



Laboratory Biosecurity: A Survey of the U.S. Bioscience Community

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Abstract

Laboratory biosecurity practices, or measures to prevent the theft or sabotage of biological research materials, must coexist with biosafety. Within the United States, laboratory biosecurity, for a list of select agents, has been regulated through several Codes of Federal Regulation. In 2004 and 2005, Sandia National Laboratories conducted a survey of the U.S. bioscience community in conjunction with Reed Research Group, to assess the extent biosecurity is implemented in laboratories and the relationship between biosecurity and biosafety and good laboratory practices in regulated select and non-select agent laboratories. This paper describes the results of this survey.

Introduction

In 1997, the first Select Agent Rule (42 CFR 73) went into effect, regulating the transfer of a small number of human pathogens. The United States significantly enhanced its regulatory approach for security of pathogens and toxins following the passage of the USA PATRIOT Act of 2001 and the Bioterrorism Preparedness Act of 2002. In February 2003, three interim Codes of Federal Regulations (CFRs) became effective which specified security measures for approximately 80 pathogens and toxins—now known as select agents—deemed to pose a threat to human (47 CFR 73), animal (9 CFR 121), or plant (7 CFR 331) populations. The regulations required any laboratory that possesses one of these agents or toxins to enforce and adhere to specific security measures, which include facility registration; designation of a responsible official; security risk assessments for individuals with access to the listed agents; laboratory biosecurity plans; agent transfer rules; safety and security training and inspections; notification after theft, loss, or release of a listed agent; record maintenance; and restrictions of certain experiments. The final rules, which replaced the interim regulations in March 2005, had only a few changes that impact the implementation of biosecurity at laboratories (CDC ABSA correspondence, 2005):

1. the term “access” is now defined as possession or the

ability to gain possession;

2. notification of when a toxin or select agent is destroyed after transfer is no longer required;

3. laboratories are no longer required to keep records of when individuals exit areas with select agents; and

4. new requirement that biosecurity, biosafety, and incident response plans be exercised at least annually.

Most of the other changes were intended to harmonize the structure and format of the HHS and USDA regulations.

The final CFRs define the regulatory requirements for laboratory biosecurity in the U.S.; however, facilities that do not work with select agents (SA) are not required to implement these rules. This paper describes the results of a survey of the bioscience community in the United States. The Sandia National Laboratories (SNL) Biosecurity Team had three main goals in conducting this survey: 1) to understand the real and perceived positive and negative impacts of the interim CFRs on those facilities that work with select agents (SA respondents); 2) to understand how those facilities have implemented the required biosecurity; and 3) to learn what types of biosecurity measures, if any, are in place at facilities that work with pathogens and toxins that are not select agents (non-SA respondents).

This paper details the responses of both SA and non-SA respondents about the biosecurity measures in place at their facilities. This paper also briefly addresses the impact of the interim CFRs on bioscience facilities. Additional details on the respondents' views of security of biological materials and the CFRs, positive and negative impacts of the CFRs, the inspection process, and the effect of the CFRs on domestic and international collaborations and recruitment of qualified individuals can be found in the survey data (available at www.biosecurity.sandia.gov/survey).

Survey Methodology

SNL worked with Reed Research Group (Reed Business Information, Newton, MA) to write and conduct a survey of the U.S. bioscience community. Reed used e-mail lists to solicit potential respondents who were then

directed to a web-based survey, and assisted SNL with refining the survey and collecting the first 222 responses. The SNL Biosecurity Team also collected additional data through a web-based version of the survey on its secure server. An additional 129 responses were received through the SNL web site. Responses to the survey on the SNL web site have been solicited through the posting of a link on the American Biological Safety Association (ABSA) web site and an announcement on the ABSA e-mail listserv. The SNL web-based survey was further publicized through presentations at the ABSA Annual Meeting in October 2004 and at a meeting sponsored by the Chemical and Biological Arms Control Institute and the International Institute for Strategic Studies in December 2004 (Rivera, 2004). The results presented in this paper reflect the aggregate responses from all of the above elicitation for a total of 351 respondents. This paper only discusses results received before March 2005 (prior to the issuing of the final CFRs). Unless otherwise stated, the given response percentages are based on the responses received to the specific questions.

