SUBJECT: Minimum Security Standards for Safeguarding Biological Select Agents and Toxins

(c) Public Law 107-188, “Public Health Security and Bioterrorism Response and Preparedness Act of 2002,” June 12, 2002
(e) through (r), see Enclosure 1

1. PURPOSE

This Instruction:

1.1. Implements security policy and assigns responsibilities under Reference (a).

1.2. Establishes minimum standards for securing and safeguarding biological select agents and toxins (BSAT) in the custody or possession of the Department of Defense.

1.3 Establishes the criteria for personnel regarding BSAT, including requirements for the Biological Personnel Reliability Program (BPRP).

1.4. Permits BSAT to be used for bona fide research and other peaceful purposes. Ensures the security of BSAT from attack, theft, wrongful use, and inappropriate transfer to unauthorized personnel, organizations, and/or laboratories.
1.5. Directs responsible personnel and agencies to ensure secure access and control of applicable BSAT and to establish minimum physical security measures.

1.6. Establishes requirements for initial and periodic security reviews, threat and vulnerability assessments, and inspections.

2. APPLICABILITY

2.1. The Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities in the Department of Defense (hereafter referred to collectively as the “DoD Components”) that furnish, have custody, or have possession of BSAT.

2.2. Contractors and consultants (including foreign nationals) requiring access to DoD BSAT shall be assigned the requirements of this Instruction through appropriate contract clauses.

2.3. Cooperative Research and Development Agreements, Material Transfer Agreements, Small Business Innovative Research Agreements, and Memoranda of Agreement with other research partners and government agencies that involve furnished DoD BSAT for a DoD effort.

2.4. Overseas facilities exempted from the provisions of 42 Code of Federal Regulations (CFR) part 73 (Reference (b)), Public Law 107-188 (Reference (c)), and 7 CFR part 331 (Reference(d)) due to their location will implement this Instruction to the maximum extent possible. Where implementation of specific provisions is not feasible, handle per section E3.9.

3. DEFINITIONS

Terms used in this Instruction are defined in Enclosure 2.

4. POLICY

This Instruction implements policy established in DoD Directive 5210.88 (Reference (a)).

5. RESPONSIBILITIES

Under authority of Reference (a):

5.1. The Under Secretary of Defense for Intelligence (USD(I)) shall:

5.1.1. Establish the minimum security standards for safeguarding BSAT.

5.1.2. Establish a BPRP for individuals with access to BSAT.
5.1.3. Provide for staff oversight visits by the office of the Deputy Under Secretary of Defense for Counterintelligence and Security to assess the adequacy of security safeguards for BSAT.

5.1.4. Ensure the Director, Defense Intelligence Agency, produces a multidiscipline baseline threat assessment addressing the Foreign Intelligence and Security Services, terrorism, information operations, sabotage, and proliferation threats related to BSAT every 3 years, or more frequently if required.

5.2. The Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs (ATSD(NCB)), under the Under Secretary of Defense (Acquisition, Technology, and Logistics) shall:

5.2.1. Establish and maintain a secure database of all BSAT for certified activities at DoD-owned and -operated facilities registered with, and withdrawn from, the Health and Human Services (HHS) Centers of Disease Control and Prevention (CDC), and/or the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) and of the register of current and previous Responsible and Alternate Responsible Officials.

5.2.2. Establish and maintain a secure database of all DoD-supplied BSAT for certified activities at DoD contractor facilities registered with, and withdrawn from, the HHS/CDC and/or USDA/APHIS, and of the register of current and previous Responsible and Alternate Responsible Officials.

5.2.3. Establish and maintain procedures and a coordination plan for effective responses to accidents or incidents involving BSAT.

5.3. The Heads of the DoD Components shall:

5.3.1. Ensure that Responsible and Alternate Responsible Officials are designated to fulfill requirements according to References (b) and (c).

5.3.2. Ensure compliance with this Instruction to include planning and programming fiscal and personnel resources necessary to implement the policy.

5.3.3. Notify the ATSD(NCB) before the registration of any new DoD Biosafety Level (BSL) facility.

5.3.4. Ensure BSAT and related facilities are registered according to Federal, State, and local regulations, including HHS/CDC and USDA/APHIS guidelines.

5.3.5. Establish maximum allowable amounts of toxins and/or any reproducible select agent generated by growth in any liquid or solid media at each facility, to include research and/or test quantities, based on program requirements.
5.3.6. Develop a security plan that includes security measures designed to ensure that all BSAT are safeguarded against loss, theft, diversion, and unauthorized access or use.

5.3.7. Develop procedures to comply with the minimum security standards issued by the USD(I).

5.3.8. Coordinate public releases of information regarding BSAT with the Directorate, Freedom of Information and Security Review, Washington Headquarters Services, according to DoD Instruction 5230.29 (Reference (e)).

5.3.9. Establish and maintain a secure inventory database system to account for BSAT for certified activities at DoD and DoD contractor BSL facilities registered with, and withdrawn from, the HHS/CDC and/or USDA/APHIS, and a register of current and previous Responsible and Alternate Responsible Officials. This information will be provided to the ATSD(NCB) upon request.

5.4. The Secretary of the Army shall:

5.4.1. Develop and coordinate security classification guidance, as appropriate, and provide that guidance to the DoD Components to ensure consistency in classification and dissemination of information related to BSAT.

5.4.2. Stay current on the list of HHS/CDC and USDA/APHIS BSAT and inform the USD(I) and the ATSD(NCB) of any changes in the lists.

6. INFORMATION REQUIREMENTS

The reporting requirements referred to in section E3.5. of this Directive are exempt from licensing according to paragraph C4.4.2. of DoD 8910.1-M (Reference (f)).

7. PROCEDURES

Minimum security standards and criteria for the BPRP are at Enclosures 3 and 4.
8. **EFFECTIVE DATE**

This Instruction is effective immediately. Full compliance to Enclosures 3 and 4 is required within 90 days from the date of this Instruction.

