October 2011 Issue 1

SCIENCE, SAFETY, SECURITY Quarterly

News for the Federal Biorisk Management Policy Community

Editors: Laura Kwinn, Ph.D. , Laura.Kwinn@hhs.gov and Jean Richards, DVM, Jean.Richards@hhs.gov

Contents

Welcome to the first edition of the S3 biorisk management policy newsletter!

This newsletter is intended to inform and connect Federal leaders and policymakers who work to promote best practices and policies in the fields of biosafety and biosecurity, which form the basis of "biorisk management." In order to achieve our mission, to keep science safe and secure, we must aim to leverage all available resources, communicate effectively, and coordinate our efforts in a timely manner – a challenge in this fiscal environment. We will be bringing you information each quarter to keep everyone up-to-date and connected with articles introducing key initiatives, offices, and groups; highlighting new policies, resources and tools; and announcing important meetings and deadlines. In this edition, we are proud to provide you with information on activities at the State Department, EPA and HHS. You are receiving this newsletter because you are a key component in the safety and security of our Nation, so please let us know what information would be useful to you—we welcome your ideas, submissions, and feedback. Please feel free to contact the editors at the email addresses provided above.

Informing the Public of Federal Biorisk Management Activities

In May 2011, the S3: Science, Safety, Security campaign kicked off with the launch of a website and traveling display in time for the annual American Society of Microbiology meeting in New Orleans. The website will provide a one-stop-shop for information on biorisk management practices across the United States Federal government. It contains links to a wide range of resources, from biosecurity trainings published by the CDC to import /export regulations for scientists. The most comprehensive resource on the website is the compilation of laws, regulations, guidelines, policy documents and treaties on biosafety and biosecurity. Other resources include question and answer pages on biosecurity and biosafety, information on relevant treaties, and links to US government strategies and reports.

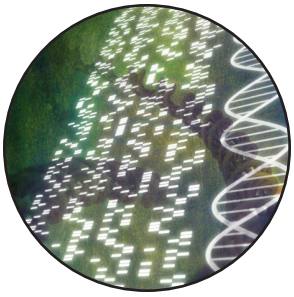
Over time, the website is intended to grow and evolve in response to comments and input received from users and the scientific community. Additional Frequently Asked Questions pages on agricultural and environmental issues are already under development and existing content will be updated as necessary. New content is created and reviewed by the Interagency Biosafety and Biosecurity Outreach Working Group on an ongoing basis. Comments and suggestions for content are welcome. Future appearances of the booth will be listed on the S3 website.

The website can be found here: www.phe.gov/S3

By Anna Muldoon, MPH anna.muldoon@hhs.gov

Policy Update: *Screening Framework Guidance for Providers of Synthetic dsDNA*

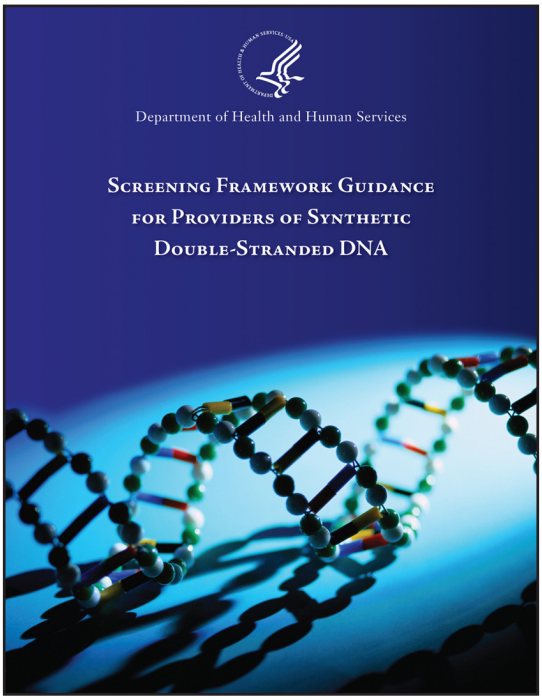
The synthetic dsDNA industry has proactively addressed the potential biosecurity risks that accompany the commercial application of dsDNA synthesis.



Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA (the Guidance) was released on October 13, 2010 in the Federal Register by the Department of Health and Human Services at the culmination of a three-year multi-agency effort. The primary goal of the Guidance is to minimize the risk that unauthorized individuals or individuals with malicious intent will obtain "toxins and agents of concern" through the use of nucleic acid synthesis technologies, and to simultaneously minimize any negative impacts on the conduct of research and business operations. The Guidance recommends baseline standards for providers of synthetic double-stranded DNA (dsDNA) products, including recommendations for screening orders so that these orders are filled in compliance with current U.S. regulations, and encourages the development of best practices in addressing potential biosecurity concerns.

