealant Failure
 - Penetration Control
 - Ducts, pipes, vents and conduits
 - Doors, door seals
 - Dynamic Conditions

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Biological Laboratory Ventilation

- Ante Room
 - CORRIDOR
 - ANTEROOM
 - LAB
 - FIRST AID SUPPLIES
 - SAFETY SUPPLIES
 - SUGGESTED (50-100 CFM)



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CDC Infectious Diseases Laboratory

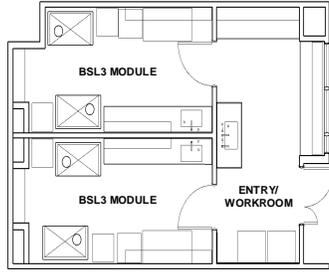
Technical Criteria BSL3

- HVAC
 - Inward directional airflow
 - 10 air change minimum
 - Manifoldd exhaust
 - Non filtered exhaust
 - Thimble connected BSC

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BSL3 Suite



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BIOSAFETY LEVEL 2/3 LABORATORY PRACTICES

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Principles of Biosafety Introduction

- **Biosafety Levels 1-3**
- Guidelines to describe combinations of:
 - Laboratory Practices and Techniques
 - Standard Practices
 - Special Practices
 - Safety Equipment (Primary Barriers)
 - Laboratory Facilities (Secondary Barriers)

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Principles of Biosafety Introduction

- **Biosafety Levels 1-3 Provide**
 - Increasing levels of personnel and environmental protection
 - Guidelines for working safely in microbiological and biomedical laboratories

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Lab Practices and Techniques

Introduction

- Knowledgeable supervisor
- Personnel
 - Aware of potential hazards
 - Proficient in practices/techniques
- Biosafety manual specific to lab

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Safety Equipment (Primary Barriers) - Introduction

- Biosafety cabinets (BSCs) [BSL-2/3]
- Personal protective clothing
 - Gloves
 - Gowns
- Pipetting Devices
- Safety centrifuge cups and rotors
- Eye and face protection
- Respiratory protection [BSL-3]

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Biosafety Level 2

Needles & Sharps Precautions

•DON'T

- Break, bend, resheath or reuse syringes or needles

•DO

- Use sharps containers



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Biosafety Level 2

Needles & Sharps Precautions

•So someone won't be injured later



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Biosafety Level 2



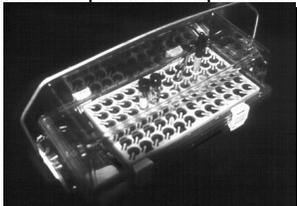
- Policies and procedures for entry
- Biohazard warning signs
- Biosafety manual specific to lab
- Training with annual updates

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Biosafety Level 2

- Use leak-proof transport containers



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Biosafety Level 2

- Immunizations
- Baseline serum samples



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Biosafety Level 2

- Decontaminate work surfaces
- Report spills and accidents
- No animals in laboratories

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Biosafety Level 2

Safety Equipment (Primary Barriers)

- **BSL-1 PLUS:**
- Use biosafety cabinets (class II) for work with infectious agents involving:
 - Aerosols and splashes
 - Large volumes
 - High concentrations

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Biosafety Level 2

•Supervision

- Supervisor is a competent scientist with increased responsibilities
 - Limits access if immunocompromised
 - Restricts access to immunized

• Lab Personnel

- Aware of potential hazards
- Proficient in practices/techniques

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Biosafety Level 3

- Suitable for work with infectious agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.

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Biosafety Level 3

- Exposure potential to pathogens spread by aerosol
- Infection serious, possibly lethal
- Examples:
 - *Burkholderia mallei*
 - Yellow Fever virus
 - *Coxiella burnetii*

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Biosafety Level 3

•BSL-2 Special Practices

PLUS:

- Work in certified BSC
- Use bioaerosol-containing equipment
- Decontaminate spills promptly



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Biosafety Level 3

Safety Equipment (Primary Barriers)

•BSL-1 and 2 Safety Equipment PLUS:

- Respiratory protection may be indicated



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Biosafety Level 3

•Supervision

- Supervisor is a competent scientist experienced working with agents
 - Establishes criteria for entry
 - Restricts access
 - Develops policies/procedures
 - Trains lab personnel

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Biosafety Level 3

- **Lab Personnel**

- Strictly follow guidelines
- Demonstrate proficiency
- Receive appropriate training
- Report incidents
- Participate in medical surveillance

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Principles of Biosafety Summary

- **BSL 1-3**

- Standard Practices
- Special Practices
- Safety Equipment (Primary Barriers)
- Laboratory Facilities (Secondary Barriers)
- Building (Tertiary Barriers)

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Select Agent Toxins - Assessing Your Facility

Robert H. Hill, Jr., Ph.D.
Office of Health and Safety
Centers for Disease Control and
Prevention

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Select Agent Toxins - Requirements

- Legal requirements
- Preventing exposure to select agent toxins

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Legal Requirements for Select Agent Toxins

- Compliance w/ OSHA's Hazard Communication Standard [29 CFR 1910.1200]
- Compliance w/ OSHA's Laboratory Standard [29 CFR 1910.1450]

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OSHA's Hazard Communication Standard

- Written hazard communication plan
- Hazardous chemical inventory
- Proper labeling
- Material safety data sheets [MSDSs]
- Employee training and information

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OSHA's Laboratory Standard

- Chemical hygiene plan
 - Standard operating procedures
 - Site-specific operating procedures
 - Procedures for handling particularly hazardous chemicals

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Handling Particularly Hazardous Chemicals

- Designated area for use
- Containment devices
- Procedures for safe removal of contaminated waste
- Decontamination procedures

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OSHA's Laboratory Standard

- Employee training and information
 - Hazards of chemicals
 - Information about specific chemicals
 - Measures to protect employees

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OSHA's Laboratory Standard

- Medical consultation and medical examinations
- Hazard identification – labels/MSDSs
- Respirators
- Record-keeping
 - Training, monitoring

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Preventing Exposures to Select Agent Toxins

- Exposure routes & prudent practices
 - Ingestion
 - Eye or ocular exposure
 - Dermal or skin
 - Inhalation