![Signature]

Stephen A. Cambone

Under Secretary of Defense for Intelligence

Enclosures - 4:
- E1. References, continued
- E2. Definitions
- E3. Minimum Security Standards
- E4. Biological Personnel Reliability Program
E1. ENCLOSURE 1

REFERENCES, continued

(p) Deputy Secretary of Defense Memorandum, “DoD Web Site Administration Policy,” January 11, 2002
E2. ENCLOSURE 2

DEFINITIONS

E2.1.1. Access. The freedom or ability to obtain and/or make use of biological select agents and toxins (BSAT) by any individual.

E2.1.2. Alcohol Abuse. The use of alcohol to the extent that it has an adverse effect on the user’s health, behavior, family, community, or the Department of Defense, or leads to unacceptable behavior as evidenced by one or more acts of alcohol-related misconduct and/or the illegal use of alcohol. Alcohol abuse may include a diagnosis of alcohol dependence.

E2.1.3. Alcohol Dependence and/or Alcoholism. Psychological and/or physiological reliance on alcohol; alcoholism is defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM) of the American Psychiatric Association, most current version.

E2.1.4. Alcohol Related Incident. Any substandard behavior or performance in which alcohol consumption by the individual is a contributing factor as determined by law enforcement with consultation from the Competent Medical Authority (e.g., intoxicated driving, domestic disturbances, assault, disorderly conduct, personal injury, failure to submit to testing, or voluntary consumption of alcohol by an individual previously diagnosed as alcohol dependent, underage drinking).

E2.1.5. Alternate Responsible Official. The person with authority and responsibility to ensure requirements are met in the absence of the Responsible Official.

E2.1.6. Biological Restricted Area. Area where access to BSAT is possible. Entry will be subject to special access restrictions. Physical security controls will be used to control access and secure property and materials. Biological Restricted Areas may be of different types depending on the nature and varying degree of access to BSAT, or other relevant matter contained in the area.

E2.1.7. Biological Select Agents and Toxins (BSAT). Biological agents and toxins that present a high bioterrorism risk to national security and have the greatest potential for adverse public health impact with mass casualties of humans and/or animals or that pose a severe threat to plant health or to plant products. The lists are reviewed and updated by HHS/CDC and USDA/APHIS. Agents and toxins that are excluded in References (b) and (d) are excluded as BSAT.

E2.1.8. Biosafety Level (BSL). Specific combinations of work practices, safety equipment, and facilities, which are designed to minimize the exposure of workers and the environment to infectious agents. There are four biosafety levels:

E2.1.8.1. Level 1. Practices, safety equipment, and facility design and construction are appropriate for undergraduate and secondary educational training and teaching laboratories, and
for other laboratories in which work is done with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans.

E2.1.8.2. **Level 2.** Practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, and other laboratories in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity.

E2.1.8.3. **Level 3.** Practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potential lethal infection.

E2.1.8.4. **Level 4.** Practices, safety equipment, and facility design and construction are applicable for work with dangerous and exotic agents that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy.

E2.1.9. **Certifying Official.** The person responsible for certifying personnel for access to BSAT and Biological Restricted Areas. Responsibilities also include implementing, administering, and managing the BPRP, and supporting the Responsible Official and/or Alternate Responsible Official.

E2.1.10. **Competent Medical Authority (CMA).** A U.S. military healthcare provider or a U.S. healthcare provider employed by or under contract or subcontract to the U.S. Government, or a U.S. Government contractor. A CMA is someone who:

E2.1.10.1 Has been awarded regular clinical privileges for independent practice – according to Service regulations by the healthcare facility responsible for the provider’s place of duty. Or, if not privileged for independent practice, the CMA is supervised by a CMA physician who is privileged to practice independently, and

E2.1.10.2 Has been specifically trained as a CMA and appointed as a CMA by the medical treatment facility commander responsible for reviewing healthcare services or conducting clinical evaluations for the purpose of the BPRP.

E2.1.11. **Continuing Evaluation.** The Certifying Official’s ongoing process by which BPRP-certified individuals are observed for compliance with reliability standards and considers duty performance, physical and psychological fitness, and on- and off-duty behavior and reliability on a continuing basis.

E2.1.12. **Counterintelligence Polygraph.** Polygraph examinations meeting the policy, requirement, and procedures of DoD Directive 5210.48 (Reference (g)).
E2.1.13. **Disqualification.** An action taken based on the receipt of disqualifying information to terminate the BPRP certification of an individual in training or being considered for assignment to duties involving access to BSAT.

E2.1.14. **Drug/Substance Abuse.** The wrongful use, possession, distribution, or introduction of a controlled substance, prescription medication, over-the-counter medication, or intoxicating substance (other than alcohol) onto a military installation or DoD-contracted facility. For the purpose of this Instruction, wrongful is defined as without legal justification or excuse, and includes use contrary to the directions of the manufacturer or prescribing healthcare provider, and use of any intoxicating substance not intended for human ingestion. It also includes all drugs and substances on the Federal Illegal Drug List.

E2.1.15. **Drug/Substance Dependence.** Psychological and/or physiological reliance on a chemical or pharmacological agent as such reliance is defined by the Diagnostic and Statistical Manual (DSM) of the American Psychiatric Association, most current version. The term does not include the continuing prescribed use of pharmaceuticals as part of the medical management of a chronic disease or medical condition.

E2.1.16. **Permanent Decertification.** Determination by a Certifying Official that an individual is no longer capable of meeting the personal reliability standards of the BPRP.

E2.1.17. **Potentially Disqualifying Information.** Any information that cast doubt about an individual’s ability or reliability to perform BSAT duties. This information may include, but is not limited to, an individual’s physical, mental, emotional status, conduct or character, on-and-off-duty. Examples of other potentially disqualifying information could include:

E2.1.17.1. Associating with or contacting an individual who is known or suspected of being associated with foreign intelligence, security, or terrorist organization.

E2.1.17.2. Seeking access to sensitive information inconsistent with present duty requirements; or, deliberate failure or recurring negligent failure to follow security/access procedures.

E2.1.18. **Reference Stock.** The lowest passage (earliest culture) of a strain of microorganisms with a documented history and defined characteristics kept in a centralized collection, or toxins that have a known origin and history (date(s) received or isolated, manufacturer, concentration, and quantity, etc.) that are stored in a centralized location and exceed the exclusion limits established by the HHS/CDC in Reference (b).

