



News for the Federal Biorisk Management Policy Community

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Feedback and Submissions Welcome

We want to hear from you! Please contact Janelle Hurwitz (janelle.hurwitz@hhs.gov) with any comments, suggestions or news ideas for future editions of S3 Newsletter. 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!

USG Hosts Stakeholder Engagement Workshop on the Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (DURC)

By Janelle Hurwitz, HHS/ASPR (janelle.hurwitz@hhs.gov)

Despite the value and benefits, certain types of research conducted for legitimate purposes can be utilized for both benevolent and harmful purposes. Such research is called "dual use research." Dual use research of concern (DURC) is a subset of dual use research defined as:

"Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, material, or national security."

On September 24, 2014, the U.S. Government (USG) released the [United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern](#). This policy articulates the practices and procedures required to ensure that dual use research of concern is identified at the institutional level and risk mitigation measures are implemented, as necessary. Funders of life sciences research and the institutions and scientists who

receive funds have a shared responsibility for oversight of DURC and for promoting the responsible conduct and communication of such research.

A comprehensive oversight system must include both the USG and institutional oversight processes. Institutional oversight of DURC is a critical component of such an oversight system because institutions are most familiar with the life sciences research conducted in their facilities and are in the best position to promote and strengthen the responsible conduct and communication of DURC.

This policy and the [March 2012 DURC Policy](#) are complementary and emphasize a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse. Like the March 2012 DURC policy, the scope of this policy is limited to a well-defined subset of life sciences research that involves 15 agents and toxins



and seven categories of experiments.

Currently the USG is soliciting feedback on the experience of institutions in implementing the policy. The USG will continue to evaluate the impact of DURC oversight on the life sciences research enterprise; assess the benefits and risks of expanding the scope of the policy to encompass additional agents and toxins and/or categories of experiments; and update the policy as warranted.

To assist institutions and stakeholders with implementation, the White House Office of Science and Technology Policy will host a stakeholder engagement workshop on July 22, 2015. The purpose of the meeting is to inform and engage stakeholders; collect feedback

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The New York Times called the 1950s variola virus vials found recently in a lab in Bethesda, “ticking vial bombs, left in boxes.”

Biological Risk Management Culture: the Good, the Bad and the Ugly

By Dana Perkins, Ph.D., HHS/ASPR (dana.perkins@hhs.gov)

*“You see, in this world, there’s two kinds of people, my friend. Those with loaded guns and those who dig. You dig.”—Blondie quote from the movie *The Good, the Bad and the Ugly* (1966)*

The recent biosafety/biosecurity lapses involving *Bacillus anthracis*, variola virus and highly pathogenic avian influenza H5N1 virus uncovered at federal laboratories raise the question whether such breaches are on the rise or instead that transparency has increased with rapid reporting of such incidents to the public. A more fundamental question would be whether our regulatory and oversight measures that are in place are effective and sufficient to deal not only with the “bad” (i.e. keeping biological agents safe and secure) but also with the “ugly” (unknown biological risks and threats of the future).

The New York Times called the 1950s variola virus vials found recently in a lab in Bethesda, “ticking vial bombs, left in boxes.” Indeed, variola virus is a “loaded gun” with much potential for harm but our regulatory and oversight system was able to function properly in all instances and mitigate the risks so that no harm was done. That is the “good” part in this metaphor.

We do have room for improvements, however. One important goal is to inculcate a culture of safety and security within the minds of the people who operate and work in very different kinds of facilities. Such a biorisk management culture focuses on “the human factor.” It is a robust and comprehensive concept of training and vigilance that not only serves to reinforce the regulatory framework of security laws and regulations, but also to foster individual and collective responsibility. Without such an ingrained culture, the goal of sustainability will remain out of reach.

An international workshop on “*CBRN Security Culture: Concept, Assessment, and Enhancement*,” was organized under the auspices of the NATO Science for Peace and Security program by the University of Georgia Center for International Trade and Security (CITS) and The Non-Proliferation Center of Armenia, in Yerevan, Armenia, 9-13 June 2014. Workshop participants discussed the common culture elements that span the

four domains: chemical (C), biological (B), radiological (R), and nuclear (N), as well as the unique features specific to each subset domain. All of these elements need to be clearly identified and coordinated. In this sense, the CBRN culture has been broadly defined as:

“An assembly of beliefs, attitudes, and patterns of behavior that can reinforce or complement operating procedures, rules, and practices, as well as professional standards and ethics designed to achieve CBRN non-proliferation goals and prevent CBRN terrorism.”

