

organisms as well as some security practices. Personnel reliability and agent accountability are addressed to some extent by the current Select Agent Rules, as discussed above, with the SRA and by requirements for recordkeeping.

Certain research facilities (notably federal) have instituted formal Personnel Reliability Programs (PRPs) to provide additional measures to help ensure that individuals with access to select agents meet additional standards of reliability. Current PRPs are modeled after those within the traditional surety programs and may include extensive background investigations with interviews of character references, security clearances, medical evaluations that may include a review of complete medical records, psychological testing, drug and alcohol testing, polygraph examinations, credit checks, and a comprehensive review of service and employment records. PRPs usually also involve formal mechanisms for ongoing monitoring that can include requirements for self-reporting, peer-reporting, ongoing monitoring by supervisors, and penalties for noncompliance. Individuals enrolled in a PRP typically undergo periodic reassessments including annual physical examinations, random drug tests, re-evaluation of medical records and medications, recurring psychological evaluations, and renewal of security clearances. Importantly, personnel reliability measures can help to reduce but cannot eliminate the risk of an insider threat.

Select agent research poses unique security challenges. Biological select agents are unlike nuclear and chemical surety material in fundamental ways that make them less-suited for traditional surety programs. First, most current biological select agents and toxins are naturally occurring and can be isolated from natural sources, such as endemic areas, soils; or infected hosts, well beyond the safe confines of laboratory walls.²² Consequently, even if the physical security of pathogens contained within research facilities could be fully guaranteed, these measures would at best only partially mitigate the overall risk of harmful application of these agents. Second, whereas nuclear and chemical materials exist in discrete quantities, most biological select agents are *living* organisms that can be grown into large quantities from a minimal starting sample, manipulated in non-laboratory settings, and disseminated. These attributes make attempts to maintain accurate inventories far more challenging.

Further distinguishing biological agents from nuclear or chemical surety material are the very natures of their respective research programs. The original PRPs were implemented for federal research programs that were “born classified” and applied to participants for whom strict security measures in the workplace were routine. Even PRPs that have been developed more recently for biological select agents have been implemented in facilities that already are more accustomed to more strict oversight by agencies that have unique research cultures, notably the U.S. Department of Energy (DOE) and Department of Defense (DoD), which stem from their long histories with surety programs. Conversely, virtually all research on biological select agents is unclassified,^{23, 24} and much of it is conducted in university settings that have a long history of

²² The disease smallpox has been eradicated in nature but the causative agent, variola virus, exists in two repositories as designated by the World Health Assembly under resolution WHA 33.4: the CDC, in Atlanta, Georgia, and the State Center of Virology and Biotechnology (VECTOR), in Kotsovo, Russia.

²³ The Department of Health and Human Services (HHS) is the largest provider of grants and contracts for select agent research and does not fund classified research. This research is aimed at developing vaccines, therapeutics, and diagnostics against diseases caused by bioterrorism agents to help first responders treat patients exposed to bioterrorism agents. See www3.niaid.nih.gov (accessed May 5, 2009) for more information about this research. In

openness, national and international collaboration, and ready sharing of research materials. This culture of openness has a long and fruitful history in academia that includes research on pathogens that only relatively recently have been designated “select agents.”

Mandating a national Personnel Reliability Program could have unintended consequences within the life sciences research community.

Although the risk of the insider threat is uncertain, it is very likely to be quite small based on history. Even in the open climate that is the hallmark of most life sciences research, the overwhelming majority of such research— including select agent research – has been conducted by responsible researchers toward commendable aims. The potential benefits of enhanced personnel reliability measures must be carefully weighed against the more likely negative consequences that such measures could have on the research community. A robust and agile research enterprise that comprises a diverse workforce, and spans government, private, and academic sectors provides innumerable benefits to society. The promulgation of additional reliability measures could serve as a powerful disincentive to those who wish to and would responsibly conduct research on select agents because the most talented young researchers, those with many options for research paths, may be far more likely to enter fields with less onerous regulatory requirements. Thus, a burdensome national personnel reliability program may not only drive scientists from important select agent research, but also drive select agent research out of academia and potentially out of the U.S. into countries with less stringent regulations.

