U.S. Department of Energy
Washington, D.C.

NOTICE

DOE N 450.7

Approved: 10-17-01
Expires: 06-17-02

SUBJECT: THE SAFE HANDLING, TRANSFER, AND RECEIPT OF BIOLOGICAL ETIOLOGIC AGENTS AT DEPARTMENT OF ENERGY FACILITIES

1. OBJECTIVES.

   a. To establish requirements and assign responsibilities for the Department of Energy (DOE), including the National Nuclear Security Administration (NNSA), biological etiologic agent program.

   b. To ensure that work involving etiologic or potentially biological etiologic agents, including biological select agents, occurs in a safe, secure, and effective manner that protects workers, the public, and the environment.

   c. To comply with 42 CFR Part 72, Interstate Shipment of Etiologic Agents, which establishes regulations for the safe handling, transfer, use, or receipt of biological etiologic agents.

   d. To provide guidance on the safe handling, transfer, and receipt of biological etiologic agents until appropriate DOE Orders are revised to reflect this guidance.

2. CANCELLATION. None.

3. APPLICABILITY.

   a. DOE Elements. Except for the exclusions in paragraph 3d, this Notice applies to any DOE-owned or -leased facilities that may transfer, use, or receive, through any means, an agent defined in 42 CFR 72.1 as an etiologic agent or in section 72.6(j) as a select agent.

   b. Contractors. Except for the exclusion in paragraph 3d, Attachment 1, Contractor Requirements Document (CRD), is intended to apply to any DOE major facilities contractor that may transfer, use, or receive etiologic agents, including biological select agents, through any means. The major facilities management contractor must comply with the CRD after the contracting officer incorporates it into the contract in accordance with the laws, regulations, and DOE directives clause of the contract. Regardless of who performs the work, the contractor is responsible for compliance with the requirements of the CRD after it is incorporated into the contract. The contractor is responsible for flowing down the requirements of the CRD to subcontracts

at any tier to the extent necessary to ensure the contractor's compliance with the requirements.

c. For the purposes of this Notice, DOE facility means any single site that may transfer, use, or receive through any means an etiologic agent, including a select agent, as defined in 42 CFR Part 72.

d. Exclusion. The Naval Nuclear Propulsion Program, which is covered under Executive Order 12344, Public Law 98-525 (42 U.S.C. 7158, note), is responsible for establishing standards to provide adequate protection for workers, the public, and the environment for facilities and activities under Naval Nuclear Propulsion Program cognizance.

4. REQUIREMENTS.

a. DOE activities involving biological etiologic agents must be performed in accordance with the regulatory requirements of 42 CFR Part 72 and 29 CFR 1910.1030, Occupational Exposures to Bloodborne Pathogens.

b. Appropriate biological etiologic agents guidelines and best practices consistent with those contained in the most current edition of the U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC) Publication No. 93-8395, *Biosafety in Microbiological and Biomedical Laboratories*; the National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant DNA Molecules*; and the World Health Organization (WHO) *Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens* must be implemented for all DOE activities involving etiologic agents.

c. DOE field elements must implement and manage a program that confirms handling, transfer, use, and receipt of biological etiologic agents is conducted by professionally and technically qualified individuals in a manner consistent with the potential hazard.

d. DOE field elements must confirm that each DOE contractor performing work with etiologic biologic agents establishes an Institutional Biosafety Committee (IBC), which will be responsible for recommending approval and reviewing proposals and programs for compliance with CDC, NIH, WHO, and other international, Federal, State, and local guidelines for work with biological etiologic agents. This review should include assessment of containment level, facilities, procedures, practices, and training and expertise of personnel. In addition, this committee should review the site's security, safeguards, and emergency management plans and procedures to ensure that they adequately address work with biological etiologic agents. DOE staff, with the requisite technical expertise and training, must participate on the facility IBC.

e. As required by the Integration of Environment, Safety and Health Into Work Planning and Execution (June 1997) contract clause as provided for in 48 CFR 970.5204-2 and consistent with DOE P 450.4, *Safety Management System Policy*, contractors operating DOE facilities must adequately address hazards. Particular emphasis should be placed on etiologic and biological select agents through review of appropriate plans, such as the site safeguards and security plans or facility or site security plans, and emergency management programs.

f. As an addendum to the annual reporting requirement of the Federal Managers Financial Integrity Act (FMFIA), each DOE field element must provide an annual written statement, based on submittals by the contractors, that programs utilizing biologic etiologic agents are compliant with the requirements of this Notice.

g. DOE field elements must maintain a copy of each CDC registration certificate issued to a DOE facility registered and approved to transfer, receive, and handle biological select agents at Biosafety Level (BSL) 2, 3, or 4 under their cognizance, and a copy of each of the CDC Form EA-101, Transfer of Select Agents, for each biological select agent received or transferred by a registered facility under their cognizance.

h. Each DOE field element must maintain an automated inventory and record of the status of biological etiologic agents at facilities under their authority, based on annual reports from contractors.

i. DOE field elements must work with the contractor to amend the contract or CRD language, when necessary when contractor employees are represented for collective bargaining by a labor organization, and as consistent with Federal labor laws.

5. RESPONSIBILITIES.

a. Heads of Departmental Headquarters Elements.

(1) Confirm that DOE facilities are registered with the CDC for the transfer or receipt of the biological select agents pursuant to 42 CFR 72.6(a) prior to requesting or receiving such biological select agents.

