The Containment Laboratory Community Advisory Committee

First Annual Report: January- September 2011

October 11, 2011

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 (at-large representative)
Mr. Peter Herz, (at-large representative)
Mr. Ray A. Hunter (at-large representative)
Mr. Joseph A. Mangiafico, Sr., MPH, (private sector health field representative)
Ms. Cynthia I. Sigler, (at-large representative)

Alternate Members:

Mr. Kim R. Loll (first alternate representative)
Ms. Roxanne Beal (second 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

_____

Beth Willis, Chair
Containment Laboratory Community Advisory Committee

Executive Summary

This report highlights the first nine months of the Containment Laboratory Community Advisory Committee's (CLCAC) work. It reviews the committee's goals, actions, accomplishments, challenges, conclusions and plans.

The CLCAC used this time to organize how it will operate and communicate. Our first priority was to establish an ongoing line of communication between the citizens of Frederick City and County and Ft. Detrick officials at the various BSL-3 and 4 containment labs. Our second priority was to educate ourselves regarding the function, mission and operations of the labs as well as the role of the Fort Detrick garrison for on-post safety, emergency response and infrastructure support. Members learned about Biosafety level 3 and 4 containment laboratory health and safety procedures and about community concerns. We touched upon most aspects of the committee's scope of responsibilities.

The CLCAC also worked to address community concerns in ways such as providing feedback to the National Research Council on risk assessment issues, hosting a public forum on emergency management, and seeking answers to core health and safety questions.

The CLCAC is currently developing a Frequently Asked Questions (FAQ) capability on its website. We will work to improve communications with a broader segment of the public. We intend to continue to grow a productive relationship with laboratory and Fort Detrick garrison leadership. We are investigating the most effective way to understand basic information about the private Biosafety Level 3 (BSL-3) laboratories in the county. We plan to host public information sessions on the specifics of BSL-3 and 4 external oversight programs conducted by the Centers for Disease Control and others.

The CLCAC believes that improved laboratory transparency with the public is essential. The CLCAC has concluded that USAMRIID and the garrison are committed to safety, and internal and independent oversight mechanisms are in place. However, information about the results of these routine reviews are not generally made available to the local community. Doing so would provide independent confirmation that operations are being conducted in a safe and secure manner.

The CLCAC believes it will also be important for all of the institutions associated with the National Interagency Biodefense Campus to implement the 2010 National Research Council recommendations relating to streamlined public communication. Transparency would also be improved if the NIBC institutions developed public-oriented websites that contain clear and specific information about the laboratories, including information about pathogens under research, guidelines for public notification in case of mishap and online information about mishaps.

The CLCAC remains committed to work that will bring benefit to the community, the laboratories and public officials.

Note: all references to "laboratories" or "containment laboratories" within this report refer to the BSL-3 and 4 laboratories within the committee's scope of responsibilities.

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 Board of County Commissioners that was established in November 2010, and began meeting in late January 2011.

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

Who are the committee members and how were they chosen?

A subcommittee of City and County elected officials selected members based upon written application. Members are volunteers, Frederick County residents representing a diversity of technical and community expertise, serving for 3-year staggered terms. Member bios: *See CLCAC website and Appendix 2, note 1 for link.*

What are the CLCAC's mission and goals?

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.

- **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.

- **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.

What is the CLCAC's scope of responsibilities?

The CLCAC is concerned with health and safety matters associated with current and future containment laboratories operating in Frederick County; past contamination issues are outside of its scope. It operates independently of all containment laboratories and has no control or authority over any containment laboratory functions. The CLCAC does not provide oversight of laboratory activities.

The CLCAC's scope includes all BSL-3 and 4 laboratories associated with the National Interagency Biodefense Campus (NIBC) at Fort Detrick, as well as any other government or private BSL-3 or 4 laboratories operating within Frederick County. Included are the existing and planned laboratories operated by the Army (USAMRIID and others), the Navy, the Department of Homeland Security, the National Institute of Allergy and Infectious Disease, the Department of Agriculture and other federal agencies. *See Appendix 2 for links to definitions of BSL3 and 4 laboratories and the pathogens they research.*

How does the CLCAC meet and operate?

