

**Biological Safety Training Programs as a Component of Personnel
Reliability**

Workshop Report

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Acknowledgements

This workshop was funded by the Bureau of International Security and Nonproliferation at the U.S. Department of State. We would like to thank the speakers and participants of the workshop who not only provided valuable discussion but also contributed to the workshop report. We want to especially thank Susan Piguet from the Frontline Foundation, who was invaluable during the organization of the workshop, and Gigi Kwik Gronvall, Ph.D. (Center for Biosecurity of UPMC), Paul Meechan, Ph.D. (Merck and Co., Inc.), and Julie Fischer, Ph.D. (Stimson Center) who all provided valuable comments on the draft report. AAAS would also like to acknowledge Mary Kate Mohlman, Vivian Cheng, Meghan Cunningham, Stephanie Heath, Cristina Kapustij, Janet Kim and Idalia Yabe for their valued efforts as AAAS interns in identifying biosafety training programs.

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Printed in the United States
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American Association for the
Advancement of Science
1200 New York Avenue, NW
Washington, DC 20005

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Executive Summary

The revelation in 2007 of an initially unreported incident from 2006 at Texas A&M University, in which a laboratory researcher was accidentally infected with *Brucella*, a pathogen that infects both humans and animals, and which was formerly weaponized by the Soviet Union, spurred a series of inquiries by Congress and the Executive Branch. Their focus was on the safety regulations and physical security of high-containment laboratories working on select agents (pathogens and toxins itemized by the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) that pose significant risks to human, animal, and/or plant health organizations (42 CFR 73)). By February 2009, 336 entities were registered with the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS) to work with select agents, and 14,612 laboratory researchers and support staff were registered to work with these agents. Along with the expansion of biodefense research on select agents and high-containment laboratories to accommodate that research came increased concern about pathogen security and laboratory safety. To address this concern, HHS established the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight to consider oversight of research conducted in high-containment laboratories, including but not limited to certification and training of scientists and appropriate non-scientists on biosafety. In 2008, the Commission on the Prevention for WMD Proliferation and Terrorism recommended in its report, *World at Risk*, that biosafety training for all life scientists should be mandatory. With the allegation against Bruce Ivins, a researcher at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the U.S. government became concerned about the “insider threat” and vetting personnel seeking access to select agents, termed “personnel reliability.” In January 2009, President George W. Bush issued an Executive Order (EO 13486), which called for an interagency review of laboratory biosecurity, including personnel reliability. Biosafety training is a cornerstone to preparing anyone entering a high-containment laboratory, and biosafety professionals generally act as gate-keepers to those laboratories.

Two units of AAAS—the Center for Science, Technology and Security Policy and the Program on Scientific Freedom, Responsibility and Law – have conducted a study of existing biosafety training programs. The **goals** of this study were:

- to document and describe existing educational programs and materials on biosafety training programs (information provided by course instructors);
- to provide recommendations for developing an educational program on biosafety; and
- to highlight major challenges in developing and implementing educational initiatives on biosafety and access to high-containment laboratories.

To address these goals, we convened a group of experts in biosafety, the life sciences, biosecurity, and relevant stakeholders (e.g., architects and engineers), on March 17, 2009 at AAAS to review biosafety training programs and to provide recommendations on how

best to design and implement similar programs. With the help of workshop participants, we identified twenty biosafety training programs (See Table).

This workshop is one of four workshops on biosecurity education; the first workshop, held on November 21, 2008, addressed education on dual use research for scientists, and the next two workshops will address public health preparedness and biodefense policy.

Workshop Summary

At the workshop, participants discussed similarities and differences in infrastructure, oversight and personnel training between biosafety level 3 (BSL-3) and biosafety level 4 (BSL-4) laboratories. There was clear consensus among the participants that hands-on proficiency training, mentorship, and didactic training are critical for establishing and evaluating the researcher's ability to work in a high-containment laboratory; a variety of individuals, from researchers to administrators and support staff to equipment service personnel, require some level of training before gaining access to high-containment laboratories; biosafety training programs have to be flexible to account for the research (one size does not fit all), model systems,¹ facilities, and job function; and the average cost of personnel training varies from \$4000-\$7000 for researchers to hundreds of dollars to \$4000 for training non-scientists, like administrators. There were differing views on the validity of programs on personnel reliability and the need for additional high-containment facilities. In addition, participants noted that there is a wide variation of appropriate levels of protective equipment depending on the risks of the research conducted.

Workshop participants identified several gaps and challenges in designing and implementing biosafety training programs and building trust between the scientific community and the public (including policymakers):

- There is a need to conduct applied biosafety research, which includes efficacy of personal protective equipment and determining the actual risk to the researcher and environment posed by working with a biological agent in modern biocontainment laboratories.
- There is a need to determine the total number hours worked in high-containment laboratories (the common denominator) to quantify the risks of research conducted in those laboratories to personnel and the surrounding community and environment.
- There is a need for databases of personnel information to help administrative staff track personnel training, potential exposures, and any health issues that may affect prevention or treatment against the agents being researched.

¹ "Model systems" refer to the biological systems used to examine a biological question. Model systems are typically small animals (rats, mice, guinea pigs, amphibians, etc.), large animal (non-human primates, cows, etc.), yeast, bacteria, fruit flies, mammalian cells, etc.

- There is a need for a national anonymous database, accessible by research institutions, to catalogue possible exposures and how they were handled.
- There is a shortage of knowledgeable and skilled facility and equipment operators and service professionals who can and are allowed to work in high-containment laboratories.
- There is a need to establish and sustain good training and confidential reporting of exposures for all laboratory safety levels, from BSL-1 to BSL-4 because all biosafety levels can contain hazards.
- There is a need for standardized, performance-based core competencies for training and evaluating the readiness of individuals before granting them access to a BSL-3 or BSL-4 laboratory
- There is a need to recognize that current employment and biosafety practices in academia, independent research institutes, and private industry may already address concerns over personnel reliability and that implementation of a personnel reliability program, as employed by USAMRIID or Lawrence Livermore National Laboratory, may be too costly for the non-governmental sector.
- There is a need for rational business plans and federal funding of indirect costs for operations and maintenance of high-containment facilities.

Recommendations

Based on the workshop discussion, we formulated several recommendations for the federal government, research institutions, and scientific organizations to address different aspects of biosafety training.

1. **The U.S. government should allocate funds to research institutions for initial and ongoing biosafety training (potentially including topics of scientific integrity and biosecurity), applied biosafety research, and maintenance of high-containment laboratories.** Research institutions receiving these funds would be held accountable for their use.
 - a. Additional funds need to be provided to maintain ongoing training of laboratory personnel.
 - b. High-containment facilities should develop a business plan and the U.S. government should provide funds for indirect costs for facility operations and maintenance.
 - c. Funds should be allocated to conduct applied biosafety research to understand better how to define biosafety training and protection standards as well as emergency procedures.
2. **The biosafety community needs to create a national, anonymous database of exposures, including lessons learned, from which biosafety professionals and relevant administrative personnel can benefit.**
3. **When considering personnel reliability programs for non-governmental research institutions, the federal government should consider existing**

employment and biosafety training practices before granting access to high-containment laboratories, as they may already contribute to vetting of personnel.

A variety of audiences, from researchers to emergency response personnel, require some biosafety training before gaining access to high-containment laboratories. The training may be more rigorous for some, such as researchers, than others, such as administrators or the public. The following recommendations are framed with the acknowledgement that the training content requirements differ for personnel with different responsibilities but that anyone who might seek access to a BSL-3 or BSL-4 laboratory should be properly trained by knowledgeable trainers.

- 4. All BSL-3 and BSL-4 biosafety training programs should incorporate proficiency (i.e., competency-based) training and testing.**
- 5. Senior scientists should continually mentor their laboratory personnel to work safely in high-containment laboratories by helping them improve their laboratory skills and be aware of current biosecurity and biosafety issues.**
- 6. Research institutions should provide realistic information about the hazards that exist in the high-containment facility to emergency responders and appropriate members of their community to help guide their response(s) in an emergency.**
- 7. Programs should include performance-based training standards developed from a set of core competencies that are critical for working in high-containment laboratories.** These standards should be included in the Biosafety for Microbiological and Biomedical Laboratories manual. Standards will change over time given evolving political, health, and scientific environment and some information will be facility-specific.
- 8. Animal accreditation organizations in cooperation with scientific societies, the USDA, and HHS should develop content for large and small animal biosafety training.**
- 9. The federal government should involve researchers and biosafety professionals in reviewing and improving biosafety standards.**
- 10. Biosafety professionals should ensure that biosecurity issues along with biosafety concepts are addressed in training programs and incorporated into the conduct of hazardous research.**
- 11. Recognizing that there is a need to keep some information confidential (e.g., proprietary information or security information), research institutions and the scientific community should openly communicate with the each other,**

their occupational health providers, policymakers, and the public about the safety and security features and procedures institutions employ to protect personnel, the surrounding community, and the environment against accidental exposure to any harmful biological agents housed in high-containment laboratories. Institutions should inform local and state public health departments of the biological agents being researched in the facilities.

