INS-O-00-01

INSPECTION REPORT

INSPECTION OF SELECTED ISSUES OF THE CHEM-BIO FACILITY AT THE OAK RIDGE NATIONAL LABORATORY

NOVEMBER 1999

U.S. DEPARTMENT OF ENERGY
OFFICE OF INSPECTOR GENERAL
OFFICE OF INSPECTIONS

Department of Energy
Washington, DC 20585

November 30, 1999

MEMORANDUM FOR THE MANAGER, OAK RIDGE OPERATIONS OFFICE

FROM: Sandra L. Schneider
Assistant Inspector General for Inspections
Office of Inspector General

SUBJECT: INFORMATION: Report on "Inspection of Selected Issues of the Chem-Bio Facility at the Oak Ridge National Laboratory"

BACKGROUND

In October 1998, a laboratory for defensive research, development, and testing using trace amounts of chemical and biological warfare agents, commonly known as the "Chem-Bio" facility, was installed at the Oak Ridge National Laboratory (ORNL) in performance of a work-for-others (WFO) contract with the U.S. Army. The Chem-Bio facility included two separate laboratories, one for research with chemical warfare agents and the other, a Biosafety Level-3 laboratory, for research with biological warfare agents. The objective of our inspection was to evaluate the financial and environmental management, by Lockheed Martin Energy Research (LMER), DOE's major operating contractor at ORNL, of the Chem-Bio facility.

RESULTS OF INSPECTION

LMER improperly used funds from ORNL overhead accounts to fund the WFO project. Specifically, $358,571 from ORNL division overhead accounts was provided to fund the WFO project. Further, the Chem-Bio facility was constructed with a Biosafety Level-3 laboratory, which, according to Departmental implementing regulations for the National Environmental Policy Act of 1969 (NEPA), would have required an environmental assessment. However, LMER did not complete the required environmental assessment for the Chem-Bio facility. Our report contained recommendations to the Oak Ridge Operations Office (ORO) Manager for corrective actions to ensure: (1) ORO division overhead funds are recouped; (2) other ORO WFO projects have not been funded with overhead funds; (3) documentation for future projects requiring NEPA compliance be completed; (4) an environmental assessment or other actions necessary to ensure NEPA compliance be completed; and (5) that the Chem-Bio facility and its contents are secure.

MANAGEMENT REACTION

Management concurred with the findings and recommendations and initiated appropriate corrective actions.

cc: Director, Office of Science
Leader, Audit Liaison Team, CR-2

INSPECTION OF SELECTED ISSUES OF THE CHEM-BIO FACILITY AT THE OAK RIDGE NATIONAL LABORATORY

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INTRODUCTION AND OBJECTIVE

The Department is seeking to increase its role in the development of new technologies to detect and counter attacks utilizing weapons of mass destruction. Such attacks include chemical and biological agents and nuclear devices. Currently, DOE is involved with this technology development for domestic counter-terrorism purposes, and is also working to assist the military with its preparation for weapons of mass destruction attacks through work-for-others programs.

In December 1996, the Department's Oak Ridge Operations Office (ORO) entered into a $32 million, four year work-for-others (WFO) interagency agreement with the Department of the Army (Army) to develop the Block II Chemical Biological Mass Spectrometer (CBMS). The purpose of the agreement was for Lockheed Martin Energy Research, Inc. (LMER), the major operating contractor at Oak Ridge National Laboratory (ORNL), to design, build and demonstrate nine CBMS instruments with the ability to rapidly detect and identify biological and chemical warfare agents in a battlefield environment. Chemical warfare agents to be detected and identified include nerve and mustard gases; biological agents such as Botulinum toxin, ricin, aflatoxins and an encephalitis virus.

The CBMS WFO agreement stated that work at ORNL be restricted to chemical and biological agent simulants and killed biological agents; work with actual agents would be performed at Department of Defense approved facilities. The agreement also stated that work with chemical materials could be performed at ORNL if and when an Army certified chemical capability was established.

