DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
2000 NAVY PENTAGON
WASHINGTON, D.C. 20350-2000

IN REPLY REFER TO
OPNAVINST 5530.16
N3AT

JUL 20 2007

OPNAV INSTRUCTION 5530.16

From: Chief of Naval Operations

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

(a) DODI 5210.89
(b) DIA Threat Assessment to Biological Select Agents and Toxins (Annual Report, SECRET)
(c) OPNAVINST 5530.14D (Navy Physical Security and Law Enforcement Instruction)
(d) OPNAVINST 3300.53A (Navy Antiterrorism Program)
(e) DODD 5210.88
(f) DODI 5230.20 (Visits, Assignments, and Exchanges of Foreign Nationals)
(g) DOD-R 5200-2 (Personnel Security Program)
(h) DODD 2040.2 (International Transfers of Technology, Goods, Services, and Munitions)
(i) DODD 5010.38 (Management Control Program)
(j) DODI 5230.29 (Security and Policy Review of DOD Information for Public Release)
(k) SECNAVINST 5510.34A (Disclosure of Classified Military Information and Controlled Unclassified Information to Foreign Governments, International Organizations, and Foreign Representatives)
(l) OPNAVINST 3100.6H (Special Incident Reporting (OPREP-3) Navy Blue, and OPREP 3 Navy Unit SITREP Procedures)
(m) OPNAVINST 5100.23G (Navy Safety and Occupational Health (SOH) Program Manual)

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 (m). This instruction implements DOD physical security requirements pertaining to surety matters for

Biological Select Agents and Toxins (BSAT).

2. Scope

a. The policies herein pertain to preventing or mitigating hostile actions against Navy facilities with BSAT. References (a) and (b) 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. Requests for clarification should be addressed to the Chief of Naval Operations, Antiterrorism and Force Protection Branch (CNO N3AT).

3. Discussion

a. This is the first issuance of a Navy BSAT instruction.

(1) This instruction was developed in conjunction with reference (a) between 2003 to 2007. 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) and the Public Health Service (PHS). Other Departments provided information and are also listed in the CFR section of this instruction.

(2) There are currently two Navy facilities in the United States that have custody or possession of BSAT; Naval Surface Warfare Center (NSWC) Dahlgren, which reports to Naval Sea Systems Command (NAVSEA), and the Navy Medical Research Center (NMRC), which reports to the Bureau of Naval Medicine and Surgery (BUMED). The Navy may increase the number of facilities in the future, and other Navy facilities may gain access or possession of BSAT due to non-routine events. Navy facilities will provide the security required in this instruction upon receipt of BSAT.

(3) Currently, Naval District Washington (NDW) contains the two Navy BSAT facilities and is required to provide support to 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 Navy military, civilian, and contractors with access to BSAT.

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

c. The term commander within this instruction includes Type Commanders, Fleet Commanders, Regional Commanders, Installation/Ship/Squadron/Activity Commanding Officers, Officers in Charge, Directors, etc.

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 policies requires a request for a waiver/exception per reference (c). Mandatory policies include the words "shall, will, or must."

(2) Recommendations, although not mandatory in nature, provide a framework to better support mandatory policies, but are not within the purview of this instruction to mandate. Recommended procedures include the word "should."

(3) 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."

(4) 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. This instruction applies to all Navy laboratories and facilities that furnish, have custody of, or have possession of BSAT as described in Appendix II of reference (a), including Navy contractors and consultants that are provided BSAT by DOD.

b. Overseas facilities exempted from the provisions of 42 Code of Federal Regulations ((CFR) part 73), Public Law 107-188 and 7 CFR part 331 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 Chief of Naval Operations (CNO) is responsible for formulation and dissemination of Navy security policies.

(1) The Branch Head, Antiterrorism and Force Protection (CNO (N3AT)) under the Director, Information, Plans and Security Division (N3IPS) is the focal point for the security standards of BSAT. CNO (N3AT) is responsible for:

(a) Review and approval of all BSAT physical security waiver/exceptions. Waiver/exceptions shall be submitted per Chapter 2, paragraph 4. Waiver/exceptions shall be forwarded via the appropriate chain of command to CNO (N3AT). CNO (N3AT) will forward approved waiver/exceptions per reference (a). Wherever the mandatory security requirements of this instruction or reference (a) cannot be met, a waiver/exception shall be submitted to the CNO (N3AT). With the exception of the BSAT Biological Personnel Reliability Program (BPRP), only CNO (N3AT) has the authority for final review of waiver/exceptions to this instruction. The format of requests for waiver/exceptions to BSAT surety will be submitted immediately upon knowledge that a variance from policy exists.

(b) Establishing overall security policy for the Navy BSAT surety program.

(c) Resolving reclamas to surety inspections conducted by NAVIG or the Defense Threat Reduction Agency (DTRA).

(d) Monitoring the lists of DHHS and Department of Agriculture BSAT and informing 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.

(e) Reviewing for approval requests for saxitoxin and ricin submitted per Appendix D.

(f) Utilizing Army BSAT security classification guidance prescribed by DOD to develop, coordinate, and provide said guidance to Navy facilities holding BSAT. This will ensure consistency in classification and dissemination of information related to BSAT.

(g) Maintaining the BSAT Surety program waiver/exception file for two years after the waiver/exception has been cancelled or expired.

b. The Assistant for Information and Personnel Security Policy CNO (N09N2) exercises authority on behalf of the CNO as the program manager for the DON Personnel Security Program and Biological Personnel Reliability Program (BPRP) and is responsible for:

(1) Forwarding waiver/exceptions dealing with the BPRP to CNO (N09N2) via the appropriate chain of command and providing CNO (N3AT) a courtesy copy.

(2) Maintaining a BPRP waiver/exception file for three years.

(3) Preparing annual BPRP report (Appendix F), with courtesy copy forwarded to CNO (N3AT).

c. Bureau of Naval Medicine and Surgery (BUMED) is responsible for:

(1) Ensuring 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) Forwarding annual BPRP report (Appendix F) to CNO (NO9N2).

d. Naval Sea Systems Command (NAVSEA) is responsible for:

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

(2) Forwarding an annual BPRP report (Appendix F) to CNO NO9N2.

e. Commander Navy Installations Command (CNIC) is responsible for Program Objective Memorandum (POM) and Program Review (PR). 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/cost index for relative ranking in order to substantiate requested physical security upgrades.

f. Regional Commanders with BSAT facilities are responsible for appointing a regional Biological Surety Officer in writing.

g. Commanders/Directors of BSAT facilities are responsible for:

(1) Assignment in writing of a Biological Surety Officer per reference (e).

(2) Development and implementation of a BSAT surety program to fulfill requirements per reference (a).

(3) Assignment in writing of a Responsible Official (RO) and alternate RO to manage the day-to-day matters involved in the inventory management of BSAT.

(4) Assignment in writing of a Certifying Official (CO).

(5) Ensuring a Competent Medical Authority (CMA) is available to provide medical evaluation for BPRP personnel.

(6) Ensuring that a military, civilian, or contracted drug/substance abuse testing facility is available for administration of the BSAT Personnel Reliability Program (BPRP).

(7) Assignment in writing of a BSAT Waiver/Exception Control Official to provide oversight of physical security and BPRP waivers/exceptions.

6. Forms. OPNAV 5510/414 (S/N 0107LF0176700) Personnel Reliability Program (PRP) Screening and Evaluation Record is available for download from Navy Forms Online https://forms.daps.dla.mil/.

7. Implementation. BSAT facilities will ensure compliance to this instruction within 90 days of issuance.

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Deputy Chief of Naval
Operations (Information,
Plans, and Strategy)

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OPNAVINST 5530.16

JUL 20 2007

MINIMUM SECURITY STANDARDS FOR SAFEGUARDING BIOLOGICAL SELECT AGENTS AND TOXINS (BSAT)

Enclosure (1)

JUL 20 2007

RECORD OF CHANGES

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

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CHAPTER 1
INTRODUCTION AND SURETY GUIDANCE

1. Purpose

a. This instruction establishes Department of Navy (DON) policy, assigns responsibilities, and prescribes procedures for the Navy Biological Surety Program. It is Navy policy that Biological Select Agents and Toxins (BSAT) in the possession or 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 (RBWM) 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/director's program. Therefore, when a process is established that is neither prescribed nor prohibited by this regulation, the judgment of the commander/director shall take precedence. For purposes of this regulation, "Commander / 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/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/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 variance/waiver/exceptions to the policy in this regulation through command channels to CNO (N3AT), 2000 Navy Pentagon, Washington, DC 20350-2000.

(1) Requests for variance/waiver/exceptions will identify compensatory measures, as appropriate.

(2) A request for a variance/waiver/exception must include a plan of action and milestones (POA&M) to correct the circumstances requiring the variance/waiver/exception. In circumstances where it is not possible to correct the circumstances requiring the variance/waiver/exemption, such as 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 is, and 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.

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 accidents and incidents.

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

3. Initiation and Termination of Facility Surety Status

a. Commands wishing to establish new facilities where BSAT are used will, in addition to other approval processes and reviews, request approval during the planning stage through the appropriate chain of command. CNO (N3AT) will be consulted regarding security requirements.

b. Navy facilities that have terminated work with BSAT will notify CNO (N3AT) and CNO (N09N2) through their chain of command when BSATs are no longer maintained at the facility.

c. CNO (N3AT) 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 Assistant to the Secretary of Defense (Nuclear, Chemical, and Biological Matters) (ATSD(NCB)) with an info copy forwarded to CNO (N09N2). New facility approvals regarding BSAT shall be provided to CNO (N3AT) by the Echelon II command to which the BSAT facility reports with an info 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 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/director.