Stakeholder and public feedback were solicited at several points throughout the process of developing the Guidance. A draft version of the Guidance was released in November 2009 after incorporating feedback from two stakeholder meetings that included members of industry, not-for-profit organizations, biosecurity experts, and the scientific community. In January 2010, the American Association for the Advancement of Science hosted a public meeting to facilitate discussion about the draft Guidance while it was still open for public comment in the Federal Register. An interagency working group considered and, when applicable, incorporated feedback received through the Federal Register comment period and the AAAS meeting when finalizing the Guidance. Since the October 2010 release of the policy, ASPR has been conducting outreach about the final Guidance at domestic and international workshops and meetings. Additionally, an interagency group has developed an implementation and evaluation plan for the Guidance.

Frequent questions about the Guidance often revolve around two issues: the voluntary nature of the policy, and the focus on synthetic dsDNA rather than single-stranded oligonucleotides. A voluntary approach is being pursued at this time for a number of reasons. The synthetic dsDNA industry has proactively addressed the potential biosecurity risks that accompany the commercial application of dsDNA synthesis. Additionally, the field of synthetic genomics presents a novel challenge, and regulations may not provide the flexibility to address this



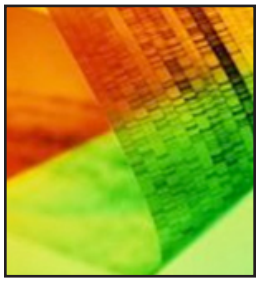
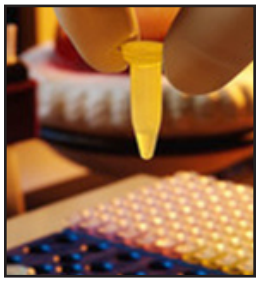
challenge. If U.S. regulations were developed, they would only cover U.S. dsDNA providers, whereas providers exist all over the world. Voluntary guidance may provide a better opportunity to establish a baseline that is relevant internationally at this time. In May 2010, when the public comment period on the draft Guidance had closed and the final Guidance was close to completion, the J. Craig Venter Institute created the first bacterial cell controlled by a chemically-synthesized genome from oligonucleotides. This development raised questions about the focus on dsDNA in the Guidance. The purpose of the Guidance is to mitigate the risks associated with custom nucleic acid synthesis, and generating or re-creating "agents of concern" using synthesized dsDNA pieces is still technically less challenging than re-creating an organism with single-stranded oligonucleotides. Additionally, because of the high volume and rapid turnaround time for single-stranded DNA orders, a screening framework for single-stranded DNA is less practical and potentially much more burdensome to researchers and industry at this time. Because the technology, the industry, and the nature of the biosecurity risks are changing rapidly, the Guidance will be reviewed by the federal interagency working group on a regular basis and revised as necessary.

Link to Guidance: www.phe.gov/syndna

By Jessica Tucker, Ph.D. jessica.tucker@hhs.gov

The National Science Advisory Board for Biosecurity (NSABB): Past, Present and Future Activities



Advances in the life sciences are critical to the development of safe, effective treatments for disease and have made possible improvements in human, animal, and plant health; the food supply; and the environment. But the knowledge, technologies, and products of certain legitimate life sciences research can also be used for destructive purposes to threaten the health and safety of humans and other forms of life. Research generating valuable knowledge that can also be put to malevolent purposes is "dual use research" and requires careful consideration and management.

A number of publications in leading scientific journals and especially the anthrax attacks of 2001 have highlighted the issue of dual use research, the risk of the "insider threat," and the need to develop effective strategies for managing the risk of misuse without hampering scientific progress. In 2004, the Federal government established the National Science Advisory Board for Biosecurity (NSABB) to provide advice regarding biosecurity oversight of dual use research to all Federal departments and agencies with an interest in life sciences research. The NSABB advises on and recommends specific strategies for the efficient and effective oversight of Federally-conducted or -supported dual use biological research, taking into consideration national security concerns and the needs of the research community.

The NSABB consists of 25 non-government voting members who provide expertise and perspectives in such areas as molecular biology, microbiology, infectious diseases and diagnostics, laboratory biosafety and biosecurity, public health, veterinary medicine, plant health, food production, bioethics, academia, national security, biodefense, intelligence, law, law enforcement, scientific publishing, industry, and public perspectives. In addition, the NSABB includes non-voting ex officio members from 15 Federal agencies, departments, and offices that have an interest in life sciences research.

The NSABB has responded to and continues to work on a series of taskings as presented by the United States government to address the challenges of the dual use dilemma. To date, the Board has published seven reports and held several roundtables and public consultations that have brought together different stakeholders such as investigators working with select agents, editors of life science journals, leadership of research organizations that house BSL-3 and -4 laboratories, as well as the international community. A few of these efforts are detailed below:

- The June 2007 report, *Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information*, articulates an oversight framework for the identification, review, conduct, and communication of life sciences research with dual use potential. The proposed framework relies primarily on the local oversight of dual use research and stresses that researchers themselves are the most critical element in this oversight. The Board also developed a series of tools to help researchers and institutions assess and manage risks associated with the potential misuse of dual use research of concern, including guidance for identifying and responsibly communicating dual use research of concern, along with a set of considerations for developing codes of conduct for researchers. For an explanation of dual use research of concern, please visit this FAQ page: http://oba.od.nih.gov/biosecurity/nsabb_faq.html

Cont. on pg. 4

Research generating valuable knowledge that can also be put to malevolent purposes is "dual use research"—a type of research that requires careful consideration and management.

