

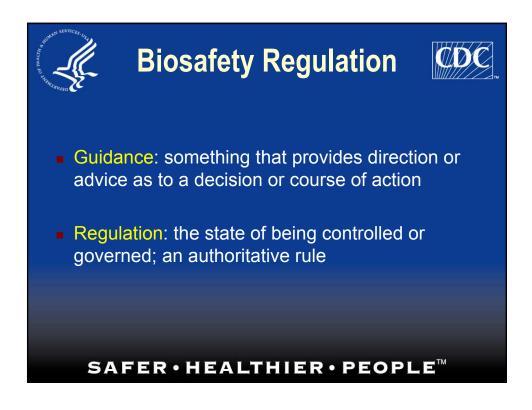


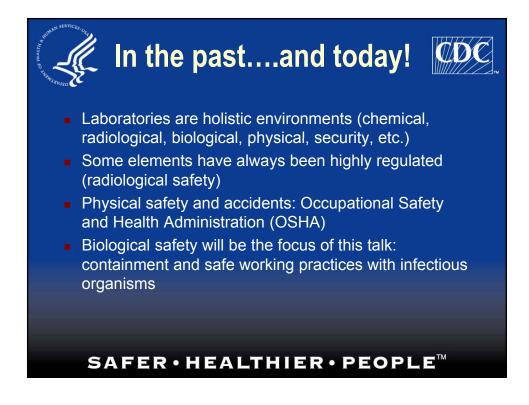
The Future of Biosafety Regulation

Martin Sanders PhD, CBSP, RBP Director (Acting) Office of Health and Safety CDC

SAFER • HEALTHIER • PEOPLE™













Final Rules: Possession, Use, and Transfe of Select Agents and Toxins 42 CFR Part 73, 9 CFR Part 121, and



7 CFR Part 331

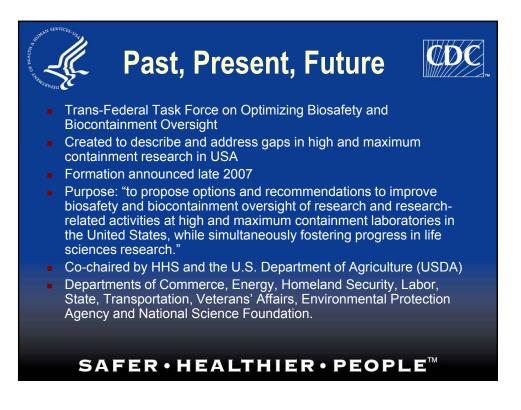
Publication date: March 18, 2005 Effective date: April 18, 2005

Implemented the provisions of the Public Health Security and **Bioterrorism Preparedness and** Response Act of 2002 (signed June 12, 2002)

SAFER • HEALTHIER • PEOPLE[™]









- 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.

SAFER • HEALTHIER • PEOPLE[™]

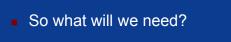












- Research to establish validated best practices
- Measure of adverse outcomes in order to measure effectiveness of methods
- Two possible courses:
 - Shift away from "regulation" to a "certification" approach (AAALAC model)
 - Shift away from individual site specific risk assessment to specific approved procedures

SAFER • HEALTHIER • PEOPLE™

