

**Report
of the
Inter-Service Council
for
Biosecurity and Biosafety**

12 December 2008



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LETTER OF TRANSMITTAL

Inter-Service Council for Biosecurity and Biosafety General Officer Steering Committee

December 12, 2008

In accordance with the Charter of the Inter-Service Council on Biosecurity and Biosafety, we hereby submit the report of the findings and recommendations of the Inter-Service Council on Biosecurity and Biosafety General Officer Steering Committee.

The mandate given to the Council was broad. We were tasked to assess Service policies and procedures to ensure compliance with biosecurity, biosafety and personnel reliability policies, identify key issues, and provide recommendations for improvement to the Services. We were also tasked to oversee internal review of biosecurity, biosafety and personnel reliability policy and procedures by each Service, as well as an assessment of the requirement to maintain Service laboratory infrastructure to conduct biological select agent and toxin (BSAT) research.

In response, we brought together a Task Force of subject matter experts from across the Services and the Department of Defense. These experts conducted in-depth research and analysis, and developed recommendations for consideration. We also visited several BSAT laboratories for first-hand observation of the facilities to assess biosecurity and biosafety, and to better understand the impact of the recommendations under consideration.

The Council's findings and recommendations focus on seven key areas of biosecurity, biosafety and personnel reliability. While the Council found that Services' policies, regulations, standards, and procedures in effect before August 2008 meet or exceed all federal and DoD requirements, the Services agreed on the need to establish common standards in each area, and recommendations for enhancing biosecurity, biosafety, and personnel reliability were developed.

Service research laboratories have made, and continue to make, significant contributions to medicine, applicable not only to the warfighter, but also to the America public, and to defend against the use of biological agents as weapons by our adversaries. While our Service biological research laboratories rank among the safest

and most secure in world, implementation of these recommendations will reduce risk, further improve safety and security, and allow this critical research to continue to provide benefits to our nation and the world.

We appreciate the honor to serve the country, the Department of Defense, and our Services in this task. Our task force staff stands ready to assist further in the implementation of the recommendations contained in this report.

Signed:

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Executive Summary

Following the announcement of the Federal Bureau of Investigation Anthrax investigation at the U.S. Army Medical Research Institute of Infectious Diseases, the Secretary of the Army organized a Task Force on 7 August 2008 to evaluate the U.S. Army biological surety program including safety, security, and personnel reliability. The Army biological surety program ensures that Army personnel properly safeguard biological select agents and toxins (BSAT) against theft, loss, diversion, or unauthorized access or use, and furthermore that they conduct operations with BSAT in a safe, secure, accountable and reliable manner. Initial actions taken by the Army were coordinated with the Navy and Air Force, and in early September, the Services met and discussed formation of an Inter-Service council to focus on biosecurity and biosafety. The Service Staff Directors agreed to form an Inter-Service Council to identify and address biosecurity and biosafety issues with the development of coordinated, common policies, and standards for Department of Defense (DoD) Service laboratories that routinely conduct research and work with biological select agents and toxins. As of September 2008, there were thirteen DoD Service laboratories that routinely work with biological select agents and toxins (BSAT): Army – six in the United States, one outside the continental United States (OCONUS); Navy – two in the United States, three OCONUS; Air Force – one in the United States.

The Inter-Service Council for Biosecurity and Biosafety (ICBB) Charter officially established the ICBB on 9 October 2008. The intent of the ICBB was to focus on Service policies, procedures, and activities to ensure compliance with DoD policies on biosecurity, biosafety, and personnel reliability; provide recommendations for improvements in key biosecurity, biosafety, and personnel reliability policy and procedural issues to the Services; ensure that each Service conducts an internal review of biosecurity, biosafety, and personnel reliability policy and implementation; and oversee that each Service assesses requirements to maintain a biological select agents and toxins (BSAT) laboratory infrastructure.

