



# **The Containment Laboratory Community Advisory Committee (CLCAC)**

**Fifth Annual Report:  
January 2015 - December 2015**

**December 31, 2015**

## **Containment Laboratory Community Advisory Committee:**

### **Regular members**

Ms. Beth Willis, Chair (at-large representative, term completed June 2015)  
Mr. Kim Loll, Vice-Chair (at-large representative)  
Mr. Peter Herz, Secretary (at-large representative)  
Dr. Dat Duthinh (at-large representative)  
Dr. Bob Hawley (private-sector life sciences industry representative)  
Mr. Ray Hunter (at-large representative, resigned October 2015)  
Mr. Joseph Mangiafico, Sr., MPH, (private-sector health field representative)

### **Alternate Members:**

Mr. George C. Rudy (alternate representative)  
Dr. J. Craig Reed (alternate representative, appointed April 2015)

### **Ex-Officio Members:**

The Honorable M.C. Keegan-Ayer, Vice-President, Frederick County Council (County Representative and non-voting member)  
The Honorable Randy McClement, Mayor, City of Frederick (City Representative and non-voting member)

### **Laboratory Liaisons to the Committee:**

Ms. Lanessa Hill, Public Affairs Specialist – Community Relations U.S. Army Garrison  
Ms. Caree Vander Linden, Public Affairs, USAMRIID

The Containment Laboratory Community Advisory Committee deeply appreciates the support of City of Frederick, Frederick County, State and Federal elected officials, without whom this work would not be possible. The City of Frederick, in particular has provided the committee with extensive support by hosting the committee's website, as well as providing meeting space and audio/video services.

Original Signed \_\_\_\_\_

Kim R. Loll, Vice-Chair  
Containment Laboratory Community Advisory Committee

## Executive Summary

This document provides a progress report of the Containment Laboratory Community Advisory Committee's (CLCAC) fifth year of work. It describes the committee's activities and accomplishments in working towards the year's goals and priorities.

The CLCAC used this year to build on its earlier work, focusing on 1) providing meaningful information to the public regarding local and national issues related to biosafety; 2) maintaining open communication with the operating containment laboratories at the National Interagency Biodefense Campus (NIBC) at Fort Detrick; 3) promoting state legislation for the registration of non-Select Agent Biological Safety Level 3 (BSL-3) laboratories; and 4) participating in the ongoing national dialogue regarding biosafety, biosecurity, and transparency. The CLCAC remains committed to the premise that transparency and open communication is essential to promoting public confidence, understanding and trust.

The CLCAC accomplished the following during 2015:

- Participated in two meetings between CLCAC representatives and Fort Detrick Garrison/NIBC Laboratory leadership to facilitate improved communications and a common understanding of issues and concerns.
- Provided written and oral testimony in March 2015 in support of Maryland Senate Bill 675 and House of Delegates Bill 665, *Department of Health and Mental Hygiene- Biosafety Level 3 (BSL-3) Laboratory Safety Program*.
- Met with Maryland State Department of Health and Mental Hygiene (DHMH) representatives to better understand their concerns regarding the proposed registration of non-Select Agent BSL-3 laboratories in Maryland.
- Met with the staff of U. S. Congressman Delaney and U. S. Congressman Van Hollen to discuss current biosafety and biosecurity issues of concern to the public and the need for improved transparency.
- Participated in a session on select agent laboratory regulation held by the White House Office of Science and Technology Policy. The two members who participated were not representing the CLCAC committee, but were invited as individuals.
- Revised the CLCAC By-Laws to reflect recent changes in the Frederick County governance structure, as well as improve CLCAC processes based on previous experience and lessons learned.

This year, the CLCAC continued to meet directly with leadership from the Fort Detrick Garrison and NIBC laboratories in an effort to foster frank discussion on subjects of mutual concern and to find a way to institutionalize the sharing of safety performance information with the public. These discussions have been informative and cordial, and some limited additional information has been made available to the public. Over the last year, members of the CLCAC participated in the ongoing national debate on biosafety, biosecurity, and transparency. On October 29, 2015, the White House issued a memorandum to the Executive Branch entitled, *Next Steps to Enhance Biosafety and Biosecurity in the United States*. The CLCAC expects to monitor the implementation of the recommendations contained in this document over the next few years.

