



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

September 4, 2012

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Upton:

Thank you for your letter requesting information related to the safety of biosafety level 3 (BSL-3) labs in the Emerging Infectious Diseases Laboratory (also known as Building 18) at the Centers for Disease Control and Prevention's (CDC) Roybal Campus. CDC is committed to ensuring the safety and security of all our staff and the public, and we welcome the Committee's interest in this very important matter.

CDC is one of the few institutions in the world that maintains comprehensive reference laboratories with the capacity and scientific expertise to detect almost all known microorganisms that cause disease in humans. These laboratories are central to supporting the agency's public health mission of protecting people in the United States and around the world. In recent years, CDC laboratories have been pivotal in detecting and responding to multiple public health incidents, including the deliberate anthrax attacks of 2001, SARS, the introductions of West Nile virus and monkeypox in the United States, outbreaks of Ebola and Marburg hemorrhagic fevers, influenza outbreaks, cases of extensively drug-resistant TB (XDR TB), and multiple foodborne disease outbreaks. In addition, CDC's infectious disease laboratories support ongoing public health programs in vaccine-preventable diseases, HIV, hepatitis, viral gastroenteritis, and bioterrorism preparedness. Our unique ability to assist with diagnosing unusual cases or outbreaks of infectious diseases is especially important when the cause of an outbreak is unknown or when special biocontainment precautions and facilities are needed. Building 18 was designed and constructed to meet these needs and to ensure that CDC can continue to serve as a national and global diagnostic center for all infectious threats, as well as a facility for public health research on a wide variety of pathogens.

These laboratory capabilities carry significant responsibilities, and CDC personnel make continuous efforts to evaluate and improve our safety procedures. Such efforts include rigorous and ongoing training, constant review of biosafety and biosecurity measures, and regular improvement of internal laboratory practices. Multiple layers of engineering and operational systems are also in place within laboratory buildings to prevent safety and security breaches. CDC has a strong safety record and employs highly trained experts at the agency for operation and oversight of our laboratories. We understand that human error may not be able to be completely avoided. For that reason, we have multiple safeguard levels, from facility and experiment design, to biosafety cabinets, to biosafety and biosecurity safeguards. In addition, staff receive regular safety training and are encouraged to express any safety-related concerns to a designated safety contact so that CDC can quickly investigate and address any problems.

In addition to the efforts of the scientists working in these laboratories, CDC has significant internal oversight systems, including the CDC Office of Safety, Health and Environment (OSHE), the CDC Institutional Biosafety Committee, the CDC Institutional Biosecurity Board, and local program safety committees to oversee the safety of this work. CDC laboratories that work with biological select agents and

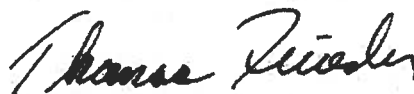
toxins are subject to mandatory regulatory oversight by the Federal Select Agent Program. This program, which is jointly administered by the USDA Animal and Plant Health Inspection Service (APHIS) and CDC's Division of Select Agents and Toxins (DSAT), performs rigorous inspections of the safety, security, and incidence response capabilities of CDC's Select Agent laboratories every three years and also conducts unscheduled inspections as deemed necessary. It should be noted that DSAT is incorporated into CDC's Office of Public Health Preparedness and Response (OPHPR), which does not operate or supervise any of the CDC laboratories. The OPHPR Director reports directly to the CDC Director. In addition to select agent oversight, the CDC smallpox research program and facilities undergo routine inspections by the World Health Organization. OSHE also completes annual inspections of the laboratories.

CDC is currently implementing several steps to enhance its use of outside expertise in reviewing its laboratories and oversight of its safe handling of hazardous pathogens. These steps include additional reliance on independent experts for inspection of the laboratories that contain select agents. CDC is reaching out to external biosafety experts, including specialists from the Public Health Agency of Canada (the entity responsible for inspections of all high containment facilities in Canada) and other national biosafety experts to provide an independent review of its laboratories. Furthermore, APHIS has agreed to assume the lead for all Federal Select Agent Program inspections of CDC-owned laboratory facilities. In addition, we have designated a senior official who will report directly to the CDC Director regarding concerns or complaints related to safety at CDC's laboratories.

Enclosed, please find an overview of Building 18 and its BSL-3 labs, including methods and systems to ensure biosafety. In addition, we have provided and are continuing to provide documents responsive to questions 1-4 of your letter through a separate response, which addresses reports of biosafety incidents, safety issues, and recommendations or solutions to address them. In some instances, these documents contain sensitive information and, in the interest of protecting the security of these laboratories, we have been working with your staff to ensure your access in an appropriate manner, while seeking limits on further disclosure.

Thank you for your interest in public health and in our efforts to ensure the safety and security of CDC's laboratories and their critical role in protecting the nation's health. We hope this information is helpful to you. If you have any additional questions, please have your staff contact Barbara Rogers, CDC Washington, at (202) 245-0600. This response is also being sent to the cosigners of your letter.

Sincerely,



Thomas R. Frieden, M.D., M.P.H.
Director, CDC

Enclosure