

Securing biological select agents and toxins will require developing a culture of trust

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The most effective way to prevent the deliberate misuse of biological select agents and toxins (BSATs) -- agents housed in laboratories across the U.S. considered to potentially pose a threat to human health -- is to instill a culture of trust and responsibility in the laboratory, says a new report from the National Research Council. Focusing on the laboratory environment will be critical for identifying and reducing concerns about facilities or personnel.

Mechanisms for fostering a safe and secure laboratory environment include engaged management, risk-based security measures, and appropriate monitoring and management of personnel, as well as training for all researchers in scientific ethics and understanding "dual-use" research that could be misused. Other methods of screening and oversight are incomplete without including the laboratory community in minimizing potential security risks, the report says. Policies and procedures that make select agent research more difficult to conduct, as opposed to more secure, diminish overall security rather than strengthen it.

Individuals cleared for access to select agents and toxins are certified for five years. Many changes can occur during this time, however, including those that impact whether an individual poses a security risk. Therefore, efforts to ensure reliable personnel should come from within the laboratories, the report says, through increased engagement and monitoring by managers and staff. The goal should be that individuals watch out for each other and take responsibility for their own

performance and that of others. In a laboratory context, some security measures can also improve safety, if there is involvement of researchers in the process.

BSAT research is presently defined by a list of more than 80 select agents and toxins, developed and jointly regulated by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS). According to the committee that wrote the report, the list should be ordered based on the potential of an agent to be used as a biothreat, and a graded series of security procedures should be applied so that the greatest resources and scrutiny go to securing agents that pose maximum risk.

Personnel issues are often the most controversial and difficult aspects of maintaining security for BSATs. Security programs can be generally divided into two categories: screening individuals to determine whether they are eligible for access, and monitoring the behavior and performance of employees working with these agents. The current Security Risk Assessment screening process, which relies on screening more than 20 criminal, immigration, and terrorist databases to identify disqualifying behavior or activities, is appropriate, the report says. However, a change that should be considered is expanding the appeal process beyond a simple determination of factual errors to include the opportunity to consider circumstances surrounding otherwise disqualifying factors, such as the length of time since an offense occurred. Currently, any discovery of disqualifying factors or behaviors automatically and permanently denies an individual's access.

Improved communication is needed among those funding research on select agents, those administering the Select Agent Program, and those conducting the research, the report says. An advisory committee with members drawn from research institutions and the private sector should be established to provide continued engagement of stakeholders.

Representatives from federal agencies would serve in an EX OFFICIO capacity. Rigorous and continuing evaluation of the Select Agent Program is needed to ensure that it is running efficiently and also to consider any intended and unintended consequences of operation.

The committee concludes that, because biological select agents can replicate, an undue reliance on accounting techniques, such as counting vials, to monitor whether a biological agent has been removed from a laboratory offers a false sense of security and is counterproductive. Instead, accountability is best achieved by controlling access to archived stocks and working materials and recording which agents are present, where they are stored, who has access to them, when that access is available, their intended use, and where they are transported, if moved to another off-site location.

Physical security is required of all facilities housing select agents, with broad regulatory guidance provided by CDC and APHIS. The variation in implementing these requirements and regulations can lead to inconsistencies and confusion as facility operators, contractors, and inspectors attempt to determine whether a facility has met the necessary security guidelines. The report calls upon the Select Agent Program to define minimum physical security requirements to assist facilities in meeting their regulatory obligations. The report also recommends laboratory inspectors have scientific and laboratory knowledge and experience, as well as appropriate training specific to BSAT research and that the inspections should be harmonized across agencies. Due to the considerable security and compliance costs involved in working with select agents, a separate category of federal funding should be made available to ensure that facilities always operate with appropriate security measures in place.

Source: National Academy of Sciences

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