The National Science Advisory Board for Biosecurity cont. from page 3

NSABB Team

Paul I. Lewis, Ph.D.
Executive Director
National Science Advisory Board for Biosecurity
NIH/OD/OSP/Office of Biotechnology Activities

Symma Finn, Ph.D.
AAAS Science and Technology Policy Fellow
NIH/OD/OSP/Office of Biotechnology Activities

Ronna S. Hill
Program Assistant (Contractor)
NIH/OD/OSP/Office of Biotechnology Activities

Ori Lev, Ph.D.
Health Science Policy Analyst (Contractor)
NIH/OD/OSP/Office of Biotechnology Activities

Erin Luetkemeier, Ph.D.
AAAS Science and Technology Policy Fellow
NIH/OD/OSP/Office of Biotechnology Activities

Allison Hodges Mistry, M.S., M.A.
Health Science Policy Analyst
NIH/OD/OSP/Office of Biotechnology Activities

Stuart L. Nightingale, M.D.
Consultant (Contractor)
NIH/OD/OSP/Office of Biotechnology Activities

- The December 2008 report, *Strategic Plan for Outreach and Education on Dual Use Research Issues*, emphasizes awareness-raising as an essential element in the oversight of dual use research. Toward this end, this report lays out a strategic plan for outreach and education that describes target audiences, key message points, and appropriate vehicles for disseminating information about dual use research issues. The proposed outreach strategies include engaging opinion leaders who can effectively promote the awareness of dual use issues as well as engaging the scientific communities directly through professional societies and associations.
- In May 2009 the NSABB issued its report, *Enhancing Personnel Reliability Among Individuals with Access to Select Agents*, wherein the Board recommends an approach to strengthen the Select Agent Regulations with the aim of effectively addressing the possibility of an insider threat. The report recommends an approach to personnel reliability that augments the current Select Agent Regulations, without promulgating a formal, national personnel reliability program.
- The NSABB's report, *Addressing Biosecurity Concerns Related to Synthetic Biology* (April 2010), focuses on the unique uncertainties and potential biosecurity risks of synthetic biology. The report recommends that synthetic biology research be subject to institutional review and oversight and notes that the NSABB's proposed oversight framework for dual use life sciences research (see above), with its focus on local level oversight, should adequately cover much of this type of research.
- The NSABB has recently completed two new reports. The first report, *Strategies to Educate Amateur Biologists and Scientists in Non-life Science Disciplines about Dual Use Research in the Life Sciences* (June 2011) presents a series of observations about the special characteristics of these communities accompanied by recommendations for specially tailored strategies for awareness building.
- The second report, *Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility* recommends a number of specific strategies and guidance for assisting the scientific community in establishing and implementing practices that promote a culture of responsibility with respect to biosecurity. The report highlights the critical role of good management practices in the development of a culture of responsibility, integrity, trust, and effective biosecurity. It also emphasizes the importance of strong institutional and laboratory leadership, clear articulation of priorities and expectations, and an institutional framework that provides training, performance review, and employee support in facilitating responsible practices, personnel reliability, safety, and security, while allowing research to flourish.

The report highlights the critical role of good management practices in the development of a culture of responsibility, integrity, trust, and effective biosecurity.

In addition to issuing these reports, NSABB members and staff are engaged in a range of ongoing activities.

- First, a major aim of the USG is to promote awareness about dual use research issues within the international community and to facilitate international engagement and information sharing on strategies for managing risks posed by dual use life sciences research of concern. The NSABB has hosted numerous international engagement activities and is exploring future international outreach activities, for example, roundtables and webcasts, and is planning future international outreach activities, including a workshop on the NIH campus Dec. 9, 2011 titled, "The Intersection of Science and Security: a Case Study Approach." Written summaries of the roundtables, archived videos of past events, and detailed information on the upcoming workshop can be found at www.biosecurityboard.gov
- Second, outreach and education activities, aimed at raising awareness about dual use research among US-based scientists are also a continual focus of NSABB staff and members. NSABB members are regularly invited to speak about dual use research to various audiences. The

Cont. on pg. 5

John Holdren Engages Microbiology Community

Dr. John Holdren, Assistant to the President for Science and Technology and Director, Office of Science and Technology Policy, presented to the participants of the American Society for Microbiology Annual Meeting in New Orleans in May. His presentation "Science and Technology Policy Challenges and Opportunities in the Obama Administration…and the Role of Microbiology" emphasized the great importance placed by the Obama Administration on S&T. He highlighted presidential appointments, speeches, events, and awards given that demonstrate President Obama's commitment to S&T, as well as current initiatives, policies, and programs. The place of science, specifically microbiology, on the President's agenda was well-outlined with examples including Executive Order 13546, "Optimizing the Security of Biological Select Agents and Toxins in the United States," and the work of the National Science Advisory Board for Biosecurity. Dr. Holdren called on microbiologists to increase their engagement with policy-makers and the public.