In October 1998, a pre-fabricated containment laboratory for defensive research, development, and testing using trace amounts of chemical and biological warfare agents, commonly known as the "Chem-Bio" facility, was installed at ORNL allowing non-simulant biological and chemical warfare agent research in developing the CBMS. The Chem-Bio facility included two separate laboratories, one for research with chemical warfare agents and the other, a Biosafety Level-3 laboratory, for research with biological warfare agents. The Chem-Bio facility was procured for three reasons: (1) to maintain an aggressive CBMS program schedule, (2) to minimize travel to the Army's testing facility in Dugway, Utah, in connection with CBMS research, and (3) for rapid addition of agents to the CBMS capability.

The OIG has issued a previous report dealing with the WFO program at Oak Ridge. In Report ER-B-97-04, Audit of Selected Hazardous Waste Remedial Actions Program Costs, it was determined that Lockheed Martin Energy Systems did not properly manage and account for costs claimed under its interagency agreements. Lockheed Martin Energy Systems transferred costs among accounts to avoid overruns and to use the maximum funds authorized. In Report DOE/IG-0307, Procurement of Services from 8(a) Contracts for the Work-for-Others Program, the OIG reported that the 8(a) contracts were not properly administered, which resulted in out-of-scope work being performed. In Report ER-B-91-15, Selected Aspects of Martin Marietta Energy Systems, Inc., Work-for-Others Management, the OIG determined that Martin Marietta Energy Systems had commenced work before Departmental approval, performed work outside the scope of funding documents, and exceeded authorized funding. The report cited examples in which labor costs were not charged to the associated task and a cost overrun was charged to an overhead account.

Our inspection included two objectives, to determine whether: (1) costs charged by LMER in the performance of the CBMS WFO project were incurred in accordance with DOE requirements and the terms of the Army's interagency agreement, and (2) environmental documentation for the Chem-Bio facility was completed as required by DOE regulations.

As part of its implementation of the Government Performance and Results Act of 1993 (GPRA), the Department must, among other things, establish program goals and measure performance against these goals. ORO, in negotiations with LMER, established the ORNL FY 1999 Critical Outcomes Plan which defined expectations and provided a basis for evaluating performance. This plan included elements regarding Business Operations and Environment, Safety and Health. For example, LMER will: (1) use efficient and effective corporate management systems to, among other efforts, reduce costs, and (2) comply with all applicable environmental laws, regulations, ordinances and associated permits. This inspection report has been prepared in part to accomplish the purposes of the GPRA, by documenting methods of improving efficiency in Federally-funded programs.

Observations and Conclusions

We found that LMER improperly used funds from ORNL overhead accounts to fund the CBMS WFO project. Specifically, $265,196 from ORNL division overhead accounts was provided to fund the CBMS WFO project to install, inspect, and test the Chem-Bio facility. Departmental requirements and the CBMS WFO interagency agreement preclude DOE from financing reimbursable work from its own appropriations or from another customer's funds. LMER reviewed a portion of the $265,196 spent on the Chem-Bio facility from the ORNL overhead account. In January 1999, LMER reversed $111,373 from ORNL overhead accounts and charged that same amount to the Army's CBMS WFO project account. At the time of our inspection, the remaining overhead funds, a total of $153,823, were placed under review by LMER.

Further, we found that LMER did not complete environmental documentation required for the Chem-Bio facility. Specifically, the Chem-Bio facility was constructed with a Biosafety Level-3 laboratory, which, according to Departmental implementing regulations for the National Environmental Policy Act of 1969 (NEPA), would have required an environmental assessment. We determined that this regulatory compliance issue required immediate management attention and it was addressed in an Office of Inspector General Management Alert, titled "Inspection of the Chem-Bio Facility at ORNL," S99IS019, issued on June 30, 1999 (Appendix B).

