



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

## IBC Professional Development Conference

**June 26, 2009**

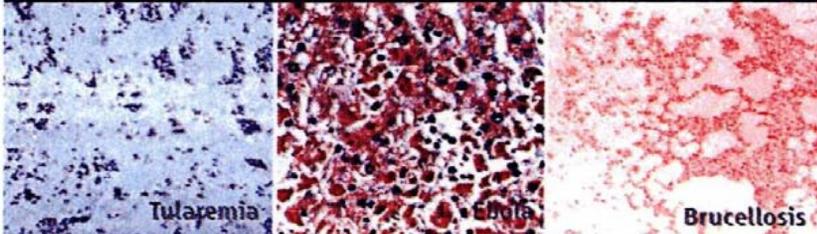
Carol D. Linden, PhD  
Principal Deputy Director  
Biomedical Advanced Research and Development Authority  
Office of the Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services



# Background

- Concerns about the risks posed by the expansion of the Nation's biodefense laboratory research capacity have surfaced
  - Recent Congressional and public inquiries have focused on safety, security and personnel reliability practices
- USG is supporting efforts to improve laboratory security, personnel reliability, and safety policies/practices

## 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)



28 SEPTEMBER 2007 VOL 317 SCIENCE www.sciencemag.org

Published by AAAS

BIOSAFETY BREACHES

## Accidents Spur a Closer Look at Risks at Biodefense Labs

GAO

United States Government Accountability Office

Testimony  
Before the Subcommittee on Oversight  
and Investigations, Committee on Energy  
and Commerce, House of Representatives

For Release on Delivery  
Expected at 10:00 a.m. EDT  
Thursday, October 4, 2007

## HIGH-CONTAINMENT BIOSAFETY LABORATORIES

Preliminary Observations  
on the Oversight of the  
Proliferation of BSL-3 and  
BSL-4 Laboratories in the  
United States

Statement of Keith Rhodes, Chief Technologist  
Center for Technology and Engineering  
Applied Research and Methods



GAO-08-108T

GAO

United States Government Accountability Office  
Report to Congressional Committees

September 2008

## BIOSAFETY LABORATORIES

Perimeter Security  
Assessment of the  
Nation's Five BSL-4  
Laboratories

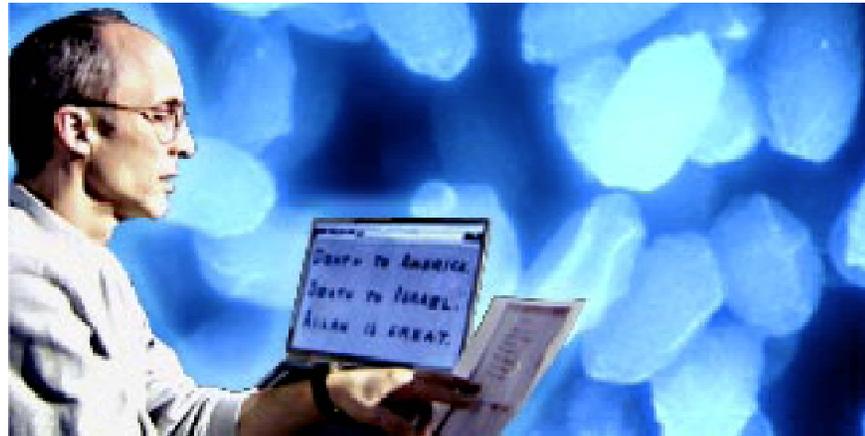


GAO-08-1092

You are in: [Americas](#)News Front  
Page

Sunday, 18 August, 2002, 02:37 GMT 03:37 UK

## Anthrax killer 'is US defence insider'

[Africa](#)**[Americas](#)**[Asia-Pacific](#)[Europe](#)[Middle East](#)[South Asia](#)[UK](#)[Business](#)[Entertainment](#)[Science/](#)[Nature](#)[Technology](#)[Health](#)

Prof Don Foster analyses the anthrax letters

An FBI forensic linguistics expert believes the US anthrax attacks were carried out by a senior scientist from within America's biological-defence community.

