

BIOSAFETY & ENVIRONMENTAL UPDATE



Monthly Update on Biosafety, Environmental Regulatory
Affairs Relating to Biopharmaceutical Industry

Volume 3, Number 12

December 15, 2003

Highlights:

- *Military Smallpox Vaccination Program Review*
- *Mass Vaccination not Required in Smallpox Outbreak*
- *CDC Publishes the Select Agent Interim Final Rule*
- *USDA Temporary Permits to Handel "Select Agents"*
- *Interim Rule to Prevent Transmission of Monkeypox*
- *USDA Center for Veterinary Biologics Issues*
- *Hospitals Receive Isolation Units*
- *National Health Network Would Reduce Medical Errors*
- *U.S., Mexico Hold Joint Terrorism Drill*

New GAO Report

SMALLPOX VACCINATION PROGRAM: REVIEW OF IMPLEMENTATION OF THE MILITARY PROGRAM

As part of the smallpox vaccination program, DOD implemented a surveillance program tracking adverse health effects following vaccination. In the first stage (pilot program) of smallpox vaccination program (started December 2002), health and military personnel at four sites were under the surveillance program.

After completion of the pilot program, DOD began full implementation of the smallpox vaccination program in mid-January 2003. DOD vaccinated its personnel in stages—prioritizing its personnel according to which groups would be most likely to respond first to a smallpox outbreak. As of October 2003, DOD had vaccinated more than 500,000 military personnel. In order to minimize the number of people who might have adverse reactions to the vaccine, DOD followed CDC guidelines by screening personnel for health conditions that precluded them from receiving smallpox vaccinations. To monitor adverse health events following the vaccinations, DOD used two health information tracking systems, CDC's Vaccine Adverse Event Reporting System (VAERS) and DOD's Defense Medical Surveillance System (DMSS).

To facilitate its vaccination program, DOD took steps to ensure the availability of the vaccine and educate its personnel. Specifically, DOD established practices to limit the amount of vaccine that could be wasted or contaminated. For example, to ensure the vaccine was not wasted due to a loss of potency, its temperature was monitored with a computer chip to ensure that the vaccine was maintained at the proper temperature during shipment.

DOD also facilitated the implementation of its vaccination program by educating its personnel—both those who administered the vaccine and those who received it—on related issues, such as vaccination procedures and potential adverse health reactions.

For More Information:

<http://www.gao.gov/cgi-bin/getrpt?GAO-04-215R>

According to a recent CDC guideline, published last week, if a smallpox outbreak occurs in the United States, federal health officials would not recommend mass vaccination.

According to the guidelines, instead of mass vaccination program the top public health priority would be to control the epidemic, according to the CDC's "Interim Smallpox Response Plan and Guidelines," which outlines CDC's strategies for responding to a smallpox emergency. "Doctors, health care workers, and hospital personnel have been trained to identify infectious diseases and then respond appropriately. The same system would identify any possible outbreak of smallpox," according to the report.

The CDC has sent the plan, which is a working draft, to all state bioterrorism coordinators, state health officers, state epidemiologists, and state immunization program managers for review and comment. The plan identifies many of the federal, state, and local public health activities that would need to be undertaken in a smallpox emergency, including response plan implementation, notification procedures for suspected cases, CDC, state, and local responsibilities and activities, and CDC vaccine and personnel mobilization.

Many of the strategies and concepts were used successfully when smallpox was declared globally eradicated in 1980. The "Interim Smallpox Plan" will remain a working document and the CDC will update it regularly.

For More Information:

[http://www.bt.cdc.gov/
DocumentsApp/Smallpox/RPG/
index.asp](http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/index.asp).

On November 3, 2003 CDC published an Interim Final Rule amending the applicability requirements to allow for the issuance of provisional registration certificates for all entities, and provisional grants of access for all individuals, from whom, prior to November 12, 2003, the Attorney General has received all of the information required by the Attorney General to conduct a security risk assessment if those entities and individuals otherwise meet all of the requirements of Part 73.