Insufficient Financial Controls on ORNL Overhead Accounts

The contract between LMER and DOE, and the CBMS WFO agreement requires LMER to comply with DOE's Chief Financial Officer's Financial Handbook. This Handbook states that DOE shall not finance reimbursable work from its own appropriations or another customer's funds.

The Chem-Bio facility, a pre-fabricated structure, cost approximately $295,000 and was funded from the Army's CBMS WFO account. However, costs associated with the design and installation of the Chem-Bio facility were not originally charged to the Army. For example, installation costs of $53,823, for Fiscal Year 1998, and installation costs of $47,747 and design costs of $9,803 for Fiscal Year 1999, for a total of $111,373, were charged to ORNL division overhead accounts. In January 1999, ORO requested that LMER conduct a review of these overhead expenditures. In a Request for Budget and Accounting Change document,

dated January 28, 1999, all three charges were reversed and transferred from ORNL's division overhead accounts to the Army's CBMS WFO account.

We were told by an LMER division accounting official that LMER had conducted a review of the ORNL division overhead account expenditures for the Chem-Bio facility. He said that since the funds were used to expand upon the initial scope of the Army's CBMS WFO project, they should have come from the Army CBMS WFO account. He said that ORNL Division Directors provide authorization to spend funds within these accounts and that efforts had been made to ensure that Division Directors were made aware of what was and what was not an appropriate division overhead account expenditure.

In addition to the $111,373 charged to ORNL division overhead funds that were reversed and charged back to the Army, an additional $153,823 of ORNL division overhead funds, from four divisions, were authorized for use on the CBMS project. ORNL's Life Sciences Division and Chemical Technology Division each authorized $25,000, the Chemical and Analytical Sciences Division authorized $50,000, and the Instrumentation and Controls Division authorized $53,823. Of these funds, $24,062 was used to register the biological laboratory with the Centers for Disease Control and Prevention (CDC) for the transfer of controlled biological agents, labor for leakage and pressure tests of a glove box, and labor for preparation of facility documents. Also, $23,879 was used for labor and materials for the set up of monitoring procedures. Other items purchased with these funds include an eyewash and a windsock. The remainder of the funds were projected to be used for, among others, building maintenance, quality assurance certification and costs of annual external reviews. As a result of our inspection activities, the LMER division accounting official told us that an internal review would be conducted regarding the use of $153,823 of ORNL division overhead funding for the CBMS WFO project.

Management Alert Response

During our review, we found that LMER did not complete environmental documentation required for the Chem-Bio facility. Specifically, the Chem-Bio facility was constructed with a Biosafety Level-3 laboratory, which, according to Departmental implementing regulations for NEPA, would have required an environmental assessment. We issued a Management Alert titled "Inspection of the Chem-Bio Facility at ORNL," S99IS019, on June 30, 1999 (Appendix B). ORO responded to this alert in an August 6, 1999, memorandum and stated that the CBMS Program Manager had been incorrect and that dry lyophilized Botulinum toxin had not been received at ORNL. Although the Material Safety Data Sheets which accompanied the Botulinum toxin in shipment stated that it was in liquid form, dry lyophilized Botulinum toxin was assumed to have been received instead. Further, ORO maintained that an environmental assessment was not required because the scope of work did not constitute microbiological or biomedical research activity. On August 20, 1999, we met with ORO representatives to discuss this response. We were told that there was no immediate intention to conduct research outside of the present scope. However, ORO said that they believed the facility represented a legitimate opportunity to establish a microbiological capability for the future.

NEPA procedures require that environmental information be made available to public officials and citizens before decisions are made, before actions are taken, and to identify and assess reasonable alternatives. Agencies are required to integrate the NEPA process with other planning at the earliest possible time to ensure that planning and decisions reflect environmental values, to avoid delays later in the process, and to head-off potential conflicts. We believe, based on documentation reviewed during this inspection and also on statements made by LMER and ORO officials, that LMER procured and installed the Chem-Bio facility with the intent for it to be used as a Biosafety Level 3 laboratory and with plans to conduct microbiological research in the future. Research conducted at the facility on biological warfare agents, including those within the present scope and those planned for future research, could be regarded as controversial and may create difficulties in completing an environmental assessment and in realizing the facility's future capabilities.

