

U.S. Army Medical Research

USAMRIID

Institute of Infectious Diseases



The Army Biosurety Program: An Overview

Gretchen Demmin, Ph.D. MT (ASCP)

**Lieutenant Colonel, MS, U.S. Army
Deputy Commander for Surety, Operations and Plans**

What is Biological Surety (Biosurety)?

**The Army Biological Surety Program (BioSurety)
was implemented 5 May 05 as a unique
commander's program governed by:**

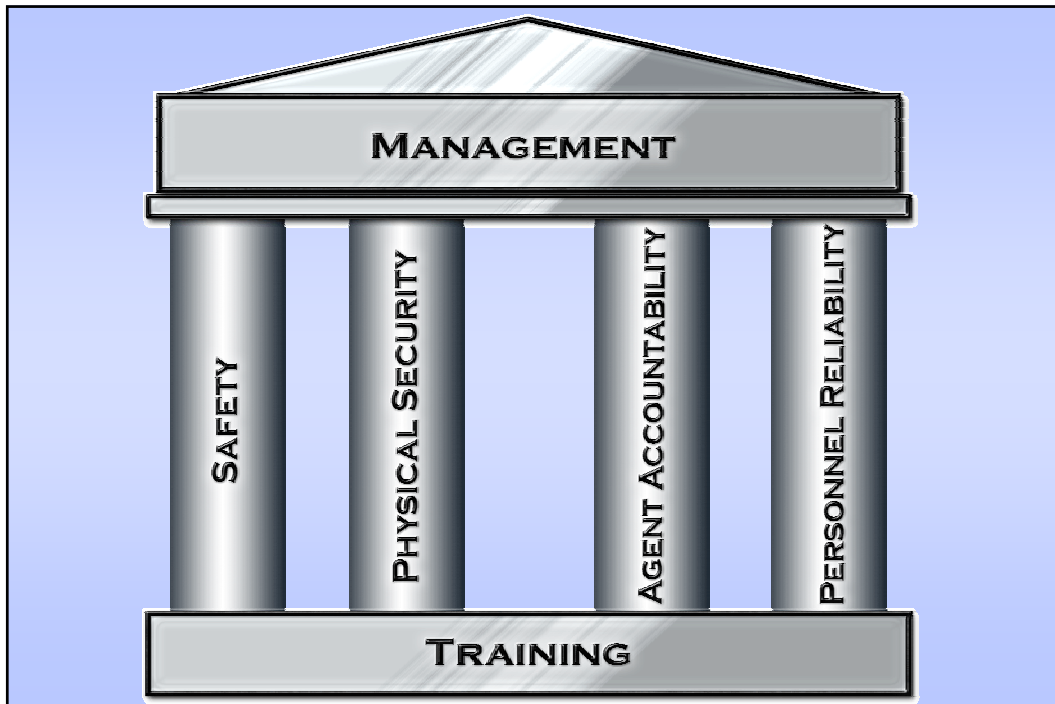
- DoD Directive 5210.88, Safeguarding Biological Select Agents and Toxins (BSAT), 11 Feb 04**
- AR 50-X, Biological Surety (DRAFT regulation, 28 Dec 04)**
- AR 190-17, Biological Select Agents and Toxins (BSAT) Security Program, 6 Sept 06**

Why Develop a Biosurety Program?

- The army has a long history with nuclear and chemical surety programs
- Give the general public an added assurance
- Provide added insurance against “strict liability” with regards to select agent fines
- Provide added protections against insider threat

Biosurety Program VS CDC SAP

- Safeguard BSATs from loss, theft, diversion, unauthorized access or use
- Full compliance with Biological Weapons Convention (BWC)
- Ensure operations with BSAT are conducted in safe, secure, reliable manner by personnel, that are properly trained and certified to be trustworthy and reliable
- Implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 107–188).
- Protects against the effects of misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts.



Biological Defense Safety Program

- Occupational Safety and Health Administration
- Environmental Protection Agency
- Nuclear Regulatory Commission
- NIH Guidelines for Research Involving Recombinant DNA Molecules
- National, state and local regulations
- Any requirements of applicable accrediting agencies

PHYSICAL SECURITY

- Discourage
 - Gates, guns, guards
 - Random exit search
- Detect
 - Access control- card reader, PIN, biometrics
 - Cameras and intrusion detection systems
- Respond
 - Security forces
 - Emergency responders



AR 190-17, Biological Select Agents and Toxins Security Program

- Physical security measures must constitute a balanced, in-depth system responsive to all credible potential vulnerabilities
- All BSAT contracts will conform to federal and DoD acquisitions and regulations. BSAT contracts entered into subsequent to the publication of this regulation must incorporate by reference the regulation's substantive requirements

Security Requirements

- Chapter 3, Physical Security Planning
- Chapter 4, Vulnerability Assessment
- Chapter 5, Physical Security Standards
- Chapter 6, Security Forces
- Chapter 7, Training Requirements
- Chapter 8, Transportation
- Appendix B, Physical Security Plan Outline

Personnel Reliability

Area of greatest vulnerability is the insider threat

CDC requirement

- Personnel who have access or ability to gain access to BSAT must have current security risk assessment (SRA)
- SRA is conducted by FBI every 5 years

DoD requirement

- SRA
- Personnel reliability program
 - System implemented to ensure that those with access to select agents are continuously assessed and determined to be trustworthy, mentally and emotionally stable, and physically capable of performing the duties assigned

BPRP - Biological Personnel Reliability Program

- Initial interview conducted by certifying official to review personal history of drug and alcohol abuse, financial problems, attitudes toward responsibility
- Personnel records review
- Personnel security investigation
 - NACLC (national agency local agency check)
 - ANACI (access national agency check with written inquiry)
- Medical evaluation
- Drug/alcohol screening
- Technical proficiency (all training complete)
- Certifying official's evaluation & briefing
- Ongoing evaluation- self reporting required

AGENT ACCOUNTABILITY

- Unique accounting considerations for replicating agents
- Many data points must be captured regarding inventory of items in long-term storage (records maintained for 5 years)
 - Name, location
 - Who accessed storage and when
 - Who returned agent to storage and when
 - Name and quantity acquired from another individual or entity
 - The select agent used and purpose of use
 - For intra-entity transfers (the select agent, the quantity transferred, the date of transfer, the sender, and the recipient)
- Short-term usage documented in laboratory notebooks



Restrictions on transfer of BSAT

“Army facilities will not provide DoD or army BSAT in any other circumstances unless approval has been received from ATSD(NCB).

Requests will identify recipient information, name and quantity of BSAT to be provided, purpose for which BSAT is used, and rationale for providing BSAT. Approval will identify if any surety and security measures are required for the recipients beyond those required by the federal regulation”

The Way Forward

Plan and request transfers far in advance of program requirements

Know that receiving BSATs from the army may require you to institute new security or personnel reliability program

**Thanks to the USAMRIID Biosurety
Team, Past and Present**

- **Jay Arrison, Physical Security**
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- **Jorge Trevino, Personnel Reliability Program Manager**
- **Rafael Torres, Select Agent Program Manager**
- **Gary Comontofski, Select Agent Program Manager**
- **Stephanie Redus, Inventory Control**
- **1LT Grant Severson, Inventory Control Officer**