Report

Introduction

Since 2001, the number of high-containment laboratories has significantly increased due mainly to increased funding for biodefense research and public health capacity.² Following the anthrax attacks in 2001, the National Institute of Allergy and Infectious Diseases (NIAID) built two national BSL-4 laboratories – Galveston National Laboratory (University of Texas Medical Branch) and National Emerging Infectious Diseases Laboratory (Boston University) – and a number of regional BSL-3 laboratories to complement the increased biodefense funding on vaccine, therapeutics, and detection and diagnostic devices against select agents by NIAID, including the Research Centers of Excellence.³ The expansion of high-containment laboratories, the fear that these laboratories provide unsupervised capability to malicious actors, the revelation in 2007 of an unreported case from 2006, in which a researcher was accidentally infected with *Brucella*, and/or the Commission on the Prevention of WMD Proliferation and Terrorism (WMD Commission) report, *World at Risk*, which criticized the oversight of high-containment facilities, have resulted in several congressional hearings⁴ and proposed/enacted legislation.⁵ For example, Senators Lieberman and Collins have expressed their concerns on this issue and are currently writing a bill on laboratory biosecurity.⁶ Following the allegation against Bruce Ivins, a researcher at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), as the suspect of the 2001 anthrax attacks, the U.S. government became concerned about the “insider threat” and vetting personnel seeking access to select agents,⁷ termed “personnel reliability.” In addition, President George W. Bush released Executive Order (EO 13486) on January 9,

² Rhodes, K. *HIGH-CONTAINMENT BIOSAFETY LABORATORIES: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*. U.S. Government Accountability Office. GAO-08-108t. 2007. (See <http://www.gao.gov/new.items/d08108t.pdf>).

³ Gronvall GK, Fitzgerald J, Chamberlain A, Inglesby TV, O'Toole T. *High-containment biodefense research laboratories: meeting report and center recommendations*. *Bio Secur Bioterror*. 2007 Mar;5(1):75-85.

⁴ U.S. House of Representatives Committee on Energy and Commerce. *Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States*. 2007. (See http://energycommerce.house.gov/index.php?option=com_content&task=view&id=640&Itemid=106); U.S. Senate Homeland Security and Governmental Affairs Committee. *World at Risk: A Report from the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism*. 2008. (See <http://hsgac.senate.gov/public/index.cfm?fuseaction=Hearings.Detail&HearingID=d0d0b4c1-d1d1-4b7a-9c16-fd9af22d97e0>); U.S. House of Representatives Committee on the Armed Services. The full committee will meet to receive testimony on preventing weapons of mass destruction proliferation and terrorism. 2009. (See http://armedservices.house.gov/hearing_information.shtml).

⁵ H.R.1225 and S. 485, *Select Agent Program and Biosafety Improvement Act*. Introduced Feb, 2009.

⁶ Senate Committee on Homeland Security and Governmental Affairs. *Senators Vow to Tighten Controls to Prevent the Release of Biological Pathogens: Based on WMD Commission Prediction of a Biological Terror Attack By 2013*. 11 Dec 2008.

⁷ Select agents are pathogens and toxins itemized by the U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) that pose significant risks to human, animal, and/or plant health (42 CFR 73).

2009,⁸ creating an interagency working group to review all U.S. policies related to laboratory biosecurity, including personnel reliability.

Many countries “construe ‘biosafety’ to include or to be synonymous with ‘biosecurity,’”⁹ thus demonstrating the lack of consistent use of these terms in the international community. The WMD Commission has recommended that biosafety concepts be taught along with biosecurity (as part of a unified “laboratory risk management” framework) to life scientists.¹⁰ In addition, the 5th Edition of the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) has a section on biosecurity.¹¹ The World Health Organization (WHO) defines laboratory biosecurity as “protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release,” and laboratory biosafety as “the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release”¹² (Figure 1). Despite these two distinct definitions, some of the physical barriers applied to high-containment laboratories to prevent accidental release of hazardous biological agents into the environment (biosafety function) can also serve to prevent unauthorized access to those agents. Currently, however, biosafety and biosecurity measures have discordant regulatory frameworks, receive different political attention, and propagate different norms and values, all of which have to be resolved before the mutual benefit of biosafety and biosecurity measures is realized. Current concerns over minimizing the “insider threat” have fuelled policy discussions on personnel reliability (vetting of individuals seeking access to high-containment laboratories and select agents). Personnel reliability contributes to both biosafety and biosecurity (Figure 1). Below is an introduction to biosecurity, personnel reliability, and biosafety. This is followed by a detailed description of a workshop convened by AAAS on biosafety training programs, which is a critical component of any potential personnel reliability program.

Biosecurity: Select Agent Program

In February 2009, 336 entities¹³ were registered with the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS) to work with select agents, and 14,612 laboratory researchers and others individuals were

⁸ President George W. Bush, *Strengthening Laboratory Biosecurity in the United States*. Executive Order 13486. 2009. (See <http://edocket.access.gpo.gov/2009/pdf/E9-818.pdf>).

⁹ Saleno, RM and Koelm, JG. *Biological Laboratory and Transportation Security and the Biological Weapons Convention*. Sandia National Laboratories Report 2002-1067P, 2002.

¹⁰ Commission on the Prevention of the Weapons of Mass Destruction Proliferation and Terrorism. *World At Risk*. Dec 2008. (See <http://www.preventwmd.org/report/>).

¹¹ For the entire manual, visit http://www.cdc.gov/OD/ohs/biosfty/bmb15/BMBL_5th_Edition.pdf. To view the section on biosecurity, see <http://www.cdc.gov/OD/ohs/biosfty/bmb15/sections/SectionVI-PrinciplesofLaboratoryBiosafety.pdf>.

¹² WHO, *Laboratory Biosafety Manual, 3rd Edition*, 2004. (See <http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf>).

¹³ “Entities” refers to government and non-government research institutions, academia, industry, and public health facilities.

registered to work with these agents.¹⁴ The select agent list contains 82 biological pathogens and toxins that could potentially be used to intentionally harm human, animal or plant health.¹⁵ Nearly all of the agents on the list are global health threats and some of these agents have been previously weaponized in state-sponsored biological weapons programs or deemed priority threats by the U.S. Department of Homeland Security (DHS). The Select Agent Program (SAP) was created by the Antiterrorism and Effective Death Penalty Act of 1996 after a member of the Aryan Nations attempted to obtain *Yersinia pestis* (the causative agent of plague). The statute restricted the transfer of dangerous biological agents to prevent bioterrorism and protect public safety while not hindering research on these agents. The program was subsequently expanded after the 2001 anthrax attacks with the USA PATRIOT Act and the Public Health Safety and Bioterrorism Preparedness Act of 2002 (Bioterrorism Preparedness Act). Together, they increased the restrictions on who could possess select agents. The Bioterrorism Preparedness Act also established an approval process for laboratory personnel by the Attorney General that incorporates a background check by the Department of Justice. On February 20, 2009, Senators Kennedy and Burr and Representatives Harmon and Rogers introduced the Select Agent and Biosafety Improvement Act (H.R. 1225 and S. 485). This bill attempts to address current concerns regarding the use of synthetic biology to create novel pathogens by revising the statutory language for the SAP to include novel biological agents as well as concerns regarding laboratory biosafety and biosecurity by including various measures to improve laboratory biosafety and reporting.

Biosafety: High-Containment Laboratories

High-containment laboratories, which refer to biosafety level 3 and 4 (BSL-3 and BSL-4) laboratories in the United States, are designed based on guidelines from the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) guidelines, which were developed by the CDC and National Institutes of Health (NIH).¹⁶ In addition to facility design, the BMBL provides guidelines for personnel protection and training and categorizes biological agents and experimental uses appropriate for each of four biosafety levels. The lowest level, biosafety level 1 (BSL-1), includes research “involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment.” Biosafety level 2 (BSL-2) includes “work involving agents that pose moderate hazards to personnel and the environment.” Biosafety level 3 (BSL-3) “is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation route exposure,” and requires that laboratory personnel receive specific training in handling pathogenic and potentially lethal agents, and be supervised by scientists competent in handling infectious agents and associated procedures. Biosafety level 4 (BSL-4), the highest level, “is required for work with dangerous and

¹⁴ Select Agent Program and Biosecurity Improvement Act of 2009 (H.R. 1225 and S. 485).

¹⁵ Select Agent Program and Biosecurity Improvement Act of 2009 (H.R. 1225 and S. 485).

¹⁶ U.S. Centers for Disease Control and Prevention and National Institutes of Health. *Biosafety in Microbiological and Biomedical Laboratories*, 5th Edition. 2007. (See <http://www.cdc.gov/OD/ohs/biosfty/bmb15/bmb15toc.htm>).

exotic agents that pose a high individual risk of life-threatening disease, aerosol transmission, or related agent with unknown risk of transmission.”¹⁷ While the BMBL is a set of guidelines, it has been used as contractual requirements in grants and contracts for work with agents requiring higher containment laboratories. The BMBL is also used as the basis by which CDC and APHIS conduct facility inspections and enforce the select agent regulations. The World Health Organization (WHO) publishes the *Laboratory Biosafety Manual*, which includes safety recommendations similar to the BMBL.¹⁸

According to the BMBL, research on some select agents, such as *Bacillus anthracis* (the causative agent of anthrax), can be safely done in BSL-2 laboratories when working with diagnostic amounts of the agent. In addition, research on hazardous public health threats, like tuberculosis, is done in BSL-3 or BSL-4 laboratories because they are serious health hazards and pose some risk of transmission. Small animal vivariums and large animal high-containment laboratories are currently being used for research on human and animal biological agents.

