



Overview of DoD Biological Select Agent and Toxin (BSAT) Policies

**Kenneth A. Cole, Ph.D.
CAPT, MSC, USN**

**Deputy and Medical Director,
Office of the Special Assistant for Chemical and Biological
Defense & Chemical Demilitarization Programs**

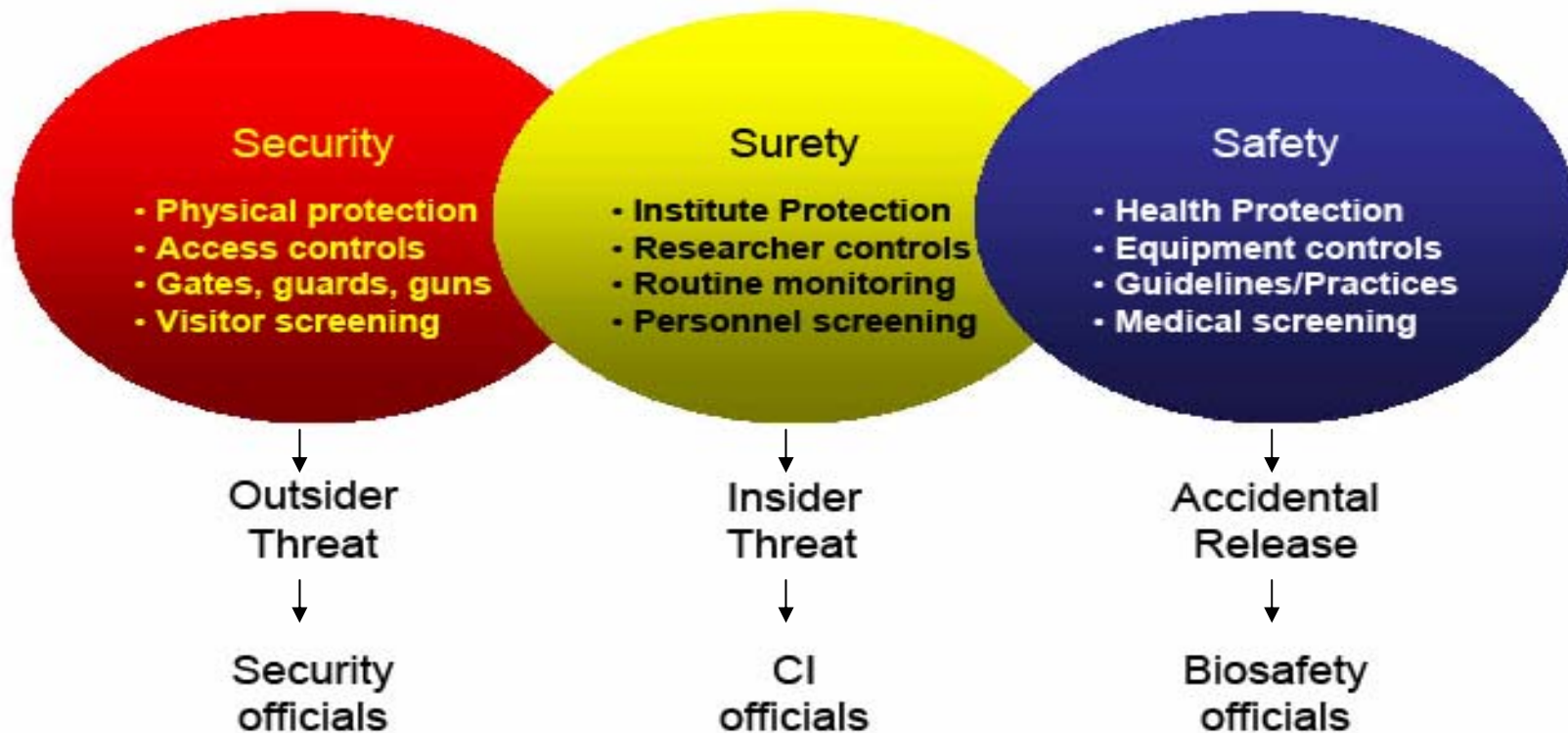
National Science Advisory Board for Biosecurity

