OPNAVINST 5530.16A
11 May 2011

MINIMUM SECURITY STANDARDS FOR SAFEGUARDING BIOLOGICAL SELECT AGENTS AND TOXINS

RECORD OF CHANGES

IDENTIFICATION OF CORRECTION OR CHANGE	DATE OF CHANGE	DATE OF ENTRY	ENTERED BY

DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
2000 NAVY PENTAGON
WASHINGTON, DC 20350-2000

IN REPLY REFER TO
OPNAVINST 5530.16A
N4
11 May 2011

OPNAV INSTRUCTION 5530.16A

From: Chief of Naval Operations

Subj: MINIMUM SECURITY STANDARDS FOR SAFEGUARDING BIOLOGICAL SELECT AGENTS AND TOXINS

Ref: (a) DoD Instruction 5210.89 of 18 April 2006
(b) Report of the Inter-Service Council for Biosecurity and Biosafety of December 2008
(c) OPNAVINST 5530.14E
(d) Defense Intelligence Agency (DIA) Threat Assessment to Biological Select Agents and Toxins (annual report, SECRET) (NOTAL)
(e) 7 CFR Part 331
(f) DoD Directive 5210.88 of 11 February 2004
(g) 42 CFR
(h) 9 CFR
(i) DoD Instruction 2040.02 of 10 July 2008
(j) OPNAVINST F3100.6J
(k) Centers for Disease Control and Prevention, Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition
(l) NAVSUP PUB 505

Encl: (1) Minimum Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT) Manual

1. Purpose. To prescribe policies, procedures, and responsibilities for the Navy Biological Surety Program per references (a) through (l). This instruction implements Department of Defense (DoD) physical security requirements pertaining to surety matters for biological select agents and toxins (BSAT).

2. Cancellation. OPNAVINST 5530.16.

3. Background

a. This instruction was developed in conjunction with references (a) and (b). It includes guidance issued by DoD

which was derived from the Code of Federal Regulations (CFR) of the Center for Disease Control (CDC), National Institute of Health (NIH), Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), U.S. Department of Commerce, U.S. Department of Health and Human Services (DHHS), Public Health Service (PHS), and reference (b). Other Departments provided information and are also listed in the CFR section of this instruction.

b. The objectives of this instruction are:

(1) Establish policy for the minimum security of BSAT at Navy facilities.

(2) Provide guidance and standards for access to BSAT for civilian and contractor personnel.

(3) Provide guidance and standards for the protection of Navy facilities housing BSAT and for the transportation of BSAT under Navy cognizance.

c. The term commander within this instruction includes type commanders; fleet commanders; regional commanders; and installation, ship, squadron, activity commanding officers, officers in charge, and directors.

d. This instruction includes:

(1) Mandatory policies that are directive in nature and provide standards, measures or actions that are required, and subject to inspection by higher headquarters and the Navy Inspector General (NAVIG). An inability to meet these requirements necessitates a request for a waiver or exception per reference (c). Mandatory policies include the words “shall,” “will,” or “must.”

(2) Enabling procedures permit actions or measures within described parameters. These are not requirements, but are offered as possible actions or measures to take at the discretion of the commander. These statements include the words “may” or “can.”

(3) Prohibitive procedures limit an individual's or command's authority to take actions or implement measures. These statements include terms such as "shall not" or "will not" if the action is prohibited without prior authorization from an appropriate authority, or "should not" if the action is advised against but left to the responsible party's judgment.

4. Applicability

a. The policies herein pertain to preventing or mitigating hostile actions against Navy facilities with BSAT. References (a) and (d) address the threat to BSAT facilities and shall be used to develop a comprehensive security plan.

b. Where this instruction conflicts with combatant commander security requirements, the combatant commander's requirements take precedence. Address requests for clarification to the Office of the Chief of Naval Operations, Operations, Security, and Public Safety Branch (OPNAV (N462)).

c. This instruction applies to all Navy laboratories and facilities that furnish, has custody of BSAT as described in appendix II of reference (a), including Navy contractors and consultants that are provided BSAT by DoD.

d. Overseas facilities exempted from the provisions of reference (e) due to their location will implement this instruction to the maximum extent possible. Where implementation of specific provisions is not feasible, handle per chapter 2 of enclosure (1).

5. Responsibilities

a. The Deputy Chief of Naval Operations for Fleet Readiness and Logistics (CNO (N4)) will formulate and disseminate Navy security policies. OPNAV (N462) is the focal point for the security standards of BSAT. OPNAV (N462) shall:

(1) Review and approval of all BSAT physical security waivers and exceptions. Waivers and exceptions shall be submitted per chapter 2, paragraph 4. Waivers and exceptions shall be forwarded via the appropriate chain of command to OPNAV (N462). OPNAV (N462) will forward approved waivers and exceptions per reference (a). Wherever the mandatory security

requirements of this instruction or reference (a) cannot be met, a waiver or exception shall be submitted to the OPNAV (N462). With the exception of the BSAT Biological Personnel Reliability Program (BPRP), only OPNAV (N462) has the authority for final review of waiver and exceptions to this instruction. Requests for waivers and exceptions to biological surety will be submitted immediately upon knowledge that a variance from policy exists.

(2) Establish overall security policy for the Navy Biological Surety program.

(3) Resolve reclamas to surety inspections conducted by the MEDIG or the Defense Threat Reduction Agency.

(4) Monitor the lists of DHHS and USDA BSAT and inform the Under Secretary of Defense (Intelligence) (USD(I)) and the Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs (ATSD(NCB)) of any changes in the lists.

(5) Review approval requests for saxitoxin and ricin submitted per appendix D.

(6) Utilize the Army BSAT security classification guidance as prescribed by DoD to develop, coordinate, and provide guidance to the Navy facilities holding BSAT. This will ensure consistency in classification and dissemination of information related to BSAT.

(7) Maintain the biological surety program waiver and exception file for 2 years after the waiver or exception has been cancelled or expired.

b. The Chief of Naval Operations (CNO), Assistant for Information and Personnel Security Policy (CNO (N09N2)) exercises authority on behalf of the CNO as the program manager for the Department of the Navy (DON) Personnel Security Program and BPRP and shall:

(1) Provide overall BPRP policy guidance and administration within the DON.

(2) Review and approve BPRP waivers and exceptions. All requests for waivers and exceptions dealing with BPRP will be sent to CNO (N09N2) via the appropriate chain of command, with a copy sent to OPNAV (N462).

(3) Maintain BPRP waiver and exception files for 3 years.

(4) Submit OPNAV 3402/1 DON Biological Personnel Reliability Program Annual Status Report to OPNAV (N462).

c. Bureau of Naval Medicine and Surgery shall:

(1) Ensure that commands or units under its cognizance that hold BSAT are provided the support required to meet the requirements of reference (a) and this instruction.

(2) Forward OPNAV 3402/1 to CNO (NO9N2) for the preceding calendar year, ending 31 December. OPNAV 3402/1s must be received by CNO (N09N2) no later than 15 January.

(3) Ensure that the medical inspector general (MEDIG) conducts biological surety inspections at all Navy BSAT facilities at a minimum of every 3 years.

d. Naval Sea Systems Command shall:

(1) Ensure commands or units under its cognizance holding BSAT are provided the support required to meet the requirements of reference (a) and this instruction.

(2) Forward OPNAV 3402/1 to CNO (NO9N2) for the preceding calendar year, ending 31 December. OPNAV 3402/1s must be received by CNO (N09N2) no later than 15 January.

e. Commander, Navy Installations Command shall submit program objective memorandum (POM) requirements. The review will use a risk-based decision-making process that incorporates threat and vulnerability, representative loss estimates, and cost of implementation to provide a meaningful benefit and cost index for relative ranking in order to substantiate requested physical security upgrades. Upgrade reviews may include physical security of facilities, secured storage equipment, secured transportation of BSAT materials, surveillance systems,

personal security processes, or other substantiated requests to assure that only the most reliable and skilled personnel have access to the materials necessary to conduct research appropriate to the mission.

f. Commanders and directors of BSAT facilities shall:

(1) Assign, in writing, a biological surety officer, per reference (f).

(2) Develop and implement a biological surety program to fulfill requirements, per reference (a).

(3) Assign, in writing, a responsible official and alternate responsible official to manage the day-to-day matters involved in the inventory management of BSAT.

(4) Assign, in writing, a certifying official.

(5) Ensure a competent medical authority (CMA) is available to provide medical evaluation for BPRP personnel.

(6) Ensure that a military, civilian, or contracted drug and substance abuse testing facility is available for administration of the BSAT BPRP.

(7) Assign, in writing, a BSAT waiver and exception control official to provide oversight of physical security and BPRP waivers and exceptions.

g. Immediate superior in command (ISIC) of BSAT facilities shall conduct biological surety inspections of subordinate BSAT facilities to ensure that each BSAT facility is inspected every 18 months by either MEDIG or the ISIC.

6. Implementation

a. BSAT facilities will ensure compliance to this instruction within 120 days of issuance.

b. Individuals certified into the BPRP prior to this instruction based on a completed and adjudicated National Agency Check with Local Agency Checks and Credit Check (NACLC) or equivalent may remain in the BPRP pending the completion and

adjudication of a Single Scope Background Investigation (SSBI), provided the SSBI is submitted within 120 days of issuance.

7. Records Management. Records created as a result of this instruction, regardless of media and format, shall be managed per Secretary of the Navy (SECNAV) Manual (M-)5210.1 of November 2007.

8. Forms and Reports Control

a. APHIS/CDC Form 1 Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins is available for download from the CDC Web site at http://www.selectagent.gov/RegistrationForm.html.

b. APHIS/CDC Form 2 Guidance Document for Request to Transfer Select Agents and Toxins is available for download from the CDC Web site at http://www.selectagent.gov/TransferForm.html.

c. The following forms are available for download from Naval Forms OnLine (NFOL) at https://navalforms.daps.dla.mil/web/public/home:

(1) OPNAV 3402/1 DON Biological Personnel Reliability Program (BPRP) Annual Status Report; and

(2) OPNAV 5510/420 Biological Personnel Reliability Program (BPRP) Screening and Evaluation Record.

d. Reports contained within this instruction are exempt from report controls per SECNAV M-5214.1 of December 2005.

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Deputy Chief of Naval Operations
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CHAPTER 1
INTRODUCTION AND SURETY GUIDANCE

1. Purpose

a. This instruction establishes DON policy, assigns responsibilities, and prescribes procedures for the Navy Biological Surety Program. It is Navy policy that BSAT in the custody of the Navy shall be properly safeguarded against theft, loss, diversion, or unauthorized access or use, and that operations with such agents are conducted in a safe, secure, and reliable manner.

b. BSAT subject to the provisions of the Navy Biological Surety Program are listed in appendix A. The requirements for managing recovered biological warfare material are outside of the Navy's Biological Surety Program, and are the responsibility of the Assistant Secretary of the Army (Installations and Environment) (ASA(I&E)).

c. Users of this regulation will establish processes to facilitate its implementation. The biological surety program is a commander’s or director’s program. Therefore, when a process is established that is neither prescribed nor prohibited by this regulation, the judgment of the commander or director shall take precedence. For purposes of this regulation, “commander or director” is the individual with responsibility for executing the biological surety mission.

d. This regulation applies to contractors who have access to Navy or DoD-supplied BSAT. Where requirements pertaining to contractors differ from those for military or DoD civilian employees, they are discussed in the body of the text.

e. Commanders or directors may cite this regulation as the authority for requesting resources necessary to meet the safety, security or personnel reliability requirements of BSAT operations.

f. Commanders or directors will restrict access to BSAT to authorized persons and keep the number of persons allowed such access to a minimum consistent with mission, safety, and security requirements.

g. Commands will forward requests with recommendations for variances, waivers, and exceptions to the policy in this regulation through command channels to OPNAV (N462), 716 Sicard Street, Suite 104, Room 45, Washington, DC 20373-5802. Requests dealing with BPRP will be sent to CNO (N09N2) via the appropriate chain of command, with a courtesy copy sent to OPNAV (N462).

(1) Requests for variances, waivers, and exceptions will identify compensatory measures, as appropriate.

(2) A request for a variance, waiver, or exception must include the plan of action and milestones to correct the circumstances requiring the variance, waiver, or exception. Where it is not possible to correct the circumstances requiring the variance, waiver, or exemption, such as it may exist at overseas facilities located on foreign national government compounds, the request must clearly state why the circumstances cannot be corrected.

h. The Navy will remain in compliance with international treaties to which the United States is a party, including the Biological Weapons Convention and the Chemical Weapons Convention (CWC).

2. Biological Surety Program Concept. Biological surety activities include:

a. Compliance with mandated and approved safety, environmental, occupational health, operational, and technical procedures.

b. Physical security measures to preclude unauthorized access to or use of BSAT.

c. Procedures to assess the reliability of personnel designated for, or assigned to, BPRP duty positions.

d. Training and or experience applicable to the position assigned and verification that each individual is proficient in the duties to be performed.

e. Safe and secure acquisition, storage, handling, maintenance, transportation, inventory management, and disposal of BSAT.

f. Emergency response to biological mishaps and incidents.

g. Assessment of organizations and activities with BSAT storage and custody, handling, transport, or management missions.

3. Initiation and Termination of Facility Surety Status

a. Commands wishing to establish new facilities where BSAT will be used must, in addition to other approval processes and reviews, request approval during the planning stage through the appropriate chain of command. OPNAV (N462) will be consulted regarding security requirements.

b. Navy facilities that have terminated work with BSAT will notify OPNAV (N462) and CNO (N09N2) through their chain of command when BSAT are no longer maintained at the facility.

c. OPNAV (N462) will furnish a copy of new facility approvals (prior to initial operation of the facilities) and notification of facilities that have terminated BSAT work to the ATSD(NCB) with an information copy forwarded to CNO (N09N2). New facility approvals regarding BSAT shall be provided to OPNAV (N462) by the echelon 2 command to which the BSAT facility reports with an information copy forwarded to CNO (N09N2).

4. Surety Officers and Surety Boards

a. Biological Surety Officers

(1) The commander of a facility with a biological surety mission will appoint a biological surety officer in writing. The biological surety officer may be a part-time or full-time duty officer position depending on the facility mission. The biological surety officer duties may be included within the duties of the reviewing officer, the assistant reviewing officer, or the certifying official if the Navy facility command structure cannot support an additional position.

(2) Biological surety officers shall:

(a) Manage day-to-day operations of the biological surety program.

(b) Monitor and evaluate the biological surety program.