Paradoxically, measures aimed at enhancing the biosecurity of select agent research could have the unintended consequence of actually decreasing national security if such measures diminished the capacity for the U.S. to prepare for, and respond to, emerging threats (including naturally occurring disease outbreaks as well as bioterrorism) by diminishing the U.S.’ ability to recruit top scientists and develop vaccines, treatments, and other countermeasures. Furthermore, the institution of reliability measures could isolate select agent researchers from the mainstream scientific community, and such isolation might increase the risk of the insider threat.

NSABB approach. To address its charge, the NSABB formed a Working Group on Personnel Reliability (see Appendix A). This group examined the current federal Select Agent Program as well as formal Personnel Reliability Programs that have been established for nuclear, chemical, and biological select agent research. It also was briefed on the following extant programs for ensuring reliability, including:

- HHS Select Agents Program;
- CDC intramural research program;
- DoD/Department of the Army Biological Personnel Reliability Program;
- DOE Select Agent Human Reliability Program;
- NIH Biological Surety Program for intramural research;
- Battelle Biomedical Research Center; and

addition, the USDA conducts research and develops countermeasures against plant and animal pathogens. Neither the USDA nor the National Science Foundation funds or conducts any classified work.

²⁴ The small fraction of individuals conducting classified research on select agents is subject to rigorous security and personnel reliability measures.

- Galveston National Lab (BSL-4 facility) at the University of Texas Medical Branch.

In addition, the Working Group consulted with:

- The intelligence community with regard to security clearances;
- Selected participants in the U.S. Government-World Health Organization International Roundtable on Dual Use Research (November 2008) on the topic of personnel reliability; and
- Experts in psychological and mental health assessments.

The group considered extant models and expert perspectives with particular interest in the costs, impacts, and effectiveness that such measures would have on the scientific enterprise, as well as the feasibility of their implementation nationally, in academic settings.

In addition, the NSABB solicited broad public input and stakeholder perspectives at the Public Consultation Meeting on Personnel Reliability held on April 3, 2009 (see Appendix C).

NSABB Findings:

During its deliberations, and broad public and expert consultations, the NSABB identified a number of important findings.

- 1. The select agent regulations have been appropriately and significantly strengthened since 2001 to include measures that address personnel reliability.** The current Select Agent Regulations are substantially different since the terrorist attacks and anthrax mailings of 2001. They have been expanded in scope to encompass possession and use, and include requirements for the registration of agents and toxins; designation of an institutional Responsible Official; implementation of security and safety measures to deter theft, loss, or release of select agents and toxins; training of staff; record keeping; and assessment of security risk for all individuals who request access to select agents and toxins.

Importantly, the requirement for a Security Risk Assessment (SRA) addresses many key aspects of personnel reliability. The SRA utilizes federal databases to learn an individual's possible criminal history and potential terrorist ties, and ascertain whether an individual falls into the restricted or prohibited categories described above. While the NSABB was initially concerned that, between SRA renewals, individuals with access to select agents could fall into a prohibited category (possibly for several years) without being detected,²⁵ it learned that not only is the FBI automatically notified when individuals with access to select agents are arrested, but that the FBI has recently begun periodically (~ 6 months) cross-checking the names of approved individuals with specified databases to identify if an individual with access to select agents slides into a restricted category between SRA renewals.

²⁵ Currently, an SRA is valid for five years unless otherwise terminated by the entity, CDC, or USDA. ROs, AROs, and individuals who own or control the entity must obtain SRA approval each time the select agent certificate of registration is renewed. Certificates of registration are valid for a maximum of three years.