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Preventing Exposures to Select Agent Toxins

- Ingestion
 - No eating, drinking, smoking, medications, cosmetic applications in laboratory
- Eye or ocular
 - Wear eye protection where chemicals are used or stored

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Preventing Exposures to Select Agent Toxins

- Solid toxins
 - Contamination of surfaces is very likely
 - Avoid use of solids
 - Use solutions rather than solids



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Preventing Exposures to Select Agent Toxins

- Toxic solids can be hazardous
 - Contaminate hands or arms if not protected
 - Use protective gloves and cover arms



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Preventing Exposures to Select Agent Toxins

- Select appropriate gloves
 - For solid toxin
 - Contact supplier
 - Probably vinyl, latex, or nitrile
 - For aqueous solutions
 - Probably vinyl, latex, or nitrile
 - For non-aqueous solutions
 - Glove based on solvent used

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Preventing Exposures to Select Agent Toxins

- Toxic solids can be hazardous
 - Form aerosols
 - Contaminate work surfaces
 - Decontamination may be difficult or impossible



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Preventing Exposures to Select Agent Toxins

- Skin and inhalation exposures
 - Hoods, BSCs, glove boxes, ventilated enclosures
 - Exhausted to outside or HEPA-filtered
 - BSC limitations w/ solvents/flammables



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Preventing Exposures to Select Agent Toxins

- Use ventilated enclosures for weighing solid toxins
- Cover surfaces w/ absorbent paper
- Clean and decontaminate surfaces frequently



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Preventing Exposures to Select Agent Toxins

- Balance in hoods have been used
- Use the tare, transfer, weigh, and dilute technique



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Preventing Exposures to Select Agent Toxins

- Decontamination
 - Know specific decontamination methods
 - Methods for biological agents may not work for toxins
- Inactivation
 - Select Agent Rule requires toxin inactivation before disposal

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Preventing Exposures to Select Agent Toxins

- Emergency procedures
 - Written
 - On-site preparation
 - Procurement of emergency kits/supplies
 - Training
 - Cleanup of spills and decontamination

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Preventing Exposures to Select Agent Toxins

- Security of toxins
 - Secured in storage
 - Under surveillance when in use
 - Maintain accurate inventory that accurately tracks quantities of chemicals used

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Preventing Exposures to Select Agent Toxins

- Active use of toxins
 - Secure when leave area
 - Lock lab doors
 - Caged areas



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Preventing Exposures to Select Agent Toxins

- Securing Select Agents in Storage
 - Locked rooms
 - Locked closets
 - Locked refrigerators or freezers
 - Lock boxes



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Preventing Exposures to Select Agent Toxins

- Lock Boxes
 - Can be stored in refrigerators or freezers
 - Attached to immovable objects to prevent removal



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What will CDC Inspectors look for?

- Security of select agent toxins
- Compliance w/
 - OSHA regulations
 - Select Agent transfer rule
- Measures to prevent exposure to select agent toxins

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Selected References for Handling Toxic Chemicals

- Prudent Practices in the Laboratory, National Research Council, National Academy Press, 1995
- CDC's Office of Health and Safety Web Site:
 - <http://www.cdc.gov/od/ohs/>

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Transfer of Select Agents: Completing Form EA-101

Richard C. Knudsen, Ph.D.
Centers for Disease Control and
Prevention

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What is Form EA-101?

- Form EA-101 must be completed by the requestor and verified by the transferor prior to the **transfer** of any select agent
- Form EA-101 must be completed and faxed to CDC after **destruction or exhaustion** of supply of an agent

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What information is required to complete Form EA-101?

- 1. Select agent description
 - * Genus/species:
 - * Toxin:
 - * Recombinant organism/molecules:
 - * Use: research___, diagnostics___
Production___, other___

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What information is required to complete Form EA-101?

➤ **2. Requestor (receiver) information**

- * Facility registration number:
- * Requestor's name, signature, phone/fax
- * Responsible facility official's Name, signature and phone/fax

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What information is required to complete Form EA-101?

➤ **3. Transferor (sender) information**

- * Facility registration number
- * Transferor's name, signature, phone/fax
- * Responsible facility official's name, signature, phone/fax

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What information is required to complete Form EA-101?

➤ **4. Shipping information**

- * Amount per primary receptacle
- * Number of primary receptacles per outer package
- * Number of outer packages
- * Date agent shipped
- * Date agent received

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What Information Is Required to Complete Form EA-101?

- 5. **Select agent supply depleted or destroyed**

Date:

Also complete select agent description and requestor information

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What is the sequence for completing Form EA-101? Who? What? When?

- **Requestor-RFO**
 - 1. Completes agent description
 - 2. Completes requestor information
 - 3. Faxes form EA-101 and registration certificate to transferor

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What is the sequence for completing Form EA-101?

- **Transferor-RFO:**
 - 4. Verifies registration information
 - 5. Completes transferor information
 - 6. Completes shipping information
 - 7. Oversees packaging and shipment agent to requestor

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What is the sequence for completing Form EA-101?

- **Requestor-RFO:**
 - 8. Receives agent.
 - 9. Transmits notification of receipt within 36 hours, and provides paper copy within 3 days.

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What is the sequence for completing Form EA-101?

- **Transferor-RFO**
 - 10. Enters date agent received in block 4
 - 11. Faxes completed form EA-101 to CDC within 24 hours

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What is the sequence for completing Form EA-101?

- **Requestor-RFO**
 - **Transferor-RFO**
- 12. Retains paper record for 5 years
 - 12. Retains paper record for 5 years

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How is Form EA-101 Verified?

- **Transferor's RFO determines if:**
 - Requesting facility registration is valid.
 - Requestor is an employee of the facility.
 - Proposed use of the agent by requester is correct.
- **By contacting:**
 - Requestor's RFO.
 - Registering entity (CDC).

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How is Form EA-101 completed before transferring an agent to a CLIA laboratory?

- **Transferor** completes form EA-101 (Transferor must be registered with CDC)
- Uses requestor's CLIA certification number
And certificate
- Notes receipt of agent on form EA-101
- Faxes form EA-101 to CDC

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How is Form EA-101 completed when an agent is being transferred from a CLIA laboratory?

