



Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight

**ABSA Meeting
October 19, 2009**

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Background and Impetus

- **Unprecedented scientific opportunity to unveil the molecular origins of pathogenicity and the mechanisms by which new infectious disease threats can emerge**
- **Growing concern about misuse of biological agents by terrorists**
- **Development of biodefense strategies and medical countermeasures becomes a national priority**
- **Rapid scale-up of federally funded programs of research utilizing highly pathogenic agents**
 - **Need for appropriate high and maximum containment facilities**



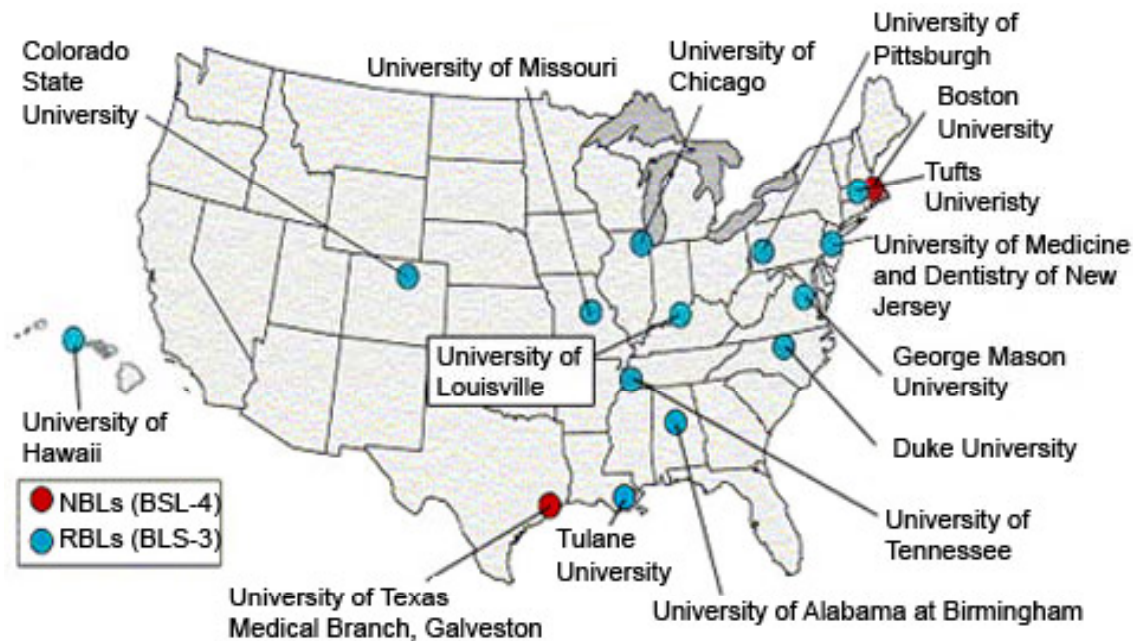
Increase in Containment Lab Construction

Consolidated Appropriations Act 2003 provided:

\$372.6 Million for extramural facilities

\$291 Million for intramural facilities

2005 Additional \$150 Million provided to NIAID in the consolidated appropriations act.



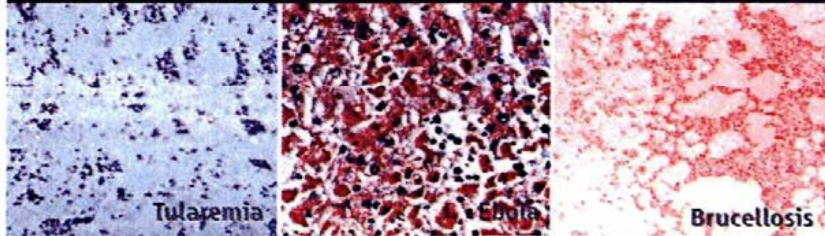
National Biocontainment Laboratories (NBL)
Regional Biocontainment Laboratories (RBL)

Scale-up of Biodefense Programs and Public Concerns

- Increasing number of institutions awarded grants for high-containment work, many for the first time
- Public concerns
 - Proximity of research to populated areas; perceived public health risks
 - Reports of dysfunctional biosafety programs at various institutions (Sunshine Project 2004)
- Laboratory incidents and exposures to pathogenic agents



