



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

**Fourth Annual Report:  
January 2014 - December 2014**

**December 31, 2014**

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

### **Regular members**

Ms. Beth Willis, Chair (at-large representative)  
Mr. David Kaye, Vice-Chair (life sciences industry representative, term completed June 2014)  
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)  
Mr. Joseph Mangiafico, Sr., MPH, (private-sector health field representative)

### **Alternate Members:**

Ms. Roxanne Beal (alternate representative, term completed June 2014)  
Mr. George C. Rudy (alternate representative)\*

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

The Honorable David Gray, Frederick Board of County Commissioners (County representative and non-voting member, term completed November 30, 2014)  
The Honorable M.C. Keegan-Ayer, 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

\*appointed October, 2014. Attended first public meeting January, 2015

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.

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Beth Willis, Chair  
Containment Laboratory Community Advisory Committee

## Executive Summary

This document provides a progress report of the Containment Laboratory Community Advisory Committee's (CLCAC) fourth 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 providing information to the public and encouraging more transparency from the operating containment laboratories at the National Interagency Biodefense Campus (NIBC) located at Fort Detrick. The CLCAC remains committed to the premise that improved transparency is essential to fostering public confidence, understanding and trust.

The CLCAC accomplished the following during 2014:

- Held two meetings between CLCAC representatives and NIBC laboratory leadership to facilitate communications and common understanding.
- Sponsored a Public Health and Safety Expo at Hood College on April 30, 2014, with participation by the Fort Detrick Garrison and tenant Laboratories, as well as Frederick City and County agencies.
- Developed a seven minute introductory video on the work of the CLCAC and posted it to the CLCAC web site.
- Participated in regional biodefense conference on Dual Use Research of Concern (DURC) in Montgomery County, MD. Presented an invited talk on the role of communities in DURC policy.
- Developed a set of questions with the goal of conducting future meetings with NIBC laboratories to better understand the safety analysis process and the controls used during the design, construction, start up and commissioning, operations, and decommissioning of high containment laboratories.
- Completed work on the State Department of Health and Mental Hygiene (DHMH) Containment Laboratory Workgroup on Private Containment Laboratories. Recommended a series of next steps, based upon issues identified by the Workgroup.

The April 30th Safety Expo was a first of its kind event, providing the community with the opportunity to meet informally with laboratory leadership and experts from all of the NIBC laboratories as well as public health, emergency management and elected officials. Planning and conducting the Expo required and demonstrated significant sustained effort, coordination and commitment from all concerned.

This year, the CLCAC continued to meet directly with laboratory leadership at the NIBC 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. While there have been productive discussions, the effort remains a work in progress and the CLCAC will consider other approaches in the coming year for obtaining information for the public.

The CLCAC did not work directly with private biosafety level 3 (BSL-3) laboratories in Frederick County during 2014, as there is no legal mechanism to know their identity or location. In December 2014, the CLCAC submitted a request to the Maryland State Delegation to take action to require that any self-regulated BSL-3 laboratories not working with biological select agents and toxins register with the State,

in order to determine the number of such laboratories in the State.

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, 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 City of Frederick and Frederick County citizens.

## 1. Committee Purpose, Scope and Organization

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

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

The committee is comprised of Frederick County residents. Currently there are seven regular members, one alternate and two ex officio elected officials, one from the City of Frederick and one from the Frederick County Council. During 2014 the terms of one regular member and one alternate member were completed, and one new member and one new alternate were appointed to fill those vacancies. The CLCAC would like to take this opportunity to extend our appreciation to Mr. David Kaye and Ms. Roxanne Beal for their dedicated service to the CLCAC since its inception in 2010. Mr. Kaye also served as the Vice-Chair of the CLCAC during this formative period.

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.

## 2. CLCAC Objectives and Accomplishments: January 2014- December 2014

The CLCAC's 2014 objectives, as defined in the 2013 annual report were to:

- Foster timely and accurate communication among the City, County, citizens and NIBC laboratories;
- Continue to champion transparency concerning safety and operations at all containment laboratories, private and federal, in Frederick County;
- Advocate for the State to take preliminary action to close the information gap on self-regulated containment laboratories operating in Maryland.
- Better understand the safety analysis processes and corresponding controls used to prevent or mitigate an accident or incident 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, and to find more effective ways to communicate this information to the public.

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 workgroup is to promote improved information flow on matters of public health and safety. Two meetings were held with the Commander for 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 the workgroup 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 January 2014 and September 2014. Both meetings were marked by open communication about mutual concerns and challenges. The January 2104 meeting focused on planning for the upcoming Safety and Health Exposition conducted in April 2014 at Hood College, which is discussed later in this report. The September 2014 meeting focused on the impressions and results from the Health and Safety Expo, as well as discussions regarding recent incidents at the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH), and 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 was on the impacts and implications of these events on the NIBC laboratories.