CDC clarified that entities holding select agents and waiting for provisional registration could continue to possess and use select agents as it has since February 2003, as long as they meet all the requirements for registration under the provisions of 42 C.F.R. Part 73.

Similarly, eligible entities eligible to receive provisional grants of access are allowed to continue to have the same access to a select agent that they have had since February 2003.

42 CFR, Part 73 (Possession, Use and Transfer of Select Agents and Toxins), Interim Final Rule was published in the Federal Register (November 3, 2003).

For a Copy of the 43 CFR Part 73 Interim Final Rule:
[http://www.cdc.gov/od/sap/docs/
42cfr73a.pdf](http://www.cdc.gov/od/sap/docs/42cfr73a.pdf)

GOVERNMENT MISSES ANTHRAX LAB INSPECTION DEADLINE

USDA TEMPORARY PERMITS TO HANDLE 'SELECT AGENTS'

The federal government missed a deadline to certify more than 500 research laboratories that use anthrax and other dangerous biological agents, partially because the FBI is still working on thousands of required employee background checks, the Associated Press reports.

A law passed last year set new guidelines on research involving potential bioterrorism agents, one of which requires the certification of labs handling certain agents. The deadline for certification was November 12.

Sen. Joe Lieberman, D-CT, said that as of November 3, none of the 513 labs awaiting certification had actually received it. Part of the reason is that the FBI still must complete 3,600 background checks. The Centers for Disease Control and Prevention (CDC), which is overseeing much of the certification, is taking its time to ensure that all labs meet security requirements, a spokesman said.

For More Information:
http://www.healthsafetyinfo.com/content.cfm?content_id=36206

The US Department of Agriculture (USDA) has moved to allow individuals and groups to continue working with certain hazardous biological agents beyond the Nov 12 deadline for complying with new registration rules while the government completes background checks on those groups.

The USDA's Animal and Plant Health Inspection Service (APHIS) will issue provisional registration certificates for those who work with "select biological agents and toxins" and have submitted all necessary information by Nov 12. The temporary certificates will allow applicants to continue their work while the Justice Department completes security risk assessments.

According to APHIS announcement, temporary permits would be issued to ensure that research, diagnostic and education program are not disrupted for lack of compliance with new registration rules.

According to the 2002 Bioterrorism legislations, groups and individuals that handle hazardous biological agents or toxins to register with the USDA or the Centers for Disease Control and Prevention. The rule covers agents or toxins that are considered a severe threat to public health or animal and plant health. The USDA and the Department of Health and Human Services published interim rules on the possession, use, and transfer of select agents and toxins in December 2002. The deadline for registration and full compliance with the rules is Nov 12. On Nov 3, APHIS published a Federal Register notice of its intent to issue temporary registration certificates to applicants that file the required information and fingerprint cards by Nov 12.

The temporary certificates will be in effect until APHIS grants or denies access to the select agents and toxins, according to the notice. The Federal Register notice is in the form of an amendment of the select agent rules. APHIS will take comments on that amendment until Jan 2, 2004.

For More Information:
http://www.aphis.usda.gov/lpa/news/2003/11/biselect_aphis.html

In 1997 the FDA implemented a fast-track program designed to accelerate the development and review process for life-saving drugs. Today, new drugs get to the market three-years earlier than they did under the former system, according to the results of a Tufts University.

The study concludes that “The fast-track program has had significant public health impact by speeding access to new drugs, particularly those that treat AIDS, breast cancer, leukemia and other diseases that afflict million of patients and result in tens of thousands of lives every year in the US”

The study found that clinical development time for fast track drugs approved between 1998 and 2003 was, on average, 2 to 2.5 years shorter than for non-fast track drugs.

For More Information:

<http://155.212.10.127/NewsEvents/RecentNews.asp?newsid=34>

JACHO REPORT ON EMERGENCY MANAGEMENT

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) will step up its scrutiny of hospitals' emergency management plans in upcoming surveys—but it has issued a resource to help hospitals comply with the stricter standards. This month's edition of the JCAHO publication, Perspectives, contains information to assist hospitals in preparing for future bioterrorism-related attacks.

