Report of the Working Group on Strengthening the Biosecurity of the United States

Table of Contents

EXECUTIVE SUMMARY

On January 9, 2009, the White House issued Executive Order (EO) 13486 entitled "Strengthening Laboratory Biosecurity in the United States." This EO established a Working Group (WG) co-chaired by the Secretary of Defense and the Secretary of Health and Human Services, or their designees. Other members of the WG included designees of the Secretaries of State, Agriculture, Commerce, Transportation, Energy, and Homeland Security, the Directors of National Intelligence and the National Science Foundation, the Administrator of the Environmental Protection Agency, and the Attorney General.

EO 13486 states that the scope of WG activities pertains to the United States' policy which reads "facilities that possess biological select agents and toxins have appropriate security and personnel assurance practices to protect against theft, misuse, or diversion to unlawful activity of such agents and toxins." Encompassed therein are "Federal and non-Federal facilities that conduct research on, manage clinical or environmental laboratory operations involving, or handle, store or transport select agents and toxins."

EO 13486 assigned three tasks to the WG:

(1) Review and evaluate the efficiency and effectiveness of existing laws, regulations, guidance, and practices relating to physical, facility, and personnel security and assurance at Federal and non-Federal facilities that function as described above.

(2) Obtain information or advice, as appropriate for the conduct of the review and evaluation, from the following: heads of executive departments and agencies; elements of foreign governments and international organizations with responsibility for biological matters, consistent with functions assigned by law or by the President to the Secretary of State; representatives of State, local, territorial, and tribal governments; and other entities or individuals.

(3) Prepare a written report to the President,180 days after the date of the EO, that (a) summarizes the efficiency and effectiveness of existing laws, regulations, guidance, and practices related to physical, facility, and personnel security and assurance at Federal and non-Federal facilities, (b) compares the range of existing personnel security and assurance programs for access to biological select agents and toxins to similar programs in other fields and industries, (c) recommends any new legislation, regulations, guidance, or practices based on the WG review and evaluation, and (d) includes options for establishing oversight mechanisms to ensure a baseline standard is consistently applied to all physical, facility, and personnel security and assurance laws, regulations, and guidance at all Federal and non-Federal facilities.

In order to carry out the tasks set forth in the EO, members of the WG met in person and via teleconference; received key stakeholder briefings from representatives of Federal Government agencies, industry and professional organizations; conducted site visits to select agent entities from all sectors; and held a public consultation meeting. Five

subgroups (on the Select Agent Regulations, transportation, physical security, personnel security and reliability, and oversight/inspection) were established in order to review existing laws, regulations, and guidance that pertain to biosecurity within facilities that possess, use, and transport select agents and toxins. The subgroups examined whether gaps are present in current laws, regulations, and guidance pertaining to biosecurity, and made recommendations to the WG to fill these gaps with the ultimate goal of strengthening biosecurity. Throughout the process, the subgroups considered the value of additional biosecurity measures in strengthening biosecurity, given the potential cost and risk to scientific progress and collaboration.

The WG arrived at final recommendations through careful consideration of proposals from subgroups, discussions with select agent entities, and comments received from the public. A compilation of the specific recommendations is in Appendix 6 and a brief summary of the key findings and recommendations is below.

A. Select Agent Regulations

Key findings: 1) There are 82 biological select agents and toxins (BSAT) on the select agent list, but not all pose the same level of risk to public or agricultural health. The list should be either reduced or stratified so that biosecurity measures can be more easily applied by the registered entities according to the level of risk. 2) The responsibility for oversight of select agent entities by various Federal, State, and local agencies beyond HHS and USDA, as well as compliance inspections by higher government and corporate headquarters, has resulted in numerous uncoordinated inspections with non-uniform standards, expectations, and interpretations. 3) Registered entities report confusion regarding appropriate inventory records, formats, and requirements.

Key Recommendations: 1) Perform a risk assessment for each select agent and toxin on the BSAT list and develop a stratification scheme that includes biodefense and biosecurity criteria, as well as risk to public health, so that security measures may be implemented based upon risk. 2) Enhance U.S. Government coordination of oversight and inspections as well as institutional implementation, compliance, oversight, and accountability. 3) Provide comprehensive guidance on inventory management and recordkeeping requirements, approaches, and templates.

B. Personnel Security

Key Finding: Improvements can be made in the current Select Agent Program regarding the screening of individuals both prior to granting access to BSAT and after access has been granted.

Key Recommendation: Enhance the Security Risk Assessment at the Federal level to allow for improved vetting of U.S. citizens and foreign nationals. Require continuous monitoring measures (supervisor accountability, self- and peer-reporting) at the local level and evaluate the feasibility of reporting of derogatory information to improve management oversight of individuals with BSAT access.

C. Physical Security

Key Finding: Physical security plans at facilities are performance-based; therefore, there are no minimum prescriptive standards for physical security at facilities that handle, store, or transport BSAT.

Key Recommendation: Develop a set of minimum prescriptive security standards based on the risk at the lowest level, allowing for enhancements as risk increases.

D. Transportation

Key Finding: Historical data indicate that there has been only one confirmed loss of a BSAT shipment in the last twenty years; this loss was not the result of criminal activity. While this may suggest that existing regulations, policies, and procedures are satisfactory and provide an appropriate level of security for BSAT in transportation, there has not been an extensive assessment to determine the threats, vulnerabilities or risks within this sector regarding BSAT.

Key Recommendation: Perform a risk assessment, focused on the security of BSAT transportation under the current regulatory framework, to determine if any risk is present during BSAT transportation.

Conclusion

The WG believes the Select Agent Program has significantly strengthened the biosecurity of the United States since its implementation. Achieving effective, comprehensive biosecurity for BSAT is a shared responsibility. Although the biosecurity measures and oversight responsibilities of the Federal Government are essential, facilities and individuals that possess, use, or transfer BSAT play key roles. The WG concludes that biosecurity could be further enhanced and strengthened at the Federal and local levels by implementing the recommendations herein.

The recommendations were developed without consideration of potential competing priorities across the Federal Government, and their implementation would be subject to the availability of funds. In addition, the potential impacts and benefits to the stakeholder community of implementation of any of these recommendations must be considered.

Chapter 1 BACKGROUND

On January 9, 2009, the White House issued Executive Order (EO) 13486[1] entitled "Strengthening Laboratory Biosecurity in the United States" (Appendix 1-A). This EO established a Working Group (WG) to be co-chaired by designees of the Secretary of Defense and the Secretary of Health and Human Services. Other members of the WG included designees of the Secretaries of State, Agriculture, Commerce, Transportation, Energy, and Homeland Security, the Directors of National Intelligence and the National Science Foundation, the Administrator of the Environmental Protection Agency, and the Attorney General (see Appendix 1-B for WG membership).

The scope of WG activities pertains to the policy of the United States that facilities that are registered to possess, use, or transfer biological select agents and toxins (BSAT),[2] including both Federal and non-Federal facilities that conduct research on, manage clinical or environmental laboratory operations involving, or handle, store or transport BSAT, have appropriate security and personnel assurance practices to protect against theft, misuse, or diversion to unlawful activity of such agents and toxins. Outside the scope of this report are the concepts of cyber-security, information systems management, and a full cost-benefit analysis of the select agent regulations or any recommendations herein.

A. What is Biosecurity?

In the context of this report, the term biosecurity refers to the protection, control of, and accountability for high-consequence biological agents and toxins, and critical relevant biological materials[3] and information within laboratories to prevent unauthorized possession, loss, theft, misuse, diversion, or intentional release.[4] Biosecurity is achieved through an aggregate of practices including the education and training of laboratory personnel, security risk assessments, BSAT access controls, physical security (facility) safeguards, and the regulated transport of BSAT.[5] Achieving effective, comprehensive biosecurity for BSAT is a shared responsibility between the Federal Government and facilities/individuals that possess, use, or transfer BSAT.

A concept complementary to biosecurity is biosafety. Biosafety refers to the implementation of laboratory practices and procedures, specific construction features of laboratory facilities, safety equipment, and appropriate occupational health programs when working with potentially infectious microorganisms and other biological hazards.

---

[1] EO 13486 is available at http://edocket.access.gpo.gov/2009/pdf/E9-818.pdf and in Appendix 1-A.

[2] BSAT are a specific group of biological pathogens and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products.

[3] "Critical relevant biological material" refers to genetic elements, recombinant nucleic acids, and recombinant organisms, regulated by the SAR – 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121.

[4] The use of the term "biosecurity" in this report does not refer to the practice of agricultural biosecurity, or the prevention of entry of a pathogen or pest into a susceptible population of plants or animals.

[5] Adapted, in part, from the WHO report available at http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

Biosafety practices and procedures are designed to reduce the exposure of laboratory personnel, the public, agriculture, and the environment to potentially infectious agents and other biological hazards. The key principles of biosafety are risk assessment and containment.

Risk assessment takes into account engineering controls, practices, protective equipment and facility design determined to be appropriate for the specific operations performed with infectious agents and allows for the categorization of the work into four biosafety levels (BSLs), assigned in ascending order based on the degree of risk. The pathogenicity and infectiousness of the agent and the severity of disease also contribute to the assignment of a BSL. The designations BSL-2, BSL-3, and BSL-4 are for working with human and zoonotic infectious agents in the lab while the terms animal BSL-2 (ABSL-2), ABSL-3, and ABSL-4 are for work with human and zoonotic infectious agent in the vivarium. BSL-3Ag is typically reserved for large animal research with non-endemic livestock pathogens that could have significant impacts upon U.S. agriculture. Laboratories designed for the safe handling of plant pathogens do not use the BSL designation. However, plant pathogens are typically contained in laboratories and greenhouses constructed with features similar to those described for containment of human and animal pathogens. It should be noted, however, that not all BSAT activities are appropriately conducted in BSL-3 or BSL-4 labs; some are appropriately conducted at BSL-2. Furthermore, many pathogens are handled at BSL-3 but are not on the select agent list (described in more detail below).

The concepts of biosecurity and biosafety are interrelated; many safeguards, including protective equipment and containment facilities, are designed to ensure biosafety and biosecurity. In particular, access controls are an important element of both biosafety and biosecurity. Some nations and U.S. entities have chosen to focus on the interplay between biosecurity and biosafety and address what is termed biorisk management, wherein both biosecurity and biosafety risks are assessed and mitigated in a single management plan.

B. Current United States Regulatory Framework

1. What is a Select Agent?

BSAT are biological pathogens and toxins whose possession, use, and transfer are regulated by the Department of Health and Human Services (HHS)/Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS) and that have the potential to pose a severe threat to public, animal, or plant health, or to animal or plant products. Many BSAT cause severe disease for which there is no treatment and/or no vaccine. For diseases that are treatable, treatment must often be administered immediately after exposure to be effective—treatment after the onset of illness might have less, if any, effect. BSAT that are regulated by both CDC and APHIS are referred to as “overlap” select agents and

toxins.[6] Entities in possession of overlap BSAT may choose to register with either CDC or APHIS, but registration with both Agencies is not required.

In determining whether to include a biological agent or toxin on the select agent list, the Bioterrorism Act requires HHS and USDA to consider a number of characteristics including the effect of exposure to the agent or toxin on human, animal, or plant health degree of pathogenicity, and ease of production, among others (see details in Appendix 1-C). The most recent HHS and USDA review of the select agent lists was completed in 2008 with publication of revised lists in the *Federal Register* on October 16, 2008.[7]

2. History of the Select Agent Regulations (SAR)

Prior to 1996, there was no special list of etiologic agents or toxins defined as meriting particular restrictions on their handling, storage or transportation. There were no licensing or permitting requirements, registrations, or reporting requirements for entities that used, possessed, or transferred what are now known as BSAT within the United States, other than the HHS/CDC Etiologic Agent Import Permit Program, and the USDA/APHIS facility inspections and permits required for work with agricultural agents. In addition, beyond the guidance contained in the "Biosafety in Microbiological and Biomedical Laboratories" (BMBL, currently in its 5th edition), published by the CDC and National Institutes of Health (NIH), there were no uniform safety or security requirements for entities performing transfers of these pathogens.

Shortly after the incident in which Larry Wayne Harris ordered strains of *Yersinia pestis* (etiologic agent of plague) from a supplier (May, 1995), and in response to the Oklahoma City bombing of a Federal building (April, 1995), Congress passed the Antiterrorism and Effective Death Penalty Act of 1996. Section 511 of the Act directed the Secretary of HHS to establish a list of BSAT that have the potential to pose a severe threat to public health and safety, and to develop regulations that establish thorough procedures for the transfer of those "select" agents and toxins. Regulation of BSAT was delegated to the CDC and resulted in the establishment of the HHS Select Agent Program.

Following the 2001 anthrax attacks, Congress passed the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act)[8], and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Response Act)[9]. The Bioterrorism Response Act expanded the scope of the SAR to include all entities that possess, use, and transfer BSAT affecting humans and granted the USDA authority comparable to that of the CDC to regulate entities that possess, use, and transfer BSAT that present a severe threat to plant or animal health or products. The SAR were designed to ensure that

[6] The list of regulated BSAT is available at http://www.cdc.gov/od/sap/docs/salist.pdf as well as in Appendix 1-C.
[7] The biennial HHS and USDA review of the select agent lists is available at http://www.selectagents.gov/resources/Biennial%20Review_CDC_20081016.pdf or http://www.selectagents.gov/resources/Biennial%20Review_APHIS_20081016.pdf, respectively.
[8] Public Law 107-56
[9] Public Law 107-188

personnel have the appropriate training and skills to handle the agents safely and that entities furnish the proper laboratory facilities in which to contain and dispose of the agents. The USDA Secretary delegated to APHIS the responsibility for promulgating and implementing the agricultural SAR.

In accordance with the Bioterrorism Response Act, the CDC and APHIS promulgated Part 73 of Title 42, Part 331 of Title 7, and Part 121 of Title 9 of the Code of Federal Regulations.[10] The final rules were published on March 18, 2005. The expanded SAR require that each individual and entity that possesses, uses, or transfers BSAT register with the CDC or APHIS and that each registered entity establish and implement safety, security, and incident response plans to facilitate safe and secure activities with BSAT. Furthermore, in accordance with the USA PATRIOT Act, the SAR provide that no "restricted person" may have access to either HHS only or overlap BSAT (Appendix 1-D). With regard to animal and plant select agents regulated only by APHIS, APHIS regulations provide that an individual's access to those agents may be denied, limited, or revoked if that individual is a "restricted person" (See 7 CFR 331.10 and 9 CFR 121.10). An entity registering to work with BSAT must identify a Responsible Official (RO), who acts as the point of contact and ensures compliance with SAR. All entities that possess, use, or transfer BSAT must comply with these regulations and there are severe penalties for non-compliance. The RO, Alternate RO, individuals that own or control the non-governmental entity and non-governmental entity itself, and any other individuals within the entity who need access to BSAT, must undergo a Security Risk Assessment conducted by the Federal Bureau of Investigation's Criminal Justice Information Services (FBI-CJIS) Division. (Additional requirements for individuals and entities registered with the Select Agent Program are found in Appendix 1-E.)

The Bioterrorism Response Act also required that USDA and HHS closely coordinate their regulatory activities concerning BSAT and review the select agent list biennially. To this end, the CDC and APHIS jointly conduct oversight of entities that possess, use, or transfer BSAT: (1) to minimize any conflicts between the regulations issued under, and activities carried out under, such programs; (2) to minimize the administrative burden on persons subject to SAR; and (3) to ensure the appropriate availability of BSAT for legitimate biomedical, agricultural, or veterinary research, education, or other such purposes.

C. International Biosecurity Initiatives

International organizations have generated a range of biosecurity initiatives (examples below). Some initiatives are treaties and/or products developed by multilateral

[10] CFR Part 73 of Title 42is available at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=3f916c97af86a994a8ce127ac2d8e92b&rgn=div5&view=text&node=42:1.0.1.6.60&idno=42 ; CFR Part 331 of Title 7 is available at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=b729ce3d56c5c9f084a9e5e07adedd7e&rgn=div5&view=text&node=7:5.1.1.1.9&idno=7 ; CFR Part 121 of Title 9 is available at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=706e95d2bed6acded9b442e25a70c021&rgn=div5&view=text&node=9:1.0.1.5.57&idno=9

international organizations of which the United States is a member nation; others represent significant international efforts by regional bodies such as the European Union (EU).

1. Biological and Toxin Weapons Convention (BTWC).[11] The BTWC bans the development, production, stockpiling, or retention of microbial agents or other biological agents and toxins that have no justification for prophylactic, protective, or other peaceful purposes.

2. Australia Group.[12] The Australia Group is an informal group of 40 countries (including the United States) that focuses on the export control of biological and chemical technologies and material. The Australia Group maintains lists of controlled technologies that require licensing for shipping outside of Australia Group countries. These lists include biological pathogens that infect humans, animals, and plants.

3. United Nations Security Council Resolution 1540 (UNSCR 1540).[13] This resolution established binding obligations on all UN member states to take and enforce effective measures against the proliferation of weapons of mass destruction (WMD), their means of delivery, and related materials. One obligation of all member states is to adopt laws prohibiting WMD proliferation. This resolution requires compliance reports every two years from participating countries. One of the compliance metrics is whether a country has passed laws controlling access of personnel or facilities to hazardous biological agents and toxins.

4. International Laboratory Biorisk Management Standard.[14] The European Committee for Standardization (CEN) convened a working group to establish a laboratory biorisk management standard. Twenty-four countries were represented, including non-EU countries such as the United States and Canada, as well as the World Health Organization (WHO). The CEN standard, published in 2008 as CWA 15793:2008, establishes requirements for controlling risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and other facilities.

5. Biorisk Management: Laboratory Biosecurity Guidance (WHO publication WHO/CDS/EPR/2006.6).[15] This WHO document complements the WHO's Laboratory Biosafety Manual. It defines laboratory biosecurity and describes a biorisk management approach in the context of biosafety procedures and practices. The document is intended to provide guidance to member states to develop their own national frameworks for the security of biological materials.

---

[11] Information about the BTWC is available at http://www.opbw.org/.
[12] Information about the Australia Group is available at http://www.australiagroup.net/en/index.html.
[13] UNSCR 1540 is available at http://www.state.gov/t/isn/c18943.htm
[14] The final version of the CEN publication, *Laboratory Biorisk Management Standard* (CWA 15793), is available at http://www.cen.eu/cenorm/sectors/technicalcommitteesworkshops/workshops/ws31.asp.
[15] This guidance is available at http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/index.html

6. European Commission (EC) Green Paper on Biopreparedness.[16] This Green paper (an official EC discussion document) was published as document COM(2007)399, and presents European policy options for reducing risk associated with hazardous biological agents and enhancing preparedness in the event of a biological threat to public safety. Among the responses to questions posed for comment were opinions on possible rules requiring the registration of researchers and/or facilities, the scope of such registrations, the necessity of security clearances for some biological research, and the need and feasibility of developing a Europe-wide select agent list. A summary of the replies (including submissions by 23 member states) entitled "Synthesis of the Replies to the Green Paper on Bio-Preparedness" was published as document SEC (2008) 2374.[17]

7. Report of the EC CBRN Task Force.[18] This report, tasked by the EC in 2007, made recommendations on possible Europe-wide initiatives to improve the security of chemical, biological, radiological and nuclear (CBRN) materials. Task force members were from industry and academia, as well as representatives of EC member states. Specific recommendations include: 1) the development of an open-ended list of special biological agents and toxins of concern (the EU biosecurity list); 2) the development of a standard for the assessment of security arrangements for registering facilities that possess substances on the EU biosecurity list; 3) within member states, the individual development of a process for performing background checks and registering individuals who work with agents on the EU biosecurity list; and 4) the development of an EU-level list of certified secure couriers of biological agents and toxins on the EU biosecurity list.

Outside of the United States, the majority of countries have no mandate for government oversight of work with biological agents and toxins. A small but growing number of developed and developing countries profess adherence to biosafety guidelines, however, only a handful of nations have enacted regulations that provide government oversight of access to hazardous biological agents and toxins; most of these nations have put such regulations into effect since 2001.

The concepts of biosafety and biosecurity are often conflated in many countries. The 2008 UNSCR 1540 report identified over 40 countries with enforced regulations requiring licensing or registration of personnel or facilities "with access to biological materials." In practice, the actual number of countries with regulatory systems that provide active government *oversight* of personnel or facilities that work on biological pathogens or toxins is significantly less. A small number of countries, including the United Kingdom and Germany, have oversight regulations that are as comprehensive as those that exist in the United States. Mechanisms for regulating personnel access to hazardous biological agents and toxins vary, from national registries like those in the United States and Australia to local registries (at the level of the facility or local law

[16] The EC Green paper "Between Prevention and Preparedness: The European Commission's Green Paper on Bio-preparedness" is available at http://eur-lex.europa.eu/LexUriServ/site/en/com/2007/com2007_0399en01.pdf

[17] www.cdep.ro/docs_comisii/IE/CE/2008/SEC_2008_2374_EN_DOCUMENTDETRAVAIL_f.doc

[18] The Bio-Subgroup of the EC CBRN Task Force generated a report entitled "BIO-SUBGROUP: DETECTION AND DIAGNOSIS (HUMAN, ANIMAL AND PLANTS)" which is available at http://www.ebsaweb.eu/index.php?id=889&suffix=pdf&nonactive=1&lang=en&site=ebsa_media.

enforcement), such as those in Germany or the United Kingdom. Facility licensing in other countries is more prevalent than personnel licensing, however, the mechanisms for overseeing hazardous biological agents and toxins facilities vary greatly, from requiring government permission to construct a BSL-3 or BSL-4 facility, to requiring a facility to notify the government of "first use" of an agent that requires BSL-3 or BSL-4 containment.

The practice of using a select list of hazardous pathogens and toxins, as in the United States, is not widespread. Among the few countries that use such a list, the number of agents varies significantly, from 22 to 105, and the context in which these lists are used (for personnel screening, facility security, and registration vs. notification requirements) varies significantly. Some countries regulate pathogen research through regulations based on biosafety risk levels (Canada, Germany, Switzerland); others use regulations for working with genetically modified organisms (Germany, France, Thailand).

D. Incidents with Biological Materials

A number of incidents have occurred with biological materials. These incidents sparked public and policymaker interest in biosecurity. Incidents may be classified as laboratory incidents,[19] which include accidental exposure to material while working in a laboratory; bioterrorism, which refers to non-State-sponsored use or threatened use of biological agents to promote or spread fear or intimidation in a population; and biocrimes, which refer to instances in which individuals use biological material with intent to inflict harm upon others.

1. Laboratory Accidents and Other Incidents. Even though many levels of security or safety protocols may be in place, human error can lead to the infection of a laboratory worker, an environmental release, or a public health concern. It is not surprising that when an accident or other incident occurs at a BSL-3 or BSL-4 facility, it triggers public attention and questions about how the incident could have occurred.

Various laboratory accidents and other incidents have occurred in laboratories that house infectious agents, although most did not involve BSAT. Additionally, the most serious accidents (*i.e.*, those resulting in infections outside the laboratory) have occurred in countries other than the United States. Of the reported accidents in U.S. laboratories since 2001, none has resulted in a public health emergency[20] or a widespread impact on plant or animal health.[21] Examples of laboratory accidents and incidents involving agents now designated as BSAT include the following:

[19] The term "incidents" is used variably by different entities; it can mean accidental exposures, laboratory-acquired infections, accidental release, deliberate release, theft, *etc.* The SAR (7 CFR 331.19, 9 CFR 121.19, and 42 CFR Section 73.19) specify incidents that require notification, based on whether the incidents involve "theft or loss" versus "a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area."
[20] Kaiser J. Accidents spur a closer look at risks at biodefense labs. *Science* 2007. 317 (5846):1852-1854.
[21] Though various incidents have occurred, the occurrence is rare.

- In 1979, a biological weapons plant in Sverdlovsk (now Ekaterinberg), Russia, released airborne *Bacillus anthracis* (the causative agent of anthrax) spores. U.S. Government reports indicate the release was probably accidental.[22] There were 68 confirmed deaths from anthrax, but the actual number of deaths is unknown. Scientists at Los Alamos National Laboratory in New Mexico determined the spores were derived from least four different strains of *B. anthracis*.
- In 2004, three Boston University researchers accidentally became infected with *Francisella tularensis* (the causative agent of tularemia) as a result of two separate incidents.[23] The researchers believed they were working with an avirulent strain of the bacterium, but a virulent strain had mistakenly been shipped to the lab. Boston University was shown to have deficient safety practices as well as no system in place to detect clusters of illness.
- In 2006, a laboratory worker at Texas A&M University became infected with *Brucella* after leaning into a contaminated safety hood to clean it.[24] University officials did not promptly report the exposure to the CDC as required under the SAR, and subsequent CDC investigations revealed that Texas A&M University had committed a dozen violations of the SAR.
- In 2007, a localized outbreak of Foot-and-Mouth Disease occurred as a result of an accidental release of the pathogen through a leaky pipe at a research facility in Pirbright, England.[25]

2. Bioterrorism and Biocrimes. In addition to unintentional laboratory releases of BSAT are acts of terrorism or criminal acts in which hazardous biological agents are disseminated intentionally. Several aspects of bioweapons are attractive to terrorist organizations and criminals: 1) biological agents may be easy to obtain because most occur in nature; 2) some biological weapons are relatively inexpensive to produce; and 3) the dissemination of a small amount of certain highly infectious organisms could cause widespread illness, contamination, economic disruption and death.

The following are examples of bioterrorism and biocrimes:

- In 1984, members of the Rajneeshee religious cult contaminated salad bars with *Salmonella typhimurium* in 10 restaurants in The Dalles, Oregon. The attack was the first bioterrorist act in the United States and resulted in 751 salmonella infections and 45 hospitalizations.[26]

[22] A compilation of reports about the 1979 anthrax incident in Sverdlovsk, Russia is available at http://www.gwu.edu/~nsarchiv/NSAEBB/NSAEBB61/.
[23] http://www.nytimes.com/2005/01/24/national/24lab.html?pagewanted=all&position=
[24] Further discussion of the incident can be found in the Government Accountability Office Testimony document GAO-08-108T, pages 15-18, available at http://www.gao.gov/new.items/d08108t.pdf.
[25] More information is available at http://www.defra.gov.uk/FootandMouth/2007/index.htm.
[26] Torok TJ, *et al*. A large community outbreak of salmonellosis caused by intentional contamination of restaurant salad bars. JAMA 1997;278:389-95. Available at http://jama.ama-assn.org/cgi/reprint/278/5/389.

- In1993, the Aum Shinrikyo cult sprayed a liquid suspension of *B. anthracis* from their headquarters building in Kameido, near Tokyo, Japan.[27] The incident gained little attention, and was thoroughly investigated only after the same religious cult disseminated sarin gas in five trains on the Tokyo subway system two years later.
- In 1996, laboratory technician Diane Thompson removed *Shigella dysenteriae* Type 2 from a Dallas, Texas hospital collection and deliberately infected co-workers; 12 people became ill. [28] She was later convicted and sentenced to 20 years in prison.
- In 2001, letters containing spores of *B. anthracis* were distributed via the U.S. postal system, infecting 22 people and resulting in five deaths, extensive social disruption, and enormous costs for emergency response, remediation, and subsequent investigation. The well-publicized FBI investigation that followed, which focused on U.S. scientists,[29] has resulted in renewed scrutiny of laboratory security.

The heightened concerns surrounding the potential misuse of dangerous pathogens available within laboratory settings has resulted in recommendations to re-examine and potentially enhance laboratory security measures aimed at ensuring personnel reliability among individuals with access to BSAT.

E. Challenges in Biosecurity for BSAT

BSAT pose unique security challenges. Most biological select agents are naturally occurring pathogens; they are living organisms that can be grown into large quantities from a small sample, making it difficult to accurately inventory and track BSAT. Furthermore, advances in genome synthesis and reverse genetic technologies now allow for the *de novo* synthesis of some viral select agents. Another challenge is the wide variety of ways in which BSAT can be disseminated and the impacts they can have on human, animal, and plant health. The characteristics of some BSAT make them amenable to aerosolization (*e.g.*, spores of *B. anthracis*), some are highly pathogenic and spread easily from person-to-person (*e.g.*, Variola major and minor and the H1N1 strain of influenza virus that caused the 1918 pandemic), and some can be disseminated in food or water (*e.g.*, Staphylococcal enterotoxin B). Some BSAT can devastate the plants or animals critical for food production (*e.g.*, Potato Wart and Foot-and-Mouth disease). Therefore, biosecurity measures need to address the variety of ways in which BSAT release can impact a population.

---

[27] Keim P., *et al*. Molecular Investigation of the Aum Shinrikyo Anthrax Release in Kameido, Japan. *J Clin Microbiol*. 2001 December; 39(12): 4566–4567, available at http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=88589

[28] Kolavix, S., *et al.* An outbreak of *Shigella dysenteriae* Type 2 among laboratory workers due to intentional food contamination. JAJA 1997;278:396-8. Available at http://jama.ama-assn.org/cgi/reprint/278/5/389.

[29] In 2008, the Department of Justice (DOJ) and the FBI announced their intention to indict a U.S. scientist working in a Federal research facility. These charges were never filed; the scientist took his own life (see DOJ Press Release http://www.usdoj.gov/opa/pr/2008/August/08-opa-697.html).

Unlike research on nuclear materials, the vast majority of BSAT research is unclassified,[30] and conducted in support of a wide variety of basic research and public health needs beyond biodefense, including cancer treatments and medical countermeasures for naturally occurring disease outbreaks. Further, much BSAT research is conducted in university settings that have a long history of openness, engage in national and international collaboration, and readily share research resources. This culture of openness has a long and fruitful history in academia, and includes research on pathogens that only recently have been designated "select agents and toxins." This open availability of information creates a challenge due to the large number of individuals who potentially have the knowledge to use BSAT in any capacity, including nefarious plans.

F. Congressional Investigations and Public Interest in BSL-3 and BSL-4 Laboratories and Their Activities

As a result of laboratory incidents, bioterrorism, biocrimes, the increased number of individuals with access to BSAT, and the rapid expansion of facilities in which to work with these agents and toxins, Congress has requested that various organizations review the Federal oversight of BSL-3 and BSL-4 facilities and their activities to determine whether the measures currently in place to ensure biosecurity and biosafety practices and procedures are adequate. In addition, legislation has been introduced in both the Senate and the House, The Select Agent Program and Biosafety Improvement Act of 2009 (S.485/H.R.1225), to mandate "improvements" in the Select Agent Program and biosafety.

Examples of these studies include the following:

- Preliminary Government Accountability Office (GAO) report, "HIGH-CONTAINMENT BIOSAFETY LABORATORIES, Preliminary Observation on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States." 2007. GAO-08-108T[31]
- GAO report, "Biosafety Laboratories: Perimeter Security Assessment of the Nation's Five BSL-4 Laboratories." 2008. GAO-08-1092[32]
- "World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism." Released December 2, 2008[33]
- GAO report, "High-Containment Biosafety Laboratories: DHS Lacks Evidence to Conclude That Foot-and-Mouth Disease Research Can Be Done Safely on the U.S. Mainland." 2008. GAO-08-821T[34]

[30] The Department of Health and Human Services, the largest provider of biodefense grants and contracts, as well as the National Science Foundation, do not fund or conduct any classified work.
[31] The preliminary GAO report is available at http://www.gao.gov/new.items/d08108t.pdf. Federal agencies, including the CDC, have submitted corrections to the 2007 GAO report, but the GAO has not published a final, corrected report.
[32] The GAO report is available at http://www.gao.gov/new.items/d081092.pdf.
[33] The WMD Commission report is available at http://www.preventwmd.gov/report/.
[34] The GAO report is available at http://www.gao.gov/products/GAO-08-821T.

- GAO report, "Biological Research Laboratories: Issues Associated with the Expansion of Laboratories Funded by the National Institute of Allergy and Infectious Diseases". 2007. GAO-07-333R[35]
- House of Representatives Committee on Energy and Commerce Hearing entitled "Germs, Viruses, and Secrets: the Silent Proliferation of Bio-Laboratories in the United States"; October 4, 2007
- The Trans-Federal Task Force on Biosafety and Biocontainment Oversight, which was created by HHS and USDA in response to the October 4, 2007 Congressional hearing on biosafety oversight, is tasked with reviewing current biosafety regulations and guidance and recommending improvements to the oversight system.

G. Federal Government Efforts to Address Biosecurity

During the past several years, the Federal Government has initiated a range of efforts to identify potential gaps in biosecurity and develop and implement policies to fill those gaps. The following are examples of these efforts. (For more information, see Appendix 1-F.)

- The Homeland Security Council Interagency Policy Committees that coordinate the development and implementation of homeland security policies throughout the Federal Government have been established to examine biosecurity.
- The National Science Advisory Board for Biosecurity (NSABB) was established to advise the Federal Government on strategies to minimize the risk of malevolent use of information and technologies derived from legitimate life sciences research. Recently, the NSABB was tasked with recommending strategies for enhancing personnel reliability among individuals with access to select agents and toxins.[36]
- The Defense Science Board (DSB) examined the biological safety, security, and personnel reliability programs of the Department of Defense's (DoD) biodefense labs, comparing them to similar operations in academia, industry, and the Federal Government.[37]
- In 2008, DoD created the Inter-Service Council for Biosecurity and Biosafety (ICBB) to undertake a thorough study of DoD policies and practices on biosecurity, biosafety, and personnel reliability, and make recommendations on strengthening these policies and practices.
- The National Academies Board on Life Sciences, by request of the White House, is currently performing a study entitled: "Laboratory Security and Personnel Reliability Assurance Systems for Laboratories Conducting Research on Biological Select Agents and Toxins."

[35] The GAO report is available at http://www.gao.gov/products/GAO-07-333R.
[36] The NSABB report on personnel reliability is available at http://oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf
[37] The DSB report is available at http://www.acq.osd.mil/dsb/reports/2009-05-Bio_Safety.pdf

- Executive Order (EO) 13486 "Strengthening Laboratory Biosecurity in the United States" was issued on January 9, 2009. EO 13486 established the Working Group on Strengthening the Biosecurity of the United States.

  EO 13486 assigned three tasks to the WG:

(1) Review and evaluate the efficiency and effectiveness of existing laws, regulations, guidance, and practices relating to physical, facility, and personnel security and assurance at Federal and non-Federal facilities that function as described above.

(2) Obtain information or advice, as appropriate for the conduct of the review and evaluation, from the following: heads of executive departments and agencies; elements of foreign governments and international organizations with responsibility for biological matters, consistent with functions assigned by law or by the President to the Secretary of State; representatives of State, local, territorial, and tribal governments; and other entities or individuals.