At the conclusion of our meeting, ORO agreed to review the reclassification of the Biosafety laboratory from level 3 to level 2 and to reconsider their registration with the CDC to receive live agents. We believe that these actions are positive steps by ORO management, but we also note that the Chem-Bio facility was prefabricated to contain a fully functioning Biosafety Level 3 laboratory and that the future microbiological capabilities of the laboratory would not be affected by simply deregistering the facility for live biological warfare agents. However, should future projects for the facility include live agents and, at that point, if a favorable determination for live agents could not be reached through an environmental assessment, then the taxpayers would have been better served if alternatives and future plans for the facility had been fully evaluated, in the spirit of NEPA compliance, prior to the expense of procurement and installation of the facility.

OTHER ISSUES

During our inspection, we identified specific concerns related to the physical security of the Chem-Bio facility and its contents. Our discussions with the CDC validated these concerns. The specific issues relating to the security of the Chem-Bio facility and its contents were discussed with ORO officials, who advised us that they were taking appropriate action to address these concerns.

RECOMMENDATIONS

We recommend that the Manager, Oak Ridge Operations Office:

1. Recoup ORNL division overhead funds used for the CBMS project.

2. Determine whether other WFO projects at ORO have been funded from overhead account funds and, if so, recoup these funds.

3. Ensure that documentation for future projects which require NEPA compliance is completed in planning phases.

4. Review the current capabilities, current CDC registration, and also future long term plans for microbiological research at the Chem-Bio facility and determine whether an environmental assessment should be completed or whether other actions are necessary to ensure NEPA compliance, such as, reclassifying the facility from a Biosafety Level 3 facility to a Biosafety Level 2 facility, and amending CDC registration as appropriate.

5. Determine whether LMER is taking appropriate measures to ensure that the Chem-Bio facility and its contents are secure.

MANAGEMENT REACTION

Management concurred with the recommendations and agreed to take corrective actions. Specifically, management said that $157,272 in division overhead accounts was identified and correctly assigned to the sponsor's account. Fully burdened, this amount would be $201, 299. Management conducted a detailed analysis of the CBMS project and identified an additional $89,926 of costing problems which were assigned to the sponsor's account. Management said that controls are in place at ORNL to regulate the funding mechanisms for WFO projects but that they are requiring the contractor to perform confirmation sampling, to be completed by March 31, 2000, to ensure that similar incidents do not exist. Management said that NEPA documentation must be completed in the planning phase of all actions and a process is in place to ensure all actions receive an early NEPA review. However, a categorical exclusion was issued without adequately considering the language of DOE Categorical Exclusion B3.12 and the categorical exclusion was issued in error. Restrictions have been placed upon the Chem-Bio facility to exclude BSL-3 actions and an environmental assessment will be conducted before any BSL-3 work is performed at the Chem-Bio facility. Management said that appropriate security measures were taken to include physical security upgrades and imposition of more stringent security policy.

INSPECTOR COMMENTS

Management's comments are responsive to the recommendations

Appendix A

SCOPE

The inspection was performed at the Oak Ridge Operations Office in Oak Ridge, Tennessee, from January 1999 through June 1999.

METHODOLOGY

This inspection was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency. As part of our inspection we interviewed officials at the Oak Ridge Operations Office and Lockheed Martin Energy Research, Inc. We also interviewed officials with the Centers for Disease Control and Prevention and the U.S. Army's Dugway Proving Grounds. We also reviewed pertinent records and documents pertaining to NEPA and the DOE Work-for-others Program

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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.

Sandra L. Schneider
Assistant Inspector General
for Inspections

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

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