APPENDIX B: INSPECTION OF DEPARTMENT OF ENERGY ACTIVITIES INVOLVING BIOLOGICAL SELECT AGENTS

DOE/IG-0492

INSPECTION REPORT

INSPECTION OF DEPARTMENT OF ENERGY ACTIVITIES INVOLVING BIOLOGICAL SELECT AGENTS

FEBRUARY 2001

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

U.S. DEPARTMENT OF ENERGY
Washington, DC 20585

February 2, 2001

MEMORANDUM FOR THE SECRETARY

FROM: Gregory H. Friedman /s/
Inspector General

SUBJECT: INFORMATION: Report on "Inspection of Department of Energy Activities Involving Biological Select Agents"

BACKGROUND

The Department of Energy's laboratories, including those managed by the National Nuclear Security Administration, conduct research involving biological select agents and select agent materials (e.g., DNA or select agents and subunits of toxins derived from select agents). For example, the laboratories are currently working to develop detection and response systems to improve preparedness in the event of a domestic attack involving the use of a biological select agent as a weapon of mass destruction. Biological select agents include about 40 viruses, bacteria, rickettsia, fungi, and toxins whose transfer within the United States is controlled. This is because such agents pose a substantial threat to public health and safety.

The objective of our inspection was to determine whether the Department has implemented appropriate environment, safety, and health measures regarding the possession and use of biological select agents and select agent materials. During our inspection, we issued four interim reports regarding the Department's biological select agent activities based on our determination that certain issues warranted immediate management attention.

RESULTS OF INSPECTION

We concluded that the Department's biological select agent activities lacked organization, coordination, and direction. Specifically, the Department's activities lacked appropriate Federal oversight, consistent policy, and standardized implementing procedures, resulting in the potential for greater risk to workers and possibly others from exposure to biological select agents and select agent materials.

For example:

- Safety and security officials, as well as senior management officials, at the Department's Albuquerque Operations Office (Albuquerque) were unaware of experiments involving biological select agents and select agent materials that were conducted at two Albuquerque laboratories.

- Some Department laboratories were not adhering to the Centers for Disease Control and Prevention (CDC) requirements in effect at the time of our review for registration of certain biological select agents and select agent materials.

- Procedures for conducting research activities involving biological select agents and select agent materials varied significantly among the Department's laboratories. The Department had not developed "best practices" to provide minimum guidance to laboratories for the conduct of their biological activities.

- The Department faces potential liability issues relating to the work of its contractors with biological agents, including liability arising from potential exposure of contractor employees who decline recommended immunizations.

- The Department's laboratories are not always receiving timely and consistent information regarding CDC registration requirements. This matter was coordinated with the Office of Inspector General at the U.S. Department of Health and Human Services.

While we consider these findings to be serious, we found no evidence that current activities had adversely impacted the safety and health of the public or of the Department's Federal or contractor workforce.

Further, during the course of our review the Department took certain actions to improve biosafety practices at its laboratories. For example, the Department of Energy Biosurety Working Group, which was chartered on September 29, 2000, is considering revisions to current policies and procedures governing potentially hazardous biological materials and select agents. Also, a biosurety program was initiated at Albuquerque to strengthen local safety and security protocols. In addition, CDC biological select agent registration requirements are being clarified, and communications concerning biological research activities have reportedly improved among Department Headquarters, the Operations Offices, the laboratories, and other Federal agencies. While these are positive steps, the potential risks associated with the use of biological select agents warrant continued senior management attention.

MANAGEMENT REACTION

The Department generally concurred with our recommendations and agreed to take corrective actions.

Attachment

cc: Under Secretary for Nuclear Security/Administrator for Nuclear Security
Acting Assistant Secretary for Environment, Safety and Health
Acting General Counsel
Acting Director, Chemical and Biological National Security Program

INSPECTION OF DEPARTMENT OF ENERGY ACTIVITIES INVOLVING BIOLOGICAL SELECT AGENTS

TABLE OF CONTENTS

OVERVIEW

Introduction and Objective…… 1

Observations and Conclusions…… 2

BACKGROUND…….. 3

DETAILS OF FINDINGS

One Operations Office Was Unaware of Biological Select Agent Activities.…… 6

Inadequate Notification of Biological Select Agent Projects…….. 9

CDC Requirements Were Not Followed…… 11

Some Laboratories Did Not Register With CDC…….. 11

Potentially Misleading Information in Registration Forms……. 13

The Department's Policies and Procedures Were Inadequate…….. 14

Required Responsibilities Not Performed…… 14

Inconsistent Receipt/Screening Procedures…… 16

Required Hazard Analysis Was Based On Incomplete Data…….. 20

Inconsistent Policies Regarding Worker Immunizations…….. 22

NEPA Reviews Not Conducted……. 23

OBSERVATIONS

Lack of Timely Response From CDC……... 24

Changes to CDC Interpretations…….….. 24

Lack of CDC Inspections…… 24

RECOMMENDATIONS……... 25

MANAGEMENT COMMENTS…….. 26

INSPECTOR COMMENTS…… 28

APPENDIX

A. Scope and Methodology……... 30

Overview

INTRODUCTION AND OBJECTIVE

Department of Energy (DOE) programs include activities to prevent and detect the spread of weapons of mass destruction, which include biological select agents, and to respond to emergencies if these weapons are ever used. The Department's laboratories, which include laboratories managed by the National Nuclear Security Administration (NNSA), conduct research involving biological select agents and select agent materials (e.g., DNA of select agents and subunits of toxins derived from select agents). The research is to develop detection and response systems to improve preparedness in the event of a domestic attack involving biological select agents. The NNSA, which was created by the National Defense Authorization Act for Fiscal Year 2000, was established within DOE on March 1, 2000. The national security functions and activities performed by certain elements of the Department, including several DOE laboratories, were transferred to the NNSA. A number of our findings involving laboratories managed by the NNSA relate to circumstances existing prior to the establishment of the NNSA.

Biological select agents have the potential to pose a severe threat to public health and safety. They include about 40 viruses, bacteria, rickettsia, fungi, and toxins whose transfer within the United States (U.S.) is controlled due to their capability to cause substantial harm to human health.

The purpose of our inspection was to evaluate the environment, safety, and health protocols at DOE laboratories, including those managed by the NNSA, that conduct research with biological select agents and select agent materials. The objective was to determine whether the Department has implemented appropriate environment, safety, and health measures regarding the possession and use of those agents and agent materials.

OBSERVATIONS AND CONCLUSIONS

We found no evidence that the Department's current biological select agent activities have adversely impacted the safety and health of DOE and contractor employees or the public. However, we found that safety and security officials, as well as senior management officials, at the Department's Albuquerque Operations Office were unaware of experiments involving biological select agents and select agent materials that were conducted at two Albuquerque laboratories. We also found that some DOE laboratories were not adhering to the Centers for Disease Control and Prevention (CDC) requirements in effect at the time of our review regarding the registration of certain biological select agents and select agent materials. In addition, we found that procedures for conducting research activities involving biological select agents and select agent materials varied significantly among the Department's laboratories. We determined that the Department had not developed and implemented policies and procedures that (1) establish clear roles and responsibilities for the conduct of activities involving biological select agents and select agent materials, and (2) ensure DOE laboratories, including those managed by the NNSA, follow "best practices" for the conduct of their biological select agent activities. We observed that, in the absence of clear direction from the Department, there were inconsistencies among the Department's laboratories regarding procedures being implemented to conduct biological select agent and select agent material activities. The failure of some DOE laboratories to implement "best practices" for the conduct of their biological select agent and select agent material activities has the potential to increase the risk to employees of exposure to these agents and materials.