(3) Prepare a written report to the President, 180 days after the date of the EO, that (a) summarizes the efficiency and effectiveness of existing laws, regulations, guidance, and practices related to physical, facility, and personnel security and assurance at Federal and non-Federal facilities, (b) compares the range of existing personnel security and assurance programs for access to biological select agents and toxins to similar programs in other fields and industries, (c) recommends any new legislation, regulations, guidance, or practices based on the WG review and evaluation, and (d) includes options for establishing oversight mechanisms to ensure a baseline standard is consistently applied to all physical, facility, and personnel security and assurance laws, regulations, and guidance at all Federal and non-Federal facilities.

The study was limited to a total of six months from the issuance of the EO. Within that time, the WG met in person and via teleconference nine times to receive briefings from key stakeholders from government, industry and professional organizations (see Appendix 1-G). In order to better understand the effects of security measures on laboratory practices, the WG conducted site visits to a variety of laboratories, including academic, government, industry, and public health laboratories, for both human and plant infectious disease research (Appendix 1-H). The visits included tours and discussion of security and personnel reliability practices with scientists, environmental health and safety professionals, biosafety officers, animal facility coordinators, and security professionals or campus police. To best collect input from stakeholders and the public, the WG held a public consultation meeting. The full agenda and a summary of public comments received afterward are available in Appendix 1-I.

The WG determined five areas of potential concern (Select Agent Regulations, transportation, physical security, personnel security and reliability, oversight/inspection) that required in-depth analysis and formed subgroups of subject matter experts from Federal agencies and departments. The subject matter experts selected were individuals who could analyze the existing laws, regulations and guidance in their areas of expertise;

determine where gaps are present in these laws, regulations, and guidance pertaining to biosecurity; and make recommendations to address these gaps to strengthen biosecurity. Throughout the process, subgroups considered the value of additional biosecurity measures in strengthening biosecurity, given the potential cost and risk to scientific progress and collaboration.

The WG arrived at final recommendations through careful consideration of proposals from subgroups, discussions with select agent entities, and comments received from the public. Subsequent chapters discuss WG findings and recommendations.

The WG believes that the Select Agent Program has significantly strengthened the biosecurity of the United States since its implementation. The enhancements recommended by the WG in the chapters that follow were designed to further strengthen U.S. biosecurity, and if implemented, will lead to the development of improved guidance to facilities and individuals working with BSAT on how to implement biosecurity measures.

The recommendations were developed without consideration of potential competing priorities across the Federal Government, and their implementation would be subject to the availability of funds. In addition, the potential impacts and benefits to the stakeholder community of implementation of any of these recommendations must be considered.

Chapter 2 SELECT AGENT REGULATIONS: The Select Agent List, Oversight and Inspections, and Inventory Management

The WG established two subgroups to examine different aspects of the SAR. One subgroup examined the current select agent list and issues regarding inventory management, while the other examined the Federal and local oversight and inspection programs at facilities that possess, use, or transport BSAT as mandated by the SAR and managed by the Select Agent Program.

Key findings: 1) There are 82 BSAT on the select agent list, but not all pose the same level of risk to public or agricultural health. The list should be either reduced or stratified so that biosecurity measures can be more easily applied by the registered entities according to the level of risk. 2) The responsibility for oversight of select agent entities by various Federal, State, and local agencies beyond HHS and USDA, as well as compliance inspections by higher government and corporate headquarters, has resulted in numerous uncoordinated inspections with non-uniform standards, expectations, and interpretations. 3) Registered entities report confusion regarding appropriate inventory records, formats, and requirements.

Key Recommendations: 1) Perform a risk assessment for each select agent and toxin on the BSAT list and develop a stratification scheme that includes biodefense and biosecurity criteria, as well as risk to public health, so that security measures may be implemented based upon risk. 2) Enhance U.S. Government coordination of oversight and inspections as well as institutional implementation, compliance, oversight, and accountability. 3) Provide comprehensive guidance on inventory management and recordkeeping requirements, approaches, and templates.

A. Current SAR

The SAR require that any entity that possesses, uses, or transfers BSAT register with the Select Agent Program. Each registered entity must establish and implement safety, security, and incident response plans to facilitate safe and secure activities with BSAT. These plans require the designation of specific secure locations for BSAT storage or work, specific authorization and training for individuals who may have access to BSAT, and a detailed accounting of the types of BSAT located at the facility and the types of procedures that are applied to these agents. The current SAR require entities to develop security plans based on a site-specific risk assessment, to include the level of risk posed by the BSAT an entity possesses, uses, and transfers. However, there is no standard methodology for conducting the site-specific risk assessment. A possible area for standardization might be the development of a risk stratification scheme based upon the risk posed by each select agent or toxin on the BSAT list. This scheme can then be used by entities as a basis for their site-specific risk assessment.

1. Current methodologies for BSAT risk assessment/stratification

Some agent risk stratification methodologies have been developed, but focus primarily on the biosafety risk (see Appendix 2-A for details). The most commonly accepted biosafety classification methodologies used in the United States are the BMBL BSLs and the *NIH Guidelines for Research involving Recombinant DNA Molecules* (*NIH Guidelines*) Risk Groups (RG). International classification methodologies include the WHO Classification of Infective Microorganisms by Risk Group, the Australian/New Zealand Standard (AS/NZS 2243.3:2002), the Canadian Laboratory Safety Guidelines, and the European Economic Community Directives 2000/54/EC and 90/679/EEC.[38] A series of workshops held by the CEN in collaboration with WHO in 2007 resulted in the publication of the "Laboratory Biorisk Management Standard,"[39] which emphasizes a risk-management approach.

In addition to the traditional biosafety classification methodologies guidances outlined above, U.S. Federal agencies and non-Federal organizations have developed stratification schemes to classify biological agents and toxins by their risk for use in bioterrorism (see Appendix 2-A for details). For example, in February 2002, the CDC published a "Public Health Assessment of Potential Biological Terrorism Agents." In 2006, the U.S. Department of Homeland Security (DHS) published its first comprehensive Bioterrorism Risk Assessment (BTRA), which employed a computational risk analysis tool to conduct end-to-end risk assessments of the bioterrorism threat posed by each BSAT. The National Science and Technology Council (NSTC) established the WMD Medical Countermeasures Subcommittee (WMD MCM) in October 2003. It formed the Animal Pathogens subgroup, which was tasked with generating a prioritized threat list of animal pathogens for the purpose of recommending methods to address gaps in countermeasure development. In January 2004, Homeland Security Presidential Directive 9 (HSPD-9) directed the Secretary of Agriculture to develop a National Veterinary Stockpile (NVS). The NVS, managed by USDA APHIS, established a Steering Committee that tasked a working group of animal disease experts to identify and prioritize the most dangerous animal disease threats to the United States.

Subgroup on Select Agent Regulations stratification of BSAT (Pilot Feasibility Project)

Based on a recommendation of the NSABB that the select agent list be reduced or stratified, and the notion that biosecurity measures could be applied commensurate with the bioterrorism risk of the BSAT, the WG tasked the subgroup on Select Agent Regulations to examine the feasibility of doing a risk assessment of BSAT in order to reduce and/or stratify the BSAT list based on this assessment. The subgroup considered utilizing existing risk rankings such as the DHS BTRA; however, the subgroup

[38] Summaries of these are available at the American Biological Safety Association Website (www.absa.org/riskgroups/index.html).

[39] For more information about the European Committee for Standardization (Comité Européen de Normalisation or CEN), see www.cen.eu. The final version of the CEN publication, *Laboratory Biorisk Management Standard* (CWA 15793), is available at http://www.cen.eu/cenorm/sectors/technicalcommitteesworkshops/workshops/ws31.asp.

determined that there was merit in re-examining the aspects of BSAT risk to include the criteria used for determining risk. Most existing rankings focus on biosafety risk, with less emphasis on biosecurity and biodefense, and fail to consider issues that affect U.S. national security (*e.g*., selection of an agent or toxin for deliberate release). Furthermore, the 2008 DHS BTRA, while a useful, iterative tool, considered only 40 BSAT on the select agent list.

The subgroup considered elements of biodefense, biosecurity, and biosafety in the determination of a risk-based stratification scheme, creating a list of criteria that combines the most important aspects of these concepts (Appendix 2-B). Subgroup members from HHS, DoD, DHS, USDA, Department of State (DOS), and the FBI formulated the criteria, and then ranked the criteria as more or less important for determining BSAT risk. A weighted scoring system was developed from these inputs (Appendix 2-B). The subgroup participants determined that the most important criteria for evaluating BSAT were:

- Ease of agent production
- Ease of agent dissemination
- Infectious dose by route of exposure
- Communicability of illness produced
- Mortality with countermeasures
- Mortality without countermeasures

The subgroup proceeded with a pilot project to stratify the select agent list. Both human BSAT regulated by CDC and animal and plant BSAT regulated by USDA were scored on a scale of 1 through 10, with the higher scores awarded for agents that would pose the greatest threat or risk to national security and public, animal or plant health based on potential outcomes. Thus, for example, the absence of medical countermeasures (beyond supportive care) for Marburg virus would receive a high score, whereas unmodified *B. anthracis*, for which vaccines and treatments exist, would receive a lower score. Scores from subgroup participants were then compiled, and weighted averages of total scores were calculated to produce the list of ranked agents for each group. Initial results of the pilot project suggested that the select agent list can be tiered according to risk (most of the BSAT currently considered as "high risk" came out at the top of the list). However, due to the small number of subject matter experts involved in this exercise and the short time frame available for the development of a stratification scheme, additional analysis and review are needed to confirm the significance of these results. The subgroup highly recommended to the WG that a follow-on group, comprised of a greater number of subject matter experts, as well as statisticians, be formed to further evaluate the merits of the criteria and methodology described herein and of the feasibility of stratifying the BSAT list based on the risk of each BSAT. This process potentially could be incorporated into the existing process for review of the select agent list.

2. Current Oversight System

a. *CDC/APHIS Inspections and Oversight*

Site-specific safety, security, and incident response plans are established by BSAT facilities with input and oversight by various local and Federal regulatory bodies in a multi-layered inspection and oversight environment. While all registered entities must comply with CDC/APHIS Select Agent Program oversight, the number of additional layers of oversight applied to a select agent facility is variable and depends upon the following factors:

- Affiliation of the facility– Different organizations have different oversight policies
- Nature of the work at the facility
- Sources of research funding for the work at the facility

Under the current SAR, entity registration must be renewed every three years, and an on-site inspection by either CDC or APHIS is required prior to the award of a new certificate of registration or the renewal of an existing registration. These inspections cover all aspects of the SAR. CDC and APHIS have collaborated to develop uniform inspection checklists. These checklists are available for review by the regulated community and the public at the national select agent program website.[40] In keeping with the spirit of the SAR, these checklists are performance-based and do not prescribe the use of specific security tools or procedures. The regulations require that each entity develop and implement site-specific safety, security and incident response programs, and that all individuals with access to BSAT undergo training upon employment and at least annually thereafter in all relevant safety, security, and incident response plans at the entity. In addition to the CDC/APHIS inspections, the SAR require each registered entity to conduct annual self-inspections, under the direction of the entity's RO.

The USA PATRIOT Act and the Bioterrorism Response Act provide CDC and APHIS with various tools to use in cases of failed compliance. These tools include administrative actions, civil monetary penalties, and criminal penalties. Entities are expected to address all inspection findings and document their remediation activities with CDC or APHIS. CDC or APHIS may conduct verification site visits to ensure that all findings have been adequately addressed. For entities that have chronic compliance issues, CDC or APHIS may work with these entities under a Performance Improvement Plan to set specific deadlines and/or milestones that the entity must meet in order to resolve compliance issues. Continued failure of compliance may result in any of the following administrative actions: suspension of some or all BSAT activities, revocation of an existing Select Agent Program registration, or denial of a new application for registration. In egregious cases, civil monetary penalties may be assessed. These penalties may be as high as $250,000 per violation for individuals and $500,000 per violation for entities. In cases involving criminal activity, imprisonment for up to 5 years per violation may be imposed.

b. Non-CDC/APHIS Inspections and Oversight

[40] An example of the inspection checklist for entity security is available at http://www.selectagents.gov/complianceAssistance.htm

Participation in the CDC/APHIS inspection program is required for all entities registered with the Select Agent Program. Entities that possess BSAT of agricultural concern must also obtain a USDA Transport Permit prior to shipping samples. USDA permitting involves site visits and compliance activities in addition to those required by APHIS under the SAR. Depending upon their organizational affiliation, registered entities may undergo additional inspections according to the safety and security policies of their parent or funding Agency or Department. Within the DoD, for example, U.S. Army select agent laboratories undergo annual inspections by either the Army Inspector General's Office or by their local command (Army Medical Command, Army Materiel Command, or Army Test and Evaluation Command). Unlike the Army, the U.S. Navy and Air Force do not currently have a service level Inspector General inspection team. Their select agent facilities are inspected by their higher headquarters on an 18-month cycle.

Other Federal agencies, such as the Department of Energy (DOE), CDC, NIH, and USDA Agriculture Research Service have their own internal offices that may perform inspections in addition to those performed by CDC/APHIS as part of the Select Agent Program. In many cases, these agencies have internal regulations or policies that are more prescriptive than the CDC/APHIS regulations.

Registered entities who receive funding from Federal agencies may also be inspected by those agencies as a condition of funding. For example, entities who receive funds from DHS to conduct laboratory work involving BSAT are subject to on-site compliance reviews and inspections by the DHS Regulatory Compliance Office.

Additional inspection and/or oversight activities may also be triggered depending upon the types of activities that occur in registered entities. Entities who receive funds from NIH for recombinant DNA research must comply with the *NIH Guidelines for Research Involving Recombinant DNA Molecules*, and may be inspected by the NIH Office of Biotechnology Activities (OBA) in conjunction with this funding. Entities that are active in the transfer of BSAT may have their shipping and handling facilities inspected by the Department of Transportation (DOT). Entities that perform animal research may undergo inspections by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) and entities that perform diagnostic testing may undergo inspections in association with the Clinical Laboratory Improvement Amendments of 1988, the College of American Pathologists, and the Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations). Facilities that maintain their laboratories in Good Laboratory Practice (GLP) standing may also be inspected by the Food and Drug Administration.

The USDA and HHS Offices of Inspector General and the Government Accountability Office have also visited select agent entities in recent years to review their records and programs for BSAT security.

3. Inventory of BSAT

The SAR outline specific kinds of records and other information that need to be documented for each BSAT. They require the entity to maintain an accurate, current inventory for each select agent in long term storage, which is defined as placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials. The SAR also require a current, accurate inventory for toxins, materials that are transferred, intra-entity transfers, movement to and from storage, and records on the amounts of select agents destroyed.

Pursuant to the SAR, the specific information to be captured on the inventory is as follows:

a. The name and characteristic (*e.g.*, strain designation, GenBank Accession number);
b. The quantity acquired from another individual or entity (*e.g.*, containers, vials, tubes), date acquisition, and the source;
c. Where stored (*e.g.*, building, room, and freezer);
d. When moved from storage and by whom and when returned to storage and by whom;
e. The select agent or toxin used and purpose of use;
f. Records created under Section 16 of 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73 (Transfers);
g. For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent or toxin, the quantity transferred, the date of transfer, the sender, and the recipient; and
h. Records created under Section 19 of 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73 (Notification of Theft, Loss, or Release).

Additional guidance for inventory is provided by various entities where work with BSAT occurs. Examples are below.

A. DHS Management Directive (MD)

The DHS Management Directive 026-03 "Select Agent and Toxin Security" provides general guidance pertaining to inventory requirements. Section VI, Policy and Procedures, states:

> Proper storage, management, and safeguards which may be issued by the Department, will be used to prevent loss, theft, diversion, damage, and unauthorized use of all select agents and toxins. Additionally, security controls, as required by Authorities D-F at Part III of this MD, shall be provided against unauthorized access.
>
> Select agents and toxins shall be actively monitored and accounted for from identification through transfer and final disposition, to include destruction, via the

employment of stringent property control processes including the execution of chain-of-control documentation and destruction logs.

B. USDA Agricultural Research Service

The USDA Agricultural Research Service has set forth policies in Departmental Manual (DM) 9610-1 "USDA Security Policies and Procedures for Biosafety Level -3 Facilities" in Section 8, entitled "Inventory Control Procedures." This section discusses three types of accountability records that are required for USDA facilities: 1) National Pathogen Inventory (NPI) system; 2) a detailed inventory of repository materials to be kept at research or diagnostic facilities; 3) materials accountability for experimental or working samples.

The NPI is a summary inventory database with limited fields that allow facility management to rapidly determine pathogens in use at each facility. The NPI must contain the agent name, agency/location/laboratory, person responsible for pathogenic material, and contact information.

The facility inventory of repository materials is a detailed inventory of both current and historical inventory records. Records are required to be retained for 5 years. The following are the components of this inventory system:

1. Agent (scientific and common name, strains)
2. Amount (number of vials or containers inventoried)
3. Biosafety Level, Agent type (bacteria, virus, *etc.*)
4. Storage location (building, room number, freezer number)
5. Storage conditions (refrigerator, freezer, -70C, -20C, liquid N_2, *etc.*)
6. Date of change of status (removal, change of custody, *etc.*)
7. Site of usage (building numbers or room numbers)
8. Disposition to include shipping, destruction, *etc.*
9. Scientist with contact information

C. Department of Energy (DOE)

The DOE has additional requirements for BSAT inventory, which are described in 10 CFR Section 851 under the Worker Safety and Health Program. It requires that contractors maintain an inventory and status of biologic etiologic agents, and submit to the laboratory Institutional Biosafety Committee (IBC) an annual report describing the status of the inventory, which the IBC then transmits to the responsible field and area office. In addition, contractors must provide a copy of the APHIS/CDC Form 2,[41] Transfer of Select Agents, to the head of the DOE Field Element with notification of the completed transfer.

B. Areas of Improvement to the SAR

[41] DOE regulations still contains reference to CDC Form EA-101, however this form has been replaced by APHIS/CDC Form 2.

The following areas for improvement in the SAR were identified:

1. Although the current SAR require entities to consider the risk posed by each agent when conducting their site-specific risk assessment, the Select Agent Program does not give clear guidance on the security risk that any one individual BSAT poses to human, animal, and plant health.
2. The current SAR require entities to develop their security plans based on a site-specific risk assessment; however, current regulations do not prescribe a standard security risk assessment methodology. Without a standardized security risk assessment methodology, it is much more difficult for entities to develop or update security plans that are commensurate with risk.
3. Although inventory requirements are described in the SAR, there is confusion among entities in the regulated community regarding appropriate inventory records, formats, and requirements.
4. Section 175(b) of Title 18, United States Code provides criminal penalties for individuals who knowingly possess BSAT under circumstances that are not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. The penalties under this provision, however, do not apply to individuals who attempt to possess BSAT.
5. The SAR do not explicitly outline the requirements necessary for the FBI to examine, for investigative purposes, evidence located in Select Agent laboratories. Therefore, FBI's ability to take custody of and perform analysis on samples collected as part of an investigation may be restricted.
6. *De minimis* quantities of toxins on the select agent list are not regulated under the SAR because these quantities were determined to be below the threshold of concern. However, this creates a potential gap in which unregistered individuals or entities could repeatedly order and stockpile *de minimis* amounts of a toxin, presumably for an illegitimate purpose. The current regulations do not provide a mechanism for institutional or regulatory officials to be made aware if stockpiling of *de minimis* amounts of toxins is occurring. In addition, the current SAR allow for multiple principal investigators within the same entity to possess, use, and transfer *de minimis* amounts of toxins without any accountability for these toxins to the entity or to regulatory officials. Finally, there is no requirement for toxin suppliers to track and report *de minimis* amounts of toxins which are shipped to an individual or entity. Under the current SAR, an individual or entity is able to receive multiple shipments of *de minimis* amounts of toxins and thereby potentially possess regulated amounts while not registered with the Select Agent Program.
7. Section 8401(e)(2)(c) of Title 7 of the United States Code (7 USC 8401(e)(2)(c) provides authority to the Secretary of the USDA, in consultation with the Attorney General, to limit or deny access to USDA-only BSAT based on the restricted categories in Appendix 1-D, if doing so is determined appropriate. This allows that the USDA Secretary can grant to an individual access to animal only or plant only select agents even if that individual falls

into a restricted category. The Secretary of HHS is not granted the same authority for human select agents. There is concern that a well-adjusted adult, who may have been committed to a mental institution or committed a felony as a juvenile, may be denied access to BSAT yet pose no safety or security risk. This statutory discrepancy should be addressed through the HHS and USDA Offices of General Council.

The following areas for improvement in the current oversight/inspection system were identified:

1. Limited coordination among inspection/oversight groups

Under the current oversight and inspection system, certain entities undergo substantially more inspections than others. In an example of an extreme case, an Army BSAT laboratory that conducts recombinant DNA research for DHS-funded projects and frequently transfers BSAT materials to collaborators could theoretically be inspected by CDC/APHIS, the Army IG, NIH OBA, DHS, and DOT all within the same year. This could significantly hinder critical research productivity at the inspected laboratory due to the time dedicated to inspections. Conversely, a private sector BSAT diagnostic laboratory that does not conduct recombinant DNA research, does not receive outside funding, and does not ship BSAT, may have only a CDC/APHIS required self-inspection in some years. For large and complex entities that work with high concentrations or large amounts of BSAT, there is ample risk-based justification for extensive oversight. However, the current system of multiple inspections could have the unintended consequence of slowing critical research and development productivity at these institutions.

2. Administrative and cost burden to entities hosting multiple site visits/inspections

An associated issue with the current oversight system and the multiple inspections described above is the indirect cost to the entities associated with accommodating these multiple inspections and site visits. Although most current oversight agencies do not assess a fee for registrations, accreditations or inspections, the time and resources invested in preparing for and undergoing an inspection can be significant, especially when an entity undergoes multiple inspections within a short time frame. Another indirect cost is the loss of research productivity incurred during the inspection process and in responding to findings and recommendations, some of which may be conflicting.

3. Different interpretations/standards between different inspection groups

In the current oversight system there is the potential for disparate guidance on safety and security issues that different oversight agencies may provide to select agent entities. Although oversight agencies make concerted efforts to be as consistent as possible in their interpretations of the select agent and related regulations, there are, and will probably always be, subjective differences in guidance provided by different

inspection teams. These differences in guidance come from multiple sources, including differences in backgrounds and experience levels of individual inspectors as well as differences in regulations and/or policies of the inspecting organizations. Individuals at CDC and APHIS who are responsible for the Select Agent Program are well aware of this issue and are continually striving to improve the consistency of inspections through annual inspector training and the development and implementation of common inspection Standard Operating Procedures.

4. Performance-based versus prescriptive oversight/inspection criteria

A significant factor in the provision of disparate guidance is the concept of performance-based versus prescriptive oversight. The SAR are, in general, performance-driven. Given the variety of facilities that are subject to the SAR, the performance approach is rational at the national level. However, various agencies have promulgated additional, more prescriptive, internal regulations that are applied over and above the national SAR. Examples of these more prescriptive regulations include Army regulations AR 50-1 and AR 190-17 and the HHS "12 step" security rules for BSAT laboratories. With the combination of performance-based and prescriptive regulations, entities that may be in compliance with the SAR may "fail" when assessed for compliance with more prescriptive departmental or agency regulations. There is potential that entities may receive mixed messages due to the lack of standardization of regulation.

5. Variable approaches to oversight/inspection at the local/institutional level

Regardless of the types and levels of oversight provided by various government agencies, registered entities themselves play central roles in ensuring institutional compliance through local oversight/inspection processes. The SAR require that ROs at registered entities ensure that annual inspections are conducted for each laboratory where BSAT are stored or used. The results of these inspections must be documented and any deficiencies must be corrected. The regulations also state that entities must implement a system to ensure that all select agent records are accurate, have controlled access, and can be verified. The registered entities (and specifically the ROs) are directly responsible for fulfilling these regulatory requirements, and must therefore implement specific local oversight/inspection processes to ensure compliance. These processes often vary significantly among registered entities, and their stringency and effectiveness may vary accordingly. For example, many entities have had institutional requirements for annual laboratory safety inspections for many years prior to the implementation of the SAR, and some may still use these inspections to meet the annual inspection requirement. However, in many cases these safety inspections cover general laboratory safety equipment, practices and procedures rather than BSAT-specific safety, security, and recordkeeping requirements. Other aspects of local BSAT oversight/inspection processes are also often subject to institutional interpretations and variations that may have adverse impacts on their effectiveness.

C. Recommendations for Improving the SAR

The WG proposes the following recommendations for improving the SAR as it relates to the select agent list, oversight and inspections, and inventory management.

1. Risk Assessment

a. Task the HHS and USDA Select Agent Program (in consultation with subject matter experts from the scientific, intelligence and security communities from the Federal and non-Federal sectors as appropriate) to conduct a risk assessment of all the BSAT on the select agent list to develop a stratification scheme (or reduce the list) to guide implementation of security policy at registered entities.

The risk assessment should consider the criteria (Appendix 2-B) developed by the subgroup on the SAR as well as those published by other groups (Appendix 2-A). In addition, the team tasked with performing the risk assessment should consult with other Federal agencies performing similar risk assessments of BSAT. This team should also engage statisticians to ensure a high level of rigor when establishing stratification. The results of the risk assessment may also lead to a recommendation for the removal of BSAT from the list or other modifications of the list, in addition to stratification.

One concern regarding BSAT stratification, and its use to guide implementation of biosecurity controls, is that a complex stratification scheme may lead to confusion regarding what measures to apply to what agents. It is therefore critical that any stratification scheme be simple and easily implemented.

b. Task the HHS and USDA Select Agent Program (in consultation with subject matter experts from the scientific, intelligence and security communities from the Federal and non-Federal sectors as appropriate) to develop standard security risk assessment methodology for use at all BSAT facilities. Guidance on how to properly execute the standard risk-assessment method should be developed and provided to all registered entities.

A standard security risk assessment methodology should takes into account the risk of the BSAT, the threat of an unintentional release of the BSAT (taking into account the activities performed, insider and external threats), and the vulnerabilities in physical, personnel, or operational security.

A standard security risk assessment methodology will ensure that registered entities are using common approaches to measuring risk and will mitigate the possibility of varied results among similar facilities. Security personnel at registered entities will have a better understanding of their security requirements as they relate to the risk.

By combining the use of a stratified list of BSAT based on risk and a standardized security risk assessment methodology, registered entities will be better able to determine the security risk at their facility and apply security measures commensurate with the risk.

2. Oversight and Inspection

Listed below are two sets of recommendations to improve the oversight process. The first set relates to better coordination between the various oversight groups. These recommendations are designed to improve the efficiency and consistency of inspections. The second set relates to improved compliance by regulated entities. These recommendations address some of the common compliance challenges that the regulated community has faced since the expansion of the SAR in 2003. These recommendations should not require statutory changes, and only minimal rulemaking. Most, if not all, of these could be implemented by policy if concurrence can be obtained by the Agencies involved.

a. Approaches to enhance US Government (USG) coordination on oversight and inspections

1. **Identify or establish a Federal entity to coordinate biosecurity oversight activities, and to ensure comprehensive and effective Federal oversight for all select agent research facilities and activities. This would include input from various stakeholder agencies (*e.g.*, CDC, APHIS, NIH, DoD, DHS, DOE, DOT, OSHA, EPA).** Given the statutory responsibility placed on USDA and HHS, these Departments would be the most likely sponsors of this activity. This coordinating body would work on the following objectives:
   - Convene meetings on a regular basis among key oversight agencies to facilitate information sharing on and coordination of regulations, policies, and inspection schedules/activities (prior to establishing permanent coordinating office).
   - Promote and enable ongoing information sharing on oversight and inspection processes, activities, and reports (facilitated by coordinating office).

This Federal entity should formally engage the regulated community in order to fully understand the needs of the regulated community with respect to the oversight and inspection process.

2. **Plan better coordination of inspections.** In conjunction with the recommendation above, oversight agencies should strive to implement joint or multi-agency inspections at complex select agent entities. This may reduce the "down time" and associated indirect costs for the entity while potentially allowing for each oversight agency to focus on areas that fall outside the scope of the SAR (such as personnel reliability programs).

3. **Promote the oversight-of-oversight approach, whereby USG regulatory and oversight bodies place significant focus on reviewing laboratory-specific and institutional oversight efforts, and utilize existing information on the oversight efforts of other USG bodies.**
   - Review the current oversight regarding registered entities' inventory management and auditing plans to determine if the processes are well-

defined and communicated (*e.g.*, additional guidance or regulatory change may be needed).
- Collect and review registered entities' annual select agent program review and facility inspection reports to enable ongoing oversight between inspection cycles.
- Ensure that stakeholder agencies have access to relevant information and reports on oversight efforts pertaining to entities for which they have shared responsibilities and interests.

4. Develop coordinated training and oversight programs for inspectors from various USG agencies and offices with oversight responsibilities.
- Develop formal and *ad hoc* partnerships between USG oversight bodies. Invite representatives from partner offices to join site visits and inspections in "observe and assist" roles.
- Hold joint training sessions to develop cross-cutting skill sets and shared knowledge bases regarding USG oversight processes. CDC and APHIS might consider the establishment of a "certification" program for inspection teams from agencies or departments that have internal oversight programs.
- Develop common standards and guidelines for inspectors whenever practical. One means for the development of these standards is the creation of a certification program by CDC/APHIS to train inspectors from other agencies with internal oversight programs.
- Conduct joint inspections and other collaborative oversight efforts when appropriate.

b. Approaches to enhance institutional implementation, compliance, oversight and accountability.

1. Provide guidance for and require entities to conduct comprehensive annual BSAT program reviews and facility inspections.
- Consider using the Institutional Animal Care and Use Committee (IACUC) and American Academy for Laboratory Animal Science (AALAS) models for conducting both comprehensive program reviews and facility inspections. Under this model, entities would be required to submit an annual report to CDC or APHIS that must address key compliance issues (to include documentation and/or verification of inventory audits) for review, inclusion in files, and ongoing oversight by these regulatory bodies.

2. Require entities to provide, as a part of registration, a select agent management plan that outlines the roles and responsibilities of the RO and other key managers for oversight to ensure compliance with the regulations.
- The plan identifies a senior official (may or may not be the RO) who is identified that takes ultimate responsibility.

- The plan describes the linkage between the chain of command for the RO and the senior official.

3. Continue to enhance existing guidance for registered entities on select agent program implementation and oversight at the institutional level.

- Focus new guidance on areas which may require clarification to avoid ongoing misinterpretation or inadvertent noncompliance.
- Provide specific, detailed guidance regarding approval procedures and select agent access for visiting scientists.
- Develop a guidance document detailing escorting requirements for laboratory and non-laboratory staff (including escort of inspectors/auditors).
- Provide further guidance and tools for RO and laboratory staff training (*e.g.*, briefing modules, sample drills and exercises).
- Establish a periodic select agent program bulletin or other notification system for dissemination of new guidance and regulatory information to registered entities.
- Update and expand the "Frequently Asked Questions" section of the National Select Agent Program website to provide standardized guidance on common issues.

3. Inventory of BSAT

Provide comprehensive guidance on inventory management and recordkeeping requirements, approaches, and templates.

a. Expand and clarify existing guidance produced by the Select Agent Program "Guidance on the Definition of Long Term Storage as Used in the Select Agent Regulations" to ensure uniform understanding and facilitate compliance.
b. Develop and distribute various inventory record templates to be adapted and utilized by registered entities on an optional basis.
c. Support the implementation of improved recordkeeping standards and practices for working stock samples (*e.g.*, laboratory notebooks, signature verifications, audits).
d. Provide guidance for and encourage entities to develop standard operating procedures for the transition and management of inventories held by departing principal investigators (PIs).
e. Require entities to submit detailed facility-specific inventory management plans as part of the registration or renewal of registration process.
    - Review the current oversight regarding registered entities' inventory management and auditing plans to determine if the processes are well-defined and communicated (*e.g.*, additional guidance or regulatory change may be needed).

- Require entities to conduct, document, and report to CDC/APHIS on the completion of periodic (at least annual) inventory audits in accordance with their approved inventory management plans.

Providing formats for records and more prescriptive requirements on inventory management should help ensure a more consistent application of the SAR by registered entities and reduce the current confusion among many entities as to the appropriate standards for inventory records. These requirements should include guidance on intra-entity transfers to address transfers of select agents between principal investigators in an entity, including a requirement for appropriate inventory and tracking of these transfers and as well as notification of the transfers to the RO.

4. Other Recommendations for Amending the SAR. Some of these recommendations will require legislative changes.

a. Amend 18 U.S.C. 175(b) to add "attempts or conspires to possess".

Pursuant to 18 U.S.C. 175(b), a person is prohibited from knowingly possessing a BSAT under circumstances that are "not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose." Anyone violating this provision may be subject to a fine and/or imprisonment of not more than 10 years. The FBI has encountered a situation in which an individual was attempting to acquire a BSAT for a purpose that was not reasonably justified under section 175(b). Because a violation of section 175(b) required the individual to take actual possession of the BSAT, the FBI needed to allow the material to be shipped to the individual before he could be arrested. Although the FBI carefully monitored the transfer, a safer option would be to expand the scope of section 175(b) to prohibit any knowing attempts by individuals to acquire BSAT for a nefarious purpose. Therefore, we recommend that the words "or attempts or conspires to possess" be added to 18 U.S.C. 175(b).

b. Revise the SAR to provide for DOJ access to conduct investigations.

The SAR should include specific language permitting DOJ officials access to laboratories in which evidence is being held in order for them to conduct their investigations. We recommend that the SAR be amended to address the DOJ concerns outlined below:

The DOJ may need to conduct forensic examinations in an investigation authorized under a Federal law, on an item or material that is, bears, or contains a BSAT, when such an item or material, identified or collected as evidence during the investigation has been transferred to and is in the possession of an entity registered under this part. These entities will provide access to the DOJ to conduct forensic examinations on these items or materials, provided:
(1) The DOJ personnel have undergone a Security Risk Assessment conducted by the FBI-CJIS and the results of that assessment are submitted to the RO for the entity or individual in possession of the item or material;

(2) The DOJ personnel possess the appropriate education or experience, or will receive the appropriate training from the individual or entity in possession of the item or material, to handle an item or material that is, bears, or contains the BSAT at issue; and
(3) The DOJ personnel are escorted by personnel from the entity with the appropriate training at all times when in the presence of the BSAT.
(4) In addition, the SAR should be clear that the DOJ has a responsibility to insure that any subsequent removal or transfer of material containing BSAT from the registered entity at which the investigation is being performed occurs only after that entity gets approval for the transfer in accordance with section 16 of the SAR.