Respondents were asked to answer the survey questions based on the following definitions of biosafety and biosecurity: Biosafety aims to reduce or eliminate exposure of individuals and the environment to potentially hazardous agents used in biological research, while biosecurity aims to protect dangerous pathogens and toxins, along with critical security-related information, from theft and sabotage by those who intend to pursue bioterrorism or biological weapons proliferation.

Results

A copy of the survey questions can be obtained from the SNL biosecurity web site (www.biosecurity.sandia.gov/survey). The site also has an Excel file with all of the survey responses (without identifying information) available for download. Survey responses represented a broad cross-section of bioscience institutions that work with select agents (180 SA respondents) and those that do not (171 non-SA respondents). According to Dr. Julie Gerberding's testimony to the U.S. Congress on July 28, 2005, there are currently 333 entities registered with the Select Agent and Toxins Program (Gerberding, 2005). Of the SA respondents to this survey, 48.9% represented universities, 8.3% represented clinical or diagnostic facilities, 13.9% represented industry, 22.2% represented government facilities, and 6.7% identified as other. Of the non-SA respondents, 37.4% represented universities, 24.6% represented clinical or diagnostic facilities, 23.4% represented industry, 7.6% represented government facilities, and 7% identified as other. The respondents were also asked to identify the principal activities of their laboratories; they could select more than one response so the percentages do not necessarily equal 100%. The principal

laboratory activities of the SA respondents were identified as basic research (57%), applied research (46%), and clinical or diagnostic work (33%), while the principal activities of non-SA respondents were clinical or diagnostic work (54%), basic research (39%), and applied research (31%).

All respondents were asked about their perceptions regarding the interim CFR. Thirty-one percent of non-SA and 19.4% of SA respondents answered that the interim CFR imposed prudent security measures. Ten percent of SA respondents and 7.6% of non-SA respondents believed the CFR were a good first step but didn't go far enough; more security was needed. Over 40% of non-SA respondents and 50% of SA respondents believed that the interim CFR were on the right track but needed to be revised to provide clarity. SA respondents generally agreed that the greatest positive impact of the CFR is the increased awareness of the risks posed by some pathogens and toxins. However, the time and effort required by staff to comply with the regulations, and the inconvenience of increased security were frequently cited as negative impacts. Very few SA respondents believed there were no positive (8%) or negative (5%) impacts associated with the interim CFR.

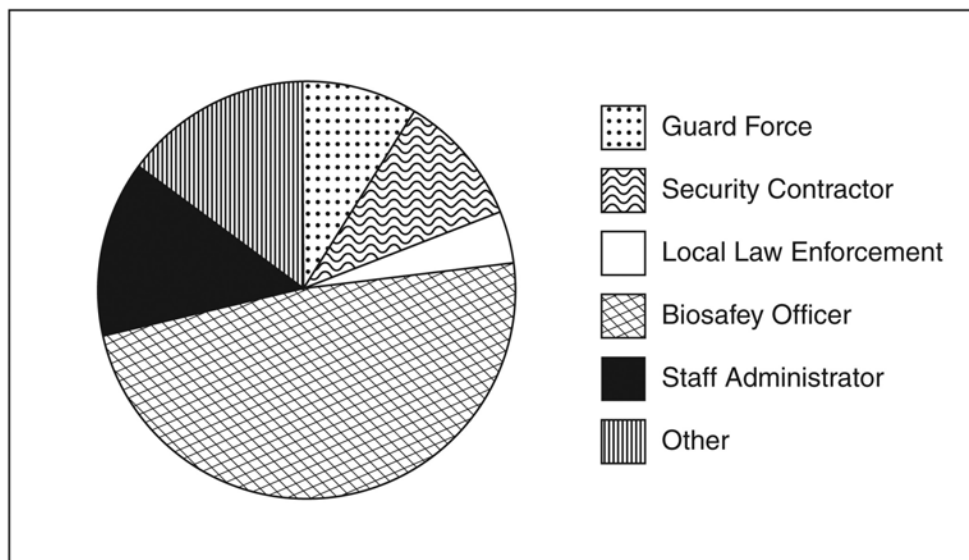
The distribution between those respondents responsible for ensuring implementation of biosecurity (biosafety officers and responsible officials), those most affected by biosecurity measures (scientists and technicians), and directors/managers was balanced. Of all survey respondents, 23.6% were biosafety officers, 9.4% were responsible officials, 16% were principal investigators, 12.3% were laboratory support staff/technicians, 27.6% were directors/managers, and 11% were identified as other.