We concluded that there was insufficient organization, coordination, and direction in the Department's biological select agent activities. Specifically, the Department's activities lacked sufficient Federal oversight, consistent policy, and standardized implementing procedures, resulting in the potential for greater risk to workers and possibly others from exposure to biological select agents and select agent materials maintained by the Department. Also, we observed that, in view of an ongoing reevaluation by CDC of their earlier interpretations of registration requirements for biological select agents, and the lack of timely responses by CDC officials to requests for information/guidance, DOE laboratories may not be receiving timely and consistent information regarding CDC registration requirements. We discussed our observations regarding CDC with a senior official in the Office of Inspector General, Department of Health and Human Services, which has cognizance over CDC.

On August 23, 2000, we issued our preliminary inspection findings to the Department in an initial draft report entitled "Inspection of Department of Energy Activities Involving Biological Select Agents." We received comments from the Department on September 28, 2000, and October 23, 2000. The Department's comments were included, as appropriate, in our final draft report, which was provided to the Department on November 14, 2000, for additional comment.

On September 29, 2000, the Secretary of Energy approved the establishment of a "DOE Biosurety Working Group." The Working Group, which was subsequently established by the Assistant Secretary for Environment, Safety and Health (EH), is considering revisions to current policies and procedures governing potentially hazardous biological materials and select agents. The Working Group is also seeking to enhance communication between sites and programs involved in managing biological hazards, as well as between the Department and other Federal and non-Federal entities, and will call attention to best practices and lessons learned across the Department.

During our inspection, we consulted extensively with CDC officials, as well as with officials at the U.S. Army Edgewood Chemical Biological Center and the U.S. Army Medical Research Institute of Infectious Diseases. The U.S. Army, which conducts the U.S. Army Biological Defense Program on behalf of the Department of Defense, has developed extensive guidelines, laboratory protocols, and "best practices" for the conduct of experiments involving biological agents. These guidelines, protocols, and practices may well be instructive for development and implementation of an effective program within the Department.

BACKGROUND

The Department has a number of ongoing activities involving biological select agents and select agent materials. These agents and materials include *Bacillus anthracis* (*B. anthracis*), *Yersinia pestis* (*Y. pestis*), *Brucella abortus* (*B. abortus*), DNA of select agents, and toxins of select agents, such as botulinum and ricin toxin.[1] For example, the NNSA Office of Nonproliferation Research and Engineering (NN-20) manages the Department's Chemical and Biological National Security Program (CBNP). The purpose of the CBNP is to develop, demonstrate, and deliver systems and the supporting technologies that will lead to major improvements in the U.S. capability to prepare for and respond to domestic chemical or biological attacks. Also, Department laboratories are conducting

[1] *B. anthracis* is the organism that causes the disease known as anthrax. *Y. pestis* is the organism that causes the disease known as plague. *B. abortus* causes herd animals to abort their fetuses. Botulinum toxin is secreted by the organism *Clostridium botulinum*, while ricin toxin is secreted by the organism *Ricinus communis*. Both of these toxins are poisonous.

Work-for-Others programs, Laboratory Directed Research and Development (LDRD)[2] projects, and Cooperative Research and Development Agreement (CRADA)[3] projects involving biological select agents and select agent materials. Most of the Department's activities to date have involved select agent toxins,[4] DNA of biological select agents, and nonviable (attenuated or dead) forms of biological select agents.[5] However, activities by DOE laboratories, including those managed by the NNSA, are beginning to involve infectious (potentially lethal) forms of biological select agents that pose a greater risk to employees. For example, two of the Department's laboratories are currently receiving intact botulinum toxin for experimentation, while another laboratory has initiated experiments with the infectious form of *Y. pestis* and *B. anthracis*. Although exact funding amounts were not available, our review of the Department's budget suggested that the cost in FY 2000 of the Department's biological agent-related activities was in excess of $90 million. We understand that of this amount, approximately $7 million involved work with specific biological select agents and select agent DNA.

The shipment, transfer, and receipt of biological select agents and select agent materials are controlled by CDC in accordance with Part 72, Title 42, Code of Federal Regulations (42 CFR Part 72). Prior to transferring or receiving a biological select agent or select agent material, a facility must register with CDC as being equipped and capable of handling that agent or material at the appropriate biosafety level. The CDC regulations are designed to assure that biological select agents and select agent materials are transferred only to facilities equipped to handle them properly, and only to those facilities that have legitimate reasons to use them. 42 CFR Part 72 also incorporates, by reference, the requirements in CDC's publication entitled "Biosafety in Microbiological and Biomedical Laboratories" (BMBL). The BMBL describes coordination of microbiological practices, laboratory facilities, and safety equipment, and recommends their use in four biosafety levels of laboratory operation with select agents infectious to humans.

During the inspection, the Office of Inspector General (OIG) issued three Management Alerts and a Letter Report regarding

[2] LDRD projects are relatively small, discretionary research and development activities conducted by the Department's laboratories, in addition to those projects provided for in a Department program or by specific designation in a Department contract.

[3] CRADAs are cost-sharing agreements between a Federal entity, such as a Department laboratory, and a private sector partner to engage in joint, scientific research aimed at providing mutual benefits to the partners, the Department, and the U.S.

[4] Select agent toxins, such as botulinum toxin, are chemicals secreted by biological select agent organisms and are poisonous, but not infectious.

[5] An attenuated form of a biological select agent is an extremely weakened form of the agent.

concerns with certain activities by the Department involving biological select agents and select agent materials. These are referred to in the following narrative.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that the Department recognizes that each of the three OIG principal findings points to areas where improvements are needed, and in fact, the OIG's review has already had the effect of drawing the attention of DOE managers more closely to these matters. He said that the Department has initiated several actions over the past year to improve coordination, oversight, and consistency in regard to biological research involving potentially hazardous materials. He also said that DOE acknowledges that there is room for improvement.

According to the Acting Director, the Department agrees that to the extent safety management systems are lacking in any regard, there is at least a theoretical potential for increased risk. He said that this is part of the reason why the Department is seeking improvements in existing policies and practices. He also said that the Department believes it is equally important to acknowledge, however, that in the specific instances covered by the OIG review there is no indication that any workers or the public were actually put at risk.

We found no evidence that the health of workers or the public was adversely affected by the Department's biological select agent activities. However, although the Acting Director stated that the biological select agents and associated materials used by DOE have "posed low risks," we identified projects that were categorized by DOE hazard analyses as having "moderate" risk. In fact, these projects were required to be conducted in a biosafety level 2 facility, which, according to CDC, is "for work involving agents of moderate potential hazard to personnel and the environment." As discussed below, we also learned that the Department has initiated projects involving more exotic biological agents.

One Operations Office Was Unaware Of Biological Select Agent Activities

We found that safety and security officials, as well as senior management officials, at the Albuquerque Operations Office (Albuquerque), were not aware of experiments involving biological select agents or select agent materials that were conducted at two of the three Albuquerque laboratories. Albuquerque laboratories include Sandia National Laboratories in California (Sandia-CA) and New Mexico (Sandia-NM), and Los Alamos National Laboratory (Los Alamos).

We were unable to determine the extent of biological select agent activities at Albuquerque laboratories from responses provided by Albuquerque officials to our inquiries. For example, a senior Kirtland Area Office (Kirtland) official told us in February 1999, and again in

November 1999, that the only activities being conducted by the Sandia National Laboratories involving actual biological agents were conducted by Sandia-CA. However, in a November 1999 response to a July 1999 OIG survey questionnaire to the Albuquerque Manager requesting information on biological agent activities being conducted at Albuquerque laboratories, we were advised by an Albuquerque official that Albuquerque laboratories "only has [sic] 'simulants,' not the real thing."

