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TO: The Deputy Secretary
Through: COS _____
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FROM: Dara Corrigan 
Acting Principal Deputy Inspector General

SUBJECT: Summary Report on Select Agent Security at Universities
(A-04-04-02000)

The attached report consolidates the Office of Inspector General (OIG) findings from select agent security reviews conducted at 11 universities during 2002 and 2003. The report also discusses the universities' responses, regulatory changes affecting select agents, and actions taken by the Centers for Disease Control and Prevention and the National Institutes of Health to address the issues raised by our reviews.

We developed this report in response to numerous requests, particularly from the academic community, for information on our 11 university reports, which are not publicly available. Accordingly, this summary, which does not compromise the sensitive nature of the individual documents, will be available to the public.

In general, our reports disclosed serious weaknesses that compromised the security of select agents at all universities we reviewed:

- Physical security weaknesses at all 11 universities left select agents vulnerable to theft or loss, thus elevating the risk of public exposure.
- Inadequate inventory and recordkeeping procedures at all 11 universities prevented us from concluding that the universities had complied with select agent transfer requirements.
- At least half of the universities had inadequate procedures to identify persons barred from accessing select agents under the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001.
- The five universities that used information technology resources for select agent data exhibited control weaknesses that could compromise the security and integrity of the data.

The universities generally agreed with our findings and recommendations, and all stated that they had begun implementing corrective actions, which we have not verified. Since performing our reviews, new requirements have become effective for securing and managing select agents, and we plan to perform additional university reviews in fiscal year 2004 to assess compliance with these latest select agent requirements.

If you have any questions or comments on our work in the select agent area, please call me or your staff may contact Donald L. Dille, Assistant Inspector General for Grants and Internal Activities, at (202) 619-1175 or through e-mail at ddille@oig.hhs.gov.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**SUMMARY REPORT ON SELECT
AGENT SECURITY AT UNIVERSITIES**



**MARCH 2004
A-04-04-02000**

SUMMARY REPORT ON SELECT AGENT SECURITY AT UNIVERSITIES

BACKGROUND

Immediately following the 2001 terrorist attacks and the subsequent anthrax release, the Office of Inspector General (OIG) initiated a program to review select agent¹ security at laboratories operated by the Department of Health and Human Services (HHS) and universities. In early 2002, we began reviews of 11 universities that received National Institutes of Health (NIH) funding for research involving select agents. Of these, 10 had select agents on the premises, and 1 planned to obtain such agents.

We used the following laws, regulations, and guidance as criteria for evaluating the adequacy of security measures at the universities we reviewed:

- “Biosafety in Microbiological and Biomedical Laboratories” (BMBL), 4th Edition, Appendix F;
- the select agent transfer regulation (42 CFR § 72.6);
- the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act); and
- Office of Management and Budget Circular A-130, Appendix III, “Security of Federal Automated Information Resources.”

The purpose of this report is to summarize our findings and discuss the universities’ responses, regulatory changes affecting select agents, and actions taken by the Centers for Disease Control and Prevention (CDC) and NIH to address the issues raised by our reviews.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

The objectives of our reviews of the 11 universities were to assess:

- physical security at the locations where select agents were used, stored, or planned to be used or stored;

¹ Select agents are micro-organisms or infectious substances, naturally occurring, bioengineered, or a synthesized component thereof, capable of causing (1) death, disease, or other biological malfunction; (2) deterioration of water, food, equipment, supplies, or materials; or (3) deleterious alteration of the environment. The Congress determined that certain biological agents, defined by regulation as select agents, have the potential to pose a severe threat to public health and safety and to be used as weapons by criminals or terrorists.

- compliance with the select agent transfer regulation;
- controls over select agent access by “restricted persons,”² as defined by the USA PATRIOT Act; and
- controls over information technology resources that process, store, or transmit select agent information.

Scope

We reviewed 11 universities that had laboratories capable of working with select agents. The universities represented a mix of public and private institutions located throughout the country that received Federal research funds. We conducted our fieldwork largely during calendar year 2002, and we issued final reports to the universities during 2003.

