

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

**Second Annual Report:  
October 2011- December 2012**

**December 31, 2012**

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

### **Regular members**

Ms. Beth Willis, Chair (at-large representative)  
Mr. David P. Kaye, Vice-Chair (private-sector life sciences industry representative)  
Dr. F. Alexander "Alex" Hamill, Ph.D., SCPM, Secretary (Resigned in July 2012)  
Mr. Peter Herz, (at-large representative)  
Mr. Ray A. Hunter (at-large representative)  
Mr. Kim R. Loll (at-large representative)  
Mr. Joseph A. Mangiafico, Sr., MPH, (private sector health field representative)  
Ms. Cynthia I. Sigler, (at-large representative)

### **Alternate Members:**

Ms. Roxanne Beal (alternate representative)

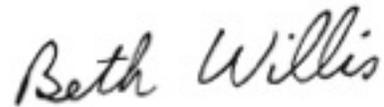
### **Ex-Officio Members:**

The Honorable David P. Gray (County representative and non-voting member)  
The Honorable Karen Young (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, County, State and federal elected officials, without whom this work would not be possible. The City, 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



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David P. Kaye, Vice-Chair  
Containment Laboratory Community Advisory Committee

## Executive Summary

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

The CLCAC used this second year to build on its first year of work, primarily focusing on serving as a conduit for providing information to the public and encouraging more transparency with the operating containment labs at the Ft. Detrick National Interagency Biodefense Campus (NIBC), as well as the private laboratories in Frederick County.

The CLCAC also endeavored to address community concerns by hosting a second public forum on emergency management, seeking answers to core health and safety questions, and sponsoring public meetings with officials from the Centers for Disease Control (CDC) and the Maryland State Department of Health and Mental Hygiene (DHMH). The committee has kept elected officials apprised of its work and has made a number of recommendations with the goal of improving transparency and communication.

The CLCAC continues to believe that transparency between containment laboratories and the citizens of Frederick County is essential to improving public understanding and trust. The committee understands that rigorous laboratory safety, and internal and independent oversight mechanisms are in place for each of the NIBC labs. However, the committee continues to seek a mechanism by which the laboratories can effectively share safety performance information with the public. Such a mechanism would provide confidence to the public that operations are being conducted in a safe and secure manner.

This year, the CLCAC has also focused attention on the private Bio-Safety Level 3 (BSL-3) containment laboratories in Frederick County. Following the committee's recommendation for legislation to address concerns about State regulatory gaps, a State-level Containment Laboratory Oversight Working Group was formed under the Maryland State Department of Health and Mental Hygiene. This Working Group, which includes representatives from the CLCAC, will make recommendations to the Maryland Legislature in June 2013, concerning any needed regulatory or legislative changes.

The CLCAC was unable to identify all of the private containment labs in Frederick County, which the committee had hoped to do with the goal of asking for their support in communications and transparency efforts. Federal law prohibits any government entity from revealing the names of high containment laboratories working with controlled substances known as Select Agents, though the labs may choose to identify themselves.

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 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, Ft. Detrick and the citizens of Frederick City and County.

### 1. Committee Purpose, Scope and Organization

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

The CLCAC is a joint committee of the City of Frederick and Frederick County; current members were appointed by the Mayor and Board of Aldermen as well as the Board of County Commissioners in November, 2010 and began meeting in late January 2011.

The committee is comprised of Frederick County residents; currently there are seven regular members, one alternate and two ex officio elected officials, one from Frederick City and one from the Frederick Board of County Commissioners.

The purpose of the committee is to **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. To **seek information about issues of public concern** and ways to address those concerns, including the implications of laboratory operations on the safety and health of the community. To **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 safety and health.

## 2. CLCAC Accomplishments: October 2011 - December 2012

**CLCAC accomplishments for 2012 reflect the priorities established for the year.**

(<http://www.cityoffrederick.com/DocumentView.aspx?DID=1229>)

**Initiated Contact with Containment Labs at Ft. Detrick:** In the Fall of 2011 the committee toured the new Department of Homeland Security and National Institute of Allergies and Infectious Diseases labs, subsequently submitting written questions and posting the responses on the CLCAC website. (<http://www.cityoffrederick.com/index.aspx?NID=127>) Additionally, committee members spoke with representatives of other entities that are performing containment lab work at Ft. Detrick: U.S. Department of Agriculture, Department of the Navy, and the Centers for Disease Control and determined that these fell into one of three categories: 1) they are not working with human pathogens, 2) they are not working at BSL-3 or BSL-4 level, or 3) they perform their work in USAMRIID labs and follow their established procedures.

