SAND2009-1084P

Biosecurity Policy Drivers

Jennifer Gaudioso, Ph.D.
International Biological Threat Reduction
Sandia National Laboratories
February 2009

www.biosecurity.sandia.gov

SAND No. 2009-XXXX
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000.

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Current International and National Framework for Biosecurity

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Biological Weapons Convention (BWC)

- **Prohibits the development, production, and stockpiling of biological weapons agents, toxins, equipment, and means of delivery by State Parties**
- **Opened for signature April 1972; entered into force March 1975**
  - 171 State Parties (16 signatories have not ratified; 23 non-signatory nations)
- **No provisions for verification of compliance**
  - Dual-use nature of biological materials, technologies, and expertise present significant challenges
  - Extreme difficulty of discerning between legitimate and illegitimate biological research

Fermentation Vessels

UNSCR 1540 and Biosecurity

- **Urges States to take preventative measures to mitigate the threat of WMD proliferation by non-state actors**
- **UNSCR 1540 requires States to**
  - Establish and enforce legal barriers to acquisition of WMD by terrorists and states
  - Submit reports to the 1540 Committee on efforts to comply
- **Paragraph 3 is the key provision that supports biosecurity**
  - "Take and enforce effective measures to establish domestic controls to prevent the proliferation of . . . biological weapons . . .; including by establishing appropriate controls over related materials"
    - **Develop and maintain appropriate effective measures to account for and secure such items in production, use, storage or transport**
    - **Develop and maintain appropriate effective physical protection measures**

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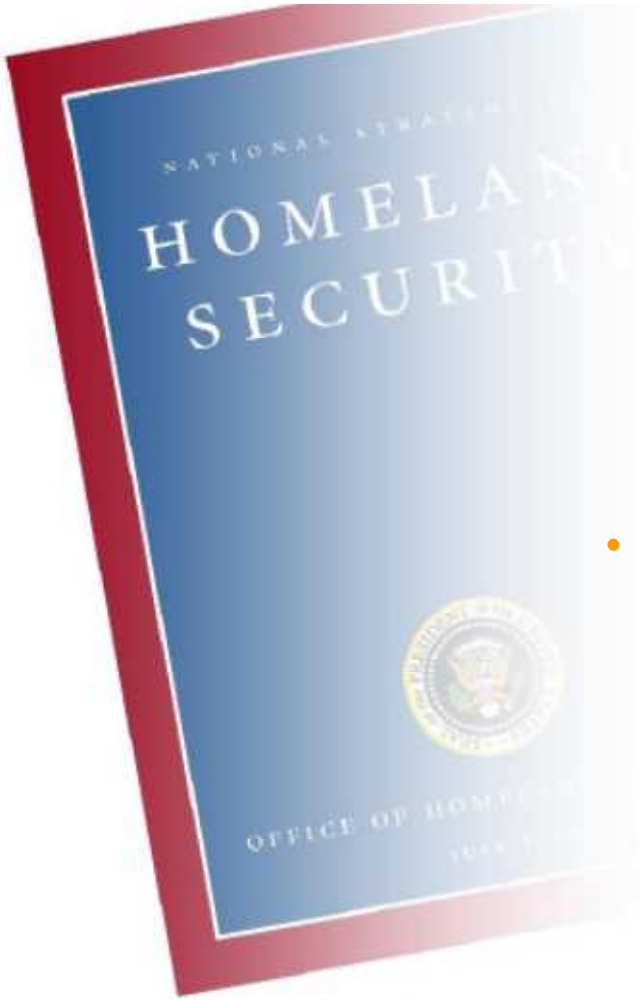
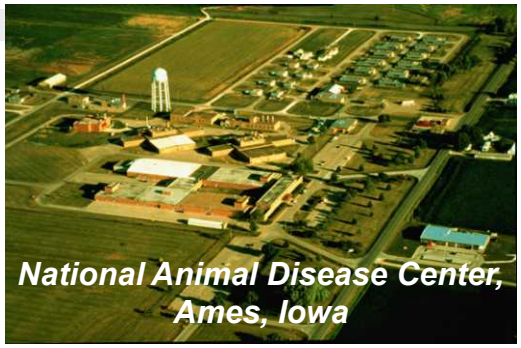
Homeland Security Presidential Directive-10