In addition, entities should maintain an accurate inventory and adequate security of all materials in their facility, which are part of such an investigation. The Department of Justice will also maintain appropriate documentation addressing the inventory of evidentiary items. The documentation will identify which items or material that are, bear, or contain a BSAT, if the presence of a BSAT has been confirmed. The documentation will also contain the amount of BSAT, if it has been determined. The RO of the entity storing the evidentiary items will be notified of any changes to the amounts of the BSATs that may occur during the course of the investigation. The Department of Justice may also choose to augment the security of the entity storing the evidentiary materials.

c. Options for addressing the potential regulatory gap for *de minimis* quantities of select toxins

The WG deliberated on options for filling the potential regulatory gap for *de minimis* quantities of select toxins identified in the previous section of this report; however, no one option was agreed upon. For this reason, the three options discussed are listed here with their respective rationales. The WG recommends that these options be revisited during the policy making process:

- **Option #1: Continue current practice of not tracking, regulating, or reporting orders and shipments of *de minimis* quantities of select toxins**

There is a perceived regulatory gap in which unregistered individuals or entities can repeatedly order, and potentially stockpile, *de minimis* quantities of a toxin for an illegitimate purpose, while eluding registration with the Select Agent Program. There have been documented incidences of this occurring but the frequency and intent of the individuals who have done this is unknown. Most commonly, repeated orders are necessary to support continued studies in which the materials are consumed. There are only a very few companies that supply select toxins and the major ones report that they already track who they ship to, amounts, and purpose, even in the absence of regulatory mandate, however, the extent to which they do so is unknown. The majority of select toxins are either ubiquitous in the environment or very difficult to obtain in any quantity. Finally, there is little risk that a *de minimis* amount of select toxin could be used for a large scale biological attack.

- **Option #2: CDC and APHIS, with input from relevant collaborating agencies, should work with suppliers of select toxins to develop toxin ordering and verification processes that require individuals and entities ordering select toxins to:**

1) verify that the entity/individual is either registered with the Select Agent Program or is exempt from registration due to only ordering exempt quantities of select toxins;
2) designate and provide contact information for the responsible investigator for the toxin to be obtained; and
3) designate and provide contact information for the biosafety officer or another authorized institutional official (other than the responsible investigator) at the ordering entity who can confirm that:

a) the order aligns with a legitimate program, requirement, or activity,

b) the appropriate risk assessment has been conducted for the receipt, possession, storage, and use of the toxin, and

c) subsequent toxin orders and aggregate quantities will be documented and tracked to ensure compliance with exempt quantity limits and enable ongoing institutional accountability and oversight.

To support implementation of this recommendation, CDC and APHIS would also provide guidance to suppliers on straightforward approaches for verifying the information provided by the ordering individuals and entities.

- **Option #3: Amend the SAR such that CDC and APHIS require that all individuals/entities ordering *de minimis* quantities of select toxins enroll in a tracking system with the Select Agent Program.**

1) Enrollment in a tracking system will allow for verification that the individual/entity is a legitimate user of the toxin (user must submit credentials to indicate legitimate use, and supplier verifies with CDC/APHIS they are enrolled prior to shipment).
2) Toxin orders would proceed using the APHIS/CDC Form 2 (or a modified version), which would allow the reporting of the toxin shipment to the CDC or APHIS.
3) Individuals/entities will not be required to register with the Select Agent Program unless the amount of a select toxin in their possession exceeds the amounts subject to the SAR. CDC/APHIS would be authorized to request these records at any time.
4) Periodic reporting of select toxin usage to CDC/APHIS must be considered (perhaps on modified Form 2 when ordering more toxin).
5) This option would require a regulatory change.

d. Consider revising the SAR to require that regulated entities maintain their select agent records for at least 10 years.

Current SAR require registered entities to maintain their records for three years. Consideration should be given to expanding this requirement to 10 years to allow a more comprehensive review of the history of the entity's possession, use, or transfer of BSAT. Many investigations involving violations of the regulations can easily require that inventory and other records be reviewed for trends in reporting or inaccuracies which could extend historically beyond three years. Records required to be maintained for 10 years would include all those required by the SAR such as for inventory, security, training, or incidence response. Consideration should be given to the burden this requirement may place on regulated entities. For example, records that are expensive or difficult to maintain, and/or are not required by the SAR, such as surveillance videotape, should be excluded from this requirement.

e. The recommendation below should be revisited at the policy phase since there was insufficient time for the WG to complete its deliberations:

Consider the feasibility of revising the statute to grant the Secretary of HHS similar authorities to those of the Secretary of the USDA to determine appropriateness of BSAT access denials for cases of prior committal to a mental institution or juvenile felony convictions.

The WG had a concern that persons who were committed to mental institutions or were convicted of felonies as juveniles are not being given the opportunity to work in fields requiring BSAT access even though they may be well-adjusted. Adjudicators for national security clearance decisions can provide waivers for some of the areas specifically prohibited by the USA PATRIOT Act including felony convictions and noted drug use. If exemptions can be made for access to classified information, it should also be considered for BSAT access. Any consideration of this statutory change must include participation of the HHS political leadership, the CDC Director, and the HHS General Counsel.

Chapter 3 PERSONNEL SECURITY

Personnel security of individuals with access to BSAT was reviewed by the WG. Specifically, the SAR were examined as well as personnel reliability programs implemented by Federal government, public, private, academic, and international institutions. The fundamental concern of the WG is the balance between ensuring that individuals with access to BSAT are trustworthy and reliable while promoting a robust environment that allows for unencumbered research on BSAT and a rapid response to public and agricultural health emergencies.

Key Finding: Improvements can be made in the current Select Agent Program regarding the screening of individuals both prior to granting access to BSAT and after access has been granted.

Key Recommendation: Enhance the Security Risk Assessment at the Federal level to allow for improved vetting of U.S. citizens and foreign nationals. Require continuous monitoring measures (supervisor accountability, self- and peer-reporting) at the local level and evaluate the feasibility of reporting of derogatory information to improve management oversight of individuals with BSAT access.

A. Current Personnel Security and Reliability Programs

Research on BSAT is critical to our nation's ability to develop strategies and products to protect public and agricultural health in the event of a natural emergency, man-made biological incident or event, or act of bioterrorism. While research on BSAT is conducted by responsible researchers, there remains the risk that someone with authorized access to BSAT will use that access to threaten the security of the United States. The most visible manifestation of this insider threat is the mailing of *Bacillus anthracis* spores to several locations in the United States in 2001. The agent used in that act of bioterrorism was subsequently determined to have originated in a Federal research facility and was likely removed from that facility by someone with authorized access – an insider.[42]

1. Current personnel security requirements under the SAR

Under the current SAR, individuals requiring access to BSAT must submit to a Security Risk Assessment, in which their status as a restricted or prohibited person is determined by the (Appendix 1-D) Federal Bureau of Investigation (FBI)-Criminal Justice Information Services Division, Bioterrorism Risk Assessment Group (CJIS-

[42] The Insider Threat Advisory Group, an inter-agency entity chartered by the National Counterintelligence Executive, defines an insider as "Anyone who has authorized access to USG resources by virtue of a relationship with the USG." Furthermore, this group defines insider threat as, "The danger that someone will capitalize on an insider's authorized access to cause harm to the security of the United States."

BRAG).[43] Individuals granted access to BSAT must undergo a new Security Risk Assessment every five years. ROs and Alternate Responsible Officials (AROs) who oversee BSAT programs must obtain a favorable Security Risk Assessment every three years, concurrently with their entity's select agent registration renewal. In addition, procedures are in place for the CJIS-BRAG to receive notification if an individual with BSAT access is arrested, fingerprinted, and subjected to a criminal history check. Access to BSAT can be denied, limited, or revoked at any time by the US government if the person falls into a prohibited category. The institutional RO has the discretion to remove a worker from their program for any reason.

In addition to the Security Risk Assessment, several agencies have implemented personnel reliability programs (PRPs) to help ensure that individuals with access to BSAT meet high standards of reliability.

2. Elements of a PRP

In some Federal research settings, personnel reliability is known as a component of chemical and nuclear weapons surety programs which were implemented to properly safeguard these materials against theft, loss, diversion, or unauthorized access or use, and to ensure that operations with such materials are conducted in a safe, secure, and reliable manner. These surety programs consist of: (1) physical security, (2) safety, (3) personnel reliability, and (4) agent/material accountability.[44,45,46] While research on BSAT is not conducted with the intent of developing weapons, some BSAT could be "misused" by individuals with nefarious intent. PRPs aim to ensure that individuals granted access to sensitive material are trustworthy, responsible, stable, competent in the performance of their duties, and not a security risk.

Features of existing PRPs may include:

- Background investigations;
- Security clearances;
- Medical records reviews and/or medical examinations;
- Psychological screening;
- Drug testing (initial and random);
- Screening for alcohol misuse, abuse, or dependence;
- Polygraph examinations;
- Credit checks;
- Comprehensive personnel record (service and employment) review; and

[43] Information is collected on the FBI form FD-961 (Appendix 3-A).
[44] Demmin, G. "Biosurety." Chapter 23 in *Medical Aspects of Biological Warfare*. Ed. Martha K. Lenhart. Fort Sam Houston, Texas, 2007. pp. 543 – 558.
[45] Carr, K., *et. al.* "Implementation of Biosurety Systems in a Department of Defense Medical Research Laboratory." *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science.* Vol. 2, Num. 1 (2004): pp. 7 – 16.
[46] Pastel, R. H., *et. al.* "Clinical Laboratories, the Select Agent Program, and Biological Surety (Biosurety)." *Clinics in Laboratory Medicine*. 26 (2006). Pp. 299 – 312.

- Mechanisms for continuous personnel monitoring (certifying official, supervisor, medical evaluator, and self- and peer-reporting).

3. Scope of PRP

PRPs often apply to individuals with "access" to BSAT. Clearly defining "access" is important when determining who should be subjected to a PRP.

At agencies that have implemented PRPs, the following individuals may be considered as reasonable expected to have access to BSAT (although not all would require SRA approvals or be subject to PRP requirements (*e.g.* couriers who transport BSAT):

- Individuals who regularly require direct access to BSAT (such as principal investigators (PIs), researchers, and other technical personnel);
- Individuals whose duties provide access, such as ROs, or access control to BSAT labs or storage (*e.g*., individuals who provide access codes or keys);
- Security personnel;
- Facility escorts at BSAT facilities;
- Maintenance, engineering, and/or janitorial staff with access to interstitial lab space or mechanical rooms associated with BSAT activities;
- Couriers who transport BSAT;
- Staff who receive shipments of BSAT;
- Animal care staff whose duties include access to BSAT; and
- Information technology staff with access to databases that hold BSAT inventory and scientific data and have access to interstitial space of labs with BSAT.

4. Extant regulations for biological PRPs

a. Federal Biological PRPs

Each of the Federal PRPs examined has common requirements that extend beyond those of the SAR. For most agencies, the PRP applies to anyone who handles, stores, or transports BSAT, which in most cases includes many of the categories of personnel described above. Individuals in most Federal PRPs have an initial evaluation of suitability for access to BSAT conducted by a certifying official (CO) or a personnel security officer, health review by a competent medical authority, and initial and random drug screening. In addition to the Security Risk Assessment, all agencies with a PRP require a National Security (clearance) and/or Suitability (position of trust) determination consistent with the Office of Personnel Management (OPM) position risk designation model[47]:

[47]The Joint Suitability and Security Reform Team (JSSRT), chartered by Presidential memorandum dated 5 February 2008 and sponsored by the OPM, is proposing changes to Federal security clearance and investigative procedures that will streamline suitability and security determinations in the future. Reinvestigations will be conducted on all individuals under the authority of EO 12968 and EO 13488. The revised practices that result may be applicable, in whole or in part, to personnel reliability efforts to address BSAT access concerns.

- Tier I: National Agency Check with Inquiries (NACI)
- Tier II: Background investigation (BI), limited background investigation (LBI), minimum background investigation (MBI), National Agency Check with Local Agency Check and Credit Check (NACLC), Access NACI (ANACI) or security clearance (Secret, L-Clearance)
- Tier III: Single Scope Background Investigation (SSBI) or security clearance (Top-Secret, Q-clearance), of which most require credit checks

Department of Defense (DoD). The DoD Instruction 5210.89 elaborates on the unique requirements for its biological PRP (BPRP). Unlike the DoD's nuclear and chemical PRPs, the BPRP allows access to foreign nationals. Foreign nationals granted access to BSAT must be approved by the Limited Access Authorization process. The DoD BPRP contains requirements for suitability determinations based on NACLC (military and contractors) or ANACI (civilians) with re-investigation every 5 years, service/personnel records review, continuous evaluation by a CO, and a competent medical authority (CMA). DoD BPRP participants must self-report any potentially disqualifying information (PDI) to the CO and/or CMA. BPRP participants who become aware of PDI of BPRP-certified co-workers are required to report this information ("peer reporting") to the CO. The Instruction establishes procedures for restricting, suspending, disqualifying and administratively terminating individuals from BPRP.

It is noted that several commercial entities such as Battelle Memorial Institute and Midwest Research Institute have adopted DoD type PRPs, because they receive funding from the DoD for BSAT work.

Department of Energy (DOE). There are at least five DOE laboratories that work with BSAT, all of which have personnel requirements above those required by the SAR. Sandia National Laboratories utilizes its Integrated Safeguards and Security Management (ISSM) process to mitigate the risks of working with BSAT. Los Alamos National Laboratory and Lawrence Livermore National Laboratory each utilize a personnel reliability and suitability program referred to as the Select Agent Human Reliability Program (SAHRP). The ISSM and SAHRP are modeled after the DOE Human Reliability Program instituted for nuclear programs within DOE. The DOE ISSM and SAHRP consist of an annual medical evaluation, an annual psychological evaluation, an annual credit check, an annual criminal records check, guidance on peer reporting procedures, and resume verification. Unlike the DOE's nuclear PRP, polygraphs are not performed.

National Institutes of Health (NIH). The NIH Biological Surety Program (BSP) applies to all personnel who work in designated facilities and all Biosafety Level 4 facilities. The BSP requires all participants to pass a Collective Foreign Threats Assessment (Appendix 3-B). Further, the NIH BSP requires continuous evaluation by the CO, self- and peer-reporting of PDI, training regarding self- and peer-reporting of PDI, targeted medical physicals as necessary and annually by a CMA, and behavioral health screening (this latter element only for BSL-4 workers). NIH also employs the two-person rule or buddy

system for health and safety purposes for those in BSL-4 facilities. Of note, based on job sensitivity, the appropriate level of background investigation is conducted.

Centers for Disease Control and Prevention (CDC). The CDC Internal Select Agent Compliance Program encompasses all CDC employees who possess, use, or transfer BSAT. The CDC written policy for the PRP is under development. Many of the elements of PRP are already fully implemented as components of the Personnel, Physical, Emergency Response and Intelligence Branches of the Office of Security and Emergency Preparedness. The following components will be integrated into policy for all personnel with BSAT access: OPM background investigation process (NACI for all personnel; individuals with access to Variola major and minor require ANACI), the drug testing program, processing of foreign nationals; occupational health screening, self- and peer-reporting, and Employee Assistance Program (EAP) counseling services.

United States Department of Agriculture (USDA). The USDA policy, DM 9610-1, describes security procedures for work with BSAT in BSL-3 laboratories. The USDA has continuous evaluation by a CO and self-reporting of PDI. The USDA has a tiered approach for background investigations. Low, moderate, and high risk public trust personnel are investigated by NACI, a LBI, and a BI, respectively. For USDA employees with a Secret or Top Secret security clearance, unescorted access is granted. For non-USDA employees, escorted access by a cleared USDA employee is required at all times unless the facility manager has granted a non-USDA employee with a Secret or Top Secret Security clearance unescorted access. USDA also has counseling services available through an EAP.

Department of Homeland Security (DHS). There are two DHS laboratories that work with BSAT (the Plum Island Animal Disease Center [PIADC] and the National Biodefense Analysis and Countermeasures Center [NBACC]). DHS does not have a formal policy for personnel reliability but elements of PRPs are implemented at the DHS labs. In addition to the SRA, LBI or National Security Investigation is required for all employees with reinvestigation every 5 years. Personnel at NBACC undergo reliability screening by a CO who combines information from human resources, security, and medical resources as a review of an employee's fitness for work with BSAT. All personnel with BSAT access will undergo screening for illegal drugs. Employees are required to self-report any PDI (including medical) to the CO (and for NBACC, the CMA). Each laboratory also has counseling services available through an EAP, which is provided off-site at no cost to the employee.

b. Academic and Public Health PRPs

Virtually all academic and public health laboratories have one or more elements of a PRP, such as background investigations, credentials verification, drug testing, credit checks, interviews, health screening, and safety and security training, to name several, incorporated into their hiring and employment practices. Their motivation for employing these measures is to ensure that they have a trustworthy and reliable workforce. Implementing Federal-type PRPs in the academic and public health sectors would pose a

number of critical challenges. A significant obstacle is that these institutions are subject to state/local laws and regulations, some of which do not permit PRP elements such as credit checks and drug testing. Also, a PRP at public health, agricultural, or environmental laboratories may be counterproductive when surge capacity requires additional support personnel during a crisis situation.

University of Texas Medical Branch (UTMB). UTMB is in the process of implementing a PRP for those who work at BSL-4 facilities. The initial screening portion consists of three major components that involve: 1) Human Resources (HR), 2) Employee Health (EH), and 3) Environmental Health and Safety (EHS). HR obtains consent for medical and employment records release, drug test, and background check; EH completes a medical and mental health assessment and medical review panel to determine if fit for duty; and EHS administers training. Reliability is incrementally and independently determined by HR, EH, and EHS, each of which report to the CO, who ensures that all reliability requirements have been fulfilled prior to granting badge access. The CO does not have access to personal information used by HR or EH to make a reliability determination. Ongoing monitoring is conducted by self- and peer-reporting and medical and mental health re-screenings.

c. International PRPs

A majority of nations have no mandate for government oversight of work on BSAT. A small but growing number of developed and developing countries profess adherence to biosafety guidelines. However, only a handful of nations have enacted regulations providing government oversight of access to BSAT. Most of these nations have put such regulations into effect after 2001. Below is a brief overview of the extant personnel regulatory practices in a few countries with well-developed or developing oversight systems. These only cover national requirements, and practices are often more stringent in government laboratories. Following are three examples of international practices, as a comprehensive review of biosecurity in other countries is beyond the scope of this study.

United Kingdom regulations regarding laboratory security for working with dangerous substances are governed by the 2001 Anti-terrorism, Crime, and Security Act (ATCSA), specifically Part 7 titled, "Security of Pathogens and Toxins." Access to BSL-4 laboratories requires security clearances. BSL-3 laboratories are subject to some personnel screening measures. British law appears to imply a strong level of local or facility oversight of personnel with local law enforcement approving the measures that a given facility puts into place. However, national "guidance" seems to strongly influence these measures.

Germany has an extensive oversight framework. All regulations apply to public and private organizations. Work with listed pathogens is licensed on a per-individual and per-pathogen basis. Working with toxins does not require a license. Licensing only enforces professional qualifications and is distinct from vetting. Personnel vetting is covered by extending the Security Vetting Act, the same act that covers security

clearances. Personnel not requiring classified access are subject to the lowest level security check, somewhat analogous to a Confidential clearance in the United States. Applicants are required to make a personal declaration providing data that will allow checks on their identity, references, qualifications, employment history, and criminal record. Intelligence community checks are also performed. However, these personnel measures are implemented locally, and local oversight of personnel appears to allow foreigners to work in pathogen laboratories with oversight by the facility or institution.

Australia recently enacted a regulatory scheme for Security Sensitive Biological Agents (SSBA). The SSBA list has two tiers covering a total of 22 agents (Appendix 3-C). Authorized persons for using Tier 1 agents undergo background checking consisting of a National Criminal History check and a Politically Motivated Violence check, which appears to be an intelligence community check. Such checks are recommended but not required in order to work with Tier 2 agents. Background checks are conducted every three years. These checks include the topics of identity, integrity, and verification of credentials. ROs may locally maintain a list of "approved," as opposed to "authorized," persons who may work with SSBAs while escorted. Students may be authorized or approved persons. Training is required for both technical competency and personal security awareness for those working with Tier 1 agents.

d. PRPs in Other Sectors

Intelligence Community. In the Intelligence Community (IC), personnel reliability is assured initially by virtue of the security clearance process and thereafter by follow-up personnel security practices and investigations. All vetting efforts are guided by nationally-approved investigative standards and adjudication guidelines which include mitigations. Compartmentalization rules, the use of polygraphs, and stringent information assurance procedures are used to protect especially sensitive information. These practices, as they apply to the IC and other national vetting systems, are currently being updated by the JSSRT referenced in footnote 46 above. Authority for these practices originates in EOs and Federal law, *e.g.*, The National Security Act of 1947.

U.S. Nuclear Regulatory Commission (NRC). Part 10 of Title 26, Code of Federal Regulations prescribes requirements and standards for the establishment, implementation, and maintenance of fitness-for-duty programs for licensees who are authorized to operate a nuclear power reactor; licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material; and others as described in § 26.3. Fitness-for-duty programs must (a) Provide reasonable assurance that individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse; (b) Provide reasonable assurance that individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties; (c) Provide reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the fitness-for-duty program; (d) Provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs and alcohol; and (e) Provide reasonable assurance

that the effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety. Program objectives are met by using drug and alcohol testing, behavioral observation, training, and employee assistance programs.

Entertainment Sector. One entertainment company practices personnel assurance to deter employees from leaking secrets which could cost the company millions of dollars. Employee trust is gained by having periodic town hall meetings and discussions of the employee's roles in the success of the company, to include keeping corporate secrets. Penalties for leaking secrets are clearly described to the employee. The company believes that a bottom up approach works best in this environment. Aside from personnel interviews and calls to prior employers, no formal background checks are performed and no formal measures are applied once employed.

Above and beyond the SAR, the scope of PRP practices across the BSAT enterprise are variable, reflecting a diverse community that spans government, private, and academic sectors; application enterprise (diagnostic, research, production); category of agent (level of risk/safety); and size (number of labs and persons). Each institution is unique and attempts to apply a formal national "standardized" program to all entities would be inappropriate and resource-intensive. The WG recognizes the need to balance national interests in the areas of research and public and agricultural health response and security and recommends some enhancements of existing requirements and application of other potentially valuable measures.

Although no personnel reliability program or individual measures can guarantee elimination of all internal threats, due diligence in this area may enhance the ability to identify anomalies and provide a framework for reporting suspicious behaviors to reduce the risk of intentional or accidental release of BSAT.

B. Areas of Improvement to Personnel Security

The WG identified opportunities for improvement in the processes used to: 1) grant initial BSAT access; 2) continually monitor personnel approved for BSAT access; and 3) terminate an individual's BSAT access and subsequently deny access at a new facility.

1. Granting Initial BSAT Access- Security Risk Assessments and Initial Access

Security Risk Assessments

a. Foreign Nationals (FN)

1. Security Risk Assessment checks are extremely limited when vetting foreign nationals (FNs) for BSAT access. The Security Risk Assessment is generally limited to U.S. government databases and therefore, information such as foreign criminal history records may not be

accessible. As a result, FNs may receive less scrutiny during the Security Risk Assessment process than U.S. citizens.

2. Background checks performed by a U.S. Consulate as part of the visa granting process do not capture all FNs who will apply for BSAT access and if performed, may not be current. FNs applying for a visa to work in the United States undergo an interview with a consular officer prior to being granted a visa. Visa candidates from countries of proliferation concern who are coming to the United States to engage in an activity identified in the Technology Alert List (TAL) may be subject to additional screens. The most common screen is a Mantis,[48] which asks the applicant for additional information on their background and technical expertise with respect to the work they will be performing in the United States. Less than half of FNs registered with the Select Agent Program are subject to Mantis screens, and the information they supply regarding their position and areas of expertise at the time of visa application may not reflect their current research position or reason for requesting BSAT access. The Mantis process is focused on identifying the proliferation of specific technologies to specific countries, and not specifically to identify individuals who may pose a risk if given BSAT access.

3. The Select Agent Program currently does not consider visa type when considering an applicant for select agent access. FNs working in the United States are required to have a visa that is appropriate for the position sought. Students, postdoctoral fellows, and researchers are commonly hired on F, J, or H visas. Due to the complexity of the visa system and a required hierarchy of rules governing which visa an applicant should apply for, other visas may be allowable subject to individual cases (*e.g.*, the spouse of an ambassador is required to have a specific type of visa, regardless of his or her technical abilities or employment status). Some visa types are not appropriate for BSAT work, such as religious visas.

4. There are gaps related to validating the immigration status of FNs. A review of the immigration check process conducted during a Security Risk Assessment revealed that queries sometimes resulted in inaccurate information. It was determined that this was due to inconsistent reporting and processing of information which was then subsequently captured in immigration databases. There also appeared to be instances when the hosting entity (*e.g.*, university principal investigator (PI)) sponsored an inappropriate visa for the visiting FN. This resulted in the loss of immigration status soon after the individual arrived in the United States. There are also occasions where FNs travel overseas and their visas

[48] The Visa Mantis program is a security review procedure involving multiple US government agencies, which aims to identify those visa applicants who may pose a threat to our national security by illegally transferring sensitive technology.

expire—sometimes they are not identified when they re-enter the United States.

b. A gap currently exists regarding the ability of CJIS-BRAG to identify individuals during the Security Risk Assessment process who may be ineligible to work with BSAT because they have been "adjudicated as a mental defective or have been committed to a mental institution."[49] [50]

The Brady Handgun Violence Prevention Act of 1993 established the National Instant Criminal Background Check System (NICS). The disqualifiers for persons seeking to purchase handguns under the Brady Act are very similar to the "restricted person" disqualifiers for those seeking to work with BSAT. In support of NICS, many states provide information to the FBI regarding individuals who have been adjudicated as a mental defective or who have been involuntarily committed to a mental institution. The information in NICS, however, cannot be accessed by CJIS-BRAG for the purpose of performing the Security Risk Assessment. Access to NICS has been limited by both regulation and Memoranda of Understanding with state and Federal agencies.

Even if CJIS-BRAG had NICS access, the mental health information available in NICS is incomplete. As of 30 September 2008, NICS contained 474,689 state records and 116,299 Federal records. The FBI reported that only 38 states voluntarily contributed information to NICS regarding individuals disqualified from purchasing a handgun for mental health reasons. Only 21 of these states, including the District of Columbia, had provided information on more than 10 individuals.

c. As previously mentioned, the USA PATRIOT Act restricts individuals who have been "adjudicated as a mental defective or have been committed to a mental institution" from access to BSAT. The term "mental defective" is not currently an accepted term among mental health professionals. There may be a more appropriate term to classify those individuals whose mental health status should preclude them from having access to BSAT. Additionally, previous commitment to a mental institution should not necessarily prohibit someone from access to BSAT, if the individual is functional and the reason for that commitment has been satisfactorily addressed.

Suitability for Initial BSAT Access

a. Although the CDC and APHIS have the responsibility at the Federal level to grant BSAT access, currently they rely solely on Security Risk Assessment results provided by

[49] These terms have been defined for purposes of NICS. Pursuant to 27 CFR 478.11 (Meaning of terms) (Commerce in Firearms and Ammunition) "adjudicated as a mental defective" means (a) A determination by a court, board, commission, or other lawful authority that a person, as a result of marked subnormal intelligence, or mental illness, incompetency, condition, or disease: (1) Is a danger to himself or to others; or (2) Lacks the mental capacity to contract or manage his own affairs. (b) The term shall include – (1) A finding of insanity by a court in a criminal case; and (2) Those persons found incompetent to stand trial or found not guilty by reason of lack of mental responsibility pursuant to articles 50a and 72b of the Uniform Code of Military Justice.

[50] 18 USC 175b(d)(2)(F)

CJIS-BRAG to determine access to BSAT. The entity's RO is the local authority for granting BSAT access but relies mostly on the CDC and/or APHIS determination after the individual is processed through the entity's HR department. Aside from the issue of access to BSAT, however, a principal investigator, laboratory director or other managerial official considers a number of factors, to include an individual's technical background and experience, training, and safety behavior before permitting them to work in a laboratory with any potentially hazardous agents or materials, including BSAT.

b. There are no nationally established criteria in the Security Risk Assessment beyond the restricted and potential prohibitive categories to determine an individual's suitability to access BSAT. For this reason, there is no requirement for further vetting of personnel or adjudication by the CDC/APHIS or the RO beyond the Security Risk Assessment before access to BSAT is granted to an individual. (Many organizations incorporate stringent screening in their hiring practices, however, as noted above.) Federal laboratories that have implemented PRPs have attempted to address this gap. However, such programs are not likely to be feasible, or necessarily desirable, at all BSAT laboratories in the United States.

c. Other than the database check performed by CJIS-BRAG under the Security Risk Assessment, there is no other requirement (such as drug testing) to determine if an individual falls into a restricted category as currently being an unlawful user of a controlled substance when they apply for BSAT access.

d. Aspects of an individual's health may be relevant to their suitability to access BSAT, but screenings to address these aspects are not addressed in the SAR. An emphasis on identification of potential health problems and review of medication or treatment that may affect security and safety is paramount. Furthermore, occupational health clinics should inform scientists of the types of medications and treatments that might have a potential deleterious effect on working safely and securely in the lab, regardless of whether BSAT are involved.

e. There is a perceived gap in the enforcement of the deemed export regulations[51] by the Department of Commerce (DOC) as they pertain to work at BSL-3 and BSL-4 conditions as well as sharing of information between DOC and the agencies enforcing SAR (CDC and APHIS). In March 2004, the DOC's Inspector General issued a report on the status of compliance with export regulations, and stated that, "Technology related to controlled equipment—regardless of how use is defined—is subject to the deemed export provisions (and the requirement to license foreign nationals having access to that equipment) *even if the research being conducted with that equipment is fundamental."*

[51] The deemed export concept is defined as the transfer or disclosure (including visually or orally) of controlled "technologies" (**EAR**) or "technical data" (**ITAR**) to a foreign entity or individual anywhere including in the U.S. (per 15 CFR 734.2 and 22 CFR 120.17). "*Technology"* is specific information necessary for the "development," "production" or "use" of items on the Commerce Control List (EAR 772.1) such as those under the ECCN 2B352 (Equipment capable of use in handling biological materials) – which includes complete containment facilities at BSL-3 and BSL-4 containment level (ECCN 2B352.a.).

2. Continual Monitoring of Personnel

a. The Security Risk Assessment is only conducted every five years unless an individual changes institutions, at which time they would undergo a new Security Risk Assessment. It is possible for an individual to fall into one of the prohibited or restricted categories and not be identified until that individual's Security Risk Assessment is rechecked.

b. Although the current SAR require entities to describe in their security plans how they deal with and report suspicious persons, it does not address any type of continuous evaluation of employed personnel, to include local institution initial and periodic interviews, self- and peer-reporting, or the reporting of circumstances that would affect or diminish an individual's ability or reliability to perform duties related to BSAT.

c. Drug testing to ensure an individual is not a current unlawful user of a controlled substance, which is a restrictive category, is not mandated in the SAR.

d. After an individual is processed by HR at an entity, there is no mechanism available to CDC/APHIS or the RO to determine if individuals who have been granted access pose either a threat to themselves or to others. Employees who display unusual behavior or are not mentally sound may pose a security risk.

e. There is no requirement for continual physical or mental health monitoring of individuals once BSAT access is granted.

3. Termination of BSAT Access and Granting New Access

a. Without a nationally established set of "suitability criteria" beyond the Security Risk Assessment determinants for BSAT access, an RO and/or CDC/APHIS cannot adequately determine when an individual should not have BSAT access because they pose a threat to public and/or agricultural health, safety, or security. This being said, the RO has the responsibility and discretion to remove an individual from BSAT access based on their judgment of that individual's ability to work in the laboratory safely and securely.

b. Although entities are required to report when an individual with access has their access terminated and the reason why access was terminated (either due to administrative or other reasons), there is no requirement that the RO report details of derogatory information that let to the termination of access. There are liability concerns and privacy requirements that may affect the nature and extent of the derogatory information that is reported by entities about an individual. This lack of reporting may lead to the BSAT community passing along personnel who may represent a security risk from one lab to the next. In making new select agent access determinations, derogatory information could be valuable in assessing risk to safety and security.

C. Recommendations for Enhancing Personnel Security

1. Overarching Recommendations

Because there is no requirement that the RO report derogatory information to the CDC or APHIS if they have removed an individual from BSAT access due to the derogatory information, the research community is potentially at risk of transferring personnel who may represent a security risk from one lab to the next. Furthermore, the WG identified that other than the restricted and prohibited criteria, ROs have not been provided guidance on determining an individual's suitability for access to BSAT or for determining when to temporarily suspend or permanently terminate that access. For this reason, the WG recommends the following:

a. **Establish a working group (WG), including Federal and non-Federal subject matter experts from the scientific, intelligence, security, human resources and healthcare (including mental health professionals) communities, that will investigate and establish guidance and training on suitability criteria, above and beyond restricted and potential prohibited categories, for use by:**

1. ROs, in addition to the Security Risk Assessment, to determine whether to grant an individual's initial access to BSAT or to temporarily or permanently restrict (or terminate) an individual's access to BSAT
2. PIs, researchers, and technicians to continuously monitor themselves and others for suitability to access BSAT
3. Occupational health professionals, to determine the suitability for BSAT access based on activities performed with the BSAT and the individual's physical and mental health, to include medications that may affect an individual's ability to perform duties with BSAT.

In developing suitability criteria, this WG should, at a minimum, consider aspects of personal and professional conduct, physical and mental health, and behaviors that indicate an individual is at risk of harming themselves or others.

b. **Assess the feasibility of the following recommendations:**

1. **An amendment to the SAR requiring that ROs report the details of derogatory information leading to permanent termination of BSAT access to CDC or APHIS for inclusion in a registry or repository.** Derogatory information may be related to suitability criteria, determined by the WG above, or restrictive/prohibitive categories. This may require a legislative change.
2. **A registry or repository containing derogatory information reported by the RO that can be used, in combination with results of the security risk assessment, for determining whether an individual should be granted BSAT access.** The FBI-CJIS, CDC, APHIS, DHS, Director of National Intelligence, Homeland Security Council, and National Security Council should collaborate to determine if adjudicative standards should be used for granting BSAT access. If such a registry is deemed legal, amend the SAR to allow the use of this registry by CDC

and APHIS, in combination with Security Risk Assessment results, to grant or deny BSAT access. This will require a legislative change.

