SCIENCE, SAFETY, SECURITY Quarterly

News for the Federal Biorisk Management Policy Community

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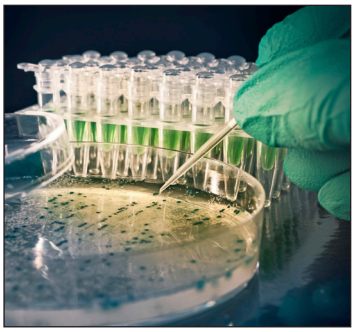
HHS Releases Important Policies on Dual Use Research of Concern

By Janelle Hurwitz (janelle.hurwitz@hhs.gov)



The United States Government (USG) has released several policies that continue to promote awareness and responsible review and conduct of dual use research of concern (DURC). The USG has defined dual use research of concern as 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 or materiel. In 2011, a controversy surrounding two NIH-funded studies which met this DURC definition led to a moratorium on H5N1 transmission studies. These two H5N1 studies examined the mammalian transmissibility of HPAI H5N1 viruses. The researchers sought to identify genetic changes that might alter the host range of the virus or correlate with increased transmissibility among mammals. Studies that enhance these and other biological properties are categorized as "gain-of-function" research. Gain-of-function research can inform the development and evaluation of vaccines, antivirals, and diagnostics for HPAI H5N1 strains that have potential human transmissibility and can also contribute to pandemic preparedness efforts. However, these studies also raised concerns regarding the potential for accidental or intentional release of a highly pathogenic engineered virus and drew attention to focused efforts that were already ongoing to address these issues.

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CDC's Development of a Biosafety Assessment Tool

By Thomas Stevens (tks3@cdc.gov)

The increased burden of diseases such as HIV, tuberculosis, and malaria in Africa continues to challenge the region's existing public health systems. As a result, national public health authorities have encountered significant challenges associated with weaknesses in laboratory systems, disease prevention and control, and the effective management of patient care. To address these needs, the World Health Organization-Africa Regional Office (WHO-AFRO) is promoting efforts to strengthen laboratory capacity in Africa.

The Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) program was launched by WHO-AFRO to strengthen laboratory capacity and help laboratories achieve Quality Management Systems (QMS) accreditation. ISO 15189 - Medical Laboratories Particular Requirements for Quality and Competence outlines laboratory safety requirements for QMS accreditation. Laboratory safety is a major component of ISO 15189. Therefore, the SLIPTA implementation process must address laboratory safety.

cont. on pg. 3

HHS Releases Important Policies on Dual Use Research of Concern

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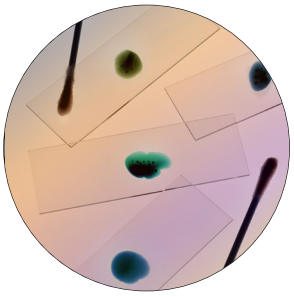
The purpose of the Department-level review is to provide balanced, multidisciplinary expertise and perspectives to consideration of proposals that involve HPAI H5N1 gain-of-function studies.



USG DURC Policy

In order to minimize risks associated with DURC in U.S. labs, the USG released a policy on March 29, 2012 entitled "United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern." This policy establishes regular review of USG-funded or -conducted research with certain high-consequence pathogens and toxins for its potential to be DURC in order to mitigate risks and inform the development of new policy, where applicable.

The USG also recently released a proposed Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, and public comments have been received. Interagency representatives are reviewing and adjudicating comments. When completed, the findings will be released with a revised policy in the Federal Register.

HHS Framework

In a related effort, the Department of Health and Human Services (HHS) recently published a "Framework for Guiding U.S. Department of Health and Human Services Funding Decisions about Research Proposals with the Potential for Generating Highly Pathogenic Avian Influenza (HPAI) H5N1 Viruses that are Transmissible among Mammals by Respiratory Droplets." This framework ensures a robust review of research proposals, prior to a funding decision, that considers the scientific and public health benefits of the proposal, the biosafety and biosecurity risks associated with the proposal, and the mitigation measures required.