Laboratories considered BSL-3 and BSL-4 are referred to as “high-containment.” High-containment laboratories are used to protect laboratory workers and the environment from accidental exposure to pathogens studied in those laboratories; they are not a security facility as presumed by many from the traditional arms control community. Research with pathogens and toxins not on the select agent list but that require greater protection from accidental exposure is conducted in BSL-3 or BSL-4 laboratories. In the US, research on the most dangerous pathogens, like Ebola virus, is conducted in BSL-4 facilities where personnel wear positive pressure full body suits. Research on harmful pathogens that are highly concentrated (e.g., Human Immunodeficiency Virus or *B. anthracis*) or can be aerosolized (e.g., *Mycobacterium tuberculosis* and *B. anthracis*) are conducted in BSL-3 facilities. To work in a BSL-3 laboratory, personnel are required to don personal protective equipment, which can include gowns, face and eye protection (masks, goggles, face shield, etc.), thicker and/or multiple gloves, shoe covers, and possibly respirators. Many of the safety features recommended in the BMBL can serve biosecurity purposes by imposing physical barriers between the laboratories and the outside community, including restricted access and anterooms for wearing or removing personal protective equipment. Most high-containment laboratories do not have armed guards, but for those that do, they are stationed mainly to protect the facility, research, and laboratory personnel against animal rights activists who have interrupted research and destroyed property in research laboratories.

Most high-containment laboratories have oversight mechanisms in place; oversight bodies can include the institution itself (i.e., internal oversight) and the local, state, and/or federal government. All BSL-4 laboratories are thought to be registered with the CDC because all house select agents. BSL-3 laboratories utilizing federal funds must be

¹⁷ CDC and NIH. *Biosafety in Microbiological and Biomedical Laboratories*, 5th Edition. (See <http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>).

¹⁸ WHO, *Laboratory Biosafety Manual*, 3rd Edition, 2004. (See <http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf>).

registered with the CDC if work with select agents is conducted in those facilities; BSL-3 facilities not housing select agents are not registered with the CDC. The DHS Plum Island Animal Research Center has BSL-3/BSL-3Ag capabilities.¹⁹ The following paragraphs describe the oversight mechanism of BSL-3 and/or BSL-4 laboratories for private industry, research institutions,²⁰ academia, and diagnostics.

Private pharmaceutical and biotechnology industries largely do not have many high-containment laboratories. There are no BSL-4 laboratories in this sector in the U.S. The production facilities and QA laboratories in the U.S. pharmaceutical and biotech industry (BSL-2 or BSL-3) are regulated by the Food and Drug Administration (FDA) for compliance with good laboratory practice (GLP) and good manufacturing practice (GMP) because they produce products for human consumption. Many, but not all of the research laboratories are also regulated under GLP. In addition, the veterinary vaccine and drug industry is jointly regulated by the FDA and APHIS. Companies working with animal models may also be accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International. Internal audits of research and laboratory capacity are routinely conducted in private industry as part of their business management practices. All materials from an abandoned research project are destroyed at the company's discretion.

Independent research institutions and academia not only have internal inspections, but they are also inspected externally by a number of federal agencies whose missions are environmental safety, worker protection, or security, if applicable. Examples of external review bodies include DHS, CDC, the Department of Defense (DoD), the Department of Transportation (DoT), the Federal Aviation Administration (FAA), USDA, the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), NIH, and state departments of health. Institutions conducting research with animal models may also be accredited by AAALAC.

Public health laboratories serve a distinct function from research-oriented institutions. Nearly all public health facilities, including some research hospitals, have a BSL-3 laboratory or biological safety cabinet to prevent accidental exposure to the laboratory worker and environment from common disease causing agents, like *M. tuberculosis*. Since hospital and public health laboratories are at the forefront of disease detection, they must have the capacity to handle and detect known or unknown (novel) biological agents. In general, the public health system is overseen by the CDC, USDA, OSHA, National Institute for Occupational Safety and Health

¹⁹ The DHS Plum Island Animal Disease Center, which has a BSL-3/BSL-3Ag laboratory, is overseen by APHIS and DHS. The DHS National Bio- and Agro-Defense Facility, which is intended to replace Plum Island will have the only agricultural BSL-4 facility on the continental U.S. (See http://www.dhs.gov/xlibrary/assets/nbaf_mfr_fsm_addendum.pdf)

²⁰ "Research institutions" refer to non-academic, non-industry research facilities. Examples include, but not limited to, Lovelace Respiratory Research Institution, Midwest Research Institute, Battelle Memorial Institute, and Howard Hughes Medical Institute.

(NIOSH), and EPA. Since all public health laboratories work with clinical samples, they are all certified under Clinical Laboratory Improvement Amendments (CLIA) and are subjected to oversight similar to that for clinical research. All state public health laboratories and some local laboratories are part of the CDC's Laboratory Response Network and are therefore registered with the SAP and overseen by the CDC. Hospital laboratories are accredited by the Joint Commission.²¹ Similarly, animal²² and plant²³ diagnostic laboratories are overseen by APHIS. Food diagnostic laboratories²⁴ are managed by the USDA Food Safety and Inspection Service, HHS, FDA, and state food testing laboratories.

Before 2001, three BSL-4 laboratories existed (USAMRIID, CDC, and the NIH) where most of the research done was for public health purposes, with only a marginal focus on biodefense. These laboratories have an exemplary record for safety and security: "Most individuals who begin work in BSL-4 suites are already experienced microbiologists. Specific training for use of the positive-pressure suits and for safe execution of all procedures is standard practice at all of the laboratories. In context of current international concern regarding potential use of some of these viruses as weapons of terror, access to the facilities and to individual laboratories is carefully controlled."²⁵

After the 2001 anthrax attacks, the U.S. government greatly expanded its biodefense activities in the non-governmental research community to include research on biological threat agents, which are listed on the select agent list, and development of medical countermeasures against those agents. As a result of this expansion, an additional ten BSL-4 laboratories were built (total of 13 laboratories at 11 sites in 2008),²⁶ and 1356 BSL-3 laboratories were registered with the CDC and APHIS to work on select agents.²⁷ Many of these laboratories are part of the HHS Regional Centers of Excellence for Emerging Infections and Biodefense, the Laboratory Response Network, and the National and Regional Biocontainment Laboratories.²⁸ The two National Biocontainment Laboratories are BSL-4, and the Regional Biocontainment Laboratories are BSL-3. For agricultural pathogens, DHS has recently selected Manhattan, Kansas as the site of the new National Bio- and Agro-Defense Facility (NBAF), which will be a BSL-4 agricultural facility.

²¹ The Joint Commission is a non-profit organization that accredits and certifies health care organizations and programs in the United States. (See <http://www.jointcommission.org/>).

²² Animal diagnostic laboratories test for animal pathogens in livestock, domesticated animals and wildlife.

²³ Plant diagnostic laboratories detect plant pathogens in all plant specimens, including crops.

²⁴ Food diagnostic laboratories examine the safety, wholesomeness, and accurate labeling of food with regard to such things as adulterants, allergens, infectious diseases and parasites.

²⁵ Johnson, KM. Biosafety at BSL-4: *More than 20 years experience at Three Major Facilities*. 15 Oct 2003. (see http://www3.niaid.nih.gov/Biodefense/Public/PDF/RMLFEISappendices_F.pdf)

²⁶ Gronvall GK, Bouri N. *Biosafety Laboratories*. *Biosecur Bioterror*. Dec2008;6(4):299-307

²⁷ Rhodes, K. *HIGH-CONTAINMENT BIOSAFETY LABORATORIES: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*. U.S. Government Accountability Office. GAO-08-108t. 2007. (See <http://www.gao.gov/new.items/d08108t.pdf>).

²⁸ See http://www3.niaid.nih.gov/research/resources/dmid/NBL_RBL/site.htm.

