U.S. Government
Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight Public Consultation

Bethesda North Marriott Hotel & Conference Center
5701 Marinelli Road
Bethesda, Maryland 20852

December 8-9, 2008

Agenda

Monday – December 8

8:30 a.m. **Welcome and Opening Remarks**
Steven Kappes, PhD, Deputy Administrator, Animal Production and Protection Agricultural Research Service, National Programs, U.S. Department of Agriculture

8:45 a.m. **Introduction to the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight**
Carol D. Linden, PhD, Principal Deputy Director, Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

9:15 a.m. **Informing Recommendations on Optimizing Biosafey and Biocontainment Oversight: Why A Public Consultation Meeting?**
Gerald Parker, DVM, PhD, MS, Principal Deputy Assistant Secretary, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

9:30 a.m. **Evolution of Biosafety**
W. Emmett Barkley, PhD, President, Proven Practices, LLC

10:00 a.m. ***Break***

10:15 a.m. **Panel I – Biosafety Competency Standards and Training in High and Maximum Containment Research Facilities**

Moderator: *Deborah E. Wilson, DrPH, CBSP, CAPT U.S. Public Health Service, Director, Division of Occupational Health and Safety, National Institutes of Health, U.S. Department of Health and Human Services*

Background: The Task Force noted the importance of ensuring that all scientists, support staff, and biosafety professionals working in high (BSL-3 and equivalent containment) and maximum containment laboratories (BSL-4 and equivalent containment) achieve and maintain a sufficient level of technical competency for working safety in the laboratory.

To address this specific need, the Task Force defined a specific objective:

Develop an overarching strategy to ensure that all individuals who work in, oversee, or manage high and maximum containment research laboratories are appropriately trained and technically competent.

The Task Force is seeking individual input on strategies to meet this objective.

Discussion questions:

- Should minimum competency and training standards be developed for all personnel who work in, oversee, or manage high and maximum containment research laboratories? (This includes scientists; technicians; engineering, animal care, housekeeping, and maintenance staff; biosafety professionals; laboratory managers; and institutional facility managers.) If so, who should develop these standards?
- What are the optimal core elements of effective biosafety laboratory training programs for all personnel working in high (BSL-3 or equivalent) and maximum (BSL-4 or equivalent) containment research laboratories?
- Are there sufficient training opportunities for personnel in high and maximum containment laboratories to ensure effective training of current and projected staff?
- Should biosafety professionals at institutions with high or maximum containment research laboratories be credentialed (certified or registered by an independent authority as competent in the application of biosafety/biocontainment practices and capable of delivering training and oversight of biosafety/biocontainment)? Should the Federal government incentivize such a requirement for high and maximum containment research laboratories?
- Should research and support staff in high and maximum containment research laboratories be certified as competent in the application of biosafety/biocontainment practices? Should the Federal government incentivize such a requirement for staff certification or registration at high and maximum containment research laboratories?
- What is the responsibility of the following with respect to biosafety training:
    - The principal investigator or laboratory supervisor?
    - The institution?
    - The Federal government? State governments?
    - Professional organizations?

<u>Panelists</u>

- *Nicole Duffee, DVM, PhD, Director, Education & Scientific Affairs, American Association for Laboratory Animal Science*
- *Christina Thompson, MS, RBP, CBSP, Biological Safety Consultant, Thompson Biosafety, LLC*
- *Robert J. Hawley, PhD, RBP, CBSP, Senior Advisor, Center for Biological Safety and Security (CBS2), Midwest Research Institute*
- *Murray Cohen, PhD, MPH, CIH, President and Chairman, Frontline Healthcare Workers Safety Foundation, Ltd.*

Discussion

12:00 p.m. ***Lunch***

1:00 p.m.

Panel II – Review of all Research Protocols in all BSL-3, BSL-4, and Equivalent Containment Facilities

Moderator: *Robert J. Hawley, PhD, RBP, CBSP, Senior Advisor, Center for Biological Safety and Security (CBS2), Midwest Research Institute*

Background: Biosafety management programs at individual institutions are fundamental to the effectiveness of the overall framework for biosafety and biocontainment. Biosafety risk assessments (biosafety review) of all research protocols are important for assigning the proper biocontainment level for each protocol and identifying safety precautions for high and maximum containment research. The *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) provide risk assessment standards that must be used by institutions receiving funding from NIH, as well as certain Federal agencies and institutions for recombinant DNA (rDNA) research. Many institutions have elected to extend similar mechanisms of review to all research involving infectious agents and toxins under high and maximum containment, however such review is not currently mandated.

The Task Force is seeking individual input on the objective to:

Ensure that all high and maximum containment research institutions have proper "biosafety review" mechanisms for research protocols.

