



U.S. Department of Energy  
Office of Inspector General  
Office of Inspections and Special Inquiries

# Inspection Report

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Coordination of Biological Select Agent  
Activities at Department of Energy Facilities

DOE/IG-0695

JULY 2005




## Department of Energy

Washington, DC 20585

July 27, 2005

MEMORANDUM FOR THE SECRETARY

FROM:

  
Gregory H. Friedman  
Inspector General

SUBJECT:

INFORMATION: Inspection Report on "Coordination of Biological Select Agent Activities at Department of Energy Facilities"

### BACKGROUND

The Department of Energy, primarily through its national laboratories, has been responsible for a significant amount of research focusing on enhancing the Nation's security against biological threats. Numerous Federal agencies, including the Department of Homeland Security, have funded biological select agent and related Work for Others projects at Department facilities.

To address the need for research involving more lethal biological select agents, the Department is in the process of planning and constructing five biosafety level-3 (BSL-3) laboratories. In addition, three BSL-3 laboratories are being constructed on Department of Energy leased land for the University of Chicago. BSL-3 laboratories are designed to contain agents with a potential for respiratory transmission that can cause serious and potentially lethal infection, such as aerosol production or culturing of *Bacillus anthracis* (anthrax) and *Yersinia pestis* (the plague).

In a 2001 report, entitled "Inspection of Department of Energy Activities Involving Biological Select Agents," we concluded that there was insufficient organization, coordination, and direction in the Department's biological select agent activities. To address these issues, management created a Biosurety Working Group. The purpose of our current inspection was to determine if biological select agent research and development activities are adequately coordinated by the Department.

### RESULTS OF INSPECTION

We determined that the Department had not established an orderly mechanism for coordinating its biological select agent research and development activities. Specifically:

- The Biosurety Working Group created by management to address coordination issues raised in our 2001 report was disbanded. No entity was subsequently assigned responsibility to coordinate biological select agent activities within the Department; and,
- The Department has not developed and executed a coordinated plan for the development, construction, and operation of the BSL-3 laboratories. Consequently, there is no assurance that projects are being directed to the laboratory best suited to meet requirements; that resources are being effectively utilized; that security implications are being addressed; and, that capabilities are not being inappropriately duplicated.



As a result of our current inspection, the Department took initial action to create a central entity to coordinate biological select agent activities. While this is a positive step, more needs to be done to ensure the Department's biological select agent activities are fully integrated with efforts underway at each of the national laboratories, as well as with other Federal agencies.

Consequently, we recommended that the Administrator, National Nuclear Security Administration, and the Director, Office of Science, work together to ensure that the Department creates an enduring entity empowered to coordinate biological select agent activities and issues across the Department, and develops a corporate strategy for establishing and operating BSL-3 laboratories.

#### MANAGEMENT REACTION

Management concurred with our findings and recommendations. Both offices stated that they would participate or assist with implementing the report recommendations. Management's comments are provided in their entirety at Appendix D of the report.

Attachment

cc: Deputy Secretary

Under Secretary for Energy, Science and Environment

Administrator, National Nuclear Security Administration

Chief of Staff

Assistant Secretary for Environment, Safety and Health

Director, Office of Science

Director, Policy and Internal Controls Management (NA-66)

Director, Office of Program Liaison and Financial Analysis (ME-100)

# COORDINATION OF BIOLOGICAL SELECT AGENT ACTIVITIES AT DEPARTMENT OF ENERGY FACILITIES

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# Overview

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## **INTRODUCTION AND OBJECTIVE**

The emerging threat to homeland security posed by the possible use of biological weapons of mass destruction has led to an increase in research and development activities involving biological select agents throughout the Federal Government, including the Department of Energy (DOE) laboratory system. The Department of Homeland Security (DHS) has provided millions of dollars to DOE for research and development, including work involving biological select agents. There was a significant increase in this funding between 2004 and 2005. Biological select agents are viruses, bacteria, rickettsia, fungi, and toxins whose possession, transfer, and use are controlled due to their capability to cause substantial harm to human health.

The Office of Inspector General (OIG) has conducted several reviews involving biological research related topics (see Appendix C). In 2001, the OIG issued a report entitled “Inspection of Department of Energy Activities Involving Biological Select Agents,” DOE/IG-0492. In that report, the OIG concluded that there was insufficient organization, coordination, and direction in DOE’s biological select agent activities. In response, the Department established a Biosurety Working Group to, among other things, review mechanisms to improve oversight, coordination, and consistency within DOE, including the National Nuclear Security Administration (NNSA), and to improve communication and coordination with other agencies.

The objective of this inspection was to determine if biological select agent research and development activities are adequately coordinated by the Department.