(c) Act as the focal point for biological surety matters.

(d) Provide oversight for biological safety, security, accident and incident response, inventory management, and personnel reliability program.

(e) Expeditiously bring any apparent incidents or shortcomings to the attention of the commander or director.

(3) For contracts that require access to Navy or DoD-supplied BSAT, the contracting organization will ensure that the statement of work requires the designation in writing of a contractor biological surety officer. The contractor biological surety officer will have responsibilities as identified in paragraph 4a(2)(a) through 4a(2)(e) above, with the exception of the BSAT BPRP and will expeditiously bring any apparent incidents or shortcomings to the attention of the contracting officer's representative. The contractor biological surety officer's position shall be designated as a "key management position". The individual selected as contractor biological surety officer must have the technical knowledge of biological agent operations and experience or training in surety procedures. The contractor biological surety officer may be a part-time or full-time duty officer position depending on the contract requirements.

b. Safety Boards

(1) The commander or director of a facility with a biological surety mission will establish a local biological surety board to assist in managing the biological surety program. The composition of the board depends on the command's mission and the staff elements and external agencies that

support it. The commander or director that establishes a board will document its composition and responsibilities (local standard operating procedure (SOP), memorandum, or charter).

(2) Commanders and directors may incorporate the function of formal surety boards within already established committees or boards.

5. Biological Surety Program Evaluations

a. Navy BSAT facilities will conduct annual self evaluations to ensure that the surety requirements of reference (a) are fully met. Self evaluations will be maintained for a period of 3 years.

b. Navy BSAT facilities co-located with other service BSAT sites will develop memoranda of understanding, where needed, to conduct joint inspections.

c. Reference (g), part 73, establishes CDC and APHIS requirements for periodic evaluation (24 to 36 months) for renewal of BSAT registration. Navy facilities shall ensure compliance.

d. Perform other external inspections, including DoD and Navy inspections, as required.

CHAPTER 2
BIOLOGICAL SELECT AGENT AND TOXIN (BSAT) SECURITY PROGRAM

1. General. Commanders or directors will implement a BSAT security program per reference (a). The BSAT facility security program will be an enclosure to the hosting facility's antiterrorism plan.

2. Threat Information, Collection, and Reporting

a. Commanders or directors will establish and maintain close coordination with Naval Criminal Investigative Service (NCIS) field offices, supporting military intelligence units, local civil and Federal law enforcement agencies, and request that such agencies provide timely information that may affect installation security.

b. NCIS will conduct foreign counterintelligence collection and disseminate information on foreign threats against the Navy as appropriate.

c. Commanders or directors will coordinate and disseminate threat information and will periodically brief personnel on the threat to themselves and the installation, as well as personnel security measures to protect themselves and deter the threat.

d. Commanders or directors will utilize the Defense Intelligence Agency (DIA) threat analysis, reference (d) to develop their security plan.

e. OPNAV (N462) will provide support to DoD and DIA for updating reference (d).

3. Physical Security Requirements. Reference (a) provides the physical security system requirements for BSAT facilities. Navy BSAT facilities will ensure the following additional requirements are completed:

a. Ensure the Navy BSAT facility security plan outlined in reference (a) includes the physical security system requirements and is included in the host facility antiterrorism and physical security plan.

b. Ensure all Navy BSAT restricted areas are identified and provided to the host facility.

c. Establish a lock and key control program per reference (c).

d. Response time requirements to intrusion detection shall not exceed 15 minutes to the area alarmed. If the alarming area is a BSAT restricted area, access to restricted areas by security forces will be determined by the BSAT facility commander or director.

e. Security force drills will be conducted periodically at the discretion of the commander or director. Security drills that include BSAT facility restricted areas will be conducted periodically at the discretion of the commander or director. Access to the restricted area by security forces will be determined by the BSAT facility commander or director. Drills may be combined.

4. BSAT Variance, Waiver, and Exception Program

a. The purpose of the BSAT variance, waiver, and exception program is to:

(1) Ensure that prescribed security standards are properly observed and implemented at all sites where BSAT are located in Navy custody, or, in the case of overseas facilities exempted from the provisions of reference (g), part 73, that prescribed security standards are observed and implemented to the maximum extent possible.

(2) Be used as a management tool to monitor corrective actions taken to ensure established security standards are maintained.

(3) Ensure that variances, waivers, and exceptions from policy with required compensatory measures are identified, endorsed, approved, and corrected by the proper level of command.

b. Waivers and exceptions for physical security facilities, plans, procedures, equipment, and monitoring standards are established in reference (a), this instruction or any

supplemental instruction shall be distinguished from waivers and exemptions from BPRP. Commanders and directors will immediately put recommended compensatory measures in place upon submission of the deviation and shall not wait for final approval to ensure that a measure of security is provided.

(1) A variance is the approved continuation of a non-standard condition that technically varies from established requirements but essentially affords the same level of security. Compensatory measures are not normally required unless more than one variance is submitted for a system(s). Compensatory measures may be required due to the inability of the substituted system to fully compensate for the system that has been replaced or is inoperable.

(2) A waiver is the approved temporary continuation of a non-standard condition that deviates from an established security standard and creates a security vulnerability to the security system, which therefore requires compensatory measures. A waiver shall normally be approved for a period not to exceed 12 months. Extensions are permissible.

(3) An exception is the approved continuation of a permanent non-standard condition that varies from an established security standard and creates a security vulnerability to the security system, which ordinarily requires compensatory measures. Overseas facilities located on foreign national compounds may represent a special case in which compensatory measures may not be possible for all non-standard conditions. All exceptions shall be granted only when correction of the non-standard condition is judged to be non-feasible or cost-prohibitive, and only after careful and critical evaluation.

(4) All variances, waivers, and exceptions shall be reviewed by the granting authority every year or when a major change in site configuration or mission offers the opportunity for corrective action to terminate the non-standard condition.

(5) Waivers are self-canceling on the expiration dates stated in the approval letters unless CNO (N4) approves extensions requested by the initiator. Cancellations do not require CNO approval.

c. Approval of physical security BSAT variances, waivers, and exceptions shall be granted by OPNAV (N462), who shall be the program manager for the BSAT waiver and exception program. Approval of BPRP variances, waivers, and exemptions shall be granted by CNO (N09N2), who shall be the program manager for the BPRP waiver and exemption program.

(1) When considering a variance, waiver, or exception request for a BSAT site, the site commander or director, and subsequent endorsing and approving authorities, shall review all other approved variances, waivers, and exceptions currently in effect for that site in order to determine if additional vulnerabilities are created which are greater than the compensatory measures in effect. Physical security variances, waivers, and exceptions submitted for the BSAT site or host facility under the requirements of reference (c) shall also be reviewed to ensure additional vulnerabilities to the BSAT site have not been created.

(2) Each variance, waiver, and exception shall be evaluated on a case-by-case basis, and blanket approvals are not authorized.

(3) A 10 percent variance from all measurable standards is permitted and does not require the submission and approval of a variance request. A measurable standard applies to physical security requirements which are measured, such as fence heights.

d. Compensatory measures shall be developed for each waiver and exception.

(1) If appropriate, one compensatory measure may suffice for more than one waiver or exception.

(2) Compensatory measure(s) shall be provided whenever two or more variances, or one or more waivers or exceptions, taken together, are determined to constitute vulnerability in the security system.

(3) Waiver and exception submissions shall include a remediation plan for their elimination (except as previously noted for overseas facilities located on foreign national compounds); a threat, vulnerability, risk assessment; and strategy for funding and implementing the solution.

(4) Compensatory measures include additional security forces, procedures, and or physical security devices, such as additional locks, alarms, lighting, and anti-intrusion items that provide a level of security comparable to the required security standard. Compensatory measures that consist primarily of instructions to the security force to increase their alertness or frequency of patrols do not provide a comparable level of security.

e. Reference (a) requires an annual BSAT variance, waiver, or exception report. The annual report shall be submitted through the appropriate chain of command for review by OPNAV (N462) and shall be submitted by 31 January, with the cycle being from January to December. The report shall include all variances, waivers, and exceptions.

f. The format for variances, waivers, and exceptions shall be as follows:

(1) Site Name:

(2) Site point of contact: (email and telephone)

(3) Type and number: (variance, waiver, exception, site unit identification code (UIC), indicate whether the variance, waiver, or exception is to DoD or OPNAV policy, number-year. For example: variance, DoD, N77777-001-09). This is a variance to reference (a) regulations from command UIC N77777 and is the first variance for 2009. DoD and OPNAV variances, waivers, and exceptions will be submitted separately and will have a separate numbering system. OPNAV (N462) is required to submit an annual DoD waiver and exception report to DoD. OPNAV will maintain Navy variances, waivers, and exceptions.

(4) BSAT requirement variances, waivers, and exceptions from: Quote the DoD or OPNAV paragraph for the measure(s) that are not being met.

(5) Variances, waivers, and exceptions description: Describe how the security deviates from policy.

(6) Compensatory measure(s): List all compensatory measures that will be in place to compensate for the particular variances, waivers, and exceptions from policy.

(7) A required physical security measure from reference (c) or this instruction is not to be considered a compensatory measure.

(8) Corrective actions: What specific project is planned to clear the variances, waivers, and exceptions? What is the risk being assumed if the action is not corrected? Has a CNO vulnerability assessment or balanced survivability assessment been conducted from which corrective actions may be derived?

(9) Funding: Indicate if the variances, waivers, and exceptions are funded and identify POM planning actions taken to remedy them.

(10) Submission date: Date of submission by the BSAT site.

(11) Closed date: For annual report use to identify when the variances, waivers, and exceptions to policy were remediated.

g. A BSAT site annual report shall be submitted through the appropriate chain of command to OPNAV (N462) in a list format that will include the site point of contact, type of variances, waivers, and exceptions and number information for the calendar year only. This listing will substantiate all variances, waivers, and exceptions valid during any part of that calendar year.

h. Variances, waivers, and exceptions and annual reports may be forwarded through the chain of command via electronic mail. Ensure signed documents and enclosures are in portable document format.

CHAPTER 3
BIOLOGICAL PERSONNEL RELIABILITY PROGRAM (BPRP)

1. General. This chapter establishes the BPRP as a tool to ensure persons with access to BSAT meet high standards of reliability.

a. The BPRP includes:

(1) Identifying positions with duties that afford access to BSAT.

(2) Designating certifying officials who will certify the reliability and suitability of individuals for the BPRP.

(3) Screening, evaluating, and certifying individuals for the BPRP.

(4) Establishing and maintaining a biological duty position roster (BDPR).

(a) The BDPR will be used as a management tool by the reviewing official and certifying official. The BDPR identifies individuals certified and assigned by the certifying official to BPRP duty positions established by the reviewing official.

(b) The BDPR will contain at a minimum the following information, formatted per local procedures:

1. Effective date.

2. Unit or organization.

3. Name (last, first, middle initial).

4. BPRP job title and or duty position.

5. Interim certification status, if applicable, based on personnel security investigation (PSI) status.

6. Name of reviewing official, certifying official, and responsible official for the certified individuals.

(c) The BDPR will be authenticated (e.g., signature or electronic authentication) and distributed per local requirements to the offices supporting the BPRP. Only individuals with a need to know shall view the BDPR.

(5) Continuing evaluation in the form of certifying official observation and evaluation; periodic reinvestigations (PRs); self-reporting by individual certified into BPRP; evaluation by supervisors, fellow workers, and support agency personnel; evaluation of medical treatment by the CMA; and periodic, random drug testing.

(6) Removing an individual from BPRP duties due to suspension, temporary decertification, permanent decertification, or administrative termination.

b. Explosive ordnance disposal and accident and incident response personnel are not required to meet the standards of this chapter and will be given entry to the BSAT facility only to the extent necessary to mitigate or eliminate a hazard during an emergency.

c. The Privacy Act of 1974 (5 U.S.C. § 552a), as amended, and DoD and DON SECNAV Privacy Program instructions will apply.

d. If an individual wishing to be considered for assignment to BPRP does not grant permission for the review of medical, personnel, and security files, that person is not eligible for BPRP duties.

2. BPRP Roles and Responsibilities

a. Facility Commander or Director

(1) In circumstances when the facility commander or director is in a BPRP position, the commander or director will be certified by his or her rater, and the commander or director position will be listed on the BDPR. The senior officer who certifies the facility commander or director and reviewing official into the BPRP does not require BPRP certification unless he or she is in a BPRP duty position outlined in paragraph 3a of this chapter.

(2) Commanders and directors shall:

(a) Be responsible for the integrity and effectiveness of the BPRP within their facility; and

(b) Designate, as appropriate, reviewing officials, assistant reviewing officials, certifying officials, and BPRP monitors. The decision to designate and the selection of the individuals so designated are entirely at the discretion of the commander or director. The individuals selected, however, must meet high standards of integrity, trust, and personal reliability.

b. Reviewing Official

(1) In most cases, commanders and directors are the reviewing officials. However, commanders and directors may designate a reviewing official as appropriate. Reviewing officials must be DON military or civilian personnel, U.S. citizens, and responsible for BSAT operations and contracts at the level above the certifying official. The reviewing official is not required to be certified into the BPRP in order to perform his or her responsibilities unless he or she is in a BPRP duty position outlined in paragraph 3a of this chapter.

(2) Reviewing officials shall:

(a) Monitor the BPRP;

(b) Establish a BDPR and identify each position that is required to be in the BPRP;

(c) Review and approve all permanent decertification decisions (the reviewing official may also monitor certification decisions of the certifying official in order to oversee the status or quality of the program);

(d) Overturn certifying official decisions when procedures have been unfairly, inconsistently, or incorrectly applied; and

(e) Certify the certifying official into the BPRP.

c. Assistant Reviewing Officials. Assistant reviewing officials may be appointed to assume the responsibilities of the reviewing official in the absence of the reviewing official. Assistant reviewing officials must be DON military or civilian personnel, U.S. citizens, responsible for BSAT operations and contracts at the level above the certifying official, and certified into the BPRP.

d. Certifying Official

(1) Commanders and directors shall designate certifying officials, in writing, to certify individuals' reliability and suitability for the BPRP. Optimally, the certifying official is a person in the supervisory chain, such as a supervisor, team leader, laboratory manager, department head, or the deputy commander or director or equivalent, and has sufficient personal contact with all subordinate BPRP personnel to permit continual evaluation of performance and reliability. Certifying officials must be DON military or civilian personnel, U.S. citizens, and certified into the BPRP by the reviewing official.