As discussed below, we subsequently learned that experiments were conducted with biological select agents or select agent materials at all three Albuquerque laboratories. We also learned that Albuquerque safety and security officials having oversight responsibility for safety and security at the laboratories, as well as senior Albuquerque and senior laboratory officials, were unaware of the presence of the biological select agents or select agent materials. In November 1999, we advised the senior Kirtland official that Sandia-NM had conducted experiments with the biological select agent *Y. pestis EV76.* According to a CDC official, the *EV76* form of *Y. pestis* required registration as a select agent with CDC. We were told that even though the Principal Investigator interpreted that the *Y. pestis EV76*, which had been used as a vaccine in the 1970s, was exempt from CDC registration requirements, the Principal Investigator had chosen to be conservative and registered the *Y. pestis EV76* with CDC. Following our notification of the senior Kirtland official, Sandia-NM safety officials, who had been unaware of the presence of the agent *Y. pestis EV76*, found some of the agent, which had been destroyed, stored in a formalin solution at the laboratory. After learning of the presence of this material, the Kirtland Manager requested that Sandia National Laboratories submit a list of all projects using or planning to use biological materials and the controls/requirements applying to their use. On March 13, 2000, the OIG issued a Letter Report entitled "Review of Applied Biophysical Lab at SNL, Albuquerque," INS-L-00-04, concerning the presence of this material.

The Albuquerque officials were also unaware of experiments being conducted at Los Alamos with attenuated *B. anthracis* and with DNA of several select agents. When we learned from a scientist at another laboratory in January 2000 that he had received select agent DNA from Los Alamos, we interviewed the Los Alamos Principal Investigator who had shipped the select agent DNA to the scientist. During the interview, the Principal Investigator acknowledged that Los Alamos had an extensive biological select agent program involving attenuated *B. anthracis*, as well as DNA of several biological select

agents. We were subsequently advised by another Los Alamos Principal Investigator that Los Alamos was proposing to begin experiments with an infectious form of *B. anthracis.*

Shortly after we advised Albuquerque officials of the experiments at Sandia-NM involving *Y. pestis EV76*, the Kirtland Environment, Safety and Health (ES&H) Team Leader, who was the Albuquerque official having line management oversight of safety for Sandia-CA and Sandia-NM, was informally tasked by the Kirtland Manager to determine the extent of work at the two laboratories with biological select agents. Also, according to an NN-20 official, a "biosurety initiative" was initiated by Albuquerque on December 1, 1999. This initiative, which was led by the Kirtland ES&H Team Leader, was to address concerns regarding biological select agent activities at the Albuquerque laboratories. We were told by the Kirtland ES&H Team Leader, however, that he did not receive formal tasking for the "biosurety initiative" from the Albuquerque Manager until early January 2000. This tasking was to conduct an assessment of all the biological select agent activities at Albuquerque. According to the Kirtland ES&H Team Leader, he was unable to spend much time on the "biosurety initiative" until April 2000, when he was able to pursue the assignment on a full time basis.

In July 2000, the Kirtland ES&H Team Leader briefed senior Albuquerque managers on his assessment of the biological select agent activities at Albuquerque. He found that, at that time, there was "no coordination or accountability between AL [Albuquerque] as a DP [Defense Programs] site, and NN-20 as the program direction organization." He also found that in the absence of such coordination, Albuquerque was unaware of what work was underway and was unable to provide safety or security oversight. Based on the Kirtland ES&H Team Leader's assessment, the work by Albuquerque laboratories with biological select agents and select agent materials appears to have been performed in the absence of safety and security oversight by Albuquerque officials.

According to an NN-20 official, his office did not provide safety and security oversight of the CBNP projects being conducted by the Department's laboratories, but instead depended on the Operations Offices to provide such oversight. In the absence of safety and security oversight of these projects by either Albuquerque or NN-20 officials, there appears to have been insufficient Federal safety and security oversight of the NN-20 work involving biological select agents and select agent materials being conducted at the Albuquerque laboratories. In September 2000, the NN-20 CBNP Director advised us that Albuquerque is "developing coordinated procedures and

processes needed to implement a comprehensive, integrated oversight program." He said that this will be structured from the "ground up" to provide effective Federal oversight while minimizing adverse impact to the laboratories and to sponsors in this important research area.

Inadequate Notification Of Biological Select Agent Projects

Albuquerque safety and security officials, as well as senior Albuquerque management officials, might not have known of the presence of certain biological select agents and select agent materials at two of their laboratories because NN-20 did not provide sufficient information to allow the Department's Operations Offices to identify CBNP projects that involved these materials. During our visit to Albuquerque in February 2000, we observed that the only mechanism in place to communicate NN-20 select agent project information to Albuquerque was via the CBNP Project Life Cycle Plans. However, the Deputy Assistant Secretary for Nonproliferation Research and National Security told us in April 2000 that there had been a "breakdown of communications" in NN-20, which resulted in a failure to provide Project Lifecycle Plans to the Operations Offices and a failure to include the Operations Office Managers in briefings regarding the CBNP projects. The CBNP Project Lifecycle Plans contain information such as the major project tasks conducted by each laboratory, the biological select agents involved, and associated funding. He said that he initiated corrective actions to address this lack of communication. He said that without Project Lifecycle Plans, briefings by NN-20 officials about the CBNP projects, and specific contract language regarding biological select agent activities, Albuquerque officials would have no way of knowing that NN-20 had contracted work to the laboratories involving biological select agents.

The Kirtland ES&H Team Leader's assessment for his July 2000 briefing to senior Albuquerque managers also found that NN-20 had not provided the field with any information on the projects proposed or underway, which he noted was an issue being pursued by the OIG. He believed that in the absence of such information or coordination "there is no ability of AL [Albuquerque] to provide oversight or security." Although we were subsequently advised in September 2000 by the NN-20 CBNP Director that copies of the CBNP Project Lifecycle Plans had been provided to the Operations Offices, he acknowledged that they had insufficient detail to identify the projects that involved the use of select agents or the DNA of select agents. In October 2000, we were told by the Kirtland ES&H Team Leader that Project Life Cycle Plans had been provided to Albuquerque budget personnel, but had not been distributed to the other Albuquerque organizations.

Although this might explain why Albuquerque safety and security officials, as well as senior Albuquerque managers, were unaware of

the CBNP research activities involving biological select agents and select agent materials that were funded by NN-20, this does not explain why these officials were unaware of other biological select agent and select agent material research activities, such as LDRD and Work-for-Others projects, that were being conducted at Albuquerque laboratories. According to the Kirtland ES&H Team Leader, all biological select agent activities "fell through the cracks" and were not reviewed by Albuquerque. He added that there had been no mechanism in place for biological select agent project information to reach him or the Albuquerque Manager.

In September 2000, the NN-20 CBNP Director advised us that the Albuquerque Laboratory Programs Division had been aware of these activities as evidenced by their programmatic review of pertinent program documents in Work-for-Others programs, LDRD projects and CRADAs. He also said that the Albuquerque Technology Development Division, which authorizes work for the CBNP, had been aware of work concerning "proposed" use of select agents. He acknowledged, however, that Albuquerque safety officials at the staff level, particularly at the Area Offices with line responsibility for laboratory activities, "were not necessarily aware of such activities."

