

Mitigating Insider Threats through Strengthening Organizations' Culture of Biosafety, Biosecurity, and Responsible Conduct

Dana Perkins, PhD, U.S. Department of Health and Human Services,

and

Eilyn Fabregas, M.S., U.S. Department of Agriculture

- Co-Chairs, Federal Experts Security Advisory Panel Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences) -

This White Paper is submitted in response to the Call for White Papers issued by the National Academies of Sciences, Engineering, and Medicine's Board on Behavioral, Cognitive, and Sensory Sciences as a part of their decadal survey on social and behavioral sciences for national security. The purpose of this White Paper is to emphasize the need for closer engagement of Intelligence Community, life sciences, and social and behavioral sciences experts in developing an analytic framework for assessing the strength of an institutional culture of biosafety, biosecurity, and responsible conduct as an approach toward mitigating insider threats.

Radicalization into terrorism has been described as a quest for personal significance rooted in a group's or individual's belief system or ideology that condones or encourages violence and is fueled by various motives such as personal grievances, group pressure, devotion to a leader, or heavenly rewards¹.

In contrast, life scientists and medical professionals' quest for personal significance is often based on positive values such as doing good, helping others, being scientifically curious, and doing work that is socially and/or scientifically significant. These motives, beliefs, and values inform an individual's initial choice to pursue a life sciences or biomedical career, and shape future academic and career paths. It is unclear how this foundational belief system degenerates in those scientists or medical professionals who are radicalized into bioterrorism or biocrime.

The anthrax attack of 2001 was planned and executed by a government scientist with a career spanning 28 years. While the FBI deemed “Amerithrax” one of the “worst biological attacks in the US history”², it is just one of several examples of bioterrorism or biocrimes perpetrated by biomedical professionals^{3,4}. Notably, the anthrax attacks spurred behavioral analyses and initiatives to address insider threats by enhancing personnel reliability programs in life sciences laboratories. For instance, the *Final Report of the Amerithrax Expert Behavioral Analysis Panel*⁵ states that Dr. Ivins’s motives for perpetrating the anthrax attacks included “revenge, a desperate need for personal validation, career preservation and professional redemption, and loss”. The report describes how a culture of complacency about Dr. Ivins’s eccentric behavior combined with respect for his scientific achievements, leading to a failure of organizational checks and balances; moreover, “failures in supervision, documentation, and communication allowed Dr. Ivins to avoid scrutiny before and after the anthrax mailings”.

While the biological select agents and toxins (BSAT) regulations (including Security Risk Assessments and Personnel Reliability for Tier 1 agents) have been strengthened over the past decade, the unique security challenges posed by BSAT demand continuous vigilance and complementary non-regulatory measures. Such non-regulatory measures should be appropriate for the life sciences research environment, which is mostly unclassified and is driven by data and material sharing, national and international collaboration, and a history of openness.

In this context, the National Science Advisory Board for Biosecurity (NSABB) noted that although “persuasive evidence is lacking that PRP [Personnel Reliability Program] assessment instruments can effectively identify individuals who pose an insider threat, enhancing the culture of responsibility and accountability among individuals with access to select agents and toxins is a way to strengthen personnel reliability”⁶. The NSABB developed *Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility* that identifies several specific practices and approaches for enhancing the culture of reliability and accountability at the organizational level. The NSABB also set a proposed goal that at every institution conducting BSAT research “personnel approved for access to select agents and toxins are behaving in a responsible and trustworthy manner that upholds public health and safety, national security, and the integrity of the scientific enterprise”^{6,7}.

In 2014, the White House National Security Council tasked the Federal Experts Security Advisory Panel (FESAP, established by Executive Order 13546 in 2010) to undertake a comprehensive review and identify specific recommendations to strengthen the Government's biosafety and biosecurity practices and oversight of federally-funded activities involving (but not limited to) BSAT, consistent with the need to realize the public health and security benefits of such activities. While directed at the federal research system, the FESAP recommendations are broadly applicable to biological risk management practices in non-federal life sciences research, in the U.S. and abroad.

The FESAP recommended actions to strengthen and sustain the culture of biosafety, biosecurity, and the responsible conduct of science at the federal level, such as the promotion of bioethics training addressing the fundamental safety and security responsibilities expected of all life scientists; development and incorporation of bioethics modules into laboratory biosafety and laboratory biosecurity training and/or research design; and development of semi-quantitative methods to evaluate the efficacy of training, education, codes of conduct, and similar interventions to reduce risk and improve biosafety and biosecurity in domestic research laboratories housing infectious agents and toxins.