E2.1.19. **Random Drug/Substance Abuse Testing.** A program where each member of the testing population has an equal chance of being selected. Random testing may include either testing of designated individuals occupying a specified area, element, or position, or testing of those individuals based on a neutral criterion, such as a digit of the social security number.
E2.1.20. **Responsible Official.** An individual who has authority and responsibility to ensure requirements are met, is designated by the Facility Commander/Director and is certified and approved by the HHS/CDC or USDA/APHIS for access to BSAT.

E2.1.21. **Restricted Person.** A person restricted from access to BSAT for one or more of the following reasons:

E2.1.21.1. They are under indictment in a civilian court or charges referred for court-martial that involves a crime punishable by imprisonment for a term exceeding 1 year;

E2.1.21.2. They have been convicted in any court of a crime punishable by imprisonment for a term exceeding 1 year;

E2.1.21.3. They are a fugitive from justice;

E2.1.21.4. They are an unlawful user of any controlled substance;

E2.1.21.5. They are an alien illegally or unlawfully in the United States;

E2.1.21.6. They have been adjudicated as a mental defective or has been committed to any mental institution;

E2.1.21.7. They are an alien (other than lawfully admitted for permanent residence) who is a national of a country as to which the Secretary of State has made a determination (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or

E2.1.21.8. They have by court-martial received a dishonorable discharge, bad conduct discharge, or have been administratively separated with an other than honorable conditions discharge.

E2.1.22. **Suspension.** To immediately remove an individual from duties requiring BPRP certification due to unfavorable personal reliability information or situations causing a need for additional investigation without starting a decertification action. When suspended, an individual is still considered to be reliable under the BPRP, but is not authorized to perform duties requiring BPRP certification.

E2.1.23. **Temporary Decertification.** Action taken by the Certifying Official to temporarily remove an individual from duties requiring BPRP certification. Temporary decertification shall occur immediately upon receipt of information that is, or appears to be, a reason for decertification from the BPRP.

E2.1.24. **Toxins.** Toxins are poisonous compounds produced by a living organism. Unlike organisms, toxins cannot replicate.
E2.1.25. **Vulnerability Assessment.** A DoD, command, or unit-level evaluation (assessment) to determine vulnerability of an installation, unit, exercise, port, ship, residence, facility, or other site to attack from the full range of threats to the security of personnel and resources. Identifies areas of improvement to withstand, mitigate, or deter acts of violence or terrorism.

E2.1.26. **Working Stock.** Any passage of a reference stock microorganism or of a regulated quantity of a toxin to meet authorized needs clearly identified in approved research protocols, test plans, and project/study directives or retained for historical purposes.
E3. ENCLOSURE 3

MINIMUM SECURITY STANDARDS FOR BIOLOGICAL SELECT AGENTS AND TOXINS

E3.1. GENERAL

This section details the minimum security standards necessary to reduce the risk of compromising BSAT security and to ensure the security of BSAT from theft, improper or unauthorized access, or compromise of BSAT. Varying degrees of access to BSAT require different levels of personnel certification based on background investigation evaluations. Personnel may also need escort and supervision by persons certified in the BPRP.

E3.1.1. Storage and work sites shall be within Biological Restricted Areas and consolidated to the maximum extent consistent with associated defense research requirements, research development and test and evaluation (RDT&E), military operational planning factors, training and teaching requirements, and clinical diagnostic laboratory requirements.

E3.1.2. The number of people authorized access to BSAT shall be kept to the minimum consistent with operational, safety, and security requirements.

E3.1.3. A restricted person, as described in paragraph E.2.21., shall not have duties that allow access to Biological Restricted Areas, storage and work areas, storage containers and equipment containing BSAT.

E3.1.4. A current and favorable personnel security investigation is required for all personnel whose duties require access to Biological Restricted Areas and BSAT. Personnel security investigations will be comprised of the following:

E3.1.4.1. A National Agency Check with Local Agency Checks and Credit Checks (NACLC) for military and contractor employees.

E3.1.4.2. An Access National Agency Check with Credit Checks and Written Inquiries (ANACI) for civilian employees.

E3.1.4.3. A favorably adjudicated security clearance at the SECRET or higher level suffices for the personnel security investigation.

E3.1.4.4. Foreign nationals with requirements for both access to classified information and access to BSAT will be adjudicated in accordance with a Limited Access Authorization (LAA) (Reference (h)) in lieu of NACLCs or ANACIs.

E3.1.4.5. Access to BSAT and classified information for consultants will be adjudicated according to Reference (h).
E3.1.4.6. Investigative and Adjudicative requirements for individuals who are BPRP certified are detailed in Enclosure 4.

E3.1.4.7. Certifying Officials may approve escorted access to BSAT pending completion of the personnel security investigation, provided the investigation has been requested and all other requirements for escorted/supervised access have been completed.

E3.1.5. All personnel with duties requiring any access to BSAT and/or Biological Restricted Areas shall submit Standard Form (SF) 86, “Questionnaire for National Security Positions,” with updates and processing of NACLC, ANACI, or LAA according to Reference (h). Individuals will also update the Certifying Official anytime information required by this form changes. Exceptions to this paragraph may include short-term visitors and inspectors with the approval of the Responsible Official.

E3.1.6. Only BPRP-certified and approved individuals can be authorized to escort and/or supervise the access of appropriately cleared and authorized personnel to BSAT.

E3.1.7. If access to classified information is required, the appropriate personnel security clearance investigation process shall be followed in Reference (h).

E3.1.8. Unauthorized access, movement or use of BSAT, or attempts to steal or divert BSAT outside physical security controls, shall be reported immediately to the Director of Security, Counterintelligence and Security (CI&S), Office of the Under Secretary of Defense for Intelligence (OUSD(I)), 5000 Defense Pentagon, Washington, DC 20301-5000. Message address: SECDEF WASHINGTON DC\INTEL-CC\ and add “Deliver to the Director of Security in the message body.