Some Recent Exposures in U.S. Biodefense Labs



2002, 2003: *E. coli* 0157:H7 infections in two USDA labs

2004: Three workers infected with tularemia, Boston University

2004: Ebola needle stick (no infection), USAMRIID

2004: Anthrax exposure (no infection), Children's Hospital, Oakland, CA

2004: Valley fever (*C. immitis*) infection, Medical College of Ohio

2005: Potential Q fever exposure, Rocky Mountain Labs, Hamilton, MT

2006: Brucellosis infection, Texas A&M

Science (28 September 2007)



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BIOSAFETY BREACHES

Accidents Spur a Closer Look at Risks at Biodefense Labs

Congressional Concerns



COMMITTEE ON ENERGY AND COMMERCE

- **Subcommittee on Oversight and Investigations**
 - “increasing concerns...raised about safety, as well as operations” of high-containment laboratories
 - Tasked the GAO with an investigation of high-containment labs, requesting answers to 3 questions:
 - 1.** *To what extent, and in what areas, has there been an expansion in the number of high-containment labs in the U.S.?*
 - 2.** *Which federal agency is responsible for tracking the expansion of high-containment labs and determining the associated aggregate risks?*
 - 3.** *What lessons can be learned from recent incidents at high-containment laboratories?*

Congressional Concerns (Cont.)

- Government Accountability Office report
 - **“Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States” (October 2007)**
- Congressional hearing
 - **“Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States” (October 4, 2007)**
 - **Witnesses: GAO, NIH, CDC, TAMU, University of Pittsburgh Center for Biosecurity, Center for Arms Control and Non-proliferation, Sunshine Project**

http://energycommerce.house.gov/index.php?option=com_content&task=view&id=640&Itemid=106

GAO Report/Testimony



- **No one agency knows the total number of high-containment laboratories in the U.S.**
- **No one agency is responsible for determining the aggregate risks associated with these laboratories**
- **Recent incidents point to the need to: (The Six Lessons)**
 - **Identify and overcome barriers to incident reporting**
 - **Train lab staff in general biosafety**
 - **Inform medical providers about agents being used in labs**
 - **Address confusion over definition of “exposure” to promote consistent reporting**
 - **Ensure that BSL-4 lab safety and security is commensurate with levels of risk**
 - **Maintain high-containment labs to ensure physical integrity**

CDC and NIH Testimony

- **Announced the establishment of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight**

For that reason, HHS, USDA, DHS, and DoD have already agreed to establish a Trans-Federal Task Force to undertake, in consultation with other relevant agencies, an intensive analysis of the current biosafety framework and to develop a set of recommendations for improvement.

Hugh Auchincloss, MD, Oct. 4, 2007

Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight

- **To explore mechanisms by which the Federal government can optimize local and Federal biosafety and biocontainment oversight of public and private sector research involving infectious agents and toxins**
- **Co-chaired by HHS and USDA**
- **Comprised of representatives of a broad range of Federal agencies that have responsibility for, and oversight of, requirements related to the management of biosafety risks**
- **Public involvement will be key**

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

Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight Membership

- Membership:
 - Department of Agriculture (**co-chair**)
 - Department of Health and Human Services (**co-chair**)
 - Department of Commerce
 - Department of Defense
 - Department of Energy
 - Department of Homeland Security
 - Department of Labor
 - Department of State
 - Department of Transportation
 - Department of Veterans' Affairs
 - Environmental Protection Agency
 - National Science Foundation

Trans-Federal Task Force Methodology

- **Utilized multiple sources of information including stakeholder briefings**
- **Held a Public Consultation Meeting December 8-9, 2008**
- **HHS and USDA Secretaries receive and approve report September 2009.**
- **Public Release – September 23, 2009**