- **Requestor** completes form EA-101
- Enter requestor's CLIA certification number
- Notes receipt of agent on form EA-101
- Faxes form EA-101 to CDC

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Do intrafacility transfers require completion of Form EA-101

- Form EA-101 is not required provided that:
 - Intended use of agent remains consistent
 - Records of each intrafacility transfer are maintained and include:
 - * Name and location of recipient
 - * Amount of agent transferred
 - * Date transferred

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How does the Transferor Package the Agent?

- **Agent is packaged in accordance with :**
 - * US DOT regulations
49 CFR parts 171-180
 - * IATA dangerous goods regulations
 - * US PHS regulations
42 CFR part 72

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PACKAGING, LABELING AND SHIPPING INFECTIOUS SUBSTANCES

INFECTIOUS SUBSTANCES

Federal and international regulations classify substances known or reasonably expected to cause infectious disease in humans or animals, and the materials or vectors that contain them, as "infectious substances" or "etiologic agents." The international term "infectious substances" has replaced "etiologic agent" in Department of Transportation (DOT) and Public Health Service (PHS) regulations. However, "etiologic agent" is still used in older regulations such as PHS 42 CFR part 71 and the United States Postal Service 39 CFR part 111.

REGULATIONS

Federal and international regulations applicable to the shipment of infectious substances are listed in Appendix 1. The International Air Transport Association (IATA) Dangerous Goods Regulations apply to shipment of infectious substances via international and domestic air transportation. PHS 42 CFR Part 72, DOT 49 Parts 171-180, and United States Postal Service (USPS) regulations apply to domestic transportation by land, air, sea and rail. Currently, IATA has the most stringent requirements for transportation of infectious substances. Additional requirements for the importation of infectious substances from foreign countries are covered in 42 CFR Part 71.54.

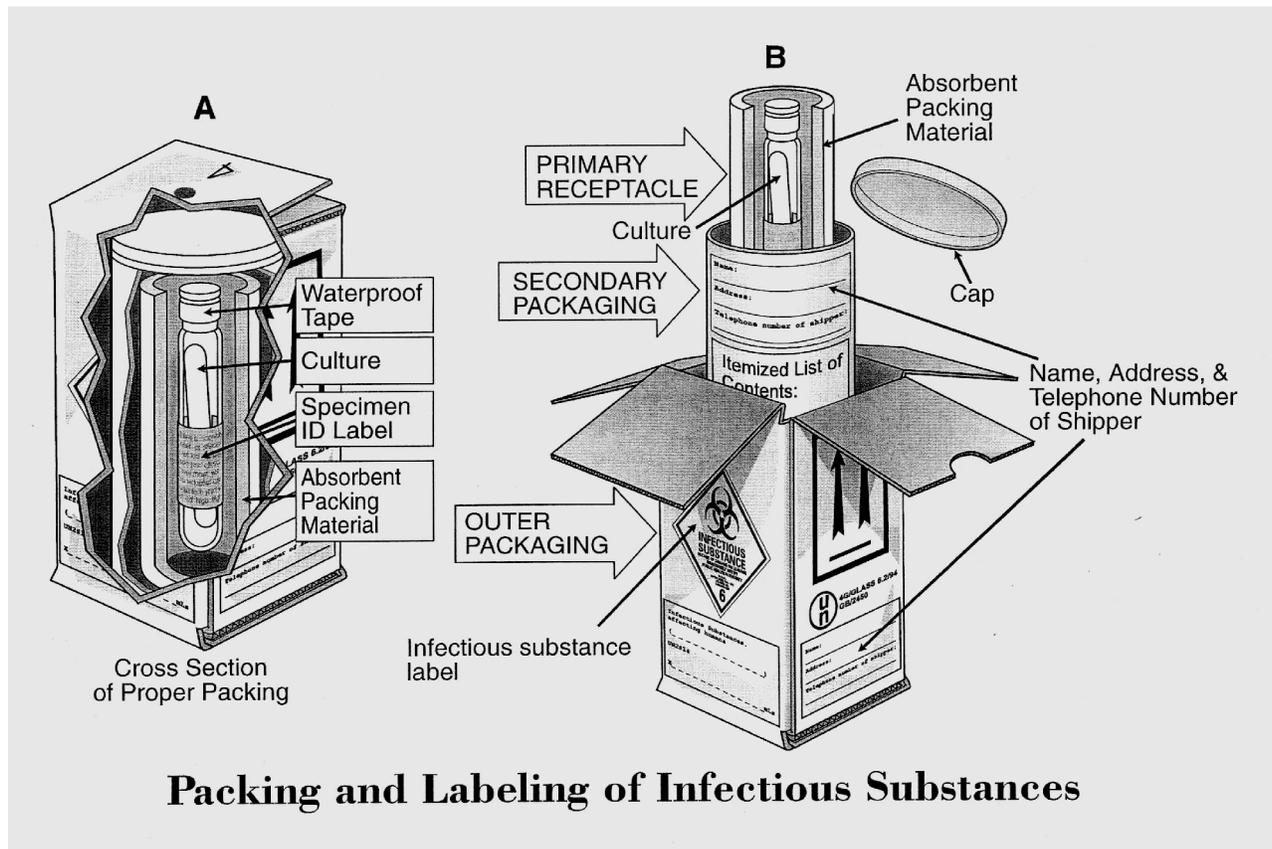
It is the responsibility of the shipper to ensure correct identification, classification, packaging, labeling, marking and documentation for all shipments of infectious substances. In addition, the shipper must make advance arrangements with the recipient (consignee) and operator (carrier), including acquisition of any permits for the importation of infectious substances from foreign countries. Failure to comply with federal and international regulations can result in refusal of the shipment by the airline, penalties of fines, jail, or both. Hand carriage of infectious substances by air is strictly prohibited by law.

