

# *Personnel Reliability Programs*

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**CSHEMA 2009**  
**New Orleans**

# *Presentation Outline*

- I. Description of Personnel Reliability Programs
- II. Context for EH&S Professionals
- III. Current Recommendations
- IV. Future Considerations



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# *Personnel Reliability Programs*

- Originally established for chemical and nuclear weapon programs
- Attempt to ensure that individuals in the program are extremely “reliable”



# *Reliability of Personnel*

- 1) Trustworthy
- 2) Physically Competent
- 3) Mentally Competent
- 4) Emotionally Stable
- 5) Financially Stable
- 6) Responsible to uphold obligations to safety, public health, national security and scientific integrity



# *Reliability of Personnel*

- 1) Trustworthy
- 2) Physically Competent
- 3) Mentally Competent
- 4) Emotionally Stable
- 5) Financially Stable
- 6) Responsible to uphold obligations to ...

- 1) Criminal History
- 2) Medical Evaluation
- 3) Mental Health History
- 4) Psych Evaluation
- 5) Credit History
- 6) Drug Testing, Peer Review, Affiliations



# *Reliability of Personnel*

- All entities of federal government have some form of Personnel Reliability Programs, per Kenneth Cole, DOD Medical Director.

05/14/09



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# *US Biosecurity Events this Decade*

## **1. 2001 Anthrax Mailings**

- 5 dead and 17 sickened



# *US Biosecurity Events this Decade*

1. 2001 Anthrax Mailings
2. **Select Agent Rule EXPANDED** [42 CFR 73, DHHS, Final Rule April 2005]
  - Regulates possession of ~80 agents of bioterror
  - Access restricted to those with background checks from FBI (aka Security Risk Assessment or SRA Clearance)
  - Other mandates physical barriers, inventory control, training, and emergency planning



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# *US Biosecurity Events this Decade*

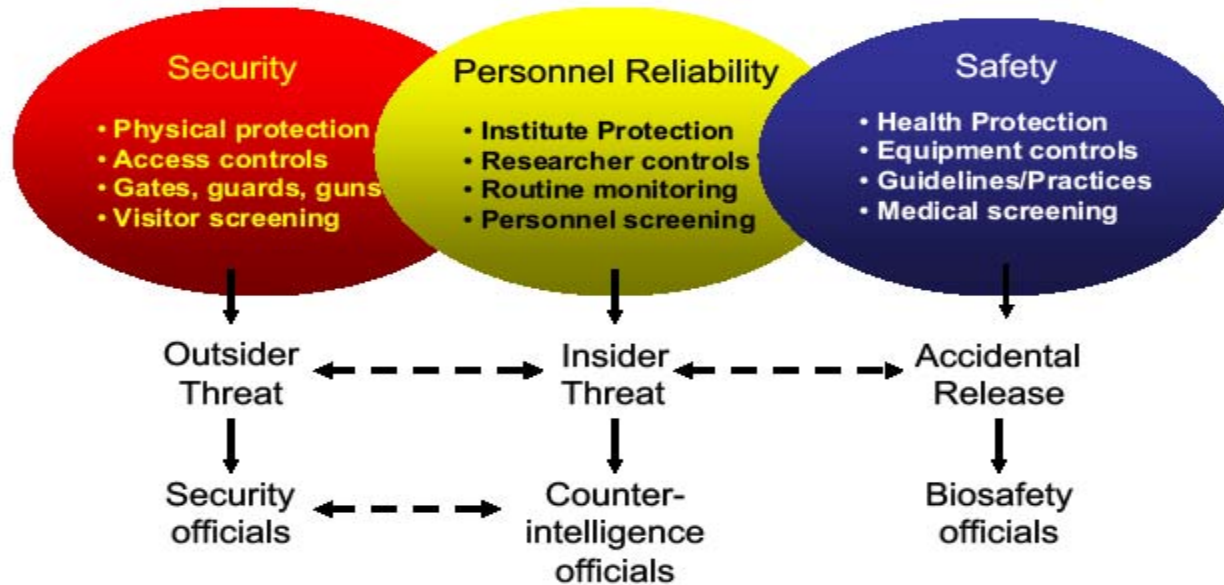
1. 2001 Anthrax Mailings
2. Select Agent Rule EXPANDED
3. **July 2008 FBI implicates US Army researcher as perpetrator of anthrax mailings**



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# Biosecurity Framework



Source: D.DiEulius, PhD, Office of the President, NSABB Meeting, 04/03/09



# *Examine the “Insider” Threat*

January 9, 2009 - Executive Order 13486

- 1) EO Working Group on Biosecurity (DOD/DHHS)
- 2) National Science Advisory Board for Biosecurity (NSABB)
  - Formed in 2005
  - Initial charge to advise on “dual use research”



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## The Danger Within

The suicide of Army researcher Bruce Ivins will inevitably mean changes in biosecurity policy, but government and academic scientists are divided on how stringent the new procedures should be

On the morning of 2 August 2008, 3 days after Army researcher Bruce Ivins committed suicide, the Biodefense Policy Coordination Committee assembled in a conference room of the Eisenhower Executive Office Building, a stone's throw from the White House. The mood around the table was somber when Robert Kadlec, committee chair and member of the Homeland Security Council, spelled out the meeting's agenda, according to one of the participants. If Ivins had indeed carried out the 2001 anthrax letter attacks, as the Federal Bureau of Investigation (FBI) claimed, what could be done to prevent another bioterrorist act by an insider at a government or academic lab?