Discussion questions:

- Should there be a Federal mandate for "biosafety review" of research at all high and maximum containment research facilities in all sectors (government, academic, and private)?
- Should all high and maximum containment research facilities in all sectors be required to have specific entities (e.g., a credentialed biosafety professional and an institutional biosafety review committee, or equivalent) to conduct risk assessments and assign the appropriate containment level for each research protocol?
- What would be the impact of mandating that all high or maximum containment research be subject to biosafety review?
- Are there additional tools and guidance that would be helpful to local review bodies and investigators? What types of infrastructure would need to be established for biosafety reviews to occur?

Panelists

- *Joseph Kanabrocki, PhD, CBSP, Assistant Dean for Biosafety, Associate Professor of Microbiology, Biological Sciences Division, University of Chicago*
- *Scott Alderman, MS, CBSP, Director of Safety, Duke Human Vaccine Institute and Director of Operations, Regional Biocontainment Laboratory, Duke University Medical Center*

- *Stephen H. Hughes, PhD, Director, HIV Drug Resistance Program, Center for Cancer Research, National Cancer Institute, National Institutes of Health*

Discussion

3:00 p.m. ***Break***

3:15 p.m. **Panel III – Biosafety and Biocontainment Standards and Guidelines for Work Performed in BSL-3, BSL-4, and Equivalent Containment Facilities**

Moderator: *Janet K.A. Nicholson, PhD, Associate Director for Laboratory Science, Coordinating Center for Infectious Diseases, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services*

Background: Currently, work performed in BSL-3, BSL-4, and equivalent containment facilities is regulated and guided by various Federal Departments and Agencies. The *Select Agent Regulations*, developed by HHS and USDA, require compliance and include mechanisms for oversight. Although all BSL-4 facilities are covered under the *Select Agent Regulations*, not all BSL-3 and equivalent facilities are covered because some do not possess, use, or transfer select agents. The laboratory manual, *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*), published jointly by CDC and NIH, has become the most widely used reference in the United States for laboratory biosafety and biocontainment principles, practices, and procedures. However, a small number of high-risk pathogens and toxins fall outside the purview of existing Federal regulations, and there is no *BMBL*-equivalent for plant and livestock pathogens. The *NIH Guidelines* apply to any project involving recombinant DNA that is conducted at or sponsored by an entity that receives NIH support for recombinant DNA research. Certain other Federal agencies also require compliance with the *NIH Guidelines* as a term and condition of their grant awards. However, institutions that do not receive funding from NIH or these other Federal agencies are not required to adhere to the *BMBL* or the *NIH Guidelines*.

The Task Force is seeking individual input on the objective to:

Ensure that biosafety and biocontainment regulations and guidelines are sufficient, and that all high and maximum containment research laboratories are in compliance.

Discussion questions:

- Are existing biosafety/biocontainment regulations and guidelines sufficiently comprehensive and consistent for work in high and maximum containment research laboratories? If not, what needs to be revised?
- Should there be uniformly applied biosafety standards required for all research taking place in high and maximum containment laboratories in all sectors? If so, how should compliance with these standards be implemented and enforced?
- Encouraging a culture of increased accountability, and compliance with biosafety and biocontainment guidelines, standards, and policies at all institutions engaged in high and maximum containment research is important. What are the best mechanisms for

achieving this goal? (Establishing an accreditation system for the review and/or inspection of biosafety management programs at individual high and maximum containment research institutions, similar to that described in the CEN standard? An expansion of Federal oversight authority of these facilities? Improved oversight at individual research institutions? Incentives to encourage voluntary compliance?)
- What are the advantages and disadvantages of accrediting biosafety management systems at high and maximum containment research laboratories?

Panelists

- *Robert A. Heckert, BSc (Agr), DVM, PhD, CBSP, BioSafety Consultant*
- *Christina Thompson, MS, RBP, CBSP, Biological Safety Consultant, Thompson Biosafety, LLC*
- *Ronald Atlas, PhD, Professor of Biology and Public Health, and Co-director, Center for Health Hazards Preparedness, University of Louisville*

Discussion

4:30 p.m. **Public Comments**

5:00 p.m **Adjourn**

Tuesday - December 9

8:30 a.m. **Welcome**

Mary Mazanec, MD, JD, Deputy Assistant Secretary for Preparedness and Response and Director, Office of Medicine, Science and Public Health, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

8:45 a.m.