International High-Containment Laboratories

The international scientific community works with hazardous pathogens and toxins in BSL-2, BSL-3, and BSL-4 laboratories. In 2006, Sandia National Laboratories published a report, documenting the lack of biosecurity measures and biosafety training in South and Southeast Asia as well as concerns of local scientists about the dangers of accidental infections and theft of laboratory pathogens.²⁹ Following that assessment, the Bureau of International Security and Nonproliferation at the Department of State under the Biosecurity Engagement Program started a program in Southeast Asia to improve physical security and safety of public health and research laboratories and enhance training of laboratory personnel. In addition, several nations, many of which have a thriving biotechnology research infrastructure or serious public health concerns, have high-containment laboratories.³⁰ The 2008 Biological Weapons Convention Intersessional Meeting addressed issues related to biosafety guidelines for high-containment laboratory research.³¹

Personnel Reliability

Personnel reliability programs have been used to psychologically evaluate whether an individual is sufficiently trustworthy to work with nuclear weapons and employed by the Departments of Defense and Energy. The U.S. Army's personnel reliability program (PRP) includes psychological screening prior to and throughout PRP certification as well as testing for drug use and alcohol abuse prior to PRP certification. The Lawrence Livermore National Laboratory's PRP for select agents was modified from its nuclear program and also includes psychological evaluation and testing for drug use and alcohol abuse. All U.S. citizens working with select agents at Lawrence Livermore National Laboratory have undergone a background check and have a top secret clearance, while foreign nationals working with select agents have gone through the FBI's security risk assessment (SRA).³²

²⁹ Sandia National Laboratories. A Survey of Asian Life Scientists: The State of Biosciences, Laboratory Biosecurity, and Biosafety in Asia. SAND2006-0842. Feb 2006.

³⁰ For a list of BSL-4 laboratories throughout the world, see Gronvall GK, Bouri N. *Biosafety Laboratories*. *Biosecur Bioterror*. Dec 2008;6(4):299-307.

³¹ Most of the offensive biological weapons programs ended before or at the time of the signing of the Biological and Toxin Weapons Convention (BWC) in 1972. The BWC prohibited the development, production, stockpiling, acquisition or retention of harmful biological agents "of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes" and methods for weaponization of these agents. Despite being a major signatory to the BWC, however, the Soviet Union had an extensive, covert offensive program that was revealed in the early 1990's. Subsequently, offensive programs in other nations – South Africa, Iraq and Libya – were revealed. Following the fall of the Soviet Union, the BWC focused on developing a verification protocol to enforce the articles of the treaty. While the verification protocol failed in 2001, the BWC instituted annual meetings between the review conferences to discuss important issues related to the BWC. See [http://www.unog.ch/80256EE600585943/\(httpPages\)/92CFF2CB73D4806DC12572BC00319612?OpenDocument](http://www.unog.ch/80256EE600585943/(httpPages)/92CFF2CB73D4806DC12572BC00319612?OpenDocument) for more information about the 2008 Intersessional Meeting.

³² The SRA is the method the Select Agent Program uses to determine whether an individual should be granted access to select agents, but is considered a minimum standard for evaluation by Lawrence Livermore.

With the recent allegation against Bruce Ivins, a researcher from USAMRIID, as the suspect in the 2001 anthrax attacks, the concept of personnel reliability has been suggested by the security community as a way of vetting personnel seeking to work with select agents. The National Science Advisory Board for Biosecurity (NSABB)³³ has been tasked by the White House to provide recommendations to the federal government on personnel reliability in the life sciences. The National Academies have been asked by the NIH to review personnel reliability. The interagency working group created by the Executive Order 13486³⁴ is also reviewing personnel reliability.

On April 3, 2009, the NSABB previewed their recommendations, which include using guiding principles for approving access to select agents that uphold public health, safety, security, and scientific integrity. These guiding principles include, but are not limited to, the importance of the research, personal responsibility, transparency, periodic evaluation, and training. The proposed Galveston National Laboratory personnel reliability program involves a security check for employment, pre-employment drug screening, mandatory annual training, annual attestation of users of their non-restrictive status, and a full medical examination with some psychological assessment.³⁵ Biosafety experts have suggested that a single PRP may not be sufficient for implementation and use by all sectors – government, academia, and industry. These experts also highlight the need for sufficient training of individuals conducting the PRP evaluations. These current PRP policy discussions do not appear to account for current procedures for graduate student, post-doctoral, or faculty recruitment and hiring/acceptance as well as biosafety training for access to high-containment laboratories. During the review of this report, the NSABB formally released their recommendations for personnel reliability programs.³⁶ Of greatest relevance to this report, the NSABB recommends against a formal, national personnel reliability program for select agent researchers, while supporting enhancement of existing measures and a culture of responsibility and accountability within institutions conducting select agent research.

Current Activities in Biosafety Training

HHS has set up a Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight to consider oversight of research conducted in high-containment laboratories, including but not limited to certification and training of scientists and appropriate non-

³³ The National Science Advisory Board for Biosecurity (NSABB) is a federal advisory committee within the NIH tasked to provide the U.S. government with recommendations for identifying and overseeing dual use life sciences research. The term “dual use” refers to legitimate research that could be misused for malicious purposes to harm human, animal, plant, and environmental health. (See <http://oba.od.nih.gov/biosecurity/biosecurity.html>).

³⁴ Executive Order 13486: *Laboratory Biosecurity*. Jan 2009. (See <http://edocket.access.gpo.gov/2009/pdf/E9-818.pdf>).

³⁵ Lemon, SM. *Managing Personnel Reliability at the Galveston National Laboratory, University of Texas Medical Branch*. Presentation at the 3Apr 2009 NSABB meeting.

³⁶ NSABB. *Enhancing Personnel Reliability among Individuals with Access to Select Agents*. 29 Apr 2009. See <http://oba.od.nih.gov/biosecurity/meetings/200904-2/NSABB%20Draft%20Report%20on%20PR%204-22-09.pdf>.

scientists on biosafety.³⁷ In its December 2008 report, the WMD Commission recommended that biosafety and biosecurity be combined into a unified “laboratory risk management” framework and that educational activities in this framework for life scientists should be mandatory.³⁸

Generally, laboratory personnel and anyone needing access to high-containment facilities, such as maintenance personnel, are trained by biosafety professionals in their institutions. This training generally includes a discussion of the relevant sections of the BMBL, personal protection, how to handle laboratory accidents, and reporting of and emergency response procedures to an exposure. Several train-the-trainer programs exist to educate and/or certify biosafety professionals to train biosafety concepts to laboratory personnel. Currently, the ABSA training programs, the National Biosafety and Biocontainment Training Program (NBBTP),³⁹ and the Emory University Science and Safety Training Program⁴⁰ exist to build a knowledgeable and capable workforce to train scientists on appropriate biosafety concepts.

The AAAS Project

Through its interactions with the scientific and policy communities, AAAS is uniquely qualified to help identify and assess existing biosafety training programs and to provide recommendations to research institutions, policymakers, and scientific organizations for developing and implementing such programs. Two units of AAAS - the Center for Science, Technology and Security Policy and the Program on Scientific Freedom, Responsibility and Law - have conducted a study of existing biosafety training programs. The **goals** of this study were:

- to document and describe existing educational programs and materials on biosafety training (information provided by course instructors);
- to provide recommendations for developing an educational program on biosafety; and
- to highlight major challenges in developing and implementing educational initiatives on biosafety and access to high-containment laboratories

³⁷ See <http://www.hhs.gov/aspr/omsph/biosafetytaskforce/index.html>.

³⁸ The WMD commission also recommends that federal agencies provide funds for development of educational materials. Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism. *World at Risk*. Dec 2008. (See <http://www.preventwmd.org/report/>).

³⁹ See <http://www.nbbtp.org/>.

⁴⁰ See <http://www.sph.emory.edu/CPHPR/biosafetytraining/index.html>.

Methods

We conducted a search of programs using the internet and word-of-mouth associations. The workshop described in this report is focused on biosafety training programs, twenty of which have been identified with the help of workshop participants (Table 1).

Biosafety Training Programs

We held a workshop on March 17, 2009 at AAAS headquarters in Washington, DC, with a group of experts in biosecurity, biosafety, the life sciences, and architects and engineers of biosafety laboratories to review current biosafety training programs and to discuss how well these programs address the needs of different audiences requiring varying degrees of biosafety information. The agenda, questions asked, and lists of speakers and participants are included in Appendix 1. Workshop reading material was provided in advance to each attendee.⁴¹ Government representatives from HHS (NIH Office of Biotechnology Activities and the CDC), Department of State, USDA, and USAMRIID attended the workshop. Also present were scientists from the Sandia National Laboratories.

We invited instructors to discuss their educational programs with the group, and workshop participants raised questions about the content of the programs, the level of understanding by students, the audience, and challenges of designing and implementing the program. Along with these discussions, workshop attendees were asked to consider other educational offerings before considering possible recommendations for designing and implementing biosafety training programs. International as well as U.S. education initiatives were discussed.

Workshop Summary

At the workshop, participants discussed similarities and differences in infrastructure, oversight, and personnel training between BSL-3 and BSL-4 laboratories. There was clear consensus among the participants that hands-on proficiency training, mentorship, and didactic training are critical for establishing and assessing the researcher's ability to work in a high-containment laboratory; a variety of individuals, from researchers to administrators and support staff to equipment personnel, require some level of training before gaining access to high-containment laboratories; biosafety training programs have to be flexible to account for the research, model systems,⁴² facilities, and personnel function (one size does not fit all); and the average cost of personnel training varies from \$4000-\$7000 for researchers to hundreds of dollars to \$4000 for training non-research personnel, like administrators.⁴³ There were differing views on the validity of programs

⁴¹ AAAS set up a workshop website with reading material. (See <http://cstsp.aaas.org/BiosecurityWorkshop/>).

