

**Testimony to the Finance Committee for
SB 758, Department of Health and Mental Hygiene,
Containment Laboratories Oversight**

**By the Containment Laboratory Community Advisory Committee,
Frederick, MD**

March 15, 2012

Introduction

Good afternoon. Thank you so much for the opportunity to provide testimony on this important Bill. I am Beth Willis, Chair of the Containment Laboratory Community Advisory Committee (CLCAC), which was established in November of 2010 as a joint committee reporting to the City of Frederick, the Frederick Board of County Commissioners, and the citizens of Frederick. We were established following a recommendation in the 2010 National Research Council Safety study regarding the new USAMRIID high containment laboratories at Fort Detrick.

We are nine members of the community and two elected officials, and we work with liaisons from containment labs at Fort Detrick. Our scope of work is health and safety matters associated with all government and private BSL-3 and 4 laboratories in Frederick County. The high containment laboratory complex located at Fort Detrick is by far the largest in the country. In addition there are an unknown number of private BSL-3 laboratories located in the County.

The CLCAC's role is to address the community's health and safety concerns about the labs as well as to facilitate two-way communication and understanding between the community and the labs. That mission is why we are speaking with you today.

The CLCAC embodies a depth and breadth of professional, technical and community experience, including the management of high containment labs, nuclear safety, high

containment laboratory facility management and engineering, public health, and the history of our community's concerns with laboratory health and safety.

We are here today to report that the CLCAC and clear majorities of the public who have communicated with us about SB 758, strongly support the need for the State to perform oversight of all of the BSL-3 laboratories in Maryland. We have also recommended some amended language, which we believe has been submitted to you, that clarifies a number of important points including the adoption vs creation of safety standards, and a requirement for safety performance tracking and reporting.

Why the community believes this Bill is needed

This legislation addresses important gaps in the public safety oversight of private research laboratories working with dangerous infectious pathogens in Maryland. This legislation requires for the **first time** that **all** private and academic Biosafety Level-3 and 4 research laboratories in the state be licensed, be subject to regular safety inspections and safety performance oversight, regardless of the focus of their research. There are currently no private BSL-4 labs in the State, so this testimony will focus on BSL-3 labs.

BSL-3 laboratories work with pathogens such as anthrax, plague, Tuberculosis, Severe Acute Respiratory Syndrome (SARS), virulent influenza, West Nile Virus and numerous other biological agents.

The community believes that this Bill is needed because there is no government oversight over an entire category of BLS-3 labs. The Centers for Disease Control and Prevention regulates and provides oversight over those laboratories working with pathogens known as select agents. These are potential bio-warfare or bioterror pathogens such as anthrax or plague.

However, no government entity regulates or provides oversight over laboratories working with BSL-3 pathogens not on the select agent list. Such organisms could include Severe Acute Respiratory Syndrome (SARS), Tuberculosis, virulent influenza, Hanta Virus, St. Louis Encephalitis Virus, Western Equine Encephalitis Virus and others.

These are highly infectious pathogens just as potentially dangerous to public health as the select agent pathogens.

Private BSL-3 research labs not working with select agents adopt safety standards voluntarily and are self-policing. There is no federal or State regulatory standards requirement for non-select agent research. No government entity tracks who they are or where they are located.

We find this astonishing given that the State currently licenses and conducts oversight for hospital, clinical, forensic and other medical laboratories. It regulates many other private entities and services in the interest of protecting public health and safety, such as hair salons and barbershops.

Existing biosafety regulation is complex. Being fragmented among a vast array of government entities complicates the matter to the detriment of everyone, including to the detriment of public safety. Depending whether or not laboratories conduct select agent research, labs must work with multiple federal, state and local entities for different aspects of safety, lab design and operations. This bill calls for coordination, integration and streamlining of the regulatory structure in Maryland.

What this Bill will do

Implementation of this bill will ensure that the appropriate steps have been taken to properly mitigate health and safety risks associated with all BSL-3 level organisms.

It will clarify regulatory and laboratory oversight issues for the public and inform the public as to what is being done to mitigate these risks.

It will address the full life cycle of these facilities, including planning, design, consistency of design-basis construction, (including weather and seismic considerations) operation, decommissioning and demolition. For example, there is currently no certification that facility space that has been used for studying BSL-3 pathogens is safe for reuse, should the research company leave the facility.

Implementing this legislation would streamline current regulatory processes into one organization, benefiting the laboratories and the public. It could be implemented largely within existing resources, without burden to the taxpayers.