Meetings with leadership at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) and the Fort Detrick Garrison occurred earlier in 2011, along with a tour of the labs. Information received from those meetings is posted on the CLCAC website. (<http://www.cityoffrederick.com/index.aspx?NID=568>)

**Developed a “Frequently Asked Questions” Section on Website:** The committee developed a set of Frequently Asked Questions (FAQ’s) about containment laboratories, basic safety operations information and core information about each of the labs. The questions were compiled based upon public queries. While the CLCAC maintained control over the content of the FAQ’s, the laboratories reviewed the materials for accuracy.

**Addressed Questions About Private Containment Labs in Frederick County:** The committee conducted a thorough search and discussion of current regulations pertaining to private biosafety level 3 (BSL-3) containment laboratories. Deputy Secretary of the Maryland Department Health and Mental Hygiene (DHMH) Fran Phillips and her senior staff met with the CLCAC in a public forum and addressed the public’s questions regarding DHMH’s role in regulation and oversight of private containment laboratories.

DHMH is prohibited by federal law from identifying containment laboratories that work with select agents. The CLCAC was left with no mechanism by which to identify private BSL-3 laboratories in the County. In addition, the committee learned that neither the State nor the CDC performs safety oversight of BSL-3 laboratories that are working with pathogens other than select agents. Such laboratories comply with bio-safety regulations voluntarily.

Senior staff at one private lab provided the CLCAC with a very informative and comprehensive biosafety and biosecurity presentation. However, this firm decided against publicly sharing their identity or basic safety program information.

The CLCAC subsequently proposed State legislation in order to address concerns about oversight and

regulatory gaps. While the legislation did not pass out of the State Finance Committee, the effort resulted in formation of a State-level Biocontainment Laboratories Oversight Working Group, convened by DHMH, at the request of Frederick's State Senator Ron Young. The Working group is charged with making legislative or regulatory recommendations to the State Senate and House by June 2013. Three members of the CLCAC serve on this Working Group, along with regulatory, academic and private sector stakeholders. <http://dhmh.maryland.gov/laboratories/containment/SitePages/Home.aspx>

**Coordinated a Meeting with the CDC to Address Public Concerns:** The CLCAC conducted a public information meeting with senior CDC officials to answer questions about the CDC's role in containment laboratory oversight as well as the processes they use to evaluate compliance. During the meeting the committee also explored the legal limitations of: 1.) Revealing safety performance information and; 2.) Conducting oversight of non-select agent containment laboratories. The CLCAC's questions and CDC's presentation is posted on the CLCAC website: <http://www.cityoffrederick.com/index.aspx?NID=558>

The committee requested, but did not receive, follow-up information regarding CDC's reporting and documentation mechanisms.

**Sought Safety Performance Data from NIBC Laboratories:** In 2012, the CLCAC has again focused on the importance of transparency with the public about laboratory biosafety and biosecurity performance. This is consistent with the 2010 National Academy of Sciences recommendations for USAMRIID and with the 2009 Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight. Representatives from the committee met in June 2012 with USAMRIID Safety staff to discuss how to structure accident and mishap information in a way that is clear and accessible to the public. Also discussed was the use of safety performance metrics and other information that would be appropriate and helpful for a publicly oriented webpage. The committee followed up with specific written recommendations, including a recommendation for a short list of safety performance metrics, based upon information already available.

The USAMRIID public affairs office has reiterated its ongoing intention to publish accident and mishap information, but the CLCAC has not received a response to its other recommendations. Accident and mishap information was posted on 1/2/13 and can be accessed via the CLCAC website: <http://www.cityoffrederick.com/index.aspx?NID=127>. The CLCAC has hoped that USAMRIID would lead in these matters, with a proof of concept, to be followed by safety information from the other labs in the National Interagency Biodefense Campus as they become operational.

The CLCAC remains committed to working collaboratively with representatives from the labs to find practical, clear and appropriate ways of providing safety information and operational safety metrics to the public.

**Sought Answers to Safety Concerns and Questions Generated by the Public.** The CLCAC has endeavored to address community questions and concerns in a variety of ways: 1.) Via frequently asked questions, including those prepared by both the CLCAC and the Homeland Security and NIAID labs. The structure of the FAQ's is informed by questions received from the public. 2.) In public forums, such as those with State DHMH officials, the CDC and Frederick Public Health and Emergency Management directors. Question lists from the community and committee were provided in advance to the presenters, in order to focus the meetings on topics of concern. Verbal Q & A's between presenters, the public and the CLCAC are a part of each of these forums. In addition, public questions and comments are received at every CLCAC meeting. 3.) Questions received from the public, via the committee's webmail or other means are forwarded to the relevant laboratory or garrison personnel. It is important to receive written responses in order to ensure that they can be accurately disseminated back to the public. At the time of publication of this report, there is a backlog of outstanding responses for 2012.