⁴² "Model systems" refer to the biological systems used to examine a biological question. Model systems are typically small animals (rats, mice, guinea pigs, amphibians, etc.), large animal (non-human primates, cows, etc.), yeast, bacteria, fruit flies, mammalian cells, etc.

⁴³ This cost includes practicing experimental techniques and demonstrating proficiency for those techniques in appropriate personal protective equipment.

on personnel reliability and the need for additional high-containment facilities. In addition, participants noted that there is a wide variation of appropriate levels of protective equipment depending on the risks of the research conducted.

The workshop began with a panel discussion about existing U.S. government oversight of high-containment laboratories, reporting mechanisms, personnel reliability, and biosafety training. The questions posed to the panelists are included in Appendix 2.

USDA. Steven Kappes, Ph.D., Deputy Administrator of Animal Production and Protection, USDA Agricultural Research Service, and co-chair, HHS Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, informed workshop attendees that the USDA has an Institutional Biosafety Committee policy to review research with all biohazards, is accredited and certified by the AAALAC, has procedures for incident reporting, and conducts periodic employee training. Researcher training is pathogen-specific, facility-specific, and duty-specific. Dr. Kappes noted that mentorship and training modules are critical components of biosafety training. Support staff and maintenance personnel are also trained in biosafety before gaining access to BSL-3 laboratories. All training is documented.

Select Agent Program. Richard Henkel, Ph.D., Chief of Policy and Compliance, CDC Division of Select Agents and Toxins, noted that the CDC SAP inspects 2500 extramural research spaces annually. They require that biosafety training according to the 5th Edition of the BMBL (i.e., didactic and practical training) be conducted before personnel can gain access to the high-containment laboratories. This encompasses safety and security training for all laboratories, including emergency response training. The CDC evaluates the training programs when it conducts its inspections.

USAMRIID. COL John Skvorak, D.V.M., Ph.D., Commander of USAMRIID, stated that his facility has BSL-3 and BSL-3 laboratories with enhancements, such as effluent treatment, High Efficiency Particulate Air (HEPA) filtration of exhaust air and a personal wet shower upon exit from the laboratory, as well as a BSL-4 laboratory. Research personnel working with select agents are registered with the CDC's SAP, and non-scientists seeking to gain access to the laboratories are subjected to the DoD personnel reliability program. USAMRIID provides a core biosafety training program for laboratory personnel, and requires research personnel to pass a series of proficiency training to gain access to higher levels of high-containment laboratories. In addition, mentorship, one-on-one training, and protective suit training are critical components of the training program.

NBACC. Kevin Anderson, Ph.D., Acting Science Director, DHS National Biodefense Analysis Countermeasure Center (NBACC), said that the NBACC will be operational by 2010 and will house select agents. Because the NBACC Science Programs are currently being conducted at USAMRIID on Fort Detrick, all personnel are subject to Army policies. NBACC personnel have received training by USAMRIID and by the National Biosafety and Biocontainment Training Program or Emory University's

Science and Safety Training Program (both programs are discussed below). Two individuals from NBACC have undergone extensive mentored training in BSL-4 at the Special Pathogens Branch of the CDC. DHS embraces the “culture of ownership” to ensure that all research personnel assume responsibility for working safely and are mindful of security concerns and policies.

This panel ended with a discussion about reporting potential exposures.⁴⁴ USAMRIID relies on individual reporting mechanisms, whereas the CDC collects all potential exposures in a secure database but only acts on those that pose a serious threat.

Following this panel were two additional panels – one focusing on the audiences and their needs for biosafety information and training, and the other on biosafety training programs. Throughout these discussions, several common themes emerged regarding preferred training methods and unaddressed gaps. Other topics, however, elicited a variety of discordant views among participants. These are discussed below.

Audiences and Needs

There is a wide range of personnel who require access to high-containment laboratories to ensure full operation of those facilities. Content for training those personnel differs based on job function, the biological agents housed in these laboratories, the institution or facility policies and procedures, and the need for access to research facilities.

Researchers. Training programs for researchers include information specific to the institution and facility (such as responsible officials, emergency contacts and procedures, and reporting structures), biological agent or research area, experimental technique(s), and model system (such as small animals, large animals, tissue culture, crop, or non-human primates).

Animal Care Personnel. Since the U.S. follows strict animal care regulations, institution staff, such as veterinarians and animal care technicians dedicated to caring for research animals, requires access to high-containment vivariums (animal housing facilities). Researchers and animal care providers need extensive training to learn how to handle the agent(s) and infected animals safely, how to safely conduct their experiments wearing protective equipment, and what to do and who to contact in response to a potential exposure. Research performed on agricultural pathogens (both livestock and crop) in high-containment pose unique research challenges as well as personnel training challenges. These include the safe handling of large animals, appropriate containment facilities to house large animals, and disposal of large animal carcasses. Existing challenges at the BSL-3 level will be exacerbated at the BSL-4 level.

⁴⁴ Panelists discussed the problem in referring to potential “exposures” as “releases” suggesting that the term “release” connotes actual infection rather than a potential “exposure.”

Institutional Administrators. At research facilities, there are some individuals, like institutional leaders and health care professionals, who do not need access to high-containment laboratories. Yet, they need to be aware of the types of training personnel, physical barriers protecting the surrounding community and environment from biological agents housed in their laboratories, the research conducted and associated risks to the surrounding community and environment, and response procedures to a potential exposure.

Public and Community First Responders. Individuals not associated with institutions operating high-containment laboratories may need knowledge of and/or access to those facilities. Members of the surrounding community, especially emergency personnel, require knowledge of the physical barriers and level of protection that facilities in their community employ, the relative risk that the agents housed in the facility pose to the community and/or environment, and the type of administrative oversight and personnel training employed at the facility. In addition, emergency personnel need to be educated on how to perform their duties wearing personal protective equipment (PPE) and any health risks associated with the biological agents housed in the facilities. Several workshop participants noted that many emergency personnel were not willing to enter a high-containment laboratory in an emergency because they were fearful of the health risks. These concerns might be at least partially addressed by the exercises and drills that the SAP requires all registered entities to conduct with emergency response personnel.

Public Health Professionals. Although not addressed in this workshop, we should note that public health laboratories, including hospital pathology laboratories and local, state, and federal public health laboratories, have unique challenges⁴⁵ concerning biosafety training and laboratory oversight, since they are on the front-lines of disease detection. These challenges are enhanced by the shortage in the public health workforce. Some of these challenges could be easily addressed by communicating with public health officials about the biological agents housed in local high-containment laboratories and the relative risk they pose to the surrounding community.

Architect and Building Contractors. With regard to facility design and maintenance, there are few new architects in the United States designing BSL-3 and BSL-4 laboratories, suggesting that existing architects, however few in number, are sufficiently knowledgeable about how to design these laboratories. However, there are several architects designing BSL-3 laboratories in developing countries with little, if any, knowledge about high-containment laboratories. Workshop participants pointed out that while the architectural designs may facilitate good research practices, some components of the facility design may be difficult to build. This dialogue highlighted the need for architects, researchers, maintenance workers, regulatory

⁴⁵ These challenges can include agent specific training and ability to respond to an accidental (or intentional) exposure to a laboratory agent.

experts, and contractors to work together to design and build high-containment laboratories that are safe, easy to use from the researcher's perspective, easy to maintain, and feasible and cost-effective to build, maintain, and operate.

Maintenance Personnel. All facilities and equipment require maintenance, and maintenance personnel need to be trained on how to safely repair broken equipment or conduct routine maintenance wearing personal protective equipment and/or an external air source. Participants noted, however, that many equipment manufacturing companies have clauses in their contracts prohibiting their personnel from entering a BSL-3 or BSL-4 laboratory to service the equipment. Some participants indicated that there is a financial and time cost associated with preparing maintenance personnel to enter high-containment laboratories to service equipment. Participants did note, however, that new technological advances are enabling some specialized equipment to be designed to minimize the surface area in contact with biological agents or materials. This becomes especially problematic when specialized equipment is used in those laboratories. In addition, several workshop participants indicated that new BSL-3 and BSL-4 laboratories are being over-engineered because institutions are not fully aware of expected requirements and possible future research needs.

Biosafety Training Programs

All research institutions in the U.S. conduct laboratory and hazard training for personnel with access to high-containment laboratories, and do so in accordance with government regulations and guidelines. Due to the intense scrutiny of potential security threats associated with BSL-3 and BSL-4 laboratories and current policy discussions on personnel reliability, a large part of the overall workshop discussion on biosafety training programs focused on personnel training and access to high-containment laboratories. It should be noted that not all pathogens housed in BSL-3 or BSL-4 laboratories are on the select agent list. Most are, however, public health threats, and important research on the biology of these agents and methods for intervention against them may be conducted in high-containment facilities.

There was a clear consensus by workshop participants that effective biosafety training must include proficiency (i.e., competency) training and mentorship along with didactic training. Examples of proficiency training include donning PPE and learning how to perform common laboratory procedures used in one's job function or research. As individuals demonstrate their competency in performing their job function wearing PPE, they are approved for additional training and/or access to the laboratory. While several programs have developed and employed competency tasks, there are no standards for what tasks are considered part of the core competencies and how to evaluate competency in those tasks. Workshop participants supported the role of mentors in establishing and maintaining best laboratory practices. However, some participants indicated that researchers and senior leadership need to be aware of the importance of mentorship in propagating best practices in high-containment laboratories. This type of approach can, and may already, contribute to personnel reliability assessment.