Building on the initial work done by the Army, the Council formed a task force with working groups composed of subject matter experts from across the Services and the DoD. The following focus areas were identified for review:

- Transportation of biological select agents and toxins (BSAT)
- Biological Safety

- Biological Security/ Physical Security
- Inspections
- Personnel Reliability Program (PRP) / Foreign Personnel
- Inventory / Accountability of BSAT
- Training of Personnel

Review of all seven areas indicate that Services' policies, regulations, standards, and procedures in effect before August 2008 meet or exceed all federal and DoD requirements.

The Services agreed on the need to establish common standards in each area. Each Service conducted an internal review of biosecurity, biosafety, and personnel reliability policy and implementation. Results of these internal reviews remain with the Services, but did provide information for analysis and development of recommendations within each of the focus areas.

Additionally, the Services agreed to request an external review to evaluate and determine requirements for maintaining laboratory capabilities and infrastructure for handling and conducting biological select agents and toxins (BSAT) research. This external review would provide an unbiased and impartial evaluation of the value and need to maintain Service BSAT laboratory capability and capacity. The ICBB recommended to the Service Secretaries that the Defense Science Board (DSB) and Defense Health Board (DHB) conduct separate external review panels.

To meet the goal of common policies and standards across the Services, and to further enhance biosafety and biosecurity at Service facilities handling biological select agents and toxins (BSAT), all Services agreed on the following enhancements in each of the seven focus areas.

Transportation of BSAT: REDACTED (b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] The ICBB approved revised guidance for air and ground shipment of BSAT by government and commercial air and ground transport, which was published by the Army in October 2008. The ICBB recommends DoD amend the Defense Transportation Regulation with the inclusion of this revised policy guidance language. REDACTED (b) (2) [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

Biosafety: The ICBB recommends that DoD adopt enhanced Army biosafety policy and standards as DoD policy and standards to provide for improved biosafety. Additionally, the Services will require annual industrial hygiene surveys, develop and prescribe uniform qualifications and training standards for biosafety personnel, and develop and prescribe requirements for reporting of biological mishaps to senior military leaders consistent with federal requirements.

Physical Security: The ICBB recommends that the Office of the Under Secretary of Defense for Intelligence (OUSD(I)) develop a BSAT-specific postulated threat assessment. OUSD(I) will coordinate the development of a postulated threat assessment, pending Service input. Additionally, OUSD(I) and OSD(AT&L) requested external security and mission assurance reviews of BSAT facilities and processes by the Defense Threat Reduction Agency (DTRA). DTRA will coordinate with Services for BSAT laboratories to be included in the Balanced Survivability Assessments (BSAs). The first of these BSAs is expected to be scheduled in the second quarter of FY09 at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Ft. Detrick, MD. Services agreed on common security standards and enhancements, to include drug screening, standardized training, medical screening and physical agility tests for security guards, and use of closed circuit television (CCTV) with observers. The Facility Commander of each BSAT laboratory/facility will determine the requirement for armed guards based on a facility vulnerability assessment and the postulated threat assessment. All Services agreed to further strengthen internal security by upgrading the level of the background check requirement, conducting random supervisor reviews, random reviews of CCTV, archiving CCTV tapes for review in the event of an incident, and increasing supervisory review and control of after-hours access. The current two-person rule requirements for reference stock and toxins will be maintained. The Navy has implemented a two-person rule at its Dahlgren, VA facility and will implement a two-person rule for all Category A BSAT research. (Category A BSAT are high-priority agents that pose a risk to national security because they can be easily disseminated or transmitted from person to person; result in high mortality rates and have the potential for major public health impact; might cause public panic and social disruption; and require special action for public health preparedness.) The Air Force uses a two-person rule for all BSAT operations due to the small scale of its BSAT operations.

Inspections: All Services will require external inspections of facilities every 18 months, annual unit self-inspections, and joint inspections where units share facilities.