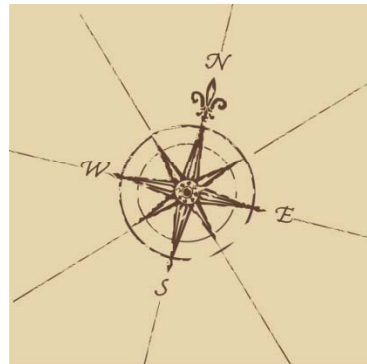
Trans-Federal Task Force Scope

- **High and maximum containment (BSL-3 and 4) research laboratories in all sectors**
 - **Pathogens that affect humans, zoonotic agents, toxins, and agricultural pathogens**
 - **Outside scope: diagnostic and treatment facilities (non-research); licensed biomedical production facilities**

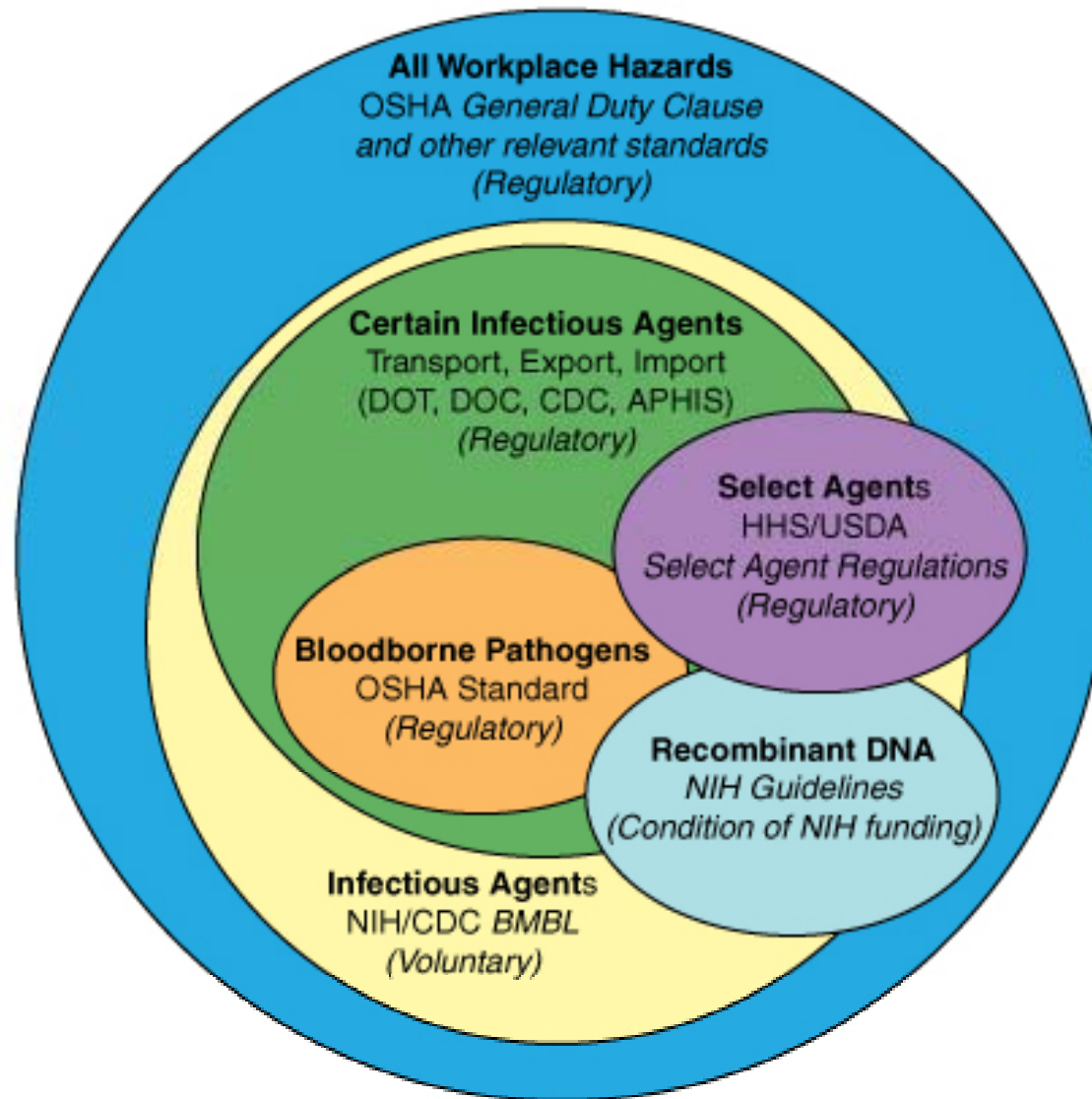


Taskforce Guiding Principles

- **Research on hazardous biological agents that require high and maximum containment facilities is vital for ensuring public and agricultural health**
- **Biosafety and biocontainment oversight must ensure the safe conduct of research without undue impediments to scientific progress**
- **Local oversight is key to effective biosafety and biocontainment**
- **Transparency and accountability are critical to the success of high and maximum containment research, as well as oversight of these research activities**
- **Periodic evaluations are essential to ensure effective oversight**



Biosafety/Biocontainment Regulations, Standards and Guidelines Relevant to Research Labs



Biosafety and Biocontainment Oversight



Task-Force Objectives

- **Enhance the overarching framework for biosafety and biocontainment oversight of high and maximum containment research through improved coordination of oversight activities.**
- **Encourage a robust culture of accountability characterized by individual and institutional compliance with biosafety and biocontainment regulations, guidelines, standards, and policies.**
- **Develop a national strategy to enable and ensure the appropriate training and technical competence of all individuals who work in, oversee, support, or manage high or maximum containment research laboratories.**
- **Obtain and analyze information about laboratory incidents to enable trend analysis, minimize the number of future incidents, and share lessons learned, with the overall goals of optimizing laboratory safety and oversight.**

Task-Force Objectives (Cont.)

- **Ensure that biosafety and biocontainment regulations and guidelines cover current and emerging hazardous biological agents, and develop an agricultural equivalent of the *BMBL*.**
- **Ensure that the infrastructure and equipment necessary for biosafety and biocontainment at high and maximum containment research facilities are in place and properly maintained.**
- **Develop and support a national research agenda for applied biosafety and biocontainment to improve the management of biohazard risks.**
- **Improve and share strategies to ensure effective public communication, outreach, and transparency about biosafety and biocontainment issues.**

