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This issue of *The CIP Report* analyzes the challenges that surround laboratory biosafety and biosecurity practices. The successful application of these elements is essential to protecting global public health.

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First, we provide a brief overview of laboratory biosafety and biosecurity. This article supplies the background information for further comprehensive analysis. Dr. Kavita Berger, the Project Director of the Center for Science, Technology, and Security Policy at the American Association for the Advancement of Science (AAAS), explores the effects of biosecurity regulations on biological scientific research. Christina Z. Thompson, Past-President of the American Biological Safety Association (ABSA), expands upon ABSA's comments to the Working Group on Strengthening Biosecurity within the United States. The Working Group, which was established by Executive Order 13486, held a public meeting in May 2009 to discuss biosafety and biosecurity related issues. The Medical and Public Health Senior Program Director at the Center for Infrastructure Protection, Dr. Donald F. Thompson, presents working hypotheses for biosafety and biosecurity reform.

This month's *Legal Insights* examines the past, present, and future of biosecurity regulations in the United States. Finally, we provide information about the new Biomedical Research Laboratory (BRL) at George Mason University.

We hope you enjoy this issue of *The CIP Report* as well as find it useful and informative. If you have ideas on how we can improve this publication, please let us know. Thank you for reviewing this newsletter and we very much appreciate your feedback.

Respectfully,

Mick Kicklighter
Director, CIP
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An Overview of Biosafety and Biosecurity

by Donald F. Thompson
Senior Medical and Public Health Program Director, CIP
& Staff

Introduction

The threat of bioterrorism, the deliberate release of disease-causing biological agents or toxins, has plagued civilizations for centuries. One of the earliest examples of biological warfare is the hurling of plague infected corpses into the Genoese city of Caffa by Tartar armies in 1346.[1] However, only within the past two decades has a succession of significant events demonstrated the need to more effectively protect against biological weapons. First, Kanatjan Alibekov, a microbiologist and physician from the Soviet Union, defected to the United States in 1992 and revealed the extent of the Soviet- sponsored clandestine biological weapons program. The Biopreparat program commenced operation in 1972 and remained in operation until at least 1992. Second, in 1995, Larry Wayne Harris, an Ohio microbiologist with ties to the Aryan Nations terrorist group, was able to purchase three vials of *Yersinia pestis*, the causative agent of the plague. This incident highlighted the lack of substantive law in the regulation of the possession, use, and transfer of potentially dangerous pathogens.

Congress attempted to close this gap through implementation of the Anti-Terrorism and Effective Death Penalty Act of 1996. This legislation resulted in the establishment of a system that is presently referred to as the Select Agent Program and is more fully described below. The events of September 11, 2001, and the subsequent anthrax attacks led to the USA PATRIOT Act and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. These laws were passed to improve protections against domestic and international terrorism, and included measures that strengthened the Select Agent Program. However, since the enactment of these laws, concerns have been raised by the scientific community that some of the security measures within the Select Agent Program have led to incongruence between laboratory safety and effective biosecurity and consequently, the hampering of scientific research by excessive emphasis on security measures within laboratories. Laboratory biosafety practices have been in place for decades to protect laboratory workers from occupational exposure to pathogens, and to protect the public from accidental release of these pathogens into the environment. Additional security measures that protect from insider and external threats are appropriate, but need to be developed and implemented in concert with existing laboratory biosafety measures, so safe and secure scientific research, public health emergency response, and clinical and industrial laboratory work may continue.

The Evolution of Definitions

Over the past 15 years, the terms laboratory biosafety and biosecurity have often been used interchangeably in the United States. However, while the two terms are complimentary, both are distinctly defined. Further confusion stems from different definitions used by the United States and international organizations.

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) publish the *Biosafety in Microbiological and Biomedical Laboratories* manual (BMBL). The most recent fifth edition defines biosafety as, *the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials.* Similarly, the World Health Organization (WHO) *Laboratory Biosafety Manual, Third Edition,* defines laboratory biosafety as, *the containment principles, technologies*

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[1] The Borden Institute, *Medical Aspects of Biological Warfare* (2007).

Overview *(Cont. from 2)*

and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release. The similarity of the domestic and international definitions suggests a universal acceptance of the fundamental practices of laboratory biosafety.

In contrast, the term biosecurity is defined differently by domestic and international sources. The BMBL defines the term biosecurity as, *the discipline addressing the security of microbiological agents and toxins and the threats posed to human and animal, health, the environment, and the economy by deliberate misuse or release.* The *WHO Biorisk Management: Laboratory Biosecurity Guidance* refers to laboratory biosecurity as, *the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.* It should be noted that this international definition uses the expression *laboratory biosecurity* in an effort to correlate biosafety and biosecurity practices and to separate biosecurity in laboratory environments from biosecurity in agricultural, ecological, and arms control environments. According to the WHO, efficient laboratory biosafety is the basis for effective laboratory biosecurity. Therefore, it is imperative to intertwine the two practices.

Laboratory Biosafety

Since the mid-twentieth century, laboratory biosafety practices have been developed to protect laboratory researchers and the public from unintentional exposure and/or release of infectious materials. These practices have been refined and institutionalized in training manuals, didactic training, and meetings such as the Annual Biological Safety Conference, and have been effective in protecting the laboratory worker while preserving scientific research. However, with the added presence of a culture of biosecurity, concerns have been raised about the sufficiency of laboratory biosafety practices, appropriate federal government oversight, and the new challenges from advancements in biotechnology. Additional complications have surfaced due to several high-profile laboratory incidents, where accidental exposures to infectious pathogens went unreported to federal authorities. Furthermore, the proliferation of high-containment laboratories (biosafety level-3 or biosafety level-4. See Biosafety Levels, page 12), the lack of key security controls at two of five operational BSL-4 laboratories, and the immense capabilities of genetic engineering give pause when biosafety and biosecurity efforts are considered. These challenges have led to a federal assessment of laboratory biosafety training, investigation of the physical security of laboratory facilities, including laboratory inspections and transportation of biological materials, and explorations of some of the issues associated with dual use research, where legitimate biological research is misused by persons with nefarious intent. Scientists are encouraging the optimization of existing laboratory biosafety training programs that allow for flexibility in training to avoid a mandated "one size fits all" approach. The American Association for the Advancement of Science thoroughly evaluated laboratory biosafety training reform in the report, *Biological Safety Training Programs as a Component of Personnel Reliability.* Concerns about physical security at laboratory facilities have incited spirited discussions about laboratory inspections and transportation of biological materials. Many facilities, particularly those that endure multiple inspections from multiple agencies, are calling for enhanced coordination between the different inspecting agencies and improved training for inspectors to avoid redundant or overwhelming financial penalties. Transportation regulations in place already discourage commercial carriers from transporting biological materials, and regulations under consideration are perceived to be more onerous. Finally, advancements in biotechnology have made it easier to synthesize new biological compounds and genetically modify existing pathogens, so additional security measures are needed that properly manage risks associated with such scientific advancement. These issues are more comprehensively described in later articles throughout *The CIP Report*.