Participants discussed how the CBRN security culture is intrinsic to high standards of professionalism as applied to the imperatives of weapons of mass destruction (WMD) non-proliferation and the prevention of terrorism. This culture enables a person or an institution to respond to familiar and unfamiliar security threats to materials and facilities—including insiders with malicious intent—out of carefully nurtured habit rather than improvisation. For instance, a WMD proliferation prevention mindset (fueled by the nurtured culture) could enhance due diligence in the process of evaluating the risk of dual use research of concern in life sciences, issuing export licenses, verifying end-users, and preventing illegal transfers of knowledge, materials and equipment.

As national security is a societal value rooted in national beliefs, values, and a certain perception of risks and threats, and as the life sciences field is a convergence of multi-disciplines and a myriad of cultural sub-sets, no one size fits all when it comes to developing a biological risk management culture holistically integrated into the CBRN Security Culture. There is a perceived need for practical guidance, education, and training on evaluation/assessment of biological risk management culture, in order to achieve a sustainable approach built on the current regulatory/legislative framework mandated internationally and dedicated to the broader CBRN Security Culture. In this context, the [Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance Document](#) published by International Biological Threat Reduction, Sandia National Laboratories, in collaboration with The International Federation of Biosafety Associations is a welcome development.

Managing compliance with laws and regulations, institutional policies, rules, and code of responsible conduct of science is a complex task that

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requires meeting the needs of various stakeholders. A useful tool may be the ISO 19600 which was developed as a *guideline* for compliance management and not as a *specification* that provides *requirements*. ISO 19600 follows a risk-based approach to compliance management that is aligned with ISO 31000 (the ISO standard for risk management).

Workshop participants agreed that the concept of nuclear/radiological security culture and its evaluation/assessment methodologies and tools are much more developed than its counterparts in the chemical and biological fields, due primarily to the leading role of the International Atomic Energy Agency internationally. The [generic model of radiological security culture](#) could be applied to chemical and biological fields, however, and would offer the opportunity of enhancing biosecurity and chemical security. Training and education programs could be improved by focusing on a more holistic and sustainable approach dedicated to CBRN security rather than the current focus which is simply raising awareness.

An added benefit of this approach is that such enhancements could be measured and tracked over time as success metrics or as part of a corrective action plan. Last but not least, the CBRN security culture provides an additional risk mitigation approach that complements the legally binding obligations set forth by the UN Security Council resolution 1540 (2004) on all States to:

- refrain from providing any form of support to non-State actors that attempt to develop, acquire, manufacture, possess, transport,



Dr. Dana Perkins, US Department of Health and Human Services, facilitates the discussions during a tabletop exercise at the workshop.

transfer or use nuclear, chemical or biological weapons and their means of delivery;

- adopt and enforce appropriate effective laws prohibiting activities involving the proliferation of such weapons and their means of delivery to non-State actors, in particular for terrorist purposes, as well any attempts to engage in such activities, assist or finance them; and
- implement and enforce appropriate controls over chemical, biological, and nuclear weapons-related materials.

Such "related materials" are defined by the UN Security Council as "*materials, equipment and technology covered by relevant multilateral treaties and arrangements, or included on national control lists, which could be used for the design, development, production or use of nuclear, chemical and biological weapons and their means of delivery.*"

For additional information, see the 1540 Compass journal vol. 7 at: http://cits.uga.edu/uploads/1540compass/1540PDFs/Compass_Magazine_7-web.pdf

An added benefit of this approach is that such enhancements could be measured and tracked over time as success metrics or as part of a corrective action plan.

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about resources needed to effectively implement the policy; and discuss stakeholder experiences, challenges, and innovative practices.

The workshop will include the following sessions:

- An interactive case study that will illustrate factors that investigators and institutions should consider when determining whether research is subject to the policy.
- A series of panels comprised of institutional representatives who will share their respective approaches to identifying research sub-

ject to the policy, developing risk mitigation plans, and methods to raise awareness and educate stakeholders about DURC.

- An open forum for participants to share individual stakeholder input on issues relating to interpretation and implementation of the policy.

The workshop will be held at the National Institutes of Health. Registration is required online at www.PHE.gov/DURCworkshop. For any additional questions regarding the policy or the upcoming workshop, please contact DURC@ostp.gov.

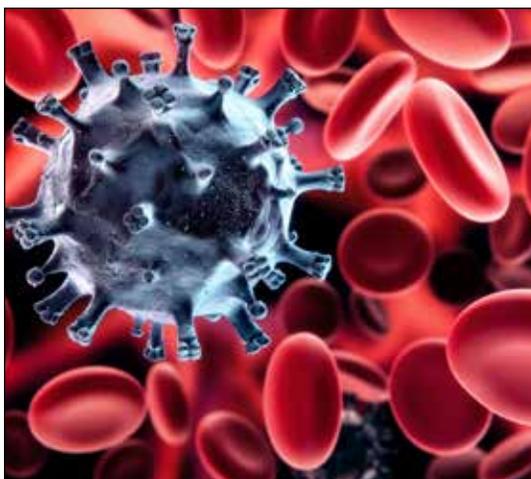
Canada and U.S. Pathogen Security Partners Meeting

By CAPT Theresa Lawrence, Ph.D., HHS/ASPR (Theresa.Lawrence@hhs.gov)

The meeting provided an opportunity to build and strengthen relationships between American and Canadian colleagues responsible for regulation, law enforcement, and intelligence as it pertains to pathogen security.