E3.1.9. Security planning and execution shall be according to DoD Directive 5200.8 (Reference (i)) as applicable, and based on the minimum standards identified in this Instruction and a specific threat and vulnerability assessment of the facility. The vulnerability assessment will be reviewed annually and updated as required based on changes to the threat or security posture of the facility.

E3.1.9.1. An appropriate risk management process will be utilized to assess the threat and vulnerabilities and provide the Responsible Official and/or facility commander/director with courses of action to mitigate the vulnerabilities and/or provide actionable information for risk acceptance. A copy of the vulnerability assessments will be forwarded to the Director of Security at the address reference paragraph E3.1.8.

E3.2. PERSONNEL

E3.2.1. Individuals identified by the Certifying Official as having a legitimate need to access BSAT and Biological Restricted Areas shall be screened for suitability and reliability. They shall be emotionally and mentally stable and trustworthy, physically competent, and adequately trained to perform the assigned duties. They shall complete a current and favorable personnel
security investigation adjudicated to national security standards, with periodic reinvestigations according to Reference (h) and described in paragraph E3.1.4. Personnel will pass a urinalysis test for illegal drug/substance use before certification for access to BSAT. They will also be subject to random urinalysis tests.

E3.2.2. Certifying Officials will ensure personnel have final adjudication of appropriate security clearances and personnel security investigations (Reference (h)) before any access to BSAT, whether or not personnel are supervised and/or escorted.

E3.2.3. When the Certifying Official has information that could negatively affect an individual’s job performance or reliability, the individual shall be decertified. Temporary decertification can be considered unless facts warrant permanent decertification. When temporarily decertified, the individual may not perform duties requiring BPRP certification. Within 15 workdays of the temporary decertification, the Certifying Official shall provide the individual in writing the reason(s) for temporary decertification. Individuals temporarily decertified will remain under continuous evaluation for BPRP purposes until permanently decertified or recertified into the BPRP.

E3.2.4. A Certifying Official can take suspension action on an individual should negative information become known; however, additional review and/or investigation is warranted before a final adjudication. Although a recommendation to suspend an individual from applicable duties may come from many sources, the Certifying Official must evaluate the individual’s situation and circumstances to determine whether suspension is appropriate.

E3.2.5. Responsible Officials and Alternate Responsible Officials must meet the requirements of the BPRP certification and approval by the HHS/CDC and/or USDA/APHIS.

E3.2.6. In addition to the previous information, individuals with duties requiring BPRP certification shall be evaluated on a continuing basis using the criteria at Enclosure 4. A Counter Intelligence polygraph is a procedure available to Responsible Officials to help ensure the reliability of his or her personnel and the BPRP. Random polygraphs will be used according to Reference (g).

E3.2.7. Personnel currently employed in positions requiring BPRP certification shall submit the required documents within 60 days of the effective date of this Instruction if not already accomplished. Responsible Officials can approve that personnel remain in their current positions during the certification process unless negative information affecting their certification status is known.

E3.2.8. After the effective date of this Instruction, personnel who require access to Biological Restricted Areas and/or under the BPRP shall not assume duties until successful adjudication of the appropriate background investigation and approval by the applicable governing agency (i.e., HHS/CDC and/or USDA/APHIS). However, if a Responsible Official determines that a person’s expertise is critical to the performance of an official government mission, a waiver may be requested, in writing, from the Head of the DoD Component.
E3.2.9. Foreign nationals who receive supervised and/or escorted access to BSAT during visits, assignments or exchanges, as specifically authorized by the Responsible Official, shall be processed according to References (b), (c), and (d), DoD Directive 5230.20 (Reference (j)), and paragraphs E3.1.4.4. and E3.2.2.

E3.3. INFORMATION SECURITY

E3.3.1. Any classified and/or unclassified but sensitive information shall be handled and protected according to DoD 5200.1-R (Reference (k)). Refer to applicable program security classification guides when discussing or processing information related to BSAT. DD Forms 254 issued to contractors must include applicable classification guidance.

E3.3.2. Public release of information shall be according to Reference (e) and DoD 5400.7-R (Reference (l)). The Department of the Army and the USD(I) Operation Enduring Freedom and Operation Noble Eagle security classification guidance shall be implemented if appropriate.

E3.4. PHYSICAL SECURITY SYSTEM

E3.4.1. The DoD Components and contractors that are provided DoD BSAT shall develop a reliable security system and process that provides the capability to detect, assess, deter, communicate, delay, and respond to unauthorized attempts to access BSAT.

E3.4.2. Components and contractors shall develop a physical security plan to ensure vulnerabilities are mitigated or accepted by the Responsible Official and/or facility commander/director according to Reference (i) as applicable. The plan shall be based on a systematic approach in which threats are identified and defined, vulnerabilities are assessed, and a risk management process is applied. The security plan must address the controls of the Responsible Official in securing the BSAT from misuse, theft, and unauthorized removal from Biological Restricted Areas. The Responsible Official and facility commander/director shall review the security plan annually and will document reports after an incident or a regulation change. The plan shall address or establish:

E3.4.2.1. Biological Restricted Areas for control of access.

E3.4.2.2. An Information Protection Plan to ensure the appropriate security of information on BSAT and the research, and/or mission being conducted.

E3.4.2.3. Initial and recurring training of personnel in security procedures for securing Biological Restricted Areas (e.g., card access, key pads, cipher locks), security and positive control of keys, changing access numbers or locks following staff changes, reporting and removing unauthorized individuals, access control and records requirements, and inventory control and other appropriate security measures.
E3.4.2.4. Procedures, reporting requirements, and administrative actions for lost or compromised keys, passwords, combinations, and security incidents and violations, etc.

E3.4.2.5. Procedures and reporting requirements for removal of suspicious or unauthorized persons or activities, potential, attempted, or actual loss or theft of BSAT, or alteration of inventory or records.

E3.4.2.6. Inventory control process to ensure strict accountability and records of access, use, and final disposition of all BSAT.

E3.4.2.7. Plans, procedures, requirements, and processes for safeguarding BSAT in the event of emergency situations (e.g., natural disasters, fires, power outages, and general emergencies in facilities containing BSAT).

E3.4.2.8. An understanding of security requirements by approved individuals who are trained and equipped to follow established procedures and maintain security of the BSAT to include:

   E3.4.2.8.1. Reporting and removing unauthorized individuals.