Biosecurity and the Select Agent Program

The national and international security events that occurred in the

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The Broader Effects of Biosecurity Regulations

by Kavita M. Berger, Ph.D.
Project Director, Center for Science, Technology, and Security Policy
American Association for the Advancement of Science

The biological sciences contribute to society in many beneficial ways. Advances in biology and biotechnologies have significantly improved science, medicine, agriculture, economies, and most recently, energy. Since the 1990s, however, security experts have become so concerned about the use of biotechnologies to create weapons and the use of infectious agents as weapons that various governmental and international bodies have imposed restrictive regulations on biological research and/or considered policies to minimize the potential security risks of the research and technologies. To many, these regulations and policy discussions are very narrowly focused and do not affect the greater biological sciences research enterprise. Simply put, this is not true. Research institutions have incurred significant financial and administrative burdens for ensuring compliance with current regulations for restricting access to dangerous pathogens. There are anecdotal reports indicating that international collaboration and research conduct have been negatively affected by the select agent regulations. In fact, some in the global health arena suggest that the regulations pose huge barriers to information and isolate sharing with American laboratories. Whether these challenges result from perception issues or the regulations themselves, health and science research and diplomacy appear to be adversely affected.

Events starting in the mid-1990s have altered the American biological research enterprise forever. Three notable events occurred during this time that catalyzed this change. First, the infamous Japanese cult, Aum Shinrikyo, successfully disseminated sarin gas in a Tokyo subway station. This event succeeded a series of failed attempts at acquiring Ebola virus from African villages during an active outbreak and lethal anthrax bacteria from an academic colleague. Although their attempts to acquire dangerous infectious agents failed, they were successful at disseminating the vaccine strain of anthrax bacteria from their office building in Tokyo. The second event was the Oklahoma City bombing, which prompted officials within the United States to become concerned about domestic terrorist activities. The third event occurred when an Aryan Nations member, Larry Wayne Harris, acquired plague bacteria under false pretenses from the American Type Tissue Collection. At the time, there were no laws or regulations in place that monitored or secured dangerous pathogens, therefore Harris was charged with mail fraud. The result of these events was the creation of the Select Agent Program, which placed controls on transportation of dangerous pathogens and created a heightened interest in preparing for a biological attack. The 2001 terrorist attacks left the United States and global community in a state of fear over terrorism and increased awareness of the possibility that biological advancements could facilitate development of biological weapons and the potential for theft of dangerous pathogens (namely those restricted by the Select Agent Program) from research facilities. The result was increased emphasis on bioterrorism preparedness, limiting access to select agents, and initiating policy discussions on the security risks of advancing biotechnologies.

Almost concurrently with the events of 2001, a few members of the scientific community began considering the potential risks of biotechnology advancements. Scientific papers describing the *de novo* synthesis of poliovirus and a bacteriophage, use of immunomodulatory proteins to alter the potency of a vaccine, and functionally testing virulence genes of dangerous pathogens incited fear in the security community that biological research could be misused to cause harm. A National Academies committee coined the

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Regulations *(Cont. from 4)*

term 'dual use dilemma' to describe legitimate biological research that could be misused by ill-intended individuals for harmful purposes. As a result of the committee's report, *Biotechnology Research in an Age of Terrorism*, the United States government established the National Science Advisory Board for Biosecurity (NSABB). Since 2004, the NSABB has been deliberating and considering policies and activities for defining and overseeing dual use research of concern. In addition, they have been asked to provide policy recommendations on synthetic biology (use of synthetic genetic materials to create new biological systems) and personnel reliability (vetting of personnel seeking access to dangerous pathogens on the select agent list).

Since the beginning of this year, the United States government has been deliberating oversight of select agent research, high-containment laboratories, and personnel reliability. Resulting from a Presidential Executive Order on Strengthening Laboratory Biosecurity (Executive Order 13486), an interagency working group, chaired by the Departments of Health and Human Services and Defense, has spent the past few months reviewing all laws, regulations, and policies regarding select agent research, transportation, and oversight. Contributing to this review, the NSABB released their recommendations for personnel reliability. Later this year, the National Academies will release their report on personnel reliability. The interagency working group report was submitted to the White House on July 9, 2009 for approval. In the Congress, the Select Agent Program and Biosafety Improvement Act was introduced in the House and Senate in February 2009. Following the Commission on Prevention of Weapons of Mass Destruction Proliferation and Terrorism report, *World at Risk*, and subsequent hearing, Senators Lieberman and Collins indicated their interest in establishing an overarching oversight system and mechanism for securing high-containment laboratories. Introduction of their bill is expected within the next few weeks.

