Containment Laboratory Community Advisory Committee:
Questions for Operators of High Containment Laboratories
March 2012

National Biodefense Analysis & Countermeasures Center Responses:

1. What is this institution's mission?

The National Biodefense Analysis and Countermeasures Center (NBACC) mission is to provide the nation with the scientific basis for characterization of biological threats and bioforensic analysis to support attribution of their use against the American public.

2. What research are you conducting? How much of the research is considered dual-use?

NBACC's National Bioforensic Analysis Center (NBFAC) conducts bioforensic analysis of evidence from a bio-crime or terrorist attack to attain a "biological fingerprint" to identify perpetrators and determine the origin and method of attack. NBFAC is designated by Presidential Directive to be the lead federal facility to conduct and facilitate the technical forensic analysis and interpretation of materials recovered following a biological attack in support of the appropriate lead federal agency.

NBACC's National Biological Threat Characterization Center (NBTCC) conducts studies and laboratory experiments to fill in information gaps to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of countermeasures such as detectors, drugs, vaccines, and decontamination technologies.

All NBACC Research & Development (R&D) projects receive an independent review for compliance with the Biological and Toxins Weapons convention (BTWC) by a policy-level committee at the Department of Homeland Security (DHS) prior to initiation of work. The NBACC Institutional Safety and Biosecurity Committee (ISBC) also evaluates studies for potential dual use issues prior to the approval and initiation of the research. Finally, NBACC and DHS diligently evaluate all scientific reports and manuscripts before publication to guard against inadvertent disclosure of information that would enable malevolent use.

3. What pathogens do you/will you work with?

NBACC can work with a range of risk group 2, 3, and 4 agents, including select agents, as well as other pathogens and toxins that might be used in biocrime or bioterrorism. Potential pathogens to be worked with at the NBACC are listed in section VIII of the Biosafety in Microbiological and Biomedical Laboratories, 5th edition (BMBL). This resource is produced by the CDC and is available at http://www.cdc.gov/biosafety/publications/bmbl5/index.htm.

4. How large is this facility, i.e., square footage of BSL-3 and square footage of BSL-4?

The BSL-4 labs occupy 10,500 square feet and BSL-3 labs occupy 34,000 square feet.

5. How many people will work in the lab?

NBACC has approximately 150 employees, including scientists and administrative and scientific support staff.

6. Who runs the labs? Who does the contractor report to in the federal sector?

The NBACC is managed and operated as a Federally Funded Research and Development Center (FFRDC) by the Battelle National Biodefense Institute, LLC (BNBI), for the US Department of Homeland Security.

7. Will you conduct any classified research?

Yes. Some NBACC projects produce or are derived from information that is sensitive and therefore has restricted distribution.

8. Who decides what research you will conduct?

The NBACC annual research portfolio is determined by DHS and other Federal sponsors.

9. What is the status of the new building? When will the building go hot? What were the issues with the building that delayed its commissioning and what is being done to address them?

On January 13, 2010, DHS transitioned operational control and management of the NBACC laboratory facility to BNBI. An "endurance testing" program was immediately implemented to demonstrate the functionality of the building, adequacy of operating procedures/protocols, and readiness of facility staff. Administrative activities and R&D that do not use biological select agents and toxins (BSAT) began in the spring of 2010.

At the end of FY2010, issues were identified with the NBACC laboratory vent and drain piping and remediation was implemented. In April 2011, NBACC requested that the select agent program offices at Centers for Disease Control and Prevention (CDC) and US Department of Agriculture (USDA) – Animal and Plant Health Inspection Service (APHIS) register NBACC for BSAT R&D. On September 21, 2011, NBACC was officially registered with the select agent program offices. This registration is for BSL-2, BSL-3, and BSL-4 activities. BSL-3 and BSL-4 activities began in November 2011 in the BSL-4 spaces.

Remediation of the BSL-3 part of the facility continues with an expected registration request to CDC/USDA-APHIS in 2012 for these spaces. Full facility lab utilization is anticipated by early 2013.

10. How do you coordinate with the other labs on the National Interagency Biodefense Campus (NIBC) re: potential accidents, events or emergencies?

In the event of an emergency, the affected NIBC partner would contact the U.S. Army Garrison, which would respond with needed resources. The Garrison functions as a hub to coordinate among all NIBC partners.

Routine collaboration among partner agencies is maintained via twice monthly meetings of the Fort Detrick Interagency Coordinating Committee (FDICC). Among the activities of the Coordinating Committee are emergency response drills and tabletop exercises to test incident response activities. The

NBACC Laboratory Director serves on the FDICC and various NBACC managers and subject matter experts support communications and cooperative efforts with other NIBC labs and the U.S. Army Garrison.

11. How do your biosecurity, biosafety and personnel reliability programs differ from USAMRIID's?

The biosecurity, biosafety, and personnel reliability programs at USAMRIID and NBACC are built on the same basic principles. The two organizations (as well as other NIBC organizations) share information on these programs in order to customize procedures to best support each facility and science mission. Best practices for safe handling of infectious agents and toxins (biosafety) are detailed in the BMBL, 5th edition. The BMBL also includes a discussion of biosecurity in high-containment settings.

