

Bioterrorism Week

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Facilities

CDC guidelines to help labs enforce 'biosecurity'

2002 DEC 30 - (NewsRx.com) -- The U.S. government has issued detailed guidelines aimed at tightening security at labs that handle dangerous pathogens but have gone largely unregulated.

It's the most detailed set of recommendations ever issued by the Centers for Disease Control and Prevention. Among them: Monitor areas where pathogens are stored, keep specimens locked up and limit access to those who are authorized to work with these agents.

The new rules were mandated by Congress in the wake of last year's anthrax attacks. The case remains unsolved, but experts suspect the anthrax sent through the mail came from a U.S. laboratory.

The CDC has published regulations requiring tighter security at labs that handle "select agents," 42 pathogens and toxins that pose the greatest dangers to the public's health. The list includes bacteria that cause anthrax and plague and viruses such as Ebola, as well as lesser known agents.

The new rules will require every lab that possesses a select agent to register with the CDC or the Agriculture Department and undergo an inspection. Previous law only required labs that transferred or received specimens to register, leaving a giant loophole that meant federal officials investigating last year's anthrax attacks initially had no idea how many labs possessed anthrax.

The rules will also require background checks for people who work with select agents and require all labs to develop a biosecurity plan. The guidelines issued December 5, 2002 are aimed at helping labs develop these plans. Past guidance was a "fairly skimpy" two pages, said Steve Ostroff, deputy director of the CDC's National Center for Infectious Diseases.

In the past, lab security was typically focused on biosafety, or protecting the people who work in labs. Now, the focus is shifting to biosecurity.

Typical security controls - such as keeping track of inventory - don't work for biological agents, which can easily grow and multiply in the right lab conditions. So the guidelines offer other suggestions, including better control over access to the pathogens and security of the facility.

It is unclear how many labs possess select agents, and CDC won't say how many are already registered because they received or transferred an agent. The last time the number was made public, about 2 years ago, about 250 labs had registered, but that number has grown by about 5-10 labs per month since then, Ostroff said. That means there could be some 350-500 already on the list.

The final number, after all labs that possess agents register, is expected to be "substantially higher," Ostroff said.

The tighter standards and the increased number of labs that are subject to them will present a significant challenge to the CDC, which according to congressional auditors has done a poor job of enforcing its earlier mandate. In November, the General Accounting Office said the CDC's enforcement of the select agent rules was fraught with problems, posing an "urgent and potentially serious public health threat."

The CDC said it has hired more staff and contractors to clear a backlog of labs awaiting inspection and otherwise improve the program.

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Information Technology

Composite Healthcare System II achieves milestone approval

2002 DEC 30 - (NewsRx.com) -- Integic Corporation announced that the Composite Healthcare System II (CHCS II) has successfully achieved milestone approval from the Department of Defense (DoD) Military Health System (MHS).

Based on successful pilot programs at four military hospitals on the East Coast, the system will begin a limited rollout to an additional three to four military hospitals in the continental U.S. in FY 2003. When fully deployed worldwide, CHCS II is expected to process 40 million outpatient encounters per year.

CHCS II is clinical information system that generates and maintains a comprehensive, life-long, computer-based patient record (CPR) for more than 8.7 million active and retired military personnel and their beneficiaries. The system links disparate networks of more than 100 MHS hospitals around the world and enables military clinicians to capture and view a real-time health history of service members; track health records in military theater; improve patient safety; reduce clinician error; and provide diagnostic and epidemiological analysis for clinicians.

"CHCS II is positively impacting the future of healthcare for our country's soldiers in the U.S. and overseas," said Robert E. LaRose, president and CEO of Integic. "Not only does this system reduce the cost associated with paper-based medical records, but it gives the MHS the ability to streamline its healthcare records and to shift the military's healthcare paradigm from a hospital-centric to a more beneficial patient-centric focus. This patient-centric focus is extremely important to the military's mobile workforce and will ensure that military clinicians can access personnel health records any place and at any time around the globe."

Prior to the completion of milestone approval, CHCS II was successfully implemented in selected clinics at four military hospitals. The use of CHCS II in four military hospitals on the East Coast has enabled doctors there to rapidly capture and catalog patient health information in clinically significant terms. The system is able to automatically build a clinical note for an encounter and identify any associated coding for diagnosis and procedures ordered for a patient.

CHCS II will enable MHS to: improve sharing of patient information among physicians, nurses, clinicians, technicians, ancillary services and administrators; provide real-time access to patient information, from medical history to current treatment and vital statistics; alert clinicians to allergies and potentially dangerous drug interactions; and automatically generate appropriate codes for submittal of insurance claims.

"One of the greatest strengths of CHCS II is the granularity of data we're able to capture on a patient," said Lawrence Albert, senior vice president of Integic's Healthcare practice. "With CHCS II, we are not just capturing the diagnosis, but also a complete family health history, a patient's symptoms, duration of sickness and many other factors to give military clinicians a phenomenally powerful epidemiological perspective on patient health and overall population health that will help the MHS improve the health of its beneficiaries and increase military readiness.

Integic started work as the prime contractor on CHCS II in March 2000, when it was awarded a contract from the DoD to design, integrate, and test the system. In February 2001, Integic announced that they had been awarded a subcontract to deploy the system to more than