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**OBSERVATIONS AND CONCLUSIONS**

We concluded that the Department has not established an orderly, coordinating mechanism for its biological select agent research and development activities. Specifically, we found that:

- The Biosurety Working Group, which was created by management to address coordination issues identified in our 2001 report, was disbanded. Further, no entity was subsequently assigned responsibility to coordinate biological select agent activities within the Department; and,
- DOE has not developed and executed a coordinated plan for the development, construction, and operation of biosafety level-3 (BSL-3) laboratories. Consequently, there is no assurance that projects are being directed to the laboratory best suited to meet requirements; that resources are being effectively utilized; that security implications are being addressed; and, that capabilities are not being inappropriately duplicated.

We believe that the establishment of a central entity to coordinate biological select agent activities within the Department, as well as with other Federal agencies, is critical. Homeland security concerns have led to an increase in work involving biological select agents being performed for other agencies at DOE laboratories. Also, work with biological select agents is involving more lethal agents. These realities have significant safety, security, and cost implications. In response to this inspection, DOE has taken initial steps to create a central entity to coordinate biological select agent activities, which is discussed on page 4 of this report. But, much remains to be done to ensure the full implementation and continuing success of the coordination effort.

## Details of Findings

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### **BACKGROUND**

Currently, research activities related to biological select agents are in process or are planned at a number of Department laboratories. NNSA and the Office of Science (Science), which have operational cognizance over the DOE laboratory facilities conducting select agent research and development activities, have certain responsibilities, to include safety and security oversight. The Office of Environment, Safety and Health (EH) is responsible for development of DOE-wide policy regarding biological research and development.

DHS is funding projects involving biological select agents and related projects at 11 DOE sites. Additionally, the Department of Defense, the National Institutes of Health, and the Federal Bureau of Investigation and other members of the Intelligence Community fund biological select agent or related Work for Others projects at various DOE sites. Although we were told by responsible Federal and contractor officials that DOE is not funding any biological select agent projects, a December 2004 DOE report to Congress listed almost \$5 million in Laboratory Directed Research and Development (LDRD) funding for biological select agent related projects at five DOE laboratories. LDRD is discretionary funding provided to the national laboratories to pursue scientific and technical development.

Projects involving biological select agents typically progress from less to more harmful forms of biological organisms, which sometimes require the use of laboratories capable of a higher level of containment for these organisms. The Centers for Disease Control and Prevention (CDC) recommends the biosafety levels under which dangerous organisms, identified and listed by CDC as select agents, can be safely handled.

BSL-3 laboratories are for containment of indigenous or exotic agents with a potential for respiratory transmission that can cause serious and potentially lethal infection, such as aerosol production or culturing of *Bacillus anthracis* (anthrax) and *Yersinia pestis* (the plague). Several BSL-3 laboratories have been constructed, are in the planning stage, or are under construction at DOE sites, although none are currently operating as BSL-3 laboratories. Appendix A contains more detailed information regarding the status of DOE's BSL-3 laboratories.

### **COORDINATION OF SELECT AGENT ACTIVITIES**

We found that the Biosurety Working Group, which was created by management to address coordination issues identified in our 2001 report, was disbanded. Officials from NNSA, Science, and

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EH advised us that the Biosurety Working Group was disbanded during 2002 and that no entity was assigned the responsibilities and activities previously assigned or undertaken by the Group. The lack of centralized coordination has led to the absence of both corporate data and a corporate strategy for decision-making regarding the Department's biological select agent mission and activities. As demonstrated during our inspection, determining the scope and status of DOE's select agent activities required our contacting numerous headquarters and field site officials. Further, we found no indication that there was communication between these officials regarding their select agent activities; thus, decision-making was site specific and did not include a DOE corporate perspective. For example, DOE currently lacks complex-wide pre-startup safety procedures for the initiation of work at BSL-3 laboratories. Currently, each facility has to develop its own pre-startup safety criteria, which have varied from site to site for BSL-3 laboratories under construction.

## **Technology Committee**

During our review, we discussed with various DOE officials the lack of coordination of biological select agent activities. Because of our concerns, during December 2004, NNSA and EH officials agreed to form a committee, called the Executive Committee for Emerging Technologies (Technology Committee), to coordinate select agent activities across the DOE complex. Further, EH and NNSA agreed to initially co-chair the Technology Committee. In February 2005, EH and NNSA initiated meetings that have been attended by representatives from EH, NNSA, Science, the Office of the General Counsel, and the Office of Safeguards and Safety Performance Assurance to discuss the possible formation of the Technology Committee. We were advised that the representatives discussed potential Technology Committee coordination issues, including biological select agents and other technology-related matters. We were further advised that suggestions regarding the role and authority of the Technology Committee ranged from obtaining formal endorsement by the Department, which would allow the Technology Committee to develop policy and make decisions regarding select agent and other technology matters, to it merely being a liaison committee to collect and disseminate information.