PACKAGING

1. General

Proper packaging includes the classification, identification, packing, marking, labeling, and documentation of materials for shipment. Infectious substances must be packed according to specific instructions and specifications and the packaging material must be certified to meet rigorous performance tests as outlined in the DOT, USPS, PHS, and IATA regulations. As stated in the PHS regulation 42 CFR Part 72, such material must be "packaged to withstand leakage of contents, shocks, pressure changes and other conditions incident to ordinary handling in transportation." Figure 1 depicts the principle of triple packaging (primary receptacle, water tight secondary packaging, durable outer packaging) upon which all regulations are built.

Figure 1. Packing and Labeling of Infectious Substances



Packing and Labeling of Infectious Substances

1.1 Primary Receptacle. The primary receptacle contains the infectious substance and must be watertight to prevent leakage. Primary receptacles include those of glass, metal, or plastic and include screw-cap tubes, flame-sealed glass ampules, or rubber-stopped glass vials fitted with metal seals. Positive means of ensuring a leakproof seal, such as a heat seal, skirted stopper, or metal crimp seal must be provided. Screw caps may be fastened with tape, shrink seals, or other comparable material. Although glass is allowed, it is preferable to use plastic primary receptacles if possible.

1.2 Secondary Packaging. One or more primary receptacles are placed in a watertight secondary packaging. The primary receptacle or the secondary packaging must withstand, without leakage, an internal pressure differential and temperature range as described in the United Nations (UN) packaging specifications and performance tests. The secondary packaging should also bear a label with the name, address, and telephone number of the shipper.

1.3 Absorbent Material. Absorbent material must be placed between the primary receptacle and secondary packaging. Multiple primary receptacles must be

individually wrapped to prevent contact between them. The absorbent material must be sufficient to absorb the entire contents of the primary container(s).

1.4 Itemized List. IATA, DOT and PHS require that an itemized list of contents must be enclosed between the secondary packaging and the outer packaging.

1.5 Outer Packaging. An outer packaging must be of adequate strength for its capacity, mass, and intended use, and must be capable of meeting specific UN performance tests. Packaging that is certified to meet the test standards must be marked with a UN specification mark .

2. Classification

All hazardous materials are classified into 9 classes of Dangerous Goods. Infectious Substances belong to Class 6, Division 6.2. Dry ice is a Dangerous Good when shipped by air, and if packaged with an infectious substance, it must be declared as Class 9.

3. Identification

Infectious substances are assigned a “proper shipping name” and a unique 4-digit UN number to identify the substance being shipped. This information is included on the Shipper’s Declaration for Dangerous Goods and the outer package. For infectious substances, UN 2814 is used for “Infectious substance, affecting humans”, and UN 2900 refers to “Infectious substance, affecting animals.” The technical name of the infectious substance must also be included if known.

3.1 Quantity Limitations. When transported by passenger airline, DOT and IATA limit the quantity per package to 50 ml or 50 g. When transported by cargo airline, IATA limits the quantity per package to 4 liters or 4 kg.

4. Certified Packaging and Packing Instructions

If the infectious substance is transported by air, IATA regulations require a UN specification mark on the outer shipping packaging. The mark includes the United Nations packaging symbol, the type of packaging, the hazard class (6.2), the year of manufacture of the packaging, the authorizing agency and the manufacturer. Each package must be capable of passing the rigorous performance tests specified in IATA Dangerous Goods Regulations for Class 6.2 and DOT 49 CFR Part 178.609. Because performance testing is normally beyond the scope of shippers, it is strongly recommended that certified containers purchased from commercial suppliers be used, regardless of the mode of transportation.

Instructions for packing infectious substances are designated in UN Packing Instruction 602 listed in the IATA Dangerous Goods Regulations and DOT 49 CFR Part 173.196. These packing instructions also specify other requirements and limitations.

4.1 Size. Packages consigned as freight must be at least 100 mm (4 in) in the smallest overall external dimension. Thus, the outer packaging must be of sufficient size to bear the required markings and labels.

4.2 Ice and Dry Ice. Ice or dry ice must be placed outside the secondary

packaging. Interior supports must be provided to secure the secondary packaging in the original position after the ice or dry ice has dissipated. If ice is used, the packaging must be leakproof. If dry ice is used, the outer packaging must permit the release of carbon dioxide gas. Dry ice is packed according to UN Packing Instruction 904 listed in the IATA Dangerous Goods Regulations.

4.3 Liquid Nitrogen. Special arrangements must be made with the carrier in advance to ensure the safe transport of liquid nitrogen. Plastic primary receptacles and secondary packaging capable of withstanding very low temperatures must be used, and special labels are required on the outer container (see Labeling below).

4.4 Overpacks. Overpacks are used to combine several triple packages into one outer unit. Each triple package inside the overpack must be properly labeled and marked and the outside of the overpack must be marked with the statement "Inner Packages Comply with Prescribed Specifications."

5. Marking and Labeling

Each package of infectious substances must be marked on the outside of the shipping container with the following:

- a) The proper shipping name, technical name and corresponding UN Number.
- b) 24-Hour Emergency Response Number. Both DOT and IATA require that this number appear on the outer shipping package and the shipping document and to be used whenever there is a spill or accident involving the shipment of an infectious substance. This number must be that of a person who is knowledgeable of the material being shipped and has emergency response and incident mitigation information. This number should not be confused with the CDC number for reporting damaged or leaking packages.
- c) The full name and address of the shipper and the consignee.
- d) For dry ice, the net weight of the dry ice within the package.

The outer packaging must be of sufficient size to accommodate all labels placed on a single surface. Labels must not overlap. Labels required on the outside of the shipping container include:

- a) Class 6, Division 6.2 "Infectious Substance" label. This diamond-shaped label should contain the telephone number of the CDC in Atlanta to which damaged or leaking packages should be reported.
- b) Class 9 "Miscellaneous Dangerous Goods" label. This diamond-shaped label is used for dry ice.
- c) "Package Orientation (This Way Up)" labels. Two package orientation labels are affixed on opposite sides of the package.
- d) If liquid nitrogen is used, 2 labels are required: Division 2.2 "Non-flammable, non-toxic gas" and the "Cryogenic Liquid" handling label.
- e) For USPS shipments, a biohazard label is required.
- f) The Shipper's Declaration for Dangerous Goods document should be attached to the outside of the outer packaging
- g) A current U.S. Public Health Service import permit label for infectious

substances imported from outside the United States.

h) "Cargo Aircraft Only" label for shipments that exceed the maximum quantity specified for passenger aircraft.

