Army Biosurety Program

Mission

The mission of the Army Biosurety Program is to provide protection to personnel, the local population, and the environment by ensuring that the biological select agents and toxins (BSAT) operations are conducted safely; that BSAT are secure; and that personnel involved in those operations meet the highest standards of reliability.

Background and Environment

The Army Biosurety Program ensures that research conducted with regulated BSAT is done safely by reliable personnel and that BSAT are secure. The program strongly emphasizes policies regarding personnel with access to BSAT. It also mandates physical security and biosafety measures for containing and handling BSAT safely.

The U.S. Army is not alone in seeking safety and security with BSAT. The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) are mandated to develop regulations to control access to and possession of BSAT or select agents. The Army Biosurety Program ensures that the Army follows all HHS and USDA regulations pertaining to select agents and toxins, including adherence to the standards and guidelines in the Centers for Disease Control and Prevention/National Institutes of Health (CDC/NIH) laboratory safety manual, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL, 5th edition).

Even though biosurety is a relatively new term, it encompasses policies and activities developed over decades to keep biological agents secure and workers and local communities safe from pathogenic agents and toxins. The Army first held a biological safety conference in 1955, which became an annual conference for the next 3 decades. In 1984, the American Biological Safety Association was founded to promote biosafety as a scientific discipline. In 1993, the Army implemented a formal biological defense safety program requirement, as directed by Army Regulation (AR) and Department of the Army (DA) Pamphlet 385-69. The Army Biosurety Program was initiated in 2001 and was implemented by 2005 through a series of interim guidance messages from the surety regulation proponent, Army G-3/5/7. In 2008, AR 50-1 ("Biological Surety") was formally implemented as the regulation that prescribes policies, procedures, and responsibilities for the Army Biosurety Program.

Biosurety comprises four areas: (1) physical security, (2) biosafety, (3) agent accountability, and (4) personnel reliability. While the overarching concepts of biosurety mandated in AR 50-1 are not necessarily new to U.S. Army Medical Research and Materiel Command (USAMRMC) laboratories with BSAT, many specific policies and procedures may be new.

Physical security is defined as the actions that secure select agents and deny access to select agents for subversive purposes. The physical security program at USAMRMC laboratories using BSAT allows only authorized individuals access to areas in which select agents are stored or used. Access is authorized only after an individual satisfactorily completes the initial interview

by the certifying official (CO), laboratory safety training, an occupational health evaluation, the appropriate drug screening and immunizations, a personnel security investigation (PSI) conducted by the Army, and a security risk assessment (SRA) conducted by the Federal Bureau of Investigation (FBI). Before an individual enters the laboratory unaccompanied, a laboratory supervisor mentors the individual on laboratory-specific tasks. Limited access to areas containing select agents is typically done by establishing restricted areas and using automated access control systems. Facilities with BSAT have redundant security measures that use identification badges and personal identification numbers to ensure access is limited to authorized personnel.

Biosafety is defined as the procedures used in the laboratory or facility to ensure that pathogenic microbes are handled safely. Any biological laboratory's primary objective is to provide a safe and secure environment for the workforce and surrounding communities. USAMRMC has a comprehensive safety program that emphasizes safety training and mentorship, risk management, environmental surveillance, and occupational health screening. All Army facilities with BSAT adhere to the CDC/NIH-published BMBL (5th edition) for defining the safe handling of BSAT and the guidelines for laboratory design, and they follow AR 385-10 (The Army Safety Program) for specific Army biological safety requirements.

Agent accountability is defined as keeping accurate inventory records and establishing an audit to ensure that agents are managed appropriately and accounted for. An audit can reveal overages, shortages, theft, loss, or mismanagement of BSAT. Some biological organisms can propagate on their own; therefore, an agent inventory is not as simple to maintain as a chemical inventory. Clear guidelines and meaningful documentation requirements are standardized to ensure accurate reporting. For example, reporting requirements need to clearly show a record of who had access to agents, as well as when and where the agents were accessed. Transferring select agents from one location to another requires oversight and advanced approval. The records are intended to show a complete audit trail from receipt to destruction or transfer.

Personnel reliability is defined as ensuring those who are granted access to agents are stable, trustworthy, and competent to perform the tasks assigned to them. Personnel reliability begins with screening people before they gain access to select agents and toxins, and it continues with monitoring the health of those individuals, conducting random drug tests, and continually evaluating personnel to ensure each employee maintains the highest standards of personal conduct.

