

**Combating Nefarious Thugs-How the
Latest in Select Agent Safety,
Security, and Regulatory Changes
Affects Health and Safety Programs
at Research Laboratories**

**Dina M. Sassone, CIH, CSP, CBSP
Los Alamos National Laboratory
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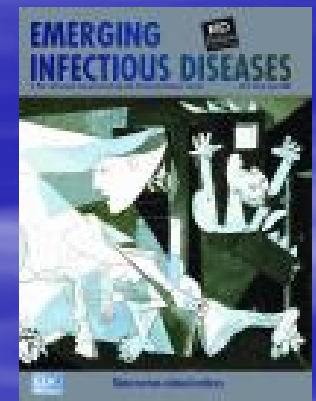
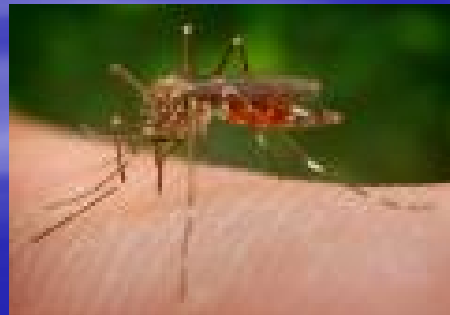


How did we get here?

- September 11, 2001/Anthrax in the mail
- Bioterrorism
- Emerging Diseases



Avian Influenza



Overview of Regulations

- Legislation

- *Uniting and Strengthening America by Providing Appropriate Tools Required To Intercept and Obstruct Terrorism (USA PATRIOT) Act of 2001*
 - *The Public Health Security and Bioterrorism Preparedness and Response Act of 2002*
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Overview of Regulations

- Regulatory Drivers

- 42 CFR 73 and 42 CFR Part 1003:
Possession, Use, and Transfer of Select Agents and Toxins
 - 7 CFR Part 331 and 9 CFR Part 121
Agricultural Bioterrorism Act of 2002:
Possession, Use, and Transfer of Biological Agents and Toxins
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Overview of New Regulations

- Other government agencies, e.g., DOE
 - 10 CFR 851

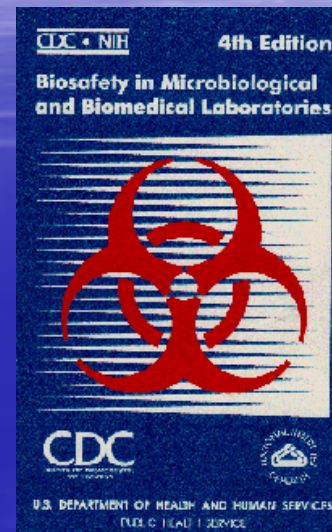


Select agents:

- Viruses, bacteria, fungi, toxins certain genetic elements, recombinant nucleic acids, and recombinant organisms, e.g., *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularemia*, and “1918 pandemic influenza A H1N1” (new)
 - HHS agents, overlap agents (HHS and USDA), and USDA agents.
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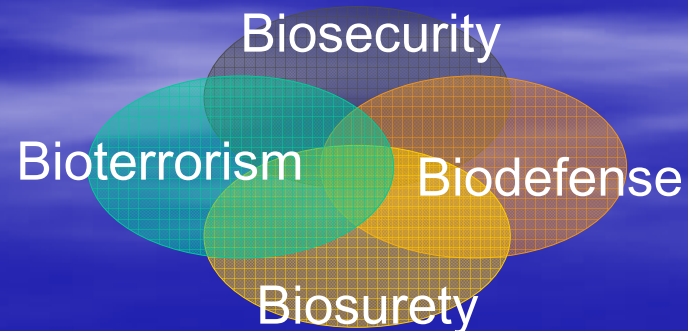
What's "new" in Biosafety:

- Select agent rules
- BMBL
- New/revised/clarified guidance on laboratory worker safety for WNV, Influenza, SARS



The "other Bio"

- MMWR: Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents
- USDA, DOE, and DOD requirements



Biosecurity

- Security Risk Assessments-Department of Justice and Security Plan for Select Agent research
- Food supply security
- Outbreaks
- Bioterrorism



Biosafety + biosecurity = biosurety

Revocation of select agent registration when facility:

- is no longer capable of handling agents at the appropriate Biosafety Level (BSL)
- is not handling agents in accordance with the Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- has or intends to use agents in a manner harmful to human health
- does not comply with provisions of the regulation.

The new direction for biosafety is dictated by:

- **Increased public awareness**
 - Anthrax
 - H5N1
 - New high containment labs
 - New federal agencies
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The new direction for biosafety is dictated by:

- **Growth of biosafety profession**



The new direction for biosafety is dictated by: GB&U Impact on research

- The good: More funding (DHS, NIH/CDC)
- The bad:



- Collegiate/“laboratorian” atmosphere gone
- Cost of implementing physical and personnel security
- Information systems control
- Fines and imprisonment
- The ugly: Many good scientists now choose not to do research in bioterrorism areas

Successful approaches

- Compliance with BMBL
 - Regular communication with regulators
 - Discussion with colleagues and peers on implementation
 - List serves
 - Fellow IH or BSOs
 - Company or university system wide approach
 - Consistent approach to inspections by regulators
 - Graded approach to security
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“Alternative” approaches

- Over-analysis of the regulations
- Under-analysis of the regulations
- Implementation of approach based on other hazards, e.g., nuclear



Impacts on medical providers

- **Infectious Disease awareness**
 - **Vaccinations/medical surveillance**
 - **Participation in emergency response (decontamination, treatment) for biological agent exposure (actual, assumed, work-related, terrorist-related)**
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Laboratory response network (LRN)

- National labs
 - Reference labs
 - Sentinel labs
 - Emergency Preparedness and Response
 - CDC: <http://www.bt.cdc.gov/>
 - OSHA:
<http://www.osha.gov/SLTC/emergencypreparedness/index.html>
 - National Response Team:
<http://www.nrt.org/>
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The new approach to health, safety, and biosecurity

- **Involve workers, safety professionals, medical professionals, and stakeholders at all stages of planning and execution of projects**
 - **Understand that traditional biosafety and medical surveillance programs need to be flexible and tailored to ever changing and rapid information**
 - **The bad guy is out there!**
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