Participants supported the “one size does not fit all” concept and repeatedly stated that although they may support core standards for biosafety training, ultimately the training has to be flexible. This means that training programs for access to high-containment laboratories must include information specific to the institution and facility (such as responsible officials, emergency contacts and procedures, and reporting mechanisms), biological agent or research area, experimental technique(s), model system (such as small animals, large animals, tissue culture, crop, or non-human primate), audience needs, and job function(s). The initial cost of training a researcher is about \$4000-\$7000, and the initial cost of training other audiences ranges from a few hundred dollars to \$4000, depending on the type of training required. Additional costs are associated with annual re-training of laboratory personnel. In recent years, a few train-the-trainer programs have emerged in response to the need for a dedicated workforce to train personnel in biosafety and, in some cases, biosecurity. Examples of train-the-trainer programs and a few sample institutional biosafety training programs are described below.

*Emory University.*⁴⁶ The Emory University Center for Public Health Preparedness and Research runs the Science and Safety Training Program that educates people on how to train various audiences on biosafety in BSL-2, BSL-3, and/or BSL-4 laboratories. Students of this program are trained in mock high-containment laboratories, learn skill-based training techniques, and learn how to reinforce positive behavior rather than to castigate employees to achieve good behavior (behavioral-based training). The program also conducts on-site training. Furthermore, it engages senior scientists as well as biosafety professionals to help train and mentor the program’s students. The program is five days long and includes seven exams (2 skills and 5 cognitive). In addition, the BSL-3 and BSL-4 training programs include lectures on the dual use dilemma in the life sciences.

*National Biosafety and Biocontainment Training Program.*⁴⁷ The NIH’s National Biosafety and Biocontainment Training Program (NBBTP) offers a 2-year post-graduate residency program, professional certificate programs, short courses, and global train-the-trainer programs on biosafety and is designed to build a workforce of biosafety trainers. Its curriculum content areas vary from biosecurity to public health to occupational safety and health. NBBTP offers training in 27 levels of competencies, including risk assessment and engineering and facility design. The program also trains various audiences in biosafety. NBBTP can be taken for continuing education credit.

*American Biological Safety Association.*⁴⁸ The American Biological Safety Association (ABSA) is the premier professional society for biosafety certification and has been educating and training biosafety professionals for years. ABSA offers a 40-hour course, which includes didactic and interactive learning, a review course that prepares professionals for their CBSP (certified biological safety professional)

⁴⁶ See <http://www.sph.emory.edu/CPHPR/biosafetytraining/index.html>.

⁴⁷ See <http://www.nbbtp.org/>.

⁴⁸ See <http://www.absa.org/>.

designation by examination administered by the National Registry of Certified Microbiologists (NRCM), a seminar series on biosafety, and pre-conference courses where the biosafety community examines different ways of training. ABSA has initiated a survey of biosafety training programs to identify gaps in training, content, audiences, and related areas, with a report scheduled for release in September 2009.

*Colorado State University.*⁴⁹ Colorado State University administers a training program for BSL-3 and animal BSL-3 laboratories. This training program includes a variety of topics - emergency procedures, the clinical characteristics of the agents researched in the laboratory, the select agent regulations, packaging and transferring infectious agents, and a respiratory fit test. The training course also includes biosecurity concepts and addresses unique issues with large animal, non-human primate, and plant biosafety and containment. The program can be taken for continuing education credit.

*Galveston National Laboratory.*⁵⁰ The University of Texas Medical Branch has developed a biosafety training program for BSL-3 and BSL-4 laboratories. The program combines didactic and competency training, and identifies deficiencies that must be addressed. This program is designed to foster safe behavior and does not promote punitive action to correct behavior. Personnel seeking access to BSL-3 laboratories must successfully demonstrate competency at BSL-2, and those seeking access to BSL-4 laboratories must successfully demonstrate competency at BSL-3 and animal BSL-3 (ABSL-3). The training program educates students about the agent they will be researching, and the risks involved with handling and conducting experiments with that agent. In addition, students are taught how to protect themselves and the environment, to achieve the technical competencies, and to report potential exposures. The program depends on continued mentorship in the laboratory.

*The Lovelace Respiratory Research Institute.*⁵¹ The Lovelace Respiratory Research Institute provides basic BSL-3 and ABSL-3 training on-site and at other laboratory locations. This training includes fundamental information about working safely in containment under normal working conditions and actions to take when unexpected situations arise. Laboratory personnel must pass written and observational quizzes and exams before work in containment can begin. Agent-specific training and job-specific training are required for its employees. In addition, Lovelace has identified 505 scientific skills specific for model systems and experimental procedures that could be used. Each of these skills can require a mixture of classroom, e-learning and structured on-the-job training before an employee is considered to be competent. Lovelace records the competency training in a database to track the personnel approved for specific agents and experimental procedures. The database helps identify Lovelace personnel approved to perform these procedures when planning a study or in an employee's absence. Lovelace also encourages a voluntary self-

⁴⁹ See <http://www.cvmb.colostate.edu/mip/crwad/BBTC.htm>.

⁵⁰ See <http://www.utmb.edu/gnl/safety/training.shtml>.

⁵¹ See <http://www.lrri.org/Default.aspx>.

reporting system that allow employees to opt out of conducting research on a day they do not feel well.

Non-Consensus Comments

Workshop participants identified several issues that were not uniformly supported. While researchers working on human or zoonotic pathogens⁵² were divided in their views about whether more high-containment laboratories should be built, the agriculture community and ABSA believed that more facilities are needed to facilitate research of existing and emerging pathogens to better understand and control outbreaks, as well as to accommodate the research currently being funded.

Much of the workshop discussion centered on personnel training for work in a BSL-3 laboratory. Those experienced with BSL-4 laboratories highlighted the differences in stress level and capability of working in a BSL-3 versus BSL-4 laboratory. For example, the positive pressure full-body suit required for access to BSL-4 laboratories affects the researchers' mobility and dexterity. Those working in BSL-4 laboratories must be properly trained and acclimated to those conditions in order to safely and efficiently conduct their work. In addition, the growing use of complex respiratory protection in BSL-3 laboratories is making that research environment increasingly more difficult in which to work.

While discussing standards for core competency training, workshop participants compared the merits of a standardized, core biosafety training program to an individualized program. Some participants supported the use of a training program that employed standardized, performance-based core competencies tailored to institutional, facility, and research needs. Others, however, did not believe that standardized, core programs would be useful when educating different audiences or personnel at different levels of their career (i.e., junior researcher versus senior scientist). In addition, there was disagreement among workshop participants as to the placement of the training programs – i.e., should they be part of a certification program or education curriculum? There was an unresolved discussion on how often training should occur, by whom, and for whom.

International Biosafety Climate

There were a few workshop participants who have worked with various nations on biosecurity and biosafety. Some were involved with the biological cooperative threat reduction programs in the former Soviet Union, and others contributed to the more recent U.S. initiatives on biosecurity engagement. The U.S. Department of State's Biosecurity Engagement Program has worked with Sandia National Laboratories and ABSA, among others, to improve research or public health facilities housing hazardous pathogens (those commonly researched at BSL-3 or BSL-4 in the U.S.) and biosafety training of laboratory personnel by educating individuals on how to train them. Workshop participants indicated that Singapore has an advanced set of biosafety guidelines for which there is

⁵² Zoonotic pathogens are biological agents that can infect both humans and animals.

uniform compliance, and these guidelines were recently codified.⁵³ Canada and European nations are struggling with the same problems and questions as the U.S. In many other countries, the BMBL is the key guidance document for biosafety. Participants also indicated that several countries view biosafety training differently than the U.S. Whereas the U.S. relies heavily on engineering and administrative controls (such as key card access or designation of a responsible official who may not necessarily have intimate knowledge of the research being conducted at the facility, respectively), the states of the former Soviet Union rely on mentorship for personnel training and oversight of research.

Gaps and Challenges

Workshop participants identified several gaps and challenges in designing programs in biosafety training, implementing these programs, and building trust between the scientific community and the public (including policymakers):

There is a need to conduct applied biosafety research, which includes efficacy of personal protective equipment and determining the actual risk to the researcher and environment posed by working with a biological agent in modern biocontainment laboratories.

The increase in biodefense research, construction of high-containment laboratories to accommodate this research, and the recent accidental laboratory exposures have raised concerns about safety and security associated with this research. There is a need to determine the total number hours worked in high-containment laboratories (the common denominator) to quantify the risks of research conducted in those laboratories to personnel and the surrounding community and environment. It should be noted that laboratories vary greatly by size, research activity, and use of animal models and these variables need to be taken into consideration when comparing exposure or injury rates.