# WORLD AT RISK

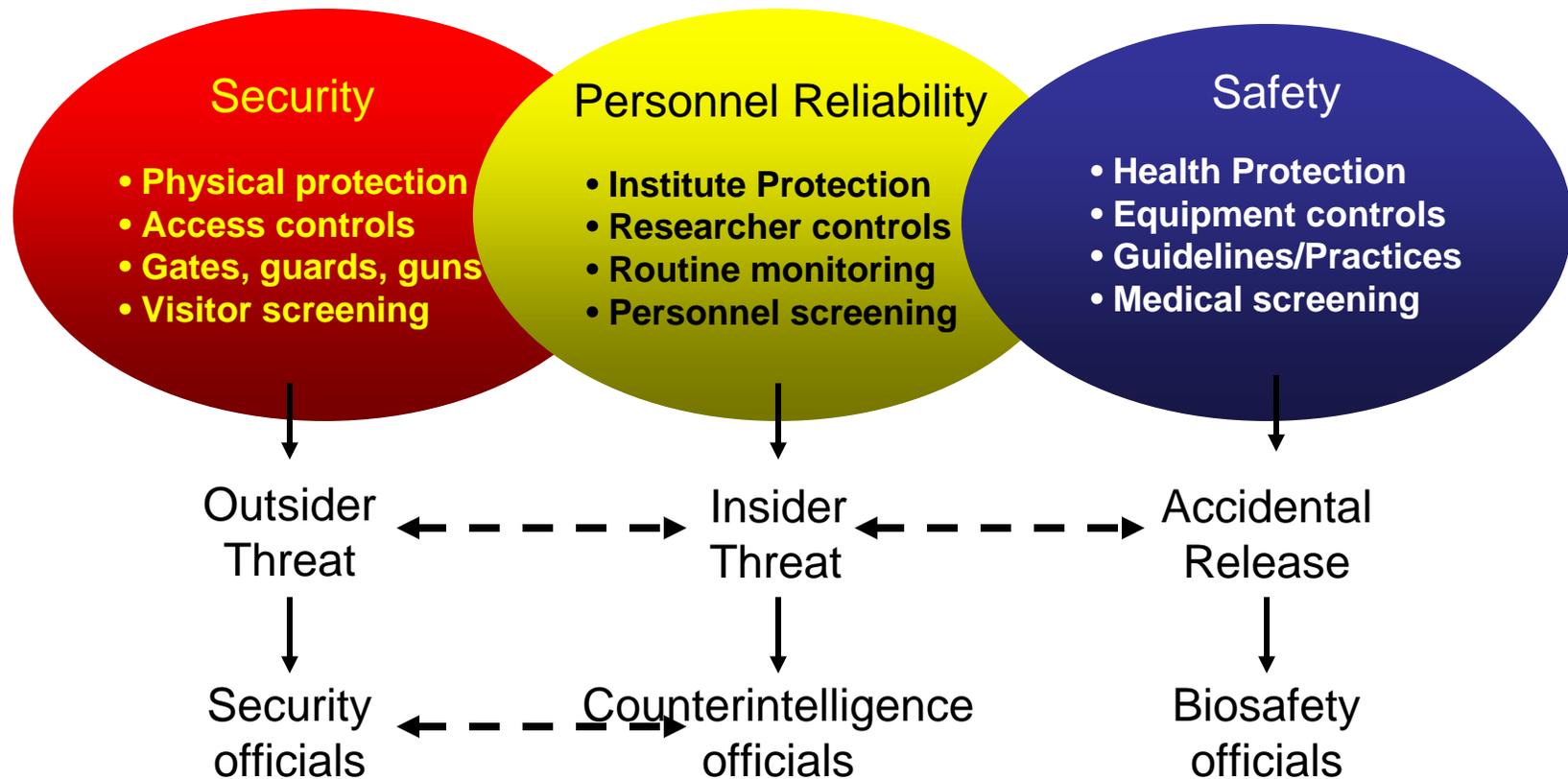
**THE REPORT OF THE COMMISSION  
ON THE PREVENTION OF  
WEAPONS OF MASS DESTRUCTION  
PROLIFERATION AND TERRORISM**

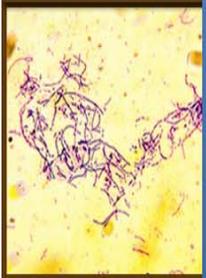
**BOB GRAHAM, Chairman  
JIM TALENT, Vice-Chairman**

Graham Allison • Robin Cleveland • Steve Rademaker  
Tim Roemer • Wendy Sherman • Henry Sokolski • Rich Verma