(3) Contractor Biological Surety Officers. 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 4.a.2.(a)-(e) above, with the exception of the BSAT Personnel Reliability Program (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 should 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 part-time or full-time duty depending on the contract requirements.

(a) Biological Surety/Safety Boards. The Commander/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/Director that establishes a board will document its composition and responsibilities (local Standing Operating Procedure (SOP), memorandum, or charter).

(b) Commander/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 three years.

b. Navy BSAT facilities co-located with other Service BSAT sites will develop Memoranda of Understanding (MOU) if local surety evaluations will be conducted that affect the Navy facility.

c. Reference (a) establishes the Center for Disease Control (CDC) and Animal and Plant Health Inspection Service (APHIS) requirement for periodic evaluation (24-36 months) for renewal of BSAT registration. Navy facilities shall ensure compliance.

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

1. General. Commanders/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/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 the installation security.

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

c. Commanders/Directors will coordinate and disseminate threat information and 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/Directors will utilize the DIA Threat Analysis (reference (b)) to develop their security plan.

e. CNO (N3AT) will provide support to DOD and DIA for updating reference (b).

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/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/director.

e. Security force drills will be conducted periodically at the discretion of the commander/director. Security drills that include BSAT facility restricted areas will be conducted periodically at the discretion of the commander/director. Access to restricted areas by security forces will be determined by the BSAT facility commander/director. Drills may be combined. Minimum periodicity recommended is semi-annual.

4. Biological Select Agent and Toxin (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 BSATs are located in Navy custody, or, in the case of overseas facilities exempted from the provisions of 42 CFR 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 variance/waiver/exceptions from policy with required compensatory measures are identified, endorsed, approved and corrected by the proper level of command.

b. Waivers and exceptions from physical security facilities, plans, procedures, equipment, and monitoring standards established in reference (a), this instruction, or any supplemental instruction shall be distinguished from waivers and exemptions from the BPRP. Commanders/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/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. Variances/waivers/exceptions shall be canceled unless the approving authority finds that they continue to be required and justified.

c. Approval of physical security BSAT variances/waivers/exceptions shall be granted by CNO (N3AT) who shall be the program manager for the BSAT waiver/exception program. Approval of BPRP variances/waivers/exemptions shall be granted by CNO (N09N2) who shall be the program manager for the BPRP waiver/exemption program.

(1) When considering a variance/waiver/exception request for a BSAT site, the site commander/director and subsequent endorsing and approving authorities shall review all other approved variances/waivers/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/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/exception shall be evaluated on a case-by-case basis, and blanket approvals are not authorized.

(3) A ten percent variance from all measurable standards is permitted and does not require the submission/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/exception

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

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

(3) Variance/waiver/exception submissions shall include a remediation plan for their elimination (except as previously noted for overseas facilities located on foreign national compounds), a threat and vulnerability assessment, and strategies for funding and implementing the solution. A risk assessment should also be conducted.

(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/exception report. The annual report shall be submitted through the appropriate chain of command for review by CNO (N3AT) and submitted by 31 January, with the cycle being from January to December. The report shall include all variances/waivers/exceptions.

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

Site Name:

Site POC: (email and telephone)

Type and number: (Variance, Waiver, Exception, Site UIC, indicate whether the variance/waiver/exception is to DOD or OPNAV policy, number-year. For example: Variance, DOD, N77777-001-07). This is a variance to DODI BSAT reference (a) regulations from command UIC N77777 and is the first variance for 2007. DOD and OPNAV variances/waivers/exceptions will be submitted separately and will have a separate numbering system. CNO (N3AT) is required to submit an annual DOD waiver/exception report to DOD. OPNAV will maintain Navy variance/waiver/exceptions.

BSAT requirement variances/waivers/exceptions from: Quote the DOD or OPNAV paragraph for the measure(s) that are not being met.

Variances/waivers/exceptions description: Describe how the security deviates from policy.

Compensatory Measure(s): List all Compensatory Measures that will be in place to compensate for the particular variances/waivers/exceptions from policy. A required physical security measure from reference (a) or this instruction is not to be considered a compensatory measure.

Corrective Actions: What specific project is planned to clear the variances/waivers/exceptions. What is the risk being assumed if the action is not corrected. Has a CNO Vulnerability Assessment been conducted from which corrective actions may be derived?

Funding: Indicate if the variances/waivers/exceptions are funded and identify POM/PR planning actions taken to remedy them.

Submission Date: Date of submission by the BSAT site.

Closed Date: For annual report use to identify when the variances/waivers/exceptions to policy were remediated.

g. A BSAT Site annual report shall be submitted through the appropriate chain of command to CNO (N3AT) in a list format that will include the Site POC, type of variances/waivers/exceptions, and number information for the calendar year only. This listing will substantiate all variances/waivers/exceptions valid during any part of that calendar year.

h. Variances/waivers/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 (PDF).

CHAPTER 3
BIOLOGICAL PERSONNEL RELIABILITY PROGRAM

1. General. This chapter establishes the Biological Personnel Reliability Program (BPRP) as a tool for commanders/directors to ensure that persons with access to biological select agents and toxins (BSAT) meet high standards of reliability. The BPRP includes:

a. Identifying positions with duties that afford access to BSAT.

b. Designating Certifying Officials who will certify the reliability and suitability of individuals for the BPRP.

c. Screening, evaluating, and certifying individuals for the BPRP.

d. Continuing evaluation in the form of periodic reinvestigations (PR), drug tests, and evaluation by supervisors, fellow workers, Certifying Officials and support agency personnel.

e. Removing an individual from BPRP duties due to medical restriction, suspension, disqualification, or administrative termination.

(1) Explosive ordnance disposal (EOD) and accident/incident response personnel are not required to meet the reliability standards of this chapter and will be given access to the BSAT facility only to the extent necessary to mitigate or eliminate a hazard during an emergency.

(2) Access by foreign nationals to BSAT during visits, assignments, and exchanges shall be processed per reference (f), reference (k), and the DON Foreign Disclosure Manual.

(3) The Privacy Act of 1974 will apply. Additionally, all personnel wishing to be considered for assignment to BPRP duties must provide written authority for release of information and records to allow the Certifying Officials and other authorized officials to review medical, personnel, and security files. If an individual does not grant permission for the

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records check and review, that person is not eligible for BPRP duties.

(4) At facilities or installations where individuals may be in multiple personnel reliability programs (e.g., the biological and chemical PRP), separate screening is not required for each program. Local procedures will address PRP processing for such individuals, to include addressing any program differences and training requirements specific to each program.

2. Identifying BPRP Duties. Commanders/Directors responsible for BSAT will identify each position that requires access to BSAT. Contractor organizations responsible for DOD-provided BSAT will recommend in writing to the CO those BPRP duty positions required for the operation of their facility. The Certifying Official is responsible for approving the list of positions. Although the following list is not all inclusive, BPRP duty positions are held by personnel who:

a. Require routine access to BSAT. In cases where access is required "routinely" but "infrequently" the commander/director will make the decision whether or not the person is granted full access or requires escort.

b. Are authorized to escort visitors to areas containing BSAT.

c. Control direct access to BSAT material.

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

e. Navy vehicle operators transporting BSAT.

3. Certifying and Reviewing Officials

a. Commanders/Directors in Charge will act as Certifying Officials and/or designate Certifying Officials in writing, to certify individuals' reliability and suitability for the BPRP. The decision to designate Certifying Officials and the selection of the individuals so designated is entirely at the discretion of the Commander/Director. The individuals selected, however, must meet high standards of integrity, trust, and personal

reliability. Optimally, the Certifying Official is a person in the individual's supervisory chain, such as a supervisor, team leader, laboratory manager, department head, or the deputy commander/director or equivalent. In the absence of the reviewing official (RO), the assistant reviewing official (ARO) assumes responsibilities of the RO. Certifying Officials, ROs and AROs must be military or DOD civilian personnel. DOD contract personnel shall not perform these duties.

b. Commanders/Directors who designate Certifying Officials become the RO for those Certifying Officials. In cases where the commander/director is a Certifying Official, then his or her rater becomes the RO.

c. Commanders/Directors may appoint BPRP monitors to assist COs in administering day-to-day functions. BPRP monitors may also be appointed at installation or activity level to administer the consolidated day-to-day functions of multiple COs. BPRP monitor duties include coordinating and disseminating BPRP information, indoctrinating and training personal reliability personnel on reliability objectives and procedures, and maintaining the biological duty position roster (BDPR). The BPRP monitor may be delegated the authority to recommend to medical restriction of an individual from performing duties with BSAT based on Competent Medical Authority (CMA) recommendation. However, in cases where the individual does not wish medical authorities to forward such personal information to the BPRP monitor, the Certifying Official must perform the medical restriction, and remove that person's access to BSAT.

d. Unless otherwise required, or unless directed by the commander/director, the position of Certifying Official or designated monitor is not a BPRP duty position.

e. A facility Commander/Director may be in a BPRP position. Such a Commanding Officer/Director will be certified by his/her rater, and the Commanding Officer/Director position listed on the facility Biological Duty Position Roster (BDPR). The reviewing official for such a Commander/Director will be the senior rater.