For many, these issues seem remote to every-day biology. However, implementation of existing and proposed laws and regulations may greatly impact national security, education, public health, and the biological research in the United States and internationally. Research institutes must comply with many federal, state, local, and international laws and regulations. Measures taken to prevent theft of dangerous pathogens or misuse of biological research, knowledge, and materials are a small portion of the laws, regulations, and guidance with which institutions must comply. The financial and time costs associated with being in compliance with the select agent regulations, for example, impacts other institutional activities. Operating costs for high-containment laboratories (biosafety levels 3 and 4) range from $5,000 to $50,000 per day without active research. In addition, the average cost for training laboratory researchers about biosafety principles and competency in the laboratory varies from $4,000-$7,000, and costs for biosafety training range from hundreds of dollars to $4,000. While few grants do provide direct funding mechanism provided to entities for building, operating, and maintaining facilities and screening, training, and re-training personnel, most do not. If these costs come out of general institutional or indirect costs, institutions may have to downsize or cut other research activities, educational, extracurricular, or other mission-associated activities to have funds available to comply with the select agent regulations. The overall impact to other activities depends on the size of the institution's select agent program, including the number of projects being conducted, the number of personnel seeking access to select agents, the funding mechanism, and the laboratory facilities. In many cases, the cost of compliance with the Select Agent Program is not proportional to the size of the program — the financial costs exceed the proportional amount for a small program. There have been, however, research institutions that choose not to conduct any select agent research because of financial and time burdens. Since many select agents are natural threats to human, animal, and plant health and a select few are top security threats, abandoning research on select agents could harm public health efforts, agricultural needs, and/or national security.

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ABSA Comments to the Working Group on Strengthening the Biosecurity of the United States

by Christina Z. Thompson, ABSA Past-President

On January 9, 2009, President Bush signed Executive Order 13486 to establish a working group on strengthening the biosecurity of the United States (Federal Register, Vol. 74, No. 9, January 14, 2009). The working group was composed of representatives from various government agencies with an interest in biological safety and security in our nation's laboratories. The working group was to:

"…review and evaluate the efficiency and effectiveness, with respect to Federal and nonfederal facilities that conduct research on, manage clinical trials or environmental laboratory operations involving, or handle, store, or transport biological select agents and toxins, of the following: (i) existing laws, regulations, and guidance with respect to physical, facility, and personnel security and assurance; and (ii) practices with respect to physical, facility, and personnel security and assurance…"

This working group was created despite the establishment of the Trans-Federal Task Force on Optimizing Biosafety Oversight, which met throughout 2008 and held a public consultation meeting in December 2008. The Working Group on Strengthening Biosecurity held a public meeting May 13 – 14, 2009 in Bethesda, Maryland. The American Biological Safety Association (ABSA) and several of its members representing their individual institutions were invited to participate in several of the panel discussions held at the public meeting. Following the meeting, all participants were invited to submit written comments to the Working Group. The ABSA Council prepared the following comments to the Working Group on each of the panel discussions.

Panel I: Select Agent Regulations

ABSA believes that the current Select Agent Regulations are sufficiently rigorous and effective. They should not be made more prescriptive. Measures used by the research community to safely work with and contain biological materials also inherently enhance the security of those materials. The list of select agents should be reviewed and revised with advice from the scientific community. This list should focus on the organisms most likely to be used as agents of bioterrorism or as biological weapons.

The topic of inventories should be revisited by the Select Agent Programs. Counting vials or volumes of a culture that can be grown overnight to exponentially increase the number of vials or the volume makes an inventory meaningless.

Panel II: Physical/Facility Security at Select Agent Program Entities

The Federal government absolutely should not develop prescriptive physical security requirements. This could inhibit or prevent much important microbiological research. Each entity must develop and implement security measures based upon their individual risk assessments, physical facilities, and operations. Stratification of select agents is of no value; each entity must develop site-specific written security, biosafety, and incident response plans.

Panel III: Oversight and Inspection of Select Agent Facilities

Inspections under the Select Agent Program could benefit by careful selection and training of inspectors to assure consistency across the country. Some inspections have enhanced biosafety and biosecurity at entities with select agent programs while some entities report unproductive requests by inspectors for additional enhancements with limited contribution to safety and security and not predicated on evidence-based risks. Many institutions have multiple inspections from several different agencies. An effort should be made by agencies to coordinate such inspections with each other to

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Working Group *(Cont. from 6)*

reduce disruptions and the administrative burden on institutions. In addition, there is a need for harmonization of inspections and interpretations across all agencies.

Panel IV: Transportation of Select Agents

ABSA and the transportation community are unaware of security problems with the transport of select agents under the current International Air Transport Association (IATA) and Department of Transportation (DOT) regulations. The transport requirements for select agents in most cases cause them to be shipped as Category A Infectious Substances, with the appropriate packaging and labeling prescribed by the regulations. Packages containing select agents should most certainly **not** be labeled differently than other infectious agents, due to security concerns. A registration program for carriers is likely to deter carriers from accepting Category A substances for transport, as it is already difficult to find carriers who transport Category A, especially internationally. Carriers have a system for security approval under the security risk assessment (SRA), so they do not need an additional security review and approval. Additional restrictions on shipping will inhibit important research and has already caused barriers to the transport of samples for diagnosis (e.g., samples for H1N1 analysis from Mexico had to be shipped to Canada because the United States import and shipping regulations were excessively restrictive).

There are no current regulations for plant pathogens; they are not regulated by IATA/ International Civil Aviation Organization (ICAO) or DOT for transit. Improper packaging and handling of plant pathogens could present a risk to the United States agricultural community, and therefore our economy.

The approval to transport select agents is well controlled by both the CDC and APHIS. Form 2 must be approved prior to shipping an agent. Form 2 allows the CDC and APHIS to confirm that both the Recipient and Sender entities and individuals are approved for the select agent(s) to be shipped. This approval process has worked very well since it was instituted in 2003.

Panel V: Personnel Security/ Reliability Programs

Existing personnel reliability programs used in other industries should not be applied to all select agent research. This would only serve to deter qualified scientists from pursuing important research on select agents. The "two person rule" must not be applied universally to select agent research; it would significantly inhibit or prohibit research at biosafety level 3 (BSL-3) in academic institutions. It must be determined by entities on an individual basis after appropriate risk assessments whether it is necessary to require a "two-person rule." ABSA strongly recommends that this working group adopt the recommendations of the NSABB personnel reliability working group.