Discussions during both meetings also focused on opportunities for additional performance information to be provided to the public, consistent with previous CLCAC written recommendations. Examples of such information are executive summaries of regulatory and oversight reviews from the CDC and other regulatory bodies, lists of the entities that conduct external oversight, and the criteria and reporting thresholds for accidents and incidents.

While discussions have been open and cordial, it has become apparent that additional information will likely not be forthcoming from the NIBC laboratories or the Fort Detrick Garrison. This may be due to a number of reasons, including limited local authority to make this information publicly available, operational security or other concerns.

Future CLCAC efforts to obtain operational performance information will need to be addressed using a different approach. This might include requests for information under the Freedom of Information Act (FOIA), requests for assistance from the City of Frederick, Frederick County, State and Federal elected officials, and formal correspondence with appropriate Federal and State regulatory agencies such as the Maryland Department of Health and Mental Hygiene, the CDC and the U. S. Department of Agriculture (USDA).

In early 2014, USAMRIID posted accident and mishap information for 2010-2013 as well as lists of oversight entities and other safety-process-related information. NBACC has provided information on its safety programs, strategic plan and the posters used at the 2014 Safety Expo for safety suits and the personnel reliability program.

- **Sponsored a Public Health and Safety Exposition at Hood College**

The CLCAC sponsored a Public Health and Safety Expo at Hood College from 4:00 PM to 8:30 PM on April 30, 2014.

The Expo provided an opportunity for the public to see safety equipment and displays and speak informally with containment laboratory leadership and experts from all of the NIBC laboratories, as well as public health and emergency management officials. Elected officials or their representatives from the City, County, State and federal levels attended. It was the first event of its kind in the County, and required a high level of commitment, effort and coordination from all who were involved in its organization.

The Expo flyer can be found at <http://www.cityoffrederick.com/DocumentCenter/View/3868>

Participants included:

- Fort Detrick Garrison, Emergency Responders
- U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
- National Biodefense Analysis and Countermeasures Center (NBACC)
- National Institute of Allergy and Infectious Diseases (NIAID) Integrated Research Facility (IRF)
- Frederick County Public Health Department
- Frederick County Department of Emergency Preparedness
- Frederick City and County First Responders

- Hood College
- Containment Laboratory Community Advisory Committee (CLCAC)

The CLCAC was responsible for outreach, logistics, promotion and advertising. The CLCAC conducted outreach to the press, the community at large, public school science departments, local colleges, community associations and the medical community. The CLCAC appeared on local radio, and arranged for public interest announcements, promoted the event on social media, wrote an editorial letter printed in the *Frederick News Post*, and distributed flyers and posters throughout the County.

The NIBC partners and other participants provided equipment displays and poster information about various aspects of laboratory safety and safety engineering. Information about safety procedures, personnel screening and training were provided. Handouts and papers discussed safety programs. Numerous staff members were available to answer questions.

Senior leadership from all of the NIBC laboratories and Fort Detrick garrison actively participated, emphasizing their commitment to public safety and communication.

The Hood College Biology Department hosted the Expo. Hood College provided significant support from its public relations department, producing all of the flyers, posters and signage.

Over 100 members of the public attended, including students and faculty from Frederick County Public Schools, Hood College, and Mount Saint Mary's College. Evaluation forms were distributed to attendees and later collected in order to obtain feedback on the benefits and opportunities for improvement on this outreach activity.

- **Prepared a CLCAC Introductory Video**

A seven minute introductory video on the work of the CLCAC was developed and posted to the CLCAC web site (<http://www.cityoffrederick.com/index.aspx?NID=127>). The City of Frederick Audio Visual Department designed and produced the video.

Much of the video was created during the Public Health and Safety Expo at Hood College on April 30, 2014. The video includes remarks from CLCAC officers, as well as laboratory officials and county representatives.

- **Participated in the University of Maryland Center for Health and Homeland Security (CHHS) and the Middle Atlantic Regional Center for Excellence in Biodefense and Emerging Infectious Disease Research (MARCE) Conference**

The focus of this conference was the safety, security and preparedness of containment laboratories involved in Dual Use Research of Concern (DURC). Dual Use Research of Concern (DURC) is defined by the National Institutes of Health as “life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.”