Dr. Holdren's remarks:
http://www.asm.org/images/pdf/Policy/2011-05-23_asm_new_orleans_jph_final.pdf

OSTP:
http://www.whitehouse.gov/administration/eop/ostp

Dr. Holdren's presentation "Science and Technology Policy Challenges and Opportunities in the Obama Administration…and the Role of Microbiology" emphasized the great importance placed by the Obama Administration on science and technology.

The National Science Advisory Board for Biosecurity cont. from pg. 4

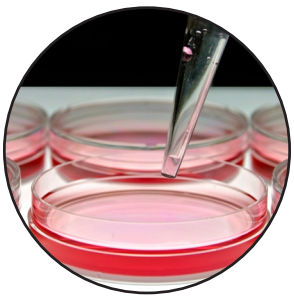
NIH Office of Biotechnology Activities, which staffs NSABB, utilizes an exhibit and a poster display to promote awareness about dual use research issues in major scientific gatherings and conferences. OBA staff have also developed a brochure and a DVD that highlight the various challenges that dual use research presents; these are being disseminated to academic institutions, investigators, and other interested parties.

The NSABB is currently engaged in developing a toolkit and an educational module for promoting the creation and dissemination of codes of conduct for dual use research by research institutions, professional societies and other relevant professional groups. Another task is focused on describing the policies that various scientific journals have in place for addressing dual use research of concern and provides options of how these policies might be improved upon.

Most people would readily acknowledge that life sciences research is a vital undertaking that yields innumerable and immeasurably important benefits. But in recognizing the value of life sciences research, we must also be mindful that even a single misuse of certain information, knowledge, or technology could have devastating effects. Since its establishment, the NSABB has been engaged in the development of effective approaches to minimizing the risk of misuse and in fostering the continued progress of the science so vital to public health and national security.

Further information about the NSABB, including NSABB membership, reports, and international events can be found at
http://oba.od.nih.gov/biosecurity/biosecurity.html

By Ori Lev, Ph.D. ori.lev@nih.gov



Biorisk Management at EPA: A Closer Look at the National Homeland Security Research Center

NHSRC Directors

Jonathan G. Herrmann, P.E., BCEE
Director, National Homeland Security Research Center (NHSRC)
Office of Research and Development
U.S. Environmental Protection Agency

Peter Jutro, Ph.D.
Deputy Director for Science and Policy
National Homeland Security Research Center, Office of Research and Development
U.S. Environmental Protection Agency

Gregory Sayles, Ph.D.
Associate to Director, NHSRC
Acting National Program Director
National Homeland Security Research Center Office of Research and Development
U.S. Environmental Protection Agency

About EPA's Homeland Security Research Program

EPA's homeland security research program is rooted in the traditional functions that decades of legislation have assigned to it. Among those are response to oil and hazardous materials releases, spill prevention and control, waste management, air quality protection, drinking water and wastewater regulation, pesticide management, radiation protection, and research and development to address the questions that need to be answered in order to better protect human health and the environment.

Following the attacks of 9/11 and the subsequent anthrax incidents in 2001, EPA formed its National Homeland Security Research Center (NHSRC) to address an emerging suite of scientific challenges. EPA's activities are risk-based. Risk assessments address the vulnerabilities of the Nation's diverse population and the sustainability of ecosystems. Before the 2001 anthrax incidents, anthrax had been thought of as a military bio-weapon, and thus, Defense Department researchers had based their assessments of anthrax exposures on a young and healthy military population. Of necessity, assumptions about civilian populations differ from those made about a military population. Historically, EPA risk assessments had dealt mostly with long term exposures to low-level environmental chemicals of concern. In 2001, EPA recognized that in the event of any wide-spread biological attack, part of its decontamination responsibility would be to assure that all vulnerable segments of the U.S. population, including children, elderly, and immuno-compromised individuals were considered. If, for example, the residents of a contaminated area wanted to know whether they could return home to retrieve their personal belongings before an area is completely decontaminated, EPA scientists would need to be able to provide federal, state, and local officials, as well as the public, information on the risks that short-term exposures might present.

The program's efforts have been shaped by the need for the Nation to be ready to respond to multiple incidents with the potential for substantial environmental and public health impact — whether acts of terrorism, large-scale accidents, or natural disasters. In order to prepare, researchers must understand the nature of these hazards and threats, and must devise, adapt and re-tool approaches, methods and technologies in order to characterize the extent and impacts, and be prepared to render harmless a different set of radiological, chemical, and biological agents and toxins than EPA has traditionally faced.