Although some institutions have created public and secure databases to help administrative staff track personnel training, potential exposures, and any health issues that may affect protection or treatment against the agents being researched, there is a need to develop these types of databases at all research institutions that house hazardous biological agents. For large facilities, there may be great benefit to having integrated data resources that track personnel issues (e.g., training, vaccination, medical clearance, security clearance), laboratory requirements (e.g., agents registered, vaccinations required, personnel cleared for entry), and agent (e.g., which agent, storage, and active use). These types of resources may not be cost effective for small facilities, which could have only 2-3 researchers in one laboratory working with a single agent.

⁵³ Dejsirilert, S. *Laboratory Biosafety and Biosecurity in Thailand*.
<http://www.biosecurity.sandia.gov/subpages/pastConf/20032005/redi/thai-biosafety-singapore.pdf>

There is also a need for a national database, accessible by research institutions, to catalogue possible exposures and how they were handled. If done anonymously and without negative repercussions for reporting, such a database would promote information sharing about hazardous conditions and corrective actions among research institutions to prevent future incidents. While the CDC does have such a database, it is not available to biosafety professionals of high-containment laboratories. The Select Agent Program and Biosafety Improvement Act of 2009 (H.R.1225 and S.485) has a voluntary reporting section to address this need. A participant did note that better biosafety records are kept now than they were 50 years ago.

There is a shortage of knowledgeable and skilled facility and equipment operators and service professionals who are capable and allowed to work in high-containment laboratories. Workshop participants noted that some contracting companies or equipment manufacturers have contractual language preventing their personnel from entering a high-containment facility. This prevents knowledgeable service personnel from being able to repair essential equipment and addressing laboratory maintenance issues. Effectively communicating the safety hazards associated with the research conducted in laboratory(ies) in question could contribute greatly to improving the overall perceptions of risks of the research and promote training of non-scientist personnel.

The need to establish and sustain good training and confidential reporting of exposures for all laboratory safety levels, from BSL-1 to BSL-4, because all biosafety levels can contain hazards. The BMBL provides guidelines for facility design, personnel protection and training, and categorizes biological agents and experimental uses appropriate for each biosafety level. These guidelines are included in grant and contractual language for federally funded research and are used by the CDC and APHIS to enforce the select agent regulations.

There was clear consensus among the workshop participants that proficiency testing and mentorship were more effective training tools and evaluation methods than didactic training (e.g., computer-based training and classroom training) alone for personnel access to high-containment laboratories. Didactic training, however, can offer good fundamental knowledge-sharing opportunities that contribute to effective proficiency training and mentoring. While many programs include both proficiency (and competency) training and mentorship, there are no standardized performance-based core competencies by which to train and evaluate the readiness of individuals before granting them access to a BSL-3 or BSL-4 laboratory.

Current policy discussions of personnel reliability for preventing malicious actors or unstable personnel from accessing high-containment laboratories and hazardous pathogens have not sufficiently been resolved in the academic and private sectors. While personnel reliability programs have been effectively implemented at some government laboratories, workshop participants were skeptical of the feasibility, cost,

and efficacy of such programs implemented in academia. Alternative and more flexible personnel reliability assessments at academic institutions were discussed briefly at the April 3, 2009 NSABB meeting. Private industry spends a great deal of time evaluating and training its personnel before they gain access to research facilities, and overseeing research performed in its facilities. There is a need to recognize that current employment and biosafety practices in academia, independent research institutes, and private industry may already address concerns about personnel reliability and that implementation of a personnel reliability program, as employed by USAMRIID or Lawrence Livermore National Laboratory, may be too costly for the non-governmental sector.

Operating costs (including but not necessarily limited to facility and equipment maintenance, staff time, security expenses, and animal care) of existing high-containment laboratories could cost from \$5000/day to over \$50,000/day without active research. The cost increases significantly when there is active research ongoing in the laboratories and especially when select agents are housed in the facilities. Operating and maintaining high-containment facilities is expensive, and there are few federal funds allocated for this.

Recommendations

Based on the workshop discussion, we formulated several recommendations for the federal government, research institutions, and scientific organizations to address different aspects of biosafety training.

1. **The U.S. government should allocate funds to research institutions for initial and ongoing biosafety training (potentially including topics of scientific integrity and biosecurity), applied biosafety research, and maintenance of high-containment laboratories.** Research institutions receiving these funds would be held accountable for their use.
 - a. Additional funds need to be provided to maintain ongoing training of laboratory personnel.
 - b. High-containment facilities should develop a business plan and the U.S. government should provide funds for indirect costs for facility operations and maintenance.
 - c. Funds should be allocated to conduct applied biosafety research to understand better how to define biosafety training and protection standards as well as emergency procedures.
2. **The biosafety community needs to create a national, anonymous database of exposures, including lessons learned from which biosafety professionals and relevant administrative personnel can benefit.** The Select Agent Program and Biosafety Improvement Act (H.R.1225 and S.485) includes provisions for a similar database run by the U.S. government.

3. **When considering personnel reliability programs for non-governmental research institutions, the federal government should consider existing employment and biosafety training practices before granting access to high-containment laboratories, as they may already contribute to vetting of personnel.**

A variety of audiences, from researchers to emergency response personnel, require some biosafety training before gaining access to high-containment laboratories. The training may be more rigorous for some, such as researchers, than others, such as administrators or the public. The following recommendations are framed with the acknowledgement that the training content and requirements differ for personnel with different functions, but that anyone who might seek access to a BSL-3 or BSL-4 laboratory should be properly trained by knowledgeable educators.

4. **All BSL-3 and BSL-4 biosafety training programs should incorporate proficiency (i.e., competency-based) training and testing.**
5. **Senior scientists should continually mentor their laboratory personnel to work safely in high-containment laboratories by helping them improve their laboratory skills and be aware of current biosecurity and biosafety issues.**
6. **Research institutions should provide realistic information of the hazards that exist in the high-containment facility to emergency responders and appropriate members of their community to help guide their response(s) in an emergency.** This information could include familiarizing emergency responders with the facility floorplan as well as safety and security features.
7. **Programs should include performance-based training standards developed from a set of core competencies that are critical for working in high-containment laboratories.** These standards should be included in the BMBL. Standards will change over time given the evolving political, health, and scientific environment and some information will be facility-specific.
8. **Animal accreditation organizations, like AAALAC International, in cooperation with scientific societies, like the American Veterinary Medical Association and ABSA, the USDA, and HHS should develop content for large and small animal biosafety training.**
9. **The federal government should involve researchers and biosafety professionals in reviewing and improving biosafety standards.** Members of the biological sciences community and research facility administrators are responsible for implementing biosafety standards.

10. **Biosafety professionals should ensure that biosecurity issues along with biosafety concepts are addressed in training programs and incorporated into the conduct of hazardous research.**
11. **Recognizing that there is a need to keep some information confidential (e.g., proprietary information or security information), research institutions and the scientific community should openly communicate with each other, occupational health providers, policymakers, and the public about the safety and security features and procedures institutions employ to protect personnel, the surrounding community, and the environment against accidental exposure to any harmful biological agents housed in high-containment laboratories. Institutions should inform the local and state public health departments of the biological agents being researched in the facilities.** For example, Galveston National Laboratory provides daily news about the facilities to its community in an effort to be more transparent and build public trust.

Conclusion

Since the revelation of the unreported case of a researcher who was accidentally infected with *Brucella* at Texas A&M University and the subsequent allegation against Bruce Ivins, a researcher at USAMRIID, as the suspect of the anthrax attacks, there have been many calls to action by the security community and policymakers regarding laboratory biosafety and security. HHS has created the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight to consider oversight of research conducted in high-containment laboratories, including but not limited to certification and training of scientists and appropriate non-scientists on biosafety. The WMD Commission recommended review of oversight of high-containment laboratories and personnel training. Most recently, President George W. Bush issued an executive order on laboratory biosecurity, which includes personnel reliability.

Many of these security-oriented policy discussions have not engaged the greater life science community or considered existing practices that address some of the security concerns. Biosafety training is a cornerstone for preparing anyone entering a high-containment laboratory, and biosafety professionals generally act as gate-keepers to those laboratories. There has been significant progress by the scientific community, including biosafety professionals, to prepare all relevant audiences with the necessary skills and knowledge to work safely and securely in high-containment laboratories, but more can be done. We hope the recommendations from the AAAS workshop will inform current and future policy discussions on biosafety and biosecurity, highlight the importance of improved data collection from which biosafety professionals and others can learn, and enhance workforce development of all stakeholders to ensure that researchers have all the tools they need to conduct their research safely and securely.