Methodology

We performed our work in accordance with generally accepted government auditing standards. To accomplish our objectives, we asked the 11 universities to complete a written questionnaire regarding their work with select agents. We visited each university, toured the areas where select agents were maintained or were planned to be maintained, reviewed university records, met with university officials involved with security and safety, and consulted with CDC select agent program officials. Because of the sensitive nature of the issues discussed in our reports, we restricted their distribution.

SERIOUS WEAKNESSES IN PROVIDING SECURITY FOR SELECT AGENTS

Serious weaknesses compromised the security of select agents at all universities reviewed. Physical security weaknesses at all 11 universities left select agents vulnerable to theft or loss, thus elevating the risk of public exposure. Inadequate inventory and recordkeeping procedures at all 11 universities prevented us from concluding that universities had complied with select agent transfer requirements. In the area of restricted persons, at least half of the universities had inadequate procedures to identify persons barred from accessing select agents under the USA PATRIOT Act. Finally, at five universities that used information technology resources for select agent data, we noted control weaknesses that could compromise the security and integrity of that data.

² A restricted person is defined as one who (1) is under indictment or is a fugitive; (2) unlawfully uses a controlled substance; (3) is an illegal alien; (4) has been adjudicated a mental defective; (5) has been dishonorably discharged; or (6) is a national from a country that supports terrorism, as determined by the Secretary of State.

Physical Security

The BMBL prescribes a variety of access controls, including locked doors, card key access, logs of persons entering labs, and locked refrigerators/freezers for storing select agents.

All of the universities had weaknesses in preventing unauthorized entry into “hot labs”³ and unauthorized removal of select agents. Intruders could have accessed buildings housing hot labs by entering through unlocked doors and hallways, “piggybacking” (following closely behind authorized persons), bypassing security officers, or forcing access through unalarmed doors. Further, at all 11 universities, once inside the buildings, intruders had unobstructed access to the floors with hot labs.

Other serious weaknesses included:

- uncontrolled issuance of hot lab door keys;
- storage of hot lab keys in open drawers;
- unlocked security doors;
- use of breakable glass panels on security doors;
- unsupervised, unimpeded access to freezers located in open areas;
- unlocked freezers in hot labs;
- a lack of closed-circuit television cameras; and
- nonenforcement of the use of identification badges.

Compliance With Select Agent Transfer Regulation

At the time of our reviews, 42 CFR § 72.6 provided public health and safety requirements for facilities that transfer (that is, receive or ship) select agents. Both the requesting facility and the shipping facility were required to register with CDC, the Federal agency that oversees select agent security and safety. The regulation also required that documents be available to assess compliance with select agent transfer requirements.

Because of inadequate inventory and recordkeeping procedures, we could not determine whether the 11 universities had complied with the transfer regulation. Of the 11 universities, 9 were registered with CDC to transfer select agents and 2 said that they were not registered because they had not been involved with transfers. The nine registered universities were not able to provide sufficient documentation for us to

³ “Hot lab” is the term we use to identify a laboratory with select agents.

determine full compliance with the select agent transfer regulation. Such documentation may have been available had the universities implemented adequate inventory and recordkeeping procedures to account for select agents. We noted, however, that principal investigators and their assistants generally did not maintain select agent records on the date that vials were placed into or removed from inventory, the source and destination of shipments, or the total inventory on hand. We also noted that the universities did not require principal investigators to physically count select agent inventories to verify their accuracy.

At the time of our fieldwork, 42 CFR § 72.6 did not explicitly prescribe inventory and recordkeeping procedures. Such formal procedures, together with training of personnel who work with select agents, would have helped to avoid the following weaknesses identified at three universities:

- Without the university's knowledge, a principal investigator registered a select agent with CDC and proceeded to remove the agent from the campus.
- A principal investigator received a select agent from another country without properly registering it with CDC before arrival and without properly notifying the university.
- A principal investigator improperly registered a select agent with CDC and failed to register others.