6. Documentation

Packages containing infectious substances that are transported by air must contain a "Shipper's Declaration for Dangerous Goods" form. This legal document must be fully and accurately completed by the shipper. Incomplete, ineligible or inaccurate documents will result in refusal of the package by the carrier.

6.1 Confirmation of Receipt. According to 42 CFR part 72.3(f), certain agents may only be transferred via registered mail or an equivalent system, which requires notification of receipt to the sender immediately upon delivery. If the package is not received within 5 days, the shipper should notify the CDC.

6.2 Air Waybill. The shipper may or may not be required to fill out the air waybill for shipments by air.

7. Training

IATA and DOT require specific training of everyone directly involved in the shipping of dangerous goods. It is the responsibility of the employer to ensure that employees shipping dangerous goods are trained. IATA requires training and recertification every 2 years, or DOT requires training and recertification every 3 years.

OTHER CONSIDERATIONS

Importation of Etiologic Agents of Human Disease

42 CFR Part 71 Foreign Quarantine. Part 71.54 Etiologic Agents, Hosts and Vectors.

This regulation requires an import permit from the Centers for Disease Control and Prevention for importing etiologic agents of human disease and any materials, including live animals or insects, that may contain them. An application and information on importation permits may be obtained by calling 1-888-CDC-FAXX and enter document number 101000 or on the Internet at:

<http://www.cdc.gov/od/ohs/biosfty/impptper.htm>

Importation of Etiologic Agents of Livestock, Poultry and Other Animal Diseases

9 CFR Parts 92, 94, 95 96, 122 and 130. These regulations requires an import permit from the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services to import or domestically transfer etiologic agents of livestock, poultry, other animals, and any materials that might contain these etiologic agents. Information may be obtained at (301) 734-3277, or from the Internet at:

<http://aphisweb.aphis.usda.gov/>

Importation and Exportation of Endangered Species of Animals and Plants

The U.S. Department of the Interior, U.S. Fish and Wildlife Service, Convention on International Trade in Endangered Species (CITES) protects many species of animals

and plants to ensure that commercial demand does not threaten their survival in the wild. The Office of Management Authority administers CITES in the U.S. and processes applications for permits. Live animal shipments must meet the IATA Live Animal Regulations or the CITES guidelines for transport. In addition, the import of live mammals and birds must meet the humane shipment regulations in 50 CFR Part 14. For more information, contact Office of Management Authority, United States Fish and Wildlife Service at 1-800-358-2104 or on the internet at:

<http://www.fws.gov/r9dia/>

Transfer of Select Biological Agents of Human Disease

42 CFR Part 72.6 Additional Requirements for Facilities Transferring or Receiving Select Agents. Facilities transferring or receiving select agents must be registered with the CDC and each transfer of a select agent must be documented. Information may be obtained by calling 404-639-4418 or through the Internet at:

<http://www.cdc.gov/od/ohs/lrsat.htm>

Export of Etiologic Agents of Humans, Animals, Plants and Related Materials

Department of Commerce. 15 CFR Parts 730 to 799. This regulation requires that exporters of a wide variety of etiologic agents of human, plant and animal diseases, including genetic material will require an export license. Information may be obtained by calling the DOC Bureau of Export Administration at 202-482-4811 or through the Internet at:

<http://bxa.fedworld.gov>, or <http://www.bxa.doc.gov>

Damaged or Leaking Packages

If damage or leakage to a package containing infectious substances is discovered, avoid further handling of the package or keep handling to a minimum, and notify the shipper, consignee and the CDC (800-232-0124).

INFORMATION SOURCES

This document is for guidance purposes only. Information sources on regulations applying to the interstate and international transportation of infectious substances are shown in Appendix 1. Appendix 2 contains a partial list of manufacturers and suppliers of shipping materials and Appendix 3 lists some suppliers of Dangerous Goods Shipper's Declaration forms and labels.

Appendix 1. INFORMATION SOURCES FOR REGULATIONS ON THE TRANSPORTATION OF INFECTIOUS SUBSTANCES

Public Health Service 42 CFR Part 72. Interstate Transportation of Etiologic Agents. This regulation is in revision to harmonize it with the other U.S. and international regulations. A copy of the current regulation may be obtained from the Internet at:

<http://www.cdc.gov/od/ohs/biosfty/shipregs.htm>

Department of Transportation. 49 CFR Parts 171-180. Hazardous Materials Regulations.

Applies to the shipment of both biological agents and clinical specimens. Information may be obtained from the Internet at:

<http://hazmat.dot.gov/rules.htm>

United States Postal Service. 39 CFR Part 111. Mailability of Etiologic Agents.

Codified in the Domestic Mail Manual 124.38: Etiologic Agent Preparations. A copy of the Domestic Mail Manual may be obtained from the Government Printing Office by calling 1-202-512-1800 or from the Internet at:

<http://www.access.gpo.gov>

Occupational Health and Safety Administration (OSHA). 29 CFR Part 1910.1030.

Occupational Exposure to Bloodborne Pathogens. Provides minimal packaging and labeling requirements for transport of blood and body fluids within the laboratory and outside of it. Information may be obtained from your local OSHA office or from the Internet:

<http://www.osha.gov>

Dangerous Goods Regulations (DGR). International Air Transport Association (IATA). These regulations provide packaging and labeling requirements for infectious substances and materials, as well as clinical specimens that have a low probability of containing an infectious substance. These are the regulations followed by the airlines. These regulations are derived from the Committee of Experts on the Transport of Dangerous Goods, United Nations Secretariat, and the Technical Instructions for the Transport of Dangerous Goods by air which is provided by the International Civil Aviation Organization (ICAO). For assistance with the requirements of the regulation, call the IATA DG hotline at 514-390-6770. A copy of the DGR may be obtained by calling 1-800-716-6326 or through the Internet at:

<http://www.iata.org/cargo/dg/>

Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens. World Health Organization, 1997.