Monthly public meetings at Frederick City Hall are broadcast on local government channel 99, and are available online for viewing. Additional public forums are held as needed. All meetings are publicized in the press, on the CLCAC website, by email, through community organizations and Neighborhood Advisory Councils. The CLCAC also meets with laboratory officials, and tours facilities to better understand current and planned operations, reporting back at public meetings. The public may provide input at all meetings. The committee seeks answers to questions raised by the public.

2. CLCAC Accomplishments: January - September 2011

Established committee structure. We refined specific committee objectives and scope and developed by-laws and first year goals. The Committee also conducted an intensive orientation with the Fort Detrick garrison, laboratory officials, local officials and the public. *See Appendix 1 for goals and actions.*

Opened lines of communication with Fort Detrick officials, and the National Interagency Biodefense Campus (NIBC) labs, local officials and the public. We established working

relationships with the Fort Detrick garrison and laboratory representatives and officials, enabling the CLCAC to refine its questions about health and safety concerns. We apprised elected officials at the local, state and federal level of the CLCAC's work and any concerns.

Obtained information about the laboratories and provided it to the public. We received information about laboratory biosurety, biosecurity, personnel reliability, lab construction, mission and research, accident and mishap history, emergency management and other related matters. We were provided with a public briefing on USAMRIID's implementation of National Research Council's 2010 recommendations. The Committee determined areas of greatest public, health and safety concern and submitted detailed follow-up questions. We provided feedback to laboratory officials. We published questions and responses on our website and recommended specific ways for labs to demonstrate safety performance to the public. We also made inquiries to the State of Maryland about access to basic information about private BSL-3 laboratories operating in the County, and made recommendations to elected officials about some ways the public could be more assured of safety vis-a-vis private laboratory operations.

Assessed community concerns and interests voiced to the CLCAC via a variety of media. We received feedback from the public via meetings, forums, email, website and personal contact. Public concerns were a primary input for CLCAC priorities, questions and actions.

Established ways to communicate information to the public. We established CLCAC website, email lists and other communication mechanisms and worked closely with local press. The CLCAC website contains all committee agendas, minutes, presentation materials, CLCAC questions and lab responses as well links to any relevant laboratory and Centers for Disease Control (CDC) websites. It is updated at least once a month. It includes CLCAC purpose and scope, the by-laws and member bios. It announces future meetings and other events. *See CLCAC website and Appendix 2, note 2 for link.*

Provided the public with information from emergency preparedness and public health officials about plans for any lab-related emergency or mishap. We put together questions we believed reflected public concerns about how any emergencies would be handled. We held a public forum and invited emergency management, first responder, police, public health officials from the City, County and Fort Detrick to talk about emergency planning and answer questions. *See CLCAC website and Appendix 2, note 3 for link to further information.*

Represented community concerns to the 2011 National Research Council risk assessment assistance study for the Army's Medical Countermeasures Test and Evaluation Facility. We attended the NRC's public meeting and provide written and verbal comments about public risk assessment concerns. We requested and obtained a follow-up meeting with the NRC and provided additional written feedback, which was also shared and discussed with representatives from the Army. *See CLCAC website and Appendix 2, note 4 for link* to further information.

3. What the CLCAC has learned

From the labs. In addition to learning a great deal about how BSL-3 and 4 laboratories operate, and USAMRIID's safety procedures, we have learned about the significant efforts to improve these safety procedures and practices in the past several years.

We have asked numerous questions. Of note is USAMRIID's reply to our questions about accidents and mishaps that have occurred in the past 5 years. USAMRIID reports no significant laboratory accidents or mishaps beyond the already-reported 2009 instance of a laboratory-acquired Tularemia infection. *See CLCAC website and Appendix 2, note 5 for link.*

From the public. The public has asked many specific questions about laboratory safety, construction and public notification in case of emergency. However, the most significant message from the public is a long-standing deep lack of trust that the laboratories are providing "straight answers" to questions. Public comments repeatedly urge the CLCAC to maintain its independence from the laboratories so that it may be a trusted source of information.