According to the Kirtland ES&H Team Leader, his "special tasking" in January 2000 from the Albuquerque Manager to review all chemical/biological projects at the Albuquerque laboratories had been based on the recognition by the Albuquerque Manager of the "void in line management oversight" of biological activities at the laboratories and the related vulnerabilities. The Kirtland ES&H Team Leader acknowledged that none of the contracts with the Albuquerque laboratories specifically addressed biological activities and there was no requirement for laboratory officials to advise Albuquerque of their activities involving biological select agents. He said, therefore, that Albuquerque is developing specific language for their laboratory contracts that will require the laboratories to address issues related to biological work, such as safeguards and security, emergency management, and biosafety.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that the OIG's draft report correctly identifies communication lapses, and the OIG review has already spurred corrective actions, which began over a year ago. He said that today communication is significantly improved and getting better. According to the Acting Director, the discreet problems identified by the OIG have been resolved, and DOE is developing and implementing plans to improve communication in the area of

potentially hazardous biological research activities throughout relevant Departmental elements. He added that the Albuquerque Biosurety Initiative mentioned in the draft report is an example of this. He mentioned as another example, that the Project Lifecycle Plans provided to the Operations Offices by the Office of Defense Nuclear Nonproliferation now describe the projects in more detail than older plans.

CDC Requirements Were Not Followed

We found that some Department laboratories were not adhering to certain CDC requirements that were in effect at the time of our review regarding the registration of biological select agents and select agent materials. We identified two laboratories that had received biological select agents or select agent materials, but had not registered with CDC. We also identified one other laboratory that appeared to have provided potentially misleading information to CDC in its registration application regarding the biosafety level of the facility that would be used for work with a biological select agent.

Some Laboratories Did Not Register With CDC

The OIG issued two Management Alerts concerning the lack of registration by two of the Department's laboratories for the receipt of biological select agents and select agent materials. One Management Alert entitled "Management Alert on Inspection of 'Chem-Bio Safety Protocols at DOE' (S99IS040)," dated October 28, 1999, concerned work at the Department's Idaho National Engineering and Environmental Laboratory (Idaho Laboratory) with non-viable (dead) *B. abortus* cells received from the Department of Agriculture. Idaho Laboratory officials told us that they did not believe they had to register the receipt of the cells with CDC because the cells were dead. In fact, the Idaho Principal Investigator believed he had been told by CDC that registration of the dead cells was not required. However, in correspondence received from CDC in October 1999, a CDC official advised us that under 42 CFR Part 72, registration of the *B. abortus* cells was required regardless of whether the cells were alive or dead. According to the CDC official, CDC had consistently provided this guidance to all inquiries. After we issued our Management Alert, Idaho Laboratory officials registered with CDC for the receipt of the *B. abortus* cells.

The second Management Alert entitled "Management Alert on Inspection of 'Chem-Bio Safety Protocols at the Department of Energy' (S00IS010)," dated January 14, 2000, concerned receipt by Sandia-CA of subunits of biological select agents (A and B strains of botulinum toxin heavy chains and both subunits of ricin) in a dry, powder form. According to Sandia-CA officials, receipt of these toxin subunits was not registered with CDC because they believed the

shipments were exempt under 42 CFR Part 72 from registration due to their low toxicity and because the agent materials would only be used for biomedical purposes.

Following our November 1999 visit to Sandia-CA, we discussed the receipt of these toxin subunits by Sandia-CA with CDC officials, who expressed concern that Sandia-CA had not registered to receive these subunits. The CDC officials said, among other things, that registration for the receipt of either botulinum heavy chains or light chains is required because if both were ordered, these subunits could be reconstituted into highly toxic botulinum toxin. CDC officials said they planned to discuss the non-registration of these subunits with Sandia-CA officials. According to the Department's Lawrence Livermore National Laboratory (Lawrence Livermore) Biosafety Officer, he had received similar guidance from CDC officials concerning the requirement to register toxin subunits. We learned that both Lawrence Livermore and the Idaho Laboratory, which also had conducted work with subunits of these toxins, had registered with CDC for the receipt of the toxin subunits.

In September 2000, we were advised by the NN-20 CBNP Director that while CDC indicated in their opinion to the OIG that these heavy chains should be registered, no such opinion has been promulgated by CDC to either the Department's line management or to the general regulated community to date. He said that Albuquerque is evaluating the impact of this for registration under the select agent rule.

Although it was the view of CDC officials following our November 1999 visit to Sandia-CA that the receipt of either strain (strain A or strain B) of a botulinum heavy chain by Sandia-CA required registration, we recently learned that CDC is reevaluating its earlier position. During discussions with CDC officials in October 2000, we were advised that CDC has begun to reevaluate some of the interpretations it made in the process of implementing 42 CFR Part 72. We were told that, in the past, CDC recognized non-toxic subunits of toxins listed in Appendix A of 42 CFR Part 72 as subject to the rule if the subunits could be reconstituted with recovered toxicity. According to CDC officials, after careful reevaluation of this interpretation, CDC now recognizes subunits of toxins listed in Appendix A to be exempt provided that the subunit itself meets the exemption listed in 42 CFR Section 72.6 (h)(ii). We were told that the results of CDC's reevaluation regarding registration of the subunits of the toxins listed in Appendix A of 42 CFR Part 72 will soon be posted on the CDC Internet web site.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated, among other things, that the laboratories did not originally register with CDC for the materials in question because of reasonable interpretations that registration was not required. However, we note that Appendix A of 42 CFR Part 72 lists the select agents that require registration with CDC, as well as any exemptions to registration. In our view, if any form of the select agents listed in Appendix A is shipped or received, the material must be registered, unless specifically exempted. We believe that CDC should be contacted if there is a question regarding the need to register an agent or a form of an agent. We found no documentation from the Idaho Laboratory, however, that officials had requested or received any guidance from CDC regarding the requirement to register dead cells of *B. abortus*, nor did we find evidence that Sandia-CA officials had contacted CDC regarding registration of the subunits of toxins. Instead, officials at both laboratories made their own determination at that time that registration was not required.

Potentially Misleading Information in Registration Forms

As previously discussed, CDC regulations requiring registration for the transfer or receipt of biological select agents and select agent materials are designed to assure that infectious agents and toxins are shipped only to facilities equipped to handle them properly, and only to those which have legitimate reasons to use them. Registration includes providing sufficient information to indicate that the applicant facility is "equipped and capable of handling the agents" at the appropriate biosafety level, depending on the agent and the type of work being performed with the agents. The facility may be inspected by CDC and the registration withdrawn upon evidence that the facility is not capable of handling covered agents at the applicable biosafety level (BSL).

We learned that officials at the Department's Brookhaven National Laboratory (Brookhaven) submitted a registration application to CDC for receipt of intact botulinum toxin and stated on the application that the work would be conducted in a BSL-2 facility. We determined, however, that some of the experiments with the botulinum toxin were actually planned for and conducted in another on-site facility, the National Synchrotron Light Source (Light Source), which had not been approved as a BSL-2 facility.

The Brookhaven registration application states that minute crystals of the intact botulinum toxin within sealed multiple containment will be brought from a BSL-2 laboratory to the Light Source for x-ray diffraction analysis. It also states that after analysis, the crystals, in sealed multiple containment, will be returned to the BSL-2 laboratory

for disposal. The emphasis in the application is that the crystals are in sealed multiple containment when transported to and from the Light Source. The application, however, does not indicate that the crystals will be removed from the sealed multiple containment for experimentation in the Light Source, a non-BSL-2 facility. Although we found no evidence that Brookhaven officials intentionally tried to mislead CDC, we believe that the application, as it was written, provided potentially misleading information to the CDC such that they could not make a knowledgeable determination regarding the level of protection being provided for the material while in the Light Source.