In addition to its role in emergency response and recovery, EPA's historical role in protecting drinking water and guiding the treatment of wastewater led to EPA's designation as the lead federal agency for water infrastructure protection under the National Infrastructure Protection Plan. Over the past decade, the Agency also received mandates from, among others, the Bioterrorism Act, and Homeland Presidential Directives (HSPD) 7 (critical infrastructure protection), HSPD 9 (defense of agriculture and food), HSPD 10 (biodefense) and HSPD 22 (domestic chemical defense).

Since 2002, EPA's Homeland Security Research Program has partnered with the White House Office of Science and Technology Policy, the National Security Staff, and other Federal agencies and departments, as well as external stakeholders. NHSRC has continued to advance the science of detecting contaminants, characterizing the extent and nature of contamination, assessing the risks to all Americans and the Nation's water infrastructure posed by these contaminants, undertaking safe and effective decontamination and disposal, and helping to protect water systems. In the process, it has tested and evaluated the effectiveness of early warning systems and decontamination technologies, developed tools to guide waste disposal decision making, and helped to develop interim guidance levels for emergency response and recovery officials and the residents of impacted communities. Although much has been accomplished over the past eight years, NHSRC continues to search for answers to critical remaining questions.

For further information, please see:
www.epa.gov/nhsrc

By Peter Jutro, Ph.D. jutro.peter@epa.gov and Brendan Doyle doyle.brendan@epamail.epa.gov

Cont. on pg. 7

Biorisk Management at the EPA: A Closer Look at the NHSRC cont. from page 6

Highlighting the Work of the NHSRC

Sampling and Analytical Methods

EPA's Homeland Security Research Program has prepared a manual, Selected Analytical Methods for Environmental Remediation and Recovery (SAM), so that Federal and state laboratories have procedures for analyzing samples while supporting responses to homeland security incidents. The current revision of SAM summarizes over 200 methods for chemical and radiochemical analytes, as well as pathogens and toxins. EPA has developed a searchable website, that in addition to a SAM Methods Query tool, searches chemical, radiochemical, pathogen, and biotoxin analytical methods, full documentation of laboratory methods (when available) and links to technical contacts and key collaborators. EPA has also been developing selected analytical protocols and sample collection procedures based on methods in the manual.

Report: http://tinyurl.com/EPA-SAM
Searchable Website: http://www.epa.gov/sam

Results From Persistence Testing of Biological Agents Under Various Conditions

The causative biological agents of diseases such as anthrax, smallpox, and plague are a significant terrorist threat. Data on how long and under what conditions agents remain viable or active influence many aspects of planning, response, containment, and recovery from biological incidents. Following a contamination event, environmental conditions could be modified to decrease the number of viable organisms prior to decontamination efforts. Such pre-treatment could potentially reduce the risks of exposure, lower the costs of cleanup, and shorten the time before re-use of a facility or an outdoor area.

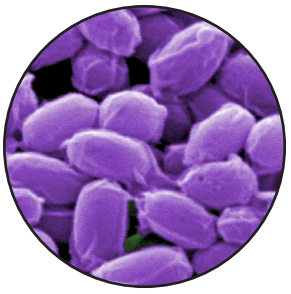
In 2011 the EPA NHSRC studied the persistence of biological agents, including *Bacillus anthracis*, *Brucella suis*, *Francisella tularensis*, Highly Pathogenic Avian Influenza (H5N1), Vaccinia virus, a surrogate for the virus that causes smallpox, and *Yersinia pestis*. Investigators found that increased temperature, increased relative humidity, and exposure to simulated sunlight (ultraviolet light with wavelengths of 280 to 400 nanometers, UV-A/B), tended to decrease the persistence of some biological agents. Generally, these environmental conditions were found to decrease persistence of agents on most of the materials that were tested. Materials tested varied among the biological agents that were evaluated.

Report: http://tinyurl.com/PersistenceTesting

Biological Inactivation Efficiency of HVAC In-Duct Ultraviolet Light Devices

The Technology Testing and Evaluation Program (TTEP), managed by EPA's Homeland Security Research Program, tests technologies in an effort to provide unbiased, third-party performance information that is useful to decision makers in purchasing and applying the tested technologies. One relevant performance evaluation involved testing nine in-duct ultraviolet light devices for effectiveness in destroying three microorganisms, two bacteria and one virus, which are reasonable surrogates for biological warfare agents (BWAs). In the event of an intentional introduction of BWAs into a building's heating, ventilation, and air-conditioning systems, this method of destroying bioaerosols could be employed as the pathogenic organisms move through the system. For results, please see report: http://tinyurl.com/EPA-HVAC

More articles are available here: http://epa.gov/nhsrc/pubs.html



The causative biological agents of diseases such as anthrax, smallpox, and plague are a significant terrorist threat.

Biorisk Management within the Bureau of International Security and Nonproliferation

To highlight the important work being done in this field and increase awareness among our federal partners working to promote comprehensive biorisk management, you will find an overview of the offices and programs within ISN.