From local officials. We learned that multi-agency and multi-disciplinary teams of Emergency Response and other health and safety personnel from the community and the garrison conduct extensive training on potential hazmat, biological mishap, or public health emergencies. We understand the procedures for dealing with these potential laboratory-related emergencies are essentially the same as non-laboratory-related emergencies in terms of public notification and response. *See CLCAC website and Appendix 2, note 6 for link.*

From the State. The state of Maryland regulates the control of information about use of select agents at private laboratories. State policy is to restrict all information, including the names of companies, to trusted emergency management partners. *See CLCAC website and Appendix 2, note 7 for link.*

4. Challenges

Committee scope. The scope of responsibilities is large. The CLCAC is charged with addressing health and safety questions associated with major BSL-3 and 4 laboratories operated by four or more cabinet level Departments as well as BSL-3 laboratories operated by private companies. The CLCAC has in its first nine months touched on aspects of its entire scope. It has also determined the most important core questions, and has worked to avoid becoming distracted by detail that does not serve its primary mission. The broad scope also means the CLCAC needs to remain both flexible and focused as it responds to evolving priorities and concerns.

Learning curve. Each CLCAC member has had a learning curve in topical areas beyond their specific expertise involving a significant time commitment.

Resources. The CLCAC has received considerable support from the City of Frederick. The City has hosted and maintains the CLCAC website, email accounts, provides meeting space and television and video access and sends out a number of notifications. County staff has also been extremely helpful, particularly as the committee was first organizing. Committee liaisons at USAMRIID and the Fort Detrick garrison have been essential partners. The garrison assisted for a number of months with support for meeting minutes. USAMRIID, Homeland Security, NIAID and garrison leadership and staff have been generous with their time and have provided extensive information and responded to our many questions. The committee is extremely grateful for all of this assistance, which has made our work possible.

That said, there remains a great deal of administrative and content-oriented work for the committee to manage without assistance, and we are aware that we therefore need to choose our tasks wisely and pace ourselves. Over the short term, the committee simply does not have the resources to quickly generate as much public information about the laboratories as we believe the public would like to see. The committee has no budget allocation and its members are volunteers.

Learning the most important questions to ask. The CLCAC has asked many questions that have served to orient us to the world of BSL-3 and 4 laboratories and the research they conduct. It has also been important for the committee to hone its understanding of what issues and questions are of core importance to public safety, health, and community concerns. Example of questions, as submitted to Homeland Security NBACC officials: *See CLCAC website and Appendix 2, note 8 for link.*

Facilitating productive communication among all parties. Communication and encouraging transparency are key factors in retaining our credibility and rapport with the public. The CLCAC encountered long-standing distrust of the laboratories on the part of many in the community, and wariness about public response on the part of many lab officials who are responsible for carrying out the mission of their institutions. The public may ask questions from a "where I live" safety perspective, and laboratories may answer in a way that reflects the complexity of the work and protection of the institution. Satisfactory communication can be elusive. The CLCAC is committed to improving this communication, and does not underestimate the task.

Obtaining answers. The CLCAC is committed to seeking answers the public can understand. We have endeavored to seek answers that "show and demonstrate" safety procedures and remedies, as opposed to simply trying to reassure the public. An example would be accident and mishap data structured in a way that demonstrates safety performance. This is a challenging process given the protective desires of the laboratories and the transparency desired by the public.

Learning how to best communicate with the public. The process of finding the best, most efficient way of communicating with the public is ongoing. We are mindful of the need to be clear, simple and accurate. While our communication mechanisms via the web, email, and with the press and in public meetings are diverse, they need to expand and reach a broader cross-section of the public.

5. Observations and Conclusions

The CLCAC makes several observations and draws the following conclusions from its first months of interactions with the Fort Detrick laboratories.

Commitment to Safety. Based on the activities described above, the committee has concluded that USAMRIID and the garrison are committed to safe and secure operations, and that internal and independent oversight mechanisms are in place. We do not yet have specific information about the safety performance of the Homeland Security research currently conducted at USMARIID. The new Homeland Security and NIAID laboratories are not yet operational.

The National Interagency Biodefense Campus. The committee notes that each of the institutions 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.

While each individual NIBC institution is subject to all of the external reviews and oversight required by law, since the NIBC is not an organizational entity, it is not structured to provide additional site-wide landlord functions or additional site-wide oversight of laboratory safety and security. In like manner, there are no formal NIBC-wide mechanisms to communicate a single integrated understanding of the research that will be conducted, safety performance etc.