Panel VI: Culture of Security and Responsibility and Training Programs

A culture of responsibility has existed in containment laboratories in the United States for decades. Federal funds could best be used to develop or enhance existing biosafety and biosecurity training programs offered by a number of organizations. Federal funds should also be used to help develop biosafety/biosecurity curricula at the baccalaureate and post baccalaureate levels in universities. The sharing of best practices and lessons learned must be encouraged and enabled in a non-threatening, non-punitive atmosphere. ABSA endorses the American Association for the Advancement of Science (AAAS) report, *Biological Safety Training Programs as a Component of Personnel Reliability*.

ABSA also addressed additional issues introduced at the public meeting:

"ABSA believes that licensure of individual researchers in the life sciences is unnecessary and undesirable. Research in the life sciences, and especially with the most hazardous microbial pathogens, has been performed by the most qualified and dedicated scientists for decades. A licensure requirement would deter many qualified scientists from pursuing work in high and maximum

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Biosecurity and Biosafety Reform: A Path for the Future

by Donald F. Thompson
Senior Medical and Public Health Program Director, CIP

The interface of science and security has come to the forefront in recent national security discussions. These discussions include the need for defense against the use of biological weapons, the advances in legitimate scientific discovery, and the widespread availability of equipment and knowledge that permit the synthesis of biologic compounds. Advances in understanding the human genome and genomes of many microbial pathogens have led to sophisticated genetic engineering technologies that hold much promise of exciting discoveries of new diagnostic and treatment opportunities, but may permit those with malicious intent to develop pathogens with altered characteristics that may defy known antibiotic or antiviral treatments. Misuse of biological pathogens for nefarious intent is nothing new, but the 2001 anthrax attacks, on the heels of the September 11, 2001 terrorist attacks, have appropriately generated both interest and response by officials responsible for national security. Many recent actions have focused on select agents, defined as a human, plant, or animal pathogen or toxin that HHS or the United States Department of Agriculture (USDA) consider to potentially pose a severe threat to human, plant, or animal health. The current select agent list has 72 HHS and USDA pathogens or toxins, with SARS-associated coronavirus as the latest proposed addition to the list.

Differing objectives and priorities of the scientific and security communities have led to safety and inspection regimes that negatively impact scientific discovery within industry and academia. The focus of the security community is twofold: protection from outsider threats by unauthorized persons who may attempt to steal pathogens; and protection from insider threats, such as legitimate laboratory workers who may attempt to use or manufacture pathogens for other than lawful medical, clinical, or scientific purposes. A third area of concern to both the scientific community and the general public is laboratory biosafety, where proper protective measures are taken that protect laboratory workers from exposure to pathogens and toxins, and prevent accidental release of pathogens into the community.

Security measures put in place to protect against outsider threats include physical protection of the facility with fences and other physical barriers, access control for staff and visitors so only those persons with legitimate business can enter, and armed guards to enforce these measures. Protection from insider threats is significantly more challenging, since such threats include industrial espionage, sharing of classified intelligence in the few facilities that are involved in classified scientific research, and protection from the legitimate worker who may become disgruntled and choose to intentionally inflict damage with pathogens or toxins at their disposal. Protective measures against insider threats include personnel screening prior to and during employment, internal institutional protocols limiting access to specific pathogens, reagents, and equipment to those with legitimate need, and institutional procedures that provide for appropriate monitoring of personnel, pathogens, and reagents.

Concerns have been raised that many of these security measures are unrealistic and misplaced, given the threat, the low relative risk from these pathogens, and the likelihood of an intentional espionage incident occurring. These concerns include:

- Too many uncoordinated inspections, and inspectors with inconsistent practices;
- Too many costly security regulations with little demonstrated effectiveness;
- A draconian response to any lapse, regardless of the true import of the error;
- Regulations that unreasonably

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Reform *(Cont. from 8)*

restrict legitimate science, such as the two-person rule where two persons must be present at all times when select agents are used, and restriction of allowing visiting scientists to be escorted by a responsible official;
- The restriction of scientific capacity development and legitimate training; and
- Limitation of domestic and international public health emergency laboratory surge capacity.

An early assessment of the Select Agent Program from the security, scientific, and economic perspectives has provided an initial clarification of actions to date, has considered the intent of various legislation, regulations, and standards, and has attempted to make preliminary recommendations in anticipation of their likely short-term and long-term effects on science and security. Finally, all-encompassing recommendations will depend on a more in-depth examination of these and other issues and concerns, but working hypotheses are presented here to generate discussion.

Early Working Hypotheses:

1. **Personnel Reliability Program:** *Do not consider for expansion.* While this program has been effective when properly applied in nuclear surety settings, it is ineffective and unenforceable in the general scientific community. It may be useful in selected government laboratories that are involved in classified life sciences research, but its costs and intrusion into civil liberties of civilian laboratory personnel are excessive and do not warrant its expansion.

2. **Two-person rule:** *Discontinue.* It has been ineffective, costly, and overly restrictive.

3. **Security Risk Assessments (SRA):** *Continue.* This approach for initial security screening is low cost and reasonable for most regular laboratory workers.

4. **Security Risk Assessment Mentor Program:** *Develop.* A waiver process should be developed where a scientist who has gone through the SRA process can assume responsibility for mentoring and overseeing visiting domestic or international researchers. Visiting international scientists will have already gone through a detailed State Department vetting process in order to acquire a visa. Such information exchanges are essential to scientific collaboration.

5. **Emphasize accountability in laboratory procedures rather than accounting:** *Discontinue quantitative inventories of pathogens on hand, and focus instead on qualitative inventories.* The focus should be on efficient laboratory leadership and management systems and effective procedures that monitor select agent inventories.

6. **Biological specimen transport restrictions:** *Discontinue.* These restrictive measures are indefensible, where even empty containers must be externally marked as biohazards and shipped according to the same restrictions as containers containing pathogens. Reasonable regulations should be similar to those used for radionuclides for research and clinical purposes.

7. **Information and pathogen sharing protocols:** *Develop.* Domestic and international information and specimen exchange is essential if the United States is to remain involved in scientific discovery. Regulations and protocols should be based on those developed by the WHO the European Union, the Australia Group, and other reputable international organizations.