4. Biological Duty Position Roster (BDPR)

a. Each commander/director responsible for BSAT will

establish and maintain a BDPR. The BDPR will be used as a management tool by the Certifying Official and the commander/director. The BDPR identifies individuals certified and assigned by the Certifying Official to those BPRP duty positions established by the commander/director. Each Commander/Director responsible for BSAT will determine whether to institute a consolidated BDPR or separate BDPRs maintained by individual Certifying Officials.

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) Last four digits of social security number (SSN).

(5) BPRP job title and/or duty position.

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

(7) Names of Certifying Officials and ROs 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.

d. Certifying Officials will ensure that individuals who are administratively terminated or disqualified are removed from the BDPR.

e. At facilities or installations where individuals may be in multiple personnel reliability programs (e.g., the biological and chemical PRP), a combined duty positions roster may be established per local requirements.

5. Standards

a. Reliability Assessment

(1) Persons who do not meet BPRP standards will not perform BPRP duties. The Certifying Official will make a judgment on the reliability and suitability of an individual for a BPRP duty position. In the absence of mandatory disqualifying factors, the Certifying Official will consider both affirmative qualifying factors and potentially disqualifying factors in determining reliability and suitability. 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 qualify an individual for, or to disqualify an individual from, the BPRP is the responsibility of the Certifying Official. No one will be entered into the BPRP until the Certifying Official screens and certifies the individual as reliable and suitable.

(2) Certifying Officials will:

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

(b) Continuously evaluate personnel assigned to BPRP duty positions, per SECNAV M-5510.30, Chapter 10.

(c) Suspend from BPRP duties any individual whose reliability becomes suspect. If the individual being suspended is a contracted employee, the Certifying Official will direct the contractor to remove the individual from BPRP duties. The Certifying Official will expeditiously resolve the issue and either reinstate or disqualify the individual.

(3) The Certifying Official will use the following sources of information to determine that the individual is qualified for the BPRP:

(a) Initial interview.

(b) Personnel Security Investigation (PSI).

(c) Personnel records review.

(d) Medical evaluation.

(e) Drug testing.

(4) The RO may monitor Certifying Official decisions to qualify individuals to oversee the status or quality of the program, and may overturn Certifying Official decisions to qualify individuals when procedures have been unfairly, inconsistently, or incorrectly applied. Reviewing officials will review all disqualification decisions.

6. Qualifying Factors/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 the subject of a current and favorably adjudicated PSI completed by the Department of the Navy Central Adjudication Facility (DONCAF).

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

d. Individuals will comply with training requirements specified in local requirements, plans, and regulations for the biological duties they perform.

e. Individuals occupying BPRP duty positions in the U.S. or its possessions will have valid DHHS approval based on a security risk assessment per Title 42, Code of Federal Regulations, Part 73 (42 CFR Part 73) before access is provided to BSAT.

f. Foreign nationals (including local nationals at facilities outside of the United States) are eligible for certification into the BPRP provided they meet the Limited Access Authorization (LAA) program requirements and have a favorably adjudicated LAA as described in SECNAV M-5510.30, Chapter 9, paragraph 9-16 and are not restricted persons as designated by the USA PATRIOT Act (Public Law 107-56). In general, foreign nationals are restricted persons if:

(1) They are illegally or unlawfully in the United States.

(2) They are a national of a country currently determined by the Secretary of State to repeatedly have provided support for acts of international terrorism, and have not been lawfully admitted into the United States for permanent residence.

7. Mandatory Disqualifying Factors. The Certifying Official will disqualify individuals from the BPRP if it is discovered that any of the traits, diagnoses, conditions, or conduct listed below exists. The Certifying Official will submit disqualification actions to the RO for review. If, during this review, the RO discovers extraordinary circumstances that warrant an exception to disqualification, they may submit a request that will include detailed supporting justification through the chain of command to CNO (N09N2) (NCIS Washington Navy Yard B176, Attn: 0024E/N09N2, 716 Secard ST SE, Washington DC 20388-5380). The individual remains disqualified until and unless the exception is approved.

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

b. Drug abuse within the five 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 should consult with the Competent Medical Authority (CMA).

c. Trafficking in illegal or controlled drugs.

d. Abuse of drugs while enrolled in the BPRP, whether admitted or as the result of a verified positive drug test.

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

8. Other Disqualifying Factors. Any of the following traits, diagnoses, conditions, or conduct listed below may be grounds for the disqualification of individuals from the BPRP, based on the Certifying Official's informed judgment.

a. Alcohol-Related Incidents/Abusing Alcohol

(1) Certifying Officials will evaluate the circumstances of alcohol-related incidents that occurred in the five years prior to the initial interview and request a medical evaluation. An individual diagnosed through such medical evaluation as currently alcohol dependent will be disqualified. Individuals diagnosed as abusing alcohol will be handled per paragraph (2) below. For an individual not diagnosed as a current alcohol dependent/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 qualify or disqualify the individual from the BPRP, as they deem appropriate.

(2) Individuals diagnosed as abusing alcohol but who are not alcohol dependent, shall at a minimum be suspended from BPRP processing pending completion of the prescribed rehabilitation program or treatment regimen prescribed by the CMA. Before the individual is certified into the program, the Certifying Official will assess whether the individual has displayed positive changes in job reliability and lifestyle, and whether the individual has a favorable medical prognosis from the CMA. Failure to satisfactorily meet these requirements shall result in disqualification.

b. Drug abuse

(1) In situations not otherwise addressed, a Certifying Official may qualify or disqualify an individual who has abused drugs more than five years before the initial BPRP interview. In deciding whether or not to disqualify individuals in these cases, the Certifying Official will request CMA evaluation and may consider extenuating or mitigating circumstances. To qualify the individual for the BPRP, the Certifying Officials documentation of the Potentially Disqualifying Information (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. Examples of potential extenuating or mitigating circumstances include, but are not limited to:

(a) Successful completion of a drug rehabilitation program.

(b) Participation in a Navy certified post rehabilitation program.

(c) Isolated experimental drug abuse.

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

(2) Certifying officials may qualify individuals who have isolated episodes of abuse of another's prescription drugs under the following circumstances:

(a) If the abuse occurred while the individual was enrolled in the BPRP, the Certifying Official will request CMA evaluation. If the Certifying Official believes the use does not represent a reliability concern and desires to retain the individual in the BPRP, the documentation recording the PDI must include an approval signed by the RO. If the RO does not approve, the individual will be disqualified from the BPRP.

(b) If the abuse occurred before the initial BPRP interview, the Certifying Official will request CMA evaluation. Certifying officials will consider such abuse in conjunction with other potentially disqualifying information in determining reliability of the individual.

c. Medical Condition. 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 personal protective equipment 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. Medical information that falls within these parameters is disqualifying if and when the Certifying Official considers it prejudicial to reliable performance of BPRP duties. In addition, the CMA will evaluate individuals and make recommendations to the Certifying Official on suitability for duty in the BPRP in the following circumstances:

(1) Individuals currently under treatment with hypnotherapy.

(2) Individuals who have attempted or threatened suicide before entry into the BPRP.

(3) Individuals that have attempted or threatened suicide while enrolled in the BPRP. To qualify such an individual for the BPRP, the Certifying Official's documentation of the PDI must include a current evaluation performed by a CMA and an approval signed by the RO.

d. Inappropriate Attitude or Behavior. 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:

(1) Negligence or delinquency in performance of duty.

(2) 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.

(3) Poor attitude or lack of motivation. Poor attitude can include arrogance, inflexibility, suspiciousness, hostility,

flippancy toward BPRP responsibilities, and extreme moods or mood swings.

(4) Aggressive/threatening behavior toward other individuals.

(5) Attempting to conceal potentially disqualifying information through false or misleading statements.

9. Screening Process

a. A Personnel 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 CO or agencies.

b. All signatures on the original record will be in ink. Facsimile stamps will not be used for signatures.

c. Errors in the record 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.

d. Corrections to errors discovered after the individual is enrolled into the BPRP should be documented, and (if necessary) place additional documentation in the individual's file as appropriate.

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

f. Locally generated forms data must be transferred to the appropriate record.

10. Initial Interview

a. The Certifying Official (or representative(s) designated in writing), 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. In addition, the Certifying Official will:

(1) Inform the candidate of the Privacy Act of 1974. If the candidate objects to the required screening, the screening process will be discontinued.

(2) Inform the candidate that they will be subject to random drug testing on an unannounced basis as a condition of employment, and that an initial negative test will be required prior to certification.

(3) Review with the candidate the concept of the BPRP and the reliability standards, both qualifying and disqualifying, for assignment to or retention in a BPRP position. The Certifying Official will ensure that the candidate understands the traits and conduct normally considered disqualifying.

(4) Determine whether any of the traits or conduct normally considered disqualifying exist.

(5) Explain that personnel assigned to BPRP duty positions may be required to wear Personal Protective Equipment (PPE). If there is any concern about their ability to wear personal protective equipment, the matter will be resolved promptly.

(6) Explain the importance of BPRP assignments and the responsibilities involved in associated BP RP duties.

(7) Explain the continuing evaluation aspects of the BPRP to include each individual's responsibility to actively participate in this evaluation and that personnel found suitable for BPRP duties remain under continual evaluation until either disqualified or administratively terminated.

(8) Explain the requirement to self-report information, such as the use of prescribed drugs, which may have a bearing on performance of PRP duties. Failure to self-report may be considered PDI.

b. 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.

c. Should the Certifying Official determine that the candidate is acceptable for further screening, the screening process will be completed per local procedures.