<http://www.who.int/emc/biosafety.html>

Appendix 2. MANUFACTURERS OF UNITED NATIONS CERTIFIED SHIPPING CONTAINERS FOR 6.2 INFECTIOUS SUBSTANCES

Action Pak, Inc.
2550 Pearl Buck Road
Bristol, PA 19007
Phone: 800-755-9764
FAX: 215-788-1760
Web: www.actionpakinc.com

Air Sea Atlanta
1234 Logan Circle
Atlanta, GA 30318
Phone: 404-351-8600
FAX: 404-364-4005
Web: <http://www.airseatlanta.com>

Air Sea Containers, Inc.
2749 NW. 82nd Avenue
Miami, FL 33122
Phone: 888-272-9883
FAX: 305-599-1668
Web: <http://www.airseacontainers.com>

All-Pak, Inc.
Corporate One West
1195 Washington Pike
Bridgeville, PA 15017-2854
Phone: 800-245-2283
FAX: 412-257-3001
Web: <http://www.allpakinc.com>

Casing Corporation
P.O. Box 820369
Dallas, TX 75382-0369
Phone: 800-358-6866
FAX: 214-320-1682
Web: <http://www.casingcorp.com>

Cin-Made Corporation
1780 Dreman Avenue
Cincinnati, OH 45223
Phone: 513-681-3600
Web: www.cin-made.com

The Compliance Center, Inc.
2150 Liberty Drive
Niagara Falls, NY 14304
Phone: 800-767-7231

Cargo Pak Corporation
306-A White Street South
Wake Forest, NC 27587
Phone: 800-266-0652
FAX: 919-554-9055
Web: <http://www.cargopak.com>

DG Supplies, Inc.
28 C Industrial Drive
Hamilton, NJ 08619
Phone: 800-347-7879
FAX: 609-860-0285
Web: www.dgsupplies.com

Environmental Packaging Systems, Ltd
1 Research Drive
Dartmouth, N.S., Canada B2y 4M9
Phone: 800-277-8675
FAX: 902-466-6889

EXAKT Technologies, Inc.
7416 North Broadway Extension, Suite E
Oklahoma City, OK 73116
Phone: 800-866-7172
FAX: 405-848-7701
Web: www.exaktpak.com

Federal Industries Corp.
2550 Niagara Lane
Plymouth, MN 55447
Phone: 800-523-9033
FAX: 612-476-8155
Web: www.chem-tran.com

HAZMATPAC, INC.
5301 Polk Avenue, Bldg 18
Houston, TX 77023

Phone: 800-923-9123
FAX: 713-923-1111
Web: <http://www.hazmatpac.com>

Inmark, Inc.
220 Fisk Drive, S.W.
Atlanta, GA 30336
Phone: 404-267-2020; 800-646-6275 (OUTSIDE GEORGIA)
FAX: 404-349-5249
Web: <http://www.inmarkinc.com>

Nalge Nunc International
75 Panorama Creek Drive
P.O. Box 20365
Rochester, NY 14625
Phone: 716-586-8800
FAX: 716-586-8987
Web: www.nalgenunc.com

O'Berk International, Inc.
3 Milltown Court
P.O. BOX 1690
Union, NJ 07083
Phone: 800-577-7624
FAX: 908-687-5157
Web: <http://www.aluminiumbottles.com>

Polyfoam Packers Corporation
2320 Foster Avenue
Wheeling, IL 60090-6572
Phone: 800-323-7442
FAX: 847-398-0653
Web: <http://www.polyfoam.com>

SAF-T-PAK, Inc.
101, 17872 - 106 Avenue
Edmonton, Alberta, Canada T5S 1V4
Phone: 800-841-7484
FAX: 403-486-0235
Web: <http://www.saftpak.com>

Sage Products, Inc.
815 Tek Drive

P.O. Box 9693
Crystal Lake, IL 60039-9693
Phone: 815-455-4700
FAX: 815-455-3310
Web: <http://www.sageproducts.com>

Source Packaging Of New England, Inc.
405 F Kilvert Street
Warwick, RI 02866
Phone: 800-200-0366
FAX: 401-738-7762
Web: <http://www.sourcepak.com>

**Appendix 3. MANUFACTURERS OF LABELS FOR
SHIPPING OF INFECTIOUS SUBSTANCES**

Label Master
5724 North Pulaski
Chicago, IL 660646
Phone: (800) 621-5808
FAX: (800) 723-4357

Shamrock, Inc.
34 Davis Drive
Bellwood, IL 60104
Phone: (800) 323-0249
FAX: (800) 248-1907

United Ad Label Company, Inc.
P.O. Box 2216
Brea, CA 92622-2216
Phone: (800)423-4643
FAX: (800) 962-0658

Additional Resources for the Select Agent Rule Satellite Broadcast:

Laboratory Registration and Select Agent Transfer Program

Office of Health and Safety

Centers for Disease Control and Prevention
1600 Clifton Rd. MS A-13
Atlanta, Georgia 30333
Tel: (404) 639-4418
FAX: (404) 639-0880
E-mail: lrsat@cdc.gov
Website: www.cdc.gov/od/ohs/lrsat.htm

General Laboratory Safety

- **CRC Handbook of Laboratory Safety.** Furr A.K. (ed.). CRC Press, Boca Raton. 1995. pp. 412-473.
- **Laboratory Safety: Principles and Practices,** 2nd ed. Fleming DO, Richardson JH, Tulis JJ, Vesley D, eds., Washington, DC. American Society for Microbiology, 1994.
- **Physical and Biological Hazards of the Workplace.** Wald, Peter H, Stave, Gregg M eds. Van Nostrand Reinhold, New York, 1994.
- **Preventing Occupational Disease and Injury.** American Public Health Association, Washington, DC, 1991.

Biological Safety

- **AHIA - Biosafety Reference Manual.** Heinsohn PA, Jacobs RR, Concoby BA eds. American Industrial Hygiene Association, Fairfax, 1995, pp 51-99.
- **Biohazards Management Handbook.** Lieberman DF, ed. New York: Marcel Dekker, 1995; 173-192.
- **CDC/National Institutes of Health Biosafety in Microbiological and Biomedical Laboratories,** 4th ed. Atlanta: U.S. Department of Health and Human Services, Public Health Service, CDC and NIH, 1999.
- **Biosafety in the Laboratory: Prudent Practices for the Handling and Disposal of Infectious Materials.** National Academy Press, Washington, D.C. 1989.