The CLCAC leadership provided written and oral testimony in March 2015 in support of Maryland Senate Bill 675 and House of Delegates Bill 665, *Department of Health and Mental Hygiene- Biosafety Level 3*

*(BSL-3) Laboratory Safety Program.* This proposed Bill would have permitted the collection of basic information about self-regulated BSL-3 laboratories in the State of Maryland. Currently no government entity at any local, State or Federal level knows how many such laboratories are operating in the State. The State therefore does not have the basic information required to address public health and safety concerns associated with BSL-3 laboratories performing non-select agent research. This Bill was a modest and inexpensive step in addressing this data gap. This Bill included no safety regulations or oversight provisions. The proposed Bill was withdrawn when it became clear that the Maryland Department of Health and Mental Hygiene would not support the Bill. The CLCAC will continue efforts to support the registration of self-regulated BSL-3 laboratories at the State or local level.

The CLCAC website (<http://www.cityoffrederick.com/index.aspx?NID=127>) contains a wide array of public information about all of the committee's activities, scope and by-laws, and includes Frequently Asked Questions (FAQs), information about known laboratories in Frederick County, definitions, presentations, and links to external regulating Federal and State organizations and emergency response information. All of the committee's meetings and forums are recorded and can be viewed online. The CLCAC remains committed to continuing its efforts to improve communication with the laboratories, Fort Detrick, and the residents of the City of Frederick and Frederick County.

## **Committee Purpose, Scope and Organization**

### **What is the Containment Laboratory Community Advisory Committee?**

The CLCAC was established in November 2010 as a joint committee sponsored by the City of Frederick and Frederick County. The CLCAC members are appointed jointly by the Mayor and Board of Aldermen, as well as the County Executive and County Council.

The committee meets quarterly, and is normally comprised of seven regular members and two alternates, all residents of Frederick County. Currently there are five regular members, two alternates and two ex officio elected officials, one from the City of Frederick and one from the Frederick County Council. The term of Ms. Beth Willis was completed in June 2015, and Mr. Ray Hunter resigned for personal reasons in October 2015. These two vacancies are expected to be filled in January 2016. The CLCAC would like to take this opportunity to extend our sincere appreciation to Ms. Beth Willis and Mr. Ray Hunter for their dedicated service to the CLCAC since its inception in 2010.

The purpose of the committee is to:

- 1) **foster and facilitate two-way communication** between the Frederick County community and the operators of the high containment laboratories operating at Fort Detrick and elsewhere in Frederick County;
- 2) **seek information about issues of public concern** and ways to address those concerns, including the implications of laboratory operations on the public health and safety of the community, and;
- 3) **advise and make recommendations on behalf of the public** to government, containment laboratory and Fort Detrick officials regarding opportunities to improve any laboratory-related matters that could impact public health and safety.

## **CLCAC Objectives and Accomplishments: January 2015- December 2015**

### **The CLCAC's 2015 objectives, as defined in the 2014 Annual Report were to:**

- Foster timely and accurate communication among the of the City of Frederick and Frederick County citizens, Fort Detrick, and the NIBC laboratories;
- Continue to champion improved transparency of operational safety performance and emergency preparedness at all containment laboratories, private and federal, in Frederick County;
- Continue to advocate for the State to take action to close the information gap on self-regulated containment laboratories operating in Maryland, including registration of self-regulated containment laboratories as an initial and necessary first step.
- Better understand and communicate to the public the safety analysis processes and corresponding controls used to prevent or mitigate accidents with potential consequences to the public. This includes the design, construction, commissioning, operations and maintenance, and the decommissioning and demolition of BSL-3 and BSL-4 laboratories.

### **The CLCAC undertook the following actions in support of its objectives:**

- **Conducted meetings with the leadership of the Garrison of Fort Detrick and the National Interagency Biodefense Campus (NIBC) Laboratories.**

The purpose of this CLCAC/lab leadership working group is to promote improved information flow on matters of public health and safety. Two meetings were held with the Commander of the Garrison at Fort Detrick, the Commander of the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), and the Directors of the Department of Homeland Security's National Biodefense Analysis and Countermeasures Center (NBACC), and the National Institute of Allergy and Infectious Diseases (NIAID)'s Integrated Research Facility (IRF) or their representatives.