The Biological Personnel Reliability Program (BPRP) is designed to ensure that each person with access to BSAT meets the highest standards of reliability. All personnel with access to BSAT must comply with the BPRP. Currently, the BPRP requires all individuals with access to areas where select biological agents are stored or used to receive extensive laboratory safety operations training, participate in a laboratory mentorship program, and satisfactorily pass a PSI conducted by the Army and an SRA conducted by the FBI. In addition to a current PSI, enrollment into the BPRP requires reviews of personnel records, a medical evaluation, and an interview with the CO highlighting the individual's responsibilities within the BPRP, reliability standards, and self-reporting requirements. During the continuous monitoring phase, BPRP personnel are required to self-report any changes in their health status and observations of other BPRP employees. Periodic reinvestigations are conducted every 5 years, and urine drug testing is conducted at least once every 12 months for military personnel and randomly for Army civilians and contractors. Medical monitoring and routine physical examinations are conducted periodically depending on the type of containment work being performed.

Key Themes and Messages

The Army Biosurety Program focuses on compliance with mandated and approved safety, security, environmental, occupational health, operational, personnel reliability, and technical procedures for the safety of workers and the local community and the security of BSAT.

The Army Biosurety Program establishes and authorizes physical security measures to preclude unauthorized access to or use of BSAT.

The Army Biosurety Program establishes evaluation procedures for and assesses the reliability of personnel designated for, or assigned to, BPRP duty positions.

The Army Biosurety Program defines the training and experience necessary for staff positions and verifies that each individual is proficient in the duties to be performed through training, mentoring, and continuous evaluations.

The Army Biosurety Program establishes the policies and procedures required for the safe and secure acquisition, storage, handling, maintenance, transportation, inventory management, and disposal of BSAT.

The Army Biosurety Program establishes policies and procedures for the emergency response to biological mishaps and incidents.

Questions and Answers

Q1. What prompted the development of the Army's Biosurety Program?

A1. The anthrax mailings in October 2001 underscored the need to heighten security and implement more stringent procedures for controlling access to infectious agents. Although the anthrax attacks were not successful in causing a large number of casualties and fatalities, they did have a significant economic and emotional impact. The CDC reported that this attack included 5 fatalities, 17 illnesses, a cost of $23 million to decontaminate one Senate office building, $2 billion in lost revenue to the U.S. Postal Service (USPS), and as much as $3 billion to decontaminate USPS buildings and procure mail-sanitizing equipment. In addition to increased security and control measures, the DA Inspector General advocated the immediate implementation of a biosurety program that is based on military experience with surety programs for both nuclear and chemical weapons. The goals of the chemical and nuclear surety program are to ensure that operations with these hazardous materials are performed safely and securely. The intent of the biological surety program is the same, but its policies also consider the unique aspects of biological agents.

Q2. What are some examples of designated biological surety agents?

A2. Designated biological surety agents (and the diseases/conditions they cause) include:

- *Bacillus anthracis* (anthrax)
- *Clostridium botulinum* (botulism)
- *Yersinia pestis* (plague)
- *Francisella tularensis* (tularemia)
- *Variola virus* (smallpox)
- Filoviruses – Ebola and Marburg viruses (hemorrhagic fever)

Q3. What measures are taken to ensure the security of BSAT?

A3. Both the physical security of BSAT and the reliability of employees working with BSAT are taken into consideration:

- Physical Security: One of the important factors in establishing a dynamic biosurety program is security. Developing a security plan begins by identifying areas containing BSAT and limiting access to those areas. Typically, this is done by establishing restricted areas and using automated access control systems. These systems provide detailed information, record access to restricted areas, and can be wired into closed-circuit television cameras to allow positive identification of personnel before they are allowed entry. Increasingly restrictive security measures help to establish layers of security perimeters commensurate with the risk related to the agents used. For example, card readers can be used to limit and identify persons entering restricted areas, whereas locks activated by personal identification number keypads allow entry into specific rooms. Laboratories containing high-risk agents, such as Ebola virus and botulinum neurotoxins, may have additional measures such as biometric readers and intrusion-detection systems. Specific requirements for access may include clearly defined and visible markings on security badges. Everyone in the facility should be aware of the ways that restricted areas are marked and who is allowed access to those areas to identify intruders. Persons who are allowed access to the restricted areas must have completed all training required for the safe conduct of laboratory procedures. Training should be evaluated through testing, or preferably, a period of mentorship within the containment. A mentorship program allows trainees to experience the working conditions and ask questions under close supervision. The time required for mentoring depends on the level of experience of the person entering containment. A trainee should not be allowed unescorted access to a containment area until the trainer is satisfied that he or she can perform a variety of tasks safely and securely.
- Reliability: The BPRP has been designed to ensure that persons with access to potentially dangerous infectious agents and toxins are reliable. More information on the BPRP can be found in the answer to Question 5.