We believe that the establishment of a central entity to provide complex-wide coordination of DOE's select agent activities is critical because of increasing levels of biological select agent work at DOE's laboratories, movement to work involving more lethal



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select agents, potential safety and security concerns, and the need to maximize economies and efficiencies. Although DOE has taken the first steps in creating such an entity, much remains to be done to ensure the full implementation and continuing success of the effort.

## **ESTABLISHMENT OF BSL-3 LABORATORIES**

We found that DOE has not developed and executed a coordinated plan for the development, construction, and operation of BSL-3 laboratories. Consequently, there is no assurance that projects are being directed to the laboratory best suited to meet requirements; that resources are being effectively utilized; that security implications are being addressed; and, that capabilities are not being inappropriately duplicated.

We identified eight BSL-3 laboratories at DOE sites that have been constructed, are in the planning stage, or are under construction. The cost to construct a BSL-3 laboratory, including costs related to compliance with National Environmental Policy Act requirements, could amount to approximately \$4 million, although a significant range is possible.

Due to the lack of centralized coordination of DOE's BSL-3 laboratories, we were required to contact numerous headquarters and field site officials to determine the status of BSL-3 activities at Science and NNSA facilities. Interviews with Science and NNSA officials regarding the coordination of BSL-3 laboratories across the DOE complex confirmed that there was no central or DOE-wide coordination of BSL-3 activities at DOE sites and that decisions regarding BSL-3 activities were made by local site officials. We did not identify any DOE entity that made corporate decisions about the establishment of BSL-3 laboratories at DOE sites, e.g., the location and necessity of the BSL-3 laboratories.

We were also told by officials that as the number and biosafety level of biological research laboratories increase, so does the risk of both insider and outsider attacks involving these facilities. Security management of biological select agents poses unique challenges because biological select agents can replicate, making theft of minute quantities significant.

We believe DOE should develop a corporate strategy to determine the number and location of BSL-3 facilities, coordinate future construction funding, ensure that work is not duplicated, and address associated safety and security issues.

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**RECOMMENDATIONS**

We recommend that the Administrator, NNSA, and the Director, Office of Science, work together to ensure that:

1. An enduring entity is created and empowered to coordinate biological select agent activities and issues across the DOE complex; and,
2. The Department develops a corporate strategy for the establishment of biosafety level laboratories, to include determining the number and location of BSL-3 facilities, coordinating future construction funding, ensuring that work is not duplicated, and addressing associated safety and security issues.

**MANAGEMENT  
COMMENTS**

Management concurred with our conclusions and recommendations. We have included management's comments in their entirety at Appendix D.

**INSPECTOR  
COMMENTS**

We found management's comments to be responsive to our report.

## Appendix A

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### **CURRENT STATUS OF BSL-3 LABORATORIES**

The following is the current status of BSL-3 facilities across the DOE complex:

- Lawrence Livermore National Laboratory is in the process of replacing some of the equipment in its BSL-3 laboratory due to incompatibility between the equipment and the organisms planned to be used in the research projects. After the work is completed, it will begin the pre-startup safety review process during the summer or fall of 2005;
- Los Alamos National Laboratory has constructed a facility containing two BSL-3 laboratories. However, the facility cannot become operational until an Environmental Impact Statement is completed, which is targeted for completion during the fall of 2006;
- Oak Ridge National Laboratory built a BSL-3 laboratory, but did not conduct an Environmental Assessment to allow it to operate at that level. Currently, the facility operates as a BSL-2 laboratory;
- Pacific Northwest National Laboratory's plan to convert an existing BSL-2 to a BSL-3 laboratory is currently on hold pending the development of a business plan to construct new buildings; and
- DOE leased land at Argonne National Laboratory to the University of Chicago (Chicago) for construction of a \$30 million Regional Biocontainment Laboratory, pending the completion of an Environmental Assessment. The Regional Biocontainment Laboratory will contain two BSL-3 laboratories for pathogens and one BSL-3 laboratory for animals. The National Institutes of Health is providing \$17 million, and Chicago is providing \$13 million. We were told that DOE has no management responsibilities over the facility because it will be owned by Chicago. However, according to the lease agreement, DOE may prescribe safety and security regulations and inspect for compliance with applicable environmental permits, licenses, and regulations.

## Appendix B

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### **SCOPE AND METHODOLOGY**

Our review included visits to Los Alamos National Laboratory, Lawrence Livermore National Laboratory, and Oak Ridge National Laboratory. We conducted interviews with NNSA, Science, and EH officials at DOE headquarters. We also reviewed related site, DOE-wide, and Government-wide criteria.