The HHS Framework applies to all HHS entities and outlines steps for both agency- and department-level reviews of proposed HPAI H5N1 research that meets certain criteria. The HHS Framework applies to funding applications that include or are reasonably anticipated to generate HPAI H5N1 viruses with gain-of-function attributes that enable respiratory droplet transmission of the virus among mammals. Characterization studies (including sequencing and testing of antigenicity, anti-viral drug susceptibility, and pathogenicity) of naturally occurring H5N1 viruses are exempted from this framework. Proposals covered by the Framework, including extramural and intramural research, first undergo scientific merit and DURC reviews prior to application of the HHS criteria from this Framework. Gain-of-function research proposals that are anticipated to produce HPAI H5N1 strains that are transmissible among mammals by respiratory droplets are acceptable for HHS funding only if the following criteria are met.

Seven Criteria for HHS Funding

1. Such a virus could be produced through a natural evolutionary process;
2. The research addresses a scientific question with high significance to public health;
3. There are no feasible alternative methods to address the same scientific question in a manner that poses less risk than does the proposed approach;
4. Biosafety risks to laboratory workers and the public can be sufficiently mitigated and managed;
5. Biosecurity risks can be sufficiently mitigated and managed;
6. The research information is anticipated to be broadly shared in order to realize its potential benefits to global health; and
7. The research will be supported through funding mechanisms that facilitate appropriate oversight of the conduct and communication of the research.

If the funding agency determines that the proposal meets these seven criteria and is considering funding the research, then department-level review is required to determine if it is acceptable for HHS funding. The funding agency will also make an initial determination of whether the proposed risk mitigation strategies identified by the biosafety and biosecurity reviews are adequate and will pass these assessments on to a review group chaired by the Assistant Secretary for Preparedness and Response.

HHS Departmental-Level Review

The Department-level review provides balanced, multidisciplinary expertise and perspectives to consideration of proposals that involve HPAI H5N1 gain-of-function studies. The HHS HPAI H5N1 Gain-of-Function (HHG) Review Group is currently chaired by Dr. Nicole Lurie, the Assistant Secretary for Preparedness and Response. Officials from eight Operating Divisions and Staff Divisions of HHS are represented in the review, with expertise in biological sciences, science policy, intelligence, security, global health, ethics, and medical countermeasures development. If the HHG Review Group finds the research acceptable for funding, the funding agency will be notified and will make the final funding decision.

The full policy can be found here.

CDC's Development of a Biosafety Assessment Tool

cont. from pg. 1

To complement the SLIPTA process, WHO-AFRO is also encouraging countries to implement the CEN Workshop Agreement (CWA) 15793 - Laboratory Biorisk Management, which outlines 14 safety program elements for biological laboratories.

Furthermore, CDC has taken a phased approach to developing a Biosafety Assessment Tool (BAT) that incorporates these safety program elements from the CWA 15793 standard.

The 14 safety program elements include:

- Management's Responsibility
- Safety Business & Administrative Programs
- Review Laboratory & Biosafety Programs
- Equipment Evaluation - Maintenance, Calibration, and Certification
- Review Building and Facility Safety Programs
- Occupational Health Program
- Chemical Management and Industrial Hygiene Programs
- Waste Management and Environmental Safety Programs
- Emergency Preparedness and Response Programs
- Agent Biosecurity
- Transport of Biological Agents
- Employee Training and Outreach Activities
- Field Activities
- Radiation Safety Programs

CDC will develop the core competencies based on a variety of references and guidance documents to include:

- CWA 15793 - Laboratory Biorisk Management Standard
- CWA 16393 - Laboratory Biorisk Management Guidelines for the Implementation of CWA 15793:2008
- ISO 15190 - Medical Laboratories-Requirements for Safety
- ISO 15189 - Medical Laboratories-Particular Requirements for Quality and Competence)
- WHO-AFRO's Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist
- WHO's Laboratory Biosafety Manual, 3rd edition
- Other professional references, such as the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition

The BAT is a guidance document and supporting implementation package for countries engaged in the development and strengthening of safety programs. The BAT will be beta-tested in Mozambique, Ethiopia, Kenya, and Tanzania.