(2) Certifying officials shall:

(a) Determine reliability and suitability and ensure that individuals are qualified, trained, and proficient before being assigned to BPRP duties;

(b) Disqualify individuals found to be unsuitable or unreliable for BPRP;

(c) Ensure individuals certified into the BPRP are placed on the BDPR;

(d) Ensure immediate supervisors know individuals in the BPRP are subject to the reliability standards in this regulation;

(e) Continuously evaluate personnel assigned to BPRP duty positions;

(f) Remove, as appropriate, individuals from the BPRP via suspension, temporary decertification, permanent decertification, or administrative termination;

(g) Ensure that individuals who are permanently decertified or administratively terminated are removed from the BDPR;

(h) Ensure the BPRP requirements found in this chapter are incorporated into all contracts or similar arrangements involving BPRP duties outlined in paragraph 3a;

(i) Notify the responsible official of determinations made regarding an individual's BPRP certification status; and

(j) In conjunction with responsible official, approve individuals who secure storage rooms and work areas containing BSAT reference stock when authorized and approved individuals, including BPRP-certified escorts or supervisors, are not present.

e. Acting Certifying Official. If the certifying official will be unavailable for time-sensitive actions required by this instruction, the commander or director may designate, in writing, an acting certifying official to assume the responsibilities of the certifying official for the duration of the absence and provide a copy of the designation to supervisors, the CMA, and supporting agencies. The acting certifying official must meet the requirements found in paragraph 2d(1).

f. BPRP Monitor

(1) Designated monitors must be U.S. citizens. Unless otherwise required or unless directed by the commander or director, the position of BPRP monitor is not a BPRP duty position.

(2) As necessary, BPRP monitors may be designated to assist the certifying official in administering day-to-day functions. BPRP monitor duties may include coordinating and disseminating BPRP information, indoctrinating and training BPRP personnel on reliability objectives and procedures, and maintaining the BDPR. BPRP monitors cannot make BPRP determinations.

g. CMA

(1) CMAs must be a U.S. physician, physician assistant, or nurse practitioner (military, civilian, or contractor) employed by or under contract or subcontract to the U.S. Government or a U.S. Government contractor. CMAs must be awarded clinical privileges for independent practice granted by the health care facility responsible for the provider's place of duty or if not privileged for independent practice (e.g., a physician assistant or nurse practitioner), then be supervised by an appropriately trained CMA physician who is privileged to practice independently. CMAs will be trained in their role and responsibility and be appointed, in writing, by the medical treatment facility commander responsible for reviewing healthcare services or conducting clinical evaluations for purposes of the BPRP.

(2) CMAs will:

(a) Screen medical records;

(b) Identify to the certifying official any medical potentially disqualifying or decertifying information (PDI) that may impact an individual's suitability for assignment to a BPRP position; and

(c) Provide a recommendation to the certifying official as to whether the PDI will preclude the individual from performing BPRP duties.

h. Supervisors. Supervisors will monitor the reliability of their subordinates in the BPRP and notify the certifying official of any PDI. Supervisors will ensure their subordinates receive the appropriate and required technical training for their specific duty positions and will inform the certifying official of individuals' training status.

i. Individuals

(1) Roles and qualifications are listed in paragraph 4 of this chapter.

(2) Individuals in the BPRP will:

(a) Provide written authorization allowing the certifying official and other authorized officials to review medical, personnel, and security files;

(b) Be subject to random drug testing on an unannounced basis as a condition of employment;

(c) Monitor their own reliability and the reliability of others performing BPRP duties;

(d) Advise supervisors and the certifying official of any factors that could have an adverse impact on their or others' performance, reliability, or safety while performing BPRP duties;

(e) Identify medical, dental, and mental health treatment and conditions of concern to the CMA using local procedures; and

(f) Wear personal protective equipment (PPE) as required.

3. Identifying Positions with Access to BSAT

a. Although the following list is not all inclusive, duty positions which have access to BSAT and require certification into the BPRP include personnel who:

(1) Have access (see definition) to BSAT;

(2) Supervise the access of appropriately cleared and authorized personnel to BSAT;

(3) Control direct access to BSAT material;

(4) Are authorized to escort others to areas containing BSAT;

(5) Issue proximity cards, personal identification numbers, keys, combinations, biometric codes, or any other mechanism that provides direct access to BSAT material;

(6) Need BPRP certification in order to fulfill the requirement for securing storage rooms and work areas which contain BSAT reference stock when authorized and approved individuals, including BPRP-certified escorts and supervisors, are not present;

(7) Are Navy vehicle operators transporting BSAT (unless accompanied by two BPRP-certified escorts); and

(8) Are certifying officials, responsible officials, and alternate responsible officials.

b. Individuals who do not perform duties outlined in paragraph 3a of this chapter and who are required to be in areas containing BSAT may be escorted into the areas when approved by the certifying official. Escorted individuals need not be placed in the BPRP. Approval requires the individual:

(1) Have, at a minimum, a current favorably adjudicated NACLC or Access National Agency Check with Credit Checks and Written Inquiries (ANACI);

(2) Meet all other local requirements to be escorted; and

(3) Be escorted and under constant observation by a BPRP-certified individual.

4. BPRP Qualifying Factors and Requirements. The following are the general suitability and reliability standards expected of all BPRP members.

a. Individuals will be mentally alert, mentally and emotionally stable, trustworthy, and physically competent. This includes dependability in accepting responsibilities and effectively performing in an approved manner, flexibility in adjusting to changes in the working environment, good social adjustment, ability to exercise sound judgment in meeting adverse or emergency situations, physical ability to perform duties required by the position, and positive attitude toward BPRP duties and the BPRP.

b. Individuals will be free from substance abuse and or dependence and will participate in initial and random (minimum annually) drug testing programs.

c. Individuals will comply with safety, security, and emergency training requirements specified in local requirements, plans, and regulations for the biological duties they perform. The certifying official will ensure the training is completed and documented per local procedures, plans, and regulations.

d. All personnel in the Continental United States (CONUS) will:

(1) Be U.S. citizens;

(2) Require an SSBI, Single Scope Background Investigation Periodic Reinvestigation (SSBI-PR), or Phased Periodic Reinvestigation (PPR), which has been completed within the past 5 years and favorably adjudicated by a central adjudication facility (CAF); and

(3) Have valid DHHS approval based on a security risk assessment per references (e), (g), part 73, and (h) before access is provided to BSAT.

e. U.S. personnel outside of the Continental U.S. (OCONUS) will require an SSBI, SSBI-PR, or PPR, which has been completed within the past 5 years and favorably adjudicated by a CAF.

f. Local nationals at OCONUS facilities may only be considered for certification into the BPRP under the following conditions:

(1) Local national BSAT access is limited to non-category A agents;

(2) OCONUS facility submits an exception request via its chain of command to CNO (N09N2), which includes a comprehensive list of the elements and scope of the Department of State (DoS) background investigation completed on local nationals working at OCONUS facilities, and CNO (N09N2) determines the DoS background investigation is comparable (to the maximum extent possible) in element and scope to a NACLC;

(a) If approved, CNO (N09N2) will send a copy of the exception approval to OPNAV (N462) and the Director of Security, Counterintelligence and Security (CI&S), Office of the Under Secretary of Defense for Intelligence (OUSD(I)).

(b) Whenever the scope of the DoS background investigation changes, the OCONUS facility will submit a request for an amendment to the exception via its chain of command to CNO (N09N2). CNO (N09N2) will review the request and notify the facility, OPNAV (N462), and the Director of Security, CI&S, OUSD(I) of its determination.

(3) Local national receives a favorably reviewed DoS background investigation (and thereafter every 5 years);

(4) Local national is not a restricted person, as defined in appendix E.

(5) Local national is supervised by BPRP-certified U.S. personnel.

5. Mandatory Disqualifying and Decertifying Factors. The certifying official will disqualify or permanently decertify individuals from the BPRP if it is discovered that any of the traits, diagnoses, conditions, or conduct listed below exists.

a. Current diagnosis of substance dependence (alcohol or drugs) based on a determination by an appropriate medical authority following the current Diagnostic and Statistical Manual of Mental Disorders of the American Psychiatric Association.

b. Drug abuse within the 5 years previous to the initial BPRP interview. Isolated incidents of use of another person’s prescribed drug will be evaluated. Certifying officials having any doubt on the status of a certain drug as illegal or controlled must consult with the CMA.

c. Trafficking in illegal or controlled drugs or substances.

d. Abuse of drugs, prescription drugs, or other substances while enrolled in the BPRP.

e. Verified positive drug test or refusal to take a drug test.

f. Use of Food and Drug Administration Schedule II, III, or IV anabolic steroid, not prescribed by a physician, while enrolled in the BPRP;

g. Inability to obtain or revocation of security clearance eligibility.

h. Inability to meet safety requirements, such as unable to correctly wear PPE required for the assigned position, other than temporary medical conditions. Questions regarding the duration of medical conditions will be referred to the CMA.

6. PDI. Any of the following traits, diagnoses, conditions, or conduct listed below may be grounds for the disqualification or permanent decertification of individuals from the BPRP, based on the certifying official's informed judgment.

a. Alcohol-Related Incidents and Abuse

(1) Certifying officials will evaluate the circumstances of alcohol-related incidents occurring within the 5 years prior to the initial interview and request a medical evaluation. Certifying officials will temporarily decertify any individual in the BPRP who is involved in an alcohol-related incident, evaluate the circumstances, and request a medical evaluation.

(2) Individuals diagnosed as abusing alcohol, but who are not alcohol dependent, shall, at a minimum, have their BPRP processing suspended or be temporarily decertified from the BPRP until the individual completes the prescribed rehabilitation program or treatment regimen prescribed by the CMA. Upon completion of the program or treatment, the certifying official will assess whether the individual has displayed positive changes in job reliability and lifestyle and verify whether the individual has received a favorable medical prognosis from the CMA. Failure of the individual to satisfactorily meet these requirements shall result in disqualification or permanent decertification.

(3) In circumstances when individuals are not diagnosed as currently alcohol dependent or abusing alcohol, including

those individuals identified as recovering alcoholics, the certifying official will determine reliability based on results of the investigation, the medical evaluation, and any extenuating or mitigating circumstances (such as successful completion of a rehabilitation program). The certifying official will then certify or disqualify the individual from the BPRP as he or she deems appropriate.

b. Drug Abuse

(1) In situations not otherwise addressed, a certifying official may certify or disqualify an individual who has abused drugs more than 5 years before the initial BPRP interview.

(a) In deciding whether or not to disqualify individuals in these cases, the certifying official will request CMA evaluation, will consider such abuse in conjunction with other PDI in determining reliability of the individual, and may consider extenuating or mitigating circumstances. To certify the individual for the BPRP, the certifying official's documentation of the PDI must include a CMA evaluation and an approval signed by the reviewing official. If the reviewing official does not approve, the individual will be disqualified from the BPRP.

(b) Examples of potential extenuating or mitigating circumstances include, but are not limited to:

1. Successful completion of a drug rehabilitation program.

2. Participation in a Navy certified post rehabilitation program.

3. Isolated experimental drug abuse.

4. Age at the time of the drug abuse ("youthful indiscretion").

(2) Abuse of prescription drugs or other substances that alter perceptions or mental faculties is unacceptable and must be reported to the certifying official for evaluation. certifying officials may certify individuals who have isolated episodes of abuse when the abuse occurred before the initial

BPRP interview. In such circumstances, certifying officials will follow guidance outlined in paragraph 6b(1)(a) of this chapter. BPRP-certified individuals who abuse prescription drugs or other substances will be permanently decertified.

(3) It is not the intent of this instruction to automatically disqualify or permanently decertify any individual in BPRP who, in an effort to self medicate, inadvertently or deliberately exceeds the recommended safe dosage of over the counter substances or his or her own prescribed medication. If the certifying official suspects, or the individual admits to, such improper usage, the BPRP screening process must be suspended or individual must be temporarily decertified and the CMA must be consulted. If, after CMA consultation, the certifying official concludes drug or substance abuse has occurred, the certifying official must disqualify or permanently decertify the individual.

c. Medical Condition

(1) Any significant mental or physical medical condition, medication usage, or medical treatment, which may result in an altered state of consciousness, impaired judgment or concentration, increased risk of impairment if exposed to biological agents, impaired ability to safely wear PPE required for the biological surety position, or inability to perform the physical requirements of the biological surety position, as substantiated by a CMA to the certifying official, is reason for disqualification or permanent decertification if and when the certifying official considers it prejudicial to reliable performance of BPRP duties.

(2) The CMA will evaluate individuals and make recommendations to the certifying official on suitability for duty in the BPRP in the following circumstances:

(a) Individuals currently under treatment with hypnotherapy.

(b) Individuals who have attempted or threatened suicide before entry into the BPRP. Any suicide attempt and or threat may be grounds for disqualification.

(c) Individuals suspected of attempting and threatening suicide while enrolled in the BPRP. Individuals will be temporarily decertified pending the results of a mental health assessment and evaluation. Any suicide attempt and or threat may be grounds for permanent decertification. Return to BPRP duties require favorable medical prognosis from the CMA and approval signed by the reviewing official.

(3) When medical information is provided to the certifying official, but the information did not come from the CMA, the certifying official will consult the CMA and may suspend the individual from BPRP duties as a precaution pending the outcome of the consultation. Examples of when suspension may be appropriate include, but are not limited to, the following:

(a) An individual taking a medically prescribed drug that may impair duty performance.

(b) Presumed temporary departures from normal emotional or mental health. Related factors may include stressful family issues, relationship or marital problems, financial trouble, bereavement, and postpartum depression, among others.

(c) A physical injury or other condition (including pregnancy) that temporarily impairs the individual's ability to perform assigned BPRP duties or correctly wear PPE. Suspension may be extended to include both a pregnancy's full term and postpartum recovery period.

(d) The CMA determines that a medical condition or symptoms require further medical evaluation to determine effects on an individual's suitability for the BPRP.

d. Inappropriate Attitude or Behavior

(1) In determining reliability, the certifying official will conduct a careful and balanced evaluation of all aspects of an individual. Specific factors to consider include, but are not limited to:

(a) Negligence or delinquency in performance of duty.

(b) Conviction of a serious incident indicating a contemptuous attitude toward the law, regulations, or other duly constituted authority. Serious incidents include, but are not limited to, assault, sexual misconduct, financial irresponsibility, contempt of court, making false official statements, habitual violation of traffic laws, and domestic violence.