As part of our review, we evaluated DOE's implementation of the "Government Performance and Results Act of 1993" in the context of the activities included in our review. We did not identify any performance measure issues regarding the coordination of biological select agent activities at DOE facilities.

This inspection was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency.

## Appendix C

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### **PRIOR BIOLOGICAL RESEARCH RELATED REPORTS**

The following are reports related to OIG reviews of biological research activities:

- “Inspection of Selected Issues of the Chem-Bio Facility at the Oak Ridge National Laboratory,” INS-O-00-01, November 1999;
- “Inspection of Department of Energy Activities Involving Biological Select Agents,” DOE/IG-0492, February 2001;
- “Homeland Security: Interagency Summary Report on Security Controls Over Biological Agents (U),” D-2003-126 (Department of Defense OIG report number), August 27, 2003 (the report is classified Secret); and
- “Concerns Regarding a Non-Viable (Dead) ‘Anthrax Spore’ Research Project at the Oak Ridge National Laboratory,” DOE/IG-0681, March 2005.




Department of Energy  
National Nuclear Security Administration  
Washington, DC 20585



JUL 05 2005

MEMORANDUM FOR Alfred K. Walter  
Assistant Inspector General  
for Inspections and Special Inquiries

FROM: Michael C. Kane   
Associate Administrator  
for Management and Administration

SUBJECT: Comments to Coordination of Biological Select  
Agent Activities Draft Report

The National Nuclear Security Administration (NNSA) appreciated the opportunity to have reviewed the Inspector General's (IG) draft report, "Coordination of Biological Select Agent Activities at Department of Energy Facilities." We understand that the IG conducted this inspection to determine if biological select agent research and development activities are adequately coordinated by the Department.

As did the Office of Science in separate correspondence, NNSA agrees with the conclusions drawn and the corresponding recommendations. NNSA will, with the Office of Science, develop a corporate strategy for the establishment of biosafety-level laboratories and will assist in the reconstitution of a more permanent "Biosurety Working Group" type of entity to coordinate activities.

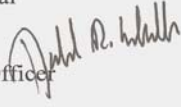
Should you have any questions related to this response, please contact Richard Speidel, Director, Policy and Internal Controls Management.

cc: Director, Office of Science  
Deputy Administrator for Defense Programs  
Senior Procurement Executive  
Director, Service Center



**Department of Energy**  
Office of Science  
Washington, DC 20585  
June 30, 2005

MEMORANDUM FOR Alfred W. Walter  
Assistant Inspector General  
for Inspections and Special Inquiries  
Office of Inspector General

FROM: Donald R. Erbschloe   
Acting Chief Operating Officer  
Office of Science

SUBJECT: Comments on Inspector General Draft Report, "Coordination of  
Biological Select Agent Activities at Department of Energy  
Facilities"

In response to your June 15, 2005, memo, the Office of Science and reviewed the subject report and offers the following comments.

General Comments

The presented facts appear to clearly support the conclusions of this report that "...the Department has not established an orderly, coordinating mechanism for its biological select agent research and development activities." The two supporting conclusions are that "DOE has not developed a coordinated plan for the development, construction, and operation of biosafety level (BSL)-3 laboratories" and "The Biosurety Working Group, created by management in response to our 2001 report, was disbanded...no entity was subsequently assigned responsibility to coordinate biological select agent activities within the Department."

The two recommendations are to urge the Department to develop a corporate strategy for the establishment of biosafety-level laboratories and to recreate an enduring entity empowered to coordinate biological select agent activities and issues across the DOE complex. Both of these recommendations make sense and should be implemented. The benefits will include limiting duplication of facilities (the tendency of each lab to "keep up with the Joneses") and greater headquarters knowledge and monitoring of (thus closer accountability for) the biological select agent activities within the DOE complex.



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Management Response to Recommendations

**“We recommend that the Administrator, NNSA, and the Director, Office of Science, work together to ensure that...”**

**Recommendation 1:** The Department develops a corporate strategy for the establishment of biosafety-level laboratories to include determining the number and location of BSL-3 facilities, coordinating future construction funding, ensuring that work is not duplicated, and addressing associated safety and security issues.

**Management Response:** Concur. The Office of Science will participate in the development of a corporate strategy responding to this recommendation. We will engage in this process as soon as NNSA and Office of Science enter upon it.

**Recommendation 2:** An enduring entity is created and empowered to coordinate biological select agent activities and issues across the DOE complex.

**Management Response:** Concur. The Office of Science will participate in a reconstituted coordinating entity (emulating, in intention, the Biosurety Working Group) to coordinate biological select agent activities and issues across the DOE Complex, as soon as such a group is begun.

Thank you for the opportunity to review and comment on this draft report.

If you have any questions regarding these comments, please contact Dan Drell, of the Office of Biological and Environmental Research, at 301-903-4742.



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