



The Future of Biosafety Regulation

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Goals

- Regulation vs. Guidance
- In the past.....
- In the present....
- In the future....

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Biosafety Regulation



- **Guidance**: something that provides direction or advice as to a decision or course of action
- **Regulation**: the state of being controlled or governed; an authoritative rule

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In the past....and today!



- Laboratories are holistic environments (chemical, radiological, biological, physical, security, etc.)
- Some elements have always been highly regulated (radiological safety)
- Physical safety and accidents: Occupational Safety and Health Administration (OSHA)
- Biological safety will be the focus of this talk: containment and safe working practices with infectious organisms

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In the past....



- BMBL: primary guidance document for biosafety
- Guidance and description of “best practices”
- NIH Recombinant DNA Guidelines: attached to NIH funding, but not “Regulation”
- Institutions and agencies developed and implemented their own plans using these documents as guidance
- No funding for comprehensive checks, no inspections, etc.

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Past, Present, Future



- Result:
 - ◆ Biosafety based on individual site specific risk assessment.
 - ◆ Everyone doing things in different ways.
 - ◆ No consensus definitions on major issues (How many BSL-3 laboratories are there? What is a BSL-3 laboratory?)
 - ◆ Little to no validation research on methods, funding for biosafety, etc.

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Past, Present, Future



- Regulation:
 - ◆ Radiation, Chemical, Shipping
 - ◆ EPA, NRC, etc.
 - ◆ OSHA – little focus on biocontainment
 - ◆ Specific Facilities and Programs (USAMRIID, CDC poxvirus)
- A series of incidents led to the National Select Agent Program

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Final Rules: Possession, Use, and Transfer of Select Agents and Toxins



**42 CFR Part 73, 9 CFR Part 121, and
7 CFR Part 331**

- Publication date: March 18, 2005
- Effective date: April 18, 2005
- Implemented the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (signed June 12, 2002)

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Entity Requirements



- Register for each select agent or toxin it possesses, uses, or transfers
- Designate a Responsible Official (RO)
- Receive government approval of entity (owners), RO, & individuals who need access to select agents
 - ◆ Based on DOJ check of electronic databases ("Security Risk Assessment" = SRA)
- Allow for inspections by APHIS &/or CDC

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Past, Present, Future



- Created a nation-wide framework to regulate biosafety and biosecurity ("safe and secure")
- Attached significant penalties to non-compliance
- Currently applies to only a certain definitive list of agents

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Past, Present, Future



- Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight
- Created to describe and address gaps in high and maximum containment research in USA
- Formation announced late 2007
- Purpose: "to propose options and recommendations to improve biosafety and biocontainment oversight of research and research-related activities at high and maximum containment laboratories in the United States, while simultaneously fostering progress in life sciences research."
- Co-chaired by HHS and the U.S. Department of Agriculture (USDA)
- Departments of Commerce, Energy, Homeland Security, Labor, State, Transportation, Veterans' Affairs, Environmental Protection Agency and National Science Foundation.

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Task Force Objectives



- OBJECTIVE 1: Enhance the overarching framework for biosafety and biocontainment oversight of high and maximum containment research through improved coordination and integration of oversight activities.
- OBJECTIVE 2: Encourage a robust culture of accountability characterized by individual and institutional compliance with biosafety and biocontainment regulations, guidelines, standards, and policies.
- OBJECTIVE 3: 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.

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Objectives



- OBJECTIVE 4: 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.
- OBJECTIVE 5: Ensure that biosafety and biocontainment regulations and guidelines cover current and emerging hazardous biological agents, and develop an agricultural equivalent of the BMBL.
- OBJECTIVE 6: Ensure that the infrastructure and equipment necessary for biosafety and biocontainment at high and maximum containment research facilities are in place and properly maintained.

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Objectives



- OBJECTIVE 7: Develop and support a national research agenda for applied biosafety and biocontainment to improve the management of biohazard risks.
- OBJECTIVE 8: Improve and share strategies to ensure effective public communication, outreach, and transparency about biosafety and biocontainment issues.

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Today and the future....



- OBA: site visits to validate compliance with NIH guidelines
- National Select Agent Program
- Task Force Recommendations....?

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Future!



- *Regulation always proceeds to the binary!*
- Why?: Easier to follow and enforce
- Easier to train inspectors
- (Interim select agent rule example at NIH)
- Requires quantifiable benchmarks, consistency among sites and entities, and the ability to hold up to legal scrutiny

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Future!



- Speed Limit example
- Real World example
- Challenges:
 - ◆ Biosafety guidance to a great extent has been qualitative and based on best practices and consensus, not directive.
 - ◆ Lack of validation research to make scientific determinations of which approaches are truly safer.
 - ◆ Like many regulatory efforts: how is effectiveness measured?

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Future!



- So what will we need?
- Research to establish validated best practices
- Measure of adverse outcomes in order to measure effectiveness of methods
- Two possible courses:
 - ◆ Shift away from “regulation” to a “certification” approach (AAALAC model)
 - ◆ Shift away from individual site specific risk assessment to specific approved procedures

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Questions?

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