Specific goals for this working group are:

- To establish a mutually agreed to, collaborative process for improving the transparency of public health and safety related matters.
- To reach agreement about what information will be shared, in specific time frames.
- To institutionalize a process and content for providing specific safety performance information.

**Outcomes:** Meetings were held in April 2015 and October 2015. Both meetings were marked by open communication about recent local and national containment laboratory news, as well as issues of mutual concern. Discussions were held regarding recent incidents at Dugway Proving Grounds and Tulane University, as well as related statements and recommendations from the U.S. Congress, Government Accountability Office (GAO), the CDC, and the White House Office of Science and Technology Policy

(OSTP). The focus of these discussions was on the impacts and implications of these events on the NIBC laboratories.

While discussions regarding the CLCAC's desire for increased transparency of safety performance information remain open and cordial, additional records of operational information are not anticipated being made available to the public. As noted in last year's CLCAC Annual Report, this may be due to a number of reasons, including limited local authority to make this information publicly available, and operational security or other concerns. It is noteworthy, however, that widely reported biological safety incidents in other parts of the United States have raised this issue to a national level debate, including hearings in the U. S. Congress.

On October 29, 2015, the White House issued a memorandum to the Executive Branch entitled, *Next Steps to Enhance Biosafety and Biosecurity in the United States*. This memorandum includes a set of recommendations to strengthen the Federal Government's biosafety and biosecurity practices and its oversight system, highlighting the following:

- 1) **Transparency of the Nation's laboratory system for public safety and security**, particularly for those facilities that possess, use or transfer Biological Select Agents and Toxins (BSAT);
- 2) **Incident reporting and accountability to the public** for biosafety and biosecurity procedures, protocols, personnel reliability, and to ensure a culture of responsibility;
- 3) **Material stewardship**, including inventory management and control for facilities and personnel that possess, use, or transfer BSAT; and
- 4) **Applicability to other biological agents that could pose a serious threat to public health or agriculture**: The three principles above should also be applied to encompass transparency, enhance incident reporting and accountability, and material stewardship for any biological agent that could pose a serious threat to public health or agriculture.

The entire White House memorandum and attachments are available on the CLCAC website:

[https://www.whitehouse.gov/sites/default/files/docs/10-2015\\_biosafety\\_and\\_biosecurity\\_memo.pdf](https://www.whitehouse.gov/sites/default/files/docs/10-2015_biosafety_and_biosecurity_memo.pdf)

It is anticipated that future meetings of the CLCAC/lab leadership working group will focus on discussions regarding the implementation of this White House policy.

In early 2015, USAMRIID posted accident and mishap information for 2012-2014 as well as lists of oversight entities and other safety-process-related information. A link to this information is available on the CLCAC website, and is available below:

<http://www.usamriid.army.mil/biosafety/index.htm>

- **Supported Efforts to enact Maryland State Legislation for the Registration of Private BSL-3 Containment Laboratories that Handle Non-Select Agents**

The CLCAC continued to focus on the need to register private self-regulated BSL-3 laboratories in the community during 2015. These are laboratories that work with pathogens other than those on the CDC

and USDA Select Agent list. These laboratories receive no independent external laboratory safety oversight. The public is concerned because there is no mechanism for any government entity to know the identity or location of these laboratories.

Self-regulated BSL-3 laboratories work with pathogens such as drug-resistant *Mycobacterium tuberculosis* (TB), virulent influenza virus, hantavirus, St. Louis Encephalitis Virus, Western Equine Encephalitis Virus and others. If not properly managed, these organisms could potentially pose a significant public health risk. In various reports, the Government Accountability Office (GAO) has also expressed concerns about self-regulated BSL-3 laboratories.

It should be noted that BSL-3 laboratories that work with biological Select Agents and toxins are regulated by federal agencies, and are reported to a State registry. However their names, and locations are not made available to the public.

From September 2012 through early 2014, the CLCAC participated in a State-wide workgroup tasked by the State legislature to identify any regulatory gaps that exist for self-regulated private containment laboratories in the State. The Workgroup was also tasked to make recommendations about how to address those gaps. The group's final report, Health and Safety Issues Associated with High Containment Laboratories was issued in October 2013 and can be found here:

<http://dhmh.maryland.gov/laboratories/containment/SitePages/Request%20for%20Comments.aspx>.