Personnel Reliability Program (PRP)/Foreign Nationals: The Services agreed to develop and implement a justification and approval process for hiring foreign nationals into biological PRP (BPRP) positions in the U.S., and coordinate with DoD Personnel Security on the review and approval of Department of State investigations for local nationals at overseas facilities. In addition, Army will implement a new investigative standard that requires a Single Scope Background Investigation (SSBI) for individuals in the biological personnel reliability program with direct access to BSAT. The Air Force will require SSBI for individuals in the BPRP, and Navy will implement an SSBI requirement beginning with individuals conducting BSAT research in the United States and for U.S. personnel overseas.

Inventory and Accountability: To improve inventory control and accountability practices, the Services agreed to implement enhanced inventory controls, publish interim guidance, and incorporate this guidance into Service regulation. Inventory enhancements include a certified 100% annual inventory, establishing an audit program, establishing limits on the amount of BSAT that can be maintained and improved control and accountability of short and long-term working stock. In addition, Service inventory databases will be integrated with a DoD centralized BSAT inventory database.

Training: The Services agreed to facilitate biosecurity and biosafety management training standardization among Services. This includes establishing common initial biosecurity management and biosafety officer training, and leveraging respective best practices.

Estimated resource requirements to implement the recommended enhancements are included in Table 1.

	Army	Navy	Air Force
Transportation	Annual - \$388K	Annual - \$3M	Annual - \$8K
Biosafety	Initial - \$80K Annual - \$20K	Initial - \$32K Annual - \$12K	Initial - \$8K Annual - \$4K
Physical Security	TBD*	Annual - \$1.5M	TBD*
Inspections	Annual - \$8.5K	No additional cost	Annual - \$8K
PRP Personnel Security Investigations Pilot	Initial - \$2.5M Annual - \$750K	Annual - \$670K	Minimal
Inventory/Accountability	Annual - \$1.9M	Annual - \$200K	No additional cost
Training	Initial - \$200K Annual - \$150K	Annual - \$35K	Annual - \$15K
TOTALS **	Initial - \$2.8M Annual - \$3.2M	Initial - \$32K Annual - \$5.4M	Initial - \$8K Annual - \$35K

*Based on Commander's assessment for armed guards

** Does not include TBD Physical Security Enhancement Costs

Table 1. Estimated Costs to Implement Enhanced Policies and Procedures

Each of the Services takes the responsibility of handling BSAT seriously and will continuously review the processes and procedures surrounding the handling, transport, and use of these materials. Although the primary mission of Service biological research laboratories is to protect America's warfighters, the research conducted by these facilities has applications that benefit society as a whole. Together, they constitute the nation's greatest capacity for the critical steps in safety and efficiency testing of possible medical countermeasures for biodefense threats.

For decades, the United States Service laboratories' groundbreaking medical research programs have developed vaccines and treatments protecting the lives of thousands of U.S. Soldiers, Sailors, Airmen, and Marines, saving American children suffering from rare diseases and infections, and combating outbreaks and viruses at home and abroad, such as the West Nile Virus and SARS. They are also working, everyday, to develop those same treatments to protect Americans and the world-at-large against those who would use disease and infection as a weapon of war. It is lifesaving work, critical to our nation's defense. In addition to these lifesaving efforts, research in defending against biological agents is also being pursued by Service research laboratories. Developing and maintaining capabilities to counter biological attacks greatly aids the defense of the nation.

Across the board, Service labs have traditionally led the nation in safety and security. As documented in this report, the Services are committed to working even harder to make sure labs and facilities remain safe from attack, whether from outside the walls or inside the labs.

Section 1: Overview

1.1 Background

The Secretary of the Army established a Task Force on 7 August 2008 to evaluate the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) biological Surety program including safety, security, and personnel reliability following the announcement of the Federal Bureau of Investigation at Fort Detrick and USAMRIID. Initially, the focus was a review of the USAMRIID biological Surety program. The focus of the Task Force expanded to include a review of all seven Army labs executing biological select agents and toxins (BSAT) related missions. Initial actions taken by the Army were coordinated with the Navy and Air Force, and in early September, the Services met and discussed formation of an Inter-Service council to focus on biosecurity and biosafety. The Service Staff Directors agreed to form an Inter-Service Council to identify and address biosecurity and biosafety issues with the development of coordinated, common policies, and standards for Department of Defense (DoD) Service laboratories that routinely conduct research and work with biological select agents and toxins. The Inter-Service Council for Biosecurity and Biosafety (ICBB) Charter officially established the ICBB on 9 October 2008 after signature by all Services.