Phase I of the project prioritized the development of the core competencies for 1) Occupational Health Programs, 2) Waste Management and Environmental Safety Programs, 3) Chemical Management and Industrial Hygiene Programs, and 4) Building and Facility Safety Programs.

The BAT will establish minimal criteria in each of the 14 safety program elements, provide guidance for institutions to develop and implement safety programs, serve as a self-assessment tool for reviewing safety programs, and facilitate the development of educational materials to assist with implementation.

As previously stated, QMS accreditation in Africa is being supported by the SLIPTA process, which is aimed at strengthening existing laboratory systems. Safety programs are a key element frequently overlooked in the accreditation process; additional support and guidance is therefore needed to help laboratories meet these standards. The BAT is designed to address these needs and guide institutions in developing more robust safety programs.

The Biosafety Assessment Tool is a guidance document and supporting implementation package for countries engaged in the development and strengthening of safety programs.

The U.S. Department of Health and Human Services participates in the International Conference on Health and Security - *Building Partnerships for Biological Threats Prevention, Preparedness, and Response*

By MAJ Dana Perkins (dana.s.perkins.mil@mail.mil)

"Just as the Biological Weapons Convention constitutes the norm against using disease as a weapon, so should the robust public health and the protection of the health of our people become the norm worldwide. We can best achieve this shared goal of a safer and healthier world by coordinating our approach and strengthening our day to day systems across our sectors to make them accessible, effective, sustainable, and built to last."

Dr. Nicole Lurie, *International Conference on Health and Security,* 5 September 2012, Washington, DC

Global health security illustrates the power of multiple sectors working together because it generates dynamic new partnerships that not only save and enhance lives but also bolster the security of all nations. Our shared goal of a safer and healthier world could only be achieved through a smart, long-term engagement of health and security communities to build global preparedness to prevent, detect, and respond to the full range of public health hazards and not only to those that may have the potential to affect national or international security.

The U.S. Department of Health and Human Services (HHS) routinely supports the U.S. delegation to the Biological Weapons Convention (BWC) and recognizes the BWC's significance for achieving the norm of peaceful uses of life sciences that the Convention embodies. In support of these efforts, the BWC has in recent years heard presentations by public health, scientific, security, and law enforcement communities that highlighted global disease challenges and the need for strengthening public health preparedness and response to public health emergencies of international concern.

Organized under the *Bio-Transparency and Openness Initiative* (formally announced by Secretary Hillary Rodham Clinton at the 7th Review Conference of the BWC in December 2011), the *International Conference on Health and Security - Building Partnerships for Biological Threats Prevention, Preparedness, and Response*, took place in Washington, DC. Representatives from the fields of law enforcement and security, public health, and foreign affairs from 30 countries were in attendance. The Conference also featured 39 speakers from 22 different departments/organizations, including HHS (ASPR and CDC). Dr. Nicole Lurie, Assistant Secretary for Preparedness and Response, provided keynote remarks on the "Intersection of Health and Security" as a "scene-setter" for the follow-on roundtable discussion on "Global Health Security" (which was chaired by the National Security Staff and included CDC representative, Dr. Scott Dowell, Director of the Division of Global Disease Detection and Emergency Response).