The work group's final report clearly outlined data and regulatory gaps and possible approaches for addressing these gaps. However, the State Department of Health and Mental Hygiene (DHMH) made no specific recommendations when it issued the final report. No action has been taken by the DHMH, or by the State Legislature. The CLCAC continues to believe that some basic and simple steps should and could be taken, and submitted comments for the public record on November 18, 2013. These comments are available only on the CLCAC website.

The report made clear that the State has no means of determining how many self-regulated containment laboratories operate in Maryland. The CLCAC recommended that the Maryland State legislature take the following steps in order to address the issues identified in the report:

- Require registration of currently self-regulated BSL-3 laboratories.
- Require reporting of laboratory-acquired infections or incidents.
- Require reporting if a laboratory relocates or closes, having worked with pathogens that require BSL-3 containment.
- Once the State has obtained basic registration data, it should then reconvene the Biocontainment Workgroup to examine that data, with the objective of determining if further action is needed.

The CLCAC forwarded its comments to Maryland State Senator Ron Young, who had sponsored the State Biocontainment Work Group. The full comments provided by the CLCAC are available at:

<http://www.cityoffrederick.com/DocumentCenter/View/3639>

In December 2014, the CLCAC submitted a request to the Maryland State Delegation to take action to require that self-regulated BSL-3 laboratories register with the State in order to determine the scope of the issue. The CLCAC also requested the support of the County Executive on this matter.

The CLCAC leadership provided written and oral testimony in March 2015 in support of Maryland Senate Bill 675 and House of Delegates Bill 665, *Department of Health and Mental Hygiene-*

*Biosafety Level 3 (BSL-3) Laboratory Safety Program.* This proposed Bill would have permitted the collection of basic information about self-regulated BSL-3 laboratories in the State of Maryland. Currently no government entity at any local, State or Federal level knows how many such laboratories are operating in the State. The State therefore does not have the basic information required to address public health and safety concerns associated with BSL-3 laboratories performing non-select agent research. This Bill was a modest and inexpensive step in addressing this data gap. This Bill included no safety regulations or oversight provisions. The proposed Bill was withdrawn when it became clear that the Maryland Department of Health and Mental Hygiene would not support the Bill. In November 2015 members of CLCAC, Maryland State Senator Ron Young, and Maryland State Delegate Karen Young met with Maryland State Department of Health and Mental Hygiene (DHMH) representatives to better understand their concerns regarding the proposed registration of non-Select Agent BSL-3 laboratories in Maryland.

The CLCAC will continue efforts to support the registration of self-regulated BSL-3 laboratories at the State or local level.

- **Maintained ongoing Communication with the Public and Elected Officials**

The CLCAC maintains ongoing communication with the public, as well as elected officials at the City, County, State and Federal level regarding its activities and any relevant issues and concerns it encounters. This connection with elected officials is vital to the CLCAC's work. A summary of key meetings and communications is provided below:

- In March 2015, the CLCAC leadership provided written and oral testimony in support of Maryland Senate Bill 675 and House of Delegates Bill 665, *Department of Health and Mental Hygiene- Biosafety Level 3 (BSL-3) Laboratory Safety Program.*
- In June 2015 the CLCAC Chair was interviewed by WHTU radio (1450 AM), discussing recent DOD shipments of live anthrax and an earlier USA Today article of Biosafety.
- In June 2015, the CLCAC Chair met separately with the staff of U. S. Congressman Delaney and U. S. Congressman Van Hollen to discuss current biosafety and biosecurity issues of concern to the public and the need for improved transparency.
- In October 2015, members of the CLCAC met with Maryland Senator Ron Young and Maryland Delegate Karen Young to discuss next steps in addressing the registration of private BSL-3 laboratories that do not handle Biological Select Agents and Toxins (BSAT).
- In November 2015 members of CLCAC, Maryland State Senator Ron Young, and Maryland State Delegate Karen Young met with Maryland State Department of Health and Mental Hygiene (DHMH) representatives to better understand their concerns regarding the proposed registration of non-Select Agent BSL-3 laboratories in Maryland.

