

Memorandum

DATE: March 1, 2002

REPL TO

ATTN OF: IG-40

SUBJECT: DOE Biological Etiologic Agent Program Requirements

TO: Director, Office of Worker Protection Policy and Programs

In a February 2001 report, entitled “Inspection of Department of Energy Activities Involving Biological Select Agents” (DOE/IG-0492), we reported that the Department of Energy’s (DOE) biological select agent activities lacked appropriate Federal oversight, consistent policy, and standardized implementing procedures. Subsequently, a DOE Notice, DOE N 450.7, “THE SAFE HANDLING, TRANSFER, AND RECEIPT OF BIOLOGICAL ETIOLOGIC AGENTS AT DEPARTMENT OF ENERGY FACILITIES,” was issued that establishes requirements and assigns responsibilities for the DOE biological etiologic agent program.

We believe the DOE Notice is a good first step by the Department to address the concerns we identified in our February 2001 report. However, we offer the following suggestions:

- . Future guidance issued by the Department regarding biological etiologic agent activities should include a discussion of the significant National Environmental Policy Act (NEPA) requirements that affect the activities. For example, the NEPA requirement for an Environmental Assessment prior to construction of a biosafety-level 3 laboratory is not discussed in the Notice.
- . DOE should develop Department-wide best practices for use by individual sites to develop site-specific best practices. According to the “Contractor Requirements Document” section of the Notice, contractors are required to implement appropriate biological etiologic agent guidelines and best practices based on several documents, such as the Centers for Disease Control and Prevention’s “Biosafety in Microbiological and Biomedical Laboratories” (BMBL). As we discussed in our February 2001 report, DOE lacked standardized policies and procedures for certain activities, such as worker immunizations, screening of shipments, or handling damaged packages. However, these types of policies and procedures are not addressed in the BMBL.

Also, we understand that the Office of General Counsel (GC) has not yet addressed the immunization-related issues we identified in our February 2001 report. We recommended in our report that GC determine the potential liability to DOE if contractor employees working with biological select agents refuse immunizations, the feasibility of requiring employees to

have immunizations, and if DOE has liability to third parties that maybe infected by contractor employees who refuse immunizations. We believe these are significant issues that warrant a timely review by GC.

If you have any questions, please contact Mr. Glenn White or me at (202) 586-4109.



Christopher R. Sharpley
Acting Assistant Inspector General
for Inspections

cc: Deputy Secretary