   E3.4.2.8.2. Security and positive control of keys and PINs.

   E3.4.2.8.3. Securing storage rooms and work areas that contain BSAT reference stock using a process that ensures two person integrity of the area when authorized and approved individuals, including BPRP certified escorts/supervisors, are not present. Both individuals must be properly approved for BSAT access by Certifying and Responsible Officials. However, only one is required to be BPRP certified.

E3.4.3. Intrusion Detection System (IDS). Biological Restricted Areas shall be equipped with an IDS to detect and report an unauthorized penetration. The IDS will meet the physical security standards according to DoD 5200.1-R (Reference (k)), Appendix 7. There shall be a sufficient security response force available at all times to respond rapidly to unauthorized attempted penetrations and prevent the unauthorized removal of BSAT or data. The time period that physical security measures must delay potential unauthorized attempted access is determined by the Responsible Official and/or facility commander/director through a threat and vulnerability assessment and risk management process that includes consideration for security force response time capability.

E3.4.4. Access Control.

   E3.4.4.1. Access control measures to BSAT shall only allow individuals that:

      E3.4.4.1.1. Successfully complete an appropriate personnel security investigation (paragraph E3.1.4.).

      E3.4.4.1.2. Are certified by the Certifying and/or Responsible Official.
E3.4.4.1.3. Are certified/approved by the HHS/CDC and USDA/APHIS if required, and

E3.4.4.1.4. For persons requiring access to BSAT that are not BPRP certified, then at least one person certified in the BPRP shall be present in the Biological Restricted Area to supervise and/or escort the individuals. If BSAT containers are locked in accordance with paragraph E3.4.5., then personnel only need to meet the requirements for access to the Biological Restricted Area. Refer to paragraph E3.4.2.8.3. concerning the two person rule for accessing BSAT reference stocks.

E3.4.4.2. The perimeter entrance to a Biological Restricted Area will be under constant visual surveillance at all times to prevent unauthorized entry. This may be accomplished by several methods (e.g., employee work stations, guards, closed circuit television). Regardless of the method used, a discriminating access control method shall be used on the entrance permitting only authorized personnel and supervision and escort by persons certified in the BPRP. See paragraph E3.4.4.4. below for an exception to this requirement.

E3.4.4.2.1. As a minimum, Biological Restricted Areas will be secured by at least two reliable security access control devices (e.g., card access system, key pads, cipher locks) when cleared and authorized individuals are not present.

E3.4.4.2.2. Apply and implement smart card technology in the form of the Common Access Card according to DoD Directive 8190.3 (Reference (n)).

E3.4.4.3. All individuals approved for access to Biological Restricted Areas and BSAT must wear visible identification badges that include, at a minimum, a photograph, the wearer’s name, and an expiration date. Facility administrators should consider using easily recognizable marks on the identification badges to indicate access to sensitive and secure areas. Visible identification badges are not required when working in the appropriate protective clothing or in BSL 3 or 4 containment suites.

E3.4.4.4. An Automated Entry Control System (AECS) may be used to control access instead of visual control if it meets the criteria stated in subparagraphs E3.4.4.4.1. or E3.4.4.4.2. The AECS shall identify an individual and authenticate the person’s authority to enter the area through the use of two separate methods of identification including (ID) badges, cards, a personal identification number (PIN) entry device, or biometric device.

E3.4.4.4.1. The ID badge or key card shall use embedded sensors, integrated circuits, magnetic stripes, or other means of encoding data that identifies the facility and the individual to whom the card is issued. Implement Reference (n) as applicable.

E3.4.4.4.2. Personal identity verification via biometrics devices shall identify the individual requesting access by one or more unique personal characteristics. Personal characteristics may include fingerprint(s), hand geometry, handwriting, retina scans, or voice recognition.
E3.4.4.5. With subparagraph E3.4.4.2., a PIN may be required. The PIN shall be separately entered into the system by each individual using a keypad device and shall consist of four or more digits, randomly selected, with no known or logical association with the individual. The PIN shall be changed if it is believed compromised.

E3.4.4.6. Authentication of the individual’s authorization to enter Biological Restricted Areas (including visitors) shall be accomplished with the system by inputs from the ID badge/card, the personal identity verification device, or the keypad with an electronic database of individuals authorized to enter the area. A procedure shall be established for immediately removing an individual’s authorization to enter the area upon reassignment, transfer, or termination, suspension or decertification. A paper-entry access control roster located outside the laboratory work and storage areas may be used as an alternative.

E3.4.4.7. Protection from tampering, destruction, and/or access control system failure shall be established and maintained for all devices or equipment that constitute the entry control system. The protections can include welding door hinges/pins, eliminating exposed screw heads, ensuring that doors and walls delay access or have IDS to respond to forced entry. These emergency systems will allow time for response forces to arrive as discussed in paragraph E3.4.3. Protection will address covert or clandestine entry into Biological Restricted Areas through electrical, communications, or HVAC distribution and/or maintenance areas.

E3.4.4.8. Locations where authorization data and personal identification or verification data is created, stored, or recorded shall be protected according to information security standards.

E3.4.4.9. Card readers, keypads, communication or interface devices located outside the entrance to a Biological Restricted Area shall have tamper resistant enclosures and be securely fastened to the wall or other permanent structure to prevent unauthorized access through breaching of attachment mechanisms (screws, pins, bolts, etc.) Control panels located within a Biological Restricted Area shall require only a minimal degree of physical security protection sufficient to preclude unauthorized access to the mechanism.

E3.4.4.10. Keypad devices shall be designed and/or installed in such a manner that an unauthorized person in the immediate vicinity cannot observe the selection of input numbers.

E3.4.4.11. Systems that use transmission lines to carry access authorizations, personal identification data or verification data between devices or equipment located outside of the restricted area shall have line supervision to restrict unauthorized access and tampering.

E3.4.4.12. Electric strikes used in access control systems shall be heavy duty, industrial grade.

E3.4.5. When not in use, all BSAT shall be stored in secured containers, including refrigerators, freezers, or other approved storage devices within Biological Restricted Areas.
BSAT reference stocks shall be secured in a manner that provides two-person integrity for verification and removal of BSAT.