1.2 Purpose/Intent of the ICBB

The ICBB was formed in September 2008, and officially chartered in October 2008, to provide an integrated and cohesive structure for addressing biosecurity, biosafety, and personnel reliability issues and to support accomplishment of the Services' missions. See Appendix A-1 for the Charter of ICBB.

As described in the Charter, the intent of the ICBB was to:

- a. Identify, define, and focus Service policies, procedures, and activities to ensure compliance with Department of Defense policies on biosecurity, biosafety, and personnel reliability.
- b. Provide a flexible mechanism for the Services to effectively address and resolve key biosecurity, biosafety, and personnel reliability policy and procedural issues, influence planning, and provide recommendations for improvement to the Services.
- c. Oversee that each Service conducts an internal review of biosecurity, biosafety, and personnel reliability policy and implementation focused on BSAT facilities, personnel, and transportation.
- d. Oversee that each Service assesses requirements to maintain a BSAT laboratory infrastructure.

Section 2: Approach

2.1 Methodology

The Inter-Service Council for Biosecurity and Biosafety (ICBB) was structured with two tiers: a General Officer Steering Committee (GOSC) and a Council of Colonels/Captains (CoC), supported by working groups (WGs), as needed, to focus on specific issues and areas of concern. See Appendix A-2 for ICBB GOSC membership. The first ICBB GOSC was convened on 18 September 2008. At this initial meeting, the Services agreed that common Service standards are the goal for biosecurity and biosafety. The Services agreed to review policies and procedures in specific key focus areas of biosecurity, biosafety, and personnel reliability during weekly GOSC meetings. See Appendix A-3 for the GOSC schedule.

Working groups for each of the key focus areas were composed of subject matter experts from all three Services, and from other Department of Defense organizations as needed. The working groups reviewed extant Federal regulations and policies, DoD policies and guidance, and individual Service policies, guidance and procedures relevant to possession, use and transport of BSAT, as well as previous reports on biosecurity and biosafety and personnel reliability. Each working group conducted in-depth analysis of its issue area, and identified potential weaknesses and opportunities for improvement, including standardization across the Services. Recommendations for enhancements to policies and procedures were developed, analyzed for feasibility of implementation, and refined. Estimates of resources needed to implement the recommendations were also developed. Recommendations were vetted within each Service.

The GOSC provided updates to Service Senior Leadership on a regular basis and received feedback which shaped the work of the GOSC and the working groups. Services Secretaries received a briefing on the final recommendations on 3 December 2008; the briefing chart for each focus area is provided in the Appendix of this report.

2.2 Focus Areas

The following biosecurity and biosafety policy areas were identified for review by the ICBB GOSC:

- Transportation of BSAT
- Biological Safety
- Physical Security / Biological Security

- Inspections
- Personnel Reliability Program (PRP) / Foreign Personnel
- Inventory / Accountability of BSAT
- Training of Personnel

To accomplish the goal of common Service standards in each area, the ICBB reviewed the status of current Service standards, compared standards across the Services and identified differences, identified best common standards, and worked to develop common standards. The GOSC developed recommendations for approval by each Service.

This work met the ICBB tasking to identify, define and focus Service policies, procedures, and activities to ensure compliance with Department of Defense policies on biosecurity, biosafety, and personnel reliability, to effectively address and resolve key biosecurity, biosafety, and personnel reliability policy and procedural issues, to influence planning, and to provide recommendations for improvement to the Services.