8. **Laboratory biosafety:** *Adherence to Good Laboratory Practice standards will meet most biosafety and biosecurity concerns.* The risks of laboratory-associated infections have been recognized for over a century, and many guidelines have been issued to provide a safe environment for workers. The *Biosafety in Microbiological and Biomedical Laboratories* manual published by the CDC and NIH is in its 5th edition, and provides excellent biosafety guidance for laboratory workers. This guidance could be augmented for select agents with pathogen-specific restrictions, and tiered biosafety education as laboratory workers work with progressively dangerous pathogens.

9. **Biosecurity can be evaluated by laboratory biosafety proxies:** *Inspections are no substitute for good laboratory leadership and management.* Strong monitoring and management of personnel, reagents, media, and other consumables; self-reporting; and on-going laboratory

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Legal Insights

Domestic Biosecurity Laws: Past, Present, and Future

by Dillon M. Martinson, JD
CIP Staff

Biological agents in criminal hands can be a silent, invisible weapon of mass destruction. A few kilograms of anthrax can kill as many people as a Hiroshima-size nuclear weapon.[1] Even with low mortality rates, the fear of bioterrorism alone can cripple the economy and paralyze daily life. Despite the threat, biosecurity laws in the United States are only now beginning to emerge.

Biosecurity is loosely defined as a set of preventive measures, made up of systems and practices, designed to prevent the intentional and malicious use of pathogens and toxins. Effective biosecurity laws must answer three questions — *who, what, and where*. Biosecurity laws must monitor *who* has access to agents, *what* agents are the most deadly and likely to be accessed, and *where* the agents are in use or being stored.

The following account is a roadmap of domestic biosecurity laws, examining past, present, and future attempts to answer the *who, what, and where* of biosecurity.

The Past

One man — Larry Wayne Harris — is largely responsible for the origins of biosecurity laws in the United States.[2] Harris, an Ohio microbiologist, worked for Superior Laboratories testing drinking water and inspecting septic systems. He was also a lieutenant in the neo-Nazi Aryan Nations and believed the United States would soon be the target of biological attacks. In 1995, Harris asked his employer to order *Yersinia pestis* (bubonic plague) for him so that he could conduct defensive research, but his employer refused.

Acting beyond the scope of his employment, Harris ordered vials of *Yersinia pestis* from the American Type Culture Company in Maryland on May 3, 1995. Needing proof of an established laboratory, Harris fraudulently used the Ohio Environmental Protection Agency approval number assigned to the laboratory where he worked. The facility shipped three vials to Harris but notified law enforcement authorities when employees became alarmed by Harris' continuous calls to check on the status of his order.

In the early morning of May 12, 1995, the Lancaster Police Department executed a search warrant to recover the vials. Police found the three vials in Harris' car, along with homemade explosive devices, grenade triggers, detonating fuses, and a sawed-off .30 caliber rifle in his home. With ties to a violent extremist group, a stockpile of weapons, and vials of deadly bacteria, the police notified the FBI of a possible bioterrorist threat.

Surprisingly, there were no laws forbidding the purchase or transfer of deadly bacteria. However, Harris plead guilty to one count of wire fraud for improperly using his employer's laboratory approval number. Judge Joseph Kinneary was lenient, ordering 200 hours of community service, assessing a $50 fee, and placing Harris on 18 months probation.

Federal officials were troubled by the availability and ease by which a person could obtain lethal amounts of biological agents. Congress responded by enacting the Anti-Terrorism and Effective Death

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[1] http://www.cdc.gov/ncidod/EID/vol5no4/siegrist.htm.
[2] Much of the information on Larry Wayne Harris comes from: Jessica Eve Stern, Larry Wayne Harris (1998), in TOXIC TERROR 227 (Jonathan B. Tucker ed., 1999).

Legal Insights *(Cont. from 10)*

Penalty Act of 1996.[3] Section 511 of this Act called on the Secretary of HHS to regulate the transfer of biological agents.

Pursuant to this authority, HHS' CDC published a rule, *Additional Requirements for Facilities Transferring or Receiving Select Agents*.[4] This rule created the select agent list. Effective April 15, 1997, all commercial suppliers, government agencies, universities, research institutions, private companies, and individuals who transferred or received a biological agent on the select agent list had to register with HHS and file a report on each transaction. The CDC rule also provided criminal penalties, including imprisonment and fines, for noncompliance.

Unfortunately, the CDC's rule only regulated the transfer of select agents, not possession:

This final rule and associated criminal penalties apply only to interstate and intrastate transfer of these agents. Possession of these agents is outside the scope of this final rule.[5]

This omission led to serious gaps in biosecurity. In the days following the terrorist attacks of 9/11, letters with deadly anthrax powder began appearing across the nation, ultimately claiming five lives. Despite anthrax's classification as a select agent, the FBI acknowledged that its investigation was hindered because the government had no comprehensive list of facilities or scientists that possessed or worked with anthrax, only those that transferred it.

As the anthrax attacks of 2001 illustrated, merely defining what biological agents posed the greatest threat and tracking their transfer was not enough. These early biosecurity laws answered the *what* of biosecurity but left out the *who* and *where*. If the government was going to effectively prevent bioterrorist attacks, it would have to fill these gaps.

The Present

On October 26, 2001, Congress took its first steps towards closing the gaps in biosecurity laws by enacting the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act (USA PATRIOT Act).[6] The USA PATRIOT Act overcomes two critical defects in early biosecurity laws.

First, section 175b of the USA PATRIOT Act restricts certain persons from shipping, receiving, transporting, or possessing select agents. The list of restricted persons includes felons (indicted or convicted), fugitives, unlawful users of controlled substances, individuals adjudicated mentally defective or committed to any mental institution, dishonorably discharged United States service members, and aliens from countries that support terrorism. For the first time, Congress restricted the *who* of biosecurity by limiting dangerous individuals' access to select agents.

Second, section 817 enhances the *what* of biosecurity by making it a crime to knowingly possess any biological agent, toxin, or delivery system that cannot be reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose. As a result, law enforcement officials no longer need to catch bioterrorists in the act of illegally transferring a select agent to prosecute them.