A facility risk assessment is the foundation of a good biosecurity program and this is acknowledged in the CFRs: "The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use." Almost half of all SA respondents (48.4%) indicated that their facility's biosafety officer conducted the risk assessment. Other facilities used multiple types of personnel to carry out the risk assessment (Figure 1) including security contractors (9.9%), local guard force (4.2%), and staff administrators (13.5%).

Management is responsible for implementing and overseeing a biosecurity program. Program management responsibilities include identifying the protection objectives, designing the security system, writing security and emergency response plans, conducting regular training and internal reviews, and allocating resources. Respondents were asked to identify what assets their security is designed to protect, people, property, or specifically pathogens and toxins. Of all SA respondents, 79% indicated that they have a security posture designed to protect

Figure 1

Who conducted the risk assessment (SA respondents)?



people, 76% have a security posture designed to protect property, and 74% have a posture designed to specifically protect pathogens and toxins. In contrast, only a small number of the non-SA respondents have a security posture designed to protect people (14%), property (14.6%), or pathogens and toxins (10%). However, the question about the security posture had a low response rate (<40%) among non-SA respondents, suggesting that perhaps these respondents were not familiar with the rationale for their institutions' security.

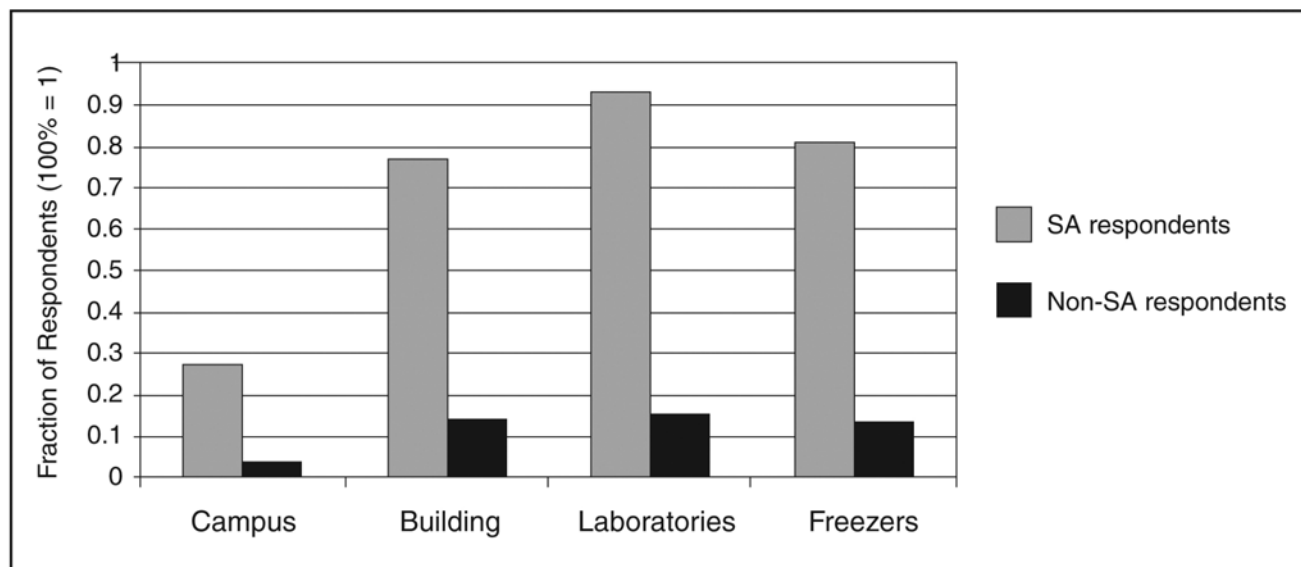
Security planning and training were other areas explored in the survey. Even though the CFRs specifically require a written security plan, only 67% of SA respondents indicated they had a written plan. Of the non-SA respondents who implement biosecurity, 39.8% had a written security plan. Biosafety training is conducted at most facilities (95% of SA and 83% of non-SA), while biosecurity training is less common at both SA facilities (72.2%) and non-SA facilities (32.7%). We anticipated that few of the non-SA respondents would have biosecurity-specific training but it is surprising that not all of the SA facilities provide such training, especially since the CFRs require biosecurity training on an annual basis for all individuals with authorized access to select agents.