Q4. What measures do scientists take to ensure their safety while working with BSAT?

A4. Multiple levels of actions are conducted to ensure the safety of scientists working with BSAT. After meeting rigid hiring requirements and attending training and mentoring programs, new scientists are prepared to work with select agents and toxins. Research is conducted under well-defined laboratory practice guidelines and safety measures. In addition to the procedures specific to their research protocol, all persons operating in containment laboratories should understand the operation of the safety equipment that serves as the primary barrier for containment. Examples of primary barriers include biological safety cabinets, glove boxes, safety centrifuge cups, or any other type of enclosure or engineering control that limits a worker's exposure to the agent. Secondary barriers are facility and design construction features that contribute to a worker's protection and that protect those outside of the laboratory from contact with or exposure to agents inside the containment facility. Examples of secondary barriers include physical separation of laboratory areas from areas that are accessible to the general public, hand-washing facilities in close proximity to exits, and specialized ventilation systems that provide directional airflow and high-efficiency particulate air filtration prior to exhaust.

Q5. What is the BPRP?

A5. The BPRP provides a system of initial and continuous evaluations to ensure that personnel with access to BSAT are reliable and suitable. For an individual to qualify for BPRP duties, an initial interview is conducted with a CO. The CO is the gatekeeper for access to BSAT and ensures that persons requesting access have met all of the qualifying conditions. Typically, the CO will evaluate a candidate through an initial interview, a PSI, a personnel records review, a medical evaluation, and a drug test. When a person has completed the interview and is certified, he or she is subject to continuous monitoring. Continuous monitoring includes drug testing and assessments by supervisors, fellow workers, COs, and support staff, in addition to self-reporting any potentially disqualifying information to the CO. Potentially disqualifying information would include, but is not limited to, an employee being charged with or convicted of a crime, having drug or alcohol problems, experiencing mental or emotional instability, or having unstable medical conditions.

The following four questions pertain specifically to the biosurety program at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID):

Q6. What type of safety training does USAMRIID require?

A6. At USAMRIID, every new laboratory employee attends a safety workshop on laboratory operations. Annual refresher training also is required. Safety-related, laboratory-essential training tasks are specified for every laboratory employee. Supervisors are held accountable for the safety of their subordinates, and a safety standard must be included in the performance objectives of all USAMRIID employees.

The safety committee, composed of USAMRIID's division chiefs and division safety representatives, meets regularly to review safety data and propose methods to prevent accidents. Safety concepts are emphasized by the publication of institute-wide safety messages and intranet-based, institute-wide, laboratory-essential training tasks for every employee. The entire workforce receives risk management training.

Q7. Who oversees PSI at USAMRIID?

A7. A personnel security section at USAMRIID is dedicated full time to documenting and coordinating PSIs with the DoD, CDC, and FBI. USAMRIID investigators who work with BSAT have to be cleared by the CDC and FBI and adjudicated by the Army.

Q8. Are USAMRIID employees evaluated on a daily basis?

A8. Supervisors at USAMRIID have the ability to make daily judgment calls as to whether an employee should work with BSAT. To avoid laboratory mishaps, if a supervisor observes that an employee is under a great deal of stress, seems unusually distracted, or is exhibiting other signs of strain, the employee's entry privileges can be temporarily suspended until the situation is resolved. This is done for the safety of both the employee and other laboratory personnel. Employees also are responsible for self-reporting any alterations in their status (e.g., changes in medical status) and reporting observations of other employees whose behavior has changed.

Q9. Have any illnesses or deaths ever resulted from a laboratory mishap at USAMRIID?

A9. USAMRIID has a comprehensive safety program that emphasizes safety training, risk management, environmental surveillance, and occupational health screening. In the past 34 years at USAMRIID, there have been only five confirmed cases of laboratory-acquired infection, all involving USAMRIID employees—not persons outside the institute. Moreover, safety records for the past 3 years have documented a steady decline in the annual rate of potential exposures from approximately 16 to 4 per 1,000 personnel in USAMRIID's

comprehensive safety program. A culture of safety and risk management is encouraged at the laboratory to maintain a safe and secure environment for the workforce and the surrounding military and civilian communities.