11. Personnel Records Screening. The supporting personnel officer (or contractor's personnel manager) or representative (designated in writing) will screen the individual's personnel records. The screening official will:

a. Determine the individual's citizenship and verify it to the Certifying Official.

b. Determine 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.

c. The Certifying Official may be designated to review personnel records by the commander/director.

12. Personnel Security Records Screening

a. The security manager or a representative (designated in writing) will determine whether:

(1) The individual is a subject of a current and favorably adjudicated Personnel Security Investigation (PSI) for BPRP purposes. If the PSI is not valid for BPRP, the security manager will notify the Certifying Official.

(2) Local security records (SF 85/SF 86 or equivalent questionnaires) contain PDI. When PDI is identified, provide it to the CO per local procedures, assuring Privacy Act requirements are not violated.

b. Personnel scheduled for initial assignment to BPRP positions must have the appropriate and favorably adjudicated PSI completed within the five years preceding certification to the BPRP. The minimum PSI required for military or contractor employees is the National Agency Check, Local Agency Check, and Credit Check (NACLC). The minimum PSI for DOD civilian employees is the Access National Agency Check with Credit Checks and Written Inquiries (ANACI); a NACLC is also acceptable for civilian employees. In cases where the investigation ended more than 5 years before BPRP certification, the PSI is outdated for BPRP purposes and a new investigation is required.

c. The PSI is considered favorably adjudicated if:

(1) It has no derogatory information (a "non-issue" PSI), based on either a "non-issue" case code or on contact with the investigating agency.

(2) The DOD-authorized central adjudication facility has favorably adjudicated the PSI or granted the individual a security clearance of SECRET or higher.

d. In circumstances where official functions must be performed prior to completion of the investigation and adjudication process, the Certifying Official may grant a temporary (90 day) interim certification, provided the request for the PSI has been submitted (electronically transmitted or mailed to CNO (N09N2) and all other requirements of the BPRP screening process have been completed:

(1) If the appropriate PSI was completed less than ten years before BPRP certification.

(2) If the PSI is at a level less than a NACLC or ANACI, provided the PSI was completed less than five years before BPRP certification.

(3) In any other circumstance, if a Certifying Official determines that a person's expertise is critical to the performance of an official government mission, the Certifying Official may submit a written request for interim certification to the CNO (NO9N2) for adjudication. The CNO (NO9N2) may grant or deny interim certification, and will establish conditions or require compensatory measures for the interim certification.

(4) 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 person's reliability.

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

13. Competent Medical Authority Evaluation (CMA)

a. The Certifying Official must be confident that the individual meets BPRP standards. The primary responsibility of the CMA is to identify to the Certifying Official any medical PDI that may reflect on an individual's suitability for assignment to a BPRP position, and to provide a recommendation to the Certifying Official as to whether the PDI will preclude the individual from performing BPRP duties.

(1) The CMA will review the military health records or civilian employee medical records.

(2) 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 a mental health consultation if either the CMA determines that such an evaluation is prudent or the CO requests it. The CMA will document all medical PDI in the individual's medical/health records.

(3) 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 the CMA identified PDI, the medical record entry will indicate the nature of the PDI and the date the CO was notified. The medical record entry will include the name, grade, and signature of the CMA and the date of the screening.

(4) 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 CMA will get this information to the Certifying Official per local procedures, assuring provisions of the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA) are not violated.

(5) 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, 42 United States Code (USC) 12101 - 12111, and implementing regulations in 29 Code of Federal Regulations (CFR) Part 1630). 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.

b. The authority to review health records also extends to Navy Substance Abuse Program information for military personnel. For civilian personnel, the authority to review health records in the Employee Assistance Program (EAP) (established by 5 USC section 7904) is limited by 42 USC section 290dd-2, as implemented by 42 CFR Part 2, which prohibits the release of substance abuse information from the patient's records without the patient's written consent. Certifying Officials cannot require civilian employees to release this information as a condition of employment. Certifying Officials must rely on the continuing evaluation aspects of the BPRP in such circumstances to detect substance abuse/dependence problems.

c. Certifying and Reviewing Officials may not release or discuss the content of health records, except as provided in the preceding paragraphs or as otherwise permitted by the Privacy Act of 1974 and HIPAA Privacy and Security Rules. Certifying and reviewing officials may refer questions concerning this restriction to their servicing legal office.

d. 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.

e. Dental records screening should be performed in conjunction with medical records screening for personnel assigned to BPRP duties.

f. Certifying Officials may maintain a separate file on each member in the BPRP with the information described above transcribed in a local form for their use only. This separate file is to be considered For Official Use Only (FOUO) and provided with the appropriate security.

14. Drug Testing. All candidates for the BPRP must complete drug testing within six months prior to initial certification into the BPRP.

a. All drug test results will be submitted to the Certifying Official before the individual is certified into the BPRP.

b. Positive test results indicating illegal drug use will result in disqualification.

c. Drug tests reported as "verified positive" or "refusal to test" will be reported to the Certifying Official and result in disqualification.

d. Drug testing will be documented.

15. Certifying Official's Evaluation and Briefing. After the screening process is completed, the Certifying Official will review all records, documentation, and any PDI provided during the screening process.

a. If the Certifying Official determines that PDI identified during the screening is not disqualifying, they will document the PDI and the decision per local procedures. (When the record review discloses potentially disqualifying medical information, the record must be referred to the CMA for documented evaluation). The Certifying Official will maintain this documentation until the individual is administratively terminated or disqualified from the BPRP, at which time it will be destroyed.

b. The Certifying Official will ensure that all core safety, security, and emergency training are completed and documented per local Standing Operating Procedures (SOPs), plans, and regulations.

c. For individuals found suitable for the BPRP, the Certifying Official will brief the individual in the following areas:

(1) The individual has been found suitable for the BPRP.

(2) The duties and responsibilities of the individual's BPRP position.

(3) Each person's obligations under the continuing evaluation aspects of the BPRP.

(4) A review of disqualifying factors. This includes a discussion of any incidents or medical issues that have occurred since the initial interview.

(5) The use of all prescription drugs must immediately be made known to a CMA or other personnel specifically trained and designated in writing to perform that function. This information may be relayed to the CMA via the command Certifying Official. While in the BPRP, improper use of drugs prescribed for another person is unacceptable and must be reported to the Certifying Official immediately for evaluation.

(6) Any restrictions placed on an individual due to interim certification requirements.

d. At the close of the briefing, the individual and the Certifying Official will complete the appropriate forms. The individual's signature indicates that a briefing on the standards and objectives of the BPRP was received and understood. The Certifying Official will retain the original form and distribute copies as follows:

(1) One copy to be retained in the individual's official personnel records.

(2) One copy to the CMA.

e. If the Certifying Official determines an individual unsuitable for a BPRP assignment, the Certifying Official will terminate the screening process and follow procedures for disqualification.

16. Technical Proficiency

a. Supervisors will ensure that individuals have the additional training appropriate or required for the technical duties the individual performs. It is also the supervisor's responsibility to keep the Certifying Official informed of any issues pertaining to an individual's training status.

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

17. Change in, or Absence of, the Certifying or Reviewing Official

a. When a biological duty position roster (BPRP) certified individual transfers to another BPRP position with a different Certifying Official and RO, 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 RO, or if the Certifying Official is replaced. To assign or retain an individual without a new screening, 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 RO 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 suspend 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 Officials 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. They will conduct the reviews in paragraph (b) above and ensure an updated BDPR is distributed per local SOP.

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

e. If the Certifying Official will be unavailable for time-sensitive actions required by this regulation, the commander/director may designate in writing an acting Certifying Official for the duration of the absence, and provide a copy of the designation to supervisors, the CMA, and supporting agencies. Acting Certifying Officials are not required to conduct the reviews and interviews per paragraph (b) above or create a new BDPR. If the designated RO is unavailable for time-sensitive actions required by this regulation, the RO may designate in writing an acting RO for the duration of the absence.

18. 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 disqualifying factors previously identified will continue to apply unless modified in this section. Continuing evaluation includes:

(1) Self reporting.

(2) Peer and supervisor observation and reporting.

(3) Evaluation of medical treatment by the CMA.

(4) Periodic reinvestigations.

(5) Periodic drug testing.

(6) Certifying Official observation and evaluation.

b. When an individual is in an administrative absence (leave, temporary duty, etc.), the Certifying Official may choose to:

(1) Rely on the individual's obligation to self-report PDI.

(2) Administratively restrict the individual.

(3) Establish a relationship with the leadership at the gaining site for PDI to be reported back to their reporting command.

c. 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 that they provide required support.

d. When the Certifying Official determines that PDI identified during continuing evaluation is not disqualifying, they will document the PDI and the decision per local procedures. (Medical PDI will be identified merely as "medical PDI from CMA".) The Certifying Official will maintain this documentation until the individual is administratively terminated or disqualified from the BPRP, at which time it will be destroyed.

19. Individual and Supervisor Responsibilities

a. Individuals assigned to BPRP duties are responsible for monitoring their own reliability and the reliability of others performing BPRP duties. Individuals will advise their supervisors and Certifying Official of any factors that could have an adverse impact on their performance, reliability, or safety while performing BPRP duties. Individuals will inform their supervisor and Certifying Official when another individual in the BPRP appears to be involved in situations that may affect reliability. The Certifying Official will consider failure to discharge these responsibilities when assessing an individual's reliability.

b. Information that would be identified during the next periodic reinvestigation should be reported to the Certifying Official as soon as possible. Information that should be reported includes:

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

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

(3) Illegal use of drugs or illegal drug activity.

