The Florida Senate

Interim Project Report 2004-145 *November 2003*

Committee on Home Defense, Public Security, and Ports James E. "Jim" King, Jr., President

UNIVERSITY LABORATORY SECURITY

SUMMARY

The 2001 attacks on America, including the anthrax attacks on government officials and members of the media emphasize the importance of securing biological agents that have the potential to pose a severe threat to both human and animal health. In the past, laboratory security has typically focused on biosafety, or ensuring that the laboratory personnel were protected from the biological agents they handled, rather than biosecurity, ensuring that such materials were safeguarded against unauthorized access.. Much attention in the media has been given to the security of hazardous materials.

Now the focus is shifting to biosecurity amid growing concern about the possible use of biological, chemical, and radioactive materials as agents for terrorism. These biological, chemical, and radioactive agents are often necessary tools in clinical and research microbiology laboratories. Many of our state's universities perform research utilizing such hazardous materials to develop cures for diseases and laboratory security is a critical part of protecting the public from the threat of bioterrorism.

BACKGROUND

University laboratories that handle hazardous biological agents and toxins are governed by guidelines established by the Centers for Disease Control and Prevention (CDC), an agency of the U.S. Department of Health and Human Services (HHS).[1] Federal law requires universities to obtain a registration to work with specific infectious agents and biological toxins such as anthrax and plague (known as "select agents") that have the capacity to cause substantial harm to human health. A select agent is a viable micro-organism, or its toxin, which causes or may cause disease in humans or animals. Traditional laboratory biosafety guidelines for laboratories have emphasized use of optimal work practices, appropriate containment equipment, well-designed facilities, and administrative controls to minimize risks of unintentional infection or injury for laboratory workers and to prevent contamination of the outside environment.[2]

The Biological Weapons Anti-Terrorism Act of 1989; Antiterrorism and Effective Death Penalty Act of 1996: The Biological Weapons Anti-Terrorism Act of 1989[3] criminalizes the use, development, or possession of biological agents, toxins, and delivery systems if such are not justified by a prophylactic, protective, bona fide research, or other peaceful purpose. Prior to September 11, 2001, the transfer of "select agents" was regulated by the Antiterrorism and Effective Death Penalty Act of 1996 (PL 104-132). This act required the Secretary of HHS to issue regulations for the use, transfer, and disposal of select agent materials including viruses, bacteria, rickettsiae, fungi, toxins, and recombinant organisms/molecules listed in 42 Code of Federal Regulations Part 72, Appendix A. In 1997, the Laboratory Registration/Select Agent Transfer Program was established at the CDC, which was responsible for developing the current list of 42 select agents covered by the program.[4]

Facilities that transfer select agents must be registered with the CDC and must demonstrate through the application process that they meet certain

[1] See 42 C.F.R. Part 72, Appendix A titled "Additional Requirements for Facilities Transferring or Receiving Select Agents," CDC (CFR 72.6); "Interstate Shipment of Etiologic Agents," CDC, (42 CFR 72)

[2] "Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents," Morbidity and Mortality Weekly Report, U.S. Centers For Disease Control and Prevention, December 6, 2002.

[3] 18 U.S.C.§ 175

[4] U.S. General Accounting Office, "Homeland Security: CDC's Oversight of the Select Agent Program," GAO-03-315R, Washington, D.C., November 22, 2002.

conditions for safety and security and that the select agents are needed for legitimate research purposes. Laboratories that possess but do not transfer select agents are not subject to the provisions of the Antiterrorism and Effective Death Penalty Act. The regulations governing the Select Agent Program became effective on April 15, 1997, and include the following primary components:

1. A list of select agents that have the potential to pose a severe threat to public health and safety.

2. Registration of facilities prior to the domestic transfer of select agents.

3. A process to document successful transfer of agents.

4. Audit, quality control, and accountability mechanisms.

5. Agent disposal requirements.

6. Research and clinical exemptions.

Research institutions, universities, agencies and other organizations are required to register with the CDC prior to "receiving or transferring" any select agents. This registration is effective for a period of 3 years, and facilities must demonstrate compliance with requirements set forth by the CDC for working with certain select agents. These requirements are provided in *Biosafety in Microbiological and Biomedical Laboratories,* which describes four biosafety levels (BSLs) consisting of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed, the documented or suspected routes of transmission of the infectious agents, and for the laboratory function or activity.[5]