**AUTHORIZED EDITION**

# Current Risk Management Framework



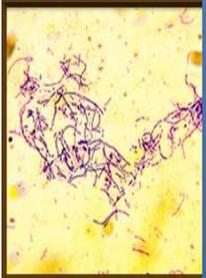


# USG Efforts to Address Laboratory Security, Personnel Reliability, and Safety

- Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight established.
- Secretary of Army commission to evaluate practices at its laboratories. Effort expanded to include evaluation of all Department of Defense select agent laboratories.
- OSTP and HSC, through the joint HSC/NSC Biodefense Policy Coordinating Committee (PCC), initiated review of existing select agent policies in Federal laboratories concerning safety, security and personnel reliability.
- Executive Order 13486, “Strengthening Laboratory Biosecurity in the United States” (January 9, 2009)

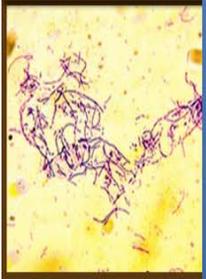
OSTP: Office of Science and Technology Policy  
NSC: National Security Council

HSC: Homeland Security Council  
USG: United States government



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

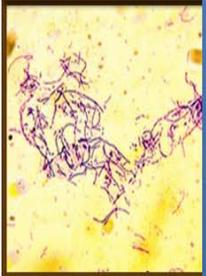
- To explore mechanisms by which the Federal government can optimize local and Federal biosafety and biocontainment oversight of public and private sector research involving infectious agents and toxins
- Co-chaired by Department of Health and Human Services and Department of Agriculture
- Comprised of representatives from Federal agencies that have responsibility for, and oversight of, the management of biosafety risks in high and maximum containment research laboratories
- Public involvement is key



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

- **Vision:**

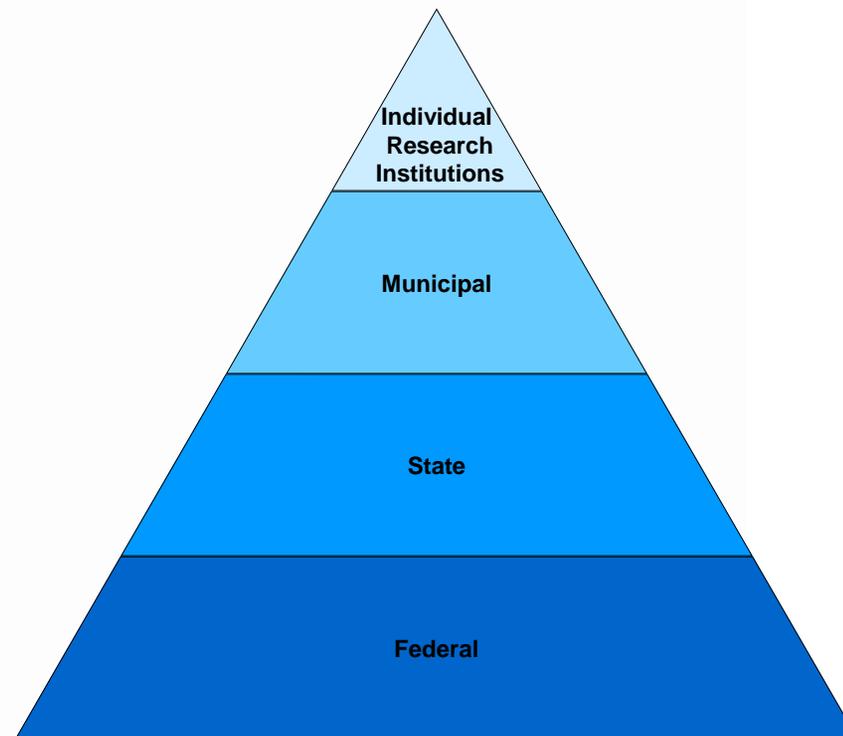
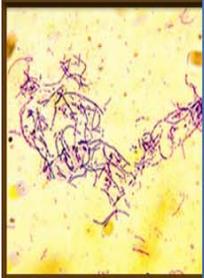
- Effective, comprehensive local and Federal biosafety and biocontainment oversight of research involving hazardous biological agents and toxins
- Executed in a manner that protects laboratory workers, public health, agriculture, and the environment while fostering the progress of life science research