(4) 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.

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

c. If the Certifying Official is not the immediate and only supervisor of the individual, the Certifying Official will ensure all the individual's immediate supervisors know that the individual is subject to the reliability standards in this regulation. Supervisors will monitor the reliability of their subordinates and notify the Certifying Official of any PDI.

d. Individuals will follow local procedures for reporting medical conditions and medical treatment (including medication) for screening (paragraph 2-20) following all medical and dental treatment.

20. BPRP Medical Evaluation

a. Each time a BPRP-certified individual identifies medical conditions of concern or receives medical treatment (including medication) of any kind from a health-care provider, the individual will notify the CMA (verbally, written, electronic) so that the treatment can be evaluated and the Certifying Official notified if there is a potential effect on the individual's reliability or duty performance. Medical treatment that must be evaluated includes dental treatment, hypnotherapy, and mental health treatment, whether provided by military or

non-military health-care providers. Ensuring that medical treatment is identified to the CMA is the responsibility of the individual.

(1) The CMA will evaluate the medical condition and treatment and determine if PDI exists. The CMA will report as PDI any medical condition, medication use, or medical treatment that may result in an altered level of consciousness, impaired judgment or concentration, impaired ability to safely wear required PPE, or impaired ability to perform the physical requirements of the BPRP position. The CMA will ensure PDI is documented in the individual's employment health records. The CMA will annotate the SF-600 or equivalent form with the nature of the PDI, the CMA evaluation, the date of the evaluation, the date this PDI was forwarded to the Certifying Official, and the name, grade, and signature of the CMA.

(2) The CMA will provide sufficient details in clear and understandable manner so the Certifying Official can make a sound decision concerning an individual's continued suitability to perform BPRP duties.

(3) The CMA will provide PDI to the Certifying Official per local procedures, ensuring that provisions of the Privacy Act and HIPAA are not violated.

(4) 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 (for example, 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.

b. 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.

c. Certifying Officials and ROs 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 ROs.

d. Certifying Officials receiving medical information regarding a BPRP employee from other than the CMA will refer the employee to the CMA for an evaluation.

21. Drug and Alcohol Abuse

a. The Certifying Official will suspend an individual suspected of drug abuse while in the BPRP and refer the individual to the CMA. The CMA will refer the individual for a drug or alcohol assistance program or Employee Assistance Program evaluation.

b. DOD civilian and military personnel in the BPRP will undergo periodic drug testing. Contractor personnel will undergo periodic drug testing per contractual requirements. Verified positive test results will be submitted to the Certifying Official.

c. Alcohol-Related Incidents. Certifying Officials will suspend any individual in the BPRP who is involved in an alcohol-related incident. The Certifying Official will evaluate the circumstances and request a medical evaluation.

22. Personnel Security Investigations (PSIs)/Periodic Reinvestigations (PRs) for BPRP Purposes

a. All personnel assigned to BPRP duties are required to have a completed and favorably adjudicated periodic reinvestigation (PR) every five years.

b. The Certifying Official may at any time request a 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.

c. 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 suspend the person from the BPRP until the PR is submitted (electronically transmitted or mailed to the investigating agency). Once the PR is submitted, the Certifying Official can return the individual to a fully qualified status.

d. 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.

23. Removal from BPRP Duties. Removal from the BPRP can be temporary (restriction or suspension), long-term (disqualification), or administrative (administrative termination) depending on the particular circumstances. The type of removal 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:

a. 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. Determination of an individual's

reliability and suitability rests solely with the Certifying Official, subject to the review of the RO.

b. 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.

c. Separation from employment/service may be appropriate for a disqualified individual, if BPRP certification is a condition of employment/service and if no positions are available for which the individual is qualified.

d. Certifying Officials will ensure that individuals are deleted from the BDPR when administratively terminated or disqualified. Personnel suspended or restricted from BPRP duties will not be deleted from the BDPR.

e. Local procedures will govern actions taken by supervisors to immediately restrict access when unexpected situations arise pending resolution by the Certifying Official.

24. Restriction

a. Medical Restriction. When performance of BPRP duties may be impaired by a temporary medical condition (including medication for the condition) or psychological condition (such as short-term stress), the Certifying Official will determine if the individual should be restricted from performing those BPRP duties. Medical restriction is a precaution based on the possibility of duty impairment, and is not an assessment of unreliability.

(1) The Certifying Official may restrict an individual based on information from the individual, supervisor, or the CMA. When the information did not come from the CMA, the Certifying Official will consult the CMA, and will restrict the individual from BPRP duties pending the outcome of the consultation.

(2) The Certifying Official will temporarily remove the individual from affected BPRP duties. The Certifying Official will notify the individual and the individual's immediate supervisor in writing of the nature and probable duration of the

restriction. "Nature of the restriction" refers to the specific duties being restricted. A copy of the notification will be maintained with the individual's file.

(3) The individual remains under continuing evaluation while restricted.

(4) When the temporary condition or situation is resolved, the Certifying Official will notify the individual and immediate supervisor per local procedures that the individual can resume assigned BPRP duties. Temporary restriction notifications will be retained by the Certifying Official until the individual is no longer required to be in the BPRP.

(5) Examples of when medical restriction 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/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. Medical restriction 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.

(6) Except for restrictions due to pregnancy, medical restrictions will not normally exceed 180 days. If the condition is expected to persist beyond this point, the Certifying Official will consult with the CMA and determine what action to take from this point (revalidation of the medical restriction, suspension or disqualification, as appropriate).

(7) Medical restriction will not be used in cases of drug or alcohol abuse, when attempted suicide is suspected or threatened, in the case of an alcohol-related incident, or in cases of aberrant behavior where a medical evaluation is requested. In these instances, the Certifying Official will immediately suspend individuals from BPRP duties.

b. Administrative Restriction. When a BPRP-certified individual will be absent from BPRP duties for a significant period of time (e.g., leave of absence or temporary duty to attend a school), the Certifying Official must decide if effective continuing evaluation can be maintained. When the ability to maintain continuing evaluation is questionable, the Certifying Official may administratively restrict such individuals from BPRP duties for the duration of the absence. Administrative restriction is not an assessment of unreliability.

(1) The Certifying Official will temporarily remove the individual from BPRP duties and access to BSAT. The Certifying Official will notify the individual and the individual's immediate supervisor in writing of the administrative restriction, and identify the individual's responsibilities upon return from absence. Maintain a copy of the notification with the individual's file.

(2) When the individual returns from the absence, the Certifying Official will interview the individual to discuss any areas of PDI and to reinforce BPRP standards. It is the individual's responsibility to disclose any PDI that may have occurred during his or her absence. If the individual identifies any instances of medical PDI, the Certifying Official will refer the individual to the CMA for further evaluation.

(3) After the interview and resolution of any PDI, the Certifying Official will notify the individual and immediate supervisor per local procedures that the individual can resume assigned BPRP duties. Restriction notifications will be destroyed.

25. Suspension. When a Certifying Official determines that an individual's reliability is suspect, the Certifying Official will immediately suspend the individual from the BPRP. Suspension is also appropriate when a medical condition

unexpectedly becomes prolonged, and the Certifying Official determines continued medical restriction is not appropriate. The Certifying Official will also suspend an individual whose PSI has expired unless and until a PR has been requested. If an individual is certified in more than one program (e.g., biological and chemical PRP), the Certifying Official must indicate at the time of suspension whether it is applicable to both programs.

NOTE: The use of the word suspension in this instruction indicates suspension from the BPRP only, and is not suspension as it relates to adverse or disciplinary action.

a. The Certifying Official will immediately remove the individual from assigned BPRP duties, restrict access to BSAT, and advise the individual and the immediate supervisor in writing of the reason for suspension. (Medical PDI will be identified merely as "medical PDI from CMA". The individual will remain under continuing evaluation. The Certifying Official will document suspension, (pencil entry) to reflect the date of the suspension.

b. 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 disqualify the individual.

c. If the individual is reinstated, the Certifying Official will inform the individual and immediate supervisor in writing and erase the pencil entry documentation. The Certifying Official will maintain the notification and reinstatement memoranda with the individual's form while the individual remains in the BPRP.

d. Suspended military personnel will not be permanently reassigned or separated from service until reinstated into or disqualified from the BPRP, unless suspension is the result of a medical condition. In that case, the individual will be administratively terminated from the BPRP before separation or reassignment.

e. Suspension will initially be for up to 30 days. The Certifying Official may extend the period of suspension up to 120 days in 30-day increments when there is not sufficient

information to remove the suspension and return the individual to BPRP duties, or to disqualify the individual. Extension decisions and their justification must be documented and maintained by the Certifying Official for the duration of the suspension. After 120 days, CNO (NO9N2) approval is required for further extensions.

26. Disqualification. When the Certifying Official determines that an individual does not meet the reliability standards of this chapter, the Certifying Official will initiate disqualification from the BDPR.

a. For individuals being screened for initial entry into the BPRP:

(1) The Certifying Official will terminate the screening process.

(2) The RO will review the action to ensure the correct, fair, and consistent application of the reliability standards in this regulation.

(3) If disqualification is inappropriate, the Certifying Official will complete the screening and BDRP processing.