Laboratories that work with agents that have a low risk of infecting people are classified as BSL-1 laboratories. Laboratories working with agents of moderate risk such as E.Coli or salmonella are classified as BSL-2 laboratories, and laboratories using agents that may cause lethal infections as a result of exposure by inhalation are classified as BSL-3. A Biosafety Level 4 classification applies to work with dangerous and exotic agents which pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy.[6]

Concerns about the use of hazardous materials to perpetrate acts of bioterrorism have resulted in the enhancement of existing federal regulations and the creation of new regulations governing laboratory security to guard against future incidents. As a result of the terrorist events of 2001, Congress considered several pieces of legislation aimed at enhancing the security of the United States. As part of the Congressional response to those events, new laws were enacted that address concerns about bioterrorism. That legislation included the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001, and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

USA PATRIOT Act. Section 817 of the USA PATRIOT Act created two new criminal offenses relating to the possession of biological agents and toxins. First, the PATRIOT Act prohibits the knowing possession of any "biological agent, toxin, or delivery system of a type or in a quantity that, under the circumstances, is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose." It provides exemptions for agents and toxins in their naturally occurring environment that have not been "cultivated, collected, or otherwise extracted from their natural source."

Prohibitions set forth in the USA PATRIOT Act regarding transporting, shipping, or possessing select agents by restricted persons, and the applicable

[5] "Biosafety in Microbiological and Biomedical Laboratories," Fourth Edition, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention and National Institutes of Health, May 1999.

[6] "Audit Report: Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture," U.S. Department of Agriculture, Report No. 50099-13-At, March 2002.

criminal penalties for violating the prohibition apply to the *individuals* who work in or support laboratories with select agents. Persons violating this provision may be fined or face a maximum imprisonment term of ten years, or both.

In response to heightened concerns about the security of laboratory security at research institutions and businesses, the PATRIOT Act also prohibits certain "restricted persons" from possessing, receiving, transporting/transferring or shipping listed and non-exempt "select agents" as defined under the regulations of the 1996 Anti-Terrorism and Effective Death Penalty Act.[7]

The USA PATRIOT Act defines the term "restricted person" to mean an individual who:

1. is under indictment for a crime punishable by imprisonment for a term exceeding 1 year;

2. has been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

3. is a fugitive from justice;

4. is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act, 21 U.S.C. 802);

5. is an alien illegally or unlawfully in the United States;

6. has been adjudicated as a mental defective or has been committed to any mental institution;

7. is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or

8. has been discharged from the Armed Services of the United States under dishonorable conditions.

[7] "USA PATRIOT ACT Self-Assessment Questionnaire," Massachusetts Institute of Technology, Environmental, Health and Safety Office, 2001.

Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188) was signed by President Bush on June 12, 2002. The Bioterrorism Preparedness and Response Act and its companion Agricultural Bioterrorism Act of 2002 are designed to: enhance the public health system's ability to handle bioterrorism; tighten control of dangerous pathogens by creating a national database of select agents and the facilities and people that handle them; promote security by reducing the risks of theft and diversion; and to protect our residents and our food and water supplies.[8]

This Act requires the Secretary of the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) to adopt regulations establishing a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety, animal or plant health, or to animal or plant products. These regulations were published on December 13, 2002, in the Federal Register by HHS/Centers for Disease Control and Prevention (CDC) at 42 C.F.R. Part 73 and by USDA/Animal and Plant Health Inspection Service (APHIS) at 7 C.F.R. Part 331 and 9 C.F.R. Part 121.