Panel IV – Incident Reporting, Analysis, and Information Sharing

Moderator: *Shanna Nesby-O'Dell DVM, MPH, Chief, External Activities Program and WHO Collaborating Center for Biosafety and Training and Centers for Disease Control and Prevention Office of Health and Safety, U.S. Department of Health and Human Services*

Background: Prompt and detailed reporting of incidents (accidents, laboratory-acquired infections [LAIs], etc.) involving high or maximum containment research is another component of biosafety oversight. Analysis of reports of biosafety and biocontainment incidents could point to the need for new or revised guidelines or practices, additional training, site visits, inspections, or penalties. Currently, OSHA and the CDC/USDA Select Agent Programs have mandated requirements and criteria for reporting severe laboratory accidents, incidents, and LAIs. However, a centralized, streamlined system for reporting biosafety and biocontainment incidents could be a useful tool. In addition, the development of a centralized database for biosafety and biocontainment incident reports could also facilitate analysis and information sharing across the Federal Government and among stakeholders.

The Task Force is seeking individual input on the objective to:

Improve reporting, analysis, and sharing of information on laboratory-acquired infections and other significant safety incidents occurring in high and maximum containment laboratories.

Discussion questions:

- What are the potential barriers to reporting LAIs and other laboratory incidents?
- Should there be a consistent, broadly applied mechanism for documenting, reporting, and analyzing biosafety and biocontainment incidents that occur in high and maximum containment research facilities in all sectors?
- Is a no-fault reporting system, such as that used for airline pilot errors, worth considering in a biosafety context?
- If so, how could the Federal government best incentivize the reporting of LAIs and other incidents?
- What information should be collected and shared, and with whom?

Panelists

- *Karen B. Byers, MS, RBP, CBSP, Biosafety Officer, Dana Farber Cancer Institute*
- *Penny H. Holeman, MPH, MS, CBSP, Director, Biosafety, Training & Biosecurity Solutions, Lovelace Respiratory Research Institute*
- *Ruth L. Berkelman, MD, Rollins Professor and Director, Center for Public Health Preparedness and Research, Rollins School of Public Health, Emory University*
- *Stanley M. Lemon, MD, John Sealy Distinguished University Chair and Director Institute for Human Infections and Immunity, Galveston National Laboratory, University of Texas Medical Branch*

Discussion

10:15 a.m. ***Break***

10:30 a.m.

Panel V – Public Communication, Outreach, and Increased Transparency

Moderator: *Christine Comer, Vice President for Public Affairs, University of Texas Medical Branch, Galveston, Texas*

Background: The Task Force has noted the importance of public communication, outreach, and transparency in dealing effectively with issues of biosafety and biocontainment.

The Task Force is seeking individual input on the objective to:

Improve and coordinate mechanisms to promote public communication, outreach, and transparency regarding oversight of high and maximum containment research.

Discussion questions:

- What kinds of public communication and outreach programs are in need of improvement?
- What are the best mechanisms to achieve this objective, and which entities are responsible (investigators, institutions, the Federal government, State and local governments, professional organizations)?

Panelists

- *Jack Murphy, PhD, Professor of Medicine and Microbiology, and Chief, Section of Molecular Medicine, Boston University School of Medicine*
- *Alisha Prather, Director of Communications, Galveston National Laboratory, University of Texas Medical Branch, Institute for Human Infections & Immunity*
- *Tom Keppeler, Associate Director of Public Relations, Cummings School of Veterinary Medicine, Tufts University*

Discussion

12:00 p.m. ***Lunch***

1:00 p.m. **Panel VI – Applied Biosafety Research Programs**

Moderator: *Joseph P. Kozlovac, M.S., RBP, CBSP, SM-NRM, Agency Biosafety Officer, Animal Production and Protection, Agricultural Research Service, National Programs, U.S. Department of Agriculture*

Background: The practices and procedures—e.g., for disinfection, decontamination, and sterilization—engineering controls, and personal protective equipment currently used in high and maximum containment research laboratories are based in large part on the decades-old results of former applied biosafety research programs that no longer exist. A vigorous applied biosafety and biocontainment research program would help improve evidence-based biosafety and biocontainment practices and procedures.

The Task Force is seeking individual input on the objective to:

Re-establish and maintain programs for applied biosafety research.

Discussion questions:

- Is there a need for new applied biosafety research programs?
- What should the focus of such programs be in order to enhance the evidence base for current and future biosafety standards and practices?

Panelists

- *Scott Rusk, Director, Pat Roberts Hall, Biosecurity Research Institute, Kansas State University*
- *John H. Keene, DrPH, CBSP, Managing Partner, Global Biohazard Technologies, Inc.*
- *W. Emmett Barkley, PhD, President, Proven Practices, LLC*

Discussion

2:00 p.m. **Public Comments**

2:30 p.m. **Wrap-up and Concluding Remarks**

Mary Mazanec, MD, JD, Deputy Assistant Secretary for Preparedness and Response and Director, Office of Medicine, Science and Public Health, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

2:45 p.m. **Adjourn**