E3.4.6. As a minimum, containers or storage devices with working stocks of BSAT maintained in a secured BSAT use room will be secured by one GSA-approved locking device or the equivalent when the containers are not under direct supervision and control of approved personnel certified under the BPRP.

E3.4.7. Procedures shall be established for package and material controls, end-of-day security checks, after-duty access controls, and access records.

E3.4.8. Procedures shall be developed for the reporting, recapture, and recovery of stolen BSAT or animals infected with BSAT. These plans will be tested annually at a minimum with security forces/law enforcement and other appropriate responders (fire department, etc.) to determine effectiveness and further improve security.

E3.4.9. Response times for security forces shall be adjusted when necessary, to include adding manpower, to ensure prompt assessment and response to deny access to structures or areas containing BSAT. Security forces must respond to unauthorized intrusions, theft, and intentional misuse of BSAT. The Head of the DoD Component or a designee is the approval authority for all changes in security response force manpower and response timing criteria.

E3.5. INVENTORY, ACCOUNTABILITY, AND RECORDS

E3.5.1. An inventory control and reporting system will be maintained and secured to prevent unauthorized access and account for all BSAT authorized for certified activities at DoD and DoD contractor BSL facilities registered with the HHS/CDC and/or USDA/APHIS.

E3.5.2. Accountability records and reports shall be maintained according to References (b), (c), and (d).

E3.5.3. The inventory and accountability control system will include specific details for the following:

E3.5.3.1. All BPRP-certified personnel approved by the HHS/CDC or USDA/APHIS for access and the name of the BSAT for which the individual has been approved.

E3.5.3.2. The current inventory of BSAT including type and quantities.

E3.5.3.3. The date and time the personnel entered and left a Biological Restricted Area (automated systems are encouraged).

E3.5.3.4. Documentation of all BSAT accessed and final disposition (including names of persons accessing BSAT, culture, destruction, and return to reference stock).
E3.5.4. The following records and reports will also be maintained:

   E3.5.4.1. Security incident reports, and threat and vulnerability assessments.

   E3.5.4.2. Inspection and exercise records and reports.

   E3.5.4.3. Corrective action/improvements.

   E3.5.4.4. Emergency response plans.

   E3.5.4.5. Training records.

   E3.5.4.6. Established maximum allowable quantitative limit of BSAT use to complete approved activity as defined by the Heads of the DoD Components.

   E3.5.5. Records and reports will be maintained for 5 years and then adjudicated according to appropriate administrative instructions.

E3.6. **IT SYSTEMS**

   E3.6.1. Data shall be processed on systems accredited according to DoD Instruction 5200.40 (Reference (o)).

   E3.6.2. Web sites shall be administered according to Deputy Secretary of Defense memorandum of January 11, 2002 (Reference (p)), as updated.

E3.7. **TRANSPORTATION**

   E3.7.1. The transportation of BSAT shall be according to References (b), (c), (d), and (r). Delivery receipts will be maintained for at least 5 years.

   E3.7.2. Packages containing BSAT shall not be left unattended or unsecured while awaiting transportation.

   E3.7.3. Movement of BSAT shall be minimized consistent with operational, research, training, teaching, and safety requirements.

   E3.7.4. Samples of presumptive or preliminary positive BSAT from detection devices or clinical samples shall be positively controlled and handled per References (b) and (c). Unknown samples from detection devices with a presumptive or preliminary positive for BSAT presence will be maintained and transferred within 7 days to a BSAT-certified facility according to chain of custody procedures. If transfer of the sample is not feasible within the 7-day timeframe, the possessing commander will secure the samples under lock and higher command will be notified to expedite transfer.
E3.7.5. During the planning and preparation stages of off-station transportation of BSAT, a current risk assessment shall be made including known threats and hazards. Planning for the move shall include appropriate security measures, such as the mode of shipment, the availability of security resources, and the source and availability of emergency assistance. All reasonable precautions shall be taken to ensure the safety and security of personnel and the BSAT.

E3.8. TRANSFER OF DoD BSAT

E3.8.1. The DoD Components may transfer DoD BSAT to other DoD Components, who will assume responsibility for the BSAT under this Instruction and their own component regulations. Transfer of the BSAT will be approved by the Responsible Official and according to appropriate Federal regulations.

E3.8.2. The DoD Components may provide DoD BSAT to other U.S. governmental agencies in support of the recipient governmental agency’s mission. For example, DoD BSAT may be transferred to an HHS/CDC-designated BSAT reference repository, to support a Department of Agriculture research program, or to the FBI when required for forensic analysis. Additionally, transfer of BSAT following National Laboratory Response Network (LRN) confirmatory testing at DoD LRN reference laboratories to state public health laboratories is acceptable. Transfer of the BSAT will be approved by the Responsible Official and according to appropriate Federal regulations.

E3.8.3. The DoD Components will not provide DoD BSAT to non-U.S. governmental recipients (such as Cooperative Research and Development Agreements or Small Business Innovative Research Agreements), or to other governmental agencies for a DoD purpose, unless approval has been received from ATSD(NCB). Approved requests will identify recipient information, name and quantity of BSAT to be provided, purpose for which the BSAT will be used, and rationale for providing BSAT. Approval will identify surety and security measures requirements for the recipients beyond those required by Federal regulations.

E3.9. WAIVERS AND EXCEPTIONS

E3.9.1. Waivers and exceptions shall be considered individually. Blanket waivers are not authorized.

E3.9.2. A waiver may be approved for temporary relief from a specific requirement prescribed in this Instruction pending actions to conform to the requirement. Such waivers shall be approved for only as long as needed and will normally not exceed 1 year. While waivers are in effect, compensatory security measures shall be required.

E3.9.3. An exception may be approved for permanent relief from a specific requirement as prescribed in this Instruction when there are unique circumstances at the facility that make conforming to the requirement impractical or an inappropriate use of resources.
E3.9.4. Requests for waivers or exceptions can be approved by the Heads of the DoD Components with a copy of the approval sent to the Director of Security at the address reference paragraph E3.1.8.