The Bioterrorism Preparedness and Response Act Builds upon requirements contained in prior laws. Section 817 of the PATRIOT Act enacted new criminal offenses concerning possession and use of select agents, but did not include a requirement for laboratories possessing select agents to register, nor did it assign regulatory authority to a specific government agency.[9] The Bioterrorism Preparedness and Response Act assigned those enforcement responsibilities to HHS and the Department of

[8] "Anti Bioterrorism Research: Laboratory Security and Safety Under the Bioterrorism Preparedness and Response Act," Robert Eisig Bienstock, University of New Mexico, July, 2003.

[9] "Supplemental Chart Regarding H.R. 3448, Public Health Security and Bioterrorism Preparedness Act of 2002," American Council on Education, June 18, 2002; "Select Agents Overview," University of Pennsylvania, Office of Environmental Health and Radiation Safety, 2002.

Agriculture. Previously, only those facilities sending or receiving (transferring) select agents were required to register; this law requires all facilities possessing biological agents and toxins on the select agent list to register.

Among other provisions, the Bioterrorism Preparedness Act requires the Secretaries of HHS and Agriculture to adopt regulations to:

1. Implement procedures for registration of all facilities possessing or using select agents and of individuals who have access to them. A facility that possess or uses select agents must apply for and receive a certificate of registration from HHS/USDA. The facility must name a Responsible Official with both the authority and the responsibility for compliance with the Act and its regulations. This official should be either the biosafety officer or a senior management official, but should not be someone who actually works with select agents. Alternate Responsible Officials may be named by the facility. Registrations are generally valid for three years and may cover a set of locations in one general area. The registration can include a complex of buildings as long as there is only one mailing address.

2. Require transfer regulations to include information regarding the characterization of agents and toxins to facilitate their identification, including their source.

3. Establish and enforce safety and training procedures governing the possession of select agents.

4. Maintain a national database that includes the names and locations of registered persons and information about the listed agents that such persons possess, use, or transfer.

5. Require all facilities to limit access of select agents to those individuals that the registered facility determines have a "legitimate need" to handle or use the agents. The Bioterrorism Preparedness Response Act requires fingerprint background checks and approvals on individuals with access to select agents; a facility must obtain fingerprint checks and approvals on its Responsible Official and any Alternate Responsible Officials. Each facility must provide identifying information about the personnel with access to select agents to the U.S. Attorney General to conduct background checks of criminal, immigration, national security, and other electronic federal databases as appropriate. Access must be denied to an individual who is identified by the Attorney General as a restricted person (as defined in the USA PATRIOT Act) or who is reasonably suspected of involvement in terrorism.

The USA PATRIOT Act prohibits restricted persons from transporting or possessing select agents. This prohibition is directed only to the restricted person and not to the facility employing the restricted person. The Bioterrorism Preparedness Response Act provides that any person who transfers a select agent to any person one knows or has reasonable cause to believe has not registered could be fined or imprisoned up to 5 years or both, and whoever knowingly possesses a select agent for which the person has not obtained a registration will be fined or imprisoned for up to 5 years

The Bioterrorism Preparedness Response Act and its regulations require select agent facilities to adopt three plans: a safety plan, an emergency plan, and a security plan.

Safety Plans: The Act does not impose new safety regulations on facilities, but provides the following guidelines in developing safety plans:

- The Biosafety in Microbiological and Biomedical Laboratories "BMBL," a CDC/National Institute of Health (NIH) publication.

- If applicable, regulations for handling toxins under the federal standards for occupational exposure to hazardous materials in laboratories and the communications standard for toxic and hazardous substances.

- If applicable, regulations for handling recombinant genetic elements contained in the "NIH Guidelines for Research Involving Recombinant DNA Molecules."

The Bioterrorism Preparedness Response Act requires facilities to establish safety provisions that are commensurate with the risk the biological agent or toxin poses to the public health and safety; both the BMBL and the NIH Guidelines provide for graded requirements based on the level of hazard posed by the specific agents and toxins.