In order to advance the implementation of the FESAP's recommendation on the culture of biosafety, biosecurity, and responsible conduct of life sciences, the U.S. Government established an interagency working group with representation from fifteen offices and organizations across five federal departments and agencies. This interagency working group is co-chaired by the U.S. Department of Health and Human Services / Office of the Assistant Secretary for Preparedness and Response and the U.S. Department of Agriculture / Animal and Plant Health Inspection Service. The working group:

- Developed a working definition of a culture of biosafety, biosecurity, and responsible conduct in life sciences;
- Defined training goals and objectives;
- Identified federal and non-federal training resources (on biosafety, biosecurity, bioethics, and laboratory quality management systems) that included curricula on a culture of biosafety, biosecurity, and responsible conduct;

- Consulted with non-governmental experts from academia, professional organizations, and other practitioners on the best practices and modalities for incorporation of training and education of the culture of biosafety, biosecurity, and responsible conduct in life sciences into existing curricula;
- Developed guiding principles to promote a culture of biosafety, biosecurity, and responsible conduct in the life sciences to assist trainers and educators with integration of culture concepts into existing curricula of bioethics and laboratory quality management systems training, and to assist organizations aiming to develop guiding principles for communication and outreach, education and training, capacity development, and raising awareness of norms and standards;
- Conducted outreach by participating in conferences, publishing articles, and encouraging federal and non-federal stakeholders to promote the working group-developed culture concepts and associated materials on their websites and into their training or educational activities; and
- Developed instructional resources to assist trainers and educators in promoting a culture of biosafety, biosecurity, and responsible conduct (fact sheet, case studies, outreach template, bioethics and laboratory quality management system guiding principles, and a crossword puzzle)⁸.

The working group emphasized that regulations or guidelines alone cannot ensure safe, secure, and responsible practices in the laboratory. Building biosafety and biosecurity cultural competence will require achieving a congruent set of behaviors, attitudes, and policies that enable a person or an organization to work in a safe and secure manner with biological agents and toxins, and have a process by which individuals and organizations respond appropriately and effectively to biological hazards. Cultural competency will complement and reinforce the knowledge and skills acquired through biosafety and biosecurity training (including compliance with rules and regulations). Such competency depends on effective risk communication based on a desire to protect the health and safety of people and the environment while maintaining the public trust in the biomedical research enterprise.

Significant progress has been achieved by reaching an agreement on what culture is in the context of biosafety and biosecurity (i.e. “an assembly of beliefs, attitudes, and patterns of

behavior of individuals and organizations that can support, complement or enhance operating procedures, rules, and practices as well as professional standards and ethics designed to prevent the loss, theft, misuse, and diversion of biological agents, related materials, technology or equipment, and the unintentional or intentional exposure to (or release of) biological agents”).

However, the FESAP working group has yet to develop an analytic framework to evaluate the strength of culture at the institutional level, including semi-quantitative methods to evaluate the efficacy of training, education, codes of conduct, and similar biorisk/biothreat reduction interventions. While the working group identified elements of a culture of biosafety, biosecurity, and responsible conduct (i.e. management systems, behavior of leadership and personnel, principles for guiding decisions and behavior as they relate to biorisk management; and beliefs and attitudes on biosafety and biosecurity), a collaborative effort between life scientists, social and behavioral science experts and the intelligence community (IC) is needed to identify culture characteristics and indicators to ensure a systematic, competent, and consistent risk assessment and an analytic evaluation framework for institutional self-assessment (with or without external evaluation support).

Periodic evaluation of the strength of institutional culture will help organizations to identify early changes in attitudes, behavior and actions indicative of insider threats or malicious behavior and to manage stakeholders’ perceptions and expectations of safety and security. Without a systematic approach to evaluating organizational culture by establishing goalposts and performance-based standards, the process of strengthening the culture of biosafety, biosecurity, and responsible conduct will remain an ad-hoc activity and an elusive target.

Lapses in a culture of biosafety, biosecurity, and responsible conduct led to multiple laboratory incidents including shipment of improperly inactivated anthrax overseas. This incident triggered the Russian Federation’s assertion that the U.S. was in “grave violation” of Articles III and IV of the BWC (Biological Weapons Convention)”⁹ Arguably, the envisioned analytic framework for evaluation of culture at the institutional level may also come to be a tool that the IC may use to assess the strength of culture at foreign biological facilities and may serve as an aid to the overall assessment of other nations’ adherence to and compliance with international biological weapons nonproliferation agreements and commitments.

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