(c) Poor attitude or lack of motivation. Poor attitude can include arrogance, inflexibility, suspiciousness, hostility, flippancy toward BPRP responsibilities, and extreme moods or mood swings.

(d) Aggressive or threatening behavior toward other individuals.

(e) Attempting to conceal PDI through false or misleading statements or willfully neglecting to report current PDI.

(2) Any of the above factors may be reason for disqualification or permanent decertification if and when the certifying official considers it prejudicial to reliable performance of BPRP duties. Individuals displaying aberrant behavior which requires a medical evaluation will be, at minimum, temporarily decertified pending the outcome of the evaluation.

7. Reliability Screening and Evaluation Process

a. General

(1) No one will be entered into the BPRP until the certifying official screens and certifies the individual as reliable and suitable. The certifying official will use the following sources of information to determine that the individual is qualified for the BPRP:

(a) Initial interview.

(b) PSI.

(c) Personnel records review.

(d) Medical evaluation.

(e) Drug testing.

(f) Technical proficiency determination.

(2) Medical PDI found or disclosed during any portion of the screening will be referred to the CMA for documented evaluation.

(3) OPNAV /414/420 Biological Personnel Reliability Program (BPRP) Screening and Evaluation Record will be completed for each individual screened and evaluated for the BPRP. The sequence of medical and personnel screening and administrative processing may be adapted to meet the needs of the certifying official.

(a) All signatures or initials on the original OPNAV 5510/420 Biological Personnel Reliability Program (BPRP) Screening and Evaluation Record will be in ink. Facsimile stamps will not be used for signatures.

(b) Errors on OPNAV 5510/420 discovered prior to initial certification will be corrected by lining through the error and or inserting the correction as appropriate, and initialing and dating the correction.

(c) Corrections to errors discovered after the individual is enrolled into the BPRP shall be documented per local procedures, and (if necessary) place additional documentation in the individual’s file as appropriate.

(d) Records initiated prior to publication of this regulation remain in effect and do not need to be restarted.

(4) The certifying official may make a determination of an individual’s unsuitability at any time during the screening process, and terminate the evaluation. If the candidate is found to be unsuitable for the BPRP, the certifying official will terminate the BPRP screening process and follow procedures for disqualification. For civil service applicants who are not current Federal employees, the certifying official will terminate the screening process and return the interview referral slip to the placement specialist.

b. Initial Interview

(1) The certifying official will conduct a personal interview with each candidate for BPRP duties to look for evidence of the individual's perception of responsibility, exercise of sound judgment, effective performance, and ability to adjust to changes in the work environment.

(2) The certifying official will:

(a) Review with the candidate the concept of the BPRP;

(b) Explain the importance of BPRP assignments and review with the candidate the reliability standards, including individual qualifications and responsibilities, found in paragraphs 2i(2) and 4 of this chapter;

(c) Review and ensure comprehension of the mandatory disqualifying and decertifying factors and PDI sections found in paragraphs 5 and 6 of this chapter;

(d) Determine whether any of the traits or conduct normally considered disqualifying exist. If there is any concern about his or her ability to wear PPE, the matter will be resolved promptly.

(3) Should the certifying official determine that the candidate is acceptable for further screening, the screening process will continue per local procedures.

c. PSI

(1) The security manager or a representative (designated in writing) will:

(a) Determine whether the individual is a subject of a current and favorably adjudicated PSI. The security manager will notify the certifying official whether the PSI is valid for BPRP.

(b) Review local security records, to include the Standard Form (SF) 85 Questionnaire for Non-Sensitive Positions or SF 86 Questionnaire for National Security Positions, or

equivalent questionnaires, for adverse information. When adverse information is identified, the security manager will provide it to the certifying official per local procedures, assuring Privacy Act requirements are not violated.

(2) In cases where the investigation was completed more than 5 years before BPRP certification, the investigation is outdated for BPRP purposes and a new investigation is required.

(3) Only U.S. citizens will be considered for interim certification. In circumstances where official functions must be performed prior to completion and adjudication of the required investigation, the certifying official may grant interim certification under the following conditions:

(a) The individual must have either:

1. An SSBI, SSBI-PR, or PPR, completed within the last 10 years and favorably adjudicated by a CAF; or

2. NACLC or ANACI, completed within the last 5 years and favorably adjudicated by a CAF.

(b) The appropriate SSBI, SSBI-PR, or PPR has been opened or scheduled.

(c) All other requirements of the BPRP screening process have been completed, revealing no PDI.

(d) Once granted, interim certification will be valid until completion of the requested PSI and adjudication; however, the certifying official may revoke it at any time based on unfavorable information identified in the course of the investigation, or if the certifying official has reason to suspect the individual is unreliable.

(e) Individuals who are interim certified must be identified to supervisory personnel, entry controllers who directly control access to exclusion areas, and others as necessary as having interim certification status. The BDPR, entry authorization lists, and any individual access badges must be specifically marked to designate interim certification status.

(f) Interim-certified individuals will not have access to BSAT unless escorted by a fully BPRP-certified individual.

d. Personnel Records Screening

(1) The supporting personnel officer or representative (designated in writing) will screen the individual’s personnel records to determine:

(a) The individual's citizenship and verify it to the certifying official; and

(b) If the individual's personnel records contain information that may preclude assignment to a BPRP position. When PDI is identified, provide it to the certifying official per local procedures, assuring Privacy Act requirements are not violated.

(2) The certifying official may be designated to screen personnel records by the commander or director.

e. Medical Evaluation

(1) The CMA will review the individual’s medical records to determine if information exists that may preclude assignment to a BPRP position. If available medical records are incomplete or inadequate, the CMA will conduct a medical evaluation to determine medical qualification under BPRP standards. The medical evaluation will include dental or mental health consultation if either the CMA determines that such an evaluation is prudent or the certifying official requests it.

(2) The CMA will annotate the medical record entry with a statement indicating that the individual and or individual's records have been screened under the reliability standards of this instruction. If PDI was identified, the CMA will provide an evaluation and recommendation to the certifying official in sufficient detail so he or she can make a sound decision concerning the individual’s suitability for the BPRP. The medical record entry will indicate the nature of the PDI and the date the certifying official was notified. The medical record entry will include the name, grade, and signature of the CMA and the date of the screening.

(a) The CMA will provide this information to the certifying official per local procedures, assuring provisions of the Privacy Act and the Health Insurance Portability and Accountability Act are not violated. Upon receipt, certifying officials and reviewing officials must protect the health records and information per the Privacy Act. Certifying officials and reviewing officials may refer questions concerning the release of protected health information to their servicing legal office.

(b) The CMA's recommendation will identify any limitations in duties or reasonable accommodations that might allow the individual to safely and reliably perform BPRP duties (see Americans with Disabilities Act). The certifying official may request a safety assessment of the reasonable accommodation, if desired. Worker safety will not be compromised. Accommodations that could cause injury to the individual or another worker will not be implemented.

(3) Certifying officials of organizations receiving medical support from non-Navy medical facilities or contract physicians will provide a copy of this regulation and other required guidance on medical PDI to the supporting medical facility contract physicians for use in evaluating personnel for the BPRP.

f. Drug Testing

(1) All candidates for the BPRP must complete drug testing within 6 months prior to initial certification into the BPRP. Drug test results will be submitted to the certifying official, who will verify the test was negative, before the individual is certified into the BPRP.

(2) Drug testing will be documented per local procedures.

g. Technical Proficiency Determination

(1) In addition to the requirements found in paragraph 4c of this chapter, individuals will receive the appropriate and required technical training for their specific BPRP duty

positions. Technical training requiring access to BSAT will be under the supervision of a BPRP-certified individual who has completed technical training.

(2) Technical proficiency determinations will be made by the certifying official, based on information provided by the individual's supervisor.

h. Certifying Official's Evaluation and Briefing

(1) After the screening process is completed, the certifying official will review all records, documentation, and any PDI discovered during the screening process. Although the certifying official may request information or advice from any support agency or activity capable of providing or interpreting such information, the decision to certify an individual for, or to disqualify an individual from, the BPRP is the responsibility of the certifying official.

(2) The certifying official will make a judgment on the reliability and suitability of an individual for a BPRP duty position.

(a) In the absence of mandatory disqualifying factors, the certifying official will consider both affirmative qualifying factors and PDI in determining reliability and suitability. If the certifying official determines that PDI identified during the screening is not disqualifying, he or she will document the PDI and the decision per local procedures.

(b) If the certifying official determines an individual is unsuitable for a BPRP assignment, the certifying official will follow procedures for disqualification.

(3) For individuals found suitable for the BPRP, the certifying official will notify the individual of the suitability determination and brief the individual in the following areas:

(a) Duties and responsibilities of the individual's BPRP position.

(b) Obligations under the continuing evaluation aspects of the BPRP.

(c) Mandatory disqualifying and decertifying factors and PDI, to include a discussion of any incidents or medical issues that have occurred since the initial interview.

(d) Any restrictions due to interim certification requirements (as applicable).

(4) At the close of the briefing, the individual and the certifying official will complete the appropriate forms, to include OPNAV 5510/420, per local procedures. The individual's signature on OPNAV 5510/420 indicates that a briefing on the standards and objectives of the BPRP was received and that individual affirms his or her responsibility to abide by the requirements to maintain BPRP certification. The certifying official will retain the official copy in the person’s BPRP folder.

(5) Upon certification into BPRP, health records will reflect the assignment of the individual to a BPRP position, ensuring the proper treatment, review, and reporting of PDI to the certifying official.

8. Change in, or Absence of, the Certifying or Reviewing Officials

a. When a BPRP-certified individual transfers to another BPRP position with a different certifying official and reviewing official, the individual will be administratively terminated by the old certifying official and screened by the new certifying official.

b. A new screening is not required when a BPRP-certified individual transfers to a BPRP position with a different certifying official while retaining the same reviewing official or when the certifying officials is replaced. However, the certifying official will review the individual’s records and documentation addressing previous PDI and interview the individual. These reviews and interviews will be completed within 30 days unless the reviewing official authorizes an extension.

(1) If questions arise during the reviews or the interview, the certifying official will attempt to resolve these questions through consultation with the CMA and or supporting

agencies. If questions remain, the certifying official will temporarily decertify the individual until the matter is resolved.

(2) Upon completion of the review and interview and or the resolution of any concerns, the certifying official and the individual will document it by signature. The certifying official's signature indicates that the individual is suitable for the BPRP.

c. A new certifying official will notify the CMA and supporting agencies of the change in certifying official upon assignment to the position so that PDI or other information can be appropriately addressed. The new certifying official will also ensure an updated BDPR is distributed per local procedures.

d. Neither a new screening nor a review is required when the reviewing official is replaced.

e. Acting certifying officials are not required to conduct the reviews and interviews per paragraph 8b or create a new BDPR.

9. Continuing Evaluation

a. General. certifying officials will ensure that all personnel assigned to BPRP positions are subject to a continuing evaluation of their reliability. Qualifying and decertifying factors continue to apply unless modified in this section. Continuing evaluation includes:

(1) Certifying official observation and evaluation.

(2) PRs.

(3) Self-reporting and observation and reporting by peers and supervisors.

(4) Evaluation of medical treatment by the CMA.

(5) Drug testing.

b. Certifying Official Observation and Evaluation

(1) Certifying officials will have sufficient contact with their BPRP subordinates to observe behavior and performance on a frequent and consistent basis. Certifying officials are responsible for ensuring all individuals meet the requirement and standards outlined in this chapter.

(a) When an individual is in an administrative absence (leave, temporary duty, etc.), the certifying official will rely on the individual's obligation to self report PDI. The certifying official may also establish a relationship with the leadership at the gaining site to ensure PDI is reported back to the BPRP command.

(b) When the ability to maintain continuing evaluation is unattainable, the certifying official will administratively terminate the individual from BPRP duties for the duration of the absence. Administrative termination is not an assessment of unreliability.

(2) To ensure that continuing evaluation is effective, certifying officials will establish and maintain close working relationships with supporting activities to ensure they are fully aware of their BPRP responsibilities and they provide required support.

(3) When PDI is identified to the certifying official, the certifying official will review and evaluate the information as outlined in paragraph 7 of this chapter and make a reliability determination.

c. PRs

(1) All personnel assigned to BPRP duties are required to receive a PR every 5 years.

(2) A request for PR will be submitted before the PSI expires, and the individual will remain qualified while the PR is being conducted. If the request for PR is not submitted before expiration of the PSI, the certifying official will temporarily decertify the person from the BPRP until the PR is submitted. Once the PR is submitted, the certifying official can return the individual to a fully qualified status.

(3) Upon notification of the completion of the PR, the security manager will notify the certifying official of the new PSI date, and whether the PR is favorable or if a dossier requires certifying official review.

(4) The security manager will notify the certifying official of all derogatory information developed on BPRP-certified individual. The certifying official will review this information and determine if the individual's reliability is affected.

(5) The certifying official may at any time request local records check if an individual's reliability becomes suspect, or may consult with the security manager to determine if a special investigative inquiry is warranted.

d. Self-Reporting and Observation and Reporting by Peers and Supervisors

(1) Information that would be identified during the next PR shall be reported to the certifying official as soon as possible. Reportable information includes:

(a) Leaving a job (including part-time or second jobs) under unfavorable circumstances.

(b) Being charged with, or convicted of, any criminal offence, including those under the Uniform Code of Military Justice.

(c) Illegal use of drugs and or substances or illegal drug activity.

(d) 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, and debt delinquency greater than 90 days.

(e) Being a party to any public record court action.

(2) Failure to self report or report PDI of a coworker or subordinate may in and of itself be considered PDI. The certifying official will consider failure to discharge these responsibilities when evaluating an individual's reliability.

e. Evaluation of Medical Treatment by the CMA

(1) BPRP-certified individual will notify the CMA (verbal, written, or electronic) each time the individual identifies medical conditions of concern or receives medical treatment from a military or non-military health care provider. Medical conditions and treatment include dental and mental health conditions and treatment. The CMA will follow procedures outlined in paragraph 7e to evaluate the condition or treatment and notify the certifying official of the effect on the individual's reliability or duty performance.

(2) Local procedures will address provisions to promptly alert the certifying officials when the CMA has forwarded information that warrants immediate action by a certifying official. In urgent medical situations, the CMA may direct the immediate supervisor to remove the individual from biological surety duties pending decision by the certifying official. Such information includes:

(a) Any prescribed or administered medication or treatment that could affect an individual's physical or mental capabilities (e.g., local anesthetics, narcotics, sedatives, and tranquilizers).