There are many offices and programs within the State Department working on issues related to biorisk management. Several of these offices are located within the Bureau of International Security and Nonproliferation (ISN). To highlight the important work being done in this field and increase awareness among our Federal partners working to promote comprehensive biorisk management, you will find below an overview of the offices and programs within ISN.

Nonproliferation and Disarmament Fund

- The Nonproliferation and Disarmament Fund (NDF), established in 1994, provides a means for the U.S. Government to respond rapidly to nonproliferation and disarmament opportunities, circumstances, or conditions that are unanticipated or unusually difficult, but of high priority.
- The role of the Office of NDF is to supplement U.S. diplomatic efforts to promote bilateral and multilateral nonproliferation and disarmament activities authorized under section 504 of the FREEDOM Support Act of 1992 (P.L. 102-511), through the development, execution, and implementation worldwide of carefully selected projects designed to:
    - Halt the proliferation of nuclear, biological, and chemical weapons, their delivery systems, related technologies, and other weapons;
    - Destroy or neutralize existing weapons of mass destruction, their delivery systems, related sensitive materials, and conventional weapons;
    - Limit the spread of advanced conventional weapons, their delivery systems, and related technologies; and
    - Track, control, and secure dangerous materials, including fissile material, radiological material, pathogens, and chemical agents.

Office of Weapons of Mass Destruction Terrorism

- The Office of Weapons of Mass Destruction Terrorism (WMDT) enhances international security against the threat of WMD terrorism by strengthening political and operational capability of international partners to deter, detect, defeat, and respond to terrorists and their facilitators.
- With good understanding of terrorist organizations, their activities, and interests, the office produces and implements strategies and plans for diplomatic and other U.S. Government activity to reduce risk of WMD terrorism.
- WMDT establishes, maintains, and continues to improve upon U.S. Government combating WMD terrorism efforts, to include diplomatic support and coordination for activities funded and agreed to by other U.S. Government agencies.
- WMDT continues to lead in developing WMDT as a joint discipline between counterproliferation and counterterrorism.

Office of Cooperative Threat Reduction

- The Office of Cooperative Threat Reduction (CTR) is funded by the Nonproliferation, Antiterrorism, De-mining and Related Programs (NADR) Account. CTR programs, also known as Global Threat Reduction (GTR) programs, are aimed at reducing the threat posed by terrorist organizations or states of concern seeking to acquire WMD expertise, materials, and equipment. In addition to continued efforts in Iraq and the former Soviet Union, GTR programs are working to reduce the rapidly growing worldwide WMD threat posed by terrorists, non-state actors, and proliferant states.
- CTR programs are threat-driven and focus on frontline states like Iraq, Afghanistan, Pakistan, and Yemen; critical states such as Indonesia and the Philippines; and in regions where the terrorist threat is on the rise, such as South Asia, the Middle East, and Africa.
- CTR supports coordination of U.S. bilateral and multilateral activities related to the G-8 Global Partnership (G8GP), which was recently extended beyond 2012 with biosecurity as one of the focal areas.
- CTR programs dealing with biorisk management include the Biosecurity Engagement Program (BEP), the Iraq Scientist Engagement Program (ISEP), and Science Centers Program.
- BEP seeks to strengthen biorisk management practices, enhance infectious disease detection

Cont. on pg. 9

Biorisk Management within the Bureau of ISN cont. from pg. 10

and surveillance, and facilitate scientist engagement worldwide to deny terrorist and other non-state actors access to potentially dangerous technical expertise and pathogens.

- ISEP seeks to minimize the terrorism and proliferation risks posed by Iraqi scientists, and engineers with weapons or weapons-applicable expertise and promote safety and security best practices at Iraqi facilities and laboratories that produce, use, and/or store potentially dangerous or dual-use biological, chemical, and radiological materials.

Office of Counterproliferation Initiatives

- The Office of Counterproliferation Initiatives (CPI) takes the lead in developing, implementing, and improving counterproliferation efforts.
- CPI key missions include:
  - Promoting, Developing, and Operationalizing the Proliferation Security Initiative;
  - Implementing UN Security Council Resolution 1540;
  - Developing Regional and Functional Counterproliferation Strategies and Evolving other Counterproliferation effort; and
  - Developing Outreach to Industry.
- All states have three primary obligations under UNSCR 1540, which was adopted in 2004 to ensure that no State or non-State actor is a source or beneficiary of WMD proliferation: to prohibit support to non-State actors seeking such items; to adopt and enforce effective laws prohibiting the proliferation of such items to non-State actors, and prohibiting assisting or financing such proliferation; and to take and enforce effective measures to control these items, in order to prevent their proliferation, as well as to control the provision of funds and services that contribute to proliferation.
- The Proliferation Security Initiative (PSI) was launched in May 2003 as a global cooperative effort that aims to stop trafficking of WMD, their delivery systems, and related materials to and from states and non-state actors of proliferation concern and reinforced in the 2010 National Security Strategy and the 2010 Quadrennial Defense Review.
- By endorsing the PSI Statement of Interdiction Principles, states voluntarily commit to establish a more coordinated and effective basis through which to impede and stop WMD, their delivery systems, and related items. The countries commit to:
  - Interdict transfers to and from states and non-state actors of proliferation concern to the extent of their capabilities and legal authorities;
  - Develop procedures to facilitate exchange of information with other countries;
  - Strengthen national legal authorities to facilitate interdiction; and
  - Take specific actions in support of interdiction efforts.
- The PSI conducts workshops, exercises, experts meetings, and other activities with other PSI-endorsing countries to assist in identifying and developing national capabilities to interdict WMD. PSI endorsing nations also interact with government, commercial, and industry enterprises to explore legal responsibilities and frameworks, with the goal of preventing them from inadvertently providing dual-use materials or assisting in the transport of those materials to potential proliferators.