- ***Biodefense for the 21st Century (also NSPD-33)*, April 2004**
  - "Biological weapons in the possession of hostile states or terrorists pose unique and grave threats to the safety and security of the United States and our allies."
  - "The United States will continue to use all means necessary to prevent, protect against, and mitigate biological weapons attacks perpetrated against our homeland and our global interests."

- **Essential pillars of our national biodefense program are**
  - Threat Awareness
  - Prevention and Protection
  - Surveillance and Detection
  - Response and Recovery

US Domestic Efforts to Reduce Access to Dangerous Biological Materials

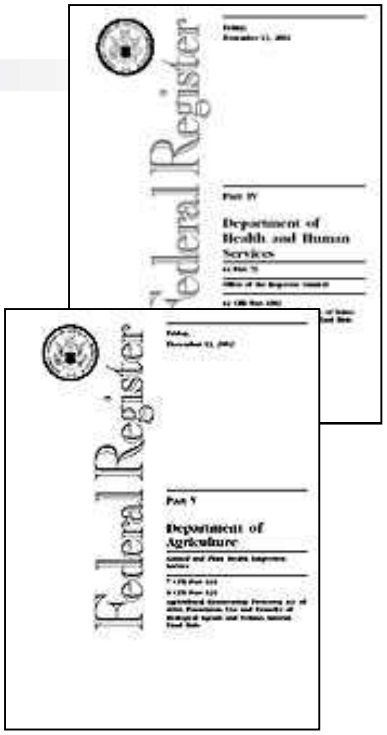

National Animal Disease Center, Ames, Iowa

- **Realization that bioscience facilities are potential sources of biological weapons material**
- **USA PATRIOT Act of 2001 – US Public Law 107-55**
  - Restricted Persons
- **Bioterrorism Preparedness Act of 2002 – US Public Law 107-188**
  - US Select Agent Rule
    - **47 CFR 73 (human and zoonotic)**
    - **9 CFR 121 (animal and zoonotic**
    - **7 CFR 331 (plant)**
- **No international standards for managing dangerous pathogens internationally**


Centers for Disease Control and Prevention, Atlanta, Georgia

US Select Agent Rule (2005)

- Facility registration if it possesses one of ~80 Select Agents
- Facility must designate a Responsible Official
- Background checks for individuals with access to Select Agents
- Access controls for areas and containers that contain Select Agents
- Detailed inventory requirements for Select Agents
- Security, safety, and emergency response plans
- Safety and security training
- Regulation of transfers of Select Agents
- Extensive documentation and recordkeeping
- Safety and security inspections



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US Select Agent Rule: Security Plan

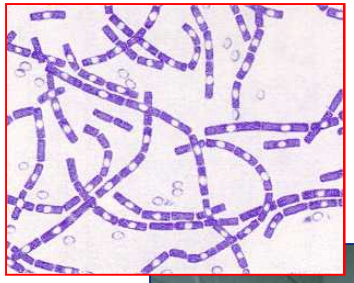
- **The security plan must**
  - Be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use.
  - Describe procedures for physical security, inventory control, and information systems control
  - Contain provisions for the control of access to select agents and toxins
  - Contain provisions for routine cleaning, maintenance, and repairs
  - Establish procedures for removing unauthorized or suspicious persons
  - Describe procedures for addressing loss or compromise of keys, passwords, combinations, etc. and protocols for changing access numbers or locks following staff changes
  - Contain procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, release of select agents or toxins, or alteration of inventory records
  - Contain provisions for ensuring that all individuals with access approval from understand and comply with the security procedures