Dr. Lurie emphasized HHS support for global health security and the department's continuous commitment to enhance inter-sectoral and international partnerships in a "whole of government" / "whole of society" manner to effectively prevent, prepare for, and respond to biological threats regardless of cause. With regard to Dr. Lurie's presentation and the other keynote speakers from the FBI, WHO, and BWC Implementation Support Unit, Ambassador Laura Kennedy (the U.S. Special Representative for BWC Issues) said that they illustrate " *...the synergies...*" between health and security communities.[1] Ambassador Kennedy also added that "*...the Secretary's Bio-Transparency and Openness Initiative reflects the Administration's commitment to creating an unprecedented level of transparency and openness in the U.S. government in order to ensure greater accountability and effectiveness in governance.*"[2]

[1]Laura Kennedy, Advancing the Biological and Toxin Weapons Convention With Bio-Transparency and Openness Initiative, DipNote: U.S. Department of State Official Blog, 26 Sep 2012, online at: http://blogs.state.gov/index.php/site/entry/biological_toxin_weapons_convention

[2]Ibid.

Global Biorisk Management Curriculum

By Michelle McKinney, Biorisk Lead, Cooperative Biological Engagement Program, (michelle.mckinney@dtra.mil)

The Cooperative Biological Engagement Program (CBEP) at the Defense Threat Reduction Agency (DTRA) strives to address the risk of outbreaks of dangerous infectious diseases by promoting best practices in biological safety and security, improving partner countries' capacities to safely and rapidly detect and report dangerous infections, and establishing and enhancing international research partnerships. To better achieve these programmatic objectives and develop jointly funded the development of the Global Biorisk Management Curriculum (GBRMC) with the U.S. Department of State's Biosecurity Engagement Program (BEP). The International Biological Threat Reduction program at Sandia National Laboratories has been the lead developer of the GBRMC, and numerous US agencies and international subject matter experts have also contributed.

The GBRMC library is repository of training courses centered around the principles and best practices of biorisk management (biosafety and biosecurity) as defined by the international consensus standard document CWA 15793:2011, Laboratory biorisk management[1] (**Figure 1**). The courses are global – intended for use by any biorisk management trainer in nearly any situation or location in the world. In order to meet that intent, the courses must be both strategic and sustainable. As such, the GBRMC is a collection of train-

The International Biological Threat Reduction program at Sandia National Laboratories has been the lead developer of the GBRMC...