This Bill will:

1. Establish procedures to license and regulate all academic, non-profit and private BSL-3/4 laboratories and any associated Animal Biosafety Level-3/4 facilities, regardless of the focus of their work; these procedures will integrate current guidelines from the Centers for Disease Control, Department of Agriculture and other industry standards.
2. Oblige the State to adopt relevant industry, federal and other pertinent standards that apply to BSL-3 laboratories. This legislation uses the same approach as the Office of Health Care Quality in that the existing industry, federal and current State standards would be adopted.
3. Coordinate relevant existing oversight functions including those performed by the Office of Laboratory Emergency Preparedness and Response (OLEPR), and Maryland Biological Agents Registry (BAR), relevant elements of Maryland Office of Safety and Health (MOSH), Maryland Department of the Environment (MDE),

as well as any others germane to the mission;

4. Create a Division that will serve as the single point of contact for laboratories and oversight information. Containment Laboratories would deal strictly with the responsible Maryland Department of Health and Mental Hygiene (DHMH) office and would not be subject to additional MDE, MOSH and/or DHMH inspections or interactions;
5. Oblige the Division to work with the Centers for Disease Control (CDC), United States Department of Agriculture (USDA), American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), National Institute of Standards (NIST) and local construction permitting jurisdictions to develop physical plant design basis standards for all Maryland containment laboratories;
6. Standardize emergency notification for the public, and response procedures through all jurisdictions in Maryland;
7. Establish a system of compliance inspections of laboratories for initial license application and renewals; Inspections would be conducted at least annually.
8. Oblige the Division to track and report safety performance, and document safety performance trends. Require corrective action if needed.
9. Oblige the Division to make use of an Advisory Committee for implementation of the legislation. The Advisory Committee would include stakeholders from industry, government and the public.

Why this is important

Accidents happen, procedures fail or are not followed; competent people make mistakes. The CDC, scientific journals and the media, have reported numerous containment laboratory accidents and mishaps in the past several years.

There is currently no mechanism for any government entity to know about or respond to the safety performance of unregulated private laboratories.

High Containment laboratories represent low probability high consequence risks. Risks include, but are not limited to:

- **Laboratory Acquired Infections.** A worker unknowingly exposed to a contagious pathogen, goes home, moves about the community and is not diagnosed for weeks. A community lab may find itself also unknowingly performing a culture from the sick worker, on an organism that should only be handled in a high containment setting. Procedures suggest that this could never happen. But it has. Similar scenarios have happened numerous times in labs around the country, including in Frederick, as recently as 2009.

There have been numerous instances of worker illness, sometimes death from laboratory-acquired infections. Fortunately, these infections have not spread to the broader community. But many more labs have opened in recent years, with many more workers.

- **Insider threat.** This occurred with the 2001 Anthrax letters, with resulting deaths, serious illnesses, trauma and economic consequences for many. The GAO and others call insider threat the single greatest risk associated with the growth of high containment labs in the last 10 years.

- **Transport risks.** In 2004 a private BSL-3 Lab in Frederick accidentally mailed live Anthrax to Children's Hospital of Oakland (CA).

There was a front-page article in the Frederick News Post this past Sunday, March 11, dealing with accident and mishap reports and trends at USAMRIID, Fort Detrick. My take away from that article, relevant to this Bill is that USAMRIID is starting to track safety performance trends and adjust procedures, training, protective clothing protocols, equipment etc. to improve safety performance based on data about what mishaps have occurred.

That's what we want to make sure is happening with Maryland's private labs. The oversight function this Bill calls for will bring to light important safety performance and trends, so that corrective actions are made before they lead to a major problem.

For virtually every major accident and incident in any industry that has been publicized in recent years, the subsequent investigations have concluded that at the root was a failure to follow procedures, management failures, and a failure of oversight to identify and require correction of the emerging problems as they were developing before the accident.

We want to see this Bill passed so that there is no failure of oversight here in Maryland.

Background and definitions

What's a containment lab? A containment laboratory employs engineering controls for managing infectious materials in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce the risk of exposure to laboratory workers, other persons and the outside environment to potentially hazardous agents. Other equally

important principles in containment labs are Biosafety, Biosecurity and proper personnel screening and training. All of these factors must work together seamlessly.

There are four designated levels of containment, each with increasing levels of control. While this Bill applies to private BSL-3 and 4 labs, there are currently no private BSL-4 labs in Maryland. The private BSL-3 research laboratories conduct proprietary research for themselves or others. They may also work under contract or grants for the Department of Defense, Department of Homeland Security, National Institute of Allergies and Infectious Disease, Department of Agriculture and others.