(<http://osp.od.nih.gov/office-biotechnology-activities/biosecurity/dual-use-research-concern>)

At the invitation of the conference organizers, Beth Willis, as Chair of CLCAC, took part in a panel discussion and provided a 30 minute presentation entitled “*The Role of the Public with Dual Use Research of Concern Policy and Research.*” The presentation discussed the experience of the CLCAC.

its purpose, functions, achievements, challenges and lessons learned, as well as broader issues relating to community rights and concerns. The presentation is available here:

<http://www.cityoffrederick.com/index.aspx?NID=558>

The conference had more than 100 participants representing academia, local, state and federal government and the press. Several members of the CLCAC attended.

- **Developed Questions for Future Discussions Regarding the Design Basis of Containment Laboratories**

Members of the CLCAC and the public have continued to seek answers to questions about laboratory design basis as related to risk. The CLCAC prepared a list of relevant questions and provided them to laboratory leadership, along with a request to meet with staff. The intent was to discuss a process for obtaining this or related information. The list of questions is posted at:

<http://www.cityoffrederick.com/index.aspx?NID=568>

Based upon discussions in the September laboratory leadership meeting, the CLCAC understands that this information will not be made available, nor will there be further discussions related to this topic in the future. The CLCAC will continue to pursue this topic to gain a complete understanding of public health and safety risks.

- **Completed work on the State Department of Health and Mental Hygiene (DHMH) Containment Laboratory Workgroup on Private Containment Laboratories**

The public continues to voice concerns about private self-regulated BSL-3 laboratories in the community. 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 such 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 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.

This basic action would not require complex legislation, significant cost or burden upon either the industry or the State. Without this action it is not possible to know whether there are 3, 30 or 300 self-regulated BSL-3 laboratories operating in the State. In the absence of any information, the State is not in a position to fulfill a core function of government in relation to these laboratories: to be concerned with public health and safety.

The Biotechnology industry is of vital economic interest within the County and the State. Safe operations are essential to the viability of this industry and to ensuring public trust. The CLCAC request is available here: <http://www.cityoffrederick.com/index.aspx?NID=127>

- **Maintained ongoing Communication with Elected Officials**

The CLCAC maintains ongoing two-way communication with 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.

All elected officials were invited to participate in the April 30 Safety Expo, which offered them an opportunity to hear constituents' concerns about laboratory safety. Elected officials and their representatives attended the Expo.

- **A Special Thanks to County Commissioner David Gray**

County Commissioner David Gray's latest term on the Frederick County Board of County Commissioners was completed on November 30, 2014. Mr. Gray played an instrumental role in the creation of the CLCAC, and he has been the CLCAC's County Elected Official representative since its inception in late 2010. He spent countless hours with the CLCAC, attending briefings and tours of containment laboratories, monthly meetings, forums and other events. He always supported the CLCAC and spoke compellingly of the rights of the community and the importance of the work the CLCAC endeavors to accomplish. His personal and political support made this work possible.

The CLCAC will miss Mr. Gray's contributions, dedication, clarity, common sense and the always pointed and insightful questions he asked on behalf of the citizens of Frederick County. The CLCAC would like to publicly thank Mr. Gray for everything he has done in support of our efforts.

- **Logistics:**

In 2014, the terms of Mr. David Kaye and Ms. Roxanne Beal expired, and Mr. George C. Rudy was appointed in October 2014 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.

### **3. Challenges**

The work of the CLCAC is a long-term endeavor. While the challenges 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 four years. In particular, USAMRIID has provided annual accident and mishap information, posted on its website, along with descriptions of its safety programs and safety oversight bodies. Other federal laboratories have also provided some responses to public questions and safety program information.

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

Having the above information publicly available is very useful. However, other previously available information provided by some federal laboratories have been removed and not replaced.

Long-term discussions about appropriate and useful safety performance information have not yet yielded an overall agreement about content or an ongoing process for making this information publicly available. As mentioned earlier in this report, the CLCAC does not believe that additional operational information will be forthcoming from the NIBC laboratories or the Fort Detrick Garrison. Although routine meetings with laboratory leadership will continue to be valuable communication opportunities, future CLCAC efforts related to seeking improved transparency of operational safety performance information will need to pursue a different approach.

The CLCAC notes that there was an extensive national discussion about need for greater safety transparency with the public during the summer of 2014 following a series of highly publicized safety mishaps at the CDC laboratories in Atlanta. The need for greater transparency was voiced by the Director of the CDC, by the Government Accountability Office, numerous members of Congress, by expert witnesses in Congressional Oversight Hearings, and in prestigious scientific journals. The CLCAC is aware that this is a national public health and safety issue. Since Frederick is home to the national headquarters for biodefense research, and the largest campus of high containment laboratories in the nation, this issue is of great importance to the Frederick community as well.

### **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.

### **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.

## **4. Goals for 2015**

The CLCAC will continue to pursue the following goals for 2015:

- 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.