Emergency Response Plans: The Act incorporates existing legal regulations including the OSHA emergency response standards for hazardous waste operations at 29 C.F.R. 1910.120 and emergency response guidance set forth in Appendix F of the BMBL, which recommends conducting a site specific risk assessment and threat analysis. The Act specifies a range of issues to be addressed, including, but not limited to: spreading biohazardous materials during emergency response; coordination with outside emergency responders; evacuations; decontamination; and site security during an emergency.

Security Plans: The Act provides an extensive list of new security requirements set forth in HHS/CDC and USDA/APHIS regulations. Some of those requirements include:

- Facilities must predetermine which individuals will have access to select agents and the reasons for each individual's access.
- Select agents may be stored and used only in predefined areas as set forth in building floor plans; access to those areas must be controlled.
- An individual may not have access to a select agent without approval, and when an approved person is not present, the select agent area must be secured. (An approved person is someone who received clearance from HHS/USDA based on a background check) Only approved individuals may have unescorted access within select agent areas. Non laboratory functions such as cleaning and maintenance may be conducted by unapproved individuals only when escorted and continually monitored by approved persons.
- The regulation of select agent access includes documentation of each act of ingress or egress, as well documentation of each access of agents from long term storage.
- The security plan must address select agent access control; each access must be documented to include dates and times, individuals involved, and for toxins, amounts removed and returned.
- The plan must provide for lockup of select agents when no approved person is present; containers must be locked when not in direct view of an approved person. The plan must provide for changing locks or access codes in the event of staff changes or accidental release of access codes.[10]

Chemical and Radiation Safety: The Occupational Safety and Health Administration (OSHA) within the U.S. Department of Labor has legal authority in employee safety matters. Universities that employ workers engaged in the laboratory use of hazardous chemicals must comply with the "Occupational Exposure to Hazardous Chemicals in Laboratories" standard set forth in 29 C.F.R. 1910.1450. This standard, generally referred to as the "Laboratory Standard," requires a laboratory to produce a written Chemical Hygiene Plan which addresses the specific hazards found in its location and its approach to those hazards. This standard is designed to provide a general framework of minimum requirements established by OSHA but allows individual laboratories to determine the procedures to meet those requirements. A designated Chemical Hygiene Officer within the university is responsible for developing, coordinating implementation, and updating the Chemical Hygiene Plan and assisting individual laboratories in implementing and complying with the plan. The officer must also institute appropriate audit methods to ensure compliance.[11]

[10] "Anti Bioterrorism Research: Laboratory Security and Safety Under the Bioterrorism Preparedness and Response Act," Robert Eisig Bienstock, University of New Mexico, July, 2003./

[11] "Chemical Hygiene Plan," Florida State University, Department of Environmental Health and Safety

The State of Florida signed an agreement with the U.S. Nuclear Regulatory Commission that empowers the state to license and regulate radioactive materials users. The Department of Health, Bureau of Radiation Control, operates eleven radiation control programs designed to reduce radiation exposure to the public.[12] Today, the program licenses more than 1,400 users, including hospitals, universities, industrial facilities, doctors, and others. Each radioactive materials license is valid for 5 years. The department performs inspections to ensure that radioactive materials are used in accordance with state regulations; these inspections are performed periodically from every 6 months to every 5 years depending on the type of license.[13]

Student and Exchange Visitor Program. The Immigration and Nationality Act (INA) governs the admission of all people to the United States. Individuals who come to the U.S. to pursue full-time academic or vocational studies or to participate in exchange visitor programs are usually admitted under the F-1, M-1, or J-1 nonimmigrant category. The F-1 category includes academic students in colleges, universities, seminaries, conservatories, academic high schools, other academic institutions, and in language training. The M-1 category includes vocational students.[14] The "J" exchange participants include students at all academic levels; trainees obtaining on-the-job training with firms, institutions, and agencies; teachers of primary, secondary, and specialized schools; professors coming to teach or perform research at institutions of higher learning; research scholars and others.[15]

Section 641 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 directed the Attorney General to develop an electronic system to monitor and report information pertaining to nonimmigrant students and scholars. The Student Exchange Visitor and Information System (SEVIS) is an internet-based computer system that links colleges and universities authorized to admit and enroll foreign students, U.S. embassies and consulates, U.S. ports of entry, Department of State, and exchange visitor programs. The USA PATRIOT Act amended section 641 to require full implementation of SEVIS prior to January 1, 2003. These laws were passed in response to the 1993 World Trade Center bombing and the September 11, 2001 terrorist attacks after it was discovered that perpetrators in both of those attacks had entered the U.S. with student visas.