2. Granting Initial BSAT Access

a. Security Risk Assessments

1. Foreign Nationals

Screening: Identify a Federal agency that will 1) develop guidelines for vetting FNs that require BSAT access and 2) will screen FNs according to these newly established criteria. The SAR should be amended such that this Federal agency, CJIS-BRAG, CDC, and APHIS collaborate to consider both the Security Risk Assessment results and the newly established criteria to grant or deny BSAT access. This screening may require providing information on their prior history in their country of origin as well as up to date information on their occupation, background, and research as well as include results from prior visa screens by the Department of State (DOS). Use of the Collective Foreign Threat Assessment tool (Appendix 3-B) may be considered.

Visas: Require that the DoS provide a list of visa types that are appropriate for work with BSAT to the Select Agent Program. Require the Select Agent Program to disseminate this information to Responsible Officials. The CDC/APHIS Select Agent Programs will provide information and guidance to institutional officials (IOs), ROs, and funding agencies on the types of visas that are adequate for work with BSAT. Inappropriate visa types will require a visa change, or a specific waiver, prior to Security Risk Assessment processing. Amend 18 U.S.C. 175b or the Bioterrorism Response Act to include "an inappropriate visa type" as a restrictor for access to BSAT.

Provide the DOJ and DHS with the statutory authority to perform immigration status checks on Security Risk Assessment-approved FNs at least every six months.

2. The CJIS-BRAG should either a) be provided the statutory authority to access the mental health component of the NICS database or b) establish a separate mental health database to allow CJIS-BRAG to determine if an individual is ineligible to have access to BSAT for mental health reasons. Moreover, in either instance, an increased emphasis must be made for states to report information regarding persons who have been "adjudicated as a mental defective or have been committed to a mental institution" in a timely and consistent manner to maintain the integrity and utility of any such database.

b. Suitability for Initial BSAT Access

1. Assess the feasibility of requiring drug testing (urinalysis) for initial BSAT access and determine whether such a testing program could be

justified under a Fourth Amendment analysis. Pursuant to 18 U.S.C.§ 175b(d)(2)(D), a person who is an unlawful user of a controlled substance is a restricted person for purposes of access to BSAT.

2. Consider amending the SAR such that persons with duties associated with the highest risk BSAT and based on the activities performed with the agent are required to be in an occupational health program. The occupational health program should at a minimum include an initial screening that assesses an individual's general health and also reviews medications for any possible conflicts with BSAT work. Description of the occupational health program will be required in the biosafety or security plan of the entity. The cost of implementing this recommendation should be weighed against the number of laboratories it will affect and the benefit that will be gained. It should be noted that this type of a change to the SAR could require a legislative amendment.

3. The DOC, CDC, and APHIS should determine how to best implement deemed export regulations with respect to the Select Agent Program-regulated community and should subsequently establish training for IOs, ROs, and funding agencies on deemed export regulation requirements for BSAT work.

3. Continual Monitoring of Personnel

a. Amend the SAR to require that a Security Risk Assessment be performed every three years for all individuals with access to BSAT.

b. Assess the feasibility of random drug testing (urinalysis) for continued BSAT access to ensure that an individual does not fall into a restricted category.

c. Amend the SAR to include a requirement that entities provide training for ROs, principal investigators, researchers, and technicians on suitability criteria as determined by the WG above; mechanisms for supervisor-, self- and peer-reporting of issues relating to the suitability criteria; and a process for temporary suspension or permanent removal of access in their security plans. Leadership, supervisors, medical personnel, peers, and individuals themselves should be aware of personal, professional, and medical (physical and mental) criteria that may impact perception or performance associated with working with or around BSAT. This may require a legislative change.

d. Ensure that all individuals who work with BSAT have access to an occupational health professional for referral of physical or mental health issues that arise after BSAT access is granted. Ensure that entities include contact information and procedures for referring individuals in the description of their occupational health programs.

4. Termination of BSAT Access and Granting New Access

a. Provide guidance to the RO regarding their role in removing individuals from BSAT access who display behaviors indicating they are at risk of doing harm to themselves or to others. Ensure that entities include procedures for referring individuals who display these behaviors in the description of their occupational health programs.

b. Ensure that entities describe procedures for temporary or permanent removal from access due to physical, occupational, or mental health concerns or other issues potentially impacting fitness-for-duty with respect to BSAT possession and use.

c. Ensure that procedures are in place for the RO to immediately notify the local FBI Weapons of Mass Destruction Coordinator in order to initiate a threat assessment process in the event that he/she becomes aware of an incident or action that may indicate possible criminal activity regarding BSAT.

5. Other Recommendations

a. Perform a study of Chemical and Nuclear Personal Reliability Programs to examine the cost of individual PRP measures and the value of eligibility/ineligibility criteria, significance of the personal interview, and effectiveness of continual review/monitoring to identify potentially disqualifying information or reliability issues that would result in an individual's permanent disqualification.

Chapter 4 PHYSICAL SECURITY

The WG findings and recommendations below were arrived at after a review of the SAR, Department- and Agency-specific policies and other existing regulations, policies, procedures, templates, and best practices related to physical security at facilities that work with BSAT (see Appendix 4-A). In addition, a questionnaire focused on physical security of BSAT was administered to Department and Agency members of the physical security subgroup, and responses were reviewed to identify physical security measures at different Federal agency labs and to identify areas for improvement.

Key Finding: Physical security plans at facilities are performance-based; therefore, there are no minimum prescriptive standards for physical security at facilities that handle, store, or transport BSAT.

Key Recommendation: Develop a set of minimum prescriptive security standards based on the risk at the lowest level, allowing for enhancements as risk increases.

A. Current Physical Security Regulations for BSAT (Physical Security and Written Security Plan Requirements)

1. Physical security requirements

As part of the regulatory oversight and management mechanism, the Select Agent Program ensures that registered individuals and entities provide adequate security to address the requirement of the Bioterrorism Response Act of 2002 to "establish and enforce safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or for any other criminal purposes;…" through the SAR.

The SAR require that any individual or entity that possesses BSAT must adequately provide physical security protection. One condition of registration is the development and implementation of a written security plan that adequately describes policy and procedures to safeguard such agents. The written security plan must demonstrate that graded protection is in place and properly maintained. Critical asset protection and essential mission capabilities are key components of physical security design. Based on a site-specific risk assessment, ROs can make graded protection requirement adjustments.

The security provisions of the SAR address three components that must be in the written security plan: 1) Physical Security, 2) Information Systems Control, and 3) Inventory Control. The SAR consider the three components collectively as the entity security plan. Furthermore, provisions cited within Section 11 of the SAR also cover operational security, such as access by Security Risk Assessment-approved individuals and the reporting of theft, loss, or release of a BSAT. These topics must be included in the written description of entity policies and procedures. The security plan must also include the following elements: control and access to BSAT, routine cleaning and maintenance of BSAT areas, suspicious person reporting, protocols for intra-entity transfers, security

escorts and training drills and exercises, to name a few, some of which are addressed in other chapters of this report.

Listed below are general categories, under each of the main components, that the SAR require the entities to address when developing their security plan and infrastructure:

- Physical Security: a) Perimeter Security, b) Entry Security, c) Interior Security, and d) Security Planning.
- Information Systems Control: a) Information Technology (IT) Infrastructure (such as firewall protection, anti-virus protection, password protection), b) Hardware Asset Protection (such as computer room protection, office protection, property pass controls, secured space for sensitive information), c) Personnel Security (such as background check for IT staff/vendors, information security manager), and d) Data Protection (such as data encryption, remote access protocols, web data sanitation, security of select agent inventories).
- Inventory Control: a) Inventory Control Management (such as inventory control manager, inventory policy, and training), b) Inventory Data Management (such as electronic data storage, log-book, destruction records), c) Tracking (such as chain-of-custody, quantities stored, inspections, audits), and d) Inventory Protection (such as electronic monitoring).

In 2007, CDC/APHIS recognized the complexity of the requirements of the written security plan and posted a security information guidance document and a security plan template on the select agent website. This is designed to assist the regulated community in preparing security plans to satisfy the conditions of the SAR.

The CDC/APHIS review involves three activities: 1) Review of the entity's registration application, including the in-place physical security components; 2) Review of the entity's written security plan, biosafety plan, and incident response plan; and 3) Review of the security inspection reports. An entity cannot receive a Certificate of Registration without government approval of their security plan.

Although the security portion of the SAR is performance-based, it does stress having deterrence/deny, detection, and delay security layers. The SAR also requires graded protection commensurate with the risk of the agent(s), based on a site-specific risk assessment. In the absence of more prescriptive requirements, the burden is on the entity to demonstrate compliance with the regulations.

2. Other Agency Physical Security Requirements (U.S. Army)

The Army physical security program applies to all U.S. Army owned and/or Army controlled laboratories and facilities that furnish, have custody of, or possess BSAT. This program also applies to their major commands, and, when incorporated into the contract, Army contractors that are provided BSAT by the Department of the Army (DA). In addition to the SAR, the following DoD Instructions and DA regulations establish the Army BSAT physical security program:

- AR 190-17 Biological Select Agents and Toxins Security Program
- AR 50-1 Biological Surety
- DoDI 5210.89 Minimum Security Standards for Safeguarding Biological Select Agents and Toxins
- AR 190-13 Army Physical Security Program
- AR 525-13 Antiterrorism

The initial planning phase for a BSAT program begins with a vulnerability assessment to determine a facility's vulnerability to sabotage, theft, loss, seizure, or unauthorized access, use, or diversion of BSAT materials from both external and internal threats. The vulnerability assessment team utilizes the DA Implementing Instructions on threats to BSAT based on the DA Implementing Instructions to the DoD Postulated Threat when assessing a facility's vulnerabilities. In addition, the Army Threat Message, Senior Mission Command (SMC) Threat Statement, and local threat statement is utilized. The vulnerability assessment requires an annual review/update.

Development of the physical security plan is the next phase and should incorporate the following: 1) Equipment and devices to detect or delay; 2) Security lighting; 3) Protective alarms; 4) Duress system; 5) Communication systems; 6) Locks and keys; 7) Measures to control vehicles and material; 8) Personnel identification system; 9) Security forces to include guard response and roving patrols; 10) Visitor control system; 11) Package and movement control system; 12) End of day checks; 13) Recapture and recovery plans; and 14) On and off post transportation plans. Annual reviews are required.

Specifically required components of physical security for BSAT rooms and laboratories include intrusion detection systems, duress alarms, proximity badges with pin for access and a back-up locking mechanism in case of system failure, and inventory security measures to include working stock containers secured with one Army property lock, reference stocks secured with two surety locks, and two person control to access reference stocks. Physical security systems are required to be connected to back up/emergency power. Cameras are an additional component of physical security utilized in some BSAT facilities although they are currently not a requirement of the Army regulation.

B. Areas for Improvement in Physical Security Regulations

There are no minimum security standards across all agencies that account for the risk of a particular BSAT and the risk assessment at the facility.

Although the current regulations allow for performance based standards established on risk, the regulated community has expressed a desire for more guidance on minimum prescriptive requirements to meet the regulations at the May 13-14, 2009, public consultation meeting convened by the WG.

C. Recommendations for Improving Physical Security Regulations

Develop minimum physical security standards based on the risk of the agent or toxin and characteristics of facilities and type of work being done.

Appendix 4-B, provided by the physical security subgroup, shows an example of how physical security standards could be applied to a stratified list of BSAT taking into consideration the type of facility and the work that is done. Using a standard security risk assessment will allow a facility to build upon the baseline or minimum physical security requirements and will ensure a standard approach while allowing for additional security requirements under current regulations.

Chapter 5 TRANSPORTATION

The WG analyzed the SAR and other current regulations, policies, procedures, templates, and best practices relating to transporting BSAT. They examined any regulatory overlaps and gaps and the vulnerabilities they may create. Recommendations were made to resolve inconsistencies and streamline these regulations to improve the safe and secure transport of BSAT.

Key Finding: Historical data indicate that there has been only one confirmed loss of a BSAT shipment in the last twenty years; this loss was not the result of criminal activity. While this may suggest that existing regulations, policies, and procedures are satisfactory and provide an appropriate level of security for BSAT in transportation, there has not been an extensive assessment to determine the threats, vulnerabilities or risks within this sector regarding BSAT.

Key Recommendation: Perform a risk assessment, focused on the security of BSAT transportation under the current regulatory framework, to determine if any risk is present during BSAT transportation.

A. Transportation of infectious substances

Over the last 20 years, many Federal agencies have revised their BSAT and other infectious agent regulations to promote greater harmony with changes to domestic and international regulations, including the USA PATRIOT Act and the Bioterrorism Response Act. While the resulting regulations enable agencies to respond more effectively to public health threats and to improve the overall safety of BSAT in transport, many of these changes increased the number and complexity of these regulations and the costs of training and complying with them. At the same time, the number of carriers transporting these materials has declined. If any of the remaining carriers were to discontinue their BSAT transport operations, delays in transporting materials caused by the lack of available carriers could adversely affect the nation's public health response and research programs.

Current regulations in the transport of infectious substances at various government agencies are described below.

1. Department of Transportation (DOT)

The DOT, through the Pipeline and Hazardous Materials Safety Administration (PHMSA), regulates BSAT in commercial transportation to, from, and within the United States. PHMSA administers a national program devoted to the safe and secure transportation of hazardous materials by air, rail, vessel, and highway. DOT oversight extends to all parts of the hazardous materials transportation system – from classification of materials, to packaging, handling, moving, loading, and unloading of hazardous materials shipments in commerce. PHMSA is responsible for maintaining and updating

Chapter I, Subtitle B of Title 49 of the Code of Federal Regulations, which include the U.S. Hazardous Materials Regulations (HMR), 49 CFR Parts 171-180. PHMSA's hazardous materials safety program focuses on preventing incidents, especially incidents with the most serious consequences, and providing guidance for emergency responders on how to mitigate the consequences of incidents that do occur. According to the HMR, BSAT are classified as either Division 6.1 (poisonous) or Division 6.2 (infectious substances) for transportation. Division 6.2 materials are further described as "UN 2814, Infectious substances, affecting humans," or "UN 2900, Infectious substances, affecting animals," and must comply with applicable shipping paper, package, marking, and labeling requirements. Shippers and carriers of BSAT are required to develop an in-depth security plan. This plan must include an assessment of the potential transportation security risks and appropriate measures to address the risks. At a minimum, the plan must address personnel security, unauthorized access and en route security. It must be revised and updated as necessary to reflect changing circumstances. The HMR require shippers and carriers to provide security awareness and in-depth security training commensurate with the security plan to their employees who affect the transport of these materials.[52]

In accordance with the DOT's Federal Motor Carrier Safety Administration (FMCSA) regulations prescribed in 49 CFR §§ 383.5 and 383.93, drivers must have a commercial driver's license (CDL) with a hazardous materials endorsement if they transport hazardous materials that are 1) required to be placarded under 49 CFR Part 172, Subpart F, or 2) any quantity of a material listed as a select agent or toxin under 42 CFR Part 73. Furthermore, the DHS's Transportation Security Administration (TSA) regulations at 49 CFR Part 1572.3 require background checks for persons who are "qualified to hold a commercial driver's license under 49 CFR parts 383 and 384, and [are] applying to obtain, renew, or transfer an HME". (See 49 CFR 1572.3(b)(1); "HME" refers to hazardous materials endorsement).

If a release does occur, shippers and carriers of BSAT are required to immediately notify the DOT or CDC and to submit a subsequent incident report to PHMSA within 30 days of the discovery of the incident. The DOT does not require PHMSA to track or regulate lost packages of BSAT under the HMR to avoid duplication with the CDC/APHIS, who perform this function under the SAR.

PHMSA periodically amends the HMR to harmonize the national regulations with the international standards and regulations prescribed in the United Nations Recommendations for the Transport of Dangerous Goods; International Civil Aviation Organization Technical Instructions for the Transport of Dangerous Goods by Air; and the International Maritime Dangerous Goods Code. PHMSA does not recognize the International Air Transport Association's Dangerous Goods Regulations. PHMSA's Associate Administrator for Hazardous Materials Safety serves as the competent authority for the United States relative to the domestic and international transportation of hazardous materials.

[52] Docket No. RSPA-02-12064 (HM-232), 57 FR 14510, Hazardous Materials: Security Requirements for Offerors and Transporters of Hazardous Materials.

Currently, the HMR do not regulate plant pathogens, including select agents for plants, but is considering a petition submitted by APHIS, Petition No. P-1529, requesting that DOT's PHMSA regulate all select agents listed by the United States Department of Agriculture (USDA) under the HMR.

PHMSA estimates that up to 1 million hazardous materials shipments occur every day. Hazardous materials incidents are relatively rare – about one for every 27 million ton-miles moved. Of the approximately 3,000 transfers of BSAT that have occurred since 2003, there has only been one confirmed loss of BSAT that occurred during shipment.[53] This loss was investigated by the FBI and it was determined that there was no criminal intent. In addition, this incident presented no adverse effect on public health, agriculture, or the environment.

2. CDC and APHIS

In addition to the DOT regulations that govern the transportation of infectious substances, the CDC and APHIS regulate BSAT transfers under the SAR. These regulations oversee the transfer of BSAT between registered entities within the United States and movement from international sources into the United States**,** and require that all BSAT packages must be under the control of an authorized person (an individual with an approved security risk assessment) while in the possession of the entity prior to shipment and after receipt by the entity.

The CDC require an import permit for importation of known etiologic agents, hosts, or vectors of human disease under 42 CFR 71.54 (Etiological Agents, Hosts and Vectors). USDA, APHIS, and Veterinary Services (VS) require that a permit be issued prior to the importation or domestic transfer (interstate movement) of known etiologic disease agents of livestock, poultry, and other animals (under 7 CFR Part 330). The USDA is developing security policies for the transportation security of biohazardous waste.[54]

Under the SAR, importation of known BSAT into the United States requires the intended recipient to be registered with either the CDC or APHIS and submit an APHIS/CDC Form 2 to obtain approval to import the BSAT prior to each importation event. Domestic transfer of BSAT between registered entities also requires an APHIS/CDC Form 2 to be approved by CDC or APHIS. The shipper must also include on the shipper's declaration for dangerous goods an emergency telephone number at its facility that can respond to calls 24-hours a day. Until being offered to a courier for transport, an individual with an approved Security Risk Assessment must be in possession of the package.

When the package arrives at its destination, the recipient confirms delivery by completing and faxing APHIS/CDC Form 2 back to the shipping facility's RO and CDC or APHIS

[53] Entities are required to report a loss even if the BSAT is subsequently recovered.
[54] Developmental Document: USDA Policies and Procedures on Biohazardous Waste Decontamination, Management, and Quality Control at Laboratories and Technical Facilities," Chapter 15 Security Parameters for Biohazardous Waste, 3-3-2009.

within two business days of receipt. If a package containing BSAT has not been received within 48 hours after the expected delivery time, or if the package has been damaged to the extent that a release of BSAT may have occurred, the receiving entity must immediately report this incident to the CDC or APHIS Select Agent Program and within seven calendar days, follow up with a written report (APHIS/CDC Form 3—Report of Theft, Loss, or Release of Select Agents and Toxins). Upon receipt of the report of the incident, the CDC or APHIS Select Agent Program will review the report to determine the appropriate action, which could include a request for additional information, administrative action, inspection, and/or referral to the FBI for further investigation. If there is a threat to the public, the CDC will notify the appropriate local, state, and Federal public health agencies.

3. Transportation Security Administration (TSA)

The TSA is the DHS agency responsible for securing the nation's transportation systems so people and commerce can move freely.[55] On 26 June 2008, TSA issued guideline security action items[56] to support the safe highway transport of specific hazardous materials (classified as Tier 1 or 2) that have the potential to cause significant fatalities and injuries or significant economic damage if released or detonated during a transportation security event.[57] BSAT were classified as Tier 2 materials. These action items are followed on a voluntary basis and request that carriers follow enhanced personnel, physical, and en route security measures for these materials. TSA is preparing a rulemaking process that would implement the voluntary Security Action Items (SAI) into security planning regulations. It was noted in the public consultation that mandating compliance with such additional regulations may reduce the number of carriers willing to implement them and transport BSAT.

4. Department of Commerce

Under 15 CFR Parts 730 to 799 (Export of Etiologic Agents of Humans, Animals, Plants and Related Materials), the Department of Commerce (DOC) requires that exporters of a wide variety of etiologic agents of human, plant, and animal diseases, including genetic material and products which might be used for culture of large amounts of agents, obtain an export license.[58]

5. Food and Drug Administration

The Food and Drug Administration (FDA) issues regulations on the transport and management of biologics that may contain infectious substances.

---

[55] The United States Government Manual, 2008-2009 Edition, page 236.
[56] http://www.tsa.gov/assets/pdf/action_memo_highway_sai_062608.pdf, http://www.tsa.gov/assets/pdf/tsai_app_a_hssm_sai.pdf, http://www.tsa.dhs.gov/assets/pdf/tsa_appendix_a1_hsssm_sai.pdf
[57] http://www.tsa.dhs.gov/assets/pdf/tsa_app_b_hssm_list.pdf
[58] For more information: http://www.access.gpo.gov/bis/index.html, or http://www.bis.doc.gov/.

6. Department of Energy/National Nuclear Security Administration national laboratories

The Department of Energy (DOE)/National Nuclear Security Administration (NNSA) national laboratories comply with the following additional regulations for the transport and receipt of BSAT:

- 10 CFR Part 851, Department of Energy Worker Safety and Health Program, Appendix A.7, Biological Safety
- DOE Order 151.1C, Comprehensive Emergency Management System, Chapter V.2.d, Offsite DOE Transportation Activities, and V.2.e, Hazardous Biological Agents or Toxins

Tracking of the package is achieved using the courier's online tracking system or the site's hazardous materials shipping office.

7. DoD

The Department of Defense (DoD) and its component Services comply with the following additional regulations for the transport and receipt of BSAT:

- DODI 5210.89 Minimum Security Standards for Safeguarding Biological Select Agents and Toxins
- DoD 4500-9R Defense Transportation Regulation
- AR 50-1 Biological Surety
- AR 190-17 Biological Select Agent and Toxin Security Program
- OPNAV 5530.16 Minimum Security Standards for Safeguarding Biological Select Agents and Toxins (BSAT)
- AFI 10-3901 Minimum Security Standards for Safeguarding Biological Agents and Toxins

Like the DOE, the DoD regulations ensure that an approved person (an individual with an approved security risk assessment and in the biological personnel reliability program) has custody of the package containing BSAT until picked up by the courier. In a recent review[59] of Federal and Service policies and procedures for BSAT transportation, it was found that 1) couriers have less stringent personnel security requirements than individuals at the entity and 2) new guidance on air and ground transportation of BSAT, to include chain of custody and positive control, were enacted at DoD facilities.

B. Areas of Improvement for the Transport of BSAT

1. Assessing Risk

[59] http://www.fredericknewspost.com/media/pdfs/bsr_apdx001.pdf

Individual BSAT may present different security risks depending on their specific characteristics. A complete assessment of BSAT and their shipment through couriers, including transfers between couriers, should be analyzed as part of a comprehensive risk assessment to fully assess the risks these materials pose in transportation.

2. BSAT Hazard Communication

The HMR do not permit the technical name of a Division 6.2 material to be marked on the outer package that contains this material. However, the HMR do require a package whose content is suspected to contain an unknown Category A infectious substance to have a Division 6.2 material assigned identification number UN 2814 or UN 2900 and to enter the words "suspected Category A infectious substance" in parentheses on the shipping paper in place of the technical name that is part of the proper shipping description. PHMSA enforcement inspectors have found that couriers of these packages are placing these shipping papers on the sides of the packages in a clear vinyl envelope, which has them serve as a marking and make it easier to identify which packages may contain Category A materials.

3. Shipment Tracking and Communication

If a package containing BSAT has not been received within 48 hours after the expected delivery time, or if the package has been damaged to the extent that a release of a BSAT may have occurred, the recipient entity is required by the SAR to immediately report this incident to the CDC or APHIS, and within seven calendar days to follow up with a written report using CDC/APHIS Form 3. However, there are no requirements mentioned in the SAR for the courier to report a theft, loss, or release of BSAT. In addition, TSA classifies BSAT as Tier 2 highway security sensitive materials and does not require tracking or notification of shipment. When packages containing BSAT are reported missing in transit, Federal agencies have found it difficult to retrieve information from couriers on these reported missing packages. This delay in the receipt of information can lead to a delay in the recovery of the package that could span days.

4. Requirements for Couriers of BSAT

a. Background investigations. Couriers of BSAT are required to have security plans in accordance with 49 CFR Part 172, Subpart I, and are required to have training on this plan as well as hazardous materials training in accordance with 49 CFR Part 172, Subpart H. In addition, FMCSA requires couriers transporting BSAT by motor vehicle to have a CDL with hazardous materials endorsement, which requires a background check. All airline and airport employees and contractors who require unescorted access to secure areas of the airport are subject to both fingerprint-based criminal history record checks through the FBI and name-based background checks through TSA.

b. Inspections of BSAT couriers. DOT PHMSA enforcement personnel conduct inspections of BSAT couriers but their efforts are hampered by the lack of information on the locations of couriers that transport BSAT. Moreover, inspections of BSAT couriers, as a discrete subset of couriers of hazardous materials, are not routinely conducted. Couriers of BSAT packages are not required to be registered with APHIS/CDC (though DOT does require

registration of hazmat couriers). There is no registration or similar recording device for couriers who handle BSAT packages.

5. Vulnerabilities for plant pathogens

Currently, plant BSAT are not subject to DOT regulations. Work is underway with United Nations Sub-Committee of Experts on the Transport of Dangerous Goods to assess whether these materials should be included. A U.S. interagency task force was established to determine potential inclusion of plant pathogens. USDA submitted a petition for rulemaking (P-1529) to DOT to include these agents in the HMR. DOT is considering a future rulemaking project in response to the petition.

C. Recommendations for Improving BSAT Transport

The SAR have been adequate in ensuring secure transportation of BSAT. There is currently no evidence to substantiate an increase in transportation security for BSAT. Furthermore, BSAT represent a tiny fraction of the hazardous materials that are routinely handled in daily commerce. Therefore, the key recommendation of the WG is to:

Task the TSA, in partnership with other USG agencies, to conduct a risk assessment to determine the risk posed by air and ground transportation of BSAT.

The risk assessment should consider:

1. The risk of the BSAT, the threat of an unintentional release of the BSAT during transportation (to include likelihood that insider or external threats may compromise a BSAT shipment), and the vulnerabilities in physical, personnel, or operational security during transportation and at stopping points along the shipping routes.

2. The risk posed by having the technical name of BSAT on the shipping paper, balanced by the need to provide enough information to meet the information needs of the emergency responder.

The results of the risk assessment can be used to determine:

1. If high risk BSAT should be shipped using more stringent security controls (*e.g.*, use of restricted service) or an enhanced tracking system (*i.e.*, global positioning systems (GPS)) device in shipments. The baseline security plan requirements contained in the HMR may be sufficient for most BSAT, however, more stringent security controls may be deemed appropriate for BSAT identified by TSA as posing a more serious security risk.

2. If additional background checks should be performed on personnel who handle BSAT, to include couriers and others in the transport chain.

3. If tighter chain of custody requirements and tracking should be implemented.

Other recommendations by the WG include the following:

1. Establish a communication plan to ensure effective communication among entities, couriers, DOT, and CDC/APHIS. This plan may involve creating agreements on security-based communications practices, or a secure web portal that would enhance tracking

capabilities or the provision of the tracking number to CDC or APHIS (APHIS/CDC Form 2, line 37 requests this information) in order to give those agencies the ability to track shipment of the package(s) through the courier's system.

2. Require CDC/APHIS to maintain a list of BSAT couriers. This will facilitate DOT inspections of BSAT couriers so that compliance with current hazmat security plan requirements can be determined. In turn, DOT, CDC, and APHIS should ensure that information on BSAT couriers is protected from disclosure that could compromise security.

3. Consider inclusion of plant BSAT in the HMR.

Chapter 6 SUMMARY AND CONCLUSIONS

A compilation of recommendations can be found in Appendix 6.

Based on the analysis of the WG, the following changes and enhancements are recommended.

Statutory changes

- Amend 18 U.S.C. 175(b) to add "or attempts or conspires to possess." (Ch. 2, 4. a)
- The CJIS-BRAG should either a) be provided the statutory authority to access the mental health component of the NICS database or b) establish a separate mental health database to allow CJIS-BRAG to determine if an individual is ineligible to have access to BSAT for mental health reasons. (Ch 3, a. 2)

Regulatory changes

- Require entities to provide, as a part of registration, a select agent management plan that outlines the roles and responsibilities of the RO and other key managers for oversight to ensure compliance with the regulations (Ch 2, 2. b. 2)
- Revise the SAR to provide for DOJ access to conduct investigations. (Ch 2, 4. b)
- Revise the SAR to require that regulated entities must maintain their select agent records for at least 10 years. (Ch 2, 4. d)
- Visas: Require that the DoS provide a list of visa types that are appropriate for work with BSAT to the Select Agent Program. Require the Select Agent Program to disseminate this information to Responsible Officials. (Ch 3, a. 1)
- Consider amending the SAR such that persons with duties associated with the highest risk BSAT and based on the activities performed with the agent are required to be in an occupational health program. (Ch 3, 2. b. 2)
- Amend the SAR to require that a Security Risk Assessment be performed every three years for all individuals with access to BSAT. (Ch 3, 3. a)
- Amend the SAR to include a requirement that entities provide training for ROs, principal investigators, researchers, and technicians on suitability criteria as determined by the WG above; mechanisms for supervisor-, self- and peer-reporting of issues relating to the suitability criteria; and a process for temporary suspension or permanent removal of access in their security plans. (Ch 3. 3. c)

Guidance documents

- Provide guidance for entities to conduct comprehensive annual BSAT program reviews and facility inspections. (Ch 2, 2.b. 1)
- Continue to expand existing guidance for registered entities on select agent program implementation and oversight at the institutional level. (Ch 2, 2.b. 3)
- Provide comprehensive guidance on inventory management and recordkeeping requirements, approaches, and templates. (Ch 2, 3)
- Provide guidance regarding accessiblity to an occupational health professional for referral of physical or mental health issues that arise after BSAT access is granted. (Ch 3, 3. d)
- Provide guidance to the RO regarding their role in removing individuals from BSAT access who display behaviors indicating they are at risk of doing harm to themselves or to others. (Ch 3, 4. a)
- Clarify procedures for entities to describe procedures for temporary or permanent removal from access due to physical, occupational, or mental health concerns or other issues potentially impacting fitness for duty with respect to BSAT possession and use. (Ch 3, 4. b)
- Clarify procedures for the RO to immediately notify the local FBI Weapons of Mass Destruction Coordinator in order to initiate a threat assessment process in the event that he/she becomes aware of an incident or action that may indicate possible criminal activity regarding BSAT. (Ch 3, 4. c)
- Encourage CDC/APHIS to maintain a list of BSAT couriers. (Ch 5. 2)
- Consider inclusion of plant BSAT in the HMR. (ch 5, 3)

Topics for which working groups must be convened

- Establish a working group, including Federal and non-Federal subject matter experts from the scientific, intelligence, security, human resources and healthcare (including mental health professionals) communities that will investigate and establish guidance and training on suitability criteria, above and beyond restricted and potential prohibited categories. (Ch 3, 1. a)
- Assess the feasibility and legality of an amendment to the SAR requiring that ROs report the details of derogatory information leading to permanent termination of BSAT access to CDC or APHIS for inclusion in a registry or repository. (Ch 3, 1. b. 1)
- Assess the feasibility and legality of a registry or repository containing derogatory information reported by the RO that can be used, in combination with results of the security risk assessment, for determining whether an individual should be granted BSAT access. (Ch 3, 1. b. 2)
- Assess the feasibility of requiring drug testing (urinalysis) for initial BSAT access and determine whether such a testing program could be justified under a 4th Amendment analysis. (Ch 3, 2. b. 1)
- Assess the feasibility and legality of random drug testing (urinalysis) for continued BSAT access to ensure that an individual does not fall into a restricted category. (Ch 3, 3. b)

- Perform a study of Chemical and Nuclear Personal Reliability Programs to examine the cost of individual PRP measures and the value of eligibility/ineligibility criteria, significance of the personal interview, and effectiveness of continual review/monitoring to identify potentially disqualifying information or reliability issues that would result in an individual's permanent disqualification. (Ch 3, 5. a)
- Task the TSA, in partnership with other USG agencies, to conduct a risk assessment to determine the risk posed by air and ground transportation of BSAT.

  The risk assessment should consider:

  1. The risk of the BSAT, the threat of an unintentional release of the BSAT during transportation (to include likelihood that insider or external threats may compromise a BSAT shipment), and the vulnerabilities in physical, personnel, or operational security during transportation and at stopping points along the shipping line.

  2. The risk posed by having the technical name of BSAT on the shipping paper when used as a marking, balanced by the need to provide enough information on the package to meet the information needs of the emergency responder. (Ch 5)

Interagency coordination needed

- Task the HHS and USDA Select Agent Program (in consultation with subject matter experts from the scientific, intelligence and security communities from the Federal and non-Federal sectors as appropriate) to conduct a risk assessment of all the BSAT on the select agent list to develop a stratification scheme to guide implementation of security policy at registered entities. (Ch 2, 1. a)
- Task the HHS and USDA Select Agent Program (in consultation with subject matter experts from the scientific, intelligence and security communities from the Federal and non-Federal sectors as appropriate) to develop standard security risk assessment methodology for use at all BSAT facilities. (Ch 2, 1. b)
- Identify or establish a Federal entity to coordinate biosecurity oversight activities, and to ensure comprehensive and effective Federal oversight for all select agent research facilities and activities. This would include input from various stakeholder agencies (*e.g.*, CDC, APHIS, NIH/OBA, DoD, DHS, DOE, DOT, OSHA, EPA). (Ch 2, 2. a. 1)
- Plan better coordination of inspections. (Ch 2, 2. a. 2)
- Promote the oversight-of-oversight approach, whereby USG regulatory and oversight bodies place significant focus on reviewing laboratory-specific and institutional oversight efforts, and utilize existing information on the oversight efforts of other USG bodies. (Ch 2, 2. a. 3)
- Develop coordinated training and oversight programs for inspectors from various USG agencies and offices with oversight responsibilities. (Ch 2, a. 4)

- Screening: Identify a Federal agency that will 1) develop guidelines for vetting FNs that require BSAT access and 2) will screen FNs according to these newly established criteria. The SAR should be amended such that this Federal agency, CJIS-BRAG, CDC, and APHIS collaborate to consider both the Security Risk Assessment results and the newly established criteria to grant or deny BSAT access. (Ch 3, 2. a. 1)
- The DOC, CDC, and APHIS should determine how to best implement deemed export regulations with respect to the Select Agent Program-regulated community and should subsequently establish training for IOs, ROs, and funding agencies on deemed export regulation requirements for BSAT work. (Ch 3, 2. b. 3)
- Develop minimum physical security standards based on the risk of the agent or toxin and characteristics of facilities and type of work being done. (Ch 4)
- Establish a communication plan to ensure effective communication among entities, couriers, DOT, and CDC/APHIS. (Ch 5, 1)

Options on which the WG could not achieve consensus or had insufficient time for deliberation

1) The WG deliberated on options for filling the potential regulatory gap for *de minimis* quantities of select toxins identified in the previous section of this report; however, no one option was agreed upon. For this reason, the three options discussed are listed here with their respective rationales. The WG recommends that these options be revisited during the policy making process:

- **Option #1: Continue current practice of not tracking, regulating, or reporting orders and shipments of *de minimis* quantities of select toxins**

- **Option #2: CDC and APHIS, with input from relevant collaborating agencies, should work with suppliers of select toxins to develop toxin ordering and verification processes that require individuals and entities ordering select toxins to:**

1) verify that the entity/individual is either registered with the Select Agent Program or is exempt from registration due to only ordering exempt quantities of select toxins;
2) designate and provide contact information for the responsible investigator for the toxin to be obtained; and
3) designate and provide contact information for the biosafety officer or another authorized institutional official (other than the responsible investigator) at the ordering entity who can confirm that:

a) the order aligns with a legitimate program, requirement, or activity,

b) the appropriate risk assessment has been conducted for the receipt, possession, storage, and use of the toxin, and

c) subsequent toxin orders and aggregate quantities will be documented and tracked to ensure compliance with exempt quantity limits and enable ongoing institutional accountability and oversight.