The NBACC Health and Safety Office directs and implements the biosafety and biosecurity programs on site at the NBACC. Biosecurity and the Personnel Reliability Program (PRP) are part of the NBACC's overall risk management approach. Personnel reliability includes: medical clearance; background investigation; Department of Justice clearance under 42 CFR 73; and a personal interview with the NBACC Certifying Official. The personnel reliability checks are a continual evaluation process with new information reviewed by the Certifying Official as it becomes available.

12. What are your memoranda of understanding with Fort Detrick, city and county hospital vis a vis emergency preparedness?

Under established agreements, all tenants at the Fort Detrick installation receive fire, police, and hazardous materials assistance from the U.S. Army Garrison as needed in the event of an emergency. In addition, the U.S. Army Garrison has formal agreements in place with the City of Frederick and Frederick County for additional emergency support if needed.

Furthermore, NBACC has a Memorandum of Agreement with Frederick Memorial Hospital, Frederick County, MD. Among points of agreement is the willingness of the hospital to provide emergency care to ill or injured NBACC workers who require critical care. For example, if a worker suffers a heart attack while working in the high-containment lab, emergency care will be provided by the hospital.

NBACC is also a party to a Memorandum of Understanding with the Special Clinical Studies Unit (SCSU) at the National Institutes of Health campus in Bethesda MD.

13. Who do officials call to get health and safety-related information? Who does the Frederick Public Health Department call with questions?

We have established direct lines of communication between the Emergency Manager for the NBACC and officials with the Frederick Public Health Department (FPHD). In the event of an incident or emergency, the U.S. Army Garrison, NBACC, and FPHD officials will be in communication as needed to address the incident.

General inquiries about the NBACC from the media, the general public or local officials should be directed to NBACC at questions@nbacc.net.

14. Who decides when a worker may need to be quarantined or treated? Who else is that decision coordinated with?

If a worker is exposed to an infectious agent, a decision regarding whether to admit the worker to the Special Clinical Studies Unit (SCSU) at the NIH Clinical Center will involve the Emergency Manager, the NBACC medical authority, infectious disease experts at NIH, SCSU management, and the worker.

15. Where would infected workers be treated? How do they get there?

If it is determined that an exposed worker requires admission for further observation or treatment, he or she would be securely transported in a specially equipped isolation ambulance (owned by the U.S. Army Garrison) from the NBACC to the SCSU in Bethesda, MD.

16. In case of accident, incident or emergency what triggers public notification? When is the public notified and by whom?

In the event of an accident or emergency, NBACC would immediately notify the U.S. Army Garrison, which would activate appropriate emergency response personnel and also alert Frederick area emergency responders as needed.

The public at large is notified about emergencies that have occurred at Fort Detrick by the U.S. Army Garrison command.

17. How often do your institutional biosafety committees meet; who generally serves on them, i.e. from what internal and external organizations?

The NBACC Institutional Biosafety Committee (IBC) meets monthly at NBACC. The committee includes representatives from the general public. Meeting minutes are available at: http://www.bnbi.org/ibc.html.

18. What is your external safety review program and who does the reviewing?

NBACC's Health and Safety Office has day-to-day, continuous oversight of the NBACC building and laboratories and insures compliance with all applicable regulations, including engineering and operational controls required by the CDC's Division of Select Agents and Toxins, the USDA-APHIS, and DHS. NBACC is inspected by CDC and USDA-APHIS on a periodic basis.

The DHS Science & Technology Directorate's Office of National Labs provides continuous and ongoing oversight of the safety, security, and compliance of NBACC's operations. DHS's Regulatory Compliance Office (RCO) provides supplemental oversight of DHS-funded biological research operations, including at NBACC; DHS RCO's oversight is often conducted in coordination with the CDC's inspections.

NBACC also maintains internal independent oversight through an Institutional Biosafety Committee, Institutional Animal Care and Use Committee, and Institutional Safety and Biosecurity Committee.

The NBACC management and operations contractor, BNBI, is overseen by a Board of Directors. The Board's Operations Committee provides regular (approximately quarterly) oversight of NBACC operational processes and performance.

19. From NBACC's perspective, how specifically do you coordinate on community health and safety and emergency preparedness with the rest of NIBC? How does the management structure interface with the rest of NIBC and the garrison?

NBACC leadership and staff are an active presence on Fort Detrick, within the National Interagency Confederation for Biological Research (NICBR), and on the National Interagency Biodefense Campus. The Laboratory Director serves as the NBACC member on the Fort Detrick Interagency Coordinating Committee. The NBACC Communications Director represents NBACC at the Fort Detrick Community Liaison Committee. Various NBACC managers and subject matter experts support collaborative efforts with other NIBC labs and the U.S. Army Garrison.

As part of the Fort Detrick community, NBACC leadership and staff are contributing members—attending regularly scheduled meetings on science, facilities planning, infrastructure, public affairs, financial and business practices, educational outreach, and environmental compliance.

In addition to participation in the NIBC, the NBACC is also part of the NICBR. The NICBR was formed in 2002 to facilitate and coordinate planning, management, and scientific interactions among the agencies co-located at Fort Detrick. Among the objectives of the NICBR is the establishment of processes for coordinating and synchronizing areas of common interest among the federal agencies involved in medical research and/or biotechnology at Fort Detrick in order to encourage efficient management practices, foster scientific interchange, and maximize productivity of research and biotechnology development.