The insider threat has never loomed so large in policy discussions on bioterrorism. The massive expansion of biodefense research after the anthrax mailings in 2001, which killed five people and sickened 17, was largely predicated on the concern that a terrorist group could launch an attack using biological weapons it had developed or stolen from a military facility. The FBI's implication of Ivins in the mailings—although still questioned and untested in a court of law—sparked the unsettling realization among researchers and biosecurity experts that “the insider threat is a lot bigger problem than we

ever thought,” says a former scientist at the U.S. Army Medical Research Institute of Infectious Diseases in Frederick, Maryland, where Ivins worked.

In recent months, that concern has echoed through the halls of the U.S. government. Soon after the 2 August meeting, the White House asked the National Science Advisory Board for Biosecurity (NSABB)—a panel set up in 2005 to address the potential security risks from life sciences research—to consider how best to ensure that academic and industry researchers working with select agents are trustworthy. It is expected to come up with recommendations next month. Independently, an interagency working group, co-chaired by the secretaries of Defense and Health and Human Services, is looking at ways to strengthen lab biosecurity.

Some change in biosecurity procedures is inevitable post-Ivins, experts agree. But how stringent any new steps should be is being hotly debated. Since NSABB got its charge from the White House, board members have been nervously discussing the costs and benefits of measures such as tougher background

investigations, psychological screenings, drug tests, and credit checks. Other possibilities include video surveillance of labs and a two-person rule prohibiting researchers from working alone.

Some of those measures are standard practice at the Department of Defense (DOD), the Department of Energy (DOE), and other agencies where scientists work with nuclear, chemical, or biological agents. But some academics worry that extending such measures to academia would undermine the open culture of life sciences research and impede biodefense research. A better approach, some say, would be to trust lab managers to keep a watchful eye on employees for signs of troubling behavior. But even advocates of self-policing concede that that approach may not allay fears of the insider threat.

### Trying to foil an insider attack

The U.S. government already vets researchers working with select agents through rules that were put in place a year after the anthrax attacks. Under those rules, institutions and individuals who wish to work with any of 80 biological entities, including the Ebola virus and botulinum toxin, must go through a Security Risk Assessment (SRA).

The SRA process involves a basic FBI background check. Disqualifying factors include a criminal history, a substance abuse or mental health problem, a dishonorable discharge from the military, or being a citizen of a country that the United States deems a sponsor of terrorism. The



Insider Bruce Ivins worked at USAMRIID.



# *NSABB Process for Analysis*

- Subcommittee of 13 NSABB Members
- Engaged numerous experts
- Review of extant models
- Developed Sub-committee Findings
- Held Public Meeting April 3, 2009



**NATIONAL  
SCIENCE  
ADVISORY  
BOARD FOR  
BIOSECURITY**

**Enhancing Personnel Reliability among  
Individuals with Access to Select Agents**



**Report of the  
National Science Advisory Board for Biosecurity  
(NSABB)**

May 2009



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## *NSABB Findings*

1. Select Agent Program has been fortified since 2001 to address personnel reliability
2. Institutions effectively screen individuals
3. Very little evidence that PRPs have predictive value for criminal activity
4. Engaged institutional leadership can mitigate the risk of insider threat



# *NSABB Recommendations*

1. A formal mandated PRP is unnecessary
2. The current SRA process should be strengthened
3. The culture of responsibility and accountability should be enhanced at institutions
4. Professional societies should continue to encourage dialogue about biosecurity
5. The list of Select Agents should be modified



# *NSABB Recommendations*

- Formally supported by ABSA
- Informally supported by academia
- Further supported by May 29, 2009 Report of the American Association for the Advancement of Science titled *“Biological Safety Training Programs as a Component of Personnel Responsibility”*



# *EO Working Group on Strengthening Biosecurity*

- Held Public Meeting: May 13-14, 2009
  - “Expansion of biodefense research raises biosecurity concerns.”
- Consulted the existing “Trans-Federal Task Force on Optimizing Biosafety” and numerous entities (private and government)
- Intends to present Executive Branch with report in July 2009



*~ Thank You ~*

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