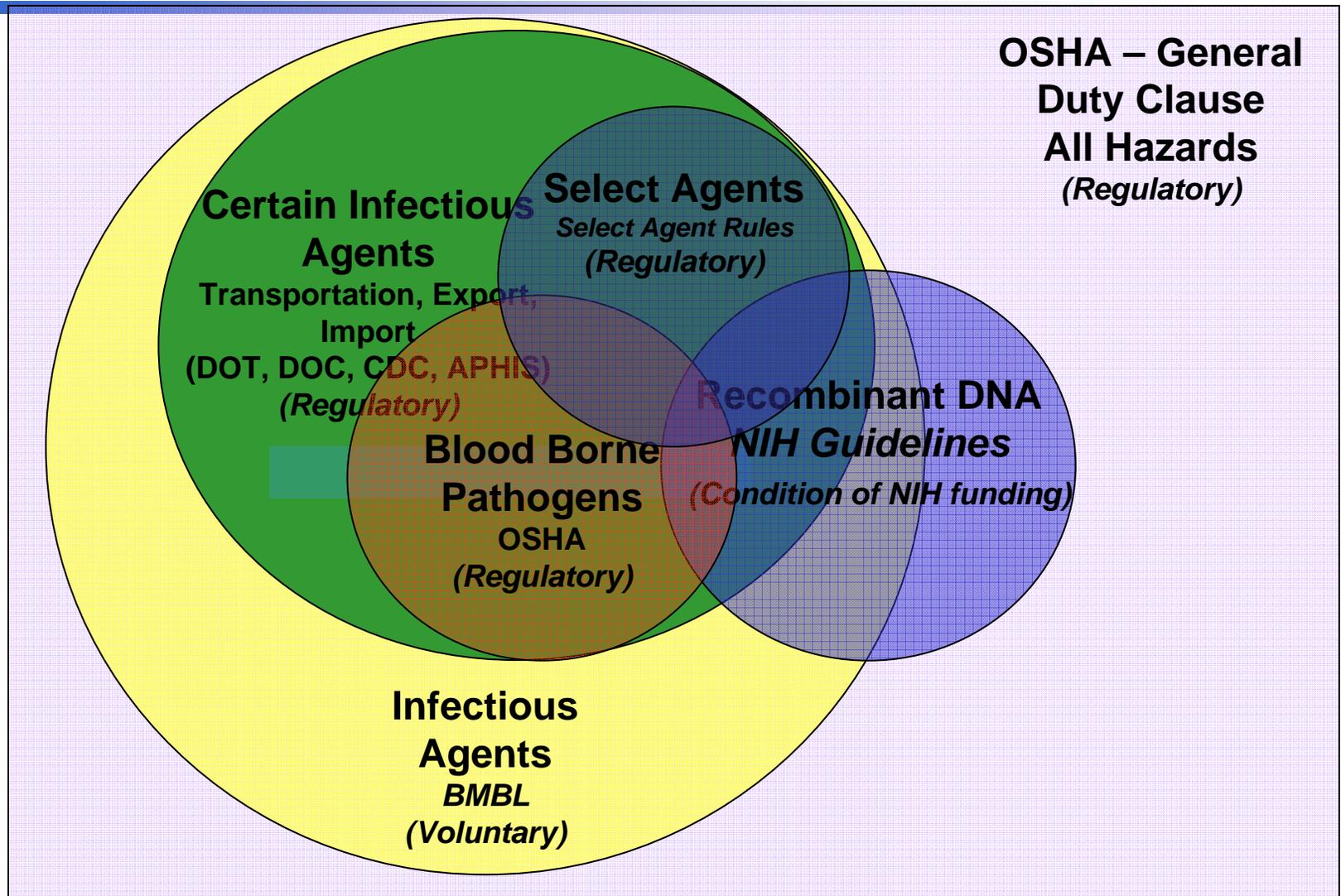
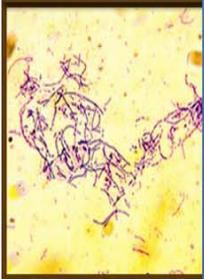
## Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight

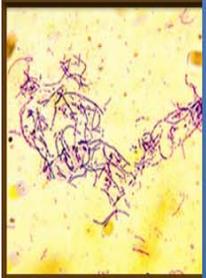
- Task Force report will address:
  - **Background and current framework** for local and Federal biosafety and biocontainment oversight of high and maximum containment research
  - **Objectives and options** for improving biosafety and biocontainment oversight of high and maximum containment research involving hazardous biological agents
  - **Recommendations** for improving the oversight framework in the short- and long-term