Need for streamlined coordination and communication among NIBC laboratories and to the public. The scale, complexity and number of independent research institutions at the NIBC is a challenge for the public to understand. The CLCAC believes it would be helpful for the NIBC institutions to implement the 2010 NRC safety study recommendations for streamlining communication. From the

point of view of the public, laboratory-level (vs garrison) NIBC laboratory communication routes are not clear. We would suggest, that a "NIBC Communication Czar" be established to coordinate this information for public dissemination.

Actions to improve transparency. The CLCAC remains convinced that transparency is critical to improving trust between the community and the institutions operating the BSL-3 and 4 laboratories. It is also important to safety. Small and simple steps to improved transparency would include the timely development of Frequently Asked Questions on the NIBC and laboratory websites, that are oriented toward the public, including links to pathogen fact sheets that are easy for the public to find. The CLCAC recommends that the NIBC laboratories develop this capability promptly and that the CLCAC be engaged in the development of pertinent questions. The CLCAC is committed to coordinating material on its own website with information on the laboratory websites. Clear written responses to the attached list of questions for example, would provide basic information for the public and local officials. *See CLCAC website and Appendix 2, note 8 for link.*

Online posting of mishap and safety information. Consistent with the 2010 USAMRIID NRC study, guidelines should be published and be available online for who, when, how, to whom, and under what circumstances the laboratories will report mishaps and laboratory acquired infections to the public and public officials. Also consistent with the NRC's recommendations, an online mishap reporting capability should be developed without further delay and with input from the CLCAC regarding the kind of basic information that that should be made available to the public. Publishing summary information about mishaps and the results of independent oversight reviews would improve transparency and demonstrate safety performance. *See CLCAC website and Appendix 2, note 9 for link.*

Private BSL-3 laboratories. The State of Maryland controls access to information about those conducting research with Select Agents, which are regulated by the Centers for Disease Control and the Dept. of Agriculture. The CLCAC recommends that the MD State legislature considers how it might provide safety oversight of BSL-3 laboratories in order to increase public confidence and safety. The program conducted by the City of Cambridge, MA has been embraced by both the large and economically vibrant Massachusetts biotech industry and the public and could serve as a useful model for a program that benefits everyone.

6. Next steps

Continue and expand dialog with NIBC labs. We intend to work further with officials at USAMRIID, the Homeland Security and NIAID labs as well as with the garrison in order to better understand their mission and safety operations as well as plans and memorandum of understanding with City, County, and State officials in the event of a laboratory acquired infection or other emergency. We intend to explore ways the NIBC labs can make information about the institutions, research and safety performance more available and understandable to the public. We will make contact with the Department of Agriculture laboratory. We will continue to ask health and safety questions, seeking written answers that we can share with the public.

Roll out Frequently Asked Questions. This is an ongoing project to provide clear information to the public on the CLCAC website, based upon questions we have heard from the public.

Learn specifics about the BSL-3 and 4 external oversight programs. We intend to learn more about independent inspections and oversight conducted by the Centers for Disease Control, the Department of Agriculture, the Department of Health and Human Services Inspector General and others. We will if at all possible hold public meetings about such oversight.

Pursue basic information about private labs. There has been no contact to date with the County's private BSL-3 labs, at least in part because of State policy that restricts access to the names of companies that work with Select Agents. We will continue to try to understand and address these restrictions. We intend to better understand the oversight of private BSL-3 laboratories and any gaps in that oversight.

Continue to participate in the risk assessment process for the Army's MCT&E. The Army suspended this effort in July 2011 as the facility scope is being reconsidered. The CLCAC will re-engage when the risk assessment process resumes, which the Army indicates may be in early to mid-2012.

Improve communication with the public and engage wider spectrum of the community. The CLCAC has taken first steps in its two-way communication with the public. We will seek new ways to share information, receive feedback and questions from the public. We are mindful that the public wants health and safety concerns to be addressed with clarity and with objective information.

Appendix 1: First Year Goals and Actions

The CLCAC established these goals in February 2011 and updated them regularly. They are first steps in an ongoing process.