E3.9.5. Whenever conditions or compensatory measures change, a request for an amendment to the waiver or extension can be approved by the Head of the DoD Component with a copy of the approval sent to the Director of Security at the address reference paragraph E3.1.8. Additionally, physical security surveys, reports, and inspections shall include and document a review of waivers to ensure that conditions described in the request were adequate and that compensatory measures were fully implemented as stated. The physical security survey or inspection report will include a comment regarding the actions taken as a result of that review.
E4. ENCLOSURE 4

BIOLOGICAL PERSONNEL RELIABILITY PROGRAM

E4.1. PURPOSE

The purpose of the BPRP is to ensure that each individual who is authorized access to BSAT, and to escort and/or supervise personnel with access to Biological Restricted Areas and BSAT, including Responsible and Certifying Officials, meets the highest standards of integrity, trust, and personal reliability. Determination of integrity and reliability shall be accomplished, in part, through the initial and continuing evaluation of individuals assigned duties associated with BSAT. The continuing evaluations will ensure these individuals do not pose a risk to the public health and safety, or national security.

E4.2. RELIABILITY STANDARDS (GENERAL)

E4.2.1. The Responsible Official shall have the final ruling for determining an individual’s eligibility for access to BSAT. He or she shall consider all relevant facts to make the final judgment before signing and submitting the certification statement to HHS/CDC or USDA/APHIS to obtain approval for an individual to have BSAT access.

E4.2.2. The Certifying Official shall certify the eligibility of an individual for access to BSAT based on factors including a favorable personnel security investigation, an evaluation of the individual’s physical and mental capability, appropriate personnel and medical records, and a personal interview. The eligible individual will sign an agreement affirming his or her responsibility to abide by the requirements for maintaining BPRP certification. Once a determination regarding an individual’s certification for access to BSAT is made, the Certifying Official will notify the Responsible Official.

E4.2.3. The BPRP requirements for escorts and supervisors covered under this Instruction shall be incorporated into all contracts or similar arrangements involving the custody, security, possession, or on site transport of these agents for any purpose. CRDAs and Material Transfer requests (MTAs) are addressed in paragraph E3.8.3.

E4.3. QUALIFYING STANDARDS

E4.3.1. The following qualifying standards represent the reliability standards expected of all individuals assigned duties requiring BPRP certification:

E4.3.1.1. Emotionally and mentally stable, trustworthy, physically competent, and adequately trained to perform the assigned duties.

E4.3.1.2. Dependability in accepting and executing BPRP responsibilities.
E4.3.1.3. Flexibility and adaptability in adjusting to a restrictive and demanding work environment with BSAT that must be strictly controlled and secured.

E4.3.2. Personnel Security Investigation (PSI). The investigative requirements in paragraphs E3.1.4. and E3.2. shall be favorably adjudicated before access to Biological Restricted Areas and according to Reference (h).

E4.3.3. Medical Evaluation

E4.3.3.1. The Certifying Official must be confident that the individual being certified is physically and mentally competent, alert and dependable, and is not a threat for compromising the BSAT program and/or mission. To that end, a Competent Medical Authority (CMA) must provide the Certifying Official an evaluation of the individual’s physical competence and mental stability to perform duties requiring BPRP certification. The primary responsibility of the CMA is to provide the Certifying Official with sufficient and timely medical information in order to make a sound judgment.

E4.3.3.2. Health records shall reflect the assignment of an individual to a position requiring BPRP certification to ensure the proper treatment, review, and reporting of potentially disqualifying information to the Certifying Official. All potentially disqualifying medical information shall be documented in the individual’s health records and transmitted to the appropriate Certifying Official. A record must be made to show evidence of the record transmission to the Certifying Official.

E4.3.4. Personal Interview. The Certifying Official shall conduct a personal interview with each BPRP candidate. Any relevant and potentially disqualifying information will be solicited and, if appropriate, discussed during the interview. Information considered on background investigations (e.g., financial issues) should be included.

E4.3.5. Position Qualification. The Certifying Official shall obtain evidence of demonstrated professional or technical proficiency, as appropriate. Evidence shall be obtained through previous employment and/or academic records and appropriate interviews of former supervisors and/or academic instructors.

E4.3.6. Drug/Substance Abuse Testing. All candidates for BPRP positions shall be tested for drug/substance abuse before being certified into the BPRP. Positions requiring BPRP certification shall be designated for random testing. Results of the drug/substance abuse test shall be submitted to the Certifying Official. Positive test results will result in a disqualification or permanent decertification, as appropriate, for the BPRP.
E4.4. DISQUALIFYING OR DECERTIFYING STANDARDS

E4.4.1. Alcohol related incidents, abuse, or dependence will be evaluated according to the following guidance. In evaluating these traits or conduct, Certifying Officials shall ensure an individual's reliability and assignment to a BPRP position is consistent with national security interests:

E4.4.1.1. Individuals being considered for certification in the BPRP with any alcohol-related incidents during the previous 5 years, or any diagnosis of alcohol abuse or alcohol dependence will be referred to the CMA for evaluation. If the CMA determines that the individual abuses alcohol or is alcohol dependent, procedures in paragraph E4.4.1.3. or E 4.4.1.4. will be followed as appropriate. In all other circumstances, the Certifying Official will review and consider the CMA evaluation as part of the certification process.

E4.4.1.2. Individuals currently certified in the BPRP who are involved in an alcohol-related incident shall be, at a minimum, suspended immediately from duties requiring BPRP certification pending an evaluation. The Certifying Official shall conduct an investigation of the circumstances and request a medical evaluation.

E4.4.1.3. If the CMA determines that the individual is currently abusing alcohol or is alcohol dependent, procedures in paragraph E4.4.1.3. or E 4.4.1.4. will be followed as appropriate. In all other circumstances, the Certifying Official will assess the individual's reliability based on the investigation and the CMA evaluation, and determine if the individual should be decertified or reinstated and returned to duties requiring BPRP certification.