- **Option #3: Amend the SAR such that CDC and APHIS require that all individuals/entities ordering *de minimis* quantities of select toxins enroll in a tracking system with the Select Agent Program.**

2) The WG had a concern that persons who were committed to mental institutions or were convicted of felonies as juveniles were not being given the opportunity to work in fields requiring BSAT access even though they may be well-adjusted.

The following recommendation should be revisited at the policy phase since there was insufficient time for the WG to complete deliberations on this issue:

Consider the feasibility of revising the statute to grant the Secretary of HHS similar authorities to those of the Secretary of the USDA to determine appropriateness of BSAT access denials for cases of prior committal to a mental institution or juvenile felony convictions.

APPENDICES

Appendix 1-A: Executive Order 13486

Federal Register
Vol. 74, No. 9
Wednesday, January 14, 2009

Presidential Documents

Title 3—

The President

Executive Order 13486 of January 9, 2009

Strengthening Laboratory Biosecurity in the United States

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Policy.* It is the policy of the United States that facilities that possess biological select agents and toxins have appropriate security and personnel assurance practices to protect against theft, misuse, or diversion to unlawful activity of such agents and toxins.

Sec. 2. *Establishment and Operation of the Working Group.* (a) There is hereby established, within the Department of Defense for administrative purposes only, the Working Group on Strengthening the Biosecurity of the United States (Working Group).

(b) The Working Group shall consist exclusively of the following members:

(i) the Secretary of State;

(ii) the Secretary of Defense, who shall be a Co-Chair of the Working Group;

(iii) the Attorney General;

(iv) the Secretary of Agriculture;

(v) the Secretary of Commerce;

(vi) the Secretary of Health and Human Services, who shall be a Co-Chair of the Working Group;

(vii) the Secretary of Transportation;

(viii) the Secretary of Energy;

(ix) the Secretary of Homeland Security;

(x) the Administrator of the Environmental Protection Agency;

(xi) the Director of National Intelligence;

(xii) the Director of the National Science Foundation; and

(xiii) the head of any other department or agency when designated:

(A) by the Co-Chairs of the Working Group with the concurrence of such head; or

(B) by the President.

(c) The Co-Chairs shall convene and preside at meetings of the Working Group, determine its agenda, and direct its work. The Co-Chairs may establish and direct subgroups of the Working Group, as appropriate to deal with particular subject matters, that shall consist exclusively of members of the Working Group.

(d) A member of the Working Group may designate, to perform the Working Group or Working Group subgroup functions of the member, any person who is a part of the member's agency and who is an officer of the United States appointed by the President, a member of the Senior Executive Service (SES), or the equivalent of a member of the SES.

Sec. 3. *Functions of the Working Group.* Consistent with this order, and to assist in implementing the policy set forth in section 1 of this order, the Working Group shall:

(a) review and evaluate the efficiency and effectiveness, with respect to Federal and nonfederal facilities that conduct research on, manage clinical

or environmental laboratory operations involving, or handle, store, or transport biological select agents and toxins, of the following:

(i) existing laws, regulations, and guidance with respect to physical, facility, and personnel security and assurance; and

(ii) practices with respect to physical, facility, and personnel security and assurance;

(b) obtain information or advice, as appropriate for the conduct of the review and evaluation, from the following:

(i) heads of executive departments and agencies;

(ii) elements of foreign governments and international organizations with responsibility for biological matters, consistent with functions assigned by law or by the President to the Secretary of State; and

(iii) representatives of State, local, territorial, and tribal governments, and other entities or other individuals in a manner that seeks their individual advice and does not involve collective judgment or consensus advice or deliberation; and

(c) submit a report to the President, through the Co-Chairs, not later than 180 days after the date of this order that is unclassified, with a classified annex as required, and sets forth the following:

(i) a summary of existing laws, regulations, guidance, and practices with respect to security and personnel assurance reviewed under subsection (a) of this section and their efficiency and effectiveness;

(ii) recommendations for any new legislation, regulations, guidance, or practices for security and personnel assurance for all Federal and nonfederal facilities described in subsection (a);

(iii) options for establishing oversight mechanisms to ensure a baseline standard is consistently applied for all physical, facility, and personnel security and assurance laws, regulations, and guidance at all Federal and nonfederal facilities described in subsection (a); and

(iv) a comparison of the range of existing personnel security and assurance programs for access to biological select agents and toxins to personnel security and assurance programs in other fields and industries.

Sec. 4. *Duties of Heads of Departments and Agencies.* (a) The heads of departments and agencies shall provide for the labor and travel costs of their representatives and, to the extent permitted by law, provide the Working Group such information and assistance as it needs to implement this order.

(b) To the extent permitted by law and subject to the availability of appropriations, the Secretary of Defense shall provide the Working Group with such administrative and support services as may be necessary for the performance of its functions.

Sec. 5. *Termination of the Working Group.* The Working Group shall terminate 60 days after the date of the report submitted under subsection 3(c) of this order.

Sec. 6. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to a department or agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is intended only to improve the internal management of the executive branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its agencies, instrumentalities, or entities, its officers, employees, or agents, or any other person.

Appendix 1-B: Working Group (WG) on Strengthening the Biosecurity of the United States: Executive Order WG Leadership

Working Group Executive Leadership
Ms. Rebecca Allen, Co-Chair Acting Director for Security Office of the Deputy Under Secretary of Defense for HUMINT, Counterintelligence, and Security Department of Defense
Carol D. Linden, Ph.D., Co-Chair Principal Deputy Director Biomedical Advanced Research and Development Authority (BARDA) Office of the Assistant Secretary for Preparedness and Response Department of Health and Human Services
Mr. Jean D. Reed, Co-Chair Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization (DATSD(CBD/CD) Office of the Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs (ATSD(NCB)) Department of Defense
LCDR Franca R. Jones, Co-Executive Secretary Office of the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization (DATSD(CBD/CD) Office of the Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs (ATSD(NCB)) Department of Defense
Laura A. Kwinn, Ph.D., Co-Executive Secretary Office of Medicine, Science, and Public Health Office of the Assistant Secretary for Preparedness and Response Department of Health and Human Services

Subgroup Leadership	
Select Agent Regulations	CAPT Rob Weyant Division of Select Agents and Toxins Centers for Disease Control and Prevention Dr. Freeda Isaac Animal and Plant Health Inspection Service U.S. Department of Agriculture

Inspection/Oversight	CAPT Rob Weyant Division of Select Agents and Toxins Centers for Disease Control and Prevention Dr. Charles Divan Agriculture Select Agent Program U.S. Department of Agriculture
Personnel Security and Reliability	CAPT Kenneth Cole Office of the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization Programs U.S. Department of Defense Ms. Pam Monroe Office of the Under Secretary of Defense for Intelligence U.S. Department of Defense
Physical Security	Ms. Pam Monroe Office of the Under Secretary of Defense for Intelligence U.S. Department of Defense Mr. Eric Puype Office of Infrastructure Protection U.S. Department of Homeland Security
Transportation	Mr. Bob Richard Pipeline and Hazardous Materials Administration U.S. Department of Transportation

Writing Support Staff

Sheila Barber, Ph.D.
Booz Allen Hamilton

Kakoli Niyogi, Ph.D.
Booz Allen Hamilton

Mr. Raymond Webber
Office of the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization
Department of Defense

Appendix 1-B-1: Working Group (WG) on Strengthening the Biosecurity of the United States: Executive Order WG Membership

Working Group Membership
Ms. Rebecca Allen, Department of Defense (Co-Chair) Dr. Richard Cavanagh, Department of Commerce Mr. Aaron Davenport, Office of the Vice President Mr. Rajesh De, Department of Justice Dr. Charles Divan, U.S. Department of Agriculture Dr. Peter Emanuel, Executive Office of the President Dr. Michael Glass, Office of the Director of National Intelligence Dr. Til Jolly, Department of Homeland Security Dr. Peter Jutro, Environmental Protection Agency Dr. Carol Linden, Department of Health and Human Services (Co-Chair) Dr. Robert Mikulak, Department of State Mr. Jeffrey Muller, Department of Justice/ Federal Bureau of Investigation Mr. Jean Reed, Department of Defense (Co-Chair) Mr. Robert Richard, Department of Transportation Dr. Jane Silverthorne, National Science Foundation Dr. David Thomassen, Department of Energy

Subgroup Membership	
Select Agent Regulations	Chairs: CAPT Rob Weyant, Department of Health and Human Services, Centers for Disease Control and Prevention Freeda Isaac, U.S. Department of Agriculture Rich Alt, DHS Deborah Barnes, HHS Kristine Beardsley, DOJ/FBI Diane Berry, DHS Meredith Bondurant, DoD Scott Curthoys, ODNI Dennis Dixon, HHS/NIH Peter Emanuel, EOP/OSTP Michael Estep, DoD Dominic Frasca, HHS Steve Geary, DOS Alan Giusti, DOJ/FBI Michael Glass, ODNI Eric Gormsen, DOJ Steve Greenbaum, DHS Melissa Hefferin, DHS James Holt, HHS/CDC

	Franca Jones, DoD Joanne Jones-Meehan, DHS Laura Kelley, DOJ/FBI Larry Kerr, ODNI Laura Kwinn, HHS Theresa Lawrence, HHS Dina Matz-Siegel, DOE Stephen Morse, HHS/CDC Nick Paquette, DOJ/FBI Tracy Parker, DHS Brandt Pasco, DHS Segaran Pillai, DHS Milad Pooran, HHS Erik Prentice, ODNI Christopher Rowe, DHS Serina Vandegrift, DOJ/FBI Stephen Walz, DoD Deborah Wilson, HHS/NIH Kate Wirth, DHS Edward You, DOJ/FBI **Trial Stratification of Select Agent List** Charles Divan, USDA Dennis Dixon, HHS/NIH Steve Geary, DOS Freeda Isaac, USDA Laura Kelley, DOJ/FBI Greg Mayr, DHS Stephen Morse, HHS/CDC Segaran Pillai, DHS Pat Worsham, DoD Ed You, DOJ/FBI
Oversight and Inspections	Chairs: CAPT Rob Weyant, Department of Health and Human Services, Centers for Disease Control and Prevention Charles Divan, U.S. Department of Agriculture Deborah Barnes, HHS David Bauer, HHS Diane Berry, DHS Todd Blose, DoD Michele Burgess, EPA Peter Emanuel, EOP/OSTP Dominic Frasca, HHS

	Steve Greenbaum, DHS Melissa Hefferin, DHS James Holt, HHS/CDC Franca Jones, DoD Joanne Jones-Meehan, DHS Laura Kwinn, HHS Theresa Lawrence, HHS John Olav Johnsen, DOE Tracy Parker, DHS Brandt Pasco, DHS Diane Rodi, DOE Martin Sanders, HHS Kate Wirth, DHS
Personnel Security and Reliability	Chairs: CAPT Kenneth Cole, Department of Defense Pamela Monroe, Department of Defense Lori Bane. HHS Deborah Barnes, HHS Kristine Beardsley, DOJ/FBI Diane Berry, DHS Matthew Bettridge, DHS Robert Butera, DOS Scott Curthoys, ODNI Carl Darby, ODNI Jackie Edwards, HHS/CDC Peter Emanuel, EOP/OSTP Michael Firko, USDA Dominic Frasca, HHS Alan Giusti, DOJ/FBI Michael Glass, ODNI Eric Gormsen, DOJ Steve Greenbaum, DHS Mary Groesch, HHS/NIH Wendy Hall, DHS Melissa Hefferin, DHS James Holt, HHS/CDC Stacey Jefferson, DoD Franca Jones, DoD Joanne Jones, HHS/CDC Joanne Jones-Meehan, DHS Larry Kerr, ODNI Joseph Kozlovac, USDA Laura Kwinn, HHS Theresa Lawrence, HHS

	Ron Maples, HHS/OSSI Dina Matz-Siegel, DOE Janet Nicholson, HHS Tracy Parker, DHS Brandt Pasco, DHS Amy Patterson, HHS Dana Perkins, HHS Scott Petrowski, DoD William Porter, HHS/CDC Lita Proctor, NSF Dustin Razsi, DHS Donna Rivera, DoD Diane Rodi, DOE Jane Silverthorne, NSF Serina Vandegrift, DOJ/FBI Kate Wirth, DHS Edward You, DOJ/FBI
Physical Security	Chairs: Pamela Monroe, Department of Defense Eric Puype, Department of Homeland Security Deborah Barnes, HHS David Bauer, HHS Kristine Beardsley, DOJ/FBI Diane Berry, DHS Nancy Boyd, HHS Lisa Brown, DoD Bill Cullen, HHS Steve Curren, HHS Peter Emanuel, EOP/OSTP Dominic Frasca, HHS Eric Gard, DOE Alan Giusti, DOJ/FBI Eric Gormsen, DOJ Steve Greenbaum, DHS Eric Hammett, DoD Melissa Hefferin, DHS James Holt, HHS/CDC Franca Jones, DoD Joanne Jones-Meehan, DHS Phil Joyner, HHS/CDC Laura Kwinn, HHS Theresa Lawrence, HHS Ronald Martin, HHS Brian Maxwell, DHS

	Janet Nicholson, HHS Jim Palmieri, DHS Tracy Parker, DHS Brandt Pasco, DHS Dick Patrick, DoD Nick Paquette, DOJ/FBI Scott Petrowski, DoD William Porter, HHS/CDC Lita Proctor, NSF Robert Rice, USDA Donna Rivera, DoD Martin Sanders, HHS Jane Silverthorne, NSF Austin Smith, DHS Mike Taylor, DHS Serina Vandegrift, DOJ/FBI Harry Weirath, DHS Kate Wirth, DHS Edward You, DOJ/FBI
Transportation	<u>Chair: Robert Richard, Department of Transportation</u> Jack Aherne, DHS William Arrington, DHS Lori Bane, HHS/CDC Deborah Barnes, HHS Diane Berry, DHS Chris Bonanti, DOT/FAA Rod Callewaert, DoD George Cushmac, DOT Eileen Edmonson, DOT Peter Emanuel, EOP/OSTP Dominic Frasca, HHS Wendy Hall, DHS John Heneghan, DOT Charles Hochman, DOT James Holt, HHS/CDC Maria Howard, DOT Bud Hunt, DHS/TSA Franca Jones, DoD Laura Kwinn, HHS Theresa Lawrence, HHS Ed Mazzullo, DOT Janet Nicholson, HHS/CDC Tracy Parker, DHS

	Robert Rice, USDA Frank Roberto, DOE Diane Rodi, DOE Daniel Schultz, DHS James Simmons, DOT William Stevens, DOT John Vansteenburg, DOT Michael Wilhelm, USPS

Appendix 1-C: Current Select Agent List

In determining whether to include a biological agent or toxin on the select agent list, the Bioterrorism Act requires the HHS and USDA to consider the following:

- the effect on human health (laboratory worker and public health) after exposure to the agent or toxin;
- the effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products;
- the infectivity and means of transmission of the agent or toxin to humans;
- the pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin are transferred to humans, animals or plants;
- the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin;
- any other criteria that the HHS Secretary deems appropriate to protect public health and safety;
- any other criteria that the Secretary of Agriculture deems appropriate to protect animal or plant health and safety of animal or plant products.

The Bioterrorism Act also requires the HHS and USDA to perform a biennial review of the select agent list. In conducting their review, the HHS and USDA consider the following criteria:

- Organism-specific factors
    - Degree of pathogenicity
    - Communicability
    - Ease of dissemination
    - Route of exposure
    - Environmental stability
- Production factors
    - Ease of production
    - Ability to genetically manipulate or alter
- Host factors
    - Long term effects
    - Acute morbidity
    - Acute mortality
    - Available treatment
    - Status of immunity
    - Vulnerable populations
    - Burden or impact on the health care system

The most recent HHS and USDA review of the select agent lists is below. It was completed in 2008 with publication of revised lists in the Federal Register on October 16, 2008.

HHS SELECT AGENTS AND TOXINS

Bacteria

Botulinum neurotoxin producing species of *Clostridium*
Coccidioides posadasii/Coccidioides immitis
Coxiella burnetii
Francisella tularensis
Rickettsia prowazekii
Rickettsia rickettsii
Yersinia pestis

Toxins

Abrin
Botulinum neurotoxins
Clostridium perfringens epsilon toxin
Conotoxins
Diacetoxyscirpenol
Ricin
Saxitoxin
Shiga-like ribosome inactivating proteins
Shigatoxin
Staphylococcal enterotoxins
T-2 toxin
Tetrodotoxin

Viruses

Cercopithecine herpesvirus 1 (Herpes B virus)
Crimean-Congo haemorrhagic fever virus
Eastern Equine Encephalitis virus
Ebola virus
Lassa fever virus
Marburg virus
Monkeypox virus
Reconstructed replication competent forms of the 1918
South American Haemorrhagic Fever viruses
- Flexal
- Guanarito
- Junin
- Machupo
- Sabia

Tick-borne encephalitis complex (flavi) viruses
- Central European Tick-borne encephalitis
- Far Eastern Tick-borne encephalitis
- Kyasanur Forest disease
- Omsk Hemorrhagic Fever
- Russian Spring and Summer encephalitis

Variola major virus (Smallpox virus)
Variola minor virus (Alastrim)

OVERLAP SELECT AGENTS AND TOXINS

Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly *Pseudomonas mallei*)
Burkholderia pseudomallei (formerly *Pseudomonas pseudomallei*)
Bacillus anthracis
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan Equine Encephalitis virus

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Ehrlichia ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Menangle virus
Mycoplasma capricolum subspecies *capripneumoniae* (contagious caprine pleuropneumonia)
Mycoplasma mycoides subspecies *mycoides* small colony (*Mmm*SC) (contagious bovine pleuropneumonia)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3
Virulent Newcastle disease

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXIN

Peronosclerospora phillippinensis (Peronosclerospora sacchari)
*Phoma glycinicola (*formerly *Pyrenochaeta glycines)*
Ralstonia solanacearum race 3, biovar 2
Synchytrium endobioticum
Rathayibacter toxicus
Sclerophthora rayssiae var zeae
Xanthomonas oryzae
*Xylella fastidiosa (*citrus variegated chlorosis strain)

Appendix 1-D: Restricted and Potential Prohibited Categories

A restricted person under the USA PATRIOT Act (18 U.S.C. 175b):

- is under indictment for a crime punishable by imprisonment for a term exceeding one year
- has been convicted in any court of a crime punishable by imprisonment for a term exceeding one year
- is a fugitive from justice
- is an unlawful user of any controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802))
- is an alien illegally or unlawfully in the United States
- has been adjudicated as a mental defective or has been committed to any mental institution
- is an alien (other than an alien lawfully admitted for permanent residence) who is a national of a country that has repeatedly provided support for acts of international terrorism
- has been discharged from the Armed Services of the United States under dishonorable conditions.

Under the Bioterrorism Response Act, individuals reasonably suspected by any Federal law enforcement agency or intelligence agency of any of the following categories may have their access to BSAT limited or denied.

- Committing a crime specified in 18 U.S.C. 2332b(g)(5)
- Having a knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence
- Being an agent of a foreign power (as defined in 50 USC 1801)

Appendix 1-E: Requirements for Individuals and Entities Registered with the Select Agent Program

All individuals and entities registered to possess BSAT must develop and implement a written security plan sufficient to safeguard BSAT from unauthorized access, theft, or loss. Individuals and entities also must develop and implement a written biosafety plan to safeguard against the release of BSAT. The biosafety plan must be commensurate with the risk posed by an agent or toxin, given its intended use, and describe the biosafety and containment procedures. The SAR identify the BMBL, the NIH Guidelines, and OSHA regulations found in 29 CFR parts 1910.1200 and 1910.1450 as providing guidance for the establishment of the safety provisions. Any individual or entity that intends to conduct restricted experiments, as defined in the SAR, is required to receive approval from either the HHS or USDA Select Agent Program prior to conducting such experiments. All individuals and entities that possess BSAT also are required to:

- Develop and implement a written incident-response plan that must include response procedures for any hazards associated with the BSAT.
- Provide safety and security training for all individuals who work with or visit areas containing select agents and toxins that addresses the needs of the individual, the type of work the person will do, and the risks posed by the select agents or toxins.
- Develop measures to ensure that select agents or toxins are transferred only to entities registered to possess the agent (transfers must be approved in advance by either the HHS or USDA select agent program).
- Notify one of the select agent programs upon discovery of a theft, loss, or release of a BSAT.
- Maintain records associated with BSAT possession for three years (e.g., inventory, access records, safety plans, transfer records, and training records).

All individuals or entities requesting registration under the SAR are required to be inspected prior to issuance of a certificate of registration to verify that the facility operates in accordance with the information that has been submitted in their application and that the individual or entity has procedures and processes in place necessary to ensure compliance with the SAR. The SAR also permit unannounced inspections (7 C.F.R. § 331.18(a), 9 .C.F.R. § 121.18(a), 42 C.F.R. § 73.18(a)).

Every individual and entity is also inspected during the certificate of registration renewal process, in addition to an inspection during the application process.. Inspections may also be conducted when:

1) amendments are requested with regard to an individual’s or entity’s registration information;
2) an individual or entity seeks to register a new building or laboratory;
3) an individual or entity seeks to work with a higher-risk agent or toxin;
4) a change is made in security infrastructure, policy, or procedures;
5) a theft, loss, or release incident occurs and/or;
6) a violation of the SAR occurs.

Since the publication of the select agent interim final rule in 2003 (followed by the final rule in 2005), the CDC Division of Select Agents and Toxins has conducted 840 select agent inspections and APHIS has conducted 324 select agent inspections, often in collaboration with each other and other Federal agencies.

The CDC and APHIS have released guidance to regulated individuals and entities to support compliance with the requirements of the SAR, including guidance on complying with the security requirements and the theft, loss, or release reporting requirements of the SAR. The CDC and APHIS have also released inspection checklists to assist ROs in assessing their entities' adherence to incident response requirements, record-keeping requirements, security, safety, and training. There are also two training videos available that describe the process of facility inspections. The HHS and USDA Select Agent Program also provided a comprehensive, interactive course at the 2007 American Biological Safety Association (ABSA) meeting that described the knowledge and tools necessary to develop biosafety plans, security plans, and drills and exercises to test incident response plans.

Appendix 1-F: Biosecurity Studies and Reviews

National Science Advisory Board for Biosecurity (NSABB)

In response to heightened security concerns surrounding the potential misuse of dangerous pathogens within research settings, the NSABB was charged with recommending to the United States Government strategies for enhancing personnel reliability among individuals with access to BSAT. Their final report titled, "Enhancing Personnel Reliability among Individuals with Access to Select Agents,"[1] was released in May 2009. The NSABB found that 1) the Select Agent Program has been significantly strengthened since 2001, to include measures that address personnel reliability; 2) local institutions already effectively screen individuals requiring access to BSAT, as evidenced by the extremely low rate of unfavorable security risk assessments; 3) there is very little evidence that supports the effectiveness and predictive value of many additional assessments that would be conducted under PRPs with respect to the assessments' ability to detect the traits or individuals who pose an insider threat; and 4) engaged institutional leadership has been cited often as the most effective way to mitigate the risk of an insider threat. Based on these findings, the NSABB recommended that a national PRP is not necessary but that the current SRA process could be enhanced, specifically as it relates to screening of foreign nationals. The NSABB also recommended that the culture of responsibility and accountability be enhanced at institutions that conduct BSAT research by promoting outreach and education about biosecurity, the insider threat, and dual use research of concern, among other strategies. Finally, the NSABB recommended that the list of select agents be reduced or stratified because the risk they pose to public, animal, and plant health and safety varies significantly depending on the agent, and yet the same stringent controls apply across the board.

Inter-Service Council for Biosecurity and Biosafety (ICBB)[2]

In October 2008, in response to the allegation that an Army researcher was the likely perpetrator of the "anthrax" attacks of 2001, the Army began a series of reviews at its laboratories that conduct research on BSAT. This review expanded to include Navy and Air Force laboratories and on October 9, 2008, the ICBB was officially chartered.

The intent of the ICBB was to identify, define, and focus 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 BSAT laboratory infrastructure. The ICBB found that all DoD laboratories were in compliance with Federal, DoD, and Service regulations. The ICBB recommended revised guidance for government and commercial air and ground shipment of BSAT. All Services agreed to further strengthen internal security by upgrading the level of background check requirements, conducting random supervisor reviews, random reviews of closed circuit television (CCTV),

[1] http://oba.od.nih.gov/biosecurity/meetings/200905T/NSABB%20Final%20Report%20on%20PR%205-29-09.pdf
[2] http://www.fredericknewspost.com/media/pdfs/bsr001.pdf

archiving CCTV tapes, increasing supervisory review and control of after-hours access, and implementing a justification and approval process for hiring foreign nationals into biological PRP positions. Improved control and accountability of short and long-term working stocks was recommended. The ICBB also requested an external review of the DoD biological safety and security programs by the DSB.

The DSB[3] established a task force to examine the status of biological safety, security, and personnel reliability programs of the Army, Navy, and Air Force laboratories, compared these laboratories with similar operations in academia, industry, and the Federal Government, and made recommendations for improvements in the DoD program. The task force found that the safety and security programs in the DoD facilities they assessed were as good as or better than those in comparably sized facilities in other government, industry, and academic sectors and that the DoD regulations exceed those imposed by the Select Agent Program. Because it is unclear whether the computer systems used to control access to BSAT laboratories are secure, the task force recommended that a red team be used to determine if vulnerabilities exist. The task force recommended increased monitoring of video cameras in laboratories but discouraged use of the "two-person rule." Continued use of the PRP was encouraged with the added development of consistent suitability attributes; training for certifying officials, competent medical authorities, and management; and a database (in cooperation with CDC/APHIS) of persons permanently removed from the PRP. The task force also recommended that the "lost in the crowd" approach for BSAT shipments continue and better coordination of inspections.

[3] http://www.acq.osd.mil/dsb/reports/2009-05-Bio_Safety.pdf

Appendix 1-G: Working Group (WG) on Strengthening the Biosecurity of the United States: Meetings and Briefings

The Full WG convened several meetings (February 18, March 4 and 18, April 8 and 22, May 6 and May 27, June 10 and 17, 2009). The meetings included presentations from several individuals who shared their individual perspectives with the WG on a variety of topics.

Ronald Atlas, Ph.D., Professor of Biology and Co-director of the Center for the Deterrence of Biowarfare and Bioterrorism, University of Louisville and Co-chair, American Society for Microbiology Public and Scientific Affairs Board Committee on Biodefense

- *Assuring Laboratory Biosecurity*

Robert Butera, Senior Bioengineer and Jefferson Science Fellow, Chemical/Biological Weapons Threat Reduction, Bureau of International Security and Nonproliferation, U.S. Department of State

- *Biological Select Agents and Toxins Regulations: Global Perspectives*

Kenneth A. Cole, Ph.D., CAPT, MSC, USN, Medical Director, Office of the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization Programs, Department of Defense

- *Overview of Department of Defense Biological Select Summary of Department of Defense Studies*

Colleen Crowley, Executive Program Director of Policy, Research, and Agency Support Program, Federal Investigative Services Division, U.S. Office of Personnel Management

- *Position Designation Tool*

Charles Drennen, Suitability Specialist, Suitability Adjudications Branch, Federal Investigative Services Division, U.S. Office of Personnel Management

- *Position Designation Tool*

Robert Ellis, Ph.D., CBSP, President, American Biological Safety Association

- *Biosafety Training, Risk Assessment, and Accreditation*

Peter Emanuel, Ph.D., Policy Analyst, Office of Science Technology and Policy, Executive Office of the President

- *An Analysis of Federal Biosecurity Efforts*

William Flynn, Director, Protective Security Coordination Division, Office of Infrastructure Protection, Department of Homeland Security

- *Infrastructure Protection Assessments of Biosafety Level Laboratories*

David Franz, Ph.D., Vice President and Chief Biological Scientist, Midwest Research Institute

- *International Trends: Biosafety, Biosecurity, and Personnel Reliability*

Anthony Gemmellaro, Director of Biological Safety, Boston Public Health Commission
- *Boston's Select Agent Regulations*

Michael Glass, Ph. D., Chief, Technical Counterintelligence Section, Office of the National Counterintelligence Executive, Office of the Director of National Intelligence
- *The Insider Threat*

Mary Groesch, Ph.D., Senior Advisor for Science Policy, Office of Biotechnology Activities, National Institutes of Health
- *Personnel Reliability: Update on National Science Advisory Board for Biosecurity Draft Report and Public Consultation*

Jean Guillemin, Senior Advisor, Massachusetts Institute of Technology Security Studies Program, Center for International Studies
- *France's Biosecurity Efforts*

Rosemary Humes, MS, MT (ASCP)SM, Senior Advisor, Scientific Affairs, Association of Public Health Laboratories
- *Public Health Laboratory Perspective*

Laura A. Kwinn, Ph.D., Science Policy Analyst (Contractor), Office of the Assistant Secretary for Preparedness and Response, Office of Medicine, Science, and Public Health, Department of Health and Human Services
- *Overview of Public Comments*

Theresa Lawrence, Ph.D., Senior Science Advisor, Office of Medicine, Science and Public Health, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- *Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight*

Henri Korn, M.D., Ph.D., Member, French Academy of Sciences and Professor, Department of Neurosciences, Institut Pasteur
- *France's Biosecurity Efforts*

Samson Lee, Ph.D., Project Leader, Sanofi Pasteur, Swiftwater, Pennsylvania
- *An Industry Perspective on Biosecurity and Personnel Reliability*

Carol D. Linden, Ph.D., Principal Deputy Director, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services
- *Executive Order: Strengthening Laboratory Biosecurity in the United States*

Larry Lynn, Private Consultant and Chairman, Defense Science Board Task Force on Biological Safety and Security Program for Research Involving Biological Select Agents and Toxins

- *Defense Science Board Task Force on the Department of Defense Biological Safety and Security Program for Research Involving Biological Select Agents and Toxins*

Teresa Nankivell, Department of Defense Business Transformation Agency

- *Joint Security and Suitability Reform Team Initiatives*

Eric Puype, Protective Security Advisor, Idaho District, Office of Infrastructure Protection, Department of Homeland Security

- *Infrastructure Protection Assessments of Biosafety Level Laboratories*

Robert L. Rice, Security Program Officer, Agriculture Select Agent Program, U.S. Department of Agriculture

- *Biological Select Agents and Toxins and What's Needed to Physically Secure Them: A Security Perspective*

Janet Shoemaker, Director, American Society for Microbiology Public and Scientific Affairs Board

- *Assuring Laboratory Biosecurity*

Tom Warf, Ph.D., Infrastructure Program Manager, Biomedical Advanced Research and Development Authority, Office of the Assistant Secretary for Preparedness and Response, Department of Health and Human Services

- *An Industry Perspective on Biosecurity and Personnel Reliability*

CAPT Robbin S. Weyant, Ph.D., Director, Division of Select Agents and Toxins, Coordinating Office for Terrorism Preparedness and Emergency Response, Centers for Disease Control and Prevention

- *The CDC Select Agent Program*

Appendix 1-H: Working Group (WG) on Strengthening the Biosecurity of the United States: Site Visits

To address the EO 13486 charge to review practices in facilities that handle BSAT, the WG conducted the following laboratory site visits to gain insight into laboratory practices focused on biosecurity and personnel reliability through observation and discussion:

District of Columbia Department of Health Public Health Laboratory, Washington, DC

Environmental Health and Safety, University of Maryland, Baltimore

Integrated Research Facility, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Frederick, Maryland

National Biodefense Analysis and Countermeasures Center (NBACC), Frederick, Maryland

Southern Research Institute, Frederick, Maryland

National Plant Germplasm and Biotechnology Lab, Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, Beltsville, Maryland

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), Frederick, Maryland

Appendix 1-I: Working Group (WG) on Strengthening the Biosecurity of the United States: Public Consultation Efforts

In order to gather the opinions of the community who would be most affected by changes to the SAR, the WG convened a public consultation meeting to bring together the WG, the scientific community, professional organizations, and other stakeholders to discuss several areas highlighted by the WG that required further consideration. The public meeting was held at the Hyatt Regency Bethesda on May 13-14, 2009. The public consultation meeting allowed the WG to obtain individual input from members of the public and scientific community on important aspects of biosecurity.

Approximately 150 individuals attended the meeting over the two days, representing academic, industry, and government laboratories, professional societies, policy think tanks, and policymakers from the Federal government. The meeting was organized around a series of panels focused on questions related to specific topics for which the U.S. Government solicited specific comment. Topics included the SAR, oversight and inspections, physical security, transportation, personnel security and reliability, and culture of responsibility. Appendix 1-I-1 includes the full agenda of the public meeting which documents panelists and the specific questions posed to guide discussion.

Following the public consultation meeting, efforts were made to offer stakeholders the opportunity to provide written comments to the WG including an email solicitation, notice on the Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response website for the public consultation registration, and flyers distributed at the 2009 General Meeting of the American Society for Microbiology in Philadelphia, PA. Comments from 20 institutions and individuals were received and discussed by the WG and incorporated, as appropriate, into recommendations.