1. **Establish Committee, its mission, goals, by-laws and operating processes.**
   Action: Completed Jan- Feb 2011. See by-laws and other materials on CLCAC website for details. *See CLCAC website and note Appendix 2, note 10 for link.*

2. **Establish mechanisms for communicating with the public.**
   Action: Feb 2011 onward. Worked with local press, used website, email lists and notices to civic and community groups. Worked with media to provide information to the public; address questions raised by the public. Established the CLCAC website, with support of the City (March 2011), and in process of developing online Frequently Asked Questions (Summer- Fall 2011).

3. **Obtain information about high containment laboratories in Frederick and how they operate.**
   Action: February 2011 onward. Numerous meetings, lab & facility tours, Q & A sessions with Fort Detrick Garrison, USAMRIID, Homeland Security, NIH lab officials. Published series of CLCAC / public questions about the labs, and responses on CLCAC website. (April- August 2011) Researched information and Maryland state law re: private high containment labs.

4. **Engage with the National Research Council and the Army on the risk assessment process for the Army's new Medical Countermeasures Test & Evaluation Facility.**
   Action: March- June 2011. Provided set of detailed comments and follow-up materials regarding community concerns about risk. Met with NRC committee representatives and MCT &E representative to discuss and ask questions about process.

5. **Solicit feedback from the public about their expectations of the committee.**
   Action: Held public forum in April. Receive community comments at monthly meetings and via email. Discussed and updated goals, and made inquiries to laboratories based upon community input.

6. **Engage with the public and Frederick's Emergency Management and Public Health officials about response plans in case of emergency.**

   Action: June 2011. Held community forum with Emergency Management, first responder, public health and police officials. Submitted questions to officials in preparation for forum. *See CLCAC website and Appendix 2, note 11 for link.*

Appendix 2:

Links to CLCAC website information cited in this report:

1. CLCAC Members and Bios: http://www.cityoffrederick.com/cms/page/index.php?id=562

2. Containment Laboratory Community Advisory Committee website:
   http://www.cityoffrederick.com/cms/page/index.php?id=547

3. Emergency Preparedness forum announcement:
   http://www.cityoffrederick.com/cms/files/commissions/clcac/EmergencyPlanningflyer.pdf
   Questions: http://www.cityoffrederick.com/cms/files/commissions/clcac/clcacquestions6-14.pdf

4. Comments and feedback to the National Research Council on their assistance to the Army on the risk assessment process for the Medical Countermeasures Test and Evaluation Facility: :
   http://www.cityoffrederick.com/cms/files/commissions/clcac/TestimonyNRC.pdf and
   http://www.cityoffrederick.com/cms/files/commissions/clcac/riskscenariosFeedback.pdf

5. Follow-up questions to USAMRIID about mishaps and design standards for tornados.
   USAMRIID responses: http://www.cityoffrederick.com/cms/files/commissions/clcac/USAMRIIDinfo5-20.pdf
   http://www.cityoffrederick.com/cms/files/commissions/clcac/usamriidAugustreply.pdf
   http://www.cityoffrederick.com/cms/files/commissions/clcac/USAMRIIDBuildingCodeResponse.pdf
   http://www.cityoffrederick.com/cms/files/commissions/clcac/USAMRIIDMishappiechart.pdf

6. Frederick County Emergency Preparedness website:
   http://www.frederickcountymd.gov/index.aspx?NID=4541

7. State of Maryland regulations on Select Agents:
   http://dhmh.maryland.gov/labs/pdf/Terrorism/BAR_FAQs_(2010).pdf

8. Sample questions for laboratories:
   http://www.cityoffrederick.com/cms/files/commissions/clcac/QuestionsLabsSept2011.pdf

9. National Research Council 2010 USAMRIID Safety Study report: http://www.nap.edu/catalog.php?record_id=12871#description

10. CLCAC by-laws: http://www.cityoffrederick.com/cms/files/public/CLCACby-laws.pdf

11. Questions for Emergency Management Forum:
    http://www.cityoffrederick.com/cms/files/commissions/clcac/clcacquestions6-14.pdf

Key Definitions:

Containment laboratory: *see CLCAC website and this link*
http://www.niaid.nih.gov/topics/biodefenserelated/biodefense/publicmedia/pages/biolabs.aspx

Select Agent: *see this links for list of pathogens regulated as select agents*
http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html

CDC list of bioterror pathogens: http://www.bt.cdc.gov/bioterrorism/