The Department's Policies and Procedures Were Inadequate

We found that procedures for conducting certain research activities involving biological select agents and select agent materials varied significantly among the Department's laboratories. We determined that the Department had not developed and implemented policies and procedures that (1) establish clear roles and responsibilities for the conduct of activities involving biological select agents and select agent materials, and (2) ensure DOE laboratories, including those managed by the NNSA, follow "best practices" for the conduct of their biological select agent activities.

Required Responsibilities Not Performed

We found that individuals at several sites were not performing all their required responsibilities regarding certain biological select agent activities. For example, at Brookhaven, the individual designated as the "responsible facility official" understood her responsibility for signing the CDC form for transferring and receiving biological select agents. However, she was unaware of the additional management responsibilities that are assigned by CDC regulations to the "responsible facility official," which include notification to the shipper within established time frames of the receipt of the biological select agent, and formal notification to CDC when a biological select agent is consumed or destroyed. We did not find evidence that Brookhaven failed to make the required notifications to the shipper and CDC. However, we determined that the responsibility for making the notifications was improperly delegated by the "responsible facility official" to the Principal Investigator, who received the biological select agent. According to 42 CFR Section 72.6, the "responsible facility official" should be either a safety officer, a senior management official of the facility, or both, but should not be an individual who actually transfers or receives an agent at the facility.

Also, we determined that, at the time of our visit in February 2000, the Los Alamos Industrial Hygiene and Safety Group (ESH-5), which included the Los Alamos Biological Safety Officer, had not conducted the required assessments and evaluations of the laboratory's biosafety

program. The Los Alamos Laboratory Implementation Requirements (LIR 402-530-00.1) document entitled "Biological Safety (Biosafety)" specifies the Los Alamos Biosafety Program requirements to be implemented for research and operations involving bioagents/ biohazards. According to the Los Alamos Requirements document, ESH-5 shall "determine the effectiveness of the Biosafety Program through assessments and evaluations. . . ." The Los Alamos Biosafety Requirements document also specifies certain records that shall be maintained, to include, among others, "inspections or evaluations performed by the Biological Safety Officer and evaluations performed by other members of ESH-5." During our visit, we asked for copies of all reports regarding reviews of Los Alamos biological activities. None of the reports we were provided concerned assessments or evaluations conducted by ESH-5 members, including the Los Alamos Biological Safety Officer, regarding the effectiveness of the Los Alamos Biosafety Program. Also, at the time of our site visit, the Los Alamos Biological Safety Officer acknowledged that she had not conducted any independent inspections or evaluations of the Biosafety Program.

We were advised by the NN-20 CBNP Director in October 2000, that "in lieu of the internal program review for 1999, LANL [Los Alamos] and the DOE Albuquerque Operations Office agreed that a biosafety review would be conducted as part of the scheduled external DOE 'Integrated Safety Management Milestone Review' and would substitute for the internal review." He said that this review had been conducted in April 1999 by Albuquerque staff. He said that the next annual review was conducted by the Los Alamos Biological Safety Officer beginning in September 2000. However, our review of the Los Alamos Biosafety Requirements document determined that there was no requirement for an annual "internal program review" of the effectiveness of the Biosafety Program. Instead, as discussed above, the language in the Los Alamos Biosafety Requirements document implies a continuing series of assessments and evaluations, rather than a single annual program review. Therefore, we do not believe the external annual program review conducted by Albuquerque fulfills the requirement in the Los Alamos Biosafety Requirements document for ESH-5 to conduct assessments and evaluations to determine the effectiveness of the Biosafety Program.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that the reviews were conducted by Albuquerque with members of ESH-5 present, and were at least as comprehensive as the required internal review. However, the Acting Director's comments did not address whether the Albuquerque reviews

fulfilled the requirement for ESH-5 to conduct assessments and evaluations to determine the effectiveness of the Biosafety Program.

Inconsistent Receipt/Screening Procedures

We observed that certain Department laboratories had implemented procedures for screening biological select agents and select agent materials upon receipt and for handling agents received in damaged shipping containers, while other laboratories had not. We believe that the implementation of procedures for handling damaged shipping containers, along with appropriate screening procedures, could significantly reduce the potential risk to employees of exposure to possibly harmful biological select agents.

Select Agent Screening/Verification

While some of the Department's laboratories screened biological select agents and select agent materials to ensure the material that was received was the material that was ordered, others either had inadequate screening procedures or depended on certification by the shipper that the proper material was shipped.

According to the Kirtland ES&H Team Leader, there appears to be "undue trusting acceptance" that orders placed with vendors are filled with the correct material. He said that while shippers generally do a good job in that regard, there have been "several questionable receipts when DOE laboratory staff assumed material that was received was non-pathogenic." He said that the implications and possible consequences of an inadvertent shipment of a live agent that is unknowingly handled as non-pathogenic "could be grave."

The following incidents at three of the Department's laboratories illustrate the potential risk of relying on possibly inadequate screening procedures or shipper certifications.

Although one laboratory, Los Alamos, had a screening process for select agent DNA, on one occasion the Principal Investigator was unable to determine whether he had actually received the material he had ordered. During our February 2000 visit to Los Alamos, the Principal Investigator told us that he had worked with what he thought was DNA of a select agent for four months, only to learn that the material he had received was not what he had ordered. Later, in September 2000, the NN-20 CBNP Director clarified in comments to a draft of our report that, after work had been conducted with the material for four months, Los Alamos had found that the select agent DNA that had been received was, in fact, contaminated with the DNA from a common skin microbe prior to arriving at Los Alamos. He also

said that the shipment had been screened by Los Alamos using filter-sterilization, which removes microorganisms but does not eliminate DNA contaminants. He added that he did not view the contamination with the DNA of the skin microbe to be a potential safety hazard.

We are concerned, however, that the process used by Los Alamos to screen the shipment of select agent DNA did not alert the Principal Investigator that the shipment contained unknown biological material. Although in this case the material that was included in the shipment was only the DNA of a skin microbe, future shipments of select agent DNA could contain harmful material, such as select agent toxins, that might not be totally eliminated by the process used by Los Alamos to screen DNA shipments.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that the screening process used by Los Alamos is consistent with best practices in use elsewhere. He said that it is impractical to test for all possible contaminants, and there was no significant reason to routinely screen for the presence of DNA of a skin microbe. According to the Acting Director, the matter should be viewed in the context of shipper and receiver responsibilities, and while there is not an absolute guarantee that an error will never be made, the existing protocol provides significant and widely accepted assurance that risks are minimized.

We note, however, that according to the potential hazard assessment for the Los Alamos DNA project, the shipper only had to certify that the shipment was "microbe free." In view of the presence of a contaminant in the shipment received by Los Alamos, which only after four months was discovered to be the DNA of a skin microbe, we remain concerned with the adequacy of the Los Alamos screening process.

Also, in December 1999, a Principal Scientist at another laboratory, Lawrence Livermore, told us that he had the laboratory policy changed to require screening after he realized the quality and safety benefits that could be gained by screening select agent shipments. He described an incident that occurred after the screening process was implemented, which involved the screening of a shipment of attenuated *B. anthracis*. According to the Principal Scientist, the preliminary screening process indicated that the *B. anthracis* was potentially not attenuated. However, we were advised that the particular test is subject to "false positives" and rather than using additional tests to determine whether the *B. anthracis* was, in fact, the viable, infectious form of the agent, the sample was destroyed.

Although the test results were inconclusive whether the material that was received was the viable, infectious form of *B. anthracis*, we believe this incident highlights the potential hazards associated with the receipt of biological select agents and select agent materials.