- 2. Local institutions already screen individuals requiring access to select agents.** In most if not all institutions, an individual requiring access to select agents is pre-screened prior to hiring or prior to requesting an SRA. Data presented to the NSABB by the CDC demonstrate that fewer than 1% of applicants who submit to the SRA process have been determined to fall into restricted or prohibited category.²⁶ The extremely low rate of individuals who receive unfavorable SRAs suggests that unsuitable individuals are effectively “pre-screened” by the human resources departments and other hiring offices within institutions, are deemed inappropriate to have access to select agents by the institutional Responsible Official, or are deterred by the prospect of an SRA.

Moreover, most BSL-4 laboratories already implement reliability measures that go beyond the SRA if not formal PRPs. For example, the newly constructed Galveston National Laboratory, one of only two full suit BSL-4 facilities being operated in a non-federal setting, is developing a reliability program that would integrate reliability assessments by its departments of human resources and employee health, and its biosafety officer. Many BSL-3 laboratories also have enhanced safety and security measures as well as additional personnel training and monitoring requirements.

- 3. There is little evidence regarding the effectiveness and predictive value of personnel reliability measures with respect to their ability to identify individuals who may pose an insider threat.** In light of the NSABB’s first two findings, i.e., that the SRA has been strengthened and that local institutions appear to be doing an effective job screening individuals, the NSABB carefully considered and extensively debated whether additional reliability measures, or a formal national Personnel Reliability Program for select agent research, were appropriate. In this context, it carefully examined the numerous assessments that are employed by formal Personnel Reliability Programs, including extensive background investigations with interviews of character references, security clearances, medical evaluations including review of complete medical records, psychological testing, drug and alcohol testing, polygraph examinations, credit checks, comprehensive review of service and employment records, and provisions for ongoing monitoring.

As a prelude to identifying optimal features of a personnel reliability program, the NSABB identified a number of optimal personnel characteristics that underlie trustworthy, responsible behavior. It then sought to identify methodologies to assess these characteristics, especially those using the various assessments commonly utilized in PRPs. The optimal personnel characteristics were:

- Free of felony convictions;
- No domestic or international terrorist ties;
- No history of scientific or professional misconduct in the workplace;
- Emotional stability and capacity for sound judgment;

²⁶ Robbin S. Weyant and John Stovers, “NSABB Briefing: Security Risk Assessments for Possession, Use, and Transfer of Select Agents,” (presented at the NSABB Public Consultation on Personnel Reliability Among Individuals with Access to Select Agents, Bethesda, Maryland, United States of America, April 3, 2009), oba.od.nih.gov/biosecurity/meetings/200904/Weyant.pdf (accessed May 5, 2009).

- Positive attitude toward safety and security measures, and standard operating procedures; and
- Free of vulnerability to coercion.

The NSABB considers these to be reasonable characteristics for individuals with access to select agents and toxins. It found, however, that some of the characteristics were exceedingly difficult to measure in any objective way and that it was unclear whether these characteristics were suitable surrogates (or predictors) for not posing an insider threat. Furthermore, as it considered the potential utility of the various assessments commonly utilized in PRPs, it found little evidence to suggest that personnel reliability assessments going beyond the SRA and other institutional background checks that are already in place would correlate with, or effectively identify, an insider threat. In addition, as was the case with the optimal personnel characteristics, there were no objective criteria for translating the information gathered from a given assessment into a determination of reliability.

While the NSABB considered all of the commonly used personnel reliability assessments, it focused considerable attention on the three assessments common to most PRPs:

Psychological testing. In particular, the NSABB vigorously debated whether to recommend psychological assessments for individuals with access to select agents. These tests would largely aim to assess an individual's personality attributes and capacity for sound judgment and emotional stability. Such screening would entail the establishment of a psychological baseline for an individual and require questionnaire-based assessments, interviews and evaluations by trained professionals, and access to complete medical records. Such tests would need to be conducted periodically to identify significant changes in an individual's mental health. The strength of such psychological assessments is in their ability to identify major psychological disorders; however, their ability to identify more subtle deviations or concerns is more problematic. Moreover, identifying an individual with malevolent intent appears, if not impossible, at least extremely difficult.