The Canada and United States (U.S.) Pathogen Security Partners meeting convened in Quebec, Canada on January 27 and 28 to advance biosafety, biosecurity, and pathogen control. The meeting provided an opportunity to build and strengthen relationships between American and Canadian colleagues responsible for regulation, law enforcement, and intelligence as it pertains to pathogen security. Meeting objectives included sharing lessons learned with regards to risk mitigation measures for emerging risks (emerging science and technologies, dual use, intangible technology transfer); identifying opportunities and challenges with building security awareness in the laboratory stakeholder community amid the increasingly global nature of research; supporting effective stakeholder engagement with a view to compliance promotion; addressing policy development; and addressing enforcement of pathogen security legal frameworks.

Meeting outcomes included: 1) tools and models to assist Canadian and U.S. scientific, security, and regulatory agencies with outreach initiatives, increasing overall safety and security; 2) streamlined efforts to increase awareness of biosecurity within communities common to U.S. and Canada, such as the academic, non-profit, commercial and amateur biology communities; 3) increased openness, transparency and collaboration between U.S. and Canadian colleagues, and enhanced ability to respond to emerging issues or incidents through clear lines of communication; and 4) ultimate outcomes include



sensitization in regards to U.S. and Canadian situations, perspectives, challenges and forward plans to foster collaboration on aligned pathogen security policy and regulatory interventions where possible. A full meeting report with priorities for collaboration and knowledge exchange moving forward will be developed.

The Division of Biosafety, Biosecurity, and Countering Biological Threats within the Office of the Assistant Secretary for Preparedness and Response (ASPR) collaborated with Public Health Agency of Canada to convene the meeting. Representation from the United States at the meeting included the Department of Health and Human Services (ASPR, Office of Global Affairs, Centers for Disease Control and Prevention, and the National Institutes of Health), Department of Defense, Department of Homeland Security, Department of Justice, and the Department of State. The American Association for the Advancement of Science also participated in specific sessions. Multiple agencies in Canada participated in the meeting. President of the Public Health Agency of Canada, Krista Outhwaite, and Dr. Theresa Tam, head of the Health Security Infrastructure Branch of the Public Health Agency of Canada provided remarks at the meeting.

The Pathogen Security Partners meeting provides the foundation for further collaboration and creation of synergies with Canada to advance biosafety and biosecurity.

FBI Launches International Biosecurity and Prevention Forum

By Todd Savage, FBI (Todd.Savage@IC.FBI.gov)

In 2011, several agencies and global organizations began informal discussions on ways to improve biosecurity efforts across the spectrum of global biosecurity efforts and to find ways to cut through geopolitics to improve biosecurity cooperation. Biosecurity and safety laboratories for research on human and animal diseases at Biosafety Level (BSL) -3 and -4 levels were expanding throughout the world. Globally, there exists a mixed bag of security practices, information sharing, and working with law enforcement and first responders for emergencies in the unique environments of research centers, as well as vaccine, agriculture, and food manufacturing sites. There was consensus that regardless of a nation's biosecurity agenda, each nation and the global community would benefit from raising the bar for biosecurity by sharing best practices and practical experiences. One approach receiving broad support was establishing a web-based global biosecurity forum to facilitate networking and information sharing.

In 2012, Secretary of State Hillary Clinton announced the intent to create the International Biosecurity and Prevention Forum (IBPF or Forum) at an international security conference. The IBPF was to be a web-based open forum to allow the public, the global community of biosecurity experts (e.g., law enforcement, first responders, research center Responsible Security Officials (RSOs), lead researchers, and food & vaccine production sites) to network, have access to technical & policy papers, share best practices, and advance virtual training and certification opportunities.

The IBPF's goal is to become the global "go-to" site for information, best practices, and networking on everything related to biosecurity. For international Forum members, the Forum will offer a global picture of biosecurity best practices, protocols, and regulatory oversight practices. Experts will regularly speak by live forum internet streaming with follow-on discussions. Virtual exercises will allow members to compare their skills and experiences with their global peers. On a regular basis, members and their work will be featured in the Forum. The Forum also allows for full written translations in over 90 languages.