Comments by Topic Area

The discussions at the public meeting and subsequent written comments highlighted several common themes. The stakeholder community suggested more transparency and opportunity for significant input into the policymaking process. The implementation of any further biosecurity policies or guidelines should be evidence-based. Overall, the community asked the WG to consider cost-effectiveness and to be aware that certain requirements, such as more stringent requirements for couriers currently involved in the transport of BSAT, could render their services unprofitable and thus prevent their ability to continue to provide services.

Select Agent Regulations

The community expressed satisfaction with the recent clarifications by the CDC/APHIS regarding requirements for paperwork submissions, inventory of stock vials and tissue samples, and the increased availability of Select Agent Program staff to respond to inquiries. Those who provided comments supported a decrease in the number of agents and toxins on the BSAT list or stratification of the list to allow for any more strict security requirements to pertain to only to the

pathogens of highest concern. Those who did not support stratification questioned the utility of varying the security requirements for BSAT and indicated that the management of different requirements for agents that posed different layers of risk would be more burdensome. The WG agreed with these sentiments and recommended the reduction and/or stratification of the current list of BSAT.

The community also expressed concern regarding the transparency of the policy-making process regarding select agents, safety and security. For example, there were several comments about the lack of stakeholder input in the biennial reassessment of the list of BSAT or the revision of the BMBL. To this end, the WG supported the inclusion of subject matter experts from both the Federal government and non-Federal sectors in the group tasked to assessment the risks of BSAT currently on the list for possible stratification.

Although licensure of individuals working with BSAT was discussed at the public meeting, there was little support from the stakeholder community for such a program. The WG agreed with the input received and chose not to include licensing activities as part of its recommendations.

Inventory, Inspections and Oversight

Several comments were made regarding Select Agent Program guidance regarding record-keeping of BSAT inventory at registered entities. Several members of the community highlighted inventory management as the most onerous responsibility of an entity and a few individuals cited it as the reason they have considered leaving their select agent research program.

The regulated community had many comments regarding the current regimen of inspections from the Select Agent Program and other Federal, State, and local agencies. Due to the indirect costs of lost personnel time and delay in scientific productivity, the scientific community would benefit from harmonization and coordination of inspections of their facilities. In addition, due to the large number of agency inspections at some facilities, guidance was requested on how to resolve conflicts between inspectors and recommendations from various inspection teams. The community supported more careful selection and training of inspectors from all agencies and recommended policy regarding safeguarding of proprietary information, or information of security concern be better protected during the inspections process.

In response to both of these concerns, the WG recommended the designation of a Federal entity to coordinate biosecurity oversight activities to facilitate and promote the coordination of information sharing both among different agencies of the Federal government and between the Federal government and the regulated community.

Physical Security

Overall, comments from the regulated community regarding physical security and building requirements for select agent facilities were ambivalent. The WG specifically asked if more prescriptive standards should be produced to assist entities in compliance. Comments were mixed in terms of agreement or disagreement, but had the same basic conclusion that

prescriptive minimum standards would be helpful as long as they allow for flexibility between entities. The WG agreed and recommended that minimum prescriptive security standards based on the risk at the lowest level, allowing for enhancements as risk increases.

Transportation of Select Agents

Most stakeholder comments regarding transportation requirements in place were positive. Others had misconceptions regarding a perceived lack of security once select agents were given to couriers for delivery. The WG put forth a robust effort to gain clarity on the security procedures for both ground and air transport which is included in Chapter 5 of the WG report. In addition, the WG recommended the establishment of better communication plans to ensure effective communication between entities, couriers, DOT, and CDC/APHIS.

Personnel security and reliability

The majority of discussion and written comments surrounded the implementation of personnel reliability programs (PRPs). Several stakeholders pointed out the burden posed by current PRPs such as those of the DoD and DOE. One private lab estimated the cost of elevating their security measures to that currently required by the DoD at over $1 million. Many stakeholders recommended that the WG support the finding of the NSABB that a national PRP was not necessary at this time due to a lack of evidence to support implementation of mental health screens and risk of negatively impacting scientific progress without sufficient protection against individuals with nefarious intent.

The WG agreed and performed a very careful analysis of how the Security Risk Assessment process for individuals could be enhanced for both domestic applicants and for foreign nationals. The WG chose not to recommend implementation of a nationwide PRP, but did choose to support enhancement of certain elements of a PRP such as access for all individuals working with BSAT to have access to occupational health professionals and that entities clarify their procedures for temporary or permanent removal from access due to physical, occupational, or mental health concerns or other issues potentially impacting fitness for duty with respect to BSAT possession and use.

In conclusion, the WG welcomed the feedback they received at both the public consultation meeting and in written comments. Comments were discussed by the WG and recommendations were considered with these comments in mind. The WG made every attempt to propose evidence-based recommendations, and when there was a consensus regarding a potential gap in security, but not a consensus on the best recommendation to solve that issue, the WG proposed options to be considered during future policy discussions.

Appendix 1-I-1: Working Group (WG) on Strengthening the Biosecurity of the United States: Public Consultation Meeting Agenda

Working Group on Strengthening the Biosecurity of the United States
Public Consultation Meeting

Hyatt Regency- Bethesda
7400 Wisconsin Ave
One Bethesda Metro Center
Bethesda, MD 20814
May 13-14, 2009

Agenda

Wednesday – May 13

8:30 a.m. **Welcome and Opening Remarks**
Jean D. Reed, Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization

8:45 a.m. **Introduction to EO 13486 and the Working Group on Strengthening the Biosecurity of the United States**
Carol D. Linden, Ph.D., Principal Deputy Director, Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

9:15 a.m. **Evolution of Biosecurity**
Jennifer Gaudioso, Ph.D., Technical Staff, International Biological Threat Reduction Program Sandia National Laboratories

10:00 a.m. *Break*

10:15 a.m. **Panel I –Select Agent Regulations**

Moderator: *Freeda E. Isaac, D.V.M. Director, Live Animals, Organisms and Vectors, Select Agents Technical Trade Services Team, National Center for Import/Export, Animal and Plant Health Inspection Service, U.S. Department of Agriculture*

Background:
The possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety, or animal and plant health and animal and plant products are regulated by HHS and USDA under the *Select Agent Regulations*. In determining whether to include an agent on the Select Agent List, the *Bioterrorism Act* requires that HHS and USDA consider the effect on human health after exposure to the agent or toxin; the effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products; the infectivity and means of

transmission of the agent or toxin to humans; the pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants; the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; any other criteria that the Secretary of HHS deems appropriate to protect public health and safety; and any other criteria that the Secretary of Agriculture deems appropriate to protect animal or plant health or animal or plant products.

The Working Group is seeking individual input on the following questions:

Discussion questions:

- Has the purpose and content of the Select Agent list supported enhancement of biosecurity?
- Are the current select agent regulations sufficiently comprehensive and effective?
- Should the current select agent regulations move away from performance standards to more specific prescriptive standards?
- Do you see any value in a stratification of select agents by risk? If so, which aspects of the current select agent regulations would be most amenable to a stratified approach? Do you currently utilize a stratified approach with the select agents in your facility?
- Do you have access to all select agent registered space in your facility? Do you believe that you have sufficient authority within your organization to effectively implement the select agent regulations?
- Do you find the Security Risk Assessment system currently in use by the federal select agent Program to be effective? If so, why; and if not, why not?
- What type of inventory system do you have in place to maintain for your select agent materials in long term storage? Do you use a centralized database, or separate databases for each principal investigator? Are you satisfied with the current guidance from the CDC/APHIS Select Agent Programs on long term storage? If not, how might this guidance be improved?

Panelists

Stephen A. Morse, Ph.D., Associate Director of Science, Division of Bioterrorism Preparedness and Response and Director of the Environmental Microbiology Program, U.S. Centers for Disease Control and Prevention

Ronald M. Atlas, Ph.D., Professor of Biology and Co-director of the Center for the Deterrence of Biowarfare and Bioterrorism, University of Louisville

Gigi Kwik Gronvall, Ph.D., Senior Associate, Center for Biosecurity of UPMC, Assistant Professor of Medicine, University of Pittsburgh

Laura Kahn, M.D., M.P.H., M.P.P., Research Staff, Program on Science and Global Security, Princeton University

Discussion

12:00 p.m. *Lunch*

1:00 p.m. **Panel II – Physical/Facility Security at Select Agent Program Entities**

Moderator: *Pamela Monroe, Office of the Under Secretary of Defense for Intelligence, Office of Security, U.S. Department of Defense*

Background: The *Select Agent Regulations* require that all entities that possess, use and/or transfer select agents and toxins develop *site specific written security plans* that describe how select agents and toxins in their possession are to be safeguarded against unauthorized access, theft, loss, or release. The *Bioterrorism Act* and the *Agricultural Bioterrorism Act* require respectively, the Secretaries of HHS and USDA to by regulation "[E]stablish and enforce safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or for any other criminal purpose." *[42 U.S.C. §262a(b)(2), 7U.S.C. §8401(b)(2)]*

The Task Force is seeking individual input on the following questions:

Discussion questions:

- The *Select Agent Regulations* provide a broad requirement that allows physical security requirements to be interpreted by individual or entity. Should the Federal government develop baseline prescriptive physical security requirements (e.g., minimum criteria for structure, facility entrance, interior, security systems, security operations, and administration) based on categorized risk or facility category?
- The *Select Agent Regulations* require development and implementation of a written security plan and require security plans to be designed according to site-specific risk assessments. Are there additional tools or guidance documents that would be helpful to you?
- The *Select Agent Regulations* require drills and exercises to be conducted at least annually to evaluate the written security plan. Is this adequate?

Panelists

William T. Porter, J.D., Director, Office of Security and Emergency Preparedness, U.S. Centers for Disease Control and Prevention

Robert L. Rice, Security Program Officer, Agriculture Select Agent Program, Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture

Austin Smith, Executive Director, Interagency Security Committee, U.S. Department of Homeland Security

Thomas Williams, Director of Operations and Security, Walter Reed Army Institute of Research, U.S. Department of Defense

Discussion

3:00 p.m. *Break*

3:15 p.m. **Panel III – Oversight and Inspection of Select Agent Facilities**

Moderator: *Charles L. Divan, PhD, Senior Agricultural Microbiologist, Agriculture Select Agent Program, U.S. Department of Agriculture*

Background: All entities possessing select agents or toxins are subject to inspection, prior to the issuance of a Certificate of Registration to (1) verify that the facility is accurately represented by the information submitted by the entity to the select agent program, and (2) has in place the procedures and processes necessary to ensure compliance with the *Select Agent Regulations.* In addition to an initial inspection during the application process, every entity may also be inspected during the Certificate of Registration renewal process. Additionally, inspections may be conducted when: 1) modifications are made to the entity's application; 2) a new building or laboratory is added to the registered areas; 3) a higher-risk agent/toxin is added; 4) a change is made in security infrastructure or policy and procedures; 5) a theft, loss, or release incident occurs; and/or 6) a regulatory violation is reported. The *Select Agent Regulations* also permit unannounced inspections (42 C.F.R. § 73.18(a), 9 C.F.R. § 121.18(a), 7 C.F.R. § 331.18(a)). Entities possessing select agents or toxins may experience additional inspections by third parties outside of the select agent program.

The Working Group is seeking individual input on the following questions:

Discussion questions:

- Is the current inspection regimen by the Select Agent Program effective?
- Are inspection programs in need of improvement? If so, are there recommendations for improvement?
- Is there additional guidance that would be helpful to prepare for program reviews and facility inspections?
- How many other "third party" inspection groups have visited your facility, in addition to either the CDC or APHIS Select Agent programs?
- If you've had multiple inspections by various federal government agencies, do you have any thoughts on how these inspections could be better coordinated?
- Do you have recommendations for approaches to enhance institutional implementation, compliance, oversight and accountability?

Panelists

Todd Blose, Chief, Technical Inspections Division, Army Inspector General, U.S. Department of Defense

Michael Ehret, Regional Vice President and Director of Mid-Atlantic Operations, Midwest Research Institute

Richard Henkel, Ph.D., Chief of Policy and Compliance, Division of Select Agents and Toxins, Coordinating Office for Terrorism Preparedness and Emergency Response, U.S. Centers for Disease Control and Prevention

Bruce Whitney, Ph.D., Biological Safety Officer/ Responsible Official, Division of Research and Graduate Studies, Texas A&M University

Discussion

4:30 p.m. Public Comments

5:00 p.m Adjourn

Thursday – May 14

8:30 a.m. Welcome
Carol D. Linden, Ph.D., Principal Deputy Director, Biomedical Advanced Research and Development Authority (BARDA), Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services

8:45 a.m. **Panel IV – Transportation of Select Agents**

Moderator: *Bob Richard, Pipeline and Hazardous Materials Administration, U.S. Department of Transportation*

Background: Infectious substances and the materials known or suspected to contain them are regulated as Division 6.2 (infectious) hazardous materials by DOT, under the Pipeline and Hazardous Materials Administration (PHMSA) Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). The HMR requirements are patterned after those in international transport regulations and include safety and security requirements for the transportation of infectious substances including select agents. DHS's Transportation Security Administration (TSA) recently issued highway security action items that pertain to select agents. TSA will provide an overview of these new requirements. The panel will discuss current regulations that apply to the secure transportation of select agents, potential vulnerabilities, challenges and recommendations for enhancing security while balancing the potential impact on the carrier community.

The Working Group is seeking individual input on the following questions:

Discussion questions:
- Are there vulnerabilities that exist for select agents during transportation? If so, how can they be addressed?
- What challenges do carriers currently face and how might additional security requirements and controls impact their business decision to accept and transport select agents?
- Are the chain of custody requirements sufficient and how are lost or mis-directed shipments handled?
- Should packages containing select agents be packaged or labeled differently than other infectious agents?
- At what point should facilities be held responsible for package? For example, at time of receipt at entity (e.g., shipping area) or at laboratory?
- Are there additional tools and guidance that would be helpful related to the transportation of select agents?
- Should there be a registration program for carriers?

Panelists
Lori J. Bane, Compliance Officer, Division of Select Agents and Toxins, U.S. Centers for Disease Control and Prevention

Robert L. Rice, Security Program Officer, Agriculture Select Agent Program, Animal and Plant Health Inspection Service, U.S. Department of Agriculture

Bud Hunt, Chief of Threats, Vulnerabilities and Consequences Branch, Highway and Motor Carrier Programs Office, Office of Transportation Sector Network Management, Transportation Security Administration, U.S. Department of Homeland Security

David Littlejohn, Corporate Safety Advisor, FedEx Express

Patrick Oppenheimer, Senior Manager, Safety Programs, Safety Health and Fire Prevention, FedEx Express

Discussion

10:15 a.m. *Break*

10:30 a.m. **Panel V – Personnel Security/Reliability Programs**

Moderator: *CAPT Kenneth A. Cole, Ph.D., Medical Director, Office of the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense and Chemical Demilitarization Programs, U.S. Department of Defense*

Background: Security procedures at entities with select agents are intended to prevent the theft, loss, or release of an agent from the laboratory. Personnel with access to select agents must be reviewed by the FBI through a Security Risk Assessment (SRA), to ascertain whether they meet certain criteria which would preclude them from inclusion in the Select Agent Program. While the criteria for exclusion are very specific, they do not eliminate the risk posed by an "insider threat." Personnel reliability programs (PRP) are used in other fields, such as nuclear and chemical research programs, to ensure that individuals with access are trustworthy, reliable, and physically and mentally competent. Depending on the type of PRP implemented, components can be voluntarily applied at the local level or mandated nationally to include background checks, credit checks, medical and psychological investigations, random drug testing and polygraph tests. Such a program may require additional staff and resources at the institution to manage the process, and consideration must be given to the additional value and potential loss of scientific progress imposed by any program. While no PRP can completely mitigate the risk of the insider threat, certain steps may be taken to reduce the intentional misuse of biological materials and enhance public confidence in the biodefense research enterprise.

The Working Group is seeking individual input on the following questions:

Discussion questions:

- What type of background investigations, if any, do you do that go beyond those required for compliance with the Select Agent regulations?
- Do you have a Personnel Reliability Program (PRP)? If so, what elements does it contain and who runs it? Do you have a Certifying Official, or equivalent, for your PRP?
- How effective has your PRP been in preventing potential thefts, losses, or release of select agents?

- Do you utilize the "Two person rule"? Do you believe it is of value to your safety or security plans?
- Should extant frameworks for personnel reliability be applied to all select agent research?
- What is the optimal framework for ensuring personnel reliability in a manner that balances the needs for both biosecurity and rapid progress in the life sciences?
- What are the features of an optimal PRP?
- What are the costs of implementing a PRP?
- What are the risks and benefits associated PRP?
- What metrics should be used for evaluating PRPs?

Panelists

Jean L. Patterson, Ph.D., Chair, Department of Virology & Immunology, Southwest Foundation for Biomedical Research

Gregory Saathoff, M.D., Executive Director, Critical Incident Analysis Group, Associate Professor of Research in Psychiatry and Neurobehavioral Sciences, and Associate Professor of Emergency Medicine, University of Virginia

John Humpton, Combating WMD and Proliferation Policy Division G-3/5/7, Headquarters, Department of the Army, U.S. Department of Defense

Murray Cohen, Ph.D., M.P.H., President and Chairman, Frontline Healthcare Workers® Safety Foundation, Ltd.

Paige Carness, M.S., Regulatory Specialist, Galveston National Laboratory, University of Texas Medical Branch.

Discussion

12:00 p.m. *Lunch*

1:00 p.m. **Panel VI – Culture of Security and Responsibility and Biosecurity Training Programs**

Moderator: *Peter B. Jahrling, Ph.D., Director, Office of the Chief Scientist, Integrated Research Facility, National Institute of Allergy and Infectious Diseases, National Institutes of Health*

Background: Any biosecurity program that is implemented must be done in such a way that it does not unduly burden the researcher or prevent quality research from progressing. For this reason, we need to work within a culture of responsibility and security whereby researchers understand why they're being asked to increase security precautions and awareness. Important components of this discussion include thoughts about implementations of different procedures discussed here over the last two days, the sharing of best practices among institutions, and training in methods related to high and maximum containment level work and security policies and practices.

The Working Groups seeking individual input on the following questions:

Discussion questions:

- What resources would institutions need to implement some of the activities discussed at this meeting?
- How do you currently share best practices regarding safety and security among institutions?
- Do you feel you have enough technical and financial support from Federal agencies to successfully follow Select Agent regulations and any future guidelines set forth on security?
- How many hours of training do employees have to undergo before being allowed access to select agents and toxins? What resources are used in the design of the training module?
- Should minimum competency and biosecurity training standards be developed for all personnel who work in, oversee, or manage high and maximum containment research laboratories? If so, who should develop these standards?
- Are there sufficient training opportunities for personnel in high and maximum containment laboratories to ensure effective biosecurity training of current and projected staff?
- What are the current training practices related to biosecurity at both federal and non-federal institutions?

Panelists

Vickie Sutton, M.P.A, Ph.D., J.D., Robert H. Bean Professor of Law, Director, Center for Biodefense, Law and Public Policy, Director, Law and Science Certificate Program and The JD/MS Program in the Life Sciences, Texas Institute of Environmental and Human Health, Texas Tech University School of Law

Ronald M. Atlas, Ph.D., Professor of Biology and Co-director of the Center for the Deterrence of Biowarfare and Bioterrorism, University of Louisville

Bob Hawley, Senior Advisor, Center for Biological Safety and Security (CBS2), Midwest Research Institute

Debra Sharpe Director, Compliance and Security, Southern Research Institute, President, BioSafety Solutions, LLC

Discussion

2:30 p.m. Public Comments

3:00 p.m. Wrap-up and Concluding Remarks

3:15 p.m. Adjourn

Appendix 2-A: Existing Stratification Schemes for Biological Agents

The most commonly accepted biosafety classification methodologies used in the United States are the *BMBL* Biosafety Levels (BSLs) and the *NIH Guidelines for Research involving Recombinant DNA Molecules* (*NIH Guidelines*) Risk Groups.

BMBL BSLs

The *BMBL* BSLs are combinations of safe work practices, administrative controls, safety equipment, and engineering controls to be utilized to protect workers, the public, and the environment from exposure to infectious agents and toxins. Risk assessment takes into account engineering controls, practices, protective equipment and facility design determined to be appropriate for the specific operations performed with infectious agents and allows for the categorization of the work into four biosafety levels (BSLs), assigned in ascending order based on the degree of risk. The pathogenicity and infectiousness of the agent and the severity of disease also contribute to the assignment of a BSL.

- BSL-1: For use with well characterized agents not consistently known to cause disease in healthy adult humans; of minimal potential hazard to laboratory personnel and the environment.
- BSL-2: For use with agents of moderate potential hazard to personnel and the environment.
- BSL-3: For use with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route.
- BSL-4: For use with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. These agents usually do not have well established means of prevention or treatment.

In addition to providing BSLs for laboratories, the *BMBL* also includes a similar system for use in animal facilities (Animal Biosafety Levels [ABSL 1 through 4]). The current 5th edition of the *BMBL* (http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm) contains detailed descriptions of the work practices, administrative procedures, safety equipment, and engineering controls required for each of the BSLs, along with guidance on performing risk assessments and suggested BSL assignments for infectious agents. The *BMBL* also provides a brief overview of biosecurity principles as it applies to laboratory practices, safety equipment, facility design and construction and establishing the various BSLs for containment.

NIH Guidelines

In the *NIH Guidelines* (oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm), agents are classified into four Risk Groups (RGs) according to their relative pathogenicity for healthy adult humans. The RGs are defined as follows:

- RG-1: Agents which are not associated with disease in healthy adult humans.
- RG-2: Agents which are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

- RG-3: Agents which are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.
- RG-4: Agents which are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

CDC Stratification of Potential Biological Terrorism Agents

In addition to the traditional biosafety classification methodologies outlined above, there have also been stratification schemes developed to classify biological agents and toxins by their risk for use in bioterrorism. In February 2002 the CDC published a "Public Health Assessment of Potential Biological Terrorism Agents" (Emerging Infectious Dis. Vol 8: 225-230, 2002) that presented a classification system based on the results of a working group of national experts. This classification system is as follows:

- Category A: High priority agents, including organisms 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.
- Category B: Agents of moderate priority, including organisms that:
    - Are moderately easy to disseminate;
    - Result in moderate morbidity rates and low mortality rates; and
    - Require specific enhancements of the CDC's diagnostic capacity and enhanced disease surveillance.
- Category C: Agents including emerging pathogens that could be engineered for mass dissemination in the future because of:
    - Availability;
    - Ease of production and dissemination; and
    - Potential for high morbidity and mortality rates and major health impact.

Department of Homeland Security (DHS) Bioterrorism Risk Assessment (BTRA)

In 2006, DHS published its first comprehensive BTRA. This assessment used a computational risk analysis tool to conduct end-to-end risk assessments of the bioterrorism threat. The assessment incorporated intelligence information, quantitative data, subject matter expert input, and explicit consequence modeling. This approach was applied to 28 agents and it produced risk-based prioritized groups. These groups were identified as High Risk, Moderate Risk, and Low Risk. In accordance with Homeland Security Presidential Directive 10 (HSPD-10), Biodefense for the 21st Century, this risk assessment will be updated every two years.

The DHS BTRA Program conducted the Animal Agroterrorism Agent Selection Workshop on October 23, 2006 in Arlington, Virginia. The principal objective of the Workshop was to identify the top animal agriculture threat agents affecting livestock and poultry for conducting a risk assessment.

The USDA Select Agents and Toxins lists (7 CFR § 331.3, 9 CFR §§ 121.3, 121.4) were taken as the starting point for considering animal diseases, from which the Workshop agreed to remove African Horse Sickness virus (equine diseases are not being considered in the 2008 Risk Assessment), and to add Rift Valley Fever (RVF), Nipah virus, *Brucella* species, bovine tuberculosis (TB), and pseudorabies. The criteria for ranking were based exclusively on the consequence to animals; the potential zoonotic impact was not considered.

A total of nine criteria were identified for use in the agent scoring exercise:

1. Ease of acquisition
2. Storage/transport stability
3. Ease of production
4. Ease of dissemination
5. Morbidity
6. Mortality
7. Transmissibility
8. Availability of countermeasures
9. Economic impact

The results of the DHS working group assessment are below.

	Bioterrorism Risk Assessment (BTRA)
1	Foot-and-mouth Disease Virus
2	Classical Swine Fever Virus
3	Avian Influenza Virus (Highly Pathogenic)
4	African Swine Fever Virus
5	Exotic Newcastle Disease Virus
6	Rinderpest Virus
7	Peste des Petits Ruminants Virus
8	Pseudorabies
9	Sheep Pox Virus
10	Goat Pox Virus
11	Rift Valley Fever Virus
12	Nipah Virus
13	*Cowdria ruminantium* (Heartwater)
14	*Brucella* species
15	Japanese Encephalitis Virus
16	*Mycoplasma mycoides mycoides*
17	Swine Vesicular Disease Virus
18	Malignant Catarrhal Fever Virus
19	*Mycobacterium bovis* (Bovine TB)
20	Akabane Virus
21	Bluetongue Virus
22	*Mycoplasma capricolum*
23	Lumpy Skin Disease Virus
24	Camel Pox Virus

25	Vesicular Stomatitis Virus
26	Bovine Spongiform Encephalopathy
27	Menangle Virus

Weapons of Mass Destruction Medical Countermeasures (WMD MCM) Subcommittee, Animal Pathogens Subgroup

In October 2003, The National Science and Technology Council (NSTC) established the WMD MCM Subcommittee that formed the Animal Pathogens subgroup. The Animal Pathogens subgroup was tasked with generating a prioritized animal pathogen threat list for the purpose of recommending methods to address gaps in countermeasure development. It assessed the USDA list of biological threat agents for potential impact according to the following criteria:

- Virulence and the potential for the disease to spread among the host population
- Economic impact or the potential cost to producers and society
- Zoonotic potential or potential for the disease to spread to humans
- Morbidity or the likelihood the disease will cost great loss of life among the host animal population
- Cross-species potential or the likelihood the disease would spread to other animal species

Based in part on the findings of the WMD MCM Animal Pathogen subgroup, in December 2003 the White House Office of Science and Technology Policy (OSTP) established a Blue Ribbon Panel composed of scientists, policy-makers and other key stakeholders from Federal, State, and local governments, academia, industry, and the international community. This panel was tasked with examining the possibility of biological terrorism directed against U.S. agricultural livestock, exploring the potential consequences of such an attack, and outlining priorities for future Federal defense research and development (R&D) agendas.

Four breakout groups were given the task of identifying the major research needs in their subject area, prioritizing these requirements, recommending ways to address the current gaps, and providing estimated timelines and budgets for their recommendations. The groups assessed the following areas: 1) surveillance; 2) epidemiology; 3) vaccines; and 4) diagnostic. The epidemiology, vaccines, and diagnostic breakout groups developed a prioritized list of pathogen threats in order to complete their tasks. The following summarizes their report.

In initial discussions, the OSTP Blue Ribbon Panel Diagnostic breakout group was guided by the agents of concern highlighted in the report of the WMD MCM Animal Pathogen subgroup. Although the 10 agents discussed in that report provided a valuable starting point, the group concluded that the agents of highest priority for vaccine development were not necessarily the same as those of highest priority for diagnostic testing research.

With respect to animal agents, the group concluded that diseases of highest concern should be identified based on their attractiveness to a potential bioterrorist in combination with their potential impact if released. In this context, the criteria relevant to assessing agricultural diseases include:

- Morbidity and mortality
- Disease transmissibility

- Presence of effective vectors
- Number of animal species affected
- Whether the disease is zoonotic
- Availability of control strategies
- Presence of wildlife reservoirs
- Ability of the agent to survive in the environment
- Availability of diseases to adversaries
- Technical constraints on deployment of the disease agent by adversaries
- Presence of natural diseases that might confound detection of intentional release or be confused with the agent

Based on these criteria, the OSTP Blue Ribbon Panel Diagnostic breakout group prioritized a list of agents of most concern:

- Highly Pathogenic Avian Influenza
- Bovine Spongiform Encephalitis
- Classical Swine Fever
- *Cowdria ruminantium* (Heart Water)
- Foot-and-Mouth Disease
- Rinderpest
- Bovine TB
- RVF
- Exotic Newscastle Disease
- Alphaviruses (e.g., Venezuelan Equine Encephalitis)
- Paramyxoviruses (e.g., Nipah, Hendra)

Homeland Security Presidential Directive 9 (HSPD-9), National Veterinary Stockpile (NVS)

Section 18(a) of Homeland Security Presidential Directive 9 (HSPD-9), dated January 30, 2004, established the National Veterinary Stockpile (NVS) to respond to terrorist acts, major disasters, and other emergencies. It required the NVS to deploy within 24 hours "sufficient amounts of animal vaccine, antiviral, or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy…"

The NVS, managed by APHIS, established a Steering Committee to guide its work and provide interagency support. APHIS established as a primary goal the acquisition of countermeasures against the worst animal diseases, with milestones identified for the first five and 10 years. Accordingly, in February 2005, the NVS Steering Committee organized a working group of animal disease experts to identify and prioritize the most dangerous animal disease threats to the United States.

The NVS working group used the USDA select and overlap agents lists for their assessment. The following eight criteria were identified by the NVS working group as the most appropriate for prioritizing animal disease threats:

1. Epidemic Potential **-** Ability to shed, spread, and rapidly infect target species

2. Economic Impact - Loss of revenue to a region, one or more agricultural segment (e.g., beef, dairy, broilers), the agricultural segment nationwide, and associated industries
3. Trade Impact - Loss of revenue due to trade restrictions imposed by one or more trade partners
4. Zoonotic Potential - Ability of an animal disease to spread and cause morbidity and/or mortality to a small or large number of people
5. Morbidity Mortality - The virulence potential of a pathogen and its ability to cause sub-clinical disease, moderate disease, severe disease, and/or mortality
6. Cross-species Potential - Ability with which a pathogen can cross the species barrier and infect and cause disease in other animal species, including establishing a reservoir in important domestic or wildlife species
7. Inability to Detect Rapidly - Availability of very specific and sensitive tests to rapidly detect the pathogen in the field
8. Inability to Vaccinate - Availability of vaccines that have the characteristics needed to control and eradicate the pathogen (i.e., unable to implement a vaccine strategy if vaccines are not available or not marked, and do not prevent shed and spread or colonization of target tissues in carrier animals)

The results of the NVS working group assessment are below.

NVS Working Group Assessment

Agricultural Agent	**Rank**	**Total Score**
Avian influenza virus	1	187
Foot-and-mouth disease virus	2	185
Rift Valley fever virus	3	173
Newcastle disease virus (VVND)	4	169
Nipah and Hendra viruses	5	165
Classical swine fever virus	6	158
African swine fever virus	7	155
Bovine spongiform encephalopathy agent	8	146
Rinderpest virus	9	142
Japanese encephalitis virus	9	142
African horse sickness virus	11	133
Venezuelan equine encephalitis virus	12	132
Contagious bovine pleuropneumonia	13	128
Cowdria ruminantium (Heartwater)	14	124
Eastern equine encephalitis virus	15	123
Coxiella burnetii	16	114
Akabane virus	17	103

Appendix 2-B: Subgroup on Select Agent Regulations: Criteria and Weighting System for Assessing BSAT Risk

Criteria	Scores By Pathogen		
	Score (1-10)	Weight	
Ease of Acquisition[2-1]		2	
Ease of Production[2-2]		3	
Ease of Enhancement[2-3]		2	
Ease of dissemination by worst route[2-4]		3	
Infection by "worst" route[2-5]		2	
Survivability in matrix or environment[2-6]		2	
Low infectious dose by route[2-7]		3	
Communicability (Spread through individuals or populations)[2-8]		3	
Lack of prior protective immunity[2-9]		2	
Morbidity[2-10]		2	
Burden on the health system[2-11]		2	
Lack of surveillance or detection[2-12]		1	
Lack of rapid diagnostics[2-13]		1	
Counter-measures (average score)[2-14]		2	
Vaccines			
Treatments			
Mortality with medical countermeasures[2-15]		3	
Mortality without counter-measures[2-16]		3	
Short-term Economic Impact[2-17]		1	
Difficulty of Decontamination[2-18]		1	
Persistence or Reservoir[2-19]		1	
Long-term Consequence (Health or Economic)[2-20]		2	

The criteria listed here were formulated to help determine the risk of each BSAT for the purposes of EO 13486. It was formulated by representatives from the NIH DOS, USDA, FBI, and DHS and vetted by the larger interagency WG. It is intended to be used to stratify BSAT that pose a

severe threat to human, animal or plant health or those that could potentially inflict short or long-term economic consequences on an agricultural industry.

This list is intended to address biodefense, biosecurity and biosafety issues regarding BSAT and their potential use in an adversarial biological attack. These criteria were selected to help mitigate the potential "insider threat" posed by professionals working in licensed laboratories and the threat from other entities acquiring BSAT from a commercial source. It is not intended to address the acquisition and use of pathogens from nature or other environmental sources.

Definitions for criteria listed above:

2-1 Ease of Acquisition: Refers to how easy or difficult it would be for a potential adversary to acquire a BSAT from a laboratory or commercial source. It includes regulatory issues such as import/export and/or other movement restrictions or Federal quarantines placed on pathogens or toxins by treaties, trade agreements, inspection regimens, or other laws and regulations. It also considers whether a BSAT would be held at most select agent laboratories, or whether only a few laboratories hold it. A BSAT that is relatively easy to acquire would receive a high score.

2-2 Ease of Production: Refers to factors involved with the laboratory production of a BSAT by an adversary. Also includes issues involved with formulation or post-production preparation of laboratory product. Pathogens or toxins that would be difficult to produce and formulate in quantities needed for an adversarial attack of small to mid-size would be ranked lower than those that would be easier to produce and formulate.

2-3 Ease of Enhancement: Refers to how easy or difficult it would be to modify the natural organism or toxin to enhance its pathogenicity, transmissibility, or ability to evade medical and non-medical countermeasures. This criterion addresses concepts of advanced manipulation as well as simpler, classical techniques to effect genetic transfer or organism adaptation.

2-4 Ease of dissemination by "worst" route: Refers to factors involved with the ease or difficulty of deliberate dissemination of a BSAT by an adversary. Dissemination could be aerosol, in a food or beverage intended for consumption, by topical use to create an infection through breaks in the tissue surface, or for dissemination by vector, but the score is reflective of dissemination by the "worst" route for a BSAT. Sample issues to consider include the size of an attack; whether it is in an open area or an enclosed space; device choice and stresses on the BSAT posed by the device; and shelf life or time to germination, for those pathogens disseminated in a food or soil matrix.