**Communicated with Elected Officials, Laboratory Officials and Ft. Detrick Garrison Command.** The CLCAC keeps elected officials at the local, State and federal level apprised of its goals, activities, and concerns. Members have met with Officials at each level, and have made recommendations

to them as the committee judged was appropriate. These include recommending: 1) a Memorandum of Understanding between the City and the laboratories to make explicit communication triggers and timing for communication with elected officials, including the CLCAC 2) ways to address gaps in federal and State regulation and oversight of private labs, and 3) approaches to addressing federal restrictions in providing laboratory safety information to the public.

Members have also met with Laboratory and Garrison officials in the past. In October 2012, The CLCAC requested a meeting with Fort Detrick based Laboratory Directors/commanders and the Garrison commander in order to address communication concerns, and to establish a plan for more collaborative approach to ensuring smooth and timely information flow on behalf of the public. This meeting is scheduled for January 2013.

**Redesigned the CLCAC Portion of the City's Website.** The City of Frederick hosts the CLCAC website which contains information about all CLCAC activities, information received from laboratories and government entities as well as frequently asked questions and links to emergency response, and other information relevant to the mission of the committee. The website is updated monthly. (<http://www.cityoffrederick.com/index.aspx?NID=127>)

**Facilitated Second Public Meeting on Emergency Response.** This September 2012 forum focused on what the public would need to know and how they would know what to do in the event of a public health or other emergency.

### 3. Challenges

**Communication with Laboratories:** The committee has worked closely with laboratories during its initial orientation and while developing basic information for the public. However, as the committee has sought more specific responses to questions and safety performance information, it has been difficult to establish a smoothly functioning process for a collaborative, timely and efficient information flow between the laboratories and the CLCAC. Improving two way communication and transparency is key to improving mutual trust between the local community and the laboratories. Addressing this challenge is the top priority for the CLCAC in the coming year.

In like manner, the decision of private laboratories to maintain anonymity does not further public trust.

**Resources:** The committee has expanded its access to resources at local, State and federal levels in order to leverage our ability to address public concerns. It's 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:** As reported last year, the process of finding the best, most effective way of communicating with the public is ongoing. While the CLCAC's communication mechanisms via the web, email, and with the press and in public meetings are diverse, they need to continue to expand and reach a broader cross-section of the public. In like manner, the committee needs to continue to find ways to ensure that it is hearing public comments and seek new ways to address concerns brought to its attention.

### 4. Observations and Conclusions

**The CLCAC makes several observations and draws the following conclusions from its second year of interactions with the high containment laboratories and regulatory bodies.**

**The National Interagency Biodefense Campus:** Each facility within Fort Detrick's National Interagency Biodefense Campus operates independently, under the authority of their respective parent Departments (U.S Army, Department of Homeland Security, National Institutes of Health, Department of

Agriculture, etc.) The NIBC is a term referring to the co-location of the facilities; it is not an overarching organization. Officials, staff and researchers from the institutions located at the NIBC have established committees and other ways to share their safety practices, common research interests etc. Specific researchers may conduct work at more than one facility. The Fort Detrick garrison's authority does not extend into the operations of the institutions located at the NIBC. The garrison is responsible for safety and emergency response for Fort Detrick, beyond the walls of the individual NIBC institutions. This independent and decentralized structure makes communication complex and sometimes difficult among the NIBC labs, the community, community officials and the CLCAC.

**Improving Communication:** Whether it is a result of NIBC's complex management structure or some other reason, the committee has not been successful in obtaining requested information. To address this situation, the CLCAC has proposed quarterly meetings with senior management from all the facilities that could impact public safety. The first meeting has been scheduled for January 23, 2013.

Further, the committee has concluded that it would be useful for a Memorandum of Understanding to be developed between the Frederick City elected officials and Fort Detrick to further improve communications on matters of public interest, as well as making explicit the public's understanding of the laboratory management commitment to public communication.

The CLCAC believes it is important to work further with officials at USAMRIID, the Homeland Security and NIAID labs as well as with the garrison in order find ways to better communicate their mission and safety performance to the public

**Improving Transparency:** The CLCAC continues to remain committed to the concept that transparency is critical to improving trust between the community and the institutions operating the BSL-3 and BSL-4 laboratories. It is essential to continue to advocate for ways the NIBC labs can make information about the institutions, research and safety performance more available and understandable to the public.

## **5. Goals for 2013**

The CLCAC is committed to the following goals for 2013:

- Foster timely and accurate communication among the City, County, citizens and NIBC laboratories;
- Continue to champion transparency concerning safety and operations at all containment labs, private and federal, in Frederick County;
- Support ongoing efforts of the State-level Biocontainment Laboratories Oversight Working Group to make recommendations regarding regulation and oversight of private containment laboratories;
- 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, operations and maintenance, and the decommissioning and demolition of BSL-3 and BSL-4 laboratories. Find ways for this information to be communicated to the public.