The anthrax attacks of 2001 revealed the need for a comprehensive list of individuals who not only transferred select agents but also possessed them. While the USA PATRIOT Act criminalized the nefarious possession of select agents, it did not require registration for possession. Congress cured this shortcoming by enacting the Public Health and Security Bioterrorism Preparedness and Response Act of 2002.[7]

This 2002 Act embodies Congress' most robust attempt to regulate the *who, what, and where* of biosecurity. Section 201 amends the 1996 Act by extending HHS' biosecurity authority. Pursuant to the 2002 Act, HHS is to maintain

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[3] Anti-Terrorism and Effective Death Penalty Act of 1996, Pub. L. No. 104-32, 110 Stat. 1214 (1996).
[4] 42 C.F.R. §72.1 (1996).
[5] http://grants.nih.gov/grants/policy/select_agent/42CFR_Additional_Requirements.pdf.
[6] USA PATRIOT Act, Pub. L .No. 107-56, 115 Stat. 272 (2001).
[7] Public Health and Security Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002).

The National Center for Biodefense and Infectious Diseases at George Mason University Contributes to Biomedical Research

In 2001, the National Center for Biodefense and Infectious Diseases was established to address the scientific challenges associated with biological terrorism and emerging infectious diseases. The Center is an integral part of the College of Science at George Mason University. In 2005, the National Institute of Allergy and Infectious Diseases (NIAID), an institute within NIH, awarded the National Center for Biodefense and Infectious Diseases a total of $27.7 million to construct a Biomedical Research Laboratory (BRL). George Mason University is contributing an estimated $15.3 million in matching funds and the Commonwealth of Virginia is providing $2.5 million for land acquisition. In totality, NIH awarded grants for the construction of 13 nationwide Regional Biocontainment Laboratories (RBLs) to foster biodefense and infectious disease research.

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Biosafety Levels

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessment. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in microbiology or a related science.

Biosafety Level 2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation route exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures.

Biosafety Level 4 is required for work with dangerous and exotic agents that pose a high individual risk of life-threatening disease, aerosol transmission, or related agent with unknown risk of transmission. Laboratory staff must have specific and thorough training in handling extremely hazardous infectious agents. Laboratory staff must understand the primary and secondary containment functions of standard and special practices, containment equipment, and laboratory design characteristics. All laboratory staff and supervisors must be competent in handling agents and procedures requiring BSL-4 containment. Access to the laboratory is controlled by the laboratory supervisor in accordance with institutional policies.

-Biosafety in Microbiological and Biomedical Laboratories, 5th Edition

Overview *(Cont. from 3)*

nineties understandably prompted a response from the federal government. The Select Agent Program was established to regulate the possession, use, and transfer of biological agents and toxins that may pose a severe threat to human, plant, or animal health. Specific biological agents and toxins were "selected" for inclusion on the select agent and toxin list; hence, the name of the program. While the program initially seemed to provide an appropriate working solution, security professionals and scientists disagree about the effectiveness of existing and proposed security measures. The security community is justifiably concerned with the safety and security of laboratories that work with agents and toxins that are alluring to individuals or groups with malicious intent. On the other hand, scientists are apprehensive of rigorous security measures that may impede biological science research for little to no added security benefit.

In 2008, federal law enforcement authorities fueled the debate when the Federal Bureau of Investigation (FBI) announced that a United States Army civilian microbiologist may have been responsible for the mailing of letters laced with *Bacillus anthracis* (anthrax), and the subsequent illnesses and five deaths. This declaration dramatically escalated fears about the "insider threat", prompting federal authorities to propose security measures to increase the vetting process for personnel who wish to work with select agents and toxins.

Integration of Laboratory Biosafety and Biosecurity

The successful application and integration of laboratory biosafety and biosecurity practices is crucial to protecting laboratory researchers and the public from the accidental or deliberate release of biological agents and toxins. Recent attempts by organizations such as the American Biological Safety Association (ABSA), Sandia National Laboratories, and NIH have developed new programs to incorporate both laboratory biosafety and biosecurity into laboratory training. Other encouraging efforts by the WHO and the Organization for Economic Cooperation and Development illustrate promise in fostering international cooperation and laboratory biosafety and biosecurity integration. Enforcement of international legislation such as United Nations Security Council Resolution 1540 under Chapter VII of the Charter of the United Nations (2004) and the International Health Regulations (2007) furthers international collaboration.

In addition to these domestic and international efforts to address biosecurity issues, recent public meetings have provided a forum for federal government officials, security professionals, and scientists to discuss existing laboratory biosafety and biosecurity challenges and proposed biosecurity regulations. While the public meetings provided an opportunity to share issues and experiences with existing regulations, some members of the science community prefer that additional dialogue take place before regulations are considered.

Conclusion

As this issue goes to press, Senators Joe Lieberman and Susan Collins have just introduced Senate Bill 1649, *The Weapons of Mass Destruction Prevention and Preparedness Act of 2009*. This Act contains a number of steps to enhance government oversight of laboratories, including risk-based security regulations that consider the pathogen threat, a negotiated rule-making process that includes research institutions and other key stakeholders, and personnel reliability. It recognizes that these measures can be a disincentive to research, and directs amendment of the Select Agent Program to avoid overlap or conflict with security measures developed by the Department of Homeland Security. Furthermore, it requires simultaneous inspections of laboratories using common procedures to minimize administrative burdens on laboratories. These steps represent an improvement over the current state of affairs, though much collaborative work will need to be done to successfully implement this Act. It is essential that the science community, the security community, and responsible federal government officials integrate economic, security, and scientific equities to preserve and protect the most invaluable infrastructure — global public health. ❖

Regulations *(Cont. from 5)*

For research institutions that have chosen to conduct select agent research, they must keep an accurate inventory of their agents and proposed regulations may require stringent methods for vetting personnel before they gain access to these agents. The Select Agent Program requires all researchers to inventory their select agents to determine whether theft of agents has occurred. The program requires more than just knowledge of what exists in a lab (including records and stock materials or organisms); it includes knowing the amounts of all genetic material and agents present in the laboratories. In recent years, one university has had a plague-infected rat carcass disappear and the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) suspended its research activities until a thorough audit of inventory was completed. The audit at USAMRIID identified three vials of agent that were missing. Were these missing items a safety and security threat? Other than knowing what agents are kept in the laboratory and where and who is working with which agent, there is no good way to effectively monitor each vial or exact amount of agents in each vial. Although biological agents can be stored as purified agents (which can be quantifiable), there are several forms and conditions in which biological agents can be stored for various lengths of time and at various temperatures. The viability or functionality of the agent following a freeze-thaw cycle, growth, or transfer is more important than the actual amount of particles. All good laboratories have stocks and records of their genetic material and biological agents and nearly all laboratories have records of the functionality of those agents. If inventorying is necessary, allowing laboratories to maintain a database of agent lots and their functional amounts could be helpful for researchers and serve the security requirements. Such a system may reduce the poor morale and suspension of research activities during audits and may facilitate research activities.