# Biosafety and Biocontainment Oversight



# Federal Biosafety Standards for Various Types of Research



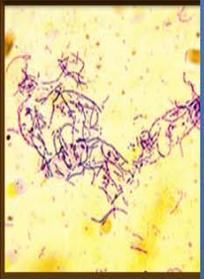


# Issues Regarding the Oversight of Research Involving Infectious Agents

- Biosafety and biocontainment oversight framework
- Culture of accountability and compliance
- Training and competency standards
- Incident-reporting
- Biosafety and biocontainment regulations and guidelines
- Infrastructure maintenance and sharing best practices
- Biosafety and biocontainment research programs
- Public communication, outreach, and increased transparency

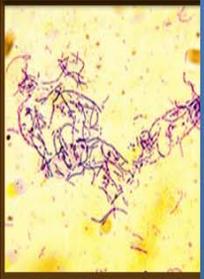
# Guiding Principles

- High and maximum containment biological research is essential to protect public health, agriculture, and the environment.
- Rigorous adherence to biosafety and biocontainment practices is essential to protecting public health, the safety of laboratory personnel, agriculture, and the environment.
- The foundations of an effective and comprehensive system of biosafety and biocontainment oversight are the personnel, processes, and procedures in place at individual research institutions.



## Guiding Principles (cont.)

- **Transparency and accountability are critical to the success of biosafety and biocontainment oversight** of high and maximum containment research.
- There is a need for **periodic and thorough evaluation** of all components of laboratory biosafety and biocontainment systems to ensure their effectiveness.



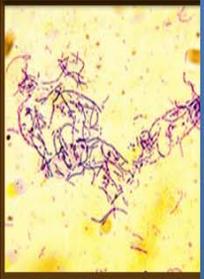
# Objectives

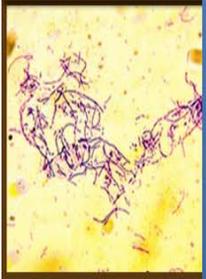
- Enhance the **overarching framework for biosafety and biocontainment oversight** of high and maximum containment research through improved coordination of oversight activities.
- Encourage a **robust culture of accountability** characterized by individual and institutional compliance with biosafety and biocontainment regulations, guidelines, standards, and policy
- 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 future incidents, and share lessons learned, with the overall goals of **optimizing laboratory safety and oversight**



## 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 containments 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.**