- **Designing a Modern Microbiological/Biomedical Laboratory: Lab Design Process and Technology.** Jonathan Y. Richmond, ed. American Public Health Association, Washington, D.C. 1997.
- **Anthology of Biosafety: I. Perspectives on Laboratory Design.** Jonathan Y. Richmond, ed. American Biological Safety Association. 1999.
- **Anthology of Biosafety: II. Facility Design Considerations.** Jonathan Y. Richmond, ed. American Biological Safety Association. 2000.
- **The Hazard of Infectious Agents in Microbiologic Laboratories.** McKinney RW, Barkley WE, Wedum AG. In: Block SS, ed. Disinfection, Sterilization, and Preservation, 4th ed. Philadelphia: Lea & Febiger, 1991:749-756.
- **Laboratory-Associated Infections and Biosafety.** Sewell DL. Clin Microbiol Rev 1995;8:389-405.
- **Aerosol Production Associated with Clinical Laboratory Procedures.** Stern E, Johnson JW, Vesley D, Halbert MM, Williams IE, Blume P. Am J Clin Pathol 1974;62:591-600.

Risk Assessment and Risk Group Classification

- **Biosafety in Microbiological and Biomedical Laboratories, 4th Ed. (CDC/NIH)** <http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm>
- **American Biological Safety Association (risk group comparison table)** <http://www.absa.org>
- **Health Canada (MSDS for microorganisms)** Health Protection Branch - Laboratory Centre for Disease Control http://www.hc-sc.gc.ca/hpb/lcdc/dpg_e.html
- **NIH Guidelines for Research Involving Recombinant DNA Molecules** <http://www4.od.nih.gov/oba/guidelines.html>
- **Laboratory Risk Assessment - What, Why, and How.** Risk Assessment in the Infectious Disease Laboratory. Satellite broadcast video tape and study booklet. <http://www.phppo.cdc.gov/dls/nltm/nltmvt.asp>

The videotape of the July 23, 1998 satellite broadcast, "Laboratory Risk Assessment: What, Why, and How" is available for loan from the [National Laboratory Training Network \(NLTN\)](#). While on loan the videotape may be copied, but the original must be returned to the

office from which it was borrowed. Calling 1-800-536-NLTN will automatically connect you with the office serving your state.

Toxins and Chemical Safety

- **Biosafety in Microbiological and Biomedical Laboratories**, 4th Ed. 1999. (CDC/NIH). Appendix I - Guidelines for Work With Toxins of Biological Origin. <http://www.cdc.gov/od/ohs/biosfty/bmb14/bmb14toc.htm>
- **Occupational Exposure to Hazardous Chemicals in the Laboratory**. 29 CFR 1910.1450 - <http://www.osha.gov/>
- **Registry of Toxic Effects of Chemical Substances (RTECS)** <http://www.cdc.gov/niosh/rtecs.html>
- **Biological Defense Safety Program**. 32 CFR Parts 626, 627n Department of the Army, DOD. <http://www.gpo.gov>
- **NIOSH/OSHA Pocket Guide to Chemical Hazards**. NIOSH Publication No.97-140, Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402,1997.
- **Prudent Practices in the Laboratory - Handling and Disposal of Chemicals**. National Research Council, National Academy Press, Washington DC, 1995.
- **American Industrial Hygiene Association - Biosafety Reference Manual**. Heinsohn P.A.; Jacobs R.R.; Concoy B.A. (eds.). American Industrial Hygiene Association, Fairfax. 1995.
- **CRC handbook of Toxicology**. Derelanko M.J., Hollinger M.A. (eds.). CRC Press, Boca Raton 1995.

Physical Safety

- **Safe Handling of Compressed Gas in Containers**. Compressed Gas Association, Inc., Publication No. P-I, 8th ed., 2235 Jefferson Davis Highway. Arlington. VA., 22207, 1991.

Ventilation and Safety Cabinets

- **Laboratory Ventilation Standard, ANSI NO. Z9.5**. American National Standards Institute. 1992. American Industrial Hygiene Association, Fairfax, VA 1993.

- **1995 Handbook - HVAC Applications.** American Society of Heating, Refrigeration, and Air-Conditioning Engineers (ASHRAE). ASHRAE, Atlanta, GA 1995,
- **Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets.** CDC/NIH. U.S. Department of Health and Human Services, Public Health Service, CDC, 1995.
- **Biological Safety Cabinetry.** Kruse RH, Puckett WH, Richardson JH. Clin Microbiol Rev 1991;4:207-41.
- **Class II (Laminar Flow) Biohazard Cabinetry.** National Sanitation Foundation (NSF). Standard 49, Ann Arbor: 1992.

Security

- **Biosafety in Microbiological and Biomedical Laboratories, 4th Ed. 1999. (CDC/NIH).** Appendix F - Laboratory Security and Emergency Response for Microbiological and Biomedical Laboratories.
<http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm>
- **Laboratory Design Principles.** Ruys, Theodorus; New York: In: Handbook of Facilities Planning. Ruys, T, ed. New York: van Nostrand Reinhold, 1990; 257-264.