What is a BSL-3 lab? BSL-3 labs are used to study microbes that can be transmitted through the air and can cause serious disease or death if untreated. These diseases are treatable with existing vaccines or treatments. Researchers perform lab work in a gas-tight room within boxes that filter the air. Other safety features include clothing decontamination, sealed windows and rooms, and specialized ventilation systems with HEPA filters. Access must be controlled. BSL-3 labs work with pathogens such as anthrax and plague, TB, SARS, virulent influenza and others.

Issues with private laboratory oversight. In the last 10 years, there has been a significant growth in the number of BSL-3 labs and lab workers in the U.S. According to a 2009 Government Accountability Report, no single government agency either regulates or even knows how many labs there are.

The Report addresses the safety consequences of “not knowing”. The GAO estimates something on the order of 1600 BSL-3 labs nation-wide, with upwards of 16,000 workers. The number of private BSL-3 labs is unknown.

The need for better oversight of all BSL-3 laboratories is under intensive national discussion. The GAO, the National Research Council, the Congressional Research Service, a number of Congressional Committee Hearings, National Institute of Health science boards, the Occupational Safety and Health Administration (OSHA), and industry groups including the American Biological Safety Association have been grappling with the need for better and more consistent safety oversight applying to all private BSL-3 laboratories. I refer you again to the 2009 GAO report that discusses issues and inadequacies with private laboratory oversight.

<http://www.gao.gov/new.items/d09574.pdf>

I also refer you to a February 15, 2012 national news article that summarizes the issues quite succinctly: <http://www.reuters.com/article/2012/02/15/us-health-biosecurity-idUSTRE81E0R420120215>

The CLCAC sponsored a public meeting on Tuesday March 13, 2012 with officials from the Centers for Disease Control and Prevention about their regulation and oversight of BSL-3 and 4 laboratories. At that meeting Dr. Rob Weyant, CDC's Director of the Division of Select Agents and Toxins, Office of Public Health Preparedness and Response made it clear that the CDC regulates only select agents, and that no federal entity performs an equivalent public health and safety oversight of BSL-3 laboratories not working with select agents.

The CLCAC also sponsored a public meeting with Deputy Secretary Fran Phillips, Department of Health and Mental Hygiene and her staff. We have learned that the State of Maryland currently has a Biological Agent Registry program that also applies only to labs working with select agents. This program was established in the wake of 9/11 and the Anthrax letter attacks. It is focused on national and state security concerns not on safety oversight.

The BAR program tightly regulates control of information about select agent labs, ensuring that only trusted first responder and public health officials have any access to information about the labs, including the names of the companies and locations.

The Maryland Office of Laboratory Emergency Preparedness and Response works with emergency planning and response in the event of an accident or threat event. It is our understanding that it is not tasked with nor does it have authority to conduct onsite safety performance oversight of any laboratories. It also deals only with laboratories that work with select agents.

Where these labs are located

These private research labs are most certainly located in Frederick County, Montgomery County, Baltimore City and Baltimore County. We have no way to know where else in the State BSL-3 labs might be located.

Summary

This Bill addresses an important gap in public health, safety and public accountability oversight in the State. It takes a step in the right direction of ensuring proper oversight for all BLS-3 laboratories, while providing relief to the laboratories by streamlining the regulatory process.

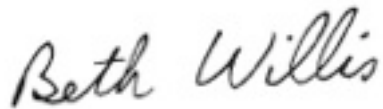
The Containment Laboratory Community Advisory Committee has been working intensively with the issues this Bill addresses for the last 15 months. We've spent many hours speaking with containment laboratory directors and safety experts; we've toured facilities and have drawn upon the decades of containment laboratory

experience embodied within our own committee. We've met with Deputy Secretary Phillips and her staff in order to better understand current State regulations.

We sponsored a public forum just this past Tuesday night with safety experts from the CDC and learned more about what oversight they do and do not perform. We've been listening carefully to what the public is concerned about. And the public is speaking. Because of the sheer number and growing number of BSL-3 and 4 laboratories and incidents in our community, the citizens of Frederick have become informed and vocal about laboratory-related safety issues.

We are clear that the State of Maryland needs to take responsibility for addressing this important health and public safety gap. This Bill is a strong start to addressing the community concerns about this dangerous gap in laboratory oversight here in Maryland. Thank you.

Respectfully submitted,

A handwritten signature in cursive script that reads "Beth Willis".

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