Discussions for the further refinement of these criteria may consider subdividing this category, scored for each route of dissemination, and the scores averaged. Subdivision would allow stratification to consider whether some pathogens can be disseminated by certain routes. For example, if multiple routes are possible, BSAT would receive a higher score; or this criterion could be weighted higher (i.e., it is operationally impossible to disseminate botulinum toxin as an open-air aerosol to multiple targets, but it makes a highly effective toxin in some foods and beverages for a multiple target attack).

2-5 Infection by "worst" route: Refers to the ease or difficulty of creating disease or illness with the adversarial delivery of an appropriate dose of a BSAT to the intended target. Infection could be through the lungs and airways, through the gastrointestinal system, or through the skin, eyes, or tongue. Scoring should be on the "worst" route of infection – that is the route that will most easily produce systemic infection. Pathogens with multiple routes of exposure would be scored higher than those with single routes of exposure.

If discussions for the further refinement of these criteria are to be held, some subgroup members thought that this category should be subdivided, scored by routes of infection, and the scores averaged. This subdivision would allow stratification to consider whether some pathogens can infect by certain routes. For example, if multiple routes are possible, an individual BSAT would receive a higher score; or this criterion could be weighted higher.

2-6 Survivability in matrix or environment: This criterion refers to how environmentally stable a BSAT is by itself (i.e., contrast the high stability of a crude botulinum toxin product to the more fragile nature of some viruses) and how well it survives in the environmental matrix used to either formulate or disseminate it. If the matrix used to disseminate it is food or soil, this criterion addresses how well the pathogen competes with commensal natural organisms or how other ingredients or chemical components affect its viability or virulence. Those BSAT that are assessed to be stable will receive high scores.

2-7 Low infectious dose by route: Refers to how small an amount of BSAT is needed to infect a target. Those organisms with very low infectious doses (i.e., *Francisella tularensis or Synchytrium endobioticum* (Potato wart)) will be given a high score.

2-8 Communicability (spread through individuals or populations): Communicability is the ability of the pathogen to create a sustainable chain of transmission from a single point or multiple sources with a single dissemination. A pathogen that is communicable across a target population would receive a high score.

2-9 Lack of prior protective immunity: Refers to whether the target population has innate immunity to a BSAT (particularly important in the case of specially bred agricultural genetically modified organisms) or whether immunity has been acquired from a source such as vaccines. BSAT to which a target population has little or no prior protective immunity would receive a high score.

2-10 Morbidity: Refers to any non-fatal illness that renders partial dysfunction to an animal or human; it is considered to be an illness lasting weeks or months that will eventually resolve with medical, veterinary, and/or supportive care. Issues of long-term or permanent morbidity are addressed by the criterion long-term consequences. A BSAT that creates a significant amount of morbidity would receive a high score. In a system using weighted criteria, morbidity should be on at least an equal footing with mortality, because of the amount of system resources that may be required.

2-11 Burden on the health system: Refers to the burden presented to the human, veterinary, or plant health system by the deliberate release of a BSAT. This criterion attempts to capture the

human, monetary, and other resources that may be called on to acquire and deliver medical and non-medical countermeasures. The length of time it takes to return to typical operations is captured under the criterion difficulty of decontamination.

2-12 Lack of surveillance or detection: Refers to the ability to detect a release of pathogens into the environment, as with BioWatch and other detection technologies, or in food, water, or soil. Sampling detection may precede the diagnosis of illness and represents an important first line of our defense against biological attacks.

2-13 Lack of rapid diagnostics: Addresses the ability of the human and agricultural health authorities to accurately and rapidly diagnose and treat the disease presented by a release of a BSAT. How widespread the use of a technology (e.g., real-time PCR) is, is crucial to this criterion (i.e., if only available in LRN laboratories and not general clinical diagnostic laboratories, the score would be lower). With many rapid detection devices in the research and development pipeline, the scores for this criterion may need to be re-evaluated as devices enter widespread deployment. This criterion includes the strengths and weaknesses of existing diagnostic criteria and can also include pathogens deliberately modified to obfuscate accurate diagnosis.

2-14 Countermeasures: Refers to the existence of countermeasures to prevent, treat, or mitigate the symptoms of a disease and/or its spread through a population. Integral to the definition of this criterion is the ability to operationalize use in a timely manner. Scores given for this category are an average of the two subcriteria vaccines and treatments.

2-14a Vaccines: Refers to availability of pre-exposure medical countermeasures. A high score may be the result of either a lack of vaccine or existence of a vaccine that is not in use by a large enough portion of the target population to create sufficient protective immunity. The ability of some vaccines to be used in a post-exposure manner would depend on either the spread of the disease or the threat posed by a second wave of infections following the original attack (as in the case of secondary aerosols) and whether vaccines could be delivered in time to offer acquired immunity or to prevent further spread. Pre-exposure non-medical countermeasures could include restrictions on the movement of pathogens and are covered in the regulatory issues criterion.

2-14b Treatments: Refers to availability of post-exposure medical countermeasures. This criterion refers to the use of pharmaceuticals known (on or off-label – as with an Emergency Use Authorization) to specifically target the mechanism or symptoms of BSAT. The timely delivery of treatments is crucial to how it is scored.

2-15 Mortality with medical countermeasures: Considers the fatality rate of disease with real-world delivery of medical countermeasures. If a BSAT causes an illness that is preventable or treatable with existing countermeasures and is unlikely to result in death in non-immunocompromised individuals, it would receive a low score.

2-16 Mortality without countermeasures: Considers the fatality rate of disease with the delivery of no medical countermeasures. If a BSAT causes an illness likely to result in death without countermeasures, it would receive a high score.

2-17 Short-term Economic Impact: Refers to short-term economic impact of a single outbreak of disease or release of a toxin. It is impact that results from voluntary or involuntary travel and trade restrictions, or from consumer choice to forego certain products. It can also refer to the costs of culling infected animals from a herd or flock, or from taking a field off-production for a period of less than one year.

2-18 Difficulty of Decontamination: Refers to the human, monetary, and other resource costs of making an area, building, industrial plant, farm, or field safe for humans, animals or plants to inhabit. This criterion is a measure of the resources required to return to typical operations. Many sporulating organisms will be difficult to decontaminate from an environment and will receive a high score.

2-19 Persistence or Reservoir: Addresses a pathogen's ability to persist in the environment or to find a reservoir that makes its recurrence more likely. Pathogens having natural reservoirs in the target environment or those known to persist would get a high score.

2-20 Long term Consequence (Health or Economic): Considers the long-term health or economic consequences caused by a single release of pathogens. For health consequences it could be the lifetime of dialysis that can result from human systemic infection with *Escherichia coli* O157:H7, or it could be the erosion of one's mind from a prion disease. Economic consequences could be those resulting from fields taken out of production for 20 years, as results from infection with potato wart.

Appendix 3-A: Form FD-961

FD-961 (Rev. 08-31-06) OMB No. 1110-0039-Exp 08-31-09

FEDERAL BUREAU OF INVESTIGATION
BIOTERRORISM PREPAREDNESS ACT: ENTITY / INDIVIDUAL INFORMATION

Section I: Entity Information (Identical to that indicated on the CDC or APHIS registration application)

1. Legal Name of Entity:

2. Address: (Not a post office box) Street City State Zip Code

3. Type of Entity:

Public ☐ Government

Other (i.e. Non-Profit, Private Academic, and Commercial)
*** **Indicate if you are a ☐ corporate officer, ☐ board of director, and/or ☐ stock holder.**

Section II: Individual Information

4. Full Name (Last, First, Middle) 4a. Aliases/Maiden Name:	5. Date of Birth (Month, Day, Year)	6. Social Security Number
7. Residence Address: (No., Street, City, State, Zip Code)		8. Sex: ☐ Male ☐ Female
9. Place of Birth (City, State or Foreign Country) *If not born in the United States please complete questions on page 2 titled Foreign Born Information.	10. Race: ☐ White ☐ Black or African ☐ Hispanic or Latino ☐ Asian/ Native Hawaiian Pacific Islander ☐ American Indian or other Alaska Native	
11. Unique Identifier Number (Supplied by APHIS or CDC):		
12. Certifications (All questions must be answered "Yes" or "No" in the box provided) *Title 18 Section 1001 of the U.S. Code provides that knowingly falsifying or concealing a material fact is a felony that may result in fines or imprisonment for not more than 5 years or both.		
12a. Are you under indictment or information in any court for a felony, or any crime, for which the judge could imprison you for more than one year? ☐ Yes ☐ No	12b. Have you been convicted in any court for a crime, for which the judge could have imprisoned you for more than one year, even if you received a shorter sentence including probation? ☐ Yes ☐ No	
12c. Are you a fugitive from justice? ☐ Yes ☐ No	12d. Are you an unlawful user of any controlled substance (as defined in Section 102 of the Controlled Substance Act [21 U.S.C. 802])? ☐ Yes ☐ No	
12e. Have you ever been adjudicated as a mental defective or been committed to any mental institution? If yes, a complete copy of medical records regarding the commitment will be required. ☐ Yes ☐ No	12f. Are you an alien illegally or unlawfully in the United States? ☐ Yes ☐ No	
12g. Are you an alien who has been lawfully admitted for permanent residence or a naturalized citizen? If yes, please complete page 2 of the application. ☐ Yes ☐ No	12h. Have you been discharged from the Armed Services of the United States under dishonorable conditions? ☐ Yes ☐ No	
I certify that the above answers are true, correct and complete. I understand that the making of a false oral or written statement is a crime. Signature		Date:

1

Foreign Born Information

This page must be completed by any individual answering YES to question 12g of page 1. All questions **MUST** be answered. Be sure to include all alien or admission numbers for question 9.

13. Country of Citizenship:

14. Mother's Full Name:

15. Father's Full Name:

16. Date of Entry to the United States:

17. Place of Entry:

18. Immigration Status at Entry:

19. Current Immigration Status:

20. Date Status Expires, if Applicable:

21. Alien Number or Admission Number (9-11 digits):

Alien registration numbers are issued by the Bureau of Immigration and Customs Enforcement for individuals who are granted permanent legal resident or a naturalized citizen status in the U.S. Other situations that individuals would have an alien registration number include the following: Employment Authorization cards, Temporary Resident cards, Border Crossing cards, I-94 or Visa numbers. If this number is not available please provide an explanation. If born to US citizen serving a military or diplomatic post in a foreign country please provide a copy of the US born abroad birth certificate.

Section III: Consent

By signing this form, I hereby authorize the U.S. Department of Justice to obtain any information relevant to assessing my suitability to access, possess, use, receive or transfer select agents and toxins from any relevant source, including, but not limited to, individuals, public sources, and government sources. This information may include, but is not limited to, biographical, financial, law enforcement and intelligence information.

I further authorize any individuals having information pertinent to such an assessment to release such information to a duly accredited representative of the U.S. Department of Justice. The authorization set forth in this paragraph is valid for five (5) years from the date on which this form is signed.

I further authorize the U.S. Department of Justice to disclose any records, results or information relating to, or obtained in connection with, my security risk assessment to: the U.S. Department of Agriculture; the Department of Health and Human Services; any agency contractors assisting in the determination of risk; and responsible officers or other appropriate personnel of pertinent entities.

I further authorize the release of records, results or information relating to, or obtained in connection with my security risk assessment to any law enforcement or intelligence authority or other federal, state or local entity with relevant jurisdiction where such information reveals a risk to human, animal and/or plant health or national security.

I further authorize disclosure of records results or information relating to, or obtained in connection with my security risk assessment to organizations or individuals, both public and private, if deemed necessary, in the sole discretion of the U.S. Department of Justice, to elicit information or cooperation from the recipient for use in assessing my suitability to access, possess, use, receive or transfer select agents and toxins.

I further authorize release of records, results or information relating to, or obtained in connection with my security risk assessment to laboratories, universities, individuals, or other entities, both public and private, responsible for making security assessments, employment and/or licensing determinations and suitability or security decisions when the information is relevant to an assessment of my suitability to access, possess, receive, use, or transfer agents or toxins

I understand that this is a legally binding document and false statements provided by me are violations of federal law and may lead to criminal prosecution or other legal action.

_____ _____

PRINTED NAME DATE

_____

SIGNATURE

Appendix 3-B: Collective Foreign Threat Assessment, Restricted Party Screening Authorities

Export-related Restricted, Denied, and Blocked Persons Lists

- Department of Commerce Denied Persons (U. S. Bureau of Industry and Security (BIS))]
- Department of Commerce Entity List (BIS)
- Department of Commerce "Unverified" List (BIS)
- U.S. Treasury Department Specially Designated Nationals (SDN) and Blocked Persons, including Cuba and Merchant Vessels, Iran, Iraq and Merchant Vessels, Sudan Blocked Vessels (OFAC)
    - Department of Treasury Specially Designated Terrorist Organizations and Individuals
    - Department of Treasury Specially Designated Narcotic Traffickers and Narcotics Kingpins
    - Department of Treasury Foreign Narcotics Kingpins
- Department of State Designated Terrorist Organizations
- Department of State Terrorist Exclusion List (TEL)
- U.S. Treasury Department Palestinian Legislative Council (PLC) List
- U.S. Federal Register General Orders

Munitions Export-related Restricted, Denied, and Blocked Persons Lists

- Department of State Arms Export Control Act Debarred Parties
- Department of State International Traffic In Arms Regulations Munitions Export Control Orders
- Department of State Nonproliferation Orders
    - Department of State Missile Proliferators
    - Department of State Chemical and Biological Weapons Concerns
    - Department of State Lethal Military Equipment Sanctions
- Foreign Persons Designated Under the Weapons of Mass Destruction Trade Control Regulations

U.S. General Services Administration and Office of Inspector General

- GSA List of Parties Excluded from Federal Procurement Programs
- GSA List of Parties Excluded from Federal Nonprocurement Programs
- GSA List of Parties Excluded from Federal Reciprocal Programs
- Office of Inspector General List of Individuals/Entities Excluded from Federal Health and Medicare Programs

Law Enforcement-related Wanted Persons Lists and other Federal Agency Lists

- Air Force Office of Special Investigations - Top Ten Fugitives
    - Focuses on four priorities: to exploit counterintelligence activities for force protection, to resolve violent crime impacting the Air Force, to combat threats to Air Force information systems and technologies, and to defeat and deter acquisition fraud.
- Bureau of Alcohol, Tobacco, Firearms and Explosives Most Wanted

  - Enforces U.S. federal laws and regulations relating to alcohol, tobacco products, firearms, explosives, and arson.
- Federal Bureau of Investigation (FBI) Ten Most Wanted Fugitives
  - Investigative functions fall into the categories of applicant matters, civil rights, counterterrorism, foreign counterintelligence, organized crime/drugs, violent crimes and major offenders, and financial crime.
- FBI Most Wanted Terrorists
  - Lists alleged terrorists that have been indicted by sitting Federal Grand Juries in various jurisdictions in the United States for the crimes reflected on their wanted posters.
- FBI Wanted Fugitives
- FBI Hijack Suspects
- FBI Seeking Information
- Food and Drug Administration – Clinical Investigators
- Food and Drug Administration – Disqualified and Restricted
- Food and Drug Administration – Debarment List
  - Individuals who have had various restrictions placed against them by the Food and Drug Administration (FDA) for certain conduct relating to products regulated by the FDA.
- Department of Homeland Security Most Wanted Fugitive Criminal Aliens
  - Persons wanted on Administrative Orders of Removal from the United States.
- Department of Homeland Security Most Wanted Human Smugglers
  - Persons wanted on account of allegedly transporting smuggled or trafficked individuals; or forcing the smuggled or trafficked persons to work as indentured servants.
- Naval Criminal Investigative Service - Wanted Fugitives
  - Conducts felony criminal investigations and counterintelligence for the Department of the Navy, and managing Navy security programs.
- Immigration and Customs Enforcement Most Wanted Fugitives
  - Investigates fugitive matters involving escaped federal prisoners, probation, parole, and bond default violators, and warrants generated U.S. Drug Enforcement Administration (DEA) investigations and certain other related felony cases.
- U.S. Drug Enforcement Administration - Major International Fugitives
  - Enforces controlled substances laws and regulations of the United States and brings to the criminal and civil justice system of the United States those entities and individuals involved in the growing, manufacture, or distribution of controlled substances appearing in or destined for illicit traffic in the United States.
- U.S. Marshals Service - Top 15 Most Wanted
- U.S. Marshals Service - Major Fugitive Cases
  - Involved in most every Federal law enforcement initiative. U.S. Marshals major cases and top 15 most wanted consist of individuals with a history of violent crimes who may be considered armed and dangerous.
- Office of Research Integrity Administrative Actions
  - The names of individuals that have had administrative actions imposed against them by the Office of Research Integrity (ORI), maintained by the Public Health

Service (PHS). The Assistant Secretary for Health (ASH) makes the final PHS decision on findings of research misconduct and the imposition of administration actions after reviewing the recommendations made by ORI.

- U.S. Postal Inspection Service - Most Wanted
    - Important areas of jurisdictions include: assaults, bombs, controlled substances, electronic crimes, mail fraud, and money laundering.
- U.S. Secret Service - Most Wanted
    - The United States Secret Service is mandated to carry out two missions: protection and criminal investigations. In criminal investigation, the Secret Service is responsible for the enforcement of laws relating to counterfeiting of obligations and securities of the United States, investigation of financial crimes including, but not limited to access device fraud, financial institution fraud, identity theft, computer fraud, telecommunications fraud, and computer based attacks on our nation's financial, banking, and telecommunications infrastructure.

Banking-related Blocked Person and Entity Lists

- World Bank Listing of Ineligible Firms
    - Lists names of firms and individuals that are ineligible to be awarded a World Bank-financed contract for the periods indicated because they were found to have violated the fraud and corruption provisions of the Procurement Guidelines or the Consultants Guidelines.
- Office of the Superintendent of Financial Institutions (OSFI) Consolidated List - Office of the Superintendent of Financial Institutions. (Entities)
- OSFI Consolidated List - Office of the Superintendent of Financial Institutions. (Individuals)
    - Issues names subject to the regulations establishing a list of entities made under the Canada Criminal Code or the United Nations suppression of terrorism regulations.
- OSFI Warning List - Office of the Superintendent of Financial Institutions. (Entities)
    - Issues entity names that may be of concern to the business community and the public.

International Terrorist, Blocked Persons, and Entity Lists

- Consolidated List of Persons, Groups and Entities Subject to European Union (EU)Financial Sanctions
- Interpol Recently Wanted
    - Lists persons that are wanted by national jurisdictions.
- Japan Foreign End Users of Concern
- Kingdom of Saudi Arabia Wanted Militants
- Canada Public Safety and Emergency Preparedness Listed Entities
- United Nations Consolidated List
    - Lists targets that have been identified by United Nations (UN), EU, and United Kingdom (UK) officials under legislation relating to Afghanistan (Taliban, Usama Bin Laden, and Al-Qa'ida), Burma/Myanmar, the prior Federal Republic of Yugoslavia (now Serbia and Montenegro), Terrorism, and Zimbabwe.
- Australia Department of Foreign Affairs and Trade Consolidated List

- Bank of England Consolidated List of Financial Sanctions Targets in the UK
- Royal Canadian Mounted Police - Wanted
    - Enforces laws made by, or under, the authority of the Parliament of Canada.

Export Risk Country Alerts

- Export Administration Regulations (EAR) Part 736 General Prohibition Three (Foreign-produced direct product re-exports)
- EAR Part 736 General Prohibition Eight (In transit shipments and items to be unladen from vessels or aircraft)
- EAR Part 746, Embargoes and Other Special Controls
- U.S. Department of Commerce EAR Country Group E:1, Terrorist Supporting Countries ("T-7 Countries")
- Office of Foreign Assets Control Sanctions
- UN Sanctions
- U.S. Department of State, State Sponsors of Terrorism
- U.S. Department of State, Countries Not Cooperating Fully with United States Antiterrorism Efforts
- Department of State U.S. Arms Embargoes
- Export destination for defense articles and defense services prohibited under the International Traffic in Arms Regulations (126.1)
- U. S. Bureau of Industry and Security India and Pakistan Export Restrictions, including Atomic Energy blocked entities
- Exports and Reexports to Afghanistan Restrictions
- Countries that may require participation in, or cooperation with, an international boycott [Section 999(b)(3) of the Internal Revenue Code of 1986]

Appendix 3-C: Australia Security Sensitive Biological Agents List

No.	Tier 1
1	Abrin
2	*Bacillus anthracis* (Anthrax-virulent forms)
3	Botulinum toxin
4	Ebola virus
5	Foot-and-mouth disease virus
6	Highly pathogenic influenza virus, infecting humans (such as 1918 pandemic Influenza A virus and H5N1 Influenza A virus)
7	Marburg virus
8	Ricin
9	Rinderpest virus
10	SARS coronavirus
11	Variola virus (Smallpox)
12	*Yersinia pestis* (Plague)
No.	**Tier 2**
1	African swine fever virus
2	Capripoxvirus *(Sheep pox virus and Goat pox virus)*
3	Classical swine fever virus
4	*Clostridium botulinum* (Botulism; toxin-producing strains)
5	*Francisella tularensis* (Tularemia)
6	Lumpy skin disease virus
7	Peste-des-petits-ruminants virus
8	*Salmonella Typhi* (Typhoid)
9	Vibrio cholerae (Cholera) (serotypes O1 and O139 only)
10	Yellow fever virus *(non-vaccine strains)*

Appendix 4-A: Documents Reviewed for Physical Security Subgroup

The following department and agency level security policies and procedures were reviewed:

- USDA 9610-001
- USDA 9610-002
- APHIS 1650
- DoD 5210.89
- USDA Integrated Physical Security Standards and Procedures Handbook
- ISC Facility Selection List Final
- ISC Physical Security Criteria for Federal Facilities
- Common Vulnerability and Protective Measures for Biosafety Laboratories

The following department and agency level supplements and other documents were reviewed:

- USDA General Requirements for 9 CFR Part 121, 7 CFR Part 331
- CDC MMWR Vol. 51 RR-19 Security and Emergency Response
- CDC Select Agent Program Regulation, 42 CFR Part 73
- Physical Security Subgroup Objective Questionnaire
- APHIS Biological Select Agents and Toxins and What's Needed to Physically Secure Them: A Security Perspective

The following department and agency templates were reviewed:

- APHIS-CDC Security Information Document
- APHIS-CDC Security Plan Template
- APHIS-CDC Incident Response Inspection Checklist
- APHIS-CDC Records Inspection Checklist
- APHIS-CDC Security Inspection Checklist
- APHIS-CDC Training Inspection Checklist

Appendix 4-B: Example of Application of Physical Security Standards to a Stratified BSAT List

Minimum Graded Security Measures Classification Table						
Type of Facility	**Diagnostic Facility**		**Research Facility**			**Production Facility**
Level of Risk	**Class I**	**Class II**	**Class I**	**Class II**	**Class III**	**Class IV**
	(D)Diagnostic	*(R)Research*	*(D)iagnostic*	*(R)esearch*	*(D)evelopment*	*D,R,D*
Category A	➢ Intrusion detection sys. ➢ 24/7 security monitoring	➢ 24/7 security monitoring ➢ I.D. badging ➢ Electronic access-control	➢ Intrusion detection sys. ➢ 24/7 security monitoring	➢ 24/7 security monitoring ➢ I.D. badging ➢ Electronic access-control	➢ 24/7 security monitoring ➢ CCTV surveillance ➢ I.D. badging ➢ Emergency power	➢ Extended perimeter ➢ CCTV surveillance ➢ 24/7 Guard patrol ➢ Parking control ➢ Emergency power
Category B	➢ Locked laboratory ➢ Inspection of packages	➢ Intrusion detection sys. ➢ Centralized delivery ➢ Locked laboratory ➢ Inspection of packages	➢ Locked laboratory ➢ Inspection of packages	➢ Intrusion detection sys. ➢ Centralized delivery ➢ Locked laboratory ➢ Inspection of packages	➢ Intrusion detection sys. ➢ Centralized delivery ➢ Electronic access-control ➢ Locked laboratory ➢ Guard patrol assessment ➢ Inspection of packages	➢ Intrusion detection sys. ➢ 24/7 security monitoring ➢ I.D. badging ➢ Centralized delivery ➢ Electronic access-control ➢ Locked laboratory ➢ Guard patrol assessment ➢ Inspection of packages
Category C	➢ Site-specific risk assessment ➢ Security training ➢ Local law enforcement ➢ Entry control procedures ➢ Visitor/contractor control ➢ Locked containers ➢ Inventory control ➢ Chain-of-custody ➢ Information control ➢ Incident response plans ➢ Drills and exercises	➢ Site-specific risk assessment ➢ Security training ➢ Local law enforcement ➢ Entry control procedures ➢ Visitor/contractor control ➢ Locked containers ➢ Inventory control ➢ Chain-of-custody ➢ Information control ➢ Incident response plans ➢ Drills and exercises	➢ Site-specific risk assessment ➢ Security training ➢ Local law enforcement ➢ Entry control procedures ➢ Visitor/contractor control ➢ Locked containers ➢ Inventory control ➢ Chain-of-custody ➢ Information control ➢ Incident response plans ➢ Drills and exercises	➢ Site-specific risk assessment ➢ Security training ➢ Local law enforcement ➢ Entry control procedures ➢ Visitor/contractor control ➢ Locked containers ➢ Inventory control ➢ Chain-of-custody ➢ Information control ➢ Incident response plans ➢ Drills and exercises	➢ Site-specific risk assessment ➢ Security training ➢ Local law enforcement ➢ Entry control procedures ➢ Visitor/contractor control. ➢ Locked containers ➢ Inventory control ➢ Chain-of-custody ➢ Information control ➢ Incident response plans ➢ Drills and exercises	➢ Site-specific risk assessment ➢ Security training ➢ Local law enforcement ➢ Entry control procedures ➢ Visitor/contractor control ➢ Locked containers ➢ Inventory control ➢ Chain-of-custody ➢ Information control ➢ Incident response plans ➢ Drills and exercises

Appendix 5

This page is intentionally blank. There are no appendices cited in Chapter 5.

Appendix 6: Compiled Recommendations

A. Recommendations for Improving the SAR

The WG proposes the following recommendations for improving the SAR as it relates to the select agent list, oversight and inspections, and inventory management.

1. Risk Assessment

a. Task the HHS and USDA Select Agent Program (in consultation with subject matter experts from the scientific, intelligence and security communities from the Federal and non-Federal sectors as appropriate) to conduct a risk assessment of all the BSAT on the select agent list to develop a stratification scheme (or reduce the list) to guide implementation of security policy at registered entities.

The risk assessment should consider the criteria (Appendix 2-B) developed by the subgroup on the SAR as well as those published by other groups (Appendix 2-A). In addition, the team tasked with performing the risk assessment should consult with other federal agencies performing similar risk assessments of BSAT. This team should also engage statisticians to ensure a high level of rigor when establishing stratification. The results of the risk assessment may also lead to a recommendation for the removal of BSAT from the list or other modifications of the list, in addition to stratification.

One concern regarding BSAT stratification, and its use to guide implementation of biosecurity controls, is that a complex stratification scheme may lead to confusion regarding what measures to apply to what agents. It is therefore critical that any stratification scheme be simple and easily implemented.

b. Task the HHS and USDA Select Agent Program (in consultation with subject matter experts from the scientific, intelligence and security communities from the Federal and non-Federal sectors as appropriate) to develop standard security risk assessment methodology for use at all BSAT facilities. Guidance on how to properly execute the standard risk-assessment method should be developed and provided to all registered entities.

A standard security risk assessment methodology should takes into account the risk of the BSAT, the threat of an unintentional release of the BSAT (taking into account the activities performed, insider and external threats), and the vulnerabilities in physical, personnel, or operational security.

A standard security risk assessment methodology will ensure that registered entities are using common approaches to measuring risk and will mitigate the possibility of varied results among similar facilities. Security personnel at registered entities will have a better understanding of their security requirements as they relate to the risk.

By combining the use of a stratified list of BSAT based on risk and a standardized security risk assessment methodology, registered entities will be better able to determine the security risk at their facility and apply security measures commensurate with the risk.

2. Oversight and Inspection

Listed below are two sets of recommendations to improve the oversight process. The first set relates to better coordination between the various oversight groups. These recommendations are designed to improve the efficiency and consistency of inspections. The second set relates to improved compliance by regulated entities. These recommendations address some of the common compliance challenges that the regulated community has faced since the expansion of the SAR in 2003. These recommendations should not require statutory changes, and only minimal rulemaking. Most, if not all, of these could be implemented by policy if concurrence can be obtained by the Agencies involved.

a. Approaches to enhance US Government (USG) coordination on oversight and inspections

1. **Identify or establish a Federal entity to coordinate biosecurity oversight activities, and to ensure comprehensive and effective Federal oversight for all select agent research facilities and activities. This would include input from various stakeholder agencies (*e.g.*, CDC, APHIS, NIH, DoD, DHS, DOE, DOT, EPA, OSHA).** Given the statutory responsibility placed on USDA and HHS, these Departments would be the most likely sponsors of this activity. This coordinating body would work on the following objectives:
   - Convene meetings on a regular basis among key oversight agencies to facilitate information sharing on and coordination of regulations, policies, and inspection schedules/activities (prior to establishing permanent coordinating office).
   - Promote and enable ongoing information sharing on oversight and inspection processes, activities, and reports (facilitated by coordinating office).

This Federal entity should formally engage the regulated community in order to fully understand the needs of the regulated community with respect to the oversight and inspection process.

2. **Plan better coordination of inspections.** In conjunction with the recommendation above, oversight agencies should strive to implement joint or multi-agency inspections at complex select agent entities. This may reduce the "down time" and associated indirect costs for the entity while potentially allowing for each oversight agency to focus on areas that fall outside the scope of the SAR (such as personnel reliability programs).

3. **Promote the oversight-of-oversight approach, whereby USG regulatory and oversight bodies place significant focus on reviewing laboratory-specific and**

institutional oversight efforts, and utilize existing information on the oversight efforts of other USG bodies.

- Review the current oversight regarding registered entities' inventory management and auditing plans to determine if the processes are well-defined and communicated (e.g., additional guidance or regulatory change may be needed).
- Collect and review registered entities' annual select agent program review and facility inspection reports to enable ongoing oversight between inspection cycles.
- Ensure that stakeholder agencies have access to relevant information and reports on oversight efforts pertaining to entities for which they have shared responsibilities and interests.

4. **Develop coordinated training and oversight programs for inspectors from various USG agencies and offices with oversight responsibilities.**
   - Develop formal and ad hoc partnerships between USG oversight bodies. Invite representatives from partner offices to join site visits and inspections in "observe and assist" roles.
   - Hold joint training sessions to develop cross-cutting skill sets and shared knowledge bases regarding USG oversight processes. CDC and APHIS might consider the establishment of a "certification" program for inspection teams from agencies or departments that have internal oversight programs.
   - Develop common standards and guidelines for inspectors whenever practical. One means for the development of these standards is the creation of a certification program by CDC/APHIS to train inspectors from other agencies with internal oversight programs.
   - Conduct joint inspections and other collaborative oversight efforts when appropriate.

b. Approaches to enhance institutional implementation, compliance, oversight and accountability.

1. **Provide guidance for and require entities to conduct comprehensive annual BSAT program reviews and facility inspections.**
   - Consider using the Institutional Animal Care and Use Committee (IACUC) and American Academy for Laboratory Animal Science (AALAS) models for conducting both comprehensive program reviews and facility inspections. Under this model, entities would be required to submit an annual report to CDC or APHIS that must address key compliance issues (to include documentation and/or verification of inventory audits) for review, inclusion in files, and ongoing oversight by these regulatory bodies.

2. **Require entities to provide, as a part of registration, a select agent management plan that outlines the roles and responsibilities of the RO and other key managers for oversight to ensure compliance with the regulations.**

- The plan identifies a senior official (may or may not be the RO) who is identified that takes ultimate responsibility.
- The plan describes the linkage between the chain of command for the RO and the senior official

3. Continue to enhance existing guidance for registered entities on select agent program implementation and oversight at the institutional level.

- Focus new guidance on areas which may require clarification to avoid ongoing misinterpretation or inadvertent noncompliance.
- Provide specific, detailed guidance regarding approval procedures and select agent access for visiting scientists.
- Develop a guidance document detailing escorting requirements for laboratory and non-laboratory staff (including escort of inspectors/auditors).
- Provide further guidance and tools for RO and laboratory staff training (e.g., briefing modules, sample drills and exercises).
- Establish a periodic select agent program bulletin or other notification system for dissemination of new guidance and regulatory information to registered entities.
- Update and expand the "Frequently Asked Questions" section of the National Select Agent Program website to provide standardized guidance on common issues.

3. Inventory of BSAT

Provide comprehensive guidance on inventory management and recordkeeping requirements, approaches, and templates.

a. Expand and clarify existing guidance produced by the Select Agent Program "Guidance on the Definition of Long Term Storage as Used in the Select Agent Regulations" to ensure uniform understanding and facilitate compliance.
b. Develop and distribute various inventory record templates to be adapted and utilized by registered entities on an optional basis.
c. Support the implementation of improved recordkeeping standards and practices for working stock samples (*e.g.*, laboratory notebooks, signature verifications, audits).
d. Provide guidance for and encourage entities to develop standard operating procedures for the transition and management of inventories held by departing principal investigators (PIs).
e. Require entities to submit detailed facility-specific inventory management plans as part of the registration or renewal of registration process.
    - Review the current oversight regarding registered entities' inventory management and auditing plans to determine if the processes are well-defined and communicated (e.g., additional guidance or regulatory change may be needed).
    - Require entities to conduct, document, and report to CDC/APHIS on the completion of periodic (at least annual) inventory audits in accordance with their approved inventory management plans.

Providing formats for records and more prescriptive requirements on inventory management should help ensure a more consistent application of the SAR by registered entities and reduce the current confusion among many entities as to the appropriate standards for inventory records. These requirements should include guidance on intra-entity transfers to address transfers of select agents between principal investigators in an entity, including a requirement for appropriate inventory and tracking of these transfers and as well as notification of the transfers to the RO.

4. Other Recommendations for Amending the SAR. Some of these recommendations will require legislative changes.

a. Amend 18 U.S.C. 175(b) to add "attempts or conspires to possess".

