Breach of Safety and Security in United states Government Institutions: How it Applies to Israel

Eitan Israeli PhD

Zabludowicz Center For Autoimmune Diseases, Sheba Medical Center, Tel Hashomer, Israel

KEY WORDS: biosafety, select agents, safe laboratory practice, biosafety level (BSL), contamination, safety breach

IMAJ 2015; 17: 316–317

Scientific research and development, as well as diagnostic procedures, involving high biohazard class organisms is a responsible and complicated mission. It calls for strict laboratory procedures in addition to safety and security rules. Institutions that work with dangerous organisms must abide by rules and regulations published by local health and safety organizations, and if not existing, by acceptable international bodies. In the United States, a law termed "Possession, Use, and Transfer of Select Agents and Toxins" regulates all aspects of this issue [1]. All scientific and industrial institutions must follow these directives. The main purpose of this law is to prevent "leakage" of organisms capable of serving as bio-terror weapons into the wrong hands. Called "The Select Agent Rule," it is a comprehensive law that also targets security of information. In 2008 Israel published a law for regulating research with infectious agents. The purpose and implementation of this law is similar to that in the U.S., and every institution in Israel – whether research, medical, diagnostic or industrial – must abide by its injunctions. A committee was appointed by the Minister of Health to lead and provide guidance for following the regulations, headed to date by Prof. Bracha Rager. It is crucial that all entities dealing with organisms on the "select agent" list be alert to breaches of safety and security in these regulations.

In recent months, the U.S. Centers for Disease Control and Prevention (CDC) announced the occurrence of three major incidents that raised concerns about the implementation of safety and security regulations within the CDC, the National Institutes of Health (NIH), and the Federal Drug Administration (FDA). These lapses of biosafety and biosecurity included the mishandling of *Bacillus anthracis* spores, the shipment of low pathogenic influenza virus unknowingly contaminated with a highly pathogenic avian strain, and an inventory lapse of hundreds of samples of biological agents including six vials of variola virus that were kept in a cold storage room for decades, unnoticed.

in this issue of *IMAJ* Weiss et al. [2] present the published data regarding these events, provide the CDC inquiry's main findings and discuss the main lessons to be taken for safer scientific practice in biomedical and microbiological services and research laboratories. Actions were taken in both the anthrax and the influenza laboratories.

In the anthrax lab these included:

- a moratorium on the movement (i.e., transfer inside or outside the agency) of biological materials from biosafety level (BSL) 3 or 4 facilities. The moratorium will remain in place pending lab-by-lab review of policies and procedures for laboratory safety and security
- the creation and appointment of a CDC Director of Laboratory Safety to serve as the single point of accountability to improve all laboratory safety protocols, practices and procedures
- establishment of an internal biosafety working group under the leadership of the CDC Director of Laboratory Safety
- establishment of an external group on biosafety comprising leading scientists and biosafety experts, which will advise the internal Biosafety Working Group
- in addition, the CDC provided the Animal and Plant Health Inspection Service with standard protocols for inactivation of anthrax as well as a plan outlining required refresher training of laboratory personnel with access to anthrax on the appropriate use of the inactivation protocol

In the influenza lab, the following steps were instituted:

- reviewing existing laboratory protocols and modifying them or developing new protocols to ensure consistency and that best laboratory protocols are used across Influenza Division laboratories
- developing better documentation processes that will improve record-keeping and compliance with protocols
- implementing standardized testing for cross-contamination of samples before they are transferred to other locations or to other laboratories within the CDC
- re-assessing current use of BSL-3 enhanced space to ensure that work done on select agents and non-select agents is separated by an appropriate amount of time to reduce the chances of cross-contamination
- identifying and closing gaps in existing skills and knowledge of laboratory staff and providing additional extensive training. This includes training to further clarify incidents that qualify as

reportable under select agent regulations and additional actions to be taken as needed.

It is crucial that the medical and scientific community in Israel take home the messages learned from these incidents, namely, the need for a biosafety management program, and fully implementing a culture of safety in order to prevent the reoccurrence of biosafety incidents. Laboratories must define compatible methods relevant to the biological agents used in its facilities, and adopt strict inactivation protocols. Transportation and shipment of any biological agent is extremely accident prone and therefore requires special attention. Cross-contamination of samples is a high risk factor in laboratories that utilize the same instruments and biosafety cabinets for multiple microorganisms or species with different pathogenicity. Biosafety programs must involve all management levels within the organization, especially the head of the pyramid.

Correspondence
Dr. E. Israeli
Zabludowicz Center For Autoimmune Diseases, Sheba Medical Center, Tel Hashomer 52621, Israel
email: eitanister@gmail.com

References

1. Department of Health and Human Services, Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review; Final Rule. 61084 Federal Register / Vol. 77, No. 194/ Friday, October 5, 2012 / Rules and Regulations
2. Weiss S, Yitzhaki S, Shapira SC. Lessons to be learned from recent biosafety incidents in the United States. *IMAJ* 2015; 17: 269-73.