2.3 Internal Reviews

As directed in the ICBB Charter, the Services conducted internal reviews of biosecurity, biosafety, and personnel reliability policy and implementation, focusing on BSAT facilities, personnel, and transportation. Results of these internal Service reviews remain with the Services, but did serve to provide information relative to the seven focus areas, as well as informing Service-specific actions as deemed appropriate.

2.4 External Reviews

To meet the Charter's mandate to assess the requirement to maintain a Service BSAT laboratory infrastructure and capability, the Services agreed to request an external review. This external evaluation would provide an unbiased and impartial evaluation of the value and need to maintain Service BSAT laboratory capability and capacity. On 22 August 2008, at the direction of the Secretary of the Army, the Army Assistant Deputy Chief of Staff (G-3/5/7) met with Office of the Secretary of Defense for Homeland Defense and Americas' Security Affairs (OSD (HD&ASA)), Office of the Special Assistant for Chemical and Biological Defense and Chemical Demilitarization Programs (OSA(CBD&CDP)), Undersecretary of Defense for Intelligence (USD(I)), and the Office of the Assistant Secretary of Defense for Health Affairs (OSD(HA)) to discuss the formation of a Blue Ribbon Panel to evaluate the biodefense laboratories in the Department of Army. This initial meeting served as the basis for expansion of the external review to include all DoD Services' biodefense laboratory facilities.

The ICBB GOSC recommended to the Service Secretaries that the Defense Health Board (DHB) and Defense Science Board (DSB) conduct separate external reviews.

In response to this recommendation, and at the request from the Service Secretaries, the Under Secretary of Defense for Acquisition, Technology and Logistics requested the DSB conduct a review focused on these key questions (see Terms of Reference (TOR) Appendix I-1 **REDACTED (b) (6)** [REDACTED]):

- Are current and proposed DoD and Service policies in the biosafety, biosecurity and personnel reliability programs adequate to safeguard against accidental or intentional loss / misuse of BSAT by external or internal actors from the RDT&E infrastructure?
- Are current Military Department laboratories or operations that use or store BSAT meeting stringent standards for safety, security, and personnel reliability?
- How do DoD and Services' programs compare to other government agency programs, academic programs, and industry programs?
- How can DoD usefully employ experience in other areas requiring utmost safety, security and reliability (e.g., the nuclear program) to biological safety, security and personnel reliability policy development and implementation?

The Surgeon General of the Army, on behalf of all the Services, requested the DHB conduct a review focused on these key questions (see TOR Appendix I-2):

- Is there a national and/or strategic defense need for the Military Service Departments (MSDs) to own and operate an infrastructure in support of mission requirements for defense capabilities (abroad and homeland) against biological warfare and biological terrorism threats?
- Are current processes effective in transferring the results of basic biological research to advanced product development and licensure?
- Does the current MSD infrastructure provide scientific or strategic return on investment for previous and current research, development, test and evaluation (RDT&E) efforts?

The DSB and DHB will provide their findings and recommendations from these external reviews to the Service Secretaries in separate reports. Interim reports were briefed to the Service Secretaries by both panels on 3 December 2008.

Section 3: Findings and Recommendations

3.1 Overview

As of September 2008, there were thirteen Department of Defense (DoD) Service laboratories that handled biological select agents and toxins (BSAT). The numbers and locations of laboratories, and the numbers of personnel in the Biological Personnel Reliability Program (BPRP), are shown in Table 2, with further detail following.

	Army	Navy	Air Force
Laboratories	7 (1 OCONUS)	5 (3 OCONUS)	1
Personnel in the Biological PRP	526	74*	3

*Navy personnel requiring enrollment in BPRP, all not yet enrolled.

Table 2: BSAT Laboratories and Personnel in the BPRP by Service

The Services have additional laboratories that are registered with the CDC and USDA and can handle BSAT, such as the Army's Laboratory Response Network Laboratories and various military hospital laboratories. However, none of these laboratories routinely work with or store BSAT, and none hold any BSAT at this time. They were therefore not included in this review.

