

Meeting Summary
“Working Group on Strengthening the Biosecurity of the United States
Public Consultation Meeting”
May 13-14, 2009

Bethesda, MD

Panel I – Select Agent Regulations

There was some discussion on stratification of the select agent list based on the risks associated with each agent. However, it was noted that the list is already stratified by the NIH/NIAID Category A, B, and C system. It was not clear how stratification would be helpful since some category A agents require BSL-3 and some require BSL-4 and what would be the outcome of stratification. Dr. Gronvall suggested that looking at a risk assessment (performed by the registered facility) that incorporates both the agent, the type of research, quantity involved, etc as well as biosafety and biosecurity issues would be most helpful.

Licensure of people working in BSL-3 and BSL-4 labs in addition to the SRA was also discussed. My personal opinion is that this will never be implemented due to the high degree of variability between individuals who have access to the BSL-3 and BSL-4 labs (level of education, job functions, etc.). Most believe that a combination of on-site training (facility specific, didactic, etc.), educational background, and work experience serves the purpose of making sure that individuals with access to select agents possess the necessary skills and training. Also, each registered facility has the responsibility for providing the biosafety training to the staff members.

Panel II – Physical/Facility Security at Select Agent Programs

Physical security was discussed and ranged from extensive (Walter Reed Army Institute of Research) to what is possible in academia. Overall, very few issues were raised regarding physical security since there have not been any security violations reported (theft, intrusion, etc) since the start of the Select Agent Program.

Panel III – Oversight and Inspection of Select Agent Facilities

Many members of the audience voiced their concerns over the level of training for inspectors and that registered facilities were often given guidance that was not based on the regulations in the CFR or were contrary to findings of other inspectors. Also, many noted that they have had multiple inspections (as many as 5-8/yr) in any given year. There seems to be consensus that it is often difficult to interpret the Select Agent regulations and that most (>50%) feel that they may inadvertently violate the regulations.

Panel IV – Transportation of Select Agents

There have been over 3000 transfers since the beginning of the Select Agent program and only two have been lost in transit (one was tracked and its destruction by incineration was verified, the other was lost and was assumed to be destroyed during shipment). A representative from FedEx was present and FedEx Express has transported 2/3 of all of the Select Agent shipments. The overall feeling was that the system is working and there is little need for changes. However, FedEx expressed concern that if the regulations concerning transport are changes in a way which results in an added burden on FedEx in order to meet the new regulations that the carrier may stop transporting Select Agents. Also, CDC noted that dedicated carriers were not effective (they did a small scale trial) and were cost prohibitive (maybe up to \$2000 per shipment).

Panel V – Personnel Security/Reliability Programs

Many facility specific personnel reliability programs were discussed including the AR 50-1 regulations for a BPRP. Most in the audience were against a national PRP program and felt that the responsibility should stay with the registered facility. They also felt that a Federal program may limit those willing or able to work with Select Agents which would weaken the research enterprise. However, this seems to be one of the public's greatest concerns which in part have stimulated a Congressional inquiry and the Executive Order 13486. *Since the "Amerithrax" investigation implicated a scientist at USAMRIID, there seems to be some pressure to increase personnel reliability programs. I do not know what the recommendation from the Working Group will be but I suspect that it may include guidance that each facility will need to implement a personnel reliability program that incorporates a minimum number of elements but will be specific to each registrant.* In my opinion, Battelle already has the elements of a PRP but the outline is not currently consolidated in our CDC/Select Agent biosecurity plans.

Panel VI – Culture of Security and Responsibility and Biosecurity Training Programs

This open discussion went in several directions including discussing PRPs and securing the agents against the "insider threat," the issues around inventory (biological agents replicate, etc), and a code of conduct for microbiologists (e.g. ASM has a code of conduct). Again, I don't think there was any consensus reached but I do not think that the recommendations will be too far from the existing regulations. The usefulness of "counting vials" is a contentious issue and will likely remain that way.

Working Group on Strengthening the Biosecurity of the United States Public Consultation Meeting

Hyatt Regency- Bethesda
7400 Wisconsin Ave
One Bethesda Metro Center
Bethesda, MD 20814
May 13-14, 2009

Agenda

Wednesday – May 13

- 8:30 a.m. **Welcome and Opening Remarks**
- 8:45 a.m. **Introduction to EO 13486 and the Working Group on Strengthening the Biosecurity of the United States**
- 9:15 a.m. **Informing Recommendations on Biosecurity: Why A Public Consultation Meeting?**
- 9:30 a.m. **Evolution of Biosecurity**
- 10:00 a.m. *Break*
- 10:15 a.m. **Panel I –*Select Agent Regulations***

Background:

The possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety, or animal and plant health and animal and plant products are regulated by HHS and USDA under the *Select Agent Regulations*. In determining whether to include an agent on the Select Agent List, the *Bioterrorism Act* requires that HHS and USDA consider the effect on human health after exposure to the agent or toxin; the effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products; the infectivity and means of transmission of the agent or toxin to humans; the pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants; the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; any other criteria that the Secretary of HHS deems appropriate to protect public health and safety; and any other criteria that the Secretary of Agriculture deems appropriate to protect animal or plant health or animal or plant products.

