

**Workgroup for Biocontainment Laboratories Oversight
Meeting Minutes
November 14, 2012**

Attendees: CHAIR: Robert A. Myers, Director, Laboratories Administration; Jennifer Newman, Deputy Director, Administrative and Support Services, Laboratories Administration; Rita Hergenbahn, Special Assistant, Laboratories Administration; Renee Scurry, Administrator, Laboratories Administration; Jim Svrjcek, Chief, OLEPR, Laboratories Administration; Renee Webster, Assistant Director, DHMH Office of Health Care Quality; David Kaye, Vice Chair, City of Frederick Containment Laboratory Community Advisory Committee; Andrew Pekosz, Associate Professor, Johns Hopkins University, Bloomberg School of Public Health; Elizabeth Willis, Chair, The City of Frederick Maryland Containment Lab Community Advisory Committee; Kim Loll, First Alternate Representative, The City of Frederick Maryland Containment Lab Community Advisory Committee; Melissa A. Morland, Assistant Director/Biosafety Officer, UM Environmental Health and Safety; Robert Hawley, Private Biosafety Consultant, UM; Don Callahan, Staff Scientist and Biosafety Officer, BD Diagnostics System; Cristina Campbell, Compliance Hygienist, DLLR Occupational Safety and Health; and Dr. Guy Hohenhaus, State Veterinarian, MDE

Non-Workgroup Attendees: Freeda Isaac, Director, Organisms, Vectors and Select Agents, National Center of Import Export and Marcienne Wright, American Association for the Advancement of Science

Discussion and Approval of October 2, 2012 Meeting Minutes

The minutes for the October 2, 2012 Workgroup meeting were distributed and discussed to ensure accuracy of the information. The Workgroup members were also invited to submit comments, edits and/or revisions to Jennifer Newman, Deputy Director, Laboratories Administration. The minutes will thereafter be approved and published on the Biocontainment Laboratories Workgroup website.

Overview of Existing Regulations

USDA – APHIS Overview

Freeda Isaac, Director of Organisms, Vectors and Select Agents for the National Center of Import Export gave a PowerPoint presentation on APHIS (Animal and Plant Health Inspection Service) Oversight of Research Laboratories regarding the effect of high containment laboratories on plants and animals. The APHIS works to protect animal and plant health and well-being.

APHIS is comprised of several sub-agencies of which particular emphasis is placed on Animal Care, Biotechnology Regulatory Services, Plant Protection and Quarantine and Veterinary Services. APHIS also operates pursuant to a number of federal statutes including the Animal Welfare Act (which excludes livestock), Horse Protection Act, Plant Protection Act (including research on the genetic engineering of plants and inspection of research facilities, namely BSL-1, BSL-2 and occasionally BSL-3) and the Agriculture Bioterrorism Protection Act of 2002.

In an effort to protect our nation's agricultural health, APHIS works to protect animal and plant resources from agricultural pests and diseases. In addition, APHIS' role in biotechnology includes regulating the importation, interstate movement and release into the environment of genetically engineered organisms that may pose risks to plant health. Its role additionally includes regulating research facilities used for certain vertebrate animals, including those that are genetically engineered.

Finally, under the Agriculture Bioterrorism Protection Act of 2002, APHIS, through its Agriculture Select Agent Program oversees the registration of biocontainment laboratories (BSL-2, BSL-3, BSL- 4 and BSL-3Ag) that engage in the possession, use and transfer of select agents (the select agent program receives the most oversight). Registration of these facilities is based on (1) agents, (2) work being performed and (3) how well facilities are equipped for containment.

Discussion of APHIS Regulatory Authority

As a multi-faceted agency charged with protecting food, agriculture and natural resources, APHS has 100% authority over animal and plant select agents. In addition, the BMBL, 5th edition (Biosafety in Microbiological and Biomedical Laboratories), is used as a guideline to determine the level of each select agent biocontainment lab (e.g. BSL-2, BSL-3 etc.) Other than the BMBL, there is no additional reference which can be utilized to identify the levels of select agent biocontainment labs, which poses a potential "gap" in regulatory authority.

With regard to animal and plant biocontainment laboratory construction, the BMBL is also a suitable reference, but it is not a guide for facility construction. Biocontainment laboratories rely on APHIS for guidance on how to build biocontainment facilities. Laboratories are additionally instructed to refer to the Agricultural Research Service (ARS) for additional guidelines. Further instruction is also available through Tradeline, Inc., an organization which provides information resources on the construction of highly technical facilities.

However, with regard to approval for construction of select agent biocontainment laboratories, there are no adequate guidelines or industry standards for these labs, which is a public concern. NIH guidelines are used as a best practice, but only required if the lab is federally funded.

A permitting authority is additionally needed to regulate biocontainment laboratories. There is permitting for non-select agent laboratories and required inspections, but they are not intense. Permitting would also cover interstate movement as well. Interstate trade labs are currently inspected and the agents and source of agents dictate the inspections. However, laboratories trading in State are not required to disclose their trading activity and as a result, they may not be regulated appropriately.

Finally, with reference to oversight of decommissioning and decontamination of biocontainment laboratories, minimal effort is generally exercised (even though the CDC requires decommissioning of biocontainment select agent programs). Biocontainment laboratories are additionally required to take an inventory before and after laboratory operations cease, but these facilities are not required to be decontaminated for infectious agents when they are vacated.