Standard elements of a biosecurity program include physical security (including access controls), personnel screening, material control and accountability measures (including inventories), transport security, and information security. As specified by the CFRs, these elements should be implemented in a graded manner based on the risk assessment. Access controls are typically considered to be an element of physical security. The CFRs require

facilities to limit unescorted access to only those who have been authorized to work with specific select agents by either the Centers for Disease Control and Prevention (CDC) or the Animal and Plant Health Inspection Service (APHIS). This authorization is predicated on the successful completion of a security risk assessment process that is conducted by the U.S. Federal Bureau of Investigations (FBI). Almost all of the SA respondents indicated that access is controlled to their SA laboratories (Figure 2). Most of their facilities also control access to buildings and freezers. In contrast, few non-SA respondents claim to limit access to their buildings, laboratories, or freezers. The types of access controls that are commonly in place at SA facilities include: electronic access controls (81%), such as a badge swipe, proximity card, or personal identification number; guard identification (41%); and mechanical lock and key (52%). Biometric access controls, including retinal/eye scanners and fingerprint or hand-geometry readers, are only employed by 14% of SA facilities. In contrast, non-SA respondents indicated that their facilities relied more heavily on less sophisticated mechanisms to control access: 55% used mechanical keys and locks and 27.6% relied on guards to control access, while only 6.5% implemented electronic access controls and 4.6% used biometric access controls.

SA facilities handle access in emergency situations by different mechanisms. A few SA facilities reported they allow emergency workers to override the access controls (14.1%), some indicated emergency workers can override those controls while under the escort of an authorized person or after receiving permission from the institution (43.4%), and some stated they do not allow emergency

Figure 2
Areas of controlled access for SA and Non-SA respondents.



workers to override the access controls at all (42.5%). The survey questions did not provide any insight into the emergency response protocols of those facilities that do not allow emergency override of the access controls.

Many respondents also stated that they controlled access to freezers where select agents are stored. SA respondents generally controlled access to freezers by mechanical key and lock (70%), but many used electronic access controls (18.9%). Most non-SA respondents who controlled access to their freezers used mechanical key and lock (39.4%).

Escorting is a standard means to provide security when visitors and other unauthorized personnel need access to controlled areas. Eighty-nine percent of the SA respondents and 80% of non-SA respondents required visitors to be escorted. Nearly three-quarters of the respondents recognized that escorting contributes to both biosecurity and biosafety at their facilities (74% of SA respondents and 71% of non-SA respondents).