The Working Group is seeking individual input on the following questions:

Discussion questions:

- Has the purpose and content of the Select Agent list supported enhancement of biosecurity?
- Are the current select agent regulations sufficiently comprehensive and effective?
- Should the current select agent regulations move away from performance standards to more specific prescriptive standards?
- Do you see any value in a stratification of select agents by risk? If so, which aspects of the current select agent regulations would be most amenable to a stratified approach? Do you currently utilize a stratified approach with the select agents in your facility?
- Do you have access to all select agent registered space in your facility? Do you believe that you have sufficient authority within your organization to effectively implement the select agent regulations?
- Do you find the Security Risk Assessment system currently in use by the federal select agent Program to be effective? If so, why; and if not, why not?
- What type of inventory system do you have in place to maintain for your select agent materials in long term storage? Do you use a centralized database, or separate databases for each principal investigator? Are you satisfied with the current guidance from the CDC/APHIS Select Agent Programs on long term storage? If not, how might this guidance be improved?

12:00 p.m. *Lunch*

1:00 p.m.

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

Background: The *Select Agent Regulations* require that all entities that possess, use and/or transfer select agents and toxins develop *site specific written security plans* that describe how select agents and toxins in their possession are to be safeguarded against unauthorized access, theft, loss, or release. The *Bioterrorism Act* and the *Agricultural Bioterrorism Act* require respectively, the Secretaries of HHS and USDA to by regulation “[E]stablish and enforce safeguard and security measures to prevent access to listed agents and toxins for use in domestic or international terrorism or for any other criminal purpose.” [42 U.S.C. §262a(b)(2), 7U.S.C. §8401(b)(2)]

The Task Force is seeking individual input on the following questions:

Discussion questions:

- The *Select Agent Regulations* provide a broad requirement that allows physical security requirements to be interpreted by individual or entity. Should the Federal government develop baseline prescriptive physical security requirements (e.g., minimum criteria for structure, facility entrance, interior, security systems, security operations, and administration) based on categorized risk or facility category?
- The *Select Agent Regulations* require development and implementation of a written security plan and require security plans to be designed according to site-specific risk

assessments. Are there additional tools or guidance documents that would be helpful to you?

- The *Select Agent Regulations* require drills and exercises to be conducted at least annually to evaluate the written security plan. Is this adequate?

3:00 p.m. *Break*

3:15 p.m.

Panel III – Oversight and Inspection of Select Agent Facilities

Background: All entities possessing select agents or toxins are subject to inspection, prior to the issuance of a Certificate of Registration to (1) verify that the facility is accurately represented by the information submitted by the entity to the select agent program, and (2) has in place the procedures and processes necessary to ensure compliance with the *Select Agent Regulations*. In addition to an initial inspection during the application process, every entity may also be inspected during the Certificate of Registration renewal process. Additionally, inspections may be conducted when: 1) modifications are made to the entity's application; 2) a new building or laboratory is added to the registered areas; 3) a higher-risk agent/toxin is added; 4) a change is made in security infrastructure or policy and procedures; 5) a theft, loss, or release incident occurs; and/or 6) a regulatory violation is reported. The *Select Agent Regulations* also permit unannounced inspections (42 C.F.R. § 73.18(a), 9 C.F.R. § 121.18(a), 7 C.F.R. § 331.18(a)). Entities possessing select agents or toxins may experience additional inspections by third parties outside of the select agent program.

The Working Group is seeking individual input on the following questions:

Discussion questions:

- Is the current inspection regimen by the Select Agent Program effective?
- Are inspection programs in need of improvement? If so, are there recommendations for improvement?
- Is there additional guidance that would be helpful to prepare for program reviews and facility inspections?
- How many other "third party" inspection groups have visited your facility, in addition to either the CDC or APHIS Select Agent programs?
- If you've had multiple inspections by various federal government agencies, do you have any thoughts on how these inspections could be better coordinated?
- Do you have recommendations for approaches to enhance institutional implementation, compliance, oversight and accountability?

4:30 p.m. Public Comments

5:00 p.m. Adjourn

Thursday – May 14

8:30 a.m. Welcome

8:45 a.m.

