DOE F 1325.8
(4/93)

United States Government **Department of Energy**

OFFICE OF INSPECTOR GENERAL

memorandum

DATE: June 30, 1999

REPLY TO
ATTN OF: IG-40

SUBJECT: Management Alert on "Inspection of the Chem-Bio Facility at ORNL," S99IS019

TO: Manager, Oak Ridge Operations Office

This Management Alert is to inform you of our concerns regarding the implementation of the National Environmental Policy Act (NEPA) of 1969 at the Oak Ridge National Laboratory (ORNL) in Oak Ridge, Tennessee, relating to the "chem-bio" facility. We believe this issue may require immediate management attention. We are issuing this Management Alert in conjunction with our ongoing review, titled "Inspection of the Chem-Bio Facility at ORNL," Inspection Number S99IS019.

In October 1998, a trace agents laboratory, commonly referred to as the "chem-bio" facility, was installed at ORNL. The purpose of the chem-bio facility is to conduct chemical and biological warfare agent research as part of the Block II Chemical Biological Mass Spectrometer (CBMS) work-for-others project sponsored by the U.S. Army. ORNL's chem-bio facility consists of two laboratories, one for chemical warfare agent research and one for biological warfare agent research.

The Centers for Disease Control and Prevention (CDC) has established four biological laboratory biosafety levels; each level consisting of combinations of laboratory practices and techniques, safety equipment, and facilities which are appropriate for safe handling of specific biological agents. According to the Program Manager of the CBMS project, ORNL's chem-bio facility is a Biosafety Level-3 laboratory because botulinum toxins, which are bacterial agents required for the development of the CBMS project, will be received as a dry "lyophilized" powder. An official from the CDC also told us that when botulinum toxins are dry lyophilized, or "freeze dried," the inhalation and associated lethality is enhanced and requires a Biosafety Level-3 laboratory for containment and safe handling.

Prior to ORNL's installation of the chem-bio facility, an internal letter to the file dated April 13, 1998, prepared by Lockheed Martin Energy Research Corporation, the major operating contractor for ORNL, categorically excluded the entire chem-bio facility from the environmental assessment requirements of NEPA. The basis for the exclusion, as cited by this memorandum, was Appendix B to Subpart D to Part 1021, Title 10, Code of Federal Regulations, Categorical Exclusions Applicable to Specific Agency Actions, Paragraph B3.6.

This paragraph provides exclusion from NEPA requirements for, among others, siting, construction (or modification), and operation of facilities for indoor bench-scale research projects and conventional laboratory operations; small-scale research and development projects; and small-scale pilot projects conducted to verify a concept before demonstration actions.

Our concern is that a categorical exclusion to NEPA requirements was granted for the Biosafety Level-3 laboratory at ORNL's chem-bio facility; and that this exclusion appears contrary to Appendix B to Subpart D to Part 1021, Title 10, Code of Federal Regulations, Categorical Exclusions Applicable to Specific Agency Actions, Paragraph B3.12. Paragraph B3.12 provides a categorical exclusion to NEPA requirements for, among others, siting, construction (or modification), and operation of microbiological research facilities. However, it specifically excludes Biosafety Level-3 facilities from the categorical exclusion from NEPA environmental assessment requirements.

Based on the above information, we are concerned that it may not be permissible under NEPA for DOE to procure, install, and commence microbiological operations at the ORNL Biosafety Level-3 laboratory without, at a minimum, an environmental assessment. The CBMS Program Manager recently told us that dry lyophilized botulinum, requiring Biosafety Level-3 containment, has been received at ORNL and is expected to be used for research beginning in early July 1999. Therefore, we believe that the Oak Ridge Operations Office should determine what actions, including NEPA review and documentation, should be completed for the ORNL Biosafety Level-3 laboratory.

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Assistant Inspector General
for Inspections

cc: Assistant Secretary, Environment, Safety and Health
Director, Office of Science
Leader, Audit Liaison Team, CR-2
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