Before researchers can work on select agents, research facilities have to be inspected by and registered with the CDC or the Animal and Plant Health Inspection Service (APHIS). Research personnel and support staff must be approved through the FBI security risk assessment and subsequently registered with the CDC or APHIS. As new agents are added to the list, those conducting research on the newly added agent have to either terminate their research or seek approval and registration within the allotted grace period. On July 13, 2009, the CDC issued a federal register notice for the proposed addition of SARS-Associated Coronavirus to the select agent list. When the announcement was first released, several SARS researchers were unaware of this notice. Although there is a grace period for registration, those in possession of a newly added agent could find themselves criminally liable for possessing or even attempting to possess (if they have requested strains) that agent if there was any delay in registration of the researchers and facilities. In addition, careers could be significantly affected if researchers working on the newly added agent were not approved to conduct the research or it was suspended until facilities and personnel were approved.

On a related topic, many proposed personnel reliability programs (PRP) do not account for existing practices for vetting personnel. Existing programs which can contribute to alleviating security concerns over the insider threat include biosafety training programs, occupational health programs, employment procedures, mentorship, and other relevant policies pertaining to allowing personnel access to laboratory space in general, animal laboratories, and high-containment laboratories. Laboratory personnel must complete initial and ongoing training for safe handling of a variety of laboratory hazards. Biosecurity concepts could be an extension of these activities; there is no evidence that new, stand-alone procedures for security would be more effective and less burdensome than adding on to existing hazard training and guidance. In fact, implementing PRPs beyond what already exists to vet personnel could be a significant financial burden on entities depending on the size of their program.

Two recent surveys have indicated that the select agent regulations and concerns over misuse of biological research have led several researchers to abandon their international

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Legal Insights *(Cont. from 11)*

a select agent list of all agents that pose a severe threat to public health and safety. All individuals who possess, use, or transfer these select agents must register with HHS, whereby HHS is to create a national database including the names and locations of registered individuals, the select agents they possess, use, or transfer and information regarding the source and characterization of those select agents.

Moreover, section 201 enhances the *who* of biosecurity by requiring HHS to submit identifying information of individuals seeking access to select agents to the Attorney General for a background check, utilizing criminal, immigration, national security, and other electronic databases. Only individuals with a legitimate need who pass the background check may possess, use, or transfer select agents.

The Agricultural Bioterrorism Protection Act, a subpart of the 2002 Act, requires USDA to establish and maintain a select agent list for agents and toxins that pose a severe threat to animal or plant health and products. Similar to section 201, individuals possessing or using these select agents must register with USDA and pass a Department of Justice background check. USDA is also charged with creating a national database for those that register with the department.

In light of the 2002 Act, both HHS and USDA maintain separate select agent lists and databases depending on whether the threat is to the public or plants and animals. There is some overlap between the two select agent lists, with about 10 agents and toxins posing threats to both groups. When a laboratory uses or possesses a select agent that is included in both select agent lists, the laboratory must choose which agency to register with — it cannot register a particular select agent with both agencies. This could create gaps in registration and/or laboratory investigations with HHS and USDA, each believing the other agency is handling the situation. The opposite is also possible — the agencies could issue conflicting regulations or guidance.

The Future

On January 9, 2009, President Bush signed Executive Order 13486 — Strengthening Laboratory Biosecurity in the United States. The Secretaries of HHS and the Department of Defense serve as co-chairs of the Working Group created by this Executive Order, with group members comprising the Secretaries of State, Agriculture, Commerce, Transportation, Energy, and Homeland Security, the Attorney General, the Administrator of the Environmental Protection Agency, the Director of National Intelligence, and the Director of the National Science Foundation.

The Working Group held a public meeting in May, 2009 to address biosecurity issues including select agent regulations, facility security, transportation of select agents, personnel background checks, and laboratory training. Participants raised concerns about overregulation disturbing research and inconsistent laboratory compliance investigations. One panel accepted comments on whether there should be a national standard for laboratory personnel training or if it is more effective to maintain site-specific regulations.

The executive order requires the group to publish a report of its findings by July 9, 2009 after which the group will terminate within 60 days. The group sent its report to the President for review but it has not yet been released to the public. The report is expected to provide recommendations for new legislation and regulations, including what to do about overlaps between HHS and USDA as well as whether the government should create a national standard for training laboratory personnel.

On February 26, 2009 Senators Richard Burr and Edward Kennedy introduced the Select Agent Program and Biosecurity Improvement Act of 2009 with similar legislation introduced in the House.[8] Among other things, the legislation would reauthorize the Select Agent Program in the 2002 Act through 2014. In addition, section 202 calls on HHS to develop minimum national standards for training laboratory personnel. Section 203 would create an integrated Biological

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[8] S. 485, 111th Cong. (2009); H.R. 1225, 111th Cong. (2009).

Legal Insights *(Cont. from 15)*

would create an integrated Biological Laboratory Incident Reporting System where individuals may voluntarily report biosecurity concerns and incidents.

This proposed legislation, introduced after the signing of Executive Order 13486 but before the Working Group public meeting, could significantly change the landscape of biosecurity laws in the United States. Before enacting this legislation, Congress should allow time for the Working Group to publish its findings and for the scientific community to respond. For example, Congress should not require HHS to create national standards for laboratory personnel training before the Working Group even decides if it would be beneficial to do so. Following the advice of a 2009 Congressional Research Service report titled, *Oversight of High-Containment Biological Laboratories: Issues for Congress*, Congress should defer action until experts can survey existing laboratory facilities, assess national needs, and conduct cost-benefit analysis of various training and oversight regulations.