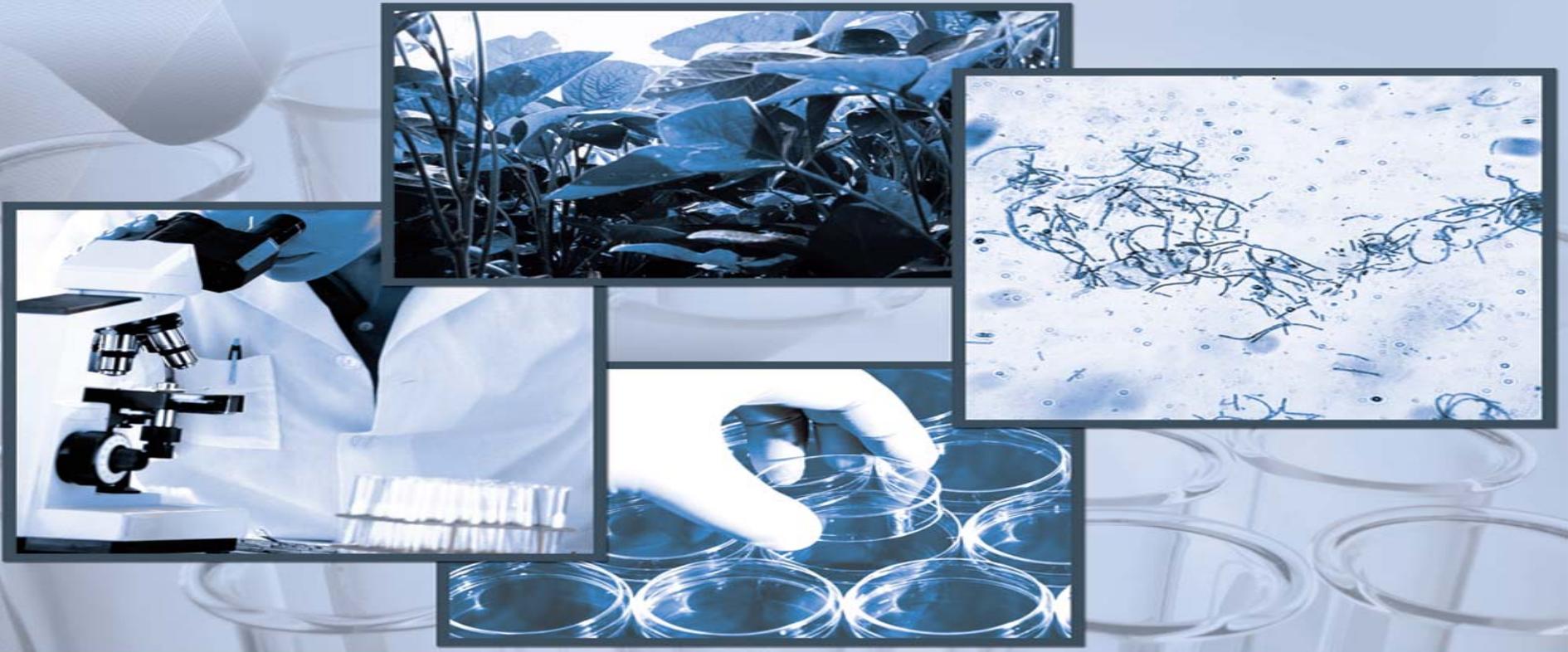




# A Recommendation of Particular Interest to IBCs

Require that, at all institutions conducting high or maximum containment research, an **appropriately constituted review body** performs a thorough risk assessment of all laboratory protocols potentially requiring high or maximum containment.

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



**Public Meeting** | December 8–9, 2008

# Public Consultation Feedback

- High and maximum containment research on hazardous biological agents is vital to protect public health and agriculture.
- We need: Strengthened biosafety and biocontainment oversight mechanisms; training; guidelines; incident-reporting; public outreach, communication, and transparency; and applied biosafety research
- Over-regulation could impede research.
- Additional resources are required for improvement of the current biosafety and biocontainment oversight framework.





# Public Consultation Topic Area Key Concepts

- **Training and Competency**
  - National training standards for all personnel working in BSL-3/4 facilities.
  - Increase number of scientists and professionals trained in biosafety
  - Professional credentialing of biosafety professionals is supported.
- **Review of research protocols**
  - Review research protocols for biosafety concerns to help ensure the consistency, credibility, and public acceptance
- **Biosafety and Biocontainment Standards and Guidelines**
  - Standards and guidelines should be flexible enough to reflect differences among institutions, facilities, and protocols.
  - Accreditation can promote consistency of training and work practices, reliability of facilities and operations, and the acceptance by the general public.



# Public Consultation Topic Area Key Concepts

- **Incident-reporting, analysis and sharing of information**
  - A simple, confidential reporting system that emphasizes root causes, lessons learned, and prevention of future incidents should be developed.
- **Applied Biosafety Research**
  - Develop an applied biosafety research program to provide new evidence-based biosafety practices and procedures.
- **Public Communication, Outreach, and Increased Transparency**
  - The value of biological research
  - Principles of biosafety and biocontainment to demystify BLS-3/4 facilities.



# Task Force Next Steps

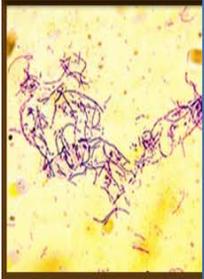
- Review of report by Federal Departments
  - Presentation of report to the HHS and USDA Secretaries for their consideration
  - Continued public engagement
- <https://www.hhs.gov/aspr/omsph/biosafetytaskforce/index.html>
- Task Force report will be considered in Executive Branch policy process this fall

**biosafetytaskforce@hhs.gov**



# Other Related Activities

- National Science Advisory Board for Biosecurity - Personnel Reliability Working Group Report
  - Recommend strategies for enhancing personnel reliability (PR) among individuals with access to biological select agents and toxins
- Working Group on Strengthening the Biosecurity of the United States under Executive Order 13486
  - Focus on physical security and personnel reliability vis-à-vis Select Agents
- National Academy of Sciences fast track study on physical security and personnel reliability



QUESTIONS?