3.1.1 Army

The Army had seven laboratories that handled BSAT as of September 2008. Six of these are located within the United States, and one is outside the continental United States (OCONUS). All BSAT was removed from the OCONUS facility in November 2008. Additionally, the Assistant Secretary of Defense for Health Affairs (ASD(HA)) approved the Army Surgeon General's recommendation to discontinue the BSAT program at the Armed Forces Institute of Pathology (AFIP) on 2 December 2008 (Appendix B-10). The Surgeon General will implement a plan for disposition of all BSAT no later than March 2011.

Locations are as follows:

- United States Army Medical Research Institute of Infectious Diseases (USAMRIID), Ft. Detrick, MD

- Armed Forces Institute of Pathology, (AFIP), Walter Reed Medical Center, Washington, DC (ASD(HA) approved the Army Surgeon General's recommendation to discontinue the BSAT program at AFIP on 2 December 2008, with transfer of all BSAT from AFIP by March 2011).
- Walter Reed Army Institute of Research, (WRAIR), co-located with the Navy Medical Research Center, Silver Spring, MD
- US Army Medical Research Institute of Chemical Defense (USAMRICD), Aberdeen Proving Ground, MD
- Edgewood Chemical Biological Center (ECBC), Aberdeen Proving Ground, MD
- West Desert Test Center Life Sciences Test Facility (WDTC-LSTF), Dugway Proving Ground, UT
- OCONUS: Armed Forces Research Institute of Medical Sciences, (AFRIMS), Bangkok, Thailand, co-located with the Royal Thai Army medical research laboratory complex (all BSAT materials were shipped to USAMRIID in early November 2008)

3.1.2 Navy

The Navy operates five BSAT laboratories. Two are in the United States, and three are OCONUS. Locations are as follows:

- Naval Medical Research Center co-located with the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD.
- Herbert H. Bateman Chemical Biological Defense Center, Dahlgren, VA
- U.S. Naval Medical Research Unit No. 3 (NAMRU-3), Cairo, Egypt
- U.S. Naval Medical Research Center Detachment (NMRCD), Lima, Peru
- U.S. Naval Medical Research Unit No. 2 (NAMRU-2), Jakarta, Indonesia

The Navy plans to remove all BSAT from NAMRU-2 at which time it will cease to be a BSAT laboratory.

3.1.3 Air Force

The Air Force Research Laboratory at Brooks City-Base, San Antonio, TX, is the only Air Force laboratory that currently works with BSAT. It is scheduled to move to Wright-Patterson AFB, OH under Base Realignment and Closure Commission reorganization.

3.2 Focus Area Findings and Recommendations

For each of the seven focus areas, the ICBB reviewed the status of current Service standards, compared standards across the Services to identify differences, identified best common standards, and worked to develop upon common standards. The GOSC developed recommendations for approval by each Service. Specific findings and recommendations are organized by focus area below.

3.2.1 Transportation of Biological Select Agents and Toxins (BSAT)

3.2.1.1 Findings

Internal review of the Services' policies and procedures indicate that BSAT transportation policies in effect before August 2008 met all federal and DoD requirements. See Appendix B-3 for a list of current BSAT transportation policies. The Services determined the average number of BSAT shipments per year, shown in Table 3.

Service	Avg. Number of Shipments Per Year
Army	200
Navy	34
Air Force	1

Table 3: Average number of BSAT shipments per year, by Service

Initial analysis of movement of BSAT noted differences between the stringent rules for control of BSAT within a laboratory versus the less stringent rules for shipment between laboratories. Specifically, movement of BSAT within a DoD facility requires use of two personnel registered with CDC or USDA and in the biological personnel reliability program to maintain integrity and positive control. Authorized shippers were not required to meet similar security measures (e.g. two-person control) for the BSAT package while in transit.

3.2.1.2 Service Agreements and ICBB Recommendations

The Inter-Service transportation working group (WG) developed guidance to improve security and accountability of ground and air transport of BSAT by government and commercial carriers. The interim policies ensure that there is a chain of custody and positive control. These were presented to the Services and the ICBB for review and approval.