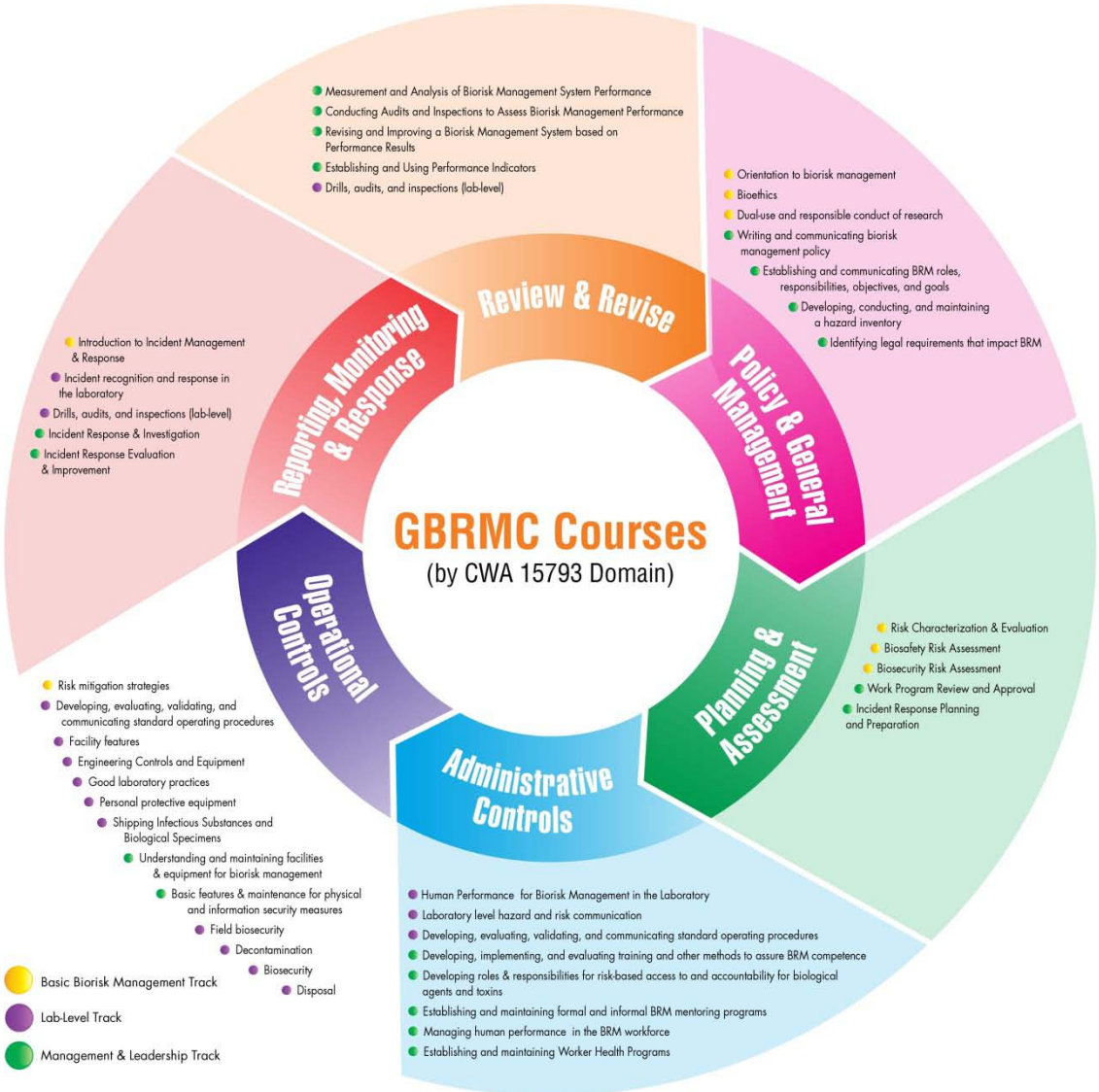


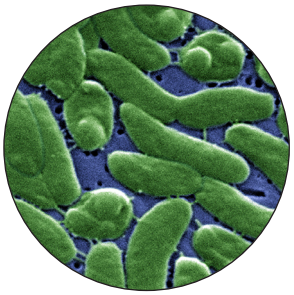
Figure 1. GBRMC Courses by CWA 15793 Domain

Global Biorisk Management Curriculum *cont. from pg. 5*

There are currently 42 courses organized into three tracks intended to meet the needs of these stakeholders.

Biorisk Management Basics	All	Awareness, biorisk management basics
Management & Leadership in Biorisk Management	Policy makers, top management, biorisk management advisors, scientific and laboratory management	Culture, capacity, infrastructure, support, budget
Laboratory-Level Biorisk Management	Biorisk management advisors, scientific and laboratory management, and laboratory workforce	Safe & secure storage, transport, handling, disposal

Table 1. GBRMC Tracks and Target Audiences



CWA 15793: 2011, and WHO biosafety[2] and biosecurity guidance[3]) and has been developed using validated instructional design and experiential learning principles to enhance the flexibility and sustainability of the curriculum.

The GBRMC library is designed to include peer-reviewed and quality-controlled training materials that can be adapted to meet local needs and provide specific training designed for primary international stakeholders in a biorisk management system including: policy makers, top management, biorisk management advisers (also called biosafety offers), scientific and/or laboratory management, and laboratory workers. There are currently 42 courses organized into three tracks intended to meet the needs of these stakeholders (**Table 1**). GBRMC courses can be used together or separately in a variety of implementation strategies based on organization and student needs and the preferred training method and environment.

Material for every GBRMC course includes:

1) a design document (course objectives, prerequisites, course outline and proposed agenda),
2) instructor's guide (detailed notes, instructions and materials for interactive exercises, handouts),
3) slide deck,
4) student guide (student workbook and references and resources),
5) instructor and student evaluation materials (level 1 and 2),
6) references and resources and
7) other materials as needed.