In recent years, a group of international associations have collaborated to identify innovative approaches to biosafety and to raise awareness on the benefits and best practices in the industry. They also work collectively to address gaps in regulatory oversight and to facilitate collaboration among international biosafety communities.

Federal Regulations Overview

Marcienne Wright, Science and Technology Policy Fellow for the American Association for the Advancement of Science (AAAS) gave an overview of Federal regulations, Guidelines and Policies Governing Biosafety and Biocontainment in High Containment Laboratories. AAAS is an international non-profit organization that is dedicated to the global advancement of science.

Dr. Wright provided a PowerPoint presentation on the (1) history of the issue with the Federal Government, (2) What the Trans-Federal Task Force Determined, (3) Existing Federal Oversight, and (4) Industry Best Practices and an International Model. Her presentation, which is outlined below, was predicated on inquiries regarding the total number of BSL-3 and BSL-4 laboratories currently operating in the United States, the level of federal oversight and whether biosafety laboratories are secure.

In a 2007 report, the Government Accountability Office (GAO) noted that no federal agency is accountable for tracking the total number of BSL-3 and BSL-4 labs (excluding BSL-4 select agent labs) in the United States. In addition, no federal agency is responsible for determining the risk relative to expanding the number of high containment labs.

As a result, the U.S. Department of Health and Human Services and the United States Department of Agriculture chaired the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight. The Trans-Federal Task Force reviewed existing oversight measures and determined that there were multiple, complementary and occasional overlapping biosafety requirements between institutional and the Municipal, State and Federal governments. Therefore, the Task Force recommended that all high and maximum containment research facilities in the United States should be entered into a registry, and short and long term steps should be explored to address gaps in biosafety and biocontainment oversight.

Currently, the existing federal regulations and standards that are leading authorities in the area of biosafety are as follows:

1. The BMBL (Biosafety in Microbiological and Biomedical Laboratories), 5th Edition are utilized as the code of practice for biosafety safe handling and containment of infectious microorganisms and hazardous biological materials.
2. The Centers for Disease Control (CDC) in partnership with the National Institutes of Health (NIH) provide guidelines to protect workers and to prevent exposures in biological laboratories.
3. The Occupational Health and Safety General Duty Clause and other relevant standards are used as guidelines for inspections where there are no applicable standards relative to the hazards involved.
4. Select agent regulations are additionally in effect which require facilities to register with the CDC, USDA and APHIS to receive full authorization for access to select agents.

5. Finally, the Department of Transportation, Department of Commerce, Environmental Protection Agency and the Food and Drug Administration provide guidelines for classifying infectious substances for intra and inter-state transportation. The working relationship between sender, carrier and receiver is also monitored to provide for the safe transport of these materials.

As for industry best practices (which are designed to prevent the misuse of biocontainment materials), guidelines have been established by:

1. The Clinical Laboratory Standards Institute – Protection of Laboratory Workers from Occupationally Acquired Infections
2. European Committee for Standardisation – Biorisk Management “Standard”
3. International organization for Standardisation (ISO) – Laboratory Quality Assurance and Medical Laboratory Safety Standards
4. Canadian Human Pathogens and Toxins Act (2009) – Model of a National Registry System

Discussion – Gaps in Existing Regulations

During the discussion, the following list of gaps in the existing regulations was generated:

1. Lack of construction guidelines; commissioning, re-commissioning and decommissioning
2. Private research, or bio-technology BSL-3 laboratories that do not receive federal funding (e.g. NIH, DoD). The NIH guidelines and other non-select agent federal biosafety regulatory oversight programs (e.g. DoD) might not apply to them.
3. BSL-3 Laboratories that already possess non-select agent pathogens and do not ship these pathogens across state lines would not be required to have a USDA permit and thus be could be unregulated.

Relative to identification, biocontainment laboratories that are not in the select agent program and are not receiving federal funding are difficult to identify. Further, it is difficult to determine the specific agents laboratories are working with. It is also difficult to determine if these labs are performing in accordance with their design and proper guidelines. However, self-identification is one approach that can be considered. Although this method depends upon the labs willingness to provide accurate and timely information, it is an avenue towards locating and identifying the non-regulated or under-regulated BSL-3 biocontainment labs. In addition, certified vendors may be able to provide assistance with identifying private BSL-3 labs.

It is also imperative to determine the risks that private BSL-3 laboratories pose to the community, i.e. lab acquired infections that are transmitted via air. These are primarily facilities that are (1) not NIH funded, (2) do not have select agents and (3) do not engage in Department of Defense (DoD) work. The issue is further exacerbated by the lack of CLIA and State regulations to address design or air handling (as CLIA and State regulations are particularly geared for physician operating labs).

Discussion - Roadmap

The meeting scheduled for January 9, 2013 will focus on the issue of mitigating risks to the community. Don Callahan, Staff Scientist and Biosafety Officer for BD Diagnostics System will provide an overview on the “History of Lab Acquired Infections and Lab Risk Releases.”

The Workgroup will also work to devise a questionnaire that can be used to potentially identify private BSL-3 biocontainment facilities. Next meeting will include discussion around incentivizing self-declaration.

Next meeting will also include discussion about types of hazard, how to assess the real risk of these hazards, and how to mitigate that risk.