Congress mandated that August 1, 2003, be the deadline for U.S. educational institutions with a foreign student population to be certified participants in SEVIS and have information about those foreign students entered into SEVIS. Under the requirements of SEVIS, schools are required to report the following registration information concerning a foreign student:

- Whether the student has enrolled at the school, dropped below a full course of study without prior authorization from the school, or failed to enroll;
- The current address of each student; and,
- The start date of the student's next session, term, semester, trimester, or quarter.

Within 21 days of a change of any information, schools are required to report information on: any student who fails to maintain status or complete his or her program; a student's legal name or address change; early graduation; or any disciplinary action taken by the school as a result of being convicted of a crime.

SEVIS enables schools to electronically transmit current data to the Bureau of Immigration and Customs Enforcement (ICE) and the Department of State during the course of a student's stay in the country. In the event that a student falls out of status, ICE is informed and able to take appropriate action. All of the

---

[12] See "The Florida Radiation Protection Act," Chapter 404, F.S., and "Control of Radiation Hazards," Chapter 64E-5, F.A.C.

[13] "Radioactive Materials," Florida Department of Health, Bureau of Radiation Control website, http://www.doh.state.fl.us/environment/radiation.

[14] "Student and Exchange Visitor Program," Bureau of Citizenship and Immigration Services, U.S. Dept. of Homeland Security, website: http://www.immigration.gov.

[15] "Tips for U.S. Visas: Exchange Visitors," U.S. Department of State, Bureau of Consular Affairs, website: http://travel.state.gov/visa;exchange.

universities that were surveyed for this report are SEVIS-certified, a certification that allows those universities to accept foreign students.[16]

METHODOLOGY

In October of 2002, the House Committee on Select Security conducted an interim study relating to security procedures of university research laboratory facilities. To perform that study, a survey was distributed to the following universities: Florida State University, Florida Atlantic University, Florida Agricultural and Mechanical University, Florida International University, Florida Gulf Coast University, New College of Florida, University of Central Florida, University of Florida, University of North Florida, University of South Florida, University of West Florida, and the University of Miami.

The House survey of university research laboratory facilities included the following questions:

Security Review: After September 11, 2001, has your university conducted a security review of the research laboratory units on your campus?

Compliance Audits: Do you routinely audit your research laboratory units to ensure compliance with established protocols?

Inventory of Research Units: Do you have a current list (inventory) of the research laboratory units on your campus?

Hazardous Material Inventory: Have you completed an inventory of all hazardous material in research laboratory units on your campus?

Restricted Access: Do you restrict access to your research laboratory units?

Background Checks: Do you conduct background checks that include international, national, and state criminal and driving records searches on persons having access to your research laboratory units?

Chain-of-Custody Protocols: Do you have established protocols regarding the chain of custody of hazardous materials in your research laboratory units?

The results of the survey are included in this report. Committee staff also conducted interviews in person and via telephone to conduct this study.

FINDINGS

The university laboratories surveyed are currently in compliance with the various federal and state laws governing the use of hazardous materials in a research environment. Most of the universities that perform laboratory research have a designated department or division dedicated to environmental health and safety issues. These departments or divisions are responsible for ensuring that the university complies with all applicable health, safety, and security laws. Supervisors and instructors work in conjunction with the environmental health and safety unit to ensure that specific safety rules, policies, and procedures are followed and they are responsible for ensuring that their employees and students are safe from hazards.

The principal investigator is the individual responsible for ensuring that a laboratory research project is conducted in accord with relevant laws and guidelines set forth by federal and state agencies and by the university. The principal investigator of a research project is the individual who bears primary responsibility for technical compliance, completion of programmatic work, fiscal stewardship of project funds and compliance with the administrative requirements of the project.