Pursuant to 18 U.S.C. 175(b), a person is prohibited from knowingly possessing a BSAT under circumstances that are "not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose." Anyone violating this provision may be subject to a fine and/or imprisonment of not more than 10 years. The FBI has encountered a situation in which an individual was attempting to acquire a BSAT for a purpose that was not reasonably justified under section 175(b). Because a violation of section 175(b) required the individual to take actual possession of the BSAT, the FBI needed to allow the material to be shipped to the individual before he could be arrested. Although the FBI carefully monitored the transfer, a safer option would be to expand the scope of section 175(b) to prohibit any knowing attempts by individuals to acquire BSAT for a nefarious purpose. Therefore, we recommend that the words "or attempts or conspires to possess" be added to 18 U.S.C. 175(b).

b. Revise the SAR to provide for DOJ access to conduct investigations.

The SAR should include specific language permitting DOJ officials access to laboratories in which evidence is being held in order for them to conduct their investigations. We recommend that the SAR be amended to address the DOJ concerns outlined below:

The DOJ may need to conduct forensic examinations in an investigation authorized under a federal law, on an item or material that is, bears, or contains a BSAT, when such an item or material, identified or collected as evidence during the investigation has been transferred to and is in the possession of an entity registered under this part. These entities will provide access to the DOJ to conduct forensic examinations on these items or materials, provided:
(1) The DOJ personnel have undergone a Security Risk Assessment conducted by the FBI-CJIS and the results of that assessment are submitted to the RO for the entity or individual in possession of the item or material;
(2) The DOJ personnel possess the appropriate education or experience, or will receive the appropriate training from the individual or entity in possession of the item or material, to handle an item or material that is, bears, or contains the BSAT at issue; and
(3) The DOJ personnel are escorted by personnel from the entity with the appropriate training at all times when in the presence of the BSAT.
(4) In addition, the SAR should be clear that the DOJ has a responsibility to insure that any subsequent removal or transfer of material containing BSAT from the registered entity at which

the investigation is being performed occurs only after that entity gets approval for the transfer in accordance with section 16 of the SAR.

In addition, entities should maintain an accurate inventory and adequate security of all materials in their facility which are part of such an investigation. The Department of Justice will also maintain appropriate documentation addressing the inventory of evidentiary items. The documentation will identify which items or material that are, bear, or contain a BSAT, if the presence of a BSAT has been confirmed. The documentation will also contain the amount of BSAT, if it has been determined. The RO of the entity storing the evidentiary items will be notified of any changes to the amounts of the BSATs that may occur during the course of the investigation. The Department of Justice may also choose to augment the security of the entity storing the evidentiary materials.

c. Options for addressing the potential regulatory gap for *de minimis* quantities of select toxins

The WG deliberated on options for filling the potential regulatory gap for *de minimis* quantities of select toxins identified in the previous section of this report; however, no one option was agreed upon. For this reason, the three options discussed are listed here with their respective rationales. The WG recommends that these options be revisited during the policy making process:

- **Option #1: Continue current practice of not tracking, regulating, or reporting orders and shipments of *de minimis* quantities of select toxins**

There is a perceived regulatory gap in which unregistered individuals or entities can repeatedly order, and potentially stockpile, *de minimis* quantities of a toxin for an illegitimate purpose, while eluding registration with the Select Agent Program. There have been documented incidences of this occurring but the frequency and intent of the individuals who have done this is unknown. Most commonly, repeated orders are necessary to support continued studies in which the materials are consumed. There are only a very few companies that supply select toxins and the major ones report that they already track who they ship to, amounts, and purpose, even in the absence of regulatory mandate, however, the extent to which they do so is unknown. The majority of select toxins are either ubiquitous in the environment or very difficult to obtain in any quantity. Finally, there is little risk that a *de minimis* amount of select toxin could be used for a large scale biological attack.

- **Option #2: CDC and APHIS, with input from relevant collaborating agencies, should work with suppliers of select toxins to develop toxin ordering and verification processes that require individuals and entities ordering select toxins to:**

1) verify that the entity/individual is either registered with the Select Agent Program or is exempt from registration due to only ordering exempt quantities of select toxins;

2) designate and provide contact information for the responsible investigator for the toxin to be obtained; and

3) designate and provide contact information for the biosafety officer or another authorized institutional official (other than the responsible investigator) at the ordering entity who can confirm that:

a) the order aligns with a legitimate program, requirement, or activity,

b) the appropriate risk assessment has been conducted for the receipt, possession, storage, and use of the toxin, and

c) subsequent toxin orders and aggregate quantities will be documented and tracked to ensure compliance with exempt quantity limits and enable ongoing institutional accountability and oversight.

To support implementation of this recommendation, CDC and APHIS would also provide guidance to suppliers on straightforward approaches for verifying the information provided by the ordering individuals and entities.

- **Option #3: Amend the SAR such that CDC and APHIS require that all individuals/entities ordering *de minimis* quantities of select toxins enroll in a tracking system with the Select Agent Program.**

1) Enrollment in a tracking system will allow for verification that the individual/entity is a legitimate user of the toxin (user must submit credentials to indicate legitimate use, and supplier verifies with CDC/APHIS they are enrolled prior to shipment).
2) Toxin orders would proceed using the APHIS/CDC Form 2 (or a modified version), which would allow the reporting of the toxin shipment to the CDC or APHIS.
3) Individuals/entities will not be required to register with the Select Agent Program unless the amount of a select toxin in their possession exceeds the amounts subject to the SAR. CDC/APHIS would be authorized to request these records at any time.
4) Periodic reporting of select toxin usage to CDC/APHIS must be considered (perhaps on modified Form 2 when ordering more toxins).
5) This option would require a regulatory change.

d. Consider revising the SAR to require that regulated entities maintain their select agent records for at least 10 years.

Current SAR require registered entities to maintain their records for three years. Consideration should be given to expanding this requirement to 10 years to allow a more comprehensive review of the history of the entity's possession, use, or transfer of BSAT. Many investigations involving violations of the regulations can easily require that inventory and other records be reviewed for trends in reporting or inaccuracies which could extend historically beyond three years. Records required to be maintained for 10 years would include all those required by the SAR such as those for inventory, security, training, or incidence response. Consideration should be given to the burden this requirement may place on regulated entities. For example, records that are expensive or difficult to maintain, and/or are not required by the SAR, such as surveillance videotape, should be excluded from this requirement.

e. The recommendation below should be revisited at the policy phase since there was insufficient time for the WG to complete its deliberations:

Consider the feasibility of revising the statute to grant the Secretary of HHS similar authorities to those of the Secretary of the USDA to determine appropriateness of BSAT access denials for cases of prior committal to a mental institution or juvenile felony convictions.

The WG had a concern that persons who were committed to mental institutions or were convicted of felonies as juveniles are not being given the opportunity to work in fields requiring BSAT access even though they may be well-adjusted. Adjudicators for national security clearance decisions can provide waivers for some of the areas specifically prohibited by the USA PATRIOT Act including felony convictions and noted drug use. If exemptions can be made for access to classified information, it should also be considered for BSAT access. Any consideration of this statutory change must include participation of the HHS political leadership, the CDC Director, and the HHS General Counsel.

B. Recommendations for Enhancing Personnel Security

1. Overarching Recommendations

Because there is no requirement that the RO report derogatory information to the CDC or APHIS if they have removed an individual from BSAT access due to the derogatory information, the research community is potentially at risk of transferring personnel who may represent a security risk from one lab to the next. Furthermore, the WG identified that other than the restricted and prohibited criteria, ROs have not been provided guidance on determining an individual's suitability for access to BSAT or for determining when to temporarily suspend or permanently terminate that access. For this reason, the WG recommends the following:

a. Establish a working group (WG), including Federal and non-Federal subject matter experts from the scientific, intelligence, security, human resources and healthcare (including mental health professionals) communities, that will investigate and establish guidance and training on suitability criteria, above and beyond restricted and potential prohibited categories, for use by:

1. ROs, in addition to the Security Risk Assessment, to determine whether to grant an individual's initial access to BSAT or to temporarily or permanently restrict (or terminate) an individual's access to BSAT
2. PIs, researchers, and technicians to continuously monitor themselves and others for suitability to access BSAT
3. Occupational health professionals, to determine the suitability for BSAT access based on activities performed with the BSAT and the individual's physical and mental health, to include medications that may affect an individual's ability to perform duties with BSAT.

In developing suitability criteria, this WG should, at a minimum, consider aspects of personal and professional conduct, physical and mental health, and behaviors that indicate an individual is at risk of harming themselves or others.

b. Assess the feasibility of the following recommendations:

1. **An amendment to the SAR requiring that ROs report the details of derogatory information leading to permanent termination of BSAT access to CDC or APHIS for inclusion in a registry or repository.** Derogatory information may be related to suitability criteria, determined by the WG above, or restrictive/prohibitive categories. This may require a legislative change.
2. **A registry or repository containing derogatory information reported by the RO that can be used, in combination with results of the security risk assessment, for determining whether an individual should be granted BSAT access.** The FBI-CJIS, CDC, APHIS, DHS, Director of National Intelligence, Homeland Security Council, and National Security Council should collaborate to determine if adjudicative standards should be used for granting BSAT access. If such a registry is deemed legal, amend the SAR to allow the use of this registry by CDC and APHIS, in combination with Security Risk Assessment results, to grant or deny BSAT access. This will require a legislative change.

2. Granting Initial BSAT Access

a. Security Risk Assessments

1. Foreign Nationals

Screening: Identify a Federal agency that will 1) develop guidelines for vetting FNs that require BSAT access and 2) will screen FNs according to these newly established criteria. The SAR should be amended such that this Federal agency, CJIS-BRAG, CDC, and APHIS collaborate to consider both the Security Risk Assessment results and the newly established criteria to grant or deny BSAT access. This screening may require providing information on their prior history in their country of origin as well as up to date information on their occupation, background, and research as well as include results from prior visa screens by the Department of State (DOS). Use of the Collective Foreign Threat Assessment tool (Appendix 3-B) may be considered.

Visas: Require that the DOS provide a list of visa types that are appropriate for work with BSAT to the Select Agent Program. Require the Select Agent Program to disseminate this information to Responsible Officials. The CDC/APHIS Select Agent Programs will provide information and guidance to institutional officials (IOs), ROs, and funding agencies on the types of visas that are adequate for work with BSAT. Inappropriate visa types will require a visa change, or a specific waiver, prior to Security Risk Assessment processing. Amend 18 U.S.C. 175b or the Bioterrorism Response Act to include “an inappropriate visa type” as a restrictor for access to BSAT.

Provide the Department of Justice and the Department of Homeland Security (DHS) with the statutory authority to perform immigration status checks on Security Risk Assessment-approved FNs at least every six months.

2. The CJIS-BRAG should either a) be provided the statutory authority to access the mental health component of the NICS database or b) establish a separate mental health database to allow CJIS-BRAG to determine if an individual is ineligible to have access to BSAT for mental health reasons. Moreover, in either instance, an increased emphasis must be made for states to report information regarding persons who have been "adjudicated as a mental defective or have been committed to a mental institution" in a timely and consistent manner to maintain the integrity and utility of any such database.

b. Suitability for Initial BSAT Access

1. Assess the feasibility of requiring drug testing (urinalysis) for initial BSAT access and determine whether such a testing program could be justified under a Fourth Amendment analysis. Pursuant to 18 U.S.C.§ 175b(d)(2)(D), a person who is an unlawful user of a controlled substance is a restricted person for purposes of access to BSAT.

2. Consider amending the SAR such that persons with duties associated with the highest risk BSAT and based on the activities performed with the agent are required to be in an occupational health program. The occupational health program should at a minimum include an initial screening that assesses an individual's general health and also reviews medications for any possible conflicts with BSAT work. Description of the occupational health program will be required in the biosafety or security plan of the entity. The cost of implementing this recommendation should be weighed against the number of laboratories it will affect and the benefit that will be gained. It should be noted that this type of a change to the SAR could require a legislative amendment.

3. The DOC, CDC, and APHIS should determine how to best implement deemed export regulations with respect to the Select Agent Program-regulated community and should subsequently establish training for IOs, ROs, and funding agencies on deemed export regulation requirements for BSAT work.

3. Continual Monitoring of Personnel

a. Amend the SAR to require that a Security Risk Assessment be performed every three years for all individuals with access to BSAT.

b. Assess the feasibility of random drug testing (urinalysis) for continued BSAT access to ensure that an individual does not fall into a restricted category.

c. Amend the SAR to include a requirement that entities provide training for ROs, principal investigators, researchers, and technicians on suitability criteria as determined by the WG above; mechanisms for supervisor-, self- and peer-reporting of issues relating to the suitability criteria; and a process for temporary suspension or permanent removal of access in their security plans. Leadership, supervisors, medical personnel, peers, and individuals themselves should be aware of personal, professional, and medical (physical and mental) criteria that may impact perception or performance associated with working with or around BSAT. This may require a legislative change.

d. Ensure that all individuals who work with BSAT have access to an occupational health professional for referral of physical or mental health issues that arise after BSAT access is granted. Ensure that entities include contact information and procedures for referring individuals in the description of their occupational health programs.

4. Termination of BSAT Access and Granting New Access

a. Provide guidance to the RO regarding their role in removing individuals from BSAT access who display behaviors indicating they are at risk of doing harm to themselves or to others. Ensure that entities include procedures for referring individuals who display these behaviors in the description of their occupational health programs.

b. Ensure that entities describe procedures for temporary or permanent removal from access due to physical, occupational, or mental health concerns or other issues potentially impacting fitness-for-duty with respect to BSAT possession and use.

c. Ensure that procedures are in place for the RO to immediately notify the local FBI Weapons of Mass Destruction Coordinator in order to initiate a threat assessment process in the event that he/she becomes aware of an incident or action that may indicate possible criminal activity regarding BSAT.

5. Other Recommendations

a. Perform a study of Chemical and Nuclear Personal Reliability Programs to examine the cost of individual PRP measures and the value of eligibility/ineligibility criteria, significance of the personal interview, and effectiveness of continual review/monitoring to identify potentially disqualifying information or reliability issues that would result in an individual's permanent disqualification.

C. Recommendations for Improving Physical Security Regulations

Develop minimum physical security standards based on the risk of the agent or toxin and characteristics of facilities and type of work being done.

Appendix 4-B, provided by the physical security subgroup shows an example of how physical security standards could be applied to a stratified list of BSAT taking into consideration the type of facility and

the work that is done. Using a standard security risk assessment will allow a facility to build upon the baseline or minimum physical security requirements and will ensure a standard approach while allowing for additional security requirements under current regulations.

D. Recommendations for Improving BSAT Transport

The SAR have been adequate in ensuring secure transportation of BSAT. There is currently no evidence to substantiate an increase in transportation security for BSAT. Furthermore, BSAT represent a tiny fraction of the hazardous materials that are routinely handled in daily commerce. Therefore, the key recommendation of the WG is to:

Task the TSA, in partnership with other USG agencies, to conduct a risk assessment to determine the risk posed by air and ground transportation of BSAT.

The risk assessment should consider:

1. The risk of the BSAT, the threat of an unintentional release of the BSAT during transportation (to include likelihood that insider or external threats may compromise a BSAT shipment), and the vulnerabilities in physical, personnel, or operational security during transportation and at stopping points along the shipping routes.

2. The risk posed by having the technical name of BSAT on the shipping paper, balanced by the need to provide enough information to meet the information needs of the emergency responder.

The results of the risk assessment can be used to determine:

1. If high risk BSAT should be shipped using more stringent security controls (*e.g.*, use of restricted service) or an enhanced tracking system (*i.e.*, global positioning systems (GPS)) device in shipments. The baseline security plan requirements contained in the HMR may be sufficient for most BSAT, however, more stringent security controls may be deemed appropriate for BSAT identified by TSA as posing a more serious security risk.

2. If additional background checks should be performed on personnel who handle BSAT, to include couriers and others in the transport chain.

3. If tighter chain of custody requirements and tracking should be implemented.

Other recommendations by the WG include the following:

1. Establish a communication plan to ensure effective communication among entities, couriers, DOT, and CDC/APHIS. This plan may involve creating agreements on security-based communications practices, or a secure web portal that would enhance tracking capabilities or the provision of the tracking number to CDC or APHIS (APHIS/CDC Form 2, line 37 requests this information) in order to give those agencies the ability to track shipment of the package(s) through the courier's system.

2. Require CDC/APHIS to maintain a list of BSAT couriers. This will facilitate DOT inspections of BSAT couriers so that compliance with current hazmat security plan requirements can be

determined. In turn, DOT, CDC, and APHIS should ensure that information on BSAT couriers is protected from disclosure that could compromise security.

3. Consider inclusion of plant BSAT in the HMR.

Appendix 7: Acronym List

AALAS	American Academy for Laboratory Animal Science
ABSA	American Biological Safety Association
ABSL	Animal Biosafety Level
ANACI	Access National Agency Checks and Inquires
APHIS	Animal and Plant Inspection Service
AR	Army Regulations
AS/NZS	Australian/New Zealand Standard
ASH	Assistant Secretary for Health
ATCSA	Anti-terrorism, Crime, and Security Act
BI	Background Investigation
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BPRP	Biological Personnel Reliability Program
BRAG	Bioterrorism Risk Assessment Group
BSAT	Biological Select Agents and Toxins
BSL	Biosafety Level
BSP	Biological Surety Program
BTRA	Bioterrorism Risk Assessment
BTWC	Biological and Toxin Weapons Convention
CBRN	Chemical, Biological, Radiological, and Nuclear
CDC	Centers for Disease Control and Prevention
CDL	Commercial Drivers License
CEN	European Committee for Standardization
CJIS	Criminal Justice Information Services
CMA	Competent Medical Authority
CO	Certifying Official
DA	Department of the Army
DHS	Department of Homeland Security
DNI	Director of National Intelligence
DOC	Department of Commerce
DoD	Department of Defense
DOE	Department of Energy
DOJ	Department of Justice
DOS	Department of State
DOT	Department of Transportation
DSB	Defense Science Board
EAP	Employee Assistance Program
EH	Employee Health
EHS	Environmental Health and Safety
EO	Executive Order
EU	European Union
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FMCSA	Federal Motor Carrier Safety Administration

FMD	Foot-and-Mouth Disease
FN	Foreign National
GAO	Government Accountability Office
GPS	Global Positioning System
GSA	General Services Administration
HHS	Department of Health and Human Services
HMR	Hazardous Materials Regulations
HR	Human Resources
HSPD	Homeland Security Presidential Directive
IACUC	Institutional Animal Care and Use Committee
ICBB	Inter-Service Council for Biosafety and Biosecurity
IG	Inspector General
IO	Institutional Official
ISSM	Integrated Safeguards and Security Management
IT	Information Technology
JSSRT	Joint Suitability and Security Reform Team
LBI	Limited Background Investigation
MBI	Minimum Background Investigation
MD	Management Directive
NACI	National Agency Checks and Inquires
NACLC	National Agency Check with Local Agency Check and Credit Check
NBACC	National Biodefense Analysis and Countermeasures Center
NICS	National Instant Criminal Background Check System
NIH	National Institutes of Health
NPI	National Pathogen Inventory
NSABB	National Science Advisory Board for Biosecurity
NSTC	National Science and Technology Council
NVS	National Veterinary Stockpile
OBA	Office of Biotechnology Activities
OFAC	Office of Foreign Assets Control
ORI	Office of Research Integrity
OSFI	Office of the Superintendent of Financial Institutions
OSHA	Occupational Safety & Health Administration
OSTP	Office of Science and Technology Policy
PDI	Potentially Disqualifying Information
PHMSA	Pipeline and Hazardous Materials Safety Administration
PHS	Public Health Service
PI	Principal Investigator
PIADC	Plum Island Animal Disease Center
PLC	Palestinian Legislative Council
PPQ	Plant Protection and Quarantine
PRP	Personnel Reliability Program
R&D	Research and Development
RG	Risk Group
RO	Responsible Official

RVF	Rift Valley Fever
SAHRP	Select Agent Human Reliability Program
SAR	Select Agent Regulation
SDN	Specially Designated Nationals and Blocked Persons
SSBA	Security Sensitive Biological Agents
SSBI	Single Scope Background Investigation
TEL	Terrorist Exclusion List
TSA	Transportation Security Administration
UN	United Nations
UNSCR	United Nations Security Council Resolution
USA PATRIOT	Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism
USAMRIID	United States Army Medical Research Institute of Infectious Diseases
USDA	United States Department of Agriculture
USG	United States Government
VVND	Newcastle Disease Virus
WG	Working Group
WHO	World Health Organization
WMD	Weapons of Mass Destruction
WMD MCM	Weapons of Mass Destruction Medical Countermeasures

Appendix 8: Lexicon for Biological Laboratory Security Efforts

The following terms are defined in the context in which they will be used in the development/clarification of policy/communications documents.

Access
An individual is deemed to have access at any point in time if the individual has possession of a select agent or toxin (for example, ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin [Part 73,10(b)42 CFR 73, Part 331.10(b) 9 CFR 121, and 7 CFR 331]. Access can be restricted by physical barriers and if escorted and continuously monitored by an individual with access approval from the HHS or USDA Administrator following a security risk assessment. (The security risk assessment is required for all federal and nonfederal individuals with BSAT access under the SAR).

Accountability
Accountability is the establishment of procedures and a system to ensure adequate control and traceability of select agents and toxins at all times, including when employees may have potential physical access to the materials.

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

Alcohol dependence
Also called alcoholism; a disease in which a person craves alcohol, is unable to limit his drinking, needs to drink greater amounts to get the same effect, and has withdrawal symptoms after stopping alcohol use. Alcoholism affects physical and mental health, and causes problems with family, friends, and work.

Australia Group
An informal forum of more than 40 countries that are signatories to the Biological and Toxin Weapons Convention (BTWC) and Chemical Weapons Convention (CWC) that created common export controls for chemical and biological agents, related equipment, and technologies to prevent chemical and biological weapons proliferation and to harmonize national export control measures. Of particular relevance are the Common Export Control Core and Warning Lists of Biological Agents controlled for export. It should be noted that these are not legally binding export control lists. These lists are, however, the basis of similar products with legal authority developed in the US for the purpose of export control (Department of Commerce, Export Administration Regulations/Commerce Control List) or domestic import regulations (HHS/USDA), and in other countries. (http://www.australiagroup.net)

Biocrime
Criminal activities with biological material whether or not the perpetrator has intent to harm. This may include disregard for SAR.

Biological Agent
Any microorganism (including, but not limited to, bacteria, viruses, fungi, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component or byproduct (toxins) of any such microorganism or infectious substance, capable of causing death, disease, or other biological disturbance in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment (from the Centers for Disease Control and Prevention (CDC) Select Agents and Toxins Final Rule. 72 CFR § 73.1 Definitions). Biological agents may exist as purified and concentrated cultures, but may also be present in a variety of materials such as body fluids, tissues, and soil samples.

Biological incident
A biological incident refers to theft, loss or release of select agents or toxins. It also may refer to an unintentional event resulting from an accidental act where a biological agent or toxin is released with the potential to harm unprotected personnel, plants, animals, or the environment. Under certain circumstances, it also may include the use of a mock biological agent intended to cause terror, political or public health action.

Biosafety
The development and implementation of administrative policies, microbiological practices, facility safeguards, and safety equipment to prevent the transmission of potentially harmful biologic agents to workers, other persons, and the environment. Containment is used to describe safe methods, facilities, and equipment for managing infectious materials in the laboratory where they are being handled or maintained. Risk assessment of the work to be done with a specific agent determines the appropriate biosafety practices.

Biosecurity (Laboratory)
The term biosecurity refers to the protection, control of, and accountability for high-consequence biological agents and toxins, and critical relevant biological materials[4] and information within laboratories to prevent unauthorized possession, loss, theft, misuse, diversion, or intentional release[5]. Biosecurity is achieved through an aggregate of practices including the education and training of laboratory personnel, security risk assessments, BSAT access controls, physical security (facility) safeguards, and the regulated transport of BSAT.[6]

Biosurety
Term used by the U.S. Army to denote a system of safety and security measures designed to provide protection to the local population, workers, and the environment by ensuring that operations are conducted safely; that biological select agents and toxins are secure; and that

[4] "Critical relevant biological material" refers to genetic elements, recombinant nucleic acids, and recombinant organisms, regulated by the SAR – 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121.
[5] The use of the term "biosecurity" in this report does not refer to the practice of agricultural biosecurity, or the prevention of entry of a pathogen or pest into a susceptible population of plants or animals.
[6] Adapted, in part, from the WHO report available at http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

personnel involved in those operations meet the highest standards of reliability. Historically, this term was derived from chemical and nuclear weapons agent programs.

Bioterrorism
The unlawful use, or threatened use, of microorganisms or toxins derived from living organisms to produce death or disease in humans, animals, or plants. The act is intended to create fear and/or intimidate governments or societies in the pursuit of political, religious, or ideological goals. (Note: this is one of many definitions for bioterrorism)

Commercial driver's license (CDL)
A license issued by a State or other jurisdiction, in accordance with the standards contained in 49 CFR Part 383 , to an individual which authorizes the individual to operate a class of a commercial motor vehicle.

Competent medical authority (CMA)
A U.S. physician, physician assistant, or nurse practitioner (military, civilian, or contractor) employed by or under contract or subcontract to the U.S. Government or a U.S. Government contractor. When the term is used in reference to the DoD Biological Personnel Reliability Program (BPRP), it refers to someone who has been specifically trained as a CMA and appointed in writing as a CMA by the medical treatment facility commander (or contracting officer's representative (COR)) responsible for reviewing healthcare services or conducting clinical evaluations for purposes of the BPRP.

Custody, chain of
Responsibility for the control of, transfer and movement of, and/or access to biological select agents and toxins. Custody also includes the maintenance of accountability, and records that account for the location and possession of a specific select agent or toxin from its receipt to the current time.

Decontamination
The process of decreasing or eliminating the amount of biological, chemical, or radiological agents on a person, object, or area by absorbing, inactivating, neutralizing, destroying, ventilating, or physically removing such agents.

Disqualification/removal of access
An individual's access approval will be denied or revoked if the individual is within any of the categories described in 18 U.S.C. 175b. An individual's access approval may be denied, limited, or revoked if (1) The individual is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime specified in 18 U.S.C. 2332b(g)(5), knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or being an agent of a foreign power (as defined in 50 U.S.C. 1801), or (2) t is determined such action is necessary to protect public health and safety.

Entity (Government recognized)

Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity (from the CDC Select Agents and Toxins Final Rule 72 CFR § 73.1 Definitions).

Federal funding
Money awarded via a mechanism (grant, award, loan, contract, or cooperative agreement) under which Federal funds are used to support the conduct of research, experimentation, testing, or infrastructure (expansion, construction, or maintenance of a facility).

Hazardous materials
As defined by 49 CFR §§ 383.5 means any material that has been designated as hazardous under 49 U.S.C. 5103 and is required to be placarded under subpart F of 49 CFR part 172 or any quantity of a material listed as a select agent or toxin in 42 CFR part 73.

Laboratory/Facility (Biological)
Laboratories are usually controlled, enclosed spaces for conducting scientific experiments or for testing, analysis, and storage of biological agents, their components or derivatives. Biological laboratories include clinical and diagnostic laboratories, regional and national reference centers, public health laboratories, and research centers (academic, pharmaceutical, environmental). Facilities include academic institutions with multiple teaching and medical research laboratories, hospitals with clinical and diagnostic laboratories, and industrial facilities with production laboratories (manufacturers of vaccines, pharmaceuticals, agricultural materials) for human, veterinary, and agricultural purposes.

Laboratory Response Network (LRN)
Established by the HHS/CDC in accordance with President Clinton's 1995 Presidential Decision Directive-39, which outlined national anti-terrorism policies and assigned specific missions to Federal departments and agencies. The LRN is a national network of Federal, State and local public health, food testing, veterinary diagnostic, and environmental testing laboratories that provide the laboratory infrastructure and capacity to respond to biological and chemical terrorism, and other health emergencies.

Limited access authorization
Authorization for access to Confidential or Secret information granted to non-U.S. citizens and immigrant aliens, which is limited to only that information necessary to the successful accomplishment of their assigned duties and based on a background investigation scoped for 10 years.

Medical Countermeasures
Medical countermeasures includes both biologic and pharmaceutical medical countermeasures (e.g. vaccines, antimicrobials, and antibody preparations), non-pharmaceutical medical countermeasures (e.g. ventilators, and personal protective equipment such as face masks and gloves), and public health interventions (e.g. contact and transmission interventions, social distancing, and community shielding) to prevent and mitigate the health effects of biological agents.

Medical records
Clinical documentation of an individual's medical record which includes the medical history, physician and allied health findings, diagnostics studies (laboratory, radiology, assays), medications, vaccinations, therapeutic procedures, and all other relevant clinical interventions or assessments may be required for a personnel reliability program.

National Agency Check (NAC)
A personnel security investigation consisting of reviews of certain National agencies' records. As a minimum, it includes checks against the Defense Clearance and Investigation Index, the FBI Headquarters and FBI Identification Division databases. A technical fingerprint search of the FBI's files is started as part of a NAC. If the fingerprint is not classifiable, a "name check only" of those files is conducted.

National agency check with local agency and credit check (NACLC)
A personnel security investigation conducted by the Office of Personnel Management (OPM) that combines a National Agency Check (NAC) with local law enforcement agencies and credit histories.

National Science Advisory Board for Biosecurity (NSABB)
A federal advisory board to the Secretary of HHS, the NIH Director, and the heads of all federal departments and agencies with a role/interest in life sciences research. The NSABB is charged with advising on ways to minimize the possibility that information and technologies emanating from vitally important biological research might be misused to threaten public health or other aspects of national security. The NSABB is a critical component of a set of federal initiatives to promote biosecurity in life sciences research. More information about the NSABB, including its Charter and reports, can be found at www.biosecurityboard.gov.

Periodic reinvestigation
An investigation conducted at specified intervals for updating a previously completed personnel security investigation.

Personnel Reliability Programs
A set of methodologies used to make risk-based assessment decisions intended to increase the likelihood that persons with access to Select Agents meet high standards of reliability, are trustworthy, and are physically and mentally competent. DoD corresponding term: Biological Personnel Reliability Program (BPRP).

Personnel security investigation
Any investigation required for determining the eligibility of individuals for access to classified information, acceptance, or retention in the Armed Forces, or assignment to, and retention in, duties requiring access to select agents.

Policy (Government)
A principle, plan, or course of action pursued by the Federal government or by State and local (municipal) governments intended to influence and determine decisions, actions, and other matters. The Executive branch of the Federal Government can establish policy through the use

of both regulations and guidance documents. Policies are generally implemented at lower levels through the development of specific agency regulations, guidelines, or standard procedures.

Potentially disqualifying information
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 duties involving biological agents.

Random drug testing
A program of drug abuse testing where each member of the testing population has an equal chance of being selected. Random testing may be either applied to testing of designated individuals occupying a specified area, element, or position, or random testing of those individuals based on a neutral criterion, such as the first digit of the social security number. Individuals are often tested for evidence of active use of cocaine, marijuana, methamphetamines, opiates, and phencyclidine (PCP).

Regulation
A rule issued under the authority of a statute. For the purposes of this report, a Federal regulation is a statement by a Federal agency designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency promulgated in accordance with the Administrative Procedure Act. Once adopted, a Federal regulation is legally binding until rescinded. The SAR are an example of Federal regulations.

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

Restricted person(s)
There are two categories of restricted persons:

For individuals who require HHS/ CDC or USDA/ APHIS registration for access to select agents: an individual who has been denied such registration as a result of an FBI determination that the individual has met the "restricted person" criteria of 18 USC, Section 175b.

For individuals who require certification in the DoD's Biological Personnel Reliability Program (BPRP) but do not require CDC or APHIS registration.

A person may be restricted from access to biological agents for one or more of the following reasons:

a. Is under indictment or has court martial charges referred to a special or general court-martial that involves a crime punishable by imprisonment for a term exceeding l year; or
b. The person has been convicted in any court of the United States of a crime, was sentenced to imprisonment for a term exceeding one year and was incarcerated as a result of that sentence for not less than a year; or

c. Is a fugitive from justice; or
d. Is an unlawful user of any controlled substance as defined in section 102 of the Controlled Substances Act 21 USC 802
e. Is an alien illegally or unlawfully in the United States; or
f. Has been adjudicated as a mental defective, or has been committed to any mental institution within the seven years preceding the person's consideration for access to select agents; or
g. Is an alien (other than lawfully admitted for permanent residence) who is a national of a country that the Secretary of State has determined (that remains in effect) that such country has repeatedly provided support for acts of international terrorism; or
h. Has by courts-martial received a dishonorable or bad conduct discharge.

Risk Assessment
A risk assessment is the report shows the results vulnerabilities to threats of a specific facility or individual.

Select Agents
Select Agents are Federally-regulated microbial pathogens and toxins that have the potential to pose a severe threat to public, animal, or plant health, or to animal or plant products and whose possession, use, and transfer are regulated by the SAR (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73). HHS/CDC regulates the possession, use, and transfer of Select Agents and Toxins that have the potential to pose a severe threat to public health and safety. The USDA/APHIS regulates the possession, use, and transfer of Select Agents and Toxins that have the potential to pose a severe threat to public health and safety, to animal health, to plant health, or to animal or plant products. Select agent and toxins that are regulated by both HHS/CDC and USDA/APHIS are referred to as "overlap" select agents and toxins. A list of Select Agents can be found at http://www.cdc.gov/od/sap/docs/salist.pdf

Select Agent Program
The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Protection Act of 2002 (the Acts) require entities to register with the HHS or USDA if they possess, use, or transfer biological agents or toxins (i.e. select agents and toxins) that could pose a severe threat to public health and safety; to animal or plant health; or animal or plant products. The Acts also require increased safeguards and security measures for these agents, including controlling access, screening entities and personnel (i.e. security risk assessments), and establishing a comprehensive and detailed national database of registered entities. The Acts also impose criminal and civil penalties for the unlawful possession, use, and transfer of select agents and toxins.

Termination of access
An action taken to remove an individual from his work duties thereby denying access to select agents. The institutional RO must immediately notify CDC or APHIS when an individual with access to select agents and toxins is terminated by the institution; institution must provide the reason(s) for termination.

Terrorism

Terrorism for the purpose of this document is defined by 6 USC 101 (15) as: includes any activity that (1) involves an act that (a) is dangerous to human life or potentially destructive of critical infrastructure or key resources; and (b) is a violation of the criminal laws of the U.S. or of any State or other subdivision of the United States; and (2) appears to be intended (a) to intimidate or coerce a civilian population; (b) to influence the policy of a government by intimidation or coercion; or (c) to affect the conduct of a government by mass destruction, assassination, or kidnapping.[7]

Toxin

The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance. (From the CDC Select Agents and Toxins Final Rule. 72 CFR §73.1 Definitions)[6]

[7] Federal Strategic Plan To Prevent, Protect Against, Respond To And Recover From Biological Attacks In The United States