December 10, 2008

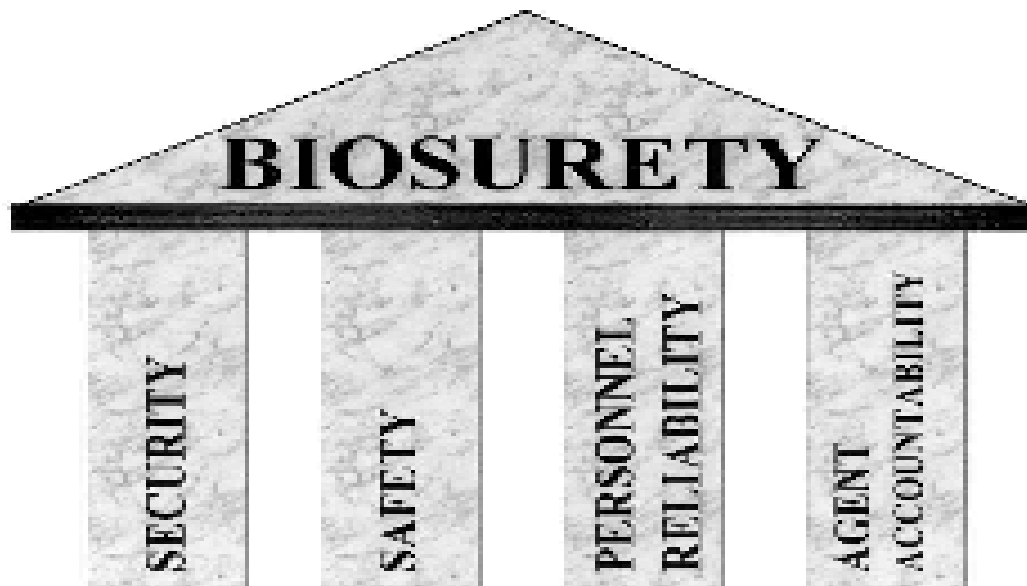
<http://www.acq.osd.mil/cp/>



Current Risk Management Framework



What inefficiencies exist within this risk management framework? Why? Do differing perspectives/practices limit the efficacy of this approach? How?



Security

- **Limited access**
- **Internal and external monitoring**
- **Intrusion alert and monitoring**
- **Random search and inspection**

Safety

- **Safety training and mentorship**
- **Risk management**
- **Environmental surveillance**
- **Occupational health screening**

Personnel Reliability

- **Background investigation**
- **Medical screening**
- **Mental health and behavior screening**
- **Urinalysis**

Agent Accountability

- **Pinpoint location and agent registration**
- **Limited access**
- **Archive and working stock accountability**
- **Traceable to laboratory notebooks**



SECURITY

Current Federal Policy

- 42 CFR 73, 7 CFR 331 and 9 CFR 121; Possession, Use, and Transfer of Select Agents and Toxins, Final Rule (18 Mar 05):
 - Requires each entity possess and implement a security plan to safeguard BSAT against unauthorized access, theft, loss, or release.
 - Physical security plan should be based on site-specific risk assessment of the BSAT and its intended use

Current DoD Policy

- DODI 5210.89, Minimum Security Standards for Safeguarding BSAT, (18 Apr 06):
 - Entry Checkpoint
 - Badge Control Access
 - Package and Materials Controls
 - Intrusion Detection Systems
 - Security Force Response
 - Vulnerability Assessment
 - Physical Security Plan
 - 2 Person Rule to Access Reference Stock

****Service physical security policies meet all DoD requirements and exceed Federal requirements***



SAFETY

Current Federal Policy

- **42 CFR 73, 7 CFR 331 and 9 CFR 121; Possession, Use, and Transfer of Select Agents and Toxins, Final Rule, (18 Mar 05) :**
 - **Use published documents as guidelines for developing local biosafety policy**
 - **BMBL**
 - **OSHA**
 - **NIH Guidelines for Research Involving Recombinant DNA Molecules**

Current DoD Policy

- **DODI 5210.89, Minimum Security Standards for Safeguarding BSAT, (18 Apr 06):**
 - **Same as above**
 - **Services have local safety offices that prescribe local policy as above**