(4) If disqualification is appropriate, the Certifying Official will notify the individual in writing. If the individual is certified in more than one PRP and has not been disqualified from other programs the notification should indicate this. In this case, maintain the notification in the individual's file. 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. The Certifying Official will maintain a copy of the notification letter for 5 years.

b. For individuals in the BPRP, the Certifying Official will terminate access to BSAT, remove the individual from BPRP duties and follow the procedures below. If the individual is certified in multiple PRPs and is not being disqualified for

all, modify the procedures below to ensure the action is taken only for the appropriate program.

(1) The Certifying Official will advise the individual in writing ("the notification letter") of their decision to initiate disqualification from the BPRP within five working days. The notification letter will:

(a) 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."

(b) Advise the individual that the disqualification action is subject to mandatory review by the RO before any permanent entries are made in the individual's records and that the Certifying Official or RO 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 RO within five working days of receipt of 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.

(2) The RO will review each disqualification 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 RO. This will be completed within ten working days of the individual receiving the notification letter.

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

(c) Within 15 working days of receipt of the disqualification documents, the RO 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 RO's decision either directly to the individual, or through their new chain of command or supervisory chain.

(d) When the RO does not approve the disqualification, the individual's records will show the individual as BPRP certified.

(3) If the RO approves disqualification of an individual:

(a) The Certifying Official will provide documentation that provides sufficient detail so that any requests for re-qualification can be appropriately assessed.

(b) The Certifying Official will provide a copy of the documentation and a copy of the notification letter and RO's approval to the custodian of the individual's personnel records for filing. This copy will be annotated with the date and method of notifying the individual.

(c) The Certifying Official will notify the CMA. If the individual is disqualified for medical reasons, the CMA will annotate the medical record entry with the following "Disqualified (date) for assignment to BPRP positions and will state the medical reason for disqualification."

(d) The Certifying Official will ensure the individual is removed from the BDPR, and will notify the individual's immediate supervisor in writing of the disqualification.

(e) The Certifying Official will notify the supporting security manager for appropriate action when the disqualification is based on credible derogatory information that could affect the individual's security clearance.

c. For a contractor employee disqualified from the BPRP

(1) If the disqualification is based solely on information developed from the PSI, the reasons for disqualification will not be disclosed to the individual's employer, to include the BPRP administration official. The Certifying Official may communicate or correspond directly with the individual being disqualified. The Certifying Official will give the individual's employer written notice that the individual is disqualified because of an unfavorable PSI, without specifying the reasons.

(2) The Certifying Official will keep the original documentation with copies of the written notification and the signed acknowledgment, in addition to a copy of the final action by the RO. The Certifying Official will provide copies, or memos, to appropriate personnel and medical support offices.

(3) If the individual has been cleared under the DOD Industrial Security Program and was disqualified for acts reflecting adversely on loyalty, character, integrity, or discretion, and the acts were clearly not consistent with National Interest, the Certifying Official (or contractor) must report this information to the Defense Security Service (DSS) for necessary action.

27. Administrative Termination

a. Administrative termination

(1) Occurs when an individual transfers from a duty position requiring BPRP certification to one not requiring BPRP certification.

(2) Occurs when an individual is permanently removed from BPRP duties within their organization.

(3) Establishes the date an individual was removed from a BPRP position for reasons other than disqualification.

(4) Terminates the requirement for continuing evaluation.

b. The Certifying Official

(1) Terminates the individual's access to BSAT.

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

(3) Ensures the individual is removed from the BDPR.

(4) Notifies the CMA in writing that the individual is no longer in the BPRP and no longer requires continuing evaluation.

28. Requalification of Disqualified Personnel

a. Request for requalification

(1) An individual disqualified from the BPRP may request requalification based on substantive evidence that the cause for disqualification 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.

(2) 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 disqualification, the basis for disqualification, and the action taken to correct or eliminate the cause for disqualification.

(3) The Certifying Official and RO will review the request, and either disapprove it or recommend its approval to CNO (N09N2). If the Certifying Official and RO disapprove the request, it will be returned to the individual with the rationale for disapproval and a copy forwarded to CNO (N09N2). If the Certifying Official decides to recommend requalification, the Certifying Official will endorse and forward the request for requalification to the RO.

(4) The RO will review the request and the Certifying Official's recommendation. The RO will either approve or deny the requalification.

(5) If the RO approves the requalification, the Certifying Official will:

(a) Forward a copy of the approval to CNO (N09N2) with supporting justification. Justification will provide a thorough summary enumerating the decertification issues and include the type of duty assignment proposed.

(b) Requalification that involved a previous medical disqualification will require a recent CMA review documenting the previous medical disqualification prior to the individual being requalified and considered for assignment to a BPRP position. Provide a copy to the CMA; if the individual was disqualified for medical reasons, the individual's BSAT BPRP file will be annotated with the following statement - "Requalified (date) for assignment to a BPRP position."

(c) If CNO (N09N2) approves the individual being considered for reassignment to a BPRP position, the Certifying Official will complete the procedures outlined in the Screening Process, except that information pertaining to the previous disqualification will not be considered disqualifying in itself.

b. Special Procedures for Alcohol Dependence/Abuse

(1) An individual disqualified for alcohol dependence may be re-qualified for BPRP duties only after meeting the following conditions:

(a) The individual successfully completes an initial intensive rehabilitation, if prescribed, followed by a one-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 re-qualification, including a mental health evaluation and a favorable prognosis by the CMA.

(c) The Certifying Official must determine that the value of returning the individual to the BPRP outweighs the risk from potential future alcohol-related incidents and document the fact that the Certifying Official has full trust and confidence in the individual's reliability.

(2) An individual disqualified for abusing alcohol but who is not alcohol dependent may be re-qualified 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 re-qualification, including a favorable prognosis by the CMA.

c. Special Procedures For Drug Abuse

(1) Individuals who were disqualified for drug abuse that occurred while they were in the BPRP are generally ineligible for re-qualification. Under extraordinary circumstances that the RO believes warrant consideration for re-qualification, they may submit a written deviation request to CNO (N09N2).

(2) In order to be considered for re-qualification in the BSAT PRP, the following must occur: Satisfactory completion of a prescribed drug treatment program approved by the CMA, including but not limited to rehabilitation and aftercare requirements, without recurrence of abuse, and a favorable prognosis by a duly qualified medical professional.

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

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

2. Acquisition of BSAT. All facilities located within the United States using, possessing, transferring, or receiving BSAT must be registered and operate per with 42 CFR 73, 7 CFR 331, and/or 9 CFR 121.

3. Responsibilities

a. Commanders/Directors will:

(1) Appoint a RO, alternate RO, and biological storage custodians in writing to oversee the implementation of this chapter. This includes the drafting of a facility-specific BSAT inventory management standing operation procedure/internal operation procedure (SOP/IOP).

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

(3) Forward a copy of the most recent version of the Laboratory Registration and Select Agent Record of Completed Transfers Data, completed per 42 CFR 73 (Additional Requirements for Facilities Transferring or Receiving Select Agents). The records of completed transfers will be maintained at the sending command for three years.

b. Contract organizations will designate, in writing, contractor personnel to perform the duties and responsibilities of the RO, custodian, and alternates, and submit their names to the responsible Contracting RO and to the DOD Accountability Manager for Schedule 1 Chemicals. This requirement will be included in the biological surety contract clauses.

4. BSAT Inventory Management

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

(1) Instructions for completing Animal and Plant Health Inspection Service/Centers for Disease Control and Prevention (APHIS/CDC) Form 2 for transfer of BSAT.

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

(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 certificates, and other documents as directed by the RO. Laboratory notebooks will be used as part of the documentation.

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

6. 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. 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 Department of Agriculture research program, or to the Federal Bureau of Investigation (FBI) when required for forensic analysis. Transfer of the BSAT will be per 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, Assistant to the Secretary of Defense (Nuclear, Chemical, and Biological) (NCB). This approval is requested through CNO (N3AT) 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 (h).

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.

7. 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, at a minimum, the following information:

(1) Name of contractor and contract number.

(2) Name(s) of principal investigators 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 and CNO (NO9N2) BPRP review.

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 three years.

CHAPTER 5
BIOLOGICAL ACCIDENT OR INCIDENT RESPONSE

1. General

a. A biological accident 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/Directors of facilities with a biological surety mission will establish plans to address biological accidents and incidents as identified in this chapter. 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 Accident or Incidents

a. Facility commanders or directors shall report biological incidents as soon as possible, and in no case later than four hours after the event is known per reference (1). 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. CNO (N3IPS) shall notify the Director of Security, Under Secretary of Defense for Intelligence (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 (NOC).

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

4. Exercise Program

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

b. Facilities/installations will include the participation of external agencies that support emergency plans in an exercise at least once every two 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/installation will re-evaluate the plan to determine if revisions are appropriate, and provide the chain of command the results of the re-evaluation. An operational risk assessment (ORM) will be conducted to determine if non-support by external agencies creates or increases physical security or personnel protection risks.

c. Commanders/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/directors will develop programs to ensure timely remedial actions are taken to correct shortcomings discovered during exercises, and to update local SOPs/IOPs as appropriate.