A third laboratory, the Department's Lawrence Berkeley National Laboratory (Lawrence Berkeley), also had established a process to screen all samples of agents it received. In November 1999, a Principal Scientist told us of an incident when a shipment of attenuated *B. anthracis* was ordered, but did not pass the laboratory's screening process that would have verified that the material was attenuated. He said the agent was not tested to determine whether it was the viable, infectious form of *B. anthracis*, but was immediately destroyed. He said that because of this incident, a laboratory official decided that in the future, all employees working with attenuated *B. anthracis* should be offered immunization and subsequently, all were immunized.

Sandia-CA, however, is one Department laboratory that does not screen shipments of select agent materials. According to Sandia-CA officials, the laboratory depends on the certification of the shipper as to the type and quality of the material shipped.

Damaged Container Procedures

While some Department laboratories had developed and implemented specific procedures to handle damaged shipping containers containing biological select agents and select agent materials, other laboratories had not. We believe that implementation of specific handling procedures for damaged containers received at the Department's laboratories could possibly reduce the risk of exposure of laboratory personnel to harmful materials, particularly in the event that the materials received are not those that were ordered.

We learned that Sandia-CA had developed and implemented procedures for handling damaged containers containing biological select agents and select agent materials. Also, the Idaho Laboratory, which received shipments of botulinum toxin, had developed written procedures for handling damaged packages of the toxin after determining that such procedures were necessary. However, at least two Department laboratories, Lawrence Berkeley and Los Alamos, had not developed specific procedures for handling damaged shipping containers containing biological select agents and select agent materials. For example, we were advised by the Lawrence Berkeley Biosafety Officer in August 2000, that Lawrence Berkeley had not developed specific procedures to handle damaged packages containing

biological select agents because, at that time, the laboratory did not order "full blown lethal select agents."

Also, Los Alamos, which has worked with attenuated *B. anthracis* and DNA of biological select agents and is proposing to conduct activities involving the viable, infectious form of *B. anthracis*, has not developed specific procedures for handling damaged packages. We were told by the Los Alamos "responsible facility official" that Los Alamos has no special procedures or specific training regarding their receipt or shipment process for select agents. In addition, we were told by the Los Alamos Biosafety Officer that Los Alamos also lacked a "hazard control plan" for damaged packages containing biological agents received by the Los Alamos shipping department.

An incident at Los Alamos involving a shipment of select agent DNA illustrates the potential risk of workers being exposed to harmful biological select agents and select agent materials when damaged containers are received in the absence of specific procedures to handle them. A Los Alamos Principal Scientist told us that the laboratory shipping and receiving department received a shipment of select agent DNA with crushed inner and outer containers. The Principal Scientist said that he destroyed the shipment because of the possibility that the shipment could have contained more than just the DNA portion of the select agent that he had ordered. The Los Alamos "responsible facility official," however, said that he did not see a need for "special handling procedures." He told us that he believed there was "zero risk" regarding the receipt of select agent DNA and, therefore, no special procedures or specific training were necessary regarding the receipt or shipment process for handling these materials. He advised us that he believed that Los Alamos' general procedures were adequate.

CDC, however, requires a BSL-2 facility for receipt and containment of DNA from biological select agents because of the possibility that the shipments may include the actual agent as well. According to a CDC official, CDC is concerned with the reliability of the shipper to provide only the DNA of the biological select agent and the ability of the receiver to determine what was actually received.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that Los Alamos has a hazard control plan for the handling of regulated materials and the control of exposures to hazardous materials from damaged packages, which was prepared by the Shipping and Receiving Group. Further, the Group's Work Procedure specifically addresses requirements for the handling of damaged packaging containing hazardous materials.

As discussed above, however, the Los Alamos Biosafety Officer told us that Los Alamos lacked a hazard control plan for damaged packages containing biological agents received by the Los Alamos shipping department. Also, we were told by the NN-20 CBNP Director in October 2000, that the Los Alamos Hazard Control Plan for Shipping and Receiving workers generically addresses the handling of hazardous materials. We believe that due to the potential safety and health risks associated with biological agents, specific procedures should be developed to handle damaged packages containing biological select agents and select agent materials received by the Los Alamos shipping department.

Required Hazard Analysis Was Based On Incomplete Data

We determined that documentation describing activities involving biological select agents at Brookhaven did not contain a sufficient level of detail for laboratory officials to fully identify potential hazards. Specifically, documentation for a project submitted to the laboratory's Institutional Biosafety Committee (IBC), which reviews and approves biological select agent experiments, contained insufficient information for the IBC members and laboratory safety and health personnel to ensure that all hazards associated with the project were identified, analyzed, and determined to be either avoidable or manageable.

At Brookhaven, a Standard Operating Procedure (SOP) document was prepared for experiments in a BSL-2 facility using intact botulinum toxin. According to the "Material Data Safety Sheet" for the botulinum toxin, the acute effects of the material include "may be fatal if inhaled, swallowed, or absorbed through the skin. The toxin is among the most powerful paralytic poisons known, having irreversible effects." The SOP states that the botulinum toxin was to be transported in sealed multiple containment to another facility on the site, the Light Source, for additional experiments. We were told by a Brookhaven Industrial Hygienist, who managed the Light Source, that one tiny crystal of the botulinum toxin could cause death if ingested. As discussed previously, the Light Source was not an approved BSL-2 facility at the time of our site visit. Although the SOP did not state that the botulinum toxin would be removed from its containment while in the Light Source, we learned from the Principal Investigator that the botulinum toxin was, in fact, routinely removed from its containment for the Light Source experiments. We also learned that as many as 30 individuals, some at work stations located only 6 to 8 feet away, could have been working on other projects in the Light Source when the botulinum toxin was removed from its containment. We did not find evidence, however, that any of these individuals was harmed by the experiments.

We determined that the project description provided to the laboratory IBC, which had approved the botulinum toxin experiments, did not state that the botulinum toxin would be removed from its containment in the Light Source. We also determined that the document submitted to the laboratory's Experiment Safety Review Committee for its safety review did not mention that the botulinum toxin would be removed from its containment while in the Light Source. This document, "Biology Department ES&H Review of Experiments," contained a section for the Principal Investigator to specifically identify, describe, and analyze the potential hazards associated with the project. At the time of our visit in January 2000, both the IBC Chairman and the Manager of Brookhaven's Safety and Health Services Division told us that they did not know that the botulinum toxin was to be removed from its containment for the Light Source experiments. However, in September 2000, the NN-20 CBNP Director reported that the IBC Chairman had known that the toxin was being removed from its container in the Light Source.

Nonetheless, after we informed the IBC Chairman in January 2000 that the botulinum toxin was being removed from its containment and manipulated in the Light Source, he initiated several corrective actions. These were to revise the SOP to require freezing of the botulinum toxin to take place only in the BSL-2 laboratory, not in the Light Source as previously permitted, and to limit where in the Light Source the botulinum toxin could be removed from its containment. Prior to the revisions, the experimenter removed the botulinum toxin from its containment on a work bench area, with other experimenters working nearby. Under the revisions, the experimenter could only remove the botulinum toxin from its containment in one of the "hutch" areas of the Light Source, which was located away from other experimenters.

In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that during the procedure in question, the toxin crystal is attached to a glass support such that ingestion would be "essentially impossible." We agree with the Acting Director's comment that ingestion of the toxin crystal would be "essentially impossible" while the crystal is attached to a glass support. However, we do not believe the Acting Director's comments adequately consider the potential for exposure resulting from accidental breakage of the glass support, either through dropping or mishandling of the glass support during the time the material is removed from its containment. Accidental separation of the crystal from the glass support, in our view, has the potential to result in

exposure to the toxin, not only from ingestion, but also from inhalation and from absorption through the skin.