Identification badges are a common method for identifying individuals who work at a particular institution or who have authorized access to a specific area within an institution. Badges can also be used as a type of key, providing access into areas controlled by electronic access control systems. Nearly three-quarters (73%) of SA respondents' facilities reported they require badges to be worn in the laboratories, except for biosafety considerations. Fifty-nine percent of non-SA respondents' facilities indicated that they require badges to be worn in the laboratories. Badges were most often required to be worn at SA government institutions (93.3%), followed by clinical and diagnostic institutions (86.7%), industrial facilities

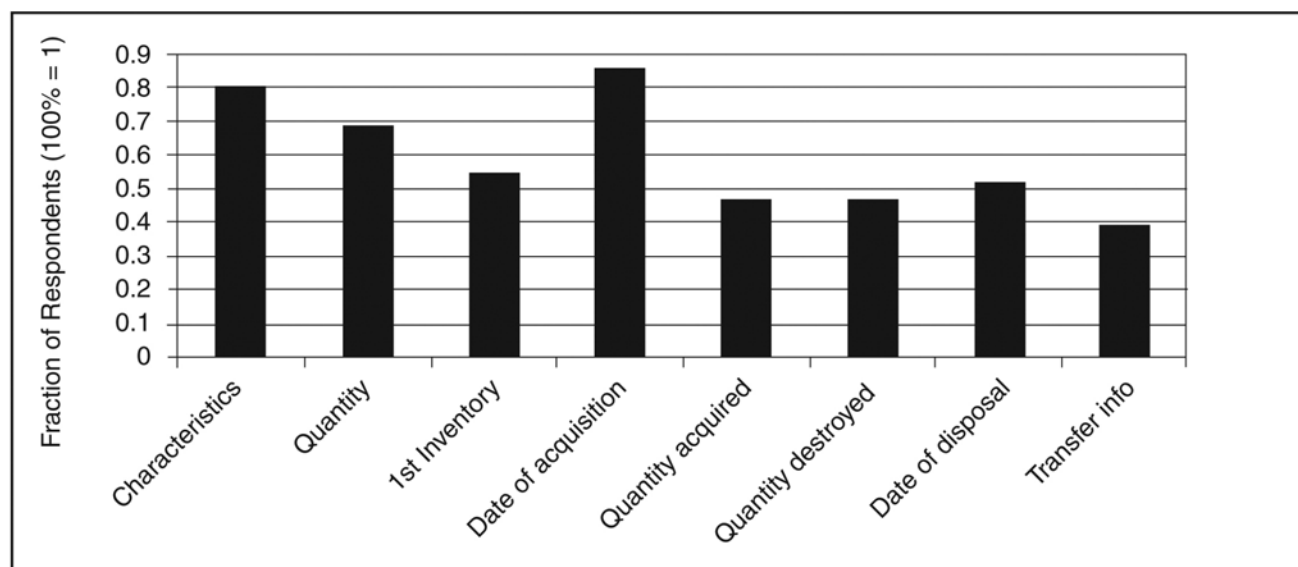
(65.4%), and universities (61.4%).

Inventory systems, a measure that helps with material control and accountability, provide a mechanism for knowing what materials are stored and handled at a facility. Inventories are good laboratory practice and serve both biosafety and biosecurity goals. A majority of the SA respondents (65%) indicated they inventory select agents differently than non-select agents at their facilities. Approximately three-quarters of the SA respondents had inventories that track select agents in seed stocks and working stocks but only 26% track animals. Nearly three-quarters of the SA respondents tracked select agent materials by vials while 37% tracked Petri dishes and only 26% tracked animals. The majority of non-SA respondents also used their inventories to track seed stocks (73%) and working stocks (64%).

The CFRs require select agent facilities to include specific information in their inventory records for select agents that are held in long-term storage, including the name and characteristics (e.g., strain designation); quantity acquired (e.g., number of vials); date of acquisition; source; storage location; when moved from storage and by whom; when returned to storage and by whom; and, for toxins, quantity amount (e.g., milligrams). The interim CFRs also required information on disposal (date of disposal and quantity, volume, or mass destroyed or otherwise disposed of). The SNL Biosecurity Team wanted to understand how many of these inventory criteria are common laboratory practice, therefore the non-SA respondents were asked which type of information is tracked in their inventory systems. All of the inventory information required by the CFRs was reported to be

Figure 3

Information collected in inventories of non-SA respondents.



included in inventories of at least 40% of the non-SA respondents (Figure 3). This demonstrates, for inventory issues, the CFRs appear to be capturing standard laboratory practices.