****Service policies for biosafety meet all DoD requirements and exceed Federal requirements***



PERSONNEL RELIABILITY

Current Federal Policy

- **42 CFR 73, 7 CFR 331 and 9 CFR 121; Possession, Use, and Transfer of Select Agents and Toxins, Final Rule, (18 Mar 05):**
 - Does not mandate Biological Personnel Reliability Program (BPRP) “surety” program
 - 42 CFR 73 applies only to laboratories in the U.S.
 - CDC Registration includes FBI “security risk assessment” (database check)

Current DoD Policy

- **DODI 5210.89, Minimum Security Standards for Safeguarding BSAT, (18 Apr 06):**
 - BPRP required for unescorted access to BSAT and to escort/supervise non-BPRP individuals
 - Current favorable PSI (ANACI or NACLIC – SECRET level PSI) for all personnel whose duties require access to BSAT
 - Overseas facilities implement the DODI to the maximum extent possible; where necessary, use waiver/exception procedures

****Service PSI policies for BPRP meet all DoD requirements and exceed Federal requirements***



PERSONNEL RELIABILITY: BBRP Duties

- **Routine unescorted access to BSAT**
- **Escort for other individuals not in the BPRP**
- **Control of direct access to BSAT**
 - e.g. security guards
- **Issue means of access to BSAT**
 - e.g. proximity cards, PIN, keys, lock combinations, biometric cards
- **Motor vehicle operator transporting BSAT**
 - unless escorted
- **Responsible official or alternate**



PERSONNEL RELIABILITY PROGRAM : ***Current SA Lab Personnel in BPRP***

- **DODI 5210.89_AFI 10-3901 Operations Minimum Security Standards for Safeguarding BSAT**
- **AR 50-1 Biological Surety**
- **OPNAV Instruction 5530.16 Minimum Security Standards for Safeguarding BSAT**

	Army	Navy	Air Force
Laboratories	7 (1 OCONUS)	5 (3 OCONUS)	2 (1 currently no BSAT)
MACOMs	3	2	1
Personnel in the BPRP	626	74	6



PERSONNEL RELIABILITY PROGRAM

- **MAIN TENANTS:**
 - Legitimate need to have access to material
 - Technically competent
 - Complete Personnel Security Investigation (PSI)
 - Approval of BSAT access by certifying official (CO)
 - usually a direct supervisor

- **CONTINUOUS MONITORING BY CO TO INCLUDE:**
 - Drug testing
 - urinalysis screen for illegal substances
 - Medical records review by competent medical authority (CMA)
 - Personnel records review
 - Self-reporting of potentially disqualifying information to CO/CMA
 - Reporting of potentially disqualifying information in peer to CO/CMA
 - 2 person rule for accessing resource stocks



CERTIFYING OFFICIALS AND REVIEWING OFFICIALS

- **Commanders/directors appoint certifying officials**
 - Certifying officials evaluate potentially disqualifying information (PDI) identified during initial screening and continuing evaluation
 - Certifying officials certify individuals into, and disqualify individuals out of, the BPRP
- **Commanders/directors are reviewing officials**
 - Reviewing officials review all disqualification decisions
 - Reviewing officials may monitor certification decisions



BPRP QUALIFYING STANDARDS

- **Mentally alert and stable**
 - trustworthy, physically competent, free of unstable medical conditions
- **Perform in approved manner**
 - Dependable, responsible
 - Flexibility in adjusting to changes in working environment
 - Physical ability to perform required duties
- **Sound judgment in adverse or emergency situations**
- **Good social adjustment**
- **Positive attitude towards the BPRP**



BPRP DISQUALIFYING STANDARDS

- **Mandatory disqualification**
 - Current diagnosis of drug/substance or alcohol dependence
 - Drug/substance abuse within 5 years of initial interview
 - Drug trafficking within 15 years of initial interview
 - Drug/substance abuse while enrolled in the PRP
 - Inability to meet safety requirements of the position

