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TOPIC:

NEW REGULATIONS ON POSSESSION, USE, AND TRANSFER OF BIOLOGICAL AGENTS AND TOXINS

DISCUSSION:

Many universities have research facilities that work with biohazardous materials. Regulations issued in December 2002 pursuant to recent federal legislation impose comprehensive new requirements for continuing to work with such materials.

This NACUALERT provides an overview of the new regulations, their requirements, and the deadlines. *Significant compliance steps are required as soon as February 7, 2003.* Failure to take these steps will result in loss of the ability to continue research with these biohazardous agents, with risks of personal and institutional criminal penalties for noncompliance [1].

Regulations Published in December 13, 2002 Federal Register

On December 13, 2002, the Centers for Disease Control and Prevention ("CDC") and the Animal and Plant Health Inspection Service ("APHIS") published [regulations](#) required by the [Public Health Security and Bioterrorism Preparedness and Response Act of 2002](#) and [Agricultural Bioterrorism Act of 2002](#) (the "Acts"), P.L. 107-188, Title II, 116 Stat. 594, primarily codified at 42 U.S.C. 262a (CDC) and 7 U.S.C. 8401 (APHIS). These regulations, relating to the control of specified biological agents and toxins, were issued as Interim Final Regulations, effective beginning February 7, 2003 for CDC and February 11, 2003 for APHIS [2].

The regulations govern the use, handling, and transfer of certain biologically hazardous bacteria, viruses, toxins, and nucleic acids. In the case of the CDC regulations (42 CFR Part 73), these agents are referred to as "select agents". The APHIS regulations apply to agents or toxins deemed a severe threat to plant health and plant products (7 CFR Part 331) and agents or toxins that pose a severe threat to animal health or animal products (9 CFR Part 121). The specific substances determined by the agencies to be hazardous to humans, animals and/or plants are set forth in lists contained in the regulations. 42 CFR § 73.4, 7 CFR § 331.3, and 9 CFR § 121.3. A good [summary of all of the lists](#) is available online from the CDC. For purposes of convenience in this NACUALERT, the various substances are referred to as "select agents."

Coverage

The regulations apply primarily to select agents in isolated form. All institutions possessing such agents must comply with the regulations. Naturally occurring select agents, such as soil samples, infected

animals and plants, and infected tissue samples, are exempt until they have been isolated. If tests reveal select agents in such contexts, they must be reported to the CDC or APHIS, and the samples either transferred to a registered facility or destroyed. 42 CFR §§ 73.4(f)(1), 73.6(a); 7 CFR §§ 331.3(b), 331.4(a); 9 CFR §§ 121.3(e), 121.4, 121.5 [\[3\]](#).

Select agents contained in products approved under certain other federal laws are also exempt, and CDC and APHIS have authority to issue other exemptions. 42 CFR §§ 73.4(f)(5), 73.5(f)(5), 73.6(c)-(e); 7 CFR § 331.4; 9 CFR § 121.4.

Registration

All facilities handling select agents must register with and be certified by CDC or APHIS. Under the prior select agent regulations, registration was required to *transfer* a select agent. The new regulations implement the Act's direction that *possession and use* also be controlled. To receive approval to handle select agents, the facility must meet a comprehensive set of safety and security requirements. The facility must complete a registration application informing CDC or APHIS [\[4\]](#) of the details of the select agents it is handling, and what it is doing with them. The application must include the names of the employees and officials involved, identifying information about the select agents, locations of the select agents (rooms and floorplans), and general research objectives. Any change in this information requires applying for a modification in the certificate of approval. Destruction or transfer of select agents also requires prior approval. 42 CFR § 73.7; 7 CFR §§ 331.5, 331.6, and 331.8; 9 CFR §§ 121.6, 121.7, and 121.9 [\[5\]](#).

Security Clearances and Restrictions on Access

Each facility, responsible official, and employee with access to select agents must obtain a security clearance from the Department of Justice (DoJ) [\[6\]](#). The DoJ will use criminal, immigration, national security, "and other electronic databases" in performing the background checks. Access will be denied to individuals who are "restricted persons" under the [USA PATRIOT Act \(18 USC § 175b\)](#) or are reasonably suspected by law enforcement or intelligence agencies of engaging in domestic or international terrorism. The DoJ promises to be able to process clearances routinely within a month or two, and faster when needed. 42 CFR § 73.8; 7 CFR § 331.7; 9 CFR § 121.8 [\[7\]](#).

Every person who enters a site in which there are select agents must either have the security clearance or must be accompanied and monitored by such a person. This includes visitors and employees performing routine cleaning, maintenance, and repairs. 42 CFR § 73.11(d); 7 CFR § 331.11; 9 CFR § 121.12. In addition, every person entering and leaving such a site must log in and log out. 42 CFR § 73.15; 7 CFR § 331.14; 9 CFR § 121.15.