Panel IV – Transportation of Select Agents

Background: Infectious substances and the materials known or suspected to contain them are regulated as Division 6.2 (infectious) hazardous materials by DOT, under the Pipeline and Hazardous Materials Administration (PHMSA) *Hazardous Materials Regulations (HMR)*; 49 CFR Parts 171-180). The *HMR* requirements are patterned after those in international transport regulations and include safety and security requirements for the transportation of infectious substances including select agents. DHS's Transportation Security Administration (TSA) recently issued highway security action items that pertain to select agents. TSA will provide an overview of these new requirements. The panel will discuss current regulations that apply to the secure transportation of select agents, potential vulnerabilities, challenges and recommendations for enhancing security while balancing the potential impact on the carrier community.

The Working Group is seeking individual input on the following questions:

Discussion questions:

- Are there vulnerabilities that exist for select agents during transportation? If so, how can they be addressed?
- What challenges do carriers currently face and how might additional security requirements and controls impact their business decision to accept and transport select agents?
- Are the chain of custody requirements sufficient and how are lost or mis-directed shipments handled?
- Should packages containing select agents be packaged or labeled differently than other infectious agents?
- At what point should facilities be held responsible for package? For example, at time of receipt at entity (e.g., shipping area) or at laboratory?
- Are there additional tools and guidance that would be helpful related to the transportation of select agents?
- Should there be a registration program for carriers?

10:15 a.m. Break

10:30 a.m.

Panel V – Personnel Security/Reliability Programs

Background: Security procedures at entities with select agents are intended to prevent the theft, loss, or release of an agent from the laboratory. Personnel with access to select

agents must be reviewed by the FBI through a Security Risk Assessment (SRA), to ascertain whether they meet certain criteria which would preclude them from inclusion in the Select Agent Program. While the criteria for exclusion are very specific, they do not eliminate the risk posed by an “insider threat.” Personnel reliability programs (PRP) are used in other fields, such as nuclear and chemical research programs, to ensure that individuals with access are trustworthy, reliable, and physically and mentally competent. Depending on the type of PRP implemented, components can be voluntarily applied at the local level or mandated nationally to include background checks, credit checks, medical and psychological investigations, random drug testing and polygraph tests. Such a program may require additional staff and resources at the institution to manage the process, and consideration must be given to the additional value and potential loss of scientific progress imposed by any program. While no PRP can completely mitigate the risk of the insider threat, certain steps may be taken to reduce the intentional misuse of biological materials and enhance public confidence in the biodefense research enterprise.

The Working Group is seeking individual input on the following questions:

Discussion questions:

- What type of background investigations, if any, do you do that go beyond those required for compliance with the Select Agent regulations?
- Do you have a Personnel Reliability Program (PRP)? If so, what elements does it contain and who runs it? Do you have a Certifying Official, or equivalent, for your PRP?
- How effective has your PRP been in preventing potential thefts, losses, or release of select agents?
- Do you utilize the "Two person rule"? Do you believe it is of value to your safety or security plans?
- Should extant frameworks for personnel reliability be applied to all select agent research?
- What is the optimal framework for ensuring personnel reliability in a manner that balances the needs for both biosecurity and rapid progress in the life sciences?
- What are the features of an optimal PRP?
- What are the costs of implementing a PRP?
- What are the risks and benefits associated PRP?
- What metrics should be used for evaluating PRPs?

12:00 p.m. *Lunch*

1:00 p.m.

Panel VI – Culture of Security and Responsibility and Training Programs

Background: Any biosecurity program that is implemented must be done in such a way that it does not unduly burden the researcher or prevent quality research from progressing. For this reason, we need to work within a culture of responsibility and security whereby researchers understand why they’re being asked to increase security precautions and awareness. Important components of this discussion include thoughts about

implementations of different procedures discussed here over the last two days, the sharing of best practices among institutions, and training in methods related to high and maximum containment level work and security policies and practices.

The Working Groups seeking individual input on the following questions:

Discussion questions:

- What resources would institutions need to implement some of the activities discussed at this meeting?
- How do you currently share best practices regarding safety and security among institutions?
- Do you feel you have enough technical and financial support from Federal agencies to successfully follow Select Agent regulations and any future guidelines set forth on security?
- How many hours of training do employees have to undergo before being allowed access to select agents and toxins? What resources are used in the design of the training module?
- Should minimum competency and biosecurity training standards be developed for all personnel who work in, oversee, or manage high and maximum containment research laboratories? If so, who should develop these standards?
- Are there sufficient training opportunities for personnel in high and maximum containment laboratories to ensure effective biosecurity training of current and projected staff?
- What are the current training practices related to biosecurity at both federal and non-federal institutions?

2:30 p.m. Public Comments

3:00 p.m. Wrap-up and Concluding Remarks

3:15 p.m. Adjourn