Select Agent Rule: Incident Response Plan

- **All registered entities must develop and implement a written incident response plan**
- **The incident response plan must fully describe the entity's response procedures for**
  - Theft, loss, or release of a select agent or toxin,
  - Inventory discrepancies,
  - Security breaches (including information systems),
  - Severe weather and other natural disasters,
  - Workplace violence,
  - Bomb threats and suspicious packages,
  - Emergencies, such as fire, gas leak, explosion, power outage, etc.
- **Plan must be reviewed annually and revised as needed**
- **Drills or exercises must be conducted at least *annually* to test and evaluate the effectiveness of the plan**

US Hazardous Material Transportation Security

- **Infectious substances (Class 6.2) and toxins (Class 6.1) are defined as Hazardous Material**
- **49 Code of Federal Regulations (CFR) 172 (2003) – HM 232 – mandates security measures for the transport of some Hazardous Material**
  - Select Agents regulated under 42 CFR 73 and 9 CFR 121 require Hazardous Material transport security measures
- **Hazardous Material regulated security requirements include:**
  - Training
    - **Security awareness training**
    - **Specific training as appropriate**
  - Written security plan
    - **Based on assessment of transportation security risks**
    - **Address personnel security, unauthorized access, en route security**



Bacillus anthracis

Coccidioides immitis

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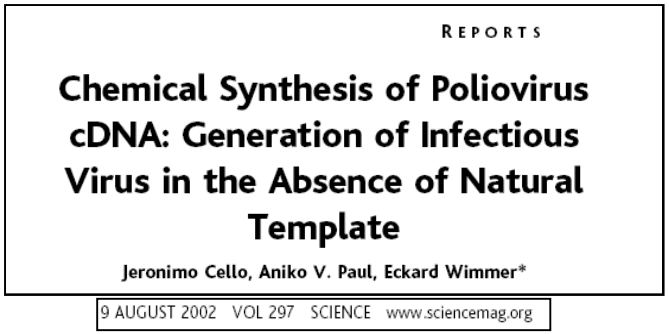
Concerns About US Select Agent Rule

- Top-down security regime not tailored to laboratory realities
- No need to steal a Select Agent to perpetrate bioterrorism
- Fear that security will trump biosafety, increasing the risk of accidental release or exposure
- Security requirements increasing operational impediments and compromising research funding
- Site-specific risk assessment is required but no guidance is provided
- No protection if personnel do not understand and accept security
- Biosafety guidelines are now regulatory requirements

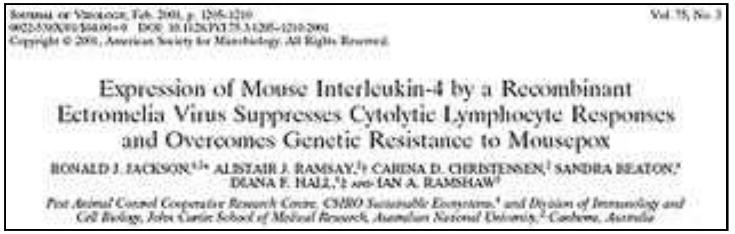


REPORTS

Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template

Jeronimo Cello, Aniko V. Paul, Eckard Wimmer*

9 AUGUST 2002 VOL 297 SCIENCE www.sciencemag.org



Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

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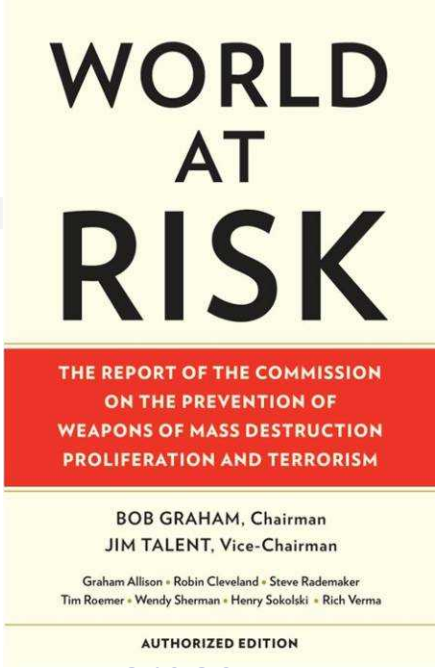
New and Upcoming Initiatives that may Influence Biosecurity