Biological Policy Staff

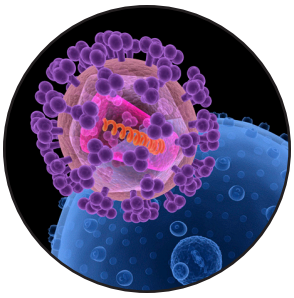
- The Biological Policy Staff (BPS) works to impede and roll back the threat of acquisition or use of biological weapons by state and non-state actors by:
  - Overseeing U.S. implementation of the Biological Weapons convention (BWC);
  - Coordinating Department efforts in support of the National Strategy for Countering Biological Threats;
  - Developing and promoting measures to prevent misuse of advances in the life sciences; and
  - Developing policies to use nonproliferation tools to impede and prevent bioterrorism.
- The Biological and Toxins Weapons Convention (BWC) entered into force in 1975 and bans the development, production, stockpiling or otherwise acquiring/retaining microbial or other biological agents or toxins whatever their origin that have no justification for prophylactic, protective or other peaceful purposes.

The Biological Policy Staff (BPS) works to impede and roll back the threat of acquisition or use of biological weapons by state and non-state actors…

Cont. on pg. 11

Countering Biological Threats: National Implementation of the Biological Weapons Convention and Multinational Outbreak Response and Bioterrorism Investigation Demonstration

Of note, the tabletop exercise was a first of its kind at the international level for awareness raising and review of the UNSGM Technical Guidelines and Procedures including their updated appendices.



The workshop on "*Countering Biological Threats: National Implementation of the Biological Weapons Convention and Multinational Outbreak Response and Bioterrorism Investigation Demonstration*" was held in Tbilisi, Georgia, 17-19 May 2011. It was organized by the U.S. Department of Defense (U.S. European Command, Armed Forces Health Surveillance Center, Center for Disaster and Humanitarian Assistance Medicine, and the Defense Threat Reduction Agency) and the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (ASPR) with the support of the National Center for Disease Control and Public Health of Georgia (NCDC), the U.S.-Georgia Central Public Health Reference Laboratory (CPHRL), and the Ministry of Internal Affairs of Georgia. It included awareness training on biological nonproliferation, a tabletop exercise designed to review the technical guidelines and procedures associated with the *United Nations Secretary General's Mechanism on Investigation of Alleged Use of Biological and Chemical Weapons* (UNSGM), and a practical demonstration of consequence management capabilities of Georgia's Ministry of Internal Affairs CBRN Rapid Response Team.

Of note, the tabletop exercise was a first of its kind at the international level for awareness raising and review of the UNSGM Technical Guidelines and Procedures including their updated appendices (available online at: http://www.un.org/disarmament/WMD/Secretary-General_Mechanism/appendicies) for timely and efficient investigations of reports on the possible use of chemical and biological weapons. The tabletop exercise was facilitated by two representatives of the U.N. Office for Disarmament Affairs (UNODA), Dr. Gabriele Kraatz-Wadsack, Chief, Weapons of Mass Destruction Branch and Mr. Franz Kolar, Political Affairs Officer.

In the spirit of President Obama's Transparency and Open Government initiative and its principles of transparency, participation, and collaboration, workshop participants were offered guided tours of the US-Georgia Central Public Health Reference Laboratory (CPHRL) whose mission is to promote public and animal health through infectious disease detection, epidemiological surveillance, and research for the benefit of Georgia, the Caucasus region, and the global community (CPHRL website at: http://www.cphrl.org).

The workshop aimed to: i) promote interagency (in particular public health-law enforcement but also civilian-military) cooperation, coordination and synchronization for preparing, detecting, and responding to infectious disease outbreaks, whether natural, accidental, or deliberate in nature; ii) establish regional partnerships to enhance training and disease surveillance and containment initiatives; and iii) strengthen the core capacities required by the WHO International Health Regulations (IHRs) and existing national measures consistent with the obligations under the Biological Weapons Convention (BWC) and the UN Security Council Resolution 1540 (UNSCR 1540) to deter, prevent, and respond to biological incidents or threats.