(b) Any behavior that suggests emotional or mental instability (including suicide attempt or suicide threat, suicide ideations or gestures) or current drug or alcohol abuse.

(3) Certifying officials receiving medical information regarding a BPRP employee from other than the CMA will refer the employee to the CMA for an evaluation.

(4) When a BPRP-certified individual is subject to medical surveillance under the occupational health provisions, the CMA will review the results of medical examinations and health screening. For BPRP-certified individuals not subject to occupational health medical surveillance, the CMA will perform at a minimum an annual health screening.

(5) Certifying officials and reviewing officials may direct the review of health records of personnel currently in the BPRP at any time for the purpose of making suitability determinations required by this regulation. The CMA will

conduct the review to prevent any possible misinterpretation of health record data. Because of the sensitive and confidential nature of health records, authority to direct such a review extends only to certifying officials and reviewing officials.

f. Drug Testing. DoD civilian and military personnel in the BPRP will undergo periodic, random drug testing. Contractor personnel will undergo periodic, random drug testing per contractual requirements. At a minimum, drug testing of all BPRP personnel will be conducted on an annual basis. Verified positive test results will be submitted to the certifying official.

10. Disqualification. If an individual is determined to not meet the reliability standards of this chapter while in training or being considered for assignment to a BPRP duty position, the certifying official will initiate disqualification from the BPRP. The process for disqualification is as follows:

a. The certifying official will terminate the screening process.

b. The reviewing official will review the action to ensure the correct, fair, and consistent application of the reliability standards in this regulation.

c. If disqualification is inappropriate, the certifying official will complete the screening and BPRP processing.

d. If disqualification is appropriate, the certifying official will notify the individual in writing. The notification letter will cite the disqualification factor(s) and the specific circumstances supporting the decision to disqualify. For medical conditions, the citation will be “medical conditions as documented in your medical records.” This will preclude violations of the Privacy Act. In these cases, the individual may obtain information pertaining to the disqualifying medical condition by contacting the certifying official or the CMA.

e. Disqualification from the BPRP is neither an adverse personnel action nor the basis for disciplinary action. However, the reason for disqualification may warrant further action. Separation from employment or service may be

appropriate for a disqualified individual if BPRP certification is a condition of employment or service and if no positions are available for which the individual is qualified.

f. The following actions apply for disqualifying contractors from BPRP:

(1) The certifying official will give the individual's employer written notice the individual is disqualified.

(2) The certifying official will keep the original documentation and copies of the notification letter and reviewing official's approval.

(3) The certifying official will notify appropriate support offices.

(4) If the individual was disqualified for acts reflecting adversely on loyalty, character, integrity, or discretion; and the acts were clearly not consistent with national interest, the contractor's facility security officer must report this information to Defense Security Service offices for necessary action.

11. Removal from BPRP Duties

a. General. The type of removal from the BPRP (suspension, temporary decertification, permanent decertification, administrative termination) depends on the circumstances, character, and transitory or continuing nature of the cause of the unsuitability or suspected unsuitability. General guidelines are listed as follow:

(1) When making a reliability determination, the issue is not an individual's guilt or innocence of some particular offense; rather, the issue is whether the individual will be retained in a BPRP position. It is not necessary to complete an investigation, take disciplinary action (either civil or military), or complete other personnel actions before the certifying official decides whether to disqualify or retain an individual in the BPRP.

(2) Personnel suspended or temporarily decertified from BPRP duties will not be deleted from the BDPR. Certifying officials will ensure that individuals are deleted from the BDPR when permanently decertified or administratively terminated.

(3) Local procedures will govern actions taken by supervisors to immediately remove access when unexpected situations arise pending resolution by the certifying official.

(4) If the individual being removed from BPRP duties is a contracted employee, the certifying official will direct the contractor to remove the individual from BPRP duties.

b. Suspension

(1) Suspension is used to immediately remove a member from BPRP duties without starting a decertification action. For example, an individual may be suspended as a precaution based on the possibility of duty impairment. Suspension will be used only when the individual's reliability is not in question, when the problem is expected to be of short duration, and while conducting an investigation or medical evaluation to determine if a situation or incident could have an adverse effect on an individual's reliability.

(2) The certifying official may suspend an individual based on information provided by the individual, supervisor, or the CMA.

(3) The certifying official will notify the individual and the individual's immediate supervisor, in writing, of the nature of the suspension and probable duration. A copy of the notification will be maintained with the individual's file.

(4) The individual will remain under continuing evaluation while suspended.

(5) Suspensions will not normally exceed 120 days. If the condition or situation is not resolved in 120 days, the certifying official will determine what action to take (e.g., extension of suspension, temporary decertification, or permanent decertification). As appropriate, the certifying official will consult with the CMA in making this determination.

(6) When the condition or situation causing the suspension is resolved, the certifying official will notify the individual and immediate supervisor per local procedures that the individual can resume assigned BPRP duties.

c. Temporary Decertification. When a certifying official determines that an individual's reliability is suspect, the certifying official will immediately temporarily decertify the individual from the BPRP. Temporary decertification is also appropriate when a medical condition unexpectedly becomes prolonged and the certifying official determines continued suspension is not appropriate. The certifying official will also temporarily decertify an individual whose PSI has expired unless and until a PR has been requested. Temporary decertification can be considered unless facts warrant permanent decertification.

(1) The certifying official will remove the individual from assigned BPRP duties immediately and document the temporary decertification to reflect the date of the temporary decertification.

(2) The certifying official will notify the individual and the immediate supervisor, in writing, of the reason for temporary decertification within 15 workdays. If the reason for suspension is medical PDI, reason will be identified to the individual and supervisor as “medical PDI from CMA.” A copy of the notification will be maintained with the individual’s file.

(3) The individual will remain under continuing evaluation while temporarily decertified.

(4) The certifying official will promptly evaluate all circumstances and obtain information pertaining to the reliability of the individual in order to determine whether to reinstate or permanently decertify the individual.

(5) Temporarily decertified military personnel will not be permanently reassigned or separated from service until they are reinstated into or permanently decertified from the BPRP, unless temporary decertification is the result of a medical condition. In that case, the individual will be administratively terminated from the BPRP before separation or reassignment.

(6) Temporary decertification will initially be for up to 30 days. The certifying official may extend the period of temporary decertification up to 120 days in 30-day increments when there is not sufficient information to return the individual to BPRP duties or to permanently decertify the individual. Extension decisions and their justification must be documented and maintained by the certifying official for the duration of the temporary decertification. After 120 days, CNO (N09N2) approval is required for further extensions.

(7) If the individual is reinstated, the certifying official will inform the individual and immediate supervisor in writing and maintain the notification and reinstatement memoranda per local procedures.

d. Permanent Decertification. When the certifying official determines that an individual no longer meets the reliability standards of this chapter, the certifying official will permanently decertify the individual from the BPRP. The process of permanent decertification is as follows:

(1) The certifying official will remove the individual from BPRP duties.

(2) The certifying official will notify the individual in writing (“the notification letter”) within 7 workdays of the decision to permanently decertify the individual. The notification letter will:

(a) Cite the factor(s) and specific circumstances supporting the decision. For medical conditions, the citation will be “medical conditions as documented in your medical records.”

(b) Advise the individual that the permanent decertification action is subject to mandatory review by the reviewing official before any permanent entries are made in the individual's records and that the certifying official or reviewing official will advise the individual of the outcome of the review.

(c) Inform the individual that a written explanation or rebuttal may be submitted through the certifying official to the reviewing official within 5 workdays of receiving the letter.

(d) Request written acknowledgement of receipt of the notification letter. If the individual refuses to acknowledge receipt, the certifying official will add a statement to the notification letter explaining the refusal.

(3) The reviewing official will review each permanent decertification action to ensure uniform application of the reliability standards specified by this chapter.

(a) The certifying official will forward a copy of the notification letter, any written explanation or rebuttal submitted by the individual, and any other pertinent information to the reviewing official. This will be completed within 10 workdays of the individual receiving the notification letter.

(b) The reviewing official will review the case. The reviewing official may seek additional information or explanations of extenuating circumstances from the certifying official, CMA, personnel officials, and the individual concerned.

(c) Within 15 workdays of receipt of the permanent decertification documents, the reviewing official will furnish a written decision to the individual through the certifying official. If the individual has departed the certifying official’s organization, the certifying official will forward a copy of the reviewing official’s decision either directly to the individual or through the individual’s new chain of command or supervisory chain.

(d) When the reviewing official does not approve the permanent decertification, the individual's records will show the individual as BPRP certified.

(4) If the reviewing official approves permanent decertification of an individual:

(a) The certifying official will provide a copy of the notification letter, the reviewing official's approval, and other pertinent documentation to the custodian of the individual’s personnel records for filing. The copy of the approval will be annotated with the date and method of notifying the individual of the reviewing official’s decision. The documentation will provide sufficient detail in order for requalification requests to be appropriately assessed.

(b) The certifying official will notify the CMA. If the individual is permanently decertified for medical reasons, the CMA will annotate the medical record entry with the permanent decertification date and will state the medical reason for permanent decertification.

(c) The certifying official will ensure the individual is removed from the BDPR and will notify the individual’s immediate supervisor, in writing, of the permanent decertification.

(d) The certifying official will notify the supporting security manager for appropriate action when the permanent decertification is based on credible derogatory information that could affect the individual's security clearance.

(5) Permanent decertification from the BPRP is neither an adverse personnel action nor the basis for disciplinary action. However, the reason for permanent decertification may warrant further action. Separation from employment or service may be appropriate for a permanently decertified individual if BPRP certification is a condition of employment or service and if no positions are available for which the individual is qualified.

(6) The actions found in paragraph 10f are applicable when permanently decertifying contractors.

e. Administrative Termination. Certifying officials will administratively terminate any individual who transfers from a duty position requiring BPRP certification to a position, either within or outside of the organization, not requiring BPRP certification. Administrative termination serves to establish the date an individual was removed from a BPRP position for

reasons other than disqualification or permanent decertification and to terminate the requirement for continuing evaluation. The certifying official will:

(1) Terminate the individual's access to BSAT and ensure the individual is removed from the BDPR.

(2) Complete appropriate documentation and forward it to the custodian of the individual's personnel records.

(3) Notify the CMA, in writing, that the individual is no longer in the BPRP and no longer requires continuing evaluation.

12. Requalification of Disqualified or Permanently Decertified Personnel

a. An individual disqualified or permanently decertified from the BPRP may request requalification based on substantive evidence that the cause for disqualification or permanent decertification no longer exists. Approval of requalification does not require that the individual be assigned or reassigned to a BPRP position; however, requalified personnel are eligible for certification into such positions.

(1) The individual may submit a request for requalification to a certifying official of the organization to which they are currently assigned, or to a certifying official of the organization where the disqualification occurred. This request will explain the circumstances leading to, the basis for, and the actions taken to correct or eliminate the cause of the disqualification or permanent decertification.

(2) The certifying official and reviewing official will review the request, and either disapprove it or recommend its approval to CNO (N09N2).

(a) If the certifying official and reviewing official disapprove the request, it will be returned to the individual with the rationale for disapproval and a copy forwarded to CNO (N09N2).

(b) If the certifying official decides to recommend requalification, the certifying official will endorse and

forward the request for requalification to the reviewing official. The reviewing official will review the request and the certifying official's recommendation.

1. Prior to approving or denying the request for requalification, the reviewing official must evaluate the potential for reoccurrence of the condition or circumstance which caused the disqualification or permanent decertification and determine whether the value of the individual's participation in BPRP outweighs the risk of potential future incidents. This evaluation will include consultation with the CMA regarding medical issues and consultation with the security manager and CAF to verify the individual's PSI and eligibility.

2. If the reviewing official approves the request for requalification, the certifying official will forward a copy of the request with supporting justification to CNO (N09N2) via the chain of command. Justification will include a thorough summary enumerating the disqualification or permanent decertification issues, a recommendation from the reviewing official based on paragraph 12a(2)(b)(1), and the type of duty assignment proposed.

(3) If CNO (N09N2) grants requalification and the organization wishes to consider the individual for assignment to a BPRP position, the certifying official will complete the procedures outlined in paragraph 7 of this chapter, however the information pertaining to the previous disqualification or permanent decertification will not be considered in itself.

b. In addition to the above requirements, the following are special procedures to be followed when considering requalification following disqualification or permanent decertification due to alcohol dependence or abuse and drug abuse:

(1) Alcohol Dependence. An individual disqualified or permanently decertified for alcohol dependence may be requalified for BPRP duties only after meeting the following conditions:

(a) The individual successfully completes an initial intensive rehabilitation, if prescribed, followed by a 1-year

period of strict compliance with aftercare requirements, regular and frequent participation in meetings with Alcoholics Anonymous or a similar organization, and abstention from alcohol.

(b) Submission of a request for requalification includes a mental health evaluation and a favorable prognosis by the CMA.

(c) The certifying official and reviewing official must document that they have full trust and confidence in the individual’s reliability.

(2) Alcohol Abuse. An individual disqualified or permanently decertified for abusing alcohol, but who is not alcohol dependent, may be requalified for BPRP duties after meeting the following conditions:

(a) The individual successfully completes a minimum 180-day rehabilitation program or treatment regimen, prescribed by or acceptable to the CMA, and demonstrates positive changes in job reliability and lifestyle.

(b) Submission of a request for requalification includes a favorable prognosis by the CMA.

(3) Drug Abuse. Individuals disqualified or permanently decertified for drug abuse are generally ineligible for requalification. Under extraordinary circumstances that the reviewing official believes warrant consideration for requalification, he or she may submit a written deviation request to CNO (N09N2). In order to be considered for requalification in the BPRP, the following must occur:

(a) The individual successfully completes a prescribed drug treatment program approved by the CMA, including, but not limited to, rehabilitation followed by strict compliance with aftercare requirements without recurrence of abuse.

(b) The individual must receive a favorable prognosis by a duly qualified medical professional.

(c) The certifying official and reviewing official must document that they have full trust and confidence in the individual’s reliability.

CHAPTER 4
CONTROL AND INVENTORY OF BIOLOGICAL SELECT AGENTS AND TOXINS (BSAT)

1. General

a. This chapter provides guidance for control and inventory of BSAT. Heads of contracting activities will ensure that provisions of this chapter are implemented by contractually binding agreements.

b. All BSAT inventory will be accounted for as either long term storage or working stock.

(1) Long term storage is BSAT that is not in active use. This includes BSAT scheduled to be used in the long term to support ongoing research protocols, test plans, projects, or studies and BSAT retained for anticipated research, or as reference stock.