World at Risk Report



- **Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism**
  - Established by Congress in 2007 in response to a recommendation in the 9/11 Commission Report
    - **Chair: Former Senator Bob Graham**
    - **Vice-chair: Former Senator Jim Talent**
  - Commission focused its recommendations in 3 main areas where it felt risks to US increasing
    - **Radically revamp our strategic policy on Pakistan. Conditions in that country pose a serious challenge to America's short-term and medium-term national security interests.**
    - **Reinvigorate the nuclear non-proliferation agenda. Nuclear terrorism is still a preventable catastrophe and it is our duty to stop nuclear trafficking and reaffirm the vision of a world free of nuclear weapons.**
    - **Develop a new blueprint to prevent biological weapons proliferation and bioterrorism.**

www.preventwmd.gov

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WMD Commission Report
Action Items for Bioterrorism

- HHS should lead an interagency review of the domestic program to secure dangerous pathogens
- DHS should take the lead in developing a national strategy for advancing microbial forensics capabilities
- HHS and DHS should lead an interagency effort to tighten government oversight of high-containment laboratories
- HHS and Congress should promote a culture of security awareness in the life sciences community
- HHS and DHS should take steps to enhance the nation's capacity for rapid response to prevent an anthrax attack from inflicting mass casualties
- DOS and HHS should press for an international conference of countries with major biotechnology industries
- DOS should lead a global assessment of biological threats and engage in targeted biological threat prevention programs in additional countries
- HHS, through CDC, should work to strengthen global disease surveillance networks
- United States should reaffirm the critical importance of the BWC

Other Key US Initiatives

- **Oversight and Investigations Subcommittee of the US House of Representatives Committee on Energy and Commerce held hearings in October 2007 and May 2008**
  - "to examine the risks associated with the recent proliferation of high-containment biological research laboratories."

- **US National Science Advisory Board on Biosecurity (NSABB)**
  - to support the development of oversight mechanisms and increase awareness and collaboration in an effort to minimize the risks and harm that could result from malevolent use of legitimate research

- **Trans-Federal Task Force on Optimizing Biosafety Oversight**
  - tasked with analyzing the current US system for biosafety oversight, and developing options to address any identified gaps

Scientists and Law Enforcement

- **FBI partnered with the American Association for the Advancement of Science to survey the scientific community in 2008**
  - 1,332 responses
- **Full report at: http://www.scienceprogress.org/2008/12/science-and-law-enforcement/**
- **Key findings: scientists are suspicious of the FBI and feel that they do not work well with the scientific community**
  - 76% believe law enforcement does not understand their work
  - 71% believe law enforcement is more interested in restricting research for security purposes than they are in the scientific value of the work
  - 63% believe law enforcement has an overzealous approach to security issues and an interest in censorship
  - 55% believe law enforcement will restrict the publication of some research
  - 64% believe it is acceptable for an IBC to monitor their science but only 14% thought it would be acceptable for the FBI to have that authority

Scientists and Law Enforcement (cont)

- **Reasons for FBI contact that were viewed favorably:**
  - Requesting technical expertise in a particular area of science
  - Aiding in an ongoing criminal investigation
- **Reasons for FBI contact that were viewed negatively:**
  - Inquiring about the activities of a colleague (regardless of whether colleague is an American citizen or not)
  - Any role that law enforcement might have which interferes with research
- **Top ways LE can improve relations with the scientific community**
  - State goals and motives upfront
  - Improve scientific literacy
  - Be less adversarial / more respectful
  - Form relationships within community
  - Try to understand and respect the research

Contact Information

Jennifer Gaudioso, Ph.D.
Sandia National Laboratories
PO Box 5800, MS 1363
Albuquerque, NM 87185
USA
Tel. 505-284-9489
email: jmgaudi@sandia.gov

www.biosecurity.sandia.gov

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