Table 1. Biosafety Training Programs in the U.S.

| Agency/Institution | Program Title | Program Objectives | Format |
|--|--|--|---|
| American Biological Safety Association | Working at Animal BSL-1, BSL-2, BSL-3 | Training in worker safety and laboratory practices when working with animals | Online videos |
| American Biological Safety Association | Principles & Practices in Biosafety | Describe potentially hazardous biological materials, the risks associated with their use, and the means to minimize risk and to protect against or prevent release or exposure; discuss ways to provide technical expertise in situations involving potentially hazardous biological materials; and identify, locate, and efficiently use key biosafety resources. | Five-day, Forty-hour biosafety course |
| American Biological Safety Association | Spring Seminar and Review Course | Understand 65 biological safety task areas that will be covered in the exam; review all critical subject matter under each of the tasks; provide an overview of regulations and critical biological safety reference materials with which they must be familiar; recognize the exam structure and format based on topics covered, create awareness of specific subject areas | Two-day, Sixteen hour course |
| Centers for Disease Control and Prevention | Laboratory Biosecurity | Differentiate biosafety and biosecurity, conduct risk assessment, develop biosecurity plan | Online modules |
| Colorado State University | Biosafety and Biosecurity Training Course | Training in general biosafety and biosecurity, training in animal and plant handling | Eight-day classroom workshop |
| Control of Biohazards, Inc | Control of Biohazards in the Research Laboratory | Introduction to biosafety for new biosafety professionals, researchers and lab managers | Five day course with lab activity |
| Department of Health and Human Services | Integrated Medical, Public Health, Preparedness and Response Training Summit | Skills development, knowledge enhancement, and information sharing | Lecture sessions followed by question and answer sessions |
| Eagle Institute | Custom courses, seminars, and conferences | Various biosafety and biosecurity concepts | Varies |
| Emory University | ALERT Training Program BSL-2, BSL-3, BSL-4 | Strengthen internal relationships and partnerships with first responders | Onsite customized training |

| | | | |
|---|--|--|---|
| Emory University | Behavioral-Based Biosafety Trainer Preparation Program | Training in laboratory practices and safety concerns for appropriate lab safety level | Five-day classroom and laboratory course |
| Emory University/Elizabeth R Griffin Research Foundation | Leadership Institute for Biosafety Professionals | Training trainers, building leadership skills | Four-day workshop |
| Frontline Healthcare Worker Safety Foundation | On-Site Training | Biosafety, Biosecurity, Laboratory practices, Animal, bio | Client site, Custom |
| Lovelace Respiratory Research Institute | BSL-3 & ABSL-3 Training | Provide scientific, technical, animal care, facilities, and security staffs with knowledge and skills for level 3 work | Forty-hours, lectures and practicum exercises |
| Midwest Research Institute - Center for Biological Safety and Security (CBS2) | National and International training programs in Biological Safety and Security Principles and Practices; Compliance with established standards and regulations; Biosafety Levels 3 and 4 and Animal Biosafety Level 3. | Tailored awareness and skill-based training in biological safety and security principles and practices. | On-site classroom laboratory-based and field site; Train-the-trainer. |
| National Institutes of Health/Frontline Healthcare Worker Safety Foundation | National Biosafety & Biocontainment Program | Operations & Maintenance or Biosafety & Biocontainment Certificate | Ten courses, final project, work practicum |
| National Institutes of Health/Frontline Healthcare Worker Safety Foundation | National Biosafety & Biocontainment Fellowship | Prepare biosafety and biocontainment professionals | Two-year fellowship |
| Sandia National Laboratory | International Biological Threat Reduction | Teach scientists, managers, and policy makers on importance of biosafety and biosecurity | Scheduled workshops and meetings |
| University of Chicago | GLRCE Cognitive and Practical Biosafety Education | Train researchers in latest biosafety principles and practices | Four-day classroom and laboratory course |
| University of Texas Medical Branch | Laboratory Biosafety Training Program | Establish base of laboratory skills and apply biosafety principles | Lectures and practicum courses |
| Washington University | MRCE Biosafety for the Research Scientist | Train researchers in latest biosafety principles and practices | Five-day classroom and laboratory course |

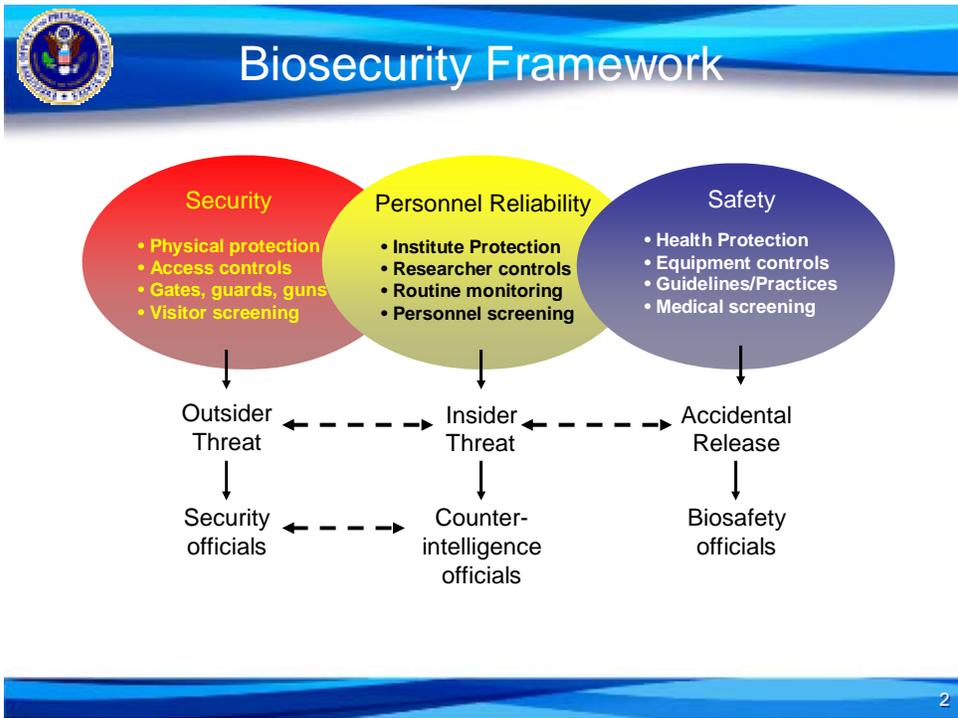


Figure 1. Schematic depicting the definitions of biosafety, biosecurity, and personnel reliability. U.S. Office of Science and Technology Policy presentation at the April 3, 2009 NSABB meeting on personnel reliability.



Appendix 1

Biosafety Training Programs

March 17, 2009
AAAS, Abelson/Haskins Room (2nd Floor)
9:00am-5:00pm

Agenda

- 9:00 **Welcome:** Opening Remarks by AAAS
- 9:15 General Overview of Oversight of High-Containment Laboratories
*COL John Skvorak, DVM, Ph.D., United States Army Medical Research
Institute for Infectious Diseases*
*Kevin Anderson, Ph.D., National Biodefense Analysis and
Countermeasure Center*
Richard Henkel, Ph.D., Centers for Disease Control and Prevention
Steven Kappes, Ph.D., US Department of Agriculture
- 10:15 am **Break**
- 10:30 am **Panel I: Needs of the Communities**
Scott Alderman, M.S., CBSP Duke University
Maureen Thompson, Emory University
Julie Johnson, Ph.D, CBSP, Kansas State University
Frank Kutlak, R.A., National Institutes of Health
- 12:30 pm **Lunch**
- 1:00 pm **Panel II: Biosafety Training programs**
Sean G. Kaufman, M.P.H., CHES, C.P.H., Emory University
Thomas Ksiazek, D.V.M, Ph.D., University of Texas Medical Branch
Murray Cohen, Ph.D., M.P.H. Frontline Foundation
Robert P. Ellis, Ph.D., Colorado State University
- 3:00 pm **Break**
- 3:15 pm **Discussion on Findings and Recommendations**
- 5:00pm **Adjourn**



Biosafety Training Programs

Discussion Questions

- What is the best program design?
 - What content/topics should be included in the program?
 - What audience (i.e. working conditions and administrative personnel) is appropriate for these programs?
 - What resources are already available and what additional resources are needed?
 - What communication methods are most effective to different audiences?
- How can we effectively implement these programs?
 - What are the challenges for implementing these programs?
- What methods for certification are there?
- How do these findings and recommendations fit both domestic and international needs?

Biosafety Training Programs

March 17, 2009

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Biosafety Training Programs

March 17, 2009

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Biosafety Training Programs

March 17, 2009

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Appendix 2

Questions Posed to Panel on Oversight of High Containment Laboratories

March 17, 2009

1. Please describe the types of high containment laboratories (level 3, 3+, 4, large/small animal, tissue culture, etc) and the percentage of those personnel who are approved for select agent work. Please indicate whether you are describing intramural or extramural research programs funded by your agency.
2. Are select agent research and non-select agent research conducted in the same laboratories?
3. Are all personnel affiliated with the high containment laboratories required to seek approval before gaining access to those laboratories regardless of whether they have to be registered for select agent work?
4. What measures are used to oversee the safety and pathogen security of high containment laboratories? Are there agency-wide standards that facilities and personnel must adhere to?
5. What are current reporting mechanisms and follow-up for laboratory accidents and accidental exposures? Are there specific medical personnel that are more knowledgeable about the work done in the laboratories to which exposed individuals are referred?
6. How are personnel trained to work in high containment laboratories? What resources are generally used? Who are trained? Is training for personnel working with select agents different than for those not working with select agents? Are there outstanding questions that are not addressed by current training materials? Are there continuing education classes for personnel already authorized to work in the lab? How are lab personnel informed of new or updated rules and procedures? How do you measure effectiveness of training?