(2) Working stock is BSAT in active use or scheduled to be used in the near term (not to exceed 6 months) to support ongoing research protocols, test plans, projects, or studies.

c. All facilities located within the United States (CONUS facilities) using, possessing, transferring, or receiving BSAT must be registered and operate per reference (e).

2. Responsibilities

a. Commanders and directors shall:

(1) Ensure that the appointed responsible official, alternate responsible official, and biological storage custodians oversee the implementation of this chapter. This includes the drafting of a facility specific BSAT inventory management SOP or internal operation procedure (IOP), which will:

(a) Ensure BSATs are maintained under a system of records that provides an audit trail of BSAT custody from receipt to destruction or transfer.

(b) Establish procedures to ensure that all BSAT within a facility are for current or future scientific purposes or historical value and can be safely and securely handled and stored.

(2) Verify and certify by memorandum that the required 100 percent annual inventory has been conducted. The certification memorandum will be forwarded through command channels to OPNAV (N462), 716 Sicard Street, Suite 104, Room 45, Washington, DC 20373-5802.

b. Responsible officials shall:

(1) Account for long term storage of BSAT by conducting a BSAT inventory annually. This may be accomplished by the responsible official, principal investigator (PI), or designee during a single inventory or conducted in increments spread over the calendar year and must be accounted for in the entity's inventory management system.

(2) Establish a standardized procedure to account for working stock BSAT and establish a program to conduct annual audits of each PI's working stock BSAT by auditing at least 25 percent of PIs each quarter. Each PI will be audited at least once annually. A disinterested person, not the PI or personnel under the PI, will conduct these audits. 100 percent of laboratory records (transfers, destructions, inventories, lab notebooks, etc.) will be reviewed for consistency and accountability. For each PI being audited, a selection of at least 25 percent of laboratory records will be verified against physical working stock BSATs at the time of audit. The results of each audit will be documented to include reviews and corrective actions taken to address inconsistencies noted during the audit. Reviews will determine if inconsistencies constitute a suspected or confirmed theft, loss, or release of BSAT.

(3) Ensure that at a minimum: BSAT with no current or future scientific purpose or historical value are destroyed or transferred; quantities of long-term storage stock do not exceed safe and secure storage capacities; and research protocols support the safe and secure maximum quantities and concentration of each BSAT grown at a given time as reported on APHIS/CDC Form 1 Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins.

(4) Contract organizations will designate, in writing, contractor personnel to perform the duties and responsibilities of the responsible official, custodian, and alternates, and submit their names to the responsible contracting officer and to the DoD accountability manager for schedule 1 chemicals. This requirement will be included in the biological surety contract clauses.

3. BSAT Inventory Management

a. The site specific BSAT inventory management SOP or IOP will include at a minimum:

(1) Instructions for completing APHIS/CDC Form 2 Guidance Document for Request to Transfer Select Agents and Toxins for transfer of BSAT.

(2) Methods for reporting and documenting agent use, transfer, or destruction to the responsible official.

(3) Documentation of BSAT destruction.

(4) Record keeping instructions.

(5) Frequency of inventories.

(6) Method of resolving inventory discrepancies.

b. Inventory management and custodial records consist of a combination of inventories, shipping, and transfer documents, location records, destruction documents, and other documents as directed by the responsible official. Laboratory notebooks will be used as part of the documentation.

4. Records Retention. The transferring facility will retain a copy of the completed APHIS/CDC Form 2 for a period of 5 years after the date of shipment. The receiving facility will retain a copy of the completed APHIS/CDC Form 2 for a period of 5 years after the agents are consumed or destroyed.

5. Transfer of BSAT

a. Navy facilities may provide DoD or Navy BSAT to other DoD components, who will assume responsibility for the BSAT

under DoD guidance and their own component regulations. Transfer may be to the other DoD component's contractor, at the DoD component's request, and will be secured under the DoD component's responsibility. Transfer of the BSAT will be per Federal regulations, as applicable. No further Navy oversight of the transferred BSAT is required.

b. Navy facilities may provide DoD or Navy BSAT to other U.S. Governmental agencies in support of the recipient governmental agency's mission. Transfer may be to the other agency's contractor, at the government agency's request. For example, Navy BSAT may be transferred to a CDC and prevention designated BSAT reference repository, to support a USDA research program, or to the Federal Bureau of Investigations (FBI) when required for forensic analysis. Transfer of the BSAT will follow Federal regulations. No further Navy oversight of the transferred BSAT is required.

c. Navy facilities will not provide DoD or Navy BSAT in any other circumstances (including cooperative research and development agreements, small business innovative research agreements, or to governmental agencies for a DoD purpose), unless approval has been received from DoD, ATSD(NCB). This approval is requested through OPNAV (N462) via the appropriate chain of command. 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 if any surety and security measures are required for the recipients beyond those required by Federal regulations.

d. Export control requirements for BSAT will be implemented per reference (i).

e. This chapter only addresses procedures for transfer of BSAT based on their status in the biological surety program. This chapter does not provide independent authority to transfer DoD property; transfers must be done under the provisions of defense financial management regulations or other substantive legal authority.

6. Annual Reporting on Contractor Facilities

a. Navy BSAT facilities utilizing contractor facilities will generate an annual report of all contracts requiring the

use of Navy-furnished BSAT in contractor facilities during the past fiscal year (1 October to 30 September), including other service or agency contracts supported with Navy-furnished BSAT. Reports will include, as a minimum, the following information:

(1) Name of contractor and contract number.

(2) Name(s) of PIs and responsible officials.

(3) Name(s) of DoD-provided BSAT and type and number of storage containers.

(4) Purpose of contract.

(5) Duration of contract.

(6) Dates of most recent biological surety inspection.

b. Annual reports will include known cases of contract denial or revocation with names of contractors and reasons for the action.

c. The reports will be maintained by the Navy BSAT facility for 3 years.

7. Serious Incident Reporting Suspected or confirmed theft, loss, or release of BSAT will be reported per chapter 5 and references (f) and (g), part 73.

CHAPTER 5
BIOLOGICAL MISHAP OR INCIDENT RESPONSE

1. General

a. A biological mishap or incident response encompasses those mitigating actions taken to save lives, preserve health and safety, protect the environment, secure BSAT, and protect property in the event of a biological accident or incident.

b. Commanders and directors of facilities with a biological surety mission will establish plans to address biological mishaps and incidents as identified in this chapter, references (g), part 73, (i), and (j). These plans may be stand-alone or incorporated into an overall installation emergency response plan.

2. Biological Accident or Incident Response Planning

a. Plans will specifically address response to natural disasters, such as severe weather and earthquakes and response to incidents during movement or transportation of BSAT.

b. Facilities and installations will coordinate plans with external agencies (local, regional, State, or Federal) that provide support identified in the plans. Facilities will coordinate any changes to the plan that affect external support with the affected external agencies.

c. Navy facilities will forward biological accident and incident response plans to the responsible Navy region for review and approval.

3. Reporting of Biological Accidents or Incidents

a. Facility commanders or directors shall report biological incidents as soon as possible, and in no case later than 3 hours after the event is known, per reference (j). Notification shall not be delayed due to lack of detailed information. Facility commanders or directors will make parallel notification to intermediate commands as directed by their higher headquarters.

b. OPNAV (N46) shall notify the Director of Security, CI&S, USD(I), as soon as possible, and in no case later than 24 hours after the accident or incident is reported. This reporting requirement may be delegated to the Navy Operations Center.

c. Facility commanders or directors shall also report biological mishaps per the procedures for biological defense mishaps per centers for APHIS/CDC following Federal requirements.

4. Exercise Program

a. Facilities and installations will conduct exercises and drills of emergency plans. Commanders and directors will ensure that exercises periodically integrate safety and security responses (security exercises periodically involve lab safety procedures and lab safety drills to include security force actions).

b. Facilities and installations will include the participation of external agencies that support emergency plans in an exercise at least once every 2 years.

(1) The intended level of participation is for the external agency to exercise planned support; the minimum level of participation is as an observer of an exercise. The level of participation will be documented in the exercise after-action report.

(2) If the external support agencies are unable or unwilling to participate in exercises, the facility or installation will re-evaluate the plan to determine if revisions are appropriate, and provide the chain of command the results of that re-evaluation. An operational risk assessment will be conducted to determine if non-support by external agencies create or increase physical security or personnel protection risks.

c. Commanders and directors will ensure that “lessons learned” from exercises are validated and documented in written after action reports. A copy of the after-action report shall be provided to the regional commander. Commanders and directors will develop programs to ensure timely remedial actions are taken to correct shortcomings discovered during exercises, and

to update local SOPs and IOPs, as appropriate. Records and reports will be maintained for 5 years and then adjudicated according to appropriate administrative instructions.

CHAPTER 6
BIOLOGICAL SELECT AGENT AND TOXIN (BSAT) SAFETY AND OCCUPATIONAL HEALTH PROGRAM

1. General. The main purpose of the BSAT Safety and Occupational Health Program is to provide maximum protection to workers, the environment, and the surrounding communities, consistent with operational requirements, including applicable national, state, and local regulations. Reference (i) provides general safety program guidance. Reference (j) provides comprehensive guidance on the establishment and maintenance of structured biological safety programs, mishap risk management, biological risk assessments to determine biological (bio) safety levels (BSLs) and safety controls to protect employees and members of the public from the hazards associated with infectious agents and toxins (IAT), including, but not limited to, BSATs from microbiological activities.

a. The areas of responsibility for occupational safety and health of laboratory employees conducting biological operations include, but are not limited to, the use and safe handling of biohazardous materials, agents, or their components (e.g., microbial agents, bloodborne pathogens, recombinant deoxyribonucleic acid (DNA), agricultural pathogens, and human or primate cell cultures) and research proposals and activities concerning animal or human subjects.

b. This section applies to workers, hosted visitors, students, participating guests, contractors, subcontractors, and supplemental personnel where Navy has management control.

2. Biosafety. For research involving microbial agents, four BSLs (BSL 1 through BSL 4) of containment have been established and are described in the current edition of reference (k). The purpose of containment is to reduce or eliminate exposure of laboratory workers, visitors, and other persons, and the environment to potentially biohazardous agents. Containment has been classified into a set of standard work practices that are generally used in microbiological laboratories and special procedures, equipment, and laboratory installations that provide physical barriers that are applied in varying degrees according to the estimated biohazard.

3. Actions

a. Commanders and directors shall establish a BSAT safety and occupational health program per references (e) and (j).

b. Commanders and directors shall conduct a hazard analysis for each lab operation involving BSAT (total operations and BSAT analysis). Supporting industrial hygiene will conduct health hazard inventories and hazard exposure assessments of other associated lab hazards. Material safety data sheets (MSDSs) will be made available and used in the lab (or the equivalent if MSDSs are not available) for all BSATs.

c. Biological research and operations at Navy laboratories shall be limited to BSLs 1, 2, and 3, as defined by CDC, APHIS, and NIH. Activities that require BSL 4 precautions are prohibited. Research operations may involve work with specific microbial (e.g., risk groups 1 through 3) agents, human tissue or body fluids, human or primate cell culture lines, or animals.

CHAPTER 7
SHIPPING, TRANSPORT, AND RECEIVING OF BSAT

1. General. The procedures listed in this chapter apply to the transportation of BSAT material originating from Navy sources. These procedures do not apply to BSAT material that originates from non-U.S. Navy sources.

2. Administrative Procedures

a. The following administrative procedures shall be followed for all Navy BSAT shipments regardless of shipping mode.

(1) Military ground transportation.

(2) Military air transportation (e.g., MILAIR).

(3) Commercial ground transportation (e.g., Federal Express, other carrier or service that meets the requirements of this chapter).

(4) Commercial air transportation (e.g., Federal Express or other carrier or service that meets the requirements of this chapter).

b. All BSAT shipments from Navy organizations must be prepared and executed using all applicable international, Federal, DoD, Navy, and State regulations, policies, and guidance documents.

c. All BSAT shipments shall be considered at least “FOR OFFICIAL USE ONLY”. Shippers will plan movement’s per references (a), (e), (g), part 71.54, and (h), part 121; 15 CFR, parts 730 through 774; and 49 CFR, parts 171 through 180, International Air Transportation Association regulations, International Civil Aviation Organization regulations, DoD Directive 4500.09E (Transportation and Traffic Management, 11 September 2007), reference (l), and local procedure to include risk assessment, mode of shipment, and security and emergency assistance in order to reasonably ensure safety and security of personnel and material. This will include operational security

considerations, protecting against release to public, which may result in harm to naval operations, personnel, or the surrounding community.

d. All BSAT shipments will be addressed to a specific person at destination and not addressed to a department or office (e.g., receiving department).

e. All BSAT shipments must remain under continuous surveillance prior to, during, and after change(s) of possession following this chapter's procedures.

f. Organizations will capture and report all additional shipping costs incurred through command channels to their respective Navy comptroller.

g. Shipments on behalf of the Navy, to other organizations, or services will be shipped following the more stringent transportation standard between the two organizations.

h. Movement of BSAT on DoD installations will be kept to a minimum, consistent with operational and safety requirements and local procedures.

3. Emergency Notification. Report BSAT loss, theft, mishaps, or incidents per reference (g), part 73.19, and other local procedures and requirements.

4. Package Receipt. In addition to the requirements of reference (e), Navy organizations will comply with the following:

a. Package must be received by a BPRP enrolled individual.

b. Package must be inspected for damage or tampering and appropriate action taken if leakage or tampering is found, including notification of the responsible official.

c. Secure package at all times to prevent unauthorized access after receipt.

d. Promptly notify the shipper via telephone, fax, or email that the BSAT shipment has been received.

e. Within 48 hours, open and inventory the package, and notify shipper via APHIS/CDC Form 2 of receipt of complete package.

f. If shipment is not received on the day expected, notification must be made to the shipper by close of business on the day that package has not arrived so they may take appropriate action to locate the package.

5. Closeout Report

a. Shippers will coordinate with receiving facility to obtain closeout reports from shipment.

b. Receivers of Navy BSAT shipments are required to promptly notify the Navy shipper via telephone, fax, or e-mail that the package has been received.

6. Military Ground Transportation

a. Military ground transport requirements include:

(1) Two technically qualified, trained, and properly equipped escort personnel enrolled in BPRP.

(2) Maintain chain of custody.

(3) Maintain constant surveillance of the package by appropriate escort personnel. The package will be maintained within 25 feet from at least one escort at all times.