In the past, biosecurity laws have been about responding to dangerous situations. Current biosecurity laws seek to prevent biological attacks before they occur by limiting dangerous individuals' access to select agents, criminalizing unjustifiable possession, and creating a comprehensive database on select agents — including their use and location. Executive Order 13486 represents the future of biosecurity laws where scientists, government officials, and the public can come together to enhance the *who, what, and where* of biosecurity. Finding the appropriate level of government oversight without chilling scientific research will be the task of future domestic biosecurity laws. ❖

GMU Research *(Cont. from 12)*

The George Mason University BRL will be situated upon 52,000 square feet on the Prince William Campus and will be comprised of biosafety level-3 laboratories. The mission of the BRL is to develop procedures and products for the detection, diagnosis, prevention, and treatment of emerging infectious diseases and biological agents that may be used as weapons. Research at the BRL will focus primarily on potential bioterrorism agents such as *Bacillus anthracis* (Anthrax), *Francisella tularensis* (Tularemia), and *Yersinia pestis* (Plague) and emerging infectious diseases such as Severe Acute Respiratory Syndrome (SARS), West Nile virus, and Influenza.

Construction of the BRL commenced in 2008. At present, construction is scheduled for completion in the spring of 2010. Once this facility is operational, the National Center for Biodefense and Infectious Diseases will possess the resources to conduct vital scientific research in an enhanced capacity. This research is essential to the future of global public health security. ❖

For more information about the George Mason University BRL, please visit: http://brl.gmu.edu/.

The George Mason University, Prince William Campus

Regulations *(Cont. from 14)*

collaborations. Not only are these collaborations important for biological science research, educating foreign nationals can help propagate United States norms regarding biological research, to develop relationships among United States and foreign scientists, and continue American competitiveness in the biological sciences. Creating barriers to developing relationships between American and foreign scientists (graduate students, undergraduate students, post doctoral fellows, professors, and international visitors) will leave the United States vulnerable to public health responses (e.g., rapid identification of novel agents and development of medical countermeasures), and prevent us from knowing what research is being conducted worldwide.

As biosecurity policies become stricter and broader, the implications of these policies on biological research, collaborations, education, and advancements in many sectors are significant. Whether these effects are financial, temporal, or interpersonal, they need to be factored into current biosecurity policy discussions to encourage the development of policies that enhance security and safety while promoting the science that benefits nearly all aspects of the human condition. ❖

Reform *(Cont. from 9)*

certification can satisfactorily address many biosecurity needs. Industry and academia should lead an initiative to develop best practices, leading to consensus standards for additional certification and perhaps regulations. Industry, not government, should develop measures and metrics for competency and experience.

10. **Certification of new laboratories should be phased in as laboratory experience is developed and demonstrated:** More frequent monitoring and inspections are reasonable until laboratory managers have demonstrated proficiency in laboratory management. An effective oversight, inspection, and mentoring process will need to be developed to support such a certification process.

11. **Public health emergency protocols must be developed**. Laboratory officials must have the authority to quickly share specimens domestically and internationally to support investigation of a public health emergency, perhaps triggered by an emergency declaration by a Federal official.

12. **Conflicting Department/Agency perspectives and equities are impeding the development of sustainable biosecurity solutions.** One Federal agency should be designated as having overall responsibility for coordinating federal regulations, inspections, and reports, and advocating for needed statutory and regulatory change. Additional policies are needed that support international health security engagement efforts; proactive disease early warning and surveillance system development, and advancement of science; research and development; and commerce. A robust public involvement and education process must be part of such policy development.

High quality scientific research and development has led to many advanced medical diagnostic and treatment options, particularly in cancer therapy. Many exciting scientific advances offer potential to continued improvement in quality of life by reducing illness and improving treatment. Furthermore, much of our economy supports scientific activities and many benefit from jobs in these career fields and related areas. The scientific, security, legal, and legislative communities should work together to provide appropriate security measures while facilitating legitimate science. ❖

Working Group *(Cont. from 7)*

containment laboratories.

The oversight of select agent research must remain with the Department of Health and Human Services (HHS)/ CDC and USDA/APHIS, as the scientific knowledge resides in these agencies. Further, oversight of select agent research must be consolidated. The ability to complete the public health and scientific mission of analysis and research on pathogens of significance to humans, animals, and plants in the United States must not be neglected or compromised."

Although ABSA believes that licensure of individual researchers is unnecessary and impractical, ABSA does believe that accreditation of high containment (BSL-3) laboratories can be beneficial. ABSA currently has a task force working on development of an accreditation program for high containment laboratories. This will be a voluntary accreditation program much like that of the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) and other accrediting organizations. The task force is currently developing a standards document based on the European Committee for Standardization (CEN) Laboratory Biorisk Management Standard (CEN Workshop Agreement 15793) for guidance in managing biological risks in high containment laboratories and *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) for the technical guidance.

The ABSA Council recognizes that its members may not all agree with all statements above, due to individual perspectives and working situations. However, the Council strives to represent the opinions of the majority, and knows that the majority of entities using select agents agree with the viewpoints stated above. We know that we will hear more on this topic in the future and anticipate that many lively discussions will ensue. ❖

Editor's note: The American Biological Safety Association (ABSA) was founded in 1984 to promote biosafety as a scientific discipline and serve the growing needs of biosafety professionals throughout the world. The Association's goals are to provide a professional association that represents the interests and needs of practitioners of biological safety, and to provide a forum for the continued and timely exchange of biosafety information. More information about ABSA may be found at http://www.absa.org/.

The Center for Infrastructure Protection works in conjunction with James Madison Univerity and seeks to fully integrate the disciplines of law, policy, and technology for enhancing the security of cyber-networks, physical systems, and economic processes supporting the Nation's critical infrastructure. The Center is funded by a grant from the National Institute of Standards and Technology (NIST).

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