Security Reviews

All of the universities surveyed reported that security reviews of research laboratory units have been conducted after September 11, 2001. These security reviews were performed by either the university police department or by a security services vendor. Generally security examinations included, but were not limited to: observation of actual security practices and processing techniques, interviews with appropriate university personnel, and inspections of research facilities.

[16] "Student and Exchange Visitor Program," Bureau of Citizenship and Immigration Services, U.S. Dept. of Homeland Security, website: http://www.immigration.gov.

Compliance Audits

Both BMBL and NIH guidelines provide for graded requirements based on the level of hazard posed by specific select agents and toxins. All 11 of the universities reported that routine audits of research laboratory units are performed to ensure compliance with federal, state, and local regulations and with protocols established by the university. Although different assessment methods are used by each university, all universities have established a laboratory risk assessment procedure based on the relative hazard of each research laboratory.

Laboratories are evaluated according to the risk assessment procedure and inspection frequencies are based on the risk assigned to each laboratory. Laboratory safety inspections may include, but are not limited to: hazardous material inventory; hazardous waste management practices, chemical storage, proper ventilation, access to means of egress, electrical and radiation safety; proper use of signage; emergency preparedness; and general housekeeping practices. Follow up inspections are conducted as necessary to verify that any recommended corrective actions have been taken.

Laboratories that use radioactive nuclides in research are required, by virtue of the university's radioactive materials license, to perform documented surveys to detect surface contamination in areas where radioactive materials are used, including storage and waste facilities.

Inventory of Research Units

The environmental health and safety departments within the universities are the entities that are generally responsible for maintaining and verifying records of laboratory inventories. Universities reported that these departments maintain inventories of laboratory units and a typical inventory record includes information about material usage, laboratory inspection results, waste pickups, and other activities.

Hazardous Material Inventory

All of the universities that use hazardous materials to conduct research maintain an inventory of those materials. Laboratories using select agents and toxins, radioactive materials, and certain high risk chemical substances maintain inventory and usage records in compliance with federal regulations. Principal investigators also maintain records on inventories along with other research project information. Some universities have enhanced their hazardous materials accountability through the development of automated tracking systems that facilitate the ordering, inventory, and disposal process.

Restricted Access

All universities surveyed reported that access to research laboratories is restricted. Access to laboratories is determined by the principal investigator based on the types of research activities and the relative hazards associated with each laboratory.

Background Checks

Currently federal law requires fingerprint based criminal history background checks for individuals handling or using select agents and toxins. Universities that use select agents in laboratory research reported that fingerprint background checks are conducted on these individuals as required by the USA PATRIOT Act and the Bioterrorism Preparedness Response Act. These background checks include only criminal history information as there are currently no state or federal laws that require checks of driving records.

Chain-of-Custody Protocols

Under the state's radioactive materials license issued by the Department of Health, chain-of-custody protocols are required for the use and disposal of radioactive isotopes. Use of radioactive materials by the laboratories is closely monitored. Typically, the environmental health and safety department authorizes the purchase of the radioactive material and receives the shipment when it is delivered to the campus.

Environmental health personnel deliver the radioactive material to the authorized principal investigator who maintains a usage inventory of the radioactive materials. Radioactive waste generated by the laboratory is picked up by environmental health personnel and maintained in a secured and locked location.

Chain-of-custody protocols are in place at the laboratories performing research with select agents, as required by the Bioterrorism Preparedness Response Act.

RECOMMENDATIONS

- Committee staff recommends that the universities continue to monitor the implementation of recent federal regulations governing the use of hazardous materials and biological select agents.

- Committee staff recommends that the universities continue to monitor the implementation of the Student and Visitor Exchange Program to ensure that the requirements for reporting information are being met.

- Committee staff recommends that an officer be designated within each university police department to act as a liaison to the local regional domestic security task force and local police intelligence units to ensure the exchange of information.

- Committee staff recommends that the Legislature continue to monitor university compliance with federal laws related to laboratory use and access.