Inconsistent Policies Regarding Worker Immunizations

Occupational Medical Physicians told us that employees working with biological select agents have the right to decline immunizations, even when highly recommended by the facility Occupational Medical Physician and the Principal Investigator. According to an official in the Department's Office of General Counsel, there may be a potential liability for the Department if contractor employees working with CDC-controlled biological select agents do not sign a statement acknowledging the risks associated with the project, the availability of immunizations, and the individual's decision not to be immunized. We confirmed, however, that not all of the Department's laboratories require employees working with biological select agents and select agent materials to sign an acknowledgement statement. At the Idaho Laboratory, for example, three scientists working with botulinum toxin decided not to be immunized, even though they were aware of the potential dangers, and were not required by the laboratory to sign an acknowledgement statement. Also, Sandia-CA does not require Principal Investigators or other laboratory participants to sign a statement if they work with biological select agents and decline to be immunized.

Other Department laboratories, however, require employees to sign statements if they decline to be immunized. According to the Los Alamos Head Occupational Health Physician, for example, all at risk personnel at Los Alamos are required to sign a statement acknowledging the risks and benefits of being immunized versus not being immunized.

An even greater potential liability for the Department may result from allowing workers who decline immunizations to continue working with infectious agents and, therefore, possibly infecting themselves or others. As Department laboratories begin experimenting with indigenous or exotic biological select agents that may cause diseases having serious or lethal consequences (such as agents requiring BSL-3 containment), the consequences of laboratory personnel infecting their spouses and others should be considered. According to CDC literature, laboratories working with infectious agents have not been shown to represent a threat to the community. However, the CDC literature also cites isolated cases when laboratory workers became infected and subsequently infected their spouses or other members of the community. Because CDC only recommends immunizations for workers, and the Department does not require workers to be immunized, the potential exists for Department laboratory personnel

who work with infectious agents, but decline to be immunized, to infect others.

NEPA Reviews Not Conducted

We determined that National Environmental Policy Act (NEPA) reviews were not conducted at two Department laboratories for activities involving biological select agents.

The OIG issued a Management Alert on June 30, 1999, entitled "Inspection of the Chem-Bio Facility at ORNL," S99IS019. The OIG found that the Department's Oak Ridge National Laboratory (ORNL) had not conducted an environmental assessment for a BSL-3 laboratory that was being constructed for work with botulinum toxins, which were to be received as "lyophilized" (freeze-dried) powder. Based on the Department's implementing regulations for NEPA, the OIG believed that an environmental assessment was required before the procurement, installation, and commencement of biological operations at the BSL-3 laboratory. Oak Ridge Operations Office officials subsequently placed restrictions on the Chem-Bio Facility to exclude BSL-3 activities, and stated they will conduct an environmental assessment before any BSL-3 work is performed in the facility.

Also, as discussed in the OIG's March 13, 2000, Letter Report, the OIG found that, although a NEPA review had been conducted by Sandia-NM of the original scope of work for a Work-for-Others project, significant changes, such as changes in work location and introduction of the select agent *Y. pestis EV76*, had been made without an additional NEPA review. Subsequently, Albuquerque officials advised us that an analysis of the existing NEPA process is ongoing to determine how to ensure Work-for-Others projects are receiving appropriate NEPA review.

Observations

Lack of Timely Response From CDC

We had difficulty obtaining timely responses from CDC officials to our inquiries for clarification of registration requirements for certain biological select agent materials. On several occasions, responses were received from CDC more than a month after our inquiry. Also, although we requested written responses to our inquiries, in most cases CDC officials only provided verbal responses. We understand that Department and laboratory officials experienced similar difficulties in obtaining timely responses from CDC.

Changes to CDC Interpretations

In the absence of written responses from CDC regarding their interpretation of registration requirements, we found it difficult to determine current registration requirements. Discussions with CDC officials, for example, indicate that CDC is re-evaluating earlier interpretations of the requirements. Therefore, some of the materials that CDC currently requires to be registered may be removed from the list of materials subject to registration, while new materials may be added. For example, CDC is re-evaluating whether such materials as "dead" cells of biological select agents and subunits of toxins require registration.

Lack of CDC Inspections

We understand that CDC can conduct on-site inspections of laboratory facilities identified on the registration application for biological select agents and select agent materials for a three-year period from the date the registration application was approved. Among other things, these inspections ensure the materials are in facilities that provide the appropriate biosafety level. However, we learned of only one such inspection of a DOE facility by CDC. We believe that such inspections by CDC would assist the Department in its efforts to ensure the safety and security of activities involving biological select agents and select agent materials.

In view of the ongoing re-evaluation by CDC of their earlier interpretations of registration requirements, and the lack of timely responses by CDC officials to requests for information/guidance, we believe the Department should take appropriate action to ensure the Department's laboratories receive timely and consistent information regarding current CDC guidance.

We discussed our observations with CDC officials. We were advised that CDC plans to provide updated information on its Internet web site regarding its interpretation of registration requirements. Specifically, CDC will post written instructions for facilities that have questions about registration, as well as updates to the list of registered materials. CDC officials also stated that CDC will improve responsiveness to DOE and other agencies by

increasing staff in the office responsible for oversight of the registration process.

RECOMMENDATIONS

We recommend that the Under Secretary for Energy, Science, and Environment and the Under Secretary for Nuclear Security jointly:

1. Identify the types and locations of activities being conducted by the Department involving biological select agents and select agent materials.

2. Initiate action to ensure: (a) appropriate Federal oversight; (b) consistency in policy; and (c) standardization of implementing procedures for biological select agent activities being conducted by the Department. Actions, for example, could include encouraging more interagency cooperation in this area and, similar to the approach taken by the U.S. Army, supplementing CDC guidance regarding activities involving biological select agents and select agent materials to address situations unique to DOE.

3. Ensure that required NEPA reviews are conducted prior to the start of biological select agent and select agent material activities and revised, as needed, when significant changes occur in the activities.

4. Initiate appropriate action to ensure the Department's laboratories, including those managed by the NNSA, receive timely and consistent information regarding current CDC guidance.

We also recommend that the General Counsel:

5. Determine the potential liability to the Department if contractor employees working with biological select agents refuse immunizations or if they do not sign a statement acknowledging the risks associated with the project, the availability of immunizations, and the individual's decision not to be immunized.

6. Determine the feasibility of requiring Department laboratory employees to be immunized in order to work with infectious agents.

7. Determine whether the Department has liability to third parties (e.g., spouses, families, members of the community) who may be infected as a result of coming in contact with a laboratory employee who works with biological select agents, but has refused to be immunized.

MANAGEMENT COMMENTS

The Department generally concurred with our recommendations. In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program stated that while there is no indication that biological safety has been compromised at any DOE facility, the draft report correctly points out operational concerns and inconsistencies that existed during the review. He provided the following examples of actions completed by the Department within the past year to improve biosafety practices at its laboratories and said that the Department is already taking steps consistent with our recommendations:

- A biosurety program was initiated on December 1, 1999, at Albuquerque to strengthen the safety and security protocols used with biological select agents.

- Communication has been improved between DOE headquarters, the Operations Offices, and the Department's laboratories, as well as between DOE and other Federal agencies involved with biological research.

- CDC select agent registration requirements are being clarified.

- The former Secretary established a Biosurety Working Group led by EH to recommend specific improvements in directives and contract language and other actions which will improve oversight and implementation of safe practices in potentially hazardous areas of biological research.