The workshop was attended by about 100 participants including civilian and military public and veterinary health (laboratory and preventive medicine personnel, epidemiologists, emergency response planners, administrators), law enforcement, intelligence, and affiliated professionals (other first responders, policy staff, representatives of academia, industry, and other non-governmental organizations) from US, Georgia, Armenia, Azerbaijan, Bulgaria, Romania, Moldova, Turkey, Poland, and Kenya; and representatives of inter-governmental organizations (WHO, UNODA, NATO, and ECDC). Opening remarks were offered by the Dr. Mikheil Dolidze - Deputy Minister, Ministry of Labor, Health and Social Affairs (MoHLSA) of Georgia; Ms. Julie Fisher, Chief of Political and Economical Affairs, US Embassy, Georgia; CAPT Kevin Russell- Director, Global Emerging Infections Surveillance and Response System (GEIS) Operations Division and Deputy Director Armed Forces Health Surveillance Center, US Department of Defense (DOD); and Dr. George Korch, Principal Deputy Assistant Secretary for Preparedness and Response (PD-ASPR), US Department of Health and Human Services (HHS). The FBI participated in this event by providing a briefing

Cont. on pg. 11

Countering Biological Threats cont. from page 10

on the Joint Criminal and Epidemiological Investigation model that is a collaboration between HHS/CDC and the FBI. This model can serve as a blueprint for other nations in their development of a robust investigative process to apprehend those who would use biological agents to cause harm.

The workshop on *Countering Biological Threats: National Implementation of the Biological Weapons Convention and Multinational Outbreak Response and Bioterrorism Investigation Demonstration* is the third such event co-organized by DOD and HHS in the European region. For more details on this workshop, please see: http://www.phe.gov/Preparedness/international/Pages/counteringthreats.aspx; details on the previous two workshops can be found at: http://www.phe.gov/about/OPP/Pages/bwc.aspx These events illustrate the US Government commitment toward the implementation of the objectives of the *National Strategy for Countering Biological Threats*, to promote global health security and transform the international dialogue on biological threats, as well as working with cross-border and global partners to enhance national, regional, and global health security in accordance with the *National Health Security Strategy.*

By Dana Perkins, Ph.D.
dana.perkins@hhs.gov

Call for Submissions

We want to hear from you! Please contact Laura Kwinn and Jean Richards with news ideas for future editions of S3 Quarterly. Feel free to submit general information for inclusion or drafted articles. If you have an idea, we are happy to work with you in drafting a piece. Articles should be in MS Word format, fewer than 1000 words, with author/contact name and email address. Pictures and diagrams in jpg format are encouraged and welcome. Thank you!

Laura.Kwinn@hhs.gov
Jean.Richards@hhs.gov

Biorisk Management within the Bureau of ISN cont. from pg. 9

- The BWC also covers weapons, equipment or means of delivery designed to use biological agents for hostile purposes or in armed conflict.
- To strengthen efforts to combat the BW threat, States Parties agreed at the November 2002 BWC Review Conference to have experts meet annually through 2006 to discuss and promote common understanding and effective action on biosecurity, national implementation measures, suspicious outbreaks of disease, disease surveillance and codes of conduct for scientists.
- The 7th Review Conference of the BWC will be held in Geneva in December 2011.

Office of Missile, Biological & Chemical Nonproliferation

- The Office of Missile, Biological & Chemical Nonproliferation (MBC) leads the working level U.S. Government effort to impede, roll back, and eliminate the proliferation of chemical and biological weapons (CBW), missile delivery systems for weapons of mass destruction (WMD – nuclear and CBW), and related equipment, materials, and technology.
- This office works closely with National Security Staff (NSS) and other agencies, including the Departments of Commerce, Defense, Energy, Homeland Security, Justice, and Treasury, in carrying out its mission.
- In furtherance of this mission, MBC leads U.S. participation in the Australia Group (AG) CBW nonproliferation regime, the Hague Code of Conduct Against Ballistic Missile Proliferation (HCOC), and the Missile Technology Control Regime (MTCR) multilateral nonproliferation organizations.
- MBC directs the interagency processes to review U.S. export license applications and visa applications for consistency with CBW and missile nonproliferation objectives, and to halt U.S. and foreign transfers that could contribute to CBW and missile proliferation. It also develops and implements procedures and strategies that seek to assure U.S. CBW- and missile-related sanctions laws are fully implemented.
- MBC chairs the Missile Trade Analysis Group (MTAG), the Missile Technology Export Control (MTEC) working group, the Missile Annex Review Committee (MARC), the SHIELD interdiction working group and the SHIELD licensing working group.
- Additionally, MBC prepares the annual report to Congress on "Proliferation of Missiles and Essential Components of Nuclear, Chemical and Biological Weapons," the semi-annual report on the national emergency with respect to the proliferation of weapons of mass destruction, the semi-annual report under the Iran, North Korea, and Syria Nonproliferation Act, and reports on countries' adherence to the MTCR. The BWC also covers weapons, equipment or means of delivery designed to use biological agents for hostile purposes or in armed conflict.

Contact Andrew Hebbeler, Ph.D.
HebbelerAM@state.gov