The core courses have been designed to address about 75 to 85% of content generally covered in basic and intermediate biorisk management training events. The remainder of necessary training content is required to be locally or situationally guided. The GBRMC library also contains examples and possible templates for some of this local or situational material, but this aspect requires input from trainers and local experts for optimal performance.

In addition to the GBRMC library of training materials, there is a complimentary Core Document collection of biosafety and biosecurity template documents that can be locally adapted to facilitate implementation of a biorisk management system such as CWA 15793:2011. CBEP partners can choose from a library of peer-reviewed and quality-controlled standard operating procedures, manuals, and other associated documents, covering safe and secure laboratory operations. Core Documents are developed as customizable templates and are adapted at each facility to promote a sustainable biorisk management program and are an excellent supplement to the GBRMC catalog.

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Global Biorisk Management Curriculum *cont. from pg. 6*

The GBRMC library

- Is a growing collection of peer-reviewed biosafety and biosecurity training materials designed to be used nearly anywhere, at any time
- Is directed towards building biorisk management capacity
- Is based on internationally recognized biosafety and biosecurity practices
- Uses highly interactive training techniques designed to sustain biorisk management knowledge and skills
- Is aligned with the CBEP Core Document library

Courses in the GBRMC library

- Are based on a comprehensive biorisk management system approach
- Are customized for different roles and responsibilities within biorisk management
- Can be configured to meet a variety of training scenarios (e.g., veterinary/field emphasis versus human/clinical/laboratory setting)
- Can be customized to include local considerations and needs, including translations

Trainers who wish to use the GBRMC library will

- Receive an orientation with details on accessing and using the library and course materials
- Be enrolled in the GBRMC Trainers' Network (GBRMCNet SharePoint site) to encourage feedback and communication about training needs and solutions
- Have ongoing access to new, updated, or translated courses, as well as to evaluations of training events using GBRMC courses

Assistance is available to

- Match the courses to the needs identified by trainers
- Provide courses in different media
- Collect and assess the feedback from the use of the GBRMC course
- Evaluate new and emerging trends in biorisk and biorisk management

What's new

- A classroom-based GBRMC Trainers' Orientation has been developed and offered to over 100+ trainers who desire to access and use the library with a distance learning option under development
- Some courses have been translated into Spanish, Ukrainian, French or Russian
- Example training blocks – 3- to 5-day agendas of training events, using GBRMC courses and guided exercises, have been developed
  - Biorisk Management Policy and Program
  - BSL3 "Operations and Standard Operating Procedures"
  - Biosecurity Toolkit
  - Trainers' Development Program
  - Veterinary/Field Biosafety and Biosecurity
- New courses for additional roles
- Distance-learning options for frequently-used courses
- Templates for common customization options
- Revisions in response to community use and evaluation

After more than a year of testing the GBRMC all over the world, some valuable lessons have been learned that are guiding future development and implantation. Strategic, biorisk management system approaches meet most needs, and students respond positively to experiential learning. Instruction of the GBRMC requires fully engaged trainers. While core GBRMC courses were designed to meet 75 to 85% of specific training needs, customized material couples well with the core courses and is available to trainers on the GBRMCNet. For more information, please contact Michelle McKinney, Biorisk Lead, Cooperative Biological Engagement Program, michelle.mckinney@dtra.mil or 703-767-7778.

References

1. CWA 15793:2011, Laboratory biorisk management (ftp://ftp.cenorm.be/CEN/Sectors/TCandWorkshops/Workshops/CWA15793_September2011.pdf)
2. WHO Laboratory Biosafety Manual, 3rd edition (http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/)
3. WHO Biorisk management: Laboratory biosecurity guidance (2006) (http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf)

Feedback and Submissions Welcome

We want to hear from you! We are currently in the process of revamping the S3 newsletter in order to better optimize the content and format for our readers. 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!