Biosecurity is often considered a niche security concern compared to high profile threats such as active shooters and cyber-attacks. Although the risk may seem low historically, the impacts related to a biosecurity breach and a possible follow-on outbreak or pandemic can threaten the core of our national and global security. The recent Ebola crisis has been a timely wake-up call for the need to manage the biosecurity threat more carefully. Just a few infected patients can overwhelm the resources of a modern hospital and the local/regional governments. On the cyber side, there are proliferating reports of malware and hackers disrupting automated systems (SCADA-Supervisory Control and Data Acquisition) for water, food, and even vaccine production, as well as the theft of proprietary research and manufacturing information.

Almost every mid-size and large city in the U.S. has at least one biosafety laboratory research center associated with a university or private sector site. Hundreds of biosafety laboratory research sites are scattered across the country and throughout the developing world; many of them do not have any detailed contingency plans for law enforcement and first responder assistance and do not regularly perform security exercises with their local first responders. The IBPF will encourage and provide support, along with the Forum partners, to carry out joint biosecurity planning and training.

The working relationships among sensitive research labs, agriculture, food and water processing sites, other private sector biological sites, local law enforcement, and the other elements of the first responder community, are a mixed situation; and can benefit from appropriate best practices and training to encourage a close working relationship between local first responders and their local biosecurity sites of concern. Best practices for using personal protective equipment (PPE) and hazardous materials (HAZMAT) containment equipment are not the complete answer for responding to BSL-3 or -4 level emergencies. A trusted, full sharing of information and risks with the infectious agents involved goes way beyond a typical HAZMAT response. Biosecurity does not end with the arrival of the first responders on the scene, but grows

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The Forum will not try to differentiate between biosafety and biosecurity issues - both are intertwined, but the Forum intends to focus on the biosecurity gaps that are prevalent everywhere.

in a very complex manner to deal with the immediate and potential risks of biological contamination, break-out, and dispersion, with even more steps if these are terrorist-related events.

The Forum will not try to differentiate between biosafety and biosecurity issues - both are intertwined, but the Forum intends to focus on the biosecurity gaps that are prevalent everywhere. The future biosecurity training and certification portal will be found on the member's site - but it is still under development. The training syllabuses and certifications will be developed jointly by the IBPF and its partners. This will ensure the latest experiences and protocols are incorporated into Forum biosecurity training, and that the responsible agency/organization protocols and policies are fully represented. The training and certification packages will be updated annually or sooner if circumstances dictate. These training modules are being developed to work flawlessly from any computer at an international research station or a laptop at a university cyber café. The IBPF will also be exploring future joint biosecurity-related conferences, workshops, and exercises with its partners.

The Forum partners include the United Nations, Department of State (DOS), Department of Justice (DOJ)-FBI, Federation of American Scientists (FAS), Interpol, the International Association of Fire Chiefs, George Mason University, and Middlebury Institute of International Studies in Monterey. Other organizations and their members are joining the IBPF daily. In response to the perceived global risks, the FBI's biosecurity outreach program within the Weapons of Mass Destruction Directorate/Biological Countermeasures Unit has agreed to assume responsibility for the technical administration of the Forum. However, the FBI as a Forum partner does not intend to suggest any best practices or policies, but will support the other Forum partners, such as the DOS, UN, FAS or Interpol, in these efforts based on local circumstances and practices.

Although IBPF launched on January 5, 2015, the portal is already undergoing major updates to incorporate advanced and more intuitive user interface features. Access to the Forum is through www.IBPFforum.org. This link will take you to a public page, and the member's separate site is password protected. Individuals must join IBPF through organizational IBPF partners and will be validated by their organization to verify

they are biosecurity-related professionals (e.g., university lab researchers, transportation managers, and local and university police/fire-EMS officials). Validation is not a background check, however; the Forum will welcome new members from any work place and country if they can verify they are biosecurity-related professionals. The IBPF is also developing criteria for welcoming non-organization associated individuals, such as the do-it-yourself bio hobbyists, or researchers and managers from foreign organizations where their organization is not prepared to join the IBPF.

The Forum is not looking to compete with its partners, but to support and enhance each member's biosecurity-related programs. Each Forum partner will have prominent dedicated Forum space to highlight their organization's biosecurity responsibilities, on-going activities, reports, calendars, and direct links back to their web sites. An organizational partnership with the Forum will impose no obligations other than to keep the posted information of interest to the biosecurity community current, provide links back to the organization's web sites, and provide contact information on the Forum's secure members' site. The IBPF will cover all forum expenses.

Contact information

All organizations such as universities with biosafety laboratory facilities, law enforcement/first responders, and bio-related agriculture, food, and water processing facilities are encouraged to join the IBPF. For further information on joining the Forum as a partner, contact:

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For individual biosecurity professionals working in an organization that is not currently a member of the IBPF but who wish to join, please contact the IBPF at:

IBPFforum@IC.FBI.gov