- **Other disqualification factors (CO judgment required)**
 - Alcohol-related incidents/alcohol abuse
 - Drug/substance abuse >5 years before initial interview
 - Medical conditions or treatment that:
 - Affects consciousness, judgment, concentration; increase risk from BSAT exposure; impair ability to wear protective equipment; or impair physical ability required for duties
 - Suicide attempts or threats
 - Inappropriate attitude, conduct, or behavior, including concealing or failing to report PDI



REMOVAL FROM BPRP DUTIES

- **Medical restriction**
 - when temporary medical condition may cause duty performance impairment
- **Administrative restriction**
 - when individual is absent from BPRP duties for a significant period of time
- **Suspension**
 - When reliability is suspect
 - During prolonged medical conditions
 - Provides time for further evaluation
 - Ultimately requires decision to reinstate or disqualify
- **Disqualification**
 - Individual is notified and provided opportunity to provide written explanation
 - Decision requires reviewing official approval
 - Disqualified individuals may later request requalification
- **Administrative termination**
 - when individual no longer performs BPRP duties



***SECURITY RISK ASSESSMENT ≠
PERSONAL RELIABILITY***



BACKGROUND CHECKS

- **In US- Access National Agency Check and Inquiries (ANACI) or National Agency Check with Local Agency and Credit Check ((NACLCLC)**
 - **SECRET level PSI for all personnel whose duties require access to BSAT**
- **Foreign Nationals with need to access both classified material and BSAT**
 - **will use Limited Access Authorization (LAA) in lieu of NACLCLCs or ANACIs**
- **Host Nationals**
 - **State Dept-Regional Security Office (RSO) to conduct a full background investigation of a Foreign Service National (FSN) or Locally Engaged Staff (LES)**



ANACI or NACLC

- **Basic National Agency Checks**
 - **Security/Suitability Investigations Index**
 - **Defense Clearance and Investigations Index**
 - **fingerprint classification**
 - **search of the FBI's investigative index**
- **Credit search covering all residence, employment, and education locations during the last 7 years**
- **Law Checks covering all locations of residence, employment, and education during the last 5 years and to all locations of admitted arrest**
- **Interview of references with social knowledge of the subject**



AGENT ACCOUNTABILITY

Current Federal Policy

- **42 CFR 73, 7 CFR 331 and 9 CFR 121; Possession, Use, and Transfer of Select Agents and Toxins, Final Rule, (18 Mar 05) :**
 - **Requires inventory to include:**
 - **Agent name and characterization of freezer archives**
 - **Quantity acquired from another entity (amount, date, source)**
 - **Where stored**
 - **Agent purpose of use**
 - **Transfer of agent highly regulated**

Current DoD Policy

- **DODI 5210.89, Minimum Security Standards for Safeguarding BSAT, (18 Apr 06):**
 - **All of the above, plus notebook records of working stocks**
 - **Tracking of freezer archives and transfers (between DoD and non-DoD) by ATSD(NCB)-developing database through contract with Battelle**

****Service policies for inventory meet all DoD requirements and exceed Federal requirements***



BSAT POLICY and IMPLEMENTATION

- **Tri-Service Task Force Review of BSAT policy and implementation was conducted between 28 Aug – 1 Dec 08**
- **Following enhancements have been agreed upon by the Services for implementation and recommendation to forward to DoD for incorporation into policy**
- **Enhancements are in:**
 - **Transportation**
 - **Biosafety**
 - **Security**
 - **Inspections**
 - **Inventory and Accountability**
 - **Training**



SUMMARY and WAY AHEAD

SUMMARY

- **Committees have been established to examine policy for DoD or Interagency programs performing biodefense research with biological select agents and toxins (BSAT)**
- **The Inter-Service Council for Biosecurity and Biosafety (ICBB) General Officer Steering Committee (GOSC) has commissioned a Defense Science Board (DSB) and Defense Health Board (DHB) to conduct independent reviews of DoD BSAT programs**

WAY AHEAD

- **The DoD WG will meet in January 2009 after release of reports from Service TFs, IGs, GOSC, DSB, and DHB (December 1) and NSABB (December 31) to collate recommendations and discuss modification of DoDI 5210.89**



Questions?