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

1. General. This section addresses generic hazards and controls for biological operations at the Navy biological laboratories. Reference (m) provides guidance on general laboratory safety. Additional federal and consensus regulatory guidance references should be considered.

a. Table 1 contains a list of agencies and their operational requirements for work with microbial agents and toxins, animal care, and human subjects.

b. 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 Deoxyribonnucleic Acid (DNA), Agricultural Pathogens, and human or primate cell cultures) and research proposals and activities concerning animal or human subjects.

c. This section applies to workers, hosted visitors, students, participating guests, contract laborers, supplemental personnel, and subcontractor workers where Navy has management control.

2. Guidance Documents. Commanders/Directors will establish an occupational health program in support of biological surety. Guidance documents, listed below, are used to determine the level of exposure to biological hazards.

a. Centers for Disease Control (CDC)/National Institutes of Health (NIH), Classification of Human Etiologic Agents on the Basis of Hazard.

b. CDC/NIH Biosafety in Microbiological and Biomedical Laboratories.

c. National Cancer Institute, Biosafety Manual for Research Involving Oncogenic Viruses.

d. NIH Guidelines for Research Involving Recombinant DNA Molecules.

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

4. Hazards Associated with Specific Agents and Materials

Table 1. Government agencies and biological hazards authority.

Agency	Microbial Agents/Toxins	Animal Care	Human Subjects
I. Federal			
U.S. Department of Agriculture (USDA)	--	9 CFR 1--3, "Animal & Plant Health Inspection Service (APHIS) Animal Welfare Act of 1966"	--
--	7 CFR 331 "Possession, Use, and Transfer of Biological Agents and Toxins"	--	--
--	9 CFR 121 "Possession, Use, and Transfer of Biological Agents and Toxins"	--	--

--	Form VS16-3, "Importation and Transport of Controlled Organisms or Vectors"	Form VS17-129, "Importation of Live Animals"	--
--	Form VS16-7, "Additional Information for Cell Cultures and Their Products"	--	--
U.S. Department of Commerce	15 CFR 742, 744, 744B, " Exportation Administration Regulations"	--	--
U.S. Department of Health and Human Services (HHS), Public Health Service (PHS), National Institutes of Health (NIH)	*66 FR 1146, "Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)," January 5, 2001 "Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)," amended April 2002	--	45 CFR 46, "Protection of Human Subjects: The Common Rule"
--	42 CFR 72, "Interstate Shipment of Etiological Agents"	PHS Policy on Humane Care and Use Lab Animals (reprinted in 1996)	--

--	42 CFR 71.54, "Foreign Quarantine: Etiologic Agents, Hosts, and Vectors"	--	--
--	*42 CFR 73, "Possession, Use, and Transfer of Select Agents and Toxins"	--	--
Centers for Disease Control (CDC)/NIH	*"Biosafety in Microbiological and Biomedical Laboratories," CDC/NIH HHS Pub CDC 93-8395	*"Biosafety in Microbiological and Biomedical Laboratories," CDC/NIH HHS Pub CDC 93-8395	--
--	"Primary Containment for Biohazards: Selection, Installation, and Use of Biological Safety Cabinets"	"Primary Containment for Biohazards: Selection, Installation, and Use of Biological Safety Cabinets"	--
Food and Drug Administration (FDA)	21 CFR 600-680, "Biologics"	--	*21 CFR 50, "Protection of Human Subjects" *21 CFR 56, "Institutional Review Boards"
U.S. Department of Labor	*29 CFR 1910.1030, "Bloodborne Pathogens"	*29 CFR 1910.1030, "Bloodborne pathogens"	--

		*29 CFR 1910.1450 , "Occupational Exposure to Hazardous Chemicals in the Laboratories"	
U.S. Department of Transportation	*49 CFR173.134(a)1, "Definitions: Infectious Substances"	*49 CFR 173.134(a)1, "Definitions: Infectious Substances"	*49 CFR 173.134(a)1, "Definitions: Infectious Substances"
U.S. Postal Service	Domestic Mail Manual (DMM)	Domestic Mail Manual (DMM)	Domestic Mail Manual (DMM)
U.S. Postal Service	International Mail Manual (IMM) "Acceptance of Hazardous, Restricted or Perishable Matter," Publication No. 52	International Mail Manual (IMM) "Acceptance of Hazardous, Restricted or Perishable Matter," Publication No. 52	--

DNA = Deoxyribonucleic Acid

CFR = Code of Federal Regulations

5. Procedures and Operational Controls

a. Biosafety levels. For research involving microbial agents, four biosafety levels (BSL 1 through BSL 4) of containment have been established and are described in the NIH Guidelines and in the 5th edition (2007) of "Biosafety in Microbiological and Biomedical Laboratories." Agent Summary Statements for work with specific bacterial, fungal, parasitic, prion, rickettsial, and viral agents can also be obtained from the NIH reference listed above. 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 two major components: 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.

b. The controls for biological activities include:

(1) General microbiological practices and techniques.

(2) Universal precautions.

(3) Good personal hygiene.

(4) Good housekeeping practices.

(5) Medical surveillance.

(6) Worker safety awareness and training.

(7) Warning signs.

(8) Procedures for:

(a) Decontamination.

(b) Environmental surveillance.

(c) Maintenance.

(d) Shipping/transport of biohazardous materials.

6. Shipping/Transport/Receiving of BSAT

a. Transportation of biological materials to offsite locations shall be per U.S. Department of Transportation, U.S. Department of Commerce, Centers for Disease Control and Prevention, U.S. Department of Agriculture, and public health regulations, depending on the materials. Importers of select agents shall comply with the Centers for Disease Control and Prevention regulation (42 CFR 71.54, and 73.7 "Etiological Agents , Hosts, and Vectors"). Exporters shall follow the Department of Commerce exportation regulation (15 CFR 742, 744, and 774), as well as applicable Department of Transportation regulations and guidance pertaining to shipping containers, supporting documentation, and placarding of transportation vehicles.

b. BSAT will be secured or in the direct control of a BPRP-certified individual while awaiting transportation.

c. Movement of BSAT on DOD installations will be kept to a minimum, consistent with operational and safety requirements.

7. Waste Disposal. Bio-hazardous waste generated from research laboratories and clinical settings should be placed in a primary autoclave bag within a labeled, durable, leak proof secondary container with a closable lid. Bio-hazardous or biological waste from animals, including animal waste, droppings, and carcasses, shall be carefully segregated and disposed of based on the hazard present.

8. Containment. The degree of containment is based on the level of health hazard or the level of impact the agent being studied poses to personal work practices and the environment.

9. Engineered Controls. Engineered controls are varied to include biological safety cabinets, high efficiency particulate

air (HEPA) filters, sinks with foot-actuated taps, easy-to-clean surfaces, heating ventilation and air conditioning (HVAC) systems that protect workers and the environment from contaminated airflow, appliances that minimize aerosol production, and security controls

10. Biological Safety Cabinets. Ventilation control of infectious agents or other biologically derived molecules is usually achieved by performing the operation using a biological safety cabinet. There are currently three primary classes of biological safety cabinets (Classes I, II, and III). Each class is distinguished by its design and its containment and cleanliness capability. The selection of an appropriate biological safety cabinet for a given operation shall be approved by the area Environmental Safety & Health Team industrial hygienist based on the specifics of the operation and an evaluation of the biosafety level classification (i.e., BSL 1, 2, 3).

a. Further descriptions of Class II and III cabinets, including schematic diagrams, can be found in the following documents:

(1) CDC/NIH Biosafety in Microbiological and Biomedical Laboratory.

(2) CDC/NIH Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets.

(3) American Industrial Hygiene Association, Biosafety Reference Manual.

(4) ANSI/NSF Standard 49.

Table 2. Performance guidelines for biological safety cabinets.

Biological safety cabinet	Description	Minimum face velocity (fpm)*	Negative pressure (inches w.g.) *
Class I	Front panel not in place	80	N/A**

	Front panel without gloves	150	N/A
	Front panel with gloves	N/A	0.5
Class II, Type A	Fixed opening height, usually 10 inches	80	N/A
Class II, Type B and 100% exhaust	Sliding sash adjustable from 8-30 inches. Experiment should be performed with 8-inch opening for proper face velocity.	100 (at 8-inch opening)	N/A
Class III	No direct opening. Access through double door sterilizer and decontaminant dunk bath.	N/A	0.5

* The manufacturer provides specifications for certain biological safety cabinets that obtained (National Sanitation Foundation certification). The information in this table is not always applicable.

** N/A = not applicable.

11. Personal Protective Equipment. PPE includes gloves, coats, gowns, shoe covers, safety shoes, boots, respirators, face shields, and safety glasses or goggles. PPE is to be used only as supplemental protection if there is still a residual risk of exposure after engineered and administrative controls are implemented. Identifying, reviewing, and assessing the workplace hazard(s), activities, and operations are key to selecting effective and appropriate PPE. Choice of PPE, and the required training for its use is determined on a case-by-case basis.

Respiratory protection is required for certain animal work at the BSL-3 level.

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 Department of Health and Human Services (DHHS) and the Department of Agriculture 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 the CDC and the APHIS, and are found in Title 42, Code of Federal Regulations, Part 73; Title 7, Code of Federal Regulations, Part 331; and Title 9, Code of Federal Regulations, 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. The lists include specific genetic elements, recombinant nucleic acids, and recombinant organisms. The lists also identify exclusions that are not considered as select agents or toxins; these exclusions are likewise not considered BSAT.
(see http://www.cdc.gov/od/sap/docs/42cfr73.pdf, http://www.aphis.usda.gov/ppq/permits/agr_bioterrorism/, and http://www.aphis.usda.gov/vs/ncie/pdf/agent_toxin_list.pdf)

3. Non-surety Biological Materiel

a. Biological agents ("non-select"). Biological Surety Program provisions in this regulation apply only to biological select agents and toxins, 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 Assistant Secretary of the Army (Installations and Environment).