Controls Over Restricted Persons as Defined by the USA PATRIOT Act

The USA PATRIOT Act criminalized the possession or receipt of select agents by restricted persons. A logical implication of this law is that institutions that work with select agents, such as universities, should implement controls to prevent restricted persons from gaining access to such agents. To assess controls in this area, we examined whether the universities had identified restricted employees and contract staff, verified foreign nationals' immigration documents, and enforced the use of employee identification badges.

At least half of the universities had inadequate procedures to identify restricted persons. Several universities did not apply identification and screening procedures to maintenance and contract staff who worked in close proximity to areas containing select agents. Five universities did not substantiate immigration documents of foreign nationals, and nine universities did not effectively enforce the use of identification badges or the escorting of visitors.

Information Technology Controls

At the five universities that used information technology resources to maintain select agent data, we noted a range of information access and service continuity problems. A particularly egregious example involved the e-mailing of an attachment containing a

central registry file of select agent data to sources outside the university. Unauthorized interception of the e-mail would have made the data available to unauthorized persons.

Other security issues included:

- a lack of written policies on the use of computers to record, transmit, or store sensitive data;
- inadequate password controls;
- environmental and physical security weaknesses;
- inadequate controls over the destruction of sensitive data; and
- service continuity weaknesses.

RECOMMENDATIONS AND UNIVERSITY RESPONSES

Our individual reports to the universities contained numerous recommendations for strengthening physical security, compliance with the select agent regulation, controls over restricted persons, and information technology controls. Generally agreeing with our findings and recommendations, all of the universities stated that they had begun implementing our recommendations or alternative procedures. We have not verified those actions.

Some universities cited concerns about the lack of criteria in the security area and the funding required to implement the necessary improvements. Some of the universities said that the BMBL was only a general guideline and not a requirement—a comment to which we took exception. Although issued as a guideline, the BMBL had been formally incorporated into the select agent regulation (42 CFR § 72.6(a)(5)) and was in effect at the time of our reviews.

NEW REQUIREMENTS FOR SELECT AGENT SECURITY

After we completed our fieldwork at the 11 universities, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 strengthened requirements in the area of select agent security. Implementing regulations were published as an interim final rule on December 13, 2002, with initial implementation by February 7, 2003 and full implementation by November 12, 2003, depending on the requirement. Following are some of the new requirements:

- Institutions must appoint a responsible official to oversee the select agent program.
- All institutions that possess and use select agents must register with CDC.

- Institutions must submit the names of persons with access to select agents to the Secretary of HHS and the Attorney General for a security risk assessment.
- Institutions must develop and implement detailed security, safety, and emergency response plans.
- Institutions must maintain detailed select agent inventory records.
- Persons who work with select agents must be trained.
- Records and databases must be accurate and verifiable.

CDC AND NIH ACTIONS

Since our reviews, both CDC and NIH, the two HHS organizations with an interest in select agent security, have responded with certain actions to improve the security environment for select agents.

According to CDC officials, the agency has developed regulation-based checklists for use during onsite visits, awarded contracts to assist in laboratory inspections of more than 300 registered entities, committed 21 full-time equivalents to select agent regulatory oversight, and is developing a security plan template to assist entities with select agents in developing their own security plans. CDC also has begun revising the BMBL and the appendix related to security, and it expects to publish a final rule on the select agent regulation late in 2004.

NIH revised the terms for awarding grants that will involve work with select agents. Before using NIH grant funds, the awardee must register with CDC (or the Department of Agriculture, depending on the agent). No funds may be used for research involving select agents if the final registration certificate is denied. During fiscal year 2004, NIH plans to add a biosecurity specialist to the compliance team that visits universities. Both CDC and NIH also have been part of an interagency select agent working group to formulate new regulations.

OIG PLANS FOR FUTURE REVIEWS

We recognize that the results of our 11 university reviews represent a snapshot of security at the time of our fieldwork—which was performed mostly during 2002—and thus may not be indicative of the current security environments at the universities. As such, we plan to perform additional university reviews in fiscal year 2004 to assess compliance with the latest select agent security requirements.