

**Security in Biological Research: Current Oversight of**  
**High-Containment Laboratories**  
**Sponsored by AAAS CSTSP and Center for Biosecurity of UPMC**  
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The safety, utility and oversight of high-containment biological research laboratories are a prominent issue for the United States federal government. Controversies including safety lapses at Texas A&M University in 2006, prosecutions for mishandling pathogens under the USA PATRIOT Act, and public protests surrounding construction of new laboratories have resulted in Congressional inquiries and hearings.

The recent assertion by the Federal Bureau of Investigation that Bruce Ivins, an army scientist, was responsible for the anthrax attacks of 2001, and the emphasis on laboratory biosecurity in the report, *World at Risk*, released by the Commission on the Prevention of WMD Proliferation and Terrorism have highlighted concerns regarding personnel reliability, the oversight of scientists working with dangerous pathogens, and the overall state of safety and security of the nations high containment biological research laboratories.

In addition, during his last week in office, President Bush issued an Executive order (January 9, 2009) mandating a review of all laws and regulations pertaining to select agents, high containment laboratories, and personnel assurance, among other relevant topics. The Select Agent Program and Biosafety Improvement Act was also introduced in the House (H.R.1225) and Senate (S.485) on February 26, 2009.

Recently, Senators Collins and Lieberman have indicated their interest in legislating laboratory biosecurity, including oversight mechanisms for high-containment laboratories, access to dangerous biological agents and/or high-containment laboratories, and personnel assurance.

In practice, regulations for high-containment laboratories in academia, research institutes, and the public health sector are complex. The American Association for the Advancement of Science, Center for Science, Technology, and Security Policy and the Center for Biosecurity of the University of Pittsburgh Medical Center organized a briefing to provide lawmakers with examples of current oversight of high-containment laboratories and personnel assurance. The following is a summary of the briefing.

Gigi Kwik Gronvall, Ph.D. from the Center for Biosecurity, opened the briefing with a short overview of the Select Agent Program. The program was originally designed to register pathogens only for transfer between facilities. After the anthrax mailings in 2001, the program was revised to include registration for possession, transfer, and personnel access to agents; agent inventory; and inspections requirements of relevant agencies. While these regulations have given the government important information that was not available before—including who works with select agents and where—the regulations

have had unintended consequences, negatively affecting aspects of public health, scientific collaborations, and research activities and information sharing. Dr. Gronvall stated that regulating biological pathogens is a difficult undertaking because infectious diseases are global, and only the U.S. has extensive controls for dangerous pathogens. With the exception of smallpox and the 1918 influenza virus, all other select agents are present in the environment. One step forward is to pursue pending legislation, the Select Agent Program and Biosafety Improvement Act (H.R. 1225 and S. 485), which calls for a full evaluation of the program.

All other speakers discussed current oversight of high-containment laboratories and select agents at their institutions, which are representative of their sector.

Michael Ehret, Regional Vice President and Director of Mid-Atlantic Operations of the Midwest Research Institute (MRI), gave an account of procedures and regulations for government contractors. Most of MRI's biocontainment work involves select agents, but they do have some projects outside of the select agent program. MRI operates BSL-2 and BSL-3 laboratories, and all of the BSL-3 laboratories voluntarily use extra safety and security measures. MRI operates under a standardized lab management model, which relies on physical security, internal policies and procedures, and employee reliability. MRI does require at least two researchers work together in the high-containment laboratories but unlike the old nuclear two-person rule, the biologists work on an experiment together. Some facilities have armed guards, but this security measure was not driven by select agent work.

Like many laboratories, MRI's in under extensive external safety and security from the Department of Homeland Security (DHS), the Centers for Disease Control and Prevention (CDC), the Department of Defense, the Department of Transportation, the Federal Aviation Administration (FAA), the U.S. Department of Agriculture (USDA), and the Maryland Department of Health. While many of the agencies have common goals for inspection, the manner in which they implement the inspection and their standards for security and safety may greatly differ between agencies. For example, background checks for personnel working with select agents are not tied to the traditional security clearance program. Mr. Ehret noted that with so many regulations, some work may have transferred overseas and that more regulation could send further work abroad. He recommends a single monitoring agency be responsible for oversight and inspections that can satisfy requirements from all agencies. He felt that the CDC has the most experience in laboratory oversight and might be the best choice but that further discussion of such an approach was warranted. He mentioned that CDC and USDA have collaborated on similar interagency inspections in the past. MRI also has an internal research oversight body.

Michael St. Clair, Senior Director of Environmental Health and Safety and the designated Responsible Official of The Ohio State University, discussed oversight at an academic institution. His university does some select agent work but mainly focuses on pathogens, not part of the Select Agent Program that require BSL-3 laboratory facilities. Oversight at academic institutions consists of coordinated regulatory compliance, internal training and

monitoring, and layered physical security. Similar to MRI, Ohio State requires that at least two people work in high-containment laboratories at any given time; this differs from the traditional two-person rule as implemented in nuclear programs. The university laboratories are monitored and inspected agencies such as by the CDC, the Animal and Plant Health Inspection Service, the National Institutes of Health, the Ohio Department of Health, DHS, the Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), and FAA in addition to internal oversight committees, such as the university Institutional Biosafety Committee. In addition to these oversight bodies, Ohio State, as do all other research institutions, must adhere to U.S. export control regulations. Because academic institutions are increasingly global, Mr. St. Clair cautioned that strictly domestic policies can harm the U.S. scientific enterprise. He reported some frustration from the faculty with current select agent regulations and has noted some faculty members threatening to leave or cease work subject to the regulations if the level of regulation increases, though these faculty members have never left.

Michael Pentella, Ph.D., Associate Director of Disease Testing at the University of Iowa Hygienic Laboratory, Iowa's State Public Health Lab, addressed oversight of high-containment laboratories in the public health sector. Public health personnel and facilities need to be ready to handle dangerous and/or novel pathogens as they are on the frontline of detection and surveillance. They also need to be able to effectively increase detection capability during an outbreak (i.e. surge capacity). Because public health laboratories work with clinical specimens, they are all certified under Clinical Laboratory Improvement Amendments (CLIA), and appropriate oversight is similar to that for clinical testing. In addition, all state and some local laboratories are part of the Laboratory Response Network, which is overseen by the CDC. Hospital laboratories are accredited by CLIA, the College of American Pathologists (CAP) or the Joint Commission (<http://www.jointcommission.org/>). Altogether, the public health system is overseen by the CDC, USDA, OSHA, National Institute for Occupational Safety and Health, and EPA. Public health laboratories have regular safety and inventory assessments as well as assessments triggered by events such as a power outage. There is also significant internal personnel training and staff must go through security clearance. Since the public health workforce is depleted, laboratories cannot afford to always have two people working in high-containment laboratories at the same time. However, with unknown pathogens, safety concerns dictate that at least two people work together to identify the infectious agent.

**More information:**

<http://cstsp.aaas.org/content.html?contentid=1969>