The first section of the report covers the JCAHO's call for a national bioterrorism response plan and how the JCAHO standards can help facilities prepare for emergencies. The next section of the report deals with preparing for mass casualties and educating staff to handle emergency events. Finally, the section called “Lessons Learned” contains information on hazardous material decontamination, common symptoms of exposure to contaminants, a list of emergency management resources, and more.

For More Details

<http://www.jcrinc.com/subscribers/perspectives.asp?durki=187>

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) will hold a public meeting on veterinary biologics next year (April 7-9, 2004), in Ames, Iowa. The public meeting will serve as a forum for the exchange of information between APHIS representatives, producers, users of veterinary biological products and other interested individuals.

APHIS invites interested individuals to use this meeting to present their ideas and suggestions concerning the licensing, manufacturing, testing and distribution of veterinary biologics.

With VEE as one of the key products under development, DVC is part of the stakeholder community.

APHIS is currently developing the meeting agenda. Once it is finalized, the agenda will be published in the *Federal Register*. Notice of this meeting was published in the Nov. 14 *Federal Register*.

For More Information:
<http://www.aphis.usda.gov/ppd/rad/webrepor.html>

According to a report from the American Hospital Association, hospitals across New Hampshire last month received portable isolation units designed to strengthen their ability to respond to a contagious diseases outbreak or bioterrorism incident.

All 26 acute care hospitals, New Hampshire Hospital, and the VA Medical Center received the portable units, which filter air before it is vented out of the room to prevent the spread of infectious diseases. The 62 units more than double the number of hospital isolation rooms in the state to 89; the units provide both negative pressure and high-efficiency particulate air filters.

Funded through a \$2 million grant, the \$140,000 worth of equipment is part of a joint effort by the New Hampshire Hospital Association and state health and safety agencies to improve the state's bioterrorism preparedness.

Portable Isolation units are critical in medical surge management in the event of a disease outbreak or bioterrorism incidence.

For More Information:

http://www.hospitalconnect.com/ahanews/jsp/display.jsp?dcrpath=AHA/AHANewsArticle/data/AHA_News_031201_NH_hospitals&domain=AHANEWS

NATIONAL HEALTH NETWORK WOULD REDUCE MEDICAL ERRORS

According to a recent Institute of Medicine (IOM) study report titled, *Patient Safety: Achieving a New Standard for Care*, a health network systems modeled after the airline industry's air traffic and weather information system should considerably reduce medical errors.

To significantly reduce the tens of thousands of deaths and injuries caused by medical errors every year, health care organizations should adopt information technology systems that are capable of collecting and sharing essential healthcare information

Although some hospitals and healthcare provider networks have established computer systems to manage patient care information, a national infrastructure for standardized data collection and exchange is what is needed to addressing provider community generated medical errors.

A routine use of electronic health records would give health care providers and patient's immediate access to complete patient information as well as tools to guide decision-making and help prevent the tens of thousands of deaths and injuries that are caused by medical errors each year.

According to a 1999 IOM report, up to 98,000 deaths occur every year in U.S. hospitals as a result of medical errors. Recent studies show that tens of thousands of additional errors occur in nursing homes and clinics.

For More Information : <http://www.nap.edu>

WEB-BASED TRAINING ON TERRORISM PREPAREDNESS

The Department of Homeland Security on November 3 made available a searchable, Internet-based database on terrorism training.

The "Compendium of Federal Terrorism Training" was originally developed by the Army in 1998 and updated and redesigned by the Federal Emergency Management Agency's Emergency Management Institute. The database provides state and local officials with a single source for detailed information on terrorism preparedness related training available from federal departments and agencies.

Users can query the system by subject area, department or agency, or alphabetically. The entries include details such as course objectives, intended audience, how the training is delivered, and how to enroll students or arrange for training in a particular jurisdiction.

To access the database:

<http://www.fema.gov/compendium>

YOUR COMMENTS AND SUGGESTIONS ARE WELCOME

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