Inventory systems can take many forms; they can be paper-based or electronic systems. Over 63% of all SA respondents maintained a paper-based inventory, such as log books, and approximately two-thirds utilized either electronic spreadsheets or electronic databases for inventory records. The percentages do not sum to 100% because many institutions used multiple inventory methods. The final CFRs require that “the individual or entity must implement a system to ensure that all records and databases created under this part are accurate, have controlled access, and that their authenticity may be verified.” The SNL Biosecurity Team’s survey responses were based on only the interim CFRs, which did not include a requirement for controlling access to records, such as inventories. Although access control was not a requirement of the CFRs, the survey did explore who had access to inventory records. Only 63% of the principal investigators (PIs) at SA facilities and 32% of the PIs at non-SA facilities had access to the inventory records. This is surprisingly low and may be due to a misinterpretation of the question by the respondents. The SNL Biosecurity Team anticipated a much higher percentage of PIs would have access to the inventory records since they would be responsible for maintaining the inventory of materials in their individual laboratories. Approximately 58% of biosafety officers and responsible officials at SA facilities also had access to the inventory records. In contrast, only 35% of biosafety officers at the non-SA facilities had such ac-

cess. Only 2.2% of SA respondents did not limit access to these records, allowing anyone to access their inventories.

Conclusions

Approximately half of the respondents (181) identified themselves as Select Agent respondents, or respondents who work with or oversee research with select agents. Only 2.3% of all respondents answered the “security of pathogens and toxins is unnecessary,” implying that over 97% believe that security of pathogens and toxins is needed. This strong consensus about the need for biosecurity of pathogens and toxins provides a positive starting point for policy makers and those who must implement. Such community “buy-in” is essential for effective implementation of biosecurity. However, the support for the rationale of biosecurity does not necessarily translate to the “how” of biosecurity. The Office of Health and Safety of the Centers for Disease Control and Prevention has provided some initial guidance on implementing biosecurity; this report stressed that the “security plan should be an integral part of daily operations” (Richmond, 2002). For modern laboratories, biosafety and biosecurity jointly define the laboratory operating environment (Gaudioso, 2006) so it is critical to carefully plan the implementation of biosecurity to avoid conflicts with biosafety. The impacted community (e.g., scientists) will be less likely to comply with biosecurity measures that jeopardize or are perceived to jeopardize their safety.

The details highlight differences in the security postures between research institutes that work with select

agents and those that do not. For instance, the CFRs require access controls to select agent laboratories, and 85% of SA respondents reported they control access to their laboratories. Surprisingly, very few non-SA respondents reported use of access controls for the building (outside doors) or laboratory at their facilities. The survey results also indicated several areas of incomplete compliance with the CFRs by SA respondents. For instance, more than 30% of those respondents lack a written biosecurity plan. In contrast, the survey results suggest that inventory practices required by the CFRs are widely implemented in non-SA laboratories. Personnel security measures, such as escorting procedures and badges, are also used in both SA and non-SA facilities.

Biosecurity measures that are standard laboratory practice (as indicated by measures in place at non-SA facilities) may have greater community acceptance. However, successful implementation of biosecurity will require time since, as one respondent indicated, it requires adaptation, especially in settings “where a culture of free and open access exists. Some measures of biosecurity require a significant paradigm shift.” Many respondents recognized, “it’s important to involve safety, law enforcement, and researchers into the process of security plan development. Each group brings a unique perspective to the table.” Despite this recognition, implementation of biosecurity, including the facility risk assessment, is often the responsibility of the institution’s biosafety officer. Thus, it is imperative that more detailed technical guidance be provided to these individuals. The results of the survey provide a foundation for understanding the prospects of successful implementation of biosecurity measures, both domestically and internationally.

Authors’ Note

This work was created under U.S. Government contract by employees of Sandia National Laboratories as part of their official duties. The U.S. Government retains non-exclusive rights to use the work.

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