(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 Chemical Weapons Convention 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. Title 18 USC, Chapter 10, Section 175, as amended by PL 107-56 (UNITING AND STRENGTHENING AMERICA BY PROVIDING APPROPRIATE TOOLS REQUIRED TO INTERCEPT AND OBSTRUCT TERRORISM (USA PATRIOT ACT) ACT OF 2001). Section 175b 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=pub1056.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 "Patterns of Global Terrorism" report at http://www.state.gov/s/ct/rls/pgtrpt/, in the section "Overview of State-Sponsored Terrorism".

2. Title 42 CFR 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.cdc.gov/od/sap/docs/42cfr73.pdf)

3. Title 7 CFR Part 331 sets forth 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.access.gpo.gov/nara/cfr/cfrhtml_00/Title_7/7cfr331_00.html).

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 will 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 paragraphs 4 and 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, ATTN: 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 Assistant to the Secretary of Defense (Nuclear, Chemical, and Biological) (ATSD(NCB)). Army will provide saxitoxin and ricin per ATSD(NCB) guidance.

7. Reporting Requirements. DOD organizations and their contractors will provide semi-annual 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 POC information for the principal investigator.

(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, ATTN: AMSSB-RCB-C/DOD Accountability Manager, E5183 Blackhawk Road, Aberdeen Proving Ground, MD 21010-5424.

APPENDIX D
BSAT CODE OF FEDERAL REGULATIONS, U.S. CODES, AND PUBLICATIONS

1. 7 CFR 331 and 9 CFR 121, Animal and Plant Health Inspection Service; Agricultural Bioterrorism Protection Act of 2002; Possession, Use and Transfer of Biological Agents and Toxins; Interim Final Rule.

2. 9 CFR Chapter 1, and Part 104, (the Animal Welfare Act of 1966), Subchapter A, "Animal Welfare," Parts 1, 2, and 3 (P.L. 89544).Permits for Biological Products.

3. 15 CFR 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. 22 CCR 65600-65628, "Minimum Standards for Permitting Medical Waste Facilities."

8. 29 CFR 1910.1030, "Bloodborne Pathogens," including Needlestick Safety and Prevention Act, January 18, 2001.

9. 29 CFR 1910.1200, "The Hazard Communication Standard."

10. 29 CFR 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories."

11. 42 CFR 73, "Possession, Use, and Transfer of Select Agents (for Humans)."

12. 42 CFR Part 2, "Confidentiality of Alcohol and Drug Abuse Patient Treatment Records."

13. 42 CFR 71.54, "Etiological Agents, Hosts and Vectors."

14. 42 CFR 72, "Interstate Shipment of Etiological Agents."

15. 42 CFR Part 73, "Select Agents and Toxins."

16. 45 CFR 46, "Protection of Human Subjects, Subpart A, B, C, and D."

17. 49 CFR Parts 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, January 5, 2001."

19. 5 USC 7904, "Employee Assistance."

20. 42 USC 290dd-2, "Confidentiality of Records."

21. Biosafety in Microbiological and Biomedical Laboratories, 4th edition, U.S. Depart. of HHS, Public Health Service, HHS Publication No. (CDC) 93-8395, May 1999.

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

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

24. 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.

25. Guidelines (Draft) for Preventing the Transmission of Tuberculosis in Healthcare Facilities, FR58:195 (October 12, 1993).

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

27. NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), April 2002.

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

29. NIOSH, Histoplasmosis: Protecting Workers at Risk, Publication No. 97-146.

30. Navy Publication No. P-467, U. S. Army, U.S. Army Field Manual 3-9: Potential Military Chemical/Biological Agents and Compounds).

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

32. U.S. Department of Public Health, National Institutes of Health, Public Health Service Policy on Humane Care and Use of Laboratory Animals, reprinted 1996.

33. Public Law 107-188, "Public Health Security and Bioterrorism Response and Preparedness Act of 2002," June 12, 2002.

APPENDIX E

GLOSSARY

1. Terms

a. 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.

b. Assistant Reviewing Official. The designated DOD military or civilian government employee who ensures requirements are met in the absence of the reviewing official. DOD contract personnel cannot perform these duties.

c. Biological accident. Unintentional event resulting from a non-deliberate act where biological select agent or toxin is released into the ambient atmosphere and has the potential to threaten unprotected personnel.

d. Biological incident. Security event 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.

e. Certifying Official (CO). 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.

f. Competent Medical Authority (CMA). A CMA shall meet the following requirements: 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. Have 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 be supervised by an appropriately trained CMA physician who is privileged to practice independently. Be specifically trained as a CMA and be appointed in writing as a CMA by the medical treatment facility commander responsible for reviewing healthcare services or conducting clinical evaluations for purposes of the BPRP.

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

h. Custody. Responsibility for the control of, transfer and movement of, and access to BSAT. Custody may or may not include accountability.

i. Drug abuse. The wrongful use, possession, or distribution of a controlled substance, or non-alcoholic intoxicating substance not intended for human ingestion (for example glue and gasoline fume sniffing).

j. 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 biological select agents or toxins, and the associated areas (laboratories or buildings) containing the biological select agents or toxins.

k. 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.

l. Recovered biological warfare materiel. Biological warfare materiel that was previously discarded, buried, or fired, and discovered either unexpectedly or during planned environmental restoration operations.

m. Reference stocks. 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.

n. Responsible Official. An official authorized to transfer and receive biological select agents and toxins on behalf of the facility. The responsible official is also responsible for the implementation of biological select agent and toxin inventory management procedures.

o. Reviewing Official (RO). The commander or 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.

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

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

r. Working stocks. Any passage of a strain of microorganisms or toxins of any quantity to meet authorized needs clearly identified in approved research protocols, test plans, and project or study directives.

APPENDIX F

BSAT AND BPRP FORMS

1. OPNAV FORM 5510/414 (Personnel Reliability Program (PRP) Screening and Evaluation Record) is found in the Navy Forms Online Website at https://forms.daps.dla.mil/.

2. BSAT Annual Report Form. The annual status report shall include, for the preceding calendar year ending 31 December, BPRP certification and permanent decertification statistics by command and category of personnel (e.g., military; Federal civilian; and defense contractor). A recommended format is provided on pages F-2 through F-7.

DON BIOLOGICAL SELECT AGENTS AND TOXINS (BSATs) PERSONNEL RELIABILITY PROGRAM ANNUAL STATUS REPORT For Calendar Year Ending 31 December

Navy Command:_____

	U.S.		Europe		Pacific		Total	
	Critical	Controlled	Critical	Controlled	Critical	Controlled	Critical	Controlled
Total number of certified personnel in the BPRP								
Active Duty Military								
Civilians								
Contractors								
Reserves								
TOTAL								

	U.S.		Europe		Pacific		Total	
	Critical	Controlled	Critical	Controlled	Critical	Controlled	Critical	Controlled
Total number of permanent PRP decertifications								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Type of decertifications								
Alcohol Abuse								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Drug Abuse								
Active Duty Military								
Civilians								
Contractors								
Reserves								

Negligence or delinquency in performance of duty								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Conviction by a military or civilian court of a serious offense; a pattern of behavior indicative of a contemptuous attitude toward the law or other duly constituted authority								
Active Duty Military								
Civilians								
Contractors								
Reserves								

	U.S.		**Europe**		**Pacific**		**Total**	
	Critical	Controlled	Critical	Controlled	Critical	Controlled	Critical	Controlled
Any significant physical or mental condition substantiated by a competent medical authority; aberrant behavior considered by the certifying official as prejudicial to reliable duty performance in a PRP critical or controlled position								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Poor attitude or lack of motivation								
Active Duty Military								
Civilians								
Contractors								
Reserves								

Drug abuse decertifications by type								
	U.S		**Europe**		**Pacific**		**Total**	
	Critical	Controlled	Critical	Controlled	Critical	Controlled	Critical	Controlled
Narcotics								
Active Duty Military								
Civilians								
Contractors								
Reserves								

Depressants								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Stimulants								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Hallucinogens								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Cannabis								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Anabolic Steroids								
Active Duty Military								
Civilians								
Contractors								
Reserves								

Serious offense decertifications by type								
	U.S.		Europe		Pacific		Total	
	Critical	Controlled	Critical	Controlled	Critical	Controlled	Critical	Controlled
Military conviction								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Civilian conviction								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Behavior pattern								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Other								
Active Duty Military								
Civilians								
Contractors								
Reserves								

Physical and/or mental decertifications								
	U.S.		**Europe**		**Pacific**		**Total**	
	Critical	Controlled	Critical	Controlled	Critical	Controlled	Critical	Controlled
Physical condition								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Mental condition								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Aberrant behavior								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Other								
Active Duty Military								
Civilians								
Contractors								
Reserves								

Poor attitude, lack of motivation decertifications by type								
	U.S.		Europe		Pacific		Total	
	Critical	Controlled	Critical	Controlled	Critical	Controlled	Critical	Controlled
Attitude								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Behavior or activity								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Mood or feeling								
Active Duty Military								
Civilians								
Contractors								
Reserves								
Other								
Active Duty Military								
Civilians								
Contractors								
Reserves								

Remarks and additional comments. Use this area to identify any other BPRP screening actions.