(4) Escort personnel will be trained and qualified to transport hazard class 6.1 and 6.2 material.

(5) Emergency response plan is in place and escorts have means to transmit a duress message via hand-held radio or cellular telephone to the shipping facility and local emergency response agencies.

(6) Provisions are made for tracking the package in transit.

(7) Shipment and written movement plan have been approved by the first O-6 in the chain of command. Movement plan must include the following:

b. Current risk assessment, including known threats and hazards.

c. Appropriate security measures, to include mode of shipment, availability of security resources, and source and availability of emergency assistance. All reasonable precautions shall be taken to ensure safety and security of personnel and the BSAT.

d. Safety and health hazards from BSAT, to include first aid and self or buddy aid procedures.

e. Escort responsibilities, including those of custody, security, and safety.

f. Communications procedures and reporting requirements.

g. BSAT labeling and placard requirements.

h. Procedures for coping with possible emergencies during movement, to include procedures for decontaminating equipment, materials, and personnel.

i. Safe and adequate procedures for maintaining continued surveillance during rest stops or halts in movement.

j. Procedures for obtaining additional security support.

7. Military Air Transportation

a. Ground legs of military air transportation of BSAT must comply with the provisions of paragraph 6 above. All MILAIR transportation of BSAT packages will comply with requirements outlined in reference (l).

b. Two technically qualified, trained, and properly equipped escort personnel enrolled in BPRP will:

(1) Maintain custody of package prior to loading on aircraft;

(2) Escort government air transport of BSAT; and

(3) Regain package custody promptly upon unloading of aircraft.

8. Commercial Ground Transportation. BSAT shipments must be performed by a DoD-approved carrier that maintains positive control, ensures chain of custody, and complies with the following as a minimum:

a. Carrier must be certified by Department of Transportation or state government to handle hazardous materials (hazmat) classes 6.1 (poisons) and 6.2 (infectious substances).

b. Two hazmat qualified drivers are required with at least one driver in the truck (not in sleeper berth) or within 25 feet of the vehicle (with an unobstructed view) at all times.

c. For BSAT shipment within CONUS, an alert button is required on vehicle that meets defense transportation tracking system (DTTS) qualifications. The vehicle requires continuous attendance and surveillance by two secret cleared drivers (protective security service).

d. For commercial OCONUS ground transport, comply with paragraphs 8a through 8c above, with the exception of DTTS, per host nation regulations that ensure positive control and chain of custody during transport.

9. Commercial Air Transportation. Ground legs of air transportation of BSAT must comply with the provisions of paragraph 8 above. Commercial air carrier has established security policies that include as a minimum:

a. Background checks of all employees involved in transportation of cargo.

b. Package security procedures that include scanning or tracking of the cargo throughout their system from pick-up, trans-shipment points, and final delivery.

c. Security measures that prevent unauthorized access to vehicles, trans-shipment facilities, and aircraft.

d. Regular and random security audits conducted by their internal security offices.

e. Package is under constant surveillance until loaded on aircraft at departure airport.

f. Package is under constant surveillance when unloaded from aircraft onto ground transportation at receiving airport.

g. Package is segregated from other cargo on the aircraft.

10. Exemptions

a. Given the grave consequences to health and operational readiness by a delay in confirmation of clinical specimens or environmental samples, presumptively identified clinical samples and environmental specimens are exempt from the provisions of this guidance; presumptively identified BSAT shipments are considered reasonably suspected of containing BSAT and must be shipped per with 49 CFR, part 173, and reference (e) and must be executed per all other applicable regulations.

b. Incoming shipments from non-navy facilities.

c. Biological agents or toxins that are exempt from references (e), (g), parts 73.5 and 73.6, and (h), part 121.6. See: http://www.selectagents.gov/Regulations.html, http://www.selectagents.gov/Permissible%20Toxin%20Amounts.html.

11. Waivers. Authority to waive the requirements of paragraph 1 to transport confirmed isolates from diagnostic, clinical laboratory specimens, or operational environmental samples is granted to the first general officer or designated O-6 within the affected unit's chain of command. The decision to waive must be based on medical (failure to do so will result in negative impact on human health), public health (failure to do so would delay timely reference lab characterization of potential epidemic agent(s) and necessary containment response, e.g., highly pathogenic avian influenza samples) or operational (failure to do so will result in mission failure) imperatives. Minimum security measures employed for transport must be most secure alternative available and ensure active monitoring and

immediate notification of delivery. Additionally, the shipment must comply with all other applicable regulations (see paragraphs 2 through 5).

APPENDIX A
CATEGORIES OF BIOLOGICAL AGENTS

1. General. The Navy Biological Surety Program applies to BSAT.

2. BSAT. For the purposes of this regulation, BSAT are biological agents and toxins selected by the DHHS and the USDA that present a high bio-terrorism 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 of select agents and toxins are reviewed and updated by DHHS, CDC, USDA, and APHIS, and are found in references (e), (g), part 73, and (h), part 121. These agents and toxins are also known as high consequence non-overlap agents and toxins, overlap agents and toxins, and listed plant pathogens. Overlap select agents are subject to regulation by both APHIS and CDC. The lists include specific genetic elements, recombinant nucleic acids, and recombinant organisms. Exclusions to the lists are identified and are not considered as select agents or toxins; these exclusions are likewise not considered BSAT. (See http://www.selectagents.gov, more specifically: http://www.selectagents.gov/Regulations.html, and http://www.selectagents.gov/Select%20Agents%20and%20Toxins.html)

3. Non-surety Biological Materiel

a. Biological Agents (“non-select”). Biological surety program provisions in this regulation apply only to BSAT, and are not applicable to other biological agents and toxins.

b. Recovered Biological Warfare Material

(1) Biological surety program provisions in this regulation are not applicable to recovered biological warfare material. Guidance for recovered biological warfare materiel will be provided by the ASA(I&E).

(2) Use of recovered biological warfare material for destruction research (such as in a prototype or test destruction device) is not subject to the biological surety program.

(3) Any biological select agent or toxin fill removed from the recovered biological warfare material, which is subsequently used for research biological defense purposes, becomes subject to the biological surety program provisions in this regulation.

4. Special Instructions for Ricin and Saxitoxin. Ricin and saxitoxin are accountable under the CWC as schedule 1 chemicals. Any production, retention, consumption, transfer, and receipt of ricin and saxitoxin must be per the provisions of appendix C even when ricin or saxitoxin might otherwise be exempt from this regulation.

APPENDIX B
APPLICABLE PROVISIONS OF FEDERAL LAW AND REGULATIONS

1. Chapter 10, Section 175, of title 18, United States Code (U.S.C.), as amended by Public Law 107-56 (Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA Patriot Act) Act of 2001). Section 175b of title 18, U.S.C., prohibits possession of select agents by restricted persons, and defines "restricted person" (see http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi?IPaddress=162.140.64.88&filename=publ056.pdf&directory=/disk3/wais/data/107_cong_public_laws). One type of "restricted person" is a national of a country currently determined by the Secretary of State to repeatedly have provided support for acts of international terrorism, and who has not been lawfully admitted into the United States for permanent residence. The Secretary of State determination can be found in the most current "State Sponsors of Terrorism" at http://www.state.gov/s/ct/c14151.htm, in the section or link "Overview of State-Sponsored Terrorism" (http://www.state.gov/s/ct/rls/crt/).

2. Reference (e) sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to plant health or to plant products. The purpose of this part is to ensure the safe handling of such agents or toxins, and to protect against the use of such agents or toxins in domestic or international terrorism or for any other criminal purpose. (See http://www.selectagents.gov/resources/7%20CFR%20331.pdf)

3. Reference (g), part 73, establishes requirements regarding possession and use in the United States, receipt from outside the United States, and transfer within the United States, of select agents and toxins. This includes requirements concerning registration, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications. (See http://www.selectagents.gov/resources/42%20CFR%2073.pdf)

4. Reference (h), part 121, sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe

threat to public health and safety, to animal health, and to animal products.
(See http://www.selectagents.gov/resources/9%20CFR%20121.pdf)

APPENDIX C
CHEMICAL WEAPONS CONVENTION (CWC) REQUIREMENTS FOR RICIN AND SAXITOXIN

1. General. Ricin and saxitoxin are accountable under the CWC as schedule 1 chemicals.

2. Responsibilities

a. Commander, Army Materiel Command (AMC) is designated the DoD accountability manager for schedule 1 chemicals. Responsibilities of the accountability manager include monitoring, tracking, and reporting of DoD production, retention, consumption, transfer, and receipt of schedule 1 chemicals. Commander, AMC also operates the single small scale facility (SSSF) for production of schedule 1 chemicals for research, medical, pharmaceutical, or protective purposes, per the applicable provisions of the CWC.

b. Heads of contracting activities shall ensure that provisions of this appendix are implemented by contractually binding agreements.

3. Ricin and Saxitoxin Obtained from the SSSF

a. DoD organizations and their contractors must obtain ricin and saxitoxin from the SSSF if used for protective purposes (those purposes directly related to protection against toxic chemicals and to protection against chemical weapons, including chemical defensive training).

b. For other purposes permitted under the CWC (research, medical, or pharmaceutical), DoD organizations and their contractors may acquire ricin and saxitoxin from the SSSF, or they may synthesize or acquire ricin and saxitoxin as described in paragraph 5 below.

c. Submit requests for ricin and saxitoxin from the SSSF to the DoD accountability manager for schedule 1 chemicals to: Director, Edgewood Chemical Biological Center, Attention: AMSSB-RCB/DoD Accountability Manager, E5183 Blackhawk Road, Aberdeen Proving Ground, MD 21010-5424). The Army retains ownership and control of ricin and saxitoxin provided by the

SSSF to DoD organizations and their contractors. Production, transportation, and overhead costs incurred by AMC will be reimbursed by the requesting organization.

4. Production. DoD organizations (other than the SSSF) and their contractors are authorized to produce (synthesize) ricin and saxitoxin for research, medical, or pharmaceutical purposes only. Concurrence of the DoD accountability manager for schedule 1 chemicals is required for production of ricin or saxitoxin that exceeds 100 milligrams per year. Submit requests at least 60 days before the first production and include the following information:

a. The location(s) where production will take place, including building and room numbers and mailing address(es).

b. The quantities planned to be produced and consumed per year for the duration of the production, and the purpose of consumption (research, medical, or pharmaceutical, with a brief description of the projects).

5. Other Transfer or Acquisition. DoD organizations and their contractors may transfer or acquire ricin or saxitoxin for research, medical, or pharmaceutical purposes from sources other than the SSSF. Concurrence of the DoD accountability manager for schedule 1 chemicals is required for acquisition or transfer of ricin or saxitoxin that exceeds 100 milligrams of ricin or saxitoxin per year. Submit approval requests at least 60 days before the transfer or acquisition and include the name of the source and recipient facilities, the quantity of ricin and saxitoxin transferred or acquired, and a brief description of the project(s), specifying the permitted purpose under the CWC (research, medical, or pharmaceutical).

6. Requests Associated With Non-DoD Work. Requests from any organization (DoD or non-DoD for use of Army produced saxitoxin or ricin for any non-DoD work will be made to the ATSD(NCB). Army will provide saxitoxin and ricin per ATSD (NCB) guidance.

7. Reporting Requirements. DoD organizations and their contractors will provide semiannual reports of all supported organizations (including government, industry, academic, and contractor facilities, but not including the SSSF) that possess,

acquire, produce, consume, store, or transfer ricin and saxitoxin. Reports are not required if the total quantity of ricin or saxitoxin under the control of the organization does not exceed 100 milligrams at any time during the calendar year.

a. One report will be prepared and submitted by 1 February to address the entire previous calendar year; an interim report will be submitted by 1 August for the current calendar year (through 30 June). The report will include the following information for each facility and each toxin:

(1) Facility name, address, and point of contact information for the PI.

(2) Maximum total quantity stored at any time during the reporting period.

(3) Quantity stored at the facility at the end of the reporting period.

(4) Quantity consumed during the reporting period, and the purpose of consumption (research, medical, pharmaceutical, or protective).

(5) Quantity produced or acquired during the reporting period.

(6) Destination, quantity, and purpose for ricin and saxitoxin transferred to other facilities. Provide contract numbers for other service or agency contracts supported with chemical agent.

(7) For contractor facilities, the name of contractor and contract number, duration of contract, and the date of most recent survey of the contractor's facility and surveying agency.

b. Reports will be sent to the DoD accountability officer for schedule 1 chemicals at: Director, Edgewood Chemical Biological Center, Attention: AMSSB-RCB-C, DoD Accountability Manager, E5183 Blackhawk Road, Aberdeen Proving Ground, MD 21010-5424).

APPENDIX D
BSAT CFRs, U.S. CODES, AND PUBLICATIONS

1. References (e) and (h), part 121, “Animal and Plant Health Inspection Service; Agricultural Bioterrorism Protection Act of 2002; Possession, Use and Transfer of Biological Agents and Toxins; Final Rule”.

2. Reference (h), chapter 1, and subchapter A, part 104, and part 122, “Animals and Animal Products, Animal and Plant Health Inspection Service, Department of Agriculture” (Animal Welfare Act of 1966); and “Animal Welfare,” parts 1, 2, and 3 (P.L. 89544); “Permits for Biological Products”; and “Organisms and Vectors.”

3. 15 CFR 730-744 (particularly 742, 744, 744B), "Exportation Administration Regulation."

4. 21 CFR 50, "Protection of Human Subjects."

5. 21 CFR 56, "Institutional Review Boards."

6. 21 CFR 600-680, "Biological Products."

7. 29 CFR 1910.1030, "Bloodborne Pathogens," including Needlestick Safety and Prevention Act, January 18, 2001.

8. 29 CFR 1910.1200, “The Hazard Communication Standard.”

9. 29 CFR 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories."

10. 29 CFR 1630, “Equal Employment Provisions of the Americans with Disabilities Act.”

11. 29 CFR 1910.1210, “Hazard Communication.”

12. Reference (g), part 2, “Confidentiality of Alcohol and Drug Abuse Patient Treatment Records.”

13. Reference (g), part 71.54, "Etiological Agents, Hosts and Vectors."

14. Reference (g), part 72, "Interstate Shipment of Etiological Agents."

15. Reference (g), part 73, “Select Agents and Toxins,” Department of Health and Human Services, Final Rule.

16. 45 CFR 46, “Protection of Human Subjects: The Common Rule, Subpart A, B, C, and D.”

