

As a National Biocontainment Laboratory (NBL) dedicated to creating tomorrow's solutions to emerging infectious diseases, the Galveston National Laboratory (GNL) researchers study a myriad of infectious agents including those which are federally regulated. Several public laws shape the oversight of this type of research, but primary regulatory focus stems from laws that govern a particular group of infectious agents termed "select agents."

Select agents are defined by [42 CFR 73.3](#) as a biological agent or toxin the HHS Secretary has determined to have the potential to pose a severe threat to public health and safety.

The select agent rules currently require entities working with the agents, such as the GNL, to register with the appropriate federal authorities. The rules impose additional requirements in an effort to prevent unauthorized access or misuse of select agents including personnel background checks and clearance, security risk assessments as well as, physical security, inventory control and management, biosafety and select agent training, incident reporting, record keeping, transfer clearance and notification, and security plan and incident response plan requirements.

The GNL takes seriously our responsibility and commitment to the public, our researchers and to those who depend on the vaccines and scientific advancements we discover. As such our team ensures that research conducted within the GNL is compliant with the rules governing research. We embrace our responsibility to conduct research in a safe and responsible manner and we remain committed to public transparency of those activities.

Entities who work with select agents are inspected by the federal agency for which they possess registered agents to ensure compliance with these regulations; in addition, other funding groups (both federal and non-federal) often conduct separate inspections to ensure compliance with regulations related to their jurisdiction.

*There are two bills currently that the select agent research community is monitoring in the 111<sup>th</sup> of the U.S. Congress:*

**1. Select Agent Program Reauthorization, S. 485/H.R. 1225:** Reauthorizes the select agent rules and provides some minor amendments including expanding the criteria for select agent determination, planning for a surge in biological samples during an emergency, establishing an integrated Biological Laboratory Incident Reporting System and developing minimum biosafety and biosecurity training standards. *(bill text available on [www.thomas.gov](http://www.thomas.gov))*

**2. WMD Prevention and Preparedness Act of 2009, S. 1649 (Lieberman/Collins):** The WMD report "World at Risk" crafted by Senators Graham and Talent in 2008, spurred this legislation which proposes several changes that would have a significant impact infectious disease research. *(bill text available on [www.thomas.gov](http://www.thomas.gov))*

- Creates a "Tier I" grouping of select agents would include select agents that have a significant potential to be used effectively in a biological attack, and/or pose a risk which requires additional biosecurity measures.
- Creates, via a negotiated rule-making process, enhanced biosecurity measures applicable to Tier I agents including standards for such items as personnel reliability programs, training for Institutional Responsible Officials and lab personnel and support personnel, training program accreditation, laboratory risk assessments and risk-based laboratory security performance as well as procedures, with appropriate restrictions, on access for sharing information including vulnerability assessments, site security plans, and other security related information, with state, local and tribal governments, law enforcement officials and emergency response providers.
- The legislation places the Department of Homeland Security in a lead role for not only developing but ensuring compliance with the promulgated standards.

*Three recent Congressional hearings discussed Select Agent research and U.S. high containment laboratories:*

**September 22, [U.S. Senate Homeland Security Committee](#)**

Hearing - "World at Risk: Weapons of Mass Destruction Prevention and Preparedness Act of 2009"

The full Committee hearing was a discussion of Senate bill S. 1649 introduced by the Committee's chairman, Sen. Joe Lieberman and ranking member, Sen. Susan Collins. Witnesses were "World at Risk" report commission leaders former Senators Bob Graham and Jim Talent. A witness from the Government Accountability Office (GAO) also testified.

**September 22, [U.S. House Energy and Commerce Committee](#)**

Hearing – "High Containment Bio-Laboratories"

This Subcommittee hearing follows a series of similar hearings held over the past two years on oversight of U.S. high containment bio-laboratories. The GAO also testified at this hearing regarding a report they released on September 21 entitled High-Containment Laboratories: National Strategy for Oversight Is Needed. The full GAO report can be found on [www.gao.gov](http://www.gao.gov).

**September 22, [U.S. Senate Judiciary Committee](#)**

Hearing - "Strengthening Security and Oversight at Biological Research Laboratories"

Similar to the hearing held in the U.S. Senate Homeland Security Committee, this Judiciary Subcommittee hearing was a discussion of the recently released report by the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism entitled "World at Risk." The full report can be found on [www.preventwmd.gov](http://www.preventwmd.gov).

*Three reports were also issued recently by the GAO on U.S. high containment facilities and Select Agent research. Full-length copies of each report can be found on [www.gao.gov](http://www.gao.gov):*

**High-Containment Laboratories: National Strategy for Oversight is Needed**

Sept. 21, 2009, GAO-09-574 (104 pages):

In response to a request from Congress, GAO compiled this report between 2005-2009 in an effort to surmise the growth of containment laboratories in the U.S., determine the responsible federal agencies for tracking these laboratories and look at lessons learned from four highly publicized past laboratory incidents.

**High-Containment Laboratories: National Strategy for Oversight is Needed**

Sept. 22, 2009, GAO-09-1036T (9 pages):

GAO testimony commenting on their Sept. 21 report – delivered before the Sept. 22 hearing of the U.S. Senate Homeland Security Committee.

**Biosafety Laboratories: BSL-4 Laboratories Improved Perimeter Security Despite Limited Action by CDC**

Sept. 22, 2009, GAO-09-1038T (18 pages):

GAO testimony following-up on a report they issued in 2007 (GAO-08-108T) which outlined the security status of five BSL4 lab locations in the U.S., including UTMB. The initial report placed UTMB maximum containment labs in a positive light and noted that we had in place the majority of the 15 security parameters measured by GAO. And, our preparations to implement the remaining security measures were underway in conjunction with the construction of the GNL. In follow-up to their 2007 report, GAO contacted UTMB to confirm that the outstanding security items had indeed been successfully implemented. While not naming UTMB directly, this 2009 follow-up report delivered in testimony before the U.S. House Committee on Energy & Commerce on Sept. 22 acknowledged that UTMB security parameters are fully implemented and equivalent to those at current federal laboratories.