- **A Special Thanks to Ms. Beth Willis**

Ms. Beth Willis' term as a member of CLCAC expired in June 2015. Beth was instrumental in the creation of the CLCAC, and has been a charter member since it was established in 2010. Especially noteworthy, Ms. Willis served as the Chair of the CLCAC during this formative period. Her tireless leadership and skillful management resulted in significant improvements in communications and understanding between Frederick County high containment laboratories and the local community. Some of her many contributions as

CLCAC Chairperson include the creation of a comprehensive website providing information to the public, standing meetings with the leadership of the Fort Detrick garrison and laboratories to enhance communications, several community events including a Safety Exposition in 2014, numerous interviews with media outlets, and many others. She has been a stalwart, energetic and dedicated leader on behalf of the community, and she will be sorely missed.

- **Logistics:**

The term of Ms. Beth Willis expired in June 2015, and Mr. Ray Hunter resigned for personal reasons in October 2015. These two positions are expected to be filled in January 2016. Dr. Craig Reed was appointed as an alternate member in April 2015 to fill a vacancy on the Committee. City and County elected officials made this appointment based upon applications from members of the community.

The Committee continues to meet quarterly. Much of the Committee's work is conducted between meetings and is reported at the quarterly public meetings.

## **Challenges**

The work of the CLCAC is a long-term endeavor. While the challenges and goals for the Committee are expected to evolve, they will also likely endure.

### **Communication with Laboratories:**

The material posted on the Committee's website attests to improved communication and transparency over the past five years. In particular, USAMRIID is providing annual accident and mishap information, posted on its website, along with descriptions of its safety programs and safety oversight activities. Other Federal laboratories have also provided responses to public questions and safety program information.

<http://www.cityoffrederick.com/index.aspx?NID=559>

Routine meetings with laboratory leadership will continue to be valuable communication opportunities, and future CLCAC efforts related to seeking improved transparency of operational safety performance information will likely focus on the implementation of the October 2015 White House memorandum discussed earlier.

### **Resources:**

The Committee continues to expand its access to resources at local, State and Federal levels in order to leverage its ability to address public concerns. Its own resources remain constrained, as a standing committee of volunteers with a large portfolio of goals. This requires setting clear priorities and engaging in projects at an appropriate pace. In particular, the Committee intends to expand its outreach efforts to community and local government organizations within the U. S. that deal with biological containment laboratory related issues and concerns to improve communications and share lessons learned.

## **Communication with the Public:**

The process of finding more effective ways of communicating with the public is ongoing. While the CLCAC's communication mechanisms via the web, email, public meetings, and with the press are diverse, efforts will continue to reach a broader cross-section of the public. The Safety and Health Expo conducted in April 2014 was another tool to effectively communicate with the citizens of Frederick County. In like manner, the committee needs to continue to find ways to ensure that it hears public comments and seeks new ways to address concerns brought to its attention.

## **Goals for 2016**

The CLCAC will continue to pursue the following goals for 2016:

- Foster timely and accurate communication among the City of Frederick and Frederick County citizens and elected officials, as well as the leadership of Fort Detrick and the NIBC laboratories. Efforts will include identifying more effective ways to communicate with the public;
- Continue CLCAC working group meetings with the leadership of Fort Detrick and NIBC laboratories, with a focus on understanding the implementation of the White House memorandum dated October 29, 2015, *Next Steps to Enhance Biosafety and Biosecurity in the United States*;
- Continue to advocate for the State of Maryland and/or Frederick County to take action to close the information gap on self-regulated containment laboratories operating in Maryland (or Frederick County), including registration of self-regulated containment laboratories as an initial and necessary first step;
- Identify and reach out to other community and local government organizations in the U. S. that deal with biological containment laboratory related issues and concerns to improve communications and share lessons learned. This includes information related to public health and safety risks as well as biosecurity risks associated with activities related to gain of function research, synthetic biology and artificial biology
- Better understand and communicate to the public the safety analysis processes and corresponding controls used to prevent or mitigate accidents with potential consequences to the public. This includes the design, construction, commissioning, operations and maintenance, and the decommissioning and demolition of BSL-3 and BSL-4 laboratories.
- Evaluate the case for expanding the CLCAC By-Laws to address BSL-2 laboratories within Frederick County, and make appropriate recommendations to the City of Frederick and Frederick County elected officials for their consideration.