Taskforce Report: Key Recommendations

- **Enhance the biosafety and biocontainment oversight framework**
 - **Identify or establish a Federal entity to coordinate biosafety and biocontainment oversight activities.**
 - **Develop a registry of all high and maximum containment facilities in the United States.**
 - **Require that institutions in all sectors have the appropriate senior officials, accredited biosafety professionals, and review bodies responsible for local oversight of biosafety.**
- **Encourage a robust culture of accountability and develop national training and competency standards**

Taskforce Report: Key Recommendations

- **Obtain and analyze information about laboratory incidents**
 - **Establish a new voluntary, non-punitive incident-reporting system mechanism for analysis and sharing of lessons learned.**
- **Ensure comprehensive regulations and guidelines to cover emerging and agricultural agents and that laboratory infrastructure is maintained.**
- **Develop and support a national research agenda for applied biosafety and biocontainment and ensure effective public communication, outreach and transparency**

One of Many

- **A number of reports have been published or shall be published soon**
 - *Biological Safety Training Programs as a Component of Personnel Reliability.* Workshop Report Prepared by AAAS Center for Science, Technology and Security Policy. March 17, 2009.
 - WMD Commission report, **“World at Risk” (2008)**
 - *Report of the Working Group on Strengthening the Biosecurity of the United States.* (Draft July 2009, Final Soon)
 - *Enhancing Personnel Reliability Among Individuals with Access To Select Agents,* NSABB (May 2009)
 - *Oversight of High-Containment Biological Laboratories: Issues for Congress,* Congressional Research Service report (March 5, 2009)
 - GAO reports
 - ***High-Containment Labs: Coordinated National Oversight is Needed*** (final report not yet released)
 - ***Biosafety Laboratories: Improved Perimeter Security Despite Limited Action by CDC*** (July 2009)
 - ***Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*** (October 2007)

Next Steps

- **These reports along with the Trans-Federal Task Force on Biosafety and Biocontainment report will be considered by the Administration and Congress in policy and legislation discussions in the coming months.**



Taskforce Information and Copy of Report

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



ACKNOWLEDGEMENTS

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Taskforce Members



THANKS

PLEASE ASK QUESTIONS