17. 49 CFR 100-185, 199, "Hazardous Materials Regulations: Toxins/Microbes," Subtitle B, Chapter I, "Research and Special Programs Administration, DOT."

18. 66 CFR 1146, “NIH Guidelines for Research Involving Recombinant DNA Molecules,” Amendment effective 22 September 2009 (74 FR 48275).

19. 5 U.S.C. 7904, “Employee Assistance.”

20. 18 U.S.C. 175, “Prohibitions with respect to biological weapons.”

21. 29 U.S.C. 655, “Occupational Safety and Health Standards.”

22. 42 U.S.C. 126, “Equal Opportunity for Individuals with Disabilities."

23. 42 U.S.C. 290dd-2, “Confidentiality of Records.”

24. Defense Federal Acquisition Regulation Supplement, subparts 201.3 (“Agency Acquisition Regulations”) and 201.4 (“Deviations from the FAR”), current edition.

25. Defense Federal Acquisition Regulation Supplement, subparts 252.223-7004, “Drug-Free Work Force.”

26. DoD Directive 4500.09E of 11 Sep 2007.

27. DoD 5220.22-M, National Industrial Security Program Operating Manual, February 2006.

28. DoD 6025.18-R, DoD Health Information Privacy Regulation, January 2003.

29. Federal Acquisition Regulation, subparts 1.3 (“Agency Acquisition Regulations”) and 1.4 (“Deviations from the FAR”).

30. TM 38-250, Air Force Interservice Manual.

31. American Industrial Hygiene Association, Biosafety Reference Manual, 2nd edition, Publication #204-RC-95, (1995), pp. 175.

32. Seymour S. Block, Disinfection, Sterilization, and Preservation, 3rd edition, (Lea & Febiger Publishers, 1983), pp. 1053.

33. David Franz, U.S. Army Defense Against Toxin Weapons (U.S. Army Medical Research Institute of Infectious Diseases, Veterinary Corps, Fort Detrick, Fredrick, Maryland), MCMR-UIZ-B.

34. Guidelines (Draft) for Preventing the Transmission of Tuberculosis in Healthcare Facilities, current edition.

35. International Air Transportation Association (IATA) Dangerous Goods Regulations, Commercial Air

36. International Civil Aviation Organization (ICAO), Technical Instructions for the Safe Transport of Dangerous Goods by Air, Commercial Air

37. National Cancer Institute, Safety Standards for Research Involving Oncogenic Viruses, DHEW, Publication No. NIH 75-790 (1974).

38. NIOSH, Criteria for a Recommended Standard Occupational Exposure to Waste Anesthetic Gases and Vapors, DHEW Publication No. 77-140, March 1977.

39. NIOSH, Histoplasmosis: Protecting Workers at Risk, Publication No. 97-146, September 1997 (superseded by Publication No. 2005-19).

40. Navy Publication No. P-467; U. S. Army, U.S. Army Field Manual 3-9; and Air Force Manual No. 355-7: Potential Military.

41. U.S. Army, Medical Management of Biological Casualties Handbook, Current Ed., (U.S. Army Medical Research, Institute of Infectious Diseases, Fort Detrick, Fredrick Maryland, August 1996).

42. U.S. Department of Public Health, NIH, and PHS Policy on Humane Care and Use of Laboratory Animals, “Guide for the Care and Use of Laboratory Animals,” reprinted 1996.

43. Public Law 107-56, “Utilizing and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001,” October 26, 2001.

44. Public Law 107-188, “Public Health Security and Bioterrorism Response and Preparedness Act of 2002,” June 12, 2002.

APPENDIX E
GLOSSARY

1. Access. The freedom or ability to obtain and or make use of BSAT by any individual.

2. Accountability. The obligation to keep accurate records of property, documents, or funds. Accountability is concerned primarily with the records and does not necessarily imply actual possession.

3. Administrative Termination. Action taken when reliability is not in question to remove an individual from a duty position requiring BPRP certification to a position, either within or outside of the organization, not requiring BPRP certification.

4. 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 DoD, 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.

5. Alcohol Dependence. Psychological and or physiological reliance on alcohol as such reliance is defined in the current Diagnostic Statistical Manual (DSM) of the American Psychiatric Association.

6. Alcohol-Related Incident. Any substandard behavior or performance in which the consumption of alcohol by the individual is a contributing factor as determined by the certifying official with consultation from the CMA (e.g., intoxicated driving, domestic disturbances, assault, disorderly conduct, personal injury, failure to go to prescribed alcohol abuse counseling, or voluntary consumption of alcohol by an individual previously diagnosed as alcohol dependent, underage drinking).

7. Biological Agents. See appendix A.

8. BPRP Duty Position. A duty position as identified in chapter 3, paragraph 3 of this instruction. Individuals assigned to BPRP duty positions must be in the BPRP.

9. Biological Incident. Security event(s) involving unauthorized access or use of BSAT; attempts to steal, release, or divert BSAT outside physical security controls; or deliberate acts (terrorism or criminal) where required control of biological select agent or toxin is threatened or compromised.

10. Biological Mishap. An event in which the failure of laboratory facilities, equipment, or procedures appropriate to the level of potential pathogenicity of an IAT may allow the unintentional, potential exposure of humans or the laboratory environment to that agent.

11. Biological Safety. The application of risk assessment, safe practices, and containment equipment to protect researchers and other laboratory workers from exposure to infectious agents and facility barrier systems that prevent the release of an agent into the environment to ensure protection of the public health.

12. Biological Security. The application of physical security, select agent accountability, and personal reliability in an effort to prevent unauthorized access to BSAT.

13. Biological Surety. The combination of safety and security measures needed to prevent access to BSAT for use in domestic or international terrorism or for any other criminal (bioterrorism) purpose.

14. Biological Surety Inspection. An inspection of Navy organizations with biological agent surety missions, conducted by the naval MEDIG or ISIC, to determine their capability to accomplish biological agent missions in a safe and secure environment through examination of the following functional areas: mission operations, safety, security, surety management, emergency response, medical support, demilitarization, and external support.

15. Biological Surety Operation. Any operation that involves biological surety is a biological surety operation (e.g., storage, shipping, handling, maintenance, laboratory activities, surveillance, decontamination, disposal, and training).

16. Biological Safety Levels (BSL). Four levels which consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the operations performed and the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity.

17. Certification. A determination by a certifying official that an individual meets the personnel reliability criteria established for assignment to a BPRP position.

18. Certifying Official. The designated DoD military or civilian government employee having sufficient personal contact with all subordinate BPRP personnel to permit continual evaluation of their performance and reliability.

19. Competent Medical Authority (CMA). A U.S. physician, physician assistant, or nurse practitioner (military, civilian, or contractor) employed by or under contract or subcontract to the U.S. Government or a U.S. Government contractor. A CMA is someone who has been awarded clinical privileges for independent practice granted by the health care facility responsible for the provider's place of duty or if not privileged for independent practice (e.g., a physician assistant or nurse practitioner), then is supervised by an appropriately trained CMA physician who is privileged to practice independently. A CMA is someone who has been specifically trained as a CMA and appointed, in writing, by a medical treatment facility commander responsible for reviewing healthcare services or conducting clinical evaluations for purposes of the BPRP.

20. Continuing Evaluation. The process by which a BPRP-certified individual is observed and evaluated for compliance with reliability standards. This is an on-going process which considers duty performance, physical and psychological fitness, and on- and off-duty behavior and reliability on a consistent and frequent basis.

21. Contracting Organization. The organization that has primary responsibility for awarding, monitoring, administering, and ensuring compliance with a contract.

22. Custody. Responsibility for the control of, transfer and movement of, and access to BSAT.

23. Decontamination. The process of decreasing the amount of biological agent on any person, object, or area by absorbing, neutralizing, destroying, ventilating, or removing biological agents.

24. Disqualification. Determination by a certifying official prior to BPRP certification that an individual does not meet the reliability standards of the BPRP.

25. Drug and 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). For the purpose of this instruction, wrongful is defined as without legal justification or excuse, and includes use contrary to the direction of the manufacturer or prescribing healthcare provider, and use of any intoxicating substance not intended for human ingestion (e.g., glue and gasoline fumes). It also includes all drugs and substances on the Federal Illegal Drug List.

26. Drug and Substance Dependence. Psychological and or physiological reliance on a chemical or pharmacological agent as such reliance is defined in the current DSM of the American Psychiatric Association. This term does not include the continuing prescribed use of pharmaceuticals as part of the medical management of a chronic disease or medical condition.

27. Exclusion Area. A designated area immediately surrounding one or more receptacles in which biological agents are contained. Normally, the boundaries of an exclusion area are the walls, floor, and ceiling of a storage structure, secure container, or a barrier that establishes the boundary of the exclusion area (e.g., a fence). The inside of a biological agent secure container is an exclusion area. In the absence of positive preventive measures, access into the exclusion area constitutes access to biological agents.

28. Explosive Ordnance Disposal. The detection, identification, field evaluations, rendering safe, recovery, and final disposal of unexploded explosive ordnance or munitions.

29. Facility. Unless otherwise characterized (for example, medical treatment facility), for the purposes of this regulation "facility" refers to an organization or program whose mission requires the storage or use of BSAT, and the associated areas (laboratories or buildings) containing the BSAT.

30. Permanent Decertification. Determination by a certifying official after BPRP certification that an individual is no longer capable of meeting the reliability standards of the BPRP.

31. Personal Protective Equipment (PPE). Protective clothing and equipment used to protect an individual from the effects of biological agents.

32. Personnel Security Investigation (PSI). Any investigation required for determining the eligibility of DoD military or civilian personnel and contractor employees for access to classified information, acceptance, or retention in the Armed Forces, or assignment, and retention in, sensitive duties (e.g., BPRP). PRs are conducted at specified intervals for updating a previously completed PSI.

33. Potentially Disqualifying Information (PDI). Any information regarding an individual's physical, mental, or emotional status, conduct, or character, on- or off-duty, which may cast doubt about the individual's reliability or ability to perform biological duties.

34. Random Drug Testing. A program of drug abuse testing where each member of the testing population has an equal chance of being selected. Random testing may be either testing of designated individual occupying a specified area, element, or position, or random testing of those individuals based on a neutral criterion, such as a digit of the social security number. Individuals will be tested at a minimum for cocaine, marijuana, methamphetamines, opiates, and pphencyclidine.

35. Recovered Biological Warfare Materiel. Biological warfare material that was previously discarded, buried, or fired, and discovered either unexpectedly or during planned environmental restoration operations.

36. Reference Stock. The lowest passage (earliest culture) of a strain of microorganisms with a documented history and defined characteristics kept in a centralized collection; toxins with a known origin and history kept in a centralized location.

37. Responsible Official. An individual who has authority and responsibility to ensure requirements are met, is designated by the facility commander or director and is certified and approved by the DHHS and CDC or USDA and APHIS for access to BSAT. An official authorized to transfer and receive BSAT on behalf of the facility. The responsible official is also responsible for the implementation of BSAT inventory management procedures.

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

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

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

c. They are a fugitive from justice;

d. They are an unlawful user of any controlled substance;

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

f. They have been adjudicated as a mental defective or have been committed to any mental institution;

g. 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;

h. They have by court-martial received a dishonorable discharge, bad conduct discharge, or have been administratively separated with other than honorable condition discharge; and

i. For individuals who require CDC of APHIS registration for access to BSAT: an individual who has been denied such registration as a result of an FBI determination that the individual has met the "restricted person" criteria of section 175b of title 18, U.S.C. For individuals who require BPRP certification but do not require CDC of APHIS registration

39. Reviewing Official. The commander or commanding officer designated DoD military or civilian government employee responsible for BSAT operations or contracts at a level above (or overseeing) the certifying official, and responsible for monitoring the BPRP and reviewing designated BPRP actions.

40. Risk Group. Classification of microbiological agents based on their association with, and resulting severity of, disease in humans, promulgated by the NIH guidelines and World Health Organizations. Risk groups are used in the determination of proper determination of BSL.

41. Schedule 1 Chemicals. Those chemicals listed in schedule 1 of the CWC schedule of chemicals and other toxic chemicals or precursors that have been developed, produced, stockpiled or used as a chemical weapon; otherwise pose a high risk to the object and purpose of the CWC by virtue of its high potential for use in activities prohibited under the CWC because one or more of the following conditions is met:

a. It possesses a chemical structure closely related to that of other toxic chemicals listed in schedule 1, and has, or can be expected to have comparable properties;

b. It possesses such lethal or incapacitating toxicity as well as other properties that would enable it to be used as a chemical weapon; or

c. It may be used as a precursor in the final technological state of production of a toxic chemical listed in schedule 1, regardless of whether this stage takes place in facilities, in munitions, or otherwise; have little or no use for purposes not prohibited under the CWC.

42. Significant Medical Condition. Acute or chronic condition with a reasonable likelihood of recurrence, which may result in (a) an altered state of consciousness, (b) impaired judgment or

concentration, (c) increases risk of infection or impairment if exposed to biological agents, (d) impaired ability to safely wear PPE required for the biological surety position, or (e) inability to perform the physical requirements of the biological surety position, as substantiated by the CMA to the certifying official.

43. Suspension. Action taken when reliability is not in question to immediately remove an individual from BPRP duties due to information or situations causing a need for additional investigation without starting a decertification action. When suspended, an individual is not authorized to perform BPRP duties.

44. Temporary Decertification. Action taken by the Certifying Official when reliability is suspect to temporarily remove the individual for 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.

45. Trafficking. The selling of illegal drugs, or possession with the intent to sell illegal drugs.

46. Waiver/Exception. A temporary or permanent relief from specific policy requirements (with compensatory measures as required) of reference (a), BSAT, or this regulation, pending corrective action to conform to the instruction.

APPENDIX F
BSAT AND BPRP FORMS INSTRUCTIONS

1. Screening and Evaluation Record. OPNAV 5510/420 will be completed for each individual screened and evaluated for the BPRP.

2. BPRP Annual Report Form. Each BSAT facility will submit an OPNAV 3402/1 to CNO (N09N2) for the preceding calendar year, ending 31 December.

a. OPNAV 3402/1s will be received by CNO (N09N2) no later than 15 January. BSAT facilities shall verify receipt by phone call or email.

b. OPNAV 3402/1 will include BPRP certification, permanent decertification, and requalification statistics by facility and category of personnel. Cover letters shall include point of contact information for the report.

c. Since permanent decertification’s generally include more than one issue, the reason for permanent decertification action should be accounted for only once under the predominant issue.