Safety and Emergency Plans

Each facility must complete and implement safety and emergency plans, based largely on existing law, such as the National Institute of Health's ("NIH's") Recombinant DNA Guidelines and the CDC/NIH publication, [Biosafety in Microbiological and Biomedical Laboratories](#). 42 CFR § 73.10; 7 CFR § 331.11; 9 CFR § 121.12 The emergency plans must address naturally occurring emergencies, such as fire, earthquake, power outages, hurricanes, etc. 42 CFR § 73.12; 7 CFR § 331.11; 9 CFR § 121.12.

Biocontainment and Security Plan

Much of the new regulatory burden is contained in the requirements for a security plan. 42 CFR § 73.11; 7 CFR § 331.11; 9 CFR § 121.12. The plans must be developed commensurate with the risks (e.g., risks of escape, transmission, toxicity) of the select agents at the facility and must include the following elements, among others:

- Physical security, including physical separation of areas in which select agents are located
- Cyber security
- Training for all employees, guests, and visitors, including systems to verify understanding
- Educational and experience criteria for employees
- Reporting requirements for a variety of problem situations
- Protocols for internal lab-to-lab transfers
- Inspection of packages on entrance/exit
- Inventory control of select agents
- Documentation of each person's entry into and exit from select agent area
- Provisions for routine cleaning, maintenance, and repairs
- Provisions for reporting suspicious persons and activities

The security plans must require annual review and a review after any incident. 42 CFR § 73.11(c); 7 CFR § 331.11(b); 9 CFR § 121.12(b).

Transfer of Select Agents

All transfers from one facility to another must have prior approval of CDC or APHIS, must be documented after the fact, and must follow certain packing and transportation requirements. 42 CFR § 73.14; 7 CFR § 331.13; 9 CFR § 121.14. [APHIS' draft form](#) to seek transfer approval is available for review.

Notifications

CDC/APHIS must be notified immediately in the event of certain reportable events, including theft, loss, or accidental release. 42 CFR § 73.17; 7 CFR § 331.16; 9 CFR § 121.17. [Draft notification forms](#) are available for review.

Compliance Calendar

An institution's compliance calendar depends on whether it has registered under prior law for transfer of select agents. 42 CFR § 73.0; 7 CFR § 331.0; 9 CFR § 121.0.

If an institution has previously registered, the compliance calendar is as follows:

February 7 for CDC/ February 11 for APHIS [8]:

- Name Responsible Official and any alternates
- Complete and implement Safety and Emergency Response Plans
- Develop and implement recordkeeping procedures, including list of approved individuals, current inventory, training records, and access and use documentation
- Begin HHS notifications for theft, loss, and release of select agents
- Safety/emergency response training begins (subject to grandfather certifications)

March 12:

- Apply for registration under the new regulations. Registration under the previous law remains valid until November 12, 2003, *provided that* the March 12, 2003 deadline is met under the new regulations. This requires complete application information regarding persons, select agents, locations, etc.
- Apply for DOJ approval for facility, responsible official, and any alternates
- Transfer requirements, including prior approval of transfers between facilities

April 11 for APHIS/April 12 for CDC:

- Apply for DOJ approval for all employees

June 12:

- Develop security plan

September 12:

- Implement security plan
- Implement training for security plan

November 12, 2003:

- Registration process to be complete and in full compliance. Failure to receive approval by this date means that possession of select agents is no longer permitted.

If the facility has not previously registered, it may begin using select agents only after applying for registration and complying with all aspects of the regulation except the security plan, for which compliance is not due prior to September 12, 2003.

For any entity working with select agents, registration must be certified by CDC/APHIS no later than November 12, 2003. Prior to that date, mere application for registration suffices, together with the application's required certification of compliance.

CONCLUSION:

Member institutions that wish to continue to possess select agents for research or other authorized purposes should carefully review the CDC and APHIS regulations issued on December 13. Appropriate university personnel should be mobilized to plan and implement in a timely fashion the numerous actions required for compliance. Failure to comply can result in the loss of authorization to possess select agents covered by the regulations, with the consequent serious adverse impact on affected research and other operations. Serious civil and criminal penalties can also result.

FOOTNOTES

RESOURCES for COUNSEL:

Statutes and Regulations:

- [Bioterrorism Preparedness and Response Act of 2002](#)
- [CDC. December 13, 2002 Interim Final Rule: Possession, Use and Transfer of Select Agents and Toxins](#)
- [APHIS. December 13, 2002 Interim Final Rule: Possession, Use and Transfer of Select Agents and Toxins](#)

Additional Government Resources:

- [List of Covered BioHazardous Material](#)
- [APHIS Draft Compliance Forms](#)
- CDC/NIH Publication: [Biosafety in Microbiological and Biomedical Laboratories, 4th Ed.](#) (See especially [Appendix E](#), Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents)

Other Web Resources:

- [Campus Safety, Health, and Environmental Management Association \(CSHEMA\)](#)
- [American Biological Safety Association](#)
- [American Society of Microbiology](#)

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