Regarding recommendation 1, the Acting Director stated that in consultation with CDC and the Department's laboratories, the Department has confirmed the location and types of current activities involving select agents. Moreover, the Department is establishing a process to ensure this information, as well as information about activities involving other biologically hazardous materials, is regularly updated and more readily available to managers.

Regarding recommendation 2, the Acting Director stated that the Department concurs with the need for appropriate Federal oversight, consistency in policy, and, when appropriate, standardized procedures for use with select agents. He said that mechanisms to improve oversight, coordination, and consistency are currently being reviewed by the Biosurety Working Group. He said that much of the Working Group's focus is on improving communication and consistency. In particular, the Working Group is drafting proposed changes to DOE's directives and contracts, and it is considering methods to improve

ongoing communication through appropriate levels of management. In considering these changes, the Working Group is examining policies and procedures developed within the Department and by other agencies, particularly CDC and the U.S. Army.

He also said that in parallel with the Working Group's actions, the Department's laboratory directors are confirming that biological research at their facilities is being appropriately addressed within their safety and health programs. Also, the Department is expanding Albuquerque's Biosurety Initiative to encompass the DOE complex and promote improved communication and sharing of lessons learned and best practices among laboratories.

In addition, he said that the Department continues to look to other agencies, especially the CDC, for direction and guidance. He said that the Department's laboratories that transfer or ship select agents are required, pursuant to 42 CFR Part 72, to follow the procedures outlined in the "Biosafety in Microbiological and Biomedical Laboratories" guidelines, unless certified by the Clinical Laboratory Improvement Amendment of 1988.

Regarding recommendation 3, the Acting Director stated that the Department is required to comply with NEPA. He said that the Department will "continue to address biological research within individual laboratory annual NEPA planning summaries and otherwise according to Departmental requirements" to ensure that appropriate consideration is given to NEPA compliance early in the planning process. In addition, the Department is acting to raise the awareness of managers to this particular area of research and expects that in doing so, NEPA compliance will be highlighted. For example, the Secretary recently tasked laboratory managers to certify that potentially hazardous biological research is appropriately addressed in annual NEPA planning summaries.

Regarding recommendation 4, the Acting Director stated that DOE concurs with the desire to have timely and consistent information from CDC, and the Department recognizes its obligation to implement CDC guidance. Through the Albuquerque Biosurety Initiative and the recently established DOE Biosurety Working Group, the Department and its laboratories are improving communication and coordination with other agencies. Additional steps will be taken, as they are identified, to better ensure the timely evaluation and appropriate adoption of any newly established CDC guidance.

Regarding recommendation 5, the Acting Director stated that staff members of the Office of General Counsel are in the process of

evaluating potential liability issues relating to the Department's contractors' work with biological agents. The issues being addressed include both potential direct and indirect liability, including such things as liability arising from the removal of contractor employees who decline to be immunized.

Regarding recommendation 6, the Acting Director stated that the Office of General Counsel is reviewing this matter. He said that the U.S. Public Health Service Advisory Committee on Immunization Practices issues current and updated recommendations for immunization. He said that the Office of General Counsel has made an initial conclusion that existing laboratory protocols should periodically be reviewed for compliance with this guidance. Where no such protocols exist, the development of protocols consistent with this guidance by qualified site professional, medical staff in consultation with at-risk individuals and the CDC is appropriate.

Regarding recommendation 7, the Acting Director stated that as discussed in his comments to recommendation 5, the Office of General Counsel is continuing to review questions of potential liability.

In addition to comments regarding the recommendations in our draft report, the Acting Director provided specific comments concerning the findings and language in our draft report. We have incorporated the Acting Director's comments in our final report, where appropriate.

INSPECTOR COMMENTS

We believe the corrective actions identified by the Department are responsive to our recommendations.

Also, in an earlier draft of our report, we had recommended that the Department determine whether overall responsibility for biological select agent activities should be centralized in one organization. In comments dated December 14, 2000, to the final draft of our report, the Acting Director of the Department's Chemical and Biological National Security Program identified existing management systems, such as the Department's Integrated Safety Management program, that govern biological select agent research to ensure it is conducted safely and effectively, and stated that a new, centralized organizational structure to manage such research is not appropriate at this time. He said that creating such an organization would unnecessarily separate biological research from the management systems in place for other aspects of the Department's work. He said that, nonetheless, DOE recognizes the need to better ensure that existing management systems effectively meet the needs of this evolving area of the Department's research activities and is taking steps toward the goal.

In view of the Acting Director's comments and the establishment of NNSA as a semiautonomous organization within the Department, we agree that establishing a new, centralized organizational structure to manage biological agent research may not be appropriate at this time. Therefore, we deleted this recommendation from our final report.

Appendix A

SCOPE AND METHODOLOGY

This inspection was conducted from July 1999 through January 2001 at Department of Energy (DOE) laboratories, including National Nuclear Security Administration (NNSA) laboratories, that we identified as conducting experiments involving biological select agents and select agent materials. These laboratories included Brookhaven National Laboratory, Idaho National Engineering and Environmental Laboratory, Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, Oak Ridge National Laboratory, Sandia National Laboratories-New Mexico, and Sandia National Laboratories-California.

To accomplish our inspection objectives, we conducted a survey of selected Department Operations Offices to identify the extent of their activities involving biological select agents and select agent materials and conducted on-site reviews at the Department laboratories listed above. We interviewed Department Headquarters officials in the Office of the Deputy Administrator for Nuclear Nonproliferation; the Office of Environment, Safety and Health; the Office of Science; the Office of Environmental Management; the Office of the Deputy Administrator for Defense Programs; the then Office of Field Management; the Office of Intelligence; and the Office of General Counsel. We also interviewed contractor personnel at each of the Department's laboratories listed above. In addition, we interviewed officials at the Centers for Disease Control and Prevention, the U.S. Army Edgewood Chemical Biological Center, and the U.S. Army Medical Research Institute of Infectious Diseases. We also reviewed pertinent Federal, Department, and contractor environment, safety and health rules and regulations implemented at each site, and compared the criteria with the rules and regulations being implemented at facilities outside of the Department.

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

CUSTOMER RESPONSE FORM

The Office of Inspector General has a continuing interest in improving the usefulness of its products. We wish to make our reports as responsive as possible to our customers' requirements, and, therefore, ask that you consider sharing your thoughts with us. On the back of this form, you may suggest improvements to enhance the effectiveness of future reports. Please include answers to the following questions if they are applicable to you:

1. What additional background information about the selection, scheduling, scope, or procedures of the inspection would have been helpful to the reader in understanding this report?

2. What additional information related to findings and recommendations could have been included in the report to assist management in implementing corrective actions?

3. What format, stylistic, or organizational changes might have made this report's overall message more clear to the reader?

4. What additional actions could the Office of Inspector General have taken on the issues discussed in this report which would have been helpful?

5. Please include your name and telephone number so that we may contact you should we nay any questions about your comments.

Name _____ Date _____

Telephone _____ Organization _____

When you have completed this form, you may telefax it to the Office of Inspector General at (202) 586-0948, or you may mail it to:

Office of Inspector General (IG-1)
Department of Energy
Washington, DC 20585

ATTN: Customer Relations

If you wish to discuss this report or your comments with a staff member of the Office of Inspector General, please contact Wilma Slaughter at (202) 586-1924.

This page intentionally left blank.

The Office of Inspector General wants to make the distribution of its reports as customer friendly and cost effective as possible. Therefore, this report will be available electronically through the Internet at the following address:

U.S. Department of Energy Office of Inspector General Home Page
http://www.ig.doe.gov

Your comments would be appreciated and can be provided on the Customer Response Form attached to the report.