(2) Notify the contracting officers to incorporate the CRD and any amendments to the CRD into the affected major facilities management contracts via the laws, regulations, and DOE directives clauses of the contracts.

b. Contracting Officer, after being notified of the affected contracts, incorporates the CRD and any amendments to the CRD, as appropriate, into the affected major facilities management contracts.

c. Assistant Secretary for, Office of Environment, Safety and Health. Prior to expiration of this Notice, assures that appropriate requirements for the safe handling, transfer, and receipt of biological etiologic agents at DOE facilities are integrated into existing DOE directives and guidance documents using integrated safety management principles.

6. REFERENCES.

a. Title 42 CFR Part 72, Interstate Shipment of Etiologic Agents, 7-21-80 (revised 10-1-00).
(http://www.cdc.gov/od/ohs/lrsat/42cfr72.htm)

b. *Biosafety in Microbiological and Biomedical Laboratories*. CDC/NIH publication (current edition).
(http://www.cdc.gov/ncidod/dvbid/Biosafety_manual_rev_1994.pdf)

c. *NIH Guidelines for Research Involving Recombinant DNA Molecules*. NIH publication MSU/1998 (current edition).
(http://www.niehs.nih.gov/odhsb/biosafe/nih/rdna-apr98.pdf)

d. *Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens*. World Health Organization publication WHO/EMC/97.3 (current edition)
(http://www.who.int/emc-documents/biosafety/docs/whoemc973.pdf)

e. Title 29 CFR 1910.1030, Occupational Exposures to Bloodborne Pathogens.
(http://www.osha-slc.gov/OshStd_data/1910_1030.html)

f. Title 29 CFR 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories.
(http://www.osha-slc.gov/OshStd_data/1910_1450.html)

g. DOE P 450.4, *Safety Management System Policy*, dated 10-15-96.

7. CONTACT. Questions concerning this Notice should be addressed to the Office of Worker Protection Policy and Programs (EH-52), 301-903-6061.

BY ORDER OF THE SECRETARY OF ENERGY:

FRANCIS S. BLAKE
Deputy Secretary

CONTRACTOR REQUIREMENTS DOCUMENT

DOE N 450.7, *The Safe Handling, Transfer, and Receipt of Biological Etiologic Agents at Department of Energy Facilities*

Regardless of the performer of the work, the contractor is responsible for compliance with this Contractor Requirements Document (CRD). The contractor is responsible for flowing down the requirements of this CRD to subcontracts at any tier to the extent necessary to ensure the contractor's compliance with the requirements. Department of Energy (DOE) contractors must provide a reasonably safe and healthful workplace for DOE workers, while also protecting the public and the environment and, in particular, must:

1. Comply with appropriate regulatory measures for the safe handling, transfer, use, or receipt of biological etiologic agents at DOE facilities (See Title 42 Code of Federal Regulations (CFR) Part 72, Interstate Shipment of Etiologic Agents and 29 CFR 1910.1030, Occupational Exposures to Bloodborne Pathogens).

2. Establish an Institutional Biosafety Committee (IBC), which will be responsible for reviewing any work with biological etiologic agents for compliance with appropriate Center for Disease Control and Prevention (CDC), National Institutes of Health (NIH), World Health Organization (WHO), and other State and local guidelines, and assessment of containment level, facilities, procedures, practices, and training and expertise of personnel. In addition, this committee should review for compliance the site's security, safeguards, and emergency management plans and procedures as related to work with biological etiologic agents.

3. Implement appropriate biological etiologic agents guidelines and best practices. See most current edition of the U.S. Department of Health and Human Services (HHS) CDC Publication No. 93-8395, *Biosafety in Microbiological and Biomedical Laboratories*; the NIH publication *Guidelines for Research Involving Recombinant DNA Molecules*; and the WHO publication *Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens.*

4. Maintain an automated inventory and status of biological etiologic agents and confirm in a written statement, within 60 days of incorporation of this CRD into the contract, to the head of DOE field element, compliance with the requirements of this Notice. Provide to the responsible field and area office, through the laboratory IBC, an annual status report describing the status and inventory of biological etiologic agents and program.

5. Submit to the head of the appropriate DOE field element, for review and concurrence, prior to transmittal to the CDC, each Laboratory Registration/Select Agent Program registration application package requesting registration of a laboratory facility at Biosafety Level 2, 3, or 4, for the purpose of transferring, receiving, or handling biological select agent(s).

6. Submit to the head of the appropriate DOE field element a copy of each CDC Form EA-101, Transfer of Select Agents, upon initial submission of the Form EA-101 to a vendor or other

supplier requesting or ordering a biological select agent for transfer, receipt, and handling in the registered facility. Submit the completed copy of the Form EA-101, documenting final disposition and/or destruction of the select agent, within 10 days of completion of the Form EA-101.

7. Confirm the site safeguards and security plans and emergency management programs address biological etiologic agents with particular emphasis on biological select agents.

8. Establish an immunization policy for personnel working with biological etiologic agents based on the recommendations contained in the U.S. Public Health Service Advisory Committee on Immunization Practices (ACIP) and as updated in the CDC *Morbidity and Mortality Weekly Report*. The ACIP provides basic guidance, but specific immunization actions should be based on the DOE facility evaluation of risk and benefit of immunization.

9. Give labor organizations timely notice of the development and implementation of procedures under this CRD, and of any changes to those procedures, when contractor employees are represented for collective bargaining by a labor organization. The requirements of the CRD do not supersede contractor's obligation to bargain with labor organizations consistent with Federal labor laws.