These types of assessments appear to have value under certain circumstances, however. A battery of psychological tests often detects major mental illness, and some psychological profiling is conducted for certain elite military units.²⁷ Psychological tests are also routinely used as a component of the employment screening process in other high stress or security-related settings, such as for airline pilots²⁸ or within the nuclear industry. Indeed, some BSL-4 facilities require (or are considering) psychological assessments for their employees,²⁹ but

²⁷ Charles A. Morgan, III, "Psychological Assessment in the Selection of Personnel for Specialized Roles in Government: Where does it fit in? What role might it play?" (presented at the NSABB Public Consultation on Personnel Reliability Among Individuals with Access to Select Agents, Bethesda, Maryland, U.S.A., April 3, 2009), oba.od.nih.gov/biosecurity/meetings/200904/Morgan.pdf (accessed May 5, 2009).

²⁸ Jeff Baker, "Psychological Assessment," (presented at the NSABB Public Consultation on Personnel Reliability Among Individuals with Access to Select Agents, Bethesda, Maryland, U.S.A., April 3, 2009), oba.od.nih.gov/biosecurity/meetings/200904/Baker.pdf (accessed May 5, 2009).

²⁹ Stanley M. Lemon, "Managing Personnel Reliability at the Galveston National Laboratory University of Texas Medical Branch," (presented at the NSABB Public Consultation on Personnel Reliability Among Individuals with Access to Select Agents, Bethesda, Maryland, U.S.A., April 3, 2009), oba.od.nih.gov/biosecurity/meetings/200904/Lemon.pdf (accessed May 5, 2009).

individuals in these high-containment laboratories operate under severe, and often continual, pressure and stress, so these assessments are typically aimed at biosafety.

Additionally, psychological tests employed for the purpose of mitigating the insider threat (particularly in academia) would be extremely resource-intensive and they lack persuasive evidence for effectiveness or their predictive value. Moreover, most universities lack the appropriate program infrastructure to effectively implement these features or to deal with their associated legal and/or privacy concerns.

National security clearances. Some PRPs require individuals to obtain a national security clearance. A security clearance investigation examines an individual's possible criminal history and potential terrorist ties, but it also evaluates an individual's financial history, drug and alcohol use, personal conduct, psychological conditions, potential for foreign influence, and previous security violations or misuse of information technology. Such investigations allow considerably more latitude to investigate an individual's personal life, acquaintances, affiliations, business partners and other factors than PRPs that do not require a clearance.

In addition to assessing one's possible criminal history and terrorist ties (which are also addressed by the current SRA), security clearances attempt to identify factors that might make an individual vulnerable to coercion. However, not only is quantifying—or even describing—one's "vulnerability to coercion" exceedingly difficult, there are certain behaviors that might make an individual vulnerable to coercion, e.g., excessive debt, marital infidelity, or numerous foreign contacts, but none of these factors, either singly or in combination, necessarily indicate that an individual would be susceptible to coercion. Not only is the assessment of the factors that may contribute to an individual's vulnerability quite challenging but determining how these vulnerabilities translate into a security risk is inexact at best.

Short of national security clearances, which are expensive, typically take months to complete, and would likely serve as a major disincentive to researchers in the academic community, the NSABB considered individual components of a security clearance to assess one's vulnerability, such as credit checks. It concluded that, while an individual with large debt might be willing to provide access to select agents in exchange for financial consideration, and while credit checks are commonly employed and may already be conducted by some hiring offices, mandating credit checks as part of a larger reliability program for select agent research is problematic because there are no objective ways to translate the information into any meaningful measure of reliability. The types of individuals who conduct select agent research range from graduate students and post-doctoral trainees to laboratory technicians to tenured professors, all of whom are at different stages in their professional and personal lives. The variability in the financial histories of select agent researchers suggests that credit checks, as an assessment of vulnerability, are essentially meaningless. Moreover, state and local legislation may prohibit credit checks being used in the employment process.