General Web Sites

- **Centers for Disease Control and Prevention** <http://www.cdc.gov/>
- **Centers for Disease Control and Prevention, Office of Health and Safety (CDC-OHS)** <http://www.cdc.gov/od/ohs/>
- **Association of Public Health Laboratories** <http://www.aphl.org/>
- **Lab Safety** <http://www.labsafety.org/sandp.htm>
- **American Biological Safety Association (ABSA)** <http://www.absa.org/>
- **European Biological Safety Association (EBSA)** <http://www.ebsa.be/>
- **American Society for Microbiology (ASM)** <http://www.asmtusa.org>

- **International Air Transport Association (IATA)** <http://www.iata.org/>,
<http://www.iata.org/cargo/dg/index.htm>
- **U.S. Department of Agriculture (USDA)** <http://www.usda.gov/>
- **Animal and Plant Health Inspection Service (APHIS)**
<http://www.aphis.usda.gov/>
- **Association of Public Health Laboratories (APHL)** <http://www.aphl.org>
- **American Association for Laboratory Animal Science (AALAS)**
<http://www.aalas.org/>
- **Eagleson Institute** <http://www.eagleson.org>
- **List of Approved Respirators** <http://www.cdc.gov/niosh/respinfo.html>
- **National Institute for Occupational Safety and Health (NIOSH)**
<http://www.cdc.gov/niosh/homepage.html>
- **Occupational Safety and Health Administration (OSHA)**
<http://www.osha.gov/>
- **American Industrial Hygiene Association (AIHA)** <http://www.aiha.org/>
-
- **National Laboratory Training Network (NLTN)**
<http://www.phppo.cdc.gov/dls/nltn/>
- **Health Canada B Laboratory Centre for Disease Control** http://www.hc-sc.gc.ca/hpb/lcdc/new_e.html
- **Association for Assessment and Accreditation of Laboratory Animal Care (AALAC)** <http://www.aaalac.org>
- **U.S. Department of Transportation** <http://www.dot.gov/>
- **U.S. Department of Commerce** <http://www.bxa.doc.gov/>
- **World Health Organization (WHO)** <http://www.who.ch/>

Select Agent Rule Post Test

The primary goals of the select agent rule are:

- True False Assuring agents are shipped only to qualified laboratories.
- True False Establishing criteria for protecting public safety during transfer of agents.

The Select Agent Rule addresses the following:

- True False The list of select agents.
- True False Registering facilities
- True False Exemptions for some research and clinical laboratories
- True False Disposal of agents
- True False Laboratory self-assessment
- True False Transfer requirements

Registered laboratories must appoint:

- a) a safety officer
- b) a responsible facility official
- c) a compliance officer
- d) a director

True False Open manipulation of BSL3 organisms must be done in a BSC.

Your laboratory may be exempted from registering under the Select Agent Rule if:

- True False You work only with botulinum toxin.
- True False You are CLIA certified and work with select agents only in diagnostic testing.
- True False You work only with recombinant DNA.
- True False You are CLIA certified and work only with select agents in teaching students.

Yes No Can the RFO be someone who actually ships select agents?

True False Labs working with toxins must complete the BSL2 section of the self assessment.

True False Inspections are done to insure compliance with the regulation.

The form to document the transfer of select agents is:

- a) Dangerous Goods Manifest
- b) Import Permit
- c) EA-101

Participant Name _____

**Select Agent Rule
Workshop Evaluation**
June 22, 2000

Please rate each of the items below using the following scale:

Excellent Good Acceptable Marginal Poor

5 4 3 2 1

(

;

How successful was this course in:

Increasing your knowledge and/or skills in the subject matter presented?	Providing material that is directly applicable to your work?	Meeting the stated objectives?
Jonathan Richmond		
Mark Hemphill		
William Howard		
Henry Mathews		
Robert Hill		
Richard Knudsen		

1. How worthwhile was this program in terms of time and money invested ? (5 4 3 2 1 ;

2. Overall, I consider this workshop:

3. What would you add to this workshop to make it more beneficial to you? (5 4 3 2 1 ;

4. What would you delete from this workshop?

5. Based on what you learned in this course, do you intend to make any changes in your laboratory practices? 9 yes 9 no

If yes, list planned changes:

If not, please explain:

6. How did you learn about this workshop: 9 mailed brochure 9 Internet 9 Other _____
(please specify)

8. Additional comments:

Registration Form Select Agent Rule

Please type or print		
(Dr., Mr., Mrs., Ms., or Miss)	(First)	(M.I.) (Last)
Social Security Number	We also need to know your Social Security Number. This number is voluntary and collected under the Public Health Service Act.	
Position Title		E-mail address
Employer's Name		Employer's Phone Number
Employer's Address		Employer's Fax Number
City	State	Zip
Course No. & Date: June 22, 2000		Location: Satellite Broadcast

(Signature of Applicant

Date

OCCUPATION (Circle one number)
01 Physician 02 Veterinarian 04 Laboratorian 05 Nursing 06 Sanitarian 07 Industrial Hygienist 08 Administration 09 Water Treatment Operator 11 Safety Professional

EDUCATION LEVEL (Circle Highest Level Attained)
01 Some High School 02 High School Graduate 03 Some College 04 Associate's Degree 05 Bachelor's Degree 06 Master's Degree 07 Doctoral Degree-MD 08 Doctoral Degree-Other than MD 09 Technical/Hospital School 10 Other _____

TYPE OF EMPLOYER Please review all categories before circling appropriate one (Circle one number)
01 State and Territorial Health Department 02 Other State & Territory Employer 03 Local, City or County Health Dept. 04 Other Local Government Employer 05 CDC 06 Other CDC Employer 09 U.S. Food & Drug Administration 11 U.S. Department of Defense 12 Veteran's Administration Hospital 15 Other Federal Government Employer 16 Foreign Employer 17 Private/Community Hospital 19 College/University 21 Private Industry 23 Private Clinical Laboratory 24 Physician Office Lab/Group Practice 25 Hospital-State Funded 26 Hospital-City/County Funded 28 Health Maintenance Organization

THE FOLLOWING PRIVACY ACT STATEMENTS IS APPLICABLE TO ALL INCLUDED FORMS NEEDING SOCIAL SECURITY NUMBER

The information requested on this form is collected under the authority of 42 U.S.C. 243. The requested information is used only to process and evaluate your application for training and may be disclosed (for verification purposes) to your employer, group leader, educational institution, etc. as necessary. An accounting of such disclosures will be furnished to you upon request. Furnishing the information requested on this form, including your Social security number (SSN), is voluntary. However, no applicant may receive Continuing Education Unit or Continuing Medical Education Unit credit unless a completed application form is received. The SSN is used for identity verification purposes and prevents the assignment of more than one identifying number to the same individual. If you do not wish to submit a SSN, CDC will assign a unique identifier.

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National Laboratory Training Network
 Southeastern Office
 P. O. Box 160385
 Nashville, TN 37207-8215

FAX: 615-262-6441