E4.4.1.4. Individuals diagnosed as abusing alcohol, but who are not alcohol dependent, shall at a minimum be suspended pending completion of rehabilitation program or treatment regimen prescribed by the CMA. Before the individual is reinstated and returned to duties requiring BPRP certification (or before the individual is certified), the Certifying Official will assess if the individual has displayed positive changes in personal reliability and lifestyle, and if the individual has a favorable medical prognosis from the CMA. Failure to satisfactorily meet these requirements shall result in disqualification or decertification.

E4.4.1.5. Individuals diagnosed as "alcohol dependent," according to DoD Directive 1010.4 (Reference (q)), shall be disqualified or decertified from the BPRP.

E4.4.1.6. Individuals disqualified or decertified for alcohol dependency may be reconsidered for BPRP duties after meeting all of the following conditions:

E4.4.1.6.1. The individual has successfully completed an initial intensive rehabilitation program and is released for duties requiring BPRP certification by the CMA.

E4.4.1.6.2. The individual has completed a 1-year period of strict compliance with an aftercare program.
E4.4.1.6.3. The individual has received a favorable prognosis by the CMA and a psychological evaluation is completed.

E4.4.1.6.4. The Certifying Official has considered the value of the individual's continued presence in the BPRP versus the risk from potential future alcohol-related incidents. The Certifying Official must document the fact that he or she has full trust and confidence in the individual's reliability.

E4.4.2. Drug/substance abuse will be evaluated according to the following guidance. In evaluating these traits or conduct, certifying officials shall ensure an individual's reliability and that assignment to a BPRP position is consistent with national security interests.

E4.4.2.1. Individuals in the following circumstances will be decertified or disqualified from the BPRP:

E4.4.2.1.1. Individuals who abused drugs/substances (as defined in E2.14) in the 5 years before the initial BPRP interview. Isolated abuse of another individual’s prescribed drugs will be evaluated per E4.4.2.2.

E4.4.2.1.2. Individuals who have ever illegally trafficked in illegal or controlled drugs/substances.

E4.4.2.1.3. Individuals who have abused drugs/substances while enrolled and/or certified in any Personnel Reliability Program (PRP), including abuse of another individual’s prescribed drugs.

E4.4.2.2. The CMA will evaluate and make recommendations regarding individuals not disqualified or decertified per E4.4.2.1. who have abused drugs more than 5 years before the initial BPRP screening, or have isolated episodes of abuse of another person’s prescribed drug within 15 years of the initial BPRP screening.

E4.4.2.3. The Certifying Official will consider the CMA’s recommendations and evaluate the individual’s reliability and adjudicate the individual’s qualifications based on the CMA evaluation, consideration of circumstances pertaining to the drug abuse (for example, frequency of drug abuse, age of individual at time of abuse) and any extenuating or mitigating circumstances (for example, successful completion of a drug rehabilitation program).

E4.4.2.4. It is not the intent of this Instruction to automatically disqualify or decertify any individual from BPRP who, in an effort to self-medicate, inadvertently or deliberately exceeds the recommended safe dosage of over the counter substances or who abuses uses his or her own prescribed medications. If the Certifying Official suspects, or the individual admits to such improper usage, the individual must be suspended from duties requiring BPRP certification and the CMA consulted. If, after CMA evaluation, the Certifying Official concludes drug/substance abuse has occurred, the Certifying Official must permanently decertify the individual.
E4.4.2.5. Any individual, who while in any PRP uses a Food and Drug Administration (FDA) Schedule II, III, or IV anabolic steroid, not prescribed by a physician, shall be immediately and permanently decertified.

E4.4.3. Negligence or Delinquency in Performance of Duty: If the Certifying Official's review of the BPRP candidate's job or duty history reveals a lack of emotional and mental stability, trustworthiness, physical competency, or adequate training to perform the assigned duties, the individual will be disqualified or decertified and removed from access. In determining reliability, the Certifying Official must evaluate all aspects of an individual's actions.

E4.4.4. A Restricted Person, as defined in paragraph E2.22. is ineligible for duties requiring BPRP certification.

E4.4.5. Any individual suspected of attempting and/or threatening suicide shall be suspended from BPRP duties pending the results of a CMA consultation and a mental health assessment/evaluation. Any suicide attempt and/or threat may be grounds for disqualification or decertification.

E4.4.6. All potentially disqualifying information on individuals assigned to a position requiring BPRP certification must be sent to the appropriate Certifying Official for further review. The Certifying Official shall evaluate this information to determine if the individual’s reliability is affected and take appropriate action.

E4.5. CONTINUING EVALUATION. Certifying Officials must observe the behavior and performance of individuals certified under the BPRP on a frequent and consistent basis and are responsible for ensuring that all individuals assigned to BPRP positions meet all of the requirements of the continuing evaluation process.

E4.6. INDIVIDUAL AND SUPERVISORY RESPONSIBILITIES

E4.6.1. Individuals assigned to duties requiring BPRP certification are responsible for monitoring themselves as well as others performing BPRP duties. Failure to discharge these responsibilities may cast doubt on an individual’s reliability. Individuals shall advise their supervisors, Certifying Official, or Responsible Official of any factors that could have an adverse impact on their performance, reliability, or security while performing duties requiring BPRP certification.

E4.6.2. Information that would be identified during the next periodic reinvestigation (SF 86 Part 2) should be reported to the Certifying Official as soon as possible, and not just during the reinvestigation process. Information that should be reported includes:
E4.6.2.1. Leaving a job (including part-time/second jobs) under unfavorable circumstances.

E4.6.2.2. Being charged with, or convicted of, any criminal offense, including those under the Uniform Code of Military Justice.

E4.6.2.3. Illegal use of drugs/substances or illegal drug activity.

E4.6.2.4. Alcohol abuse and other BPRP reportable incidents and behaviors including serious driving infractions such as reckless driving, Driving Under the Influence, and Driving While Intoxicated.

E4.6.2.5. Significant financial problems such as filing for bankruptcy, garnishment of wages, property repossession, lien against property for failure to pay taxes or debts, unpaid court judgments, debt delinquency greater than 90 days.

E4.6.2.6. Being a party to any public record court action.

E4.6.3. Certifying Officials shall ensure actions of disqualification and/or decertification, and any steps relating to re-certification are accurately recorded in the affected individual’s personnel record.