ABSA
American Biological Safety Association
1200 Allanson Road • Mundelein, IL 60060-3808 • 866-425-1385 • 847-949-1517
Fax: 847-566-4580 • E-mail: info@absa.org • Web Site: www.absa.org

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Centers for Disease Control and Prevention
Select Agent Program
1600 Clifton Road, NE., Mailstop A–46
Atlanta, GA 30333

Attn: RIN 0920– AA34

Ladies and Gentlemen,

The American Biological Safety Association (ABSA) is an international group of biological safety professionals and is known as one of the world's foremost resources on biological safety practices. ABSA has reviewed the proposed revisions to the Possession, Use, and Transfer, of Select Agents and Toxins standard which were announced in the Federal Register on October 3, 2011. We have the following comments to share regarding the proposed revisions:

Comments Specific to Sections of the Proposed Revisions

73.1 Definitions

Adjudicated as a mental defective. Use of this term prompts many human resource concerns that could be at conflict with the intent of the Select Agent standards.

This definition and the definitions for "alien", "committed to any mental institution", "controlled substances", "crime punishable by imprisonment up to 1 year", "indictment", "lawfully admitted for permanent residence", "mental institution", "restricted person", and "unlawful user of any controlled substance", appear in the definitions section of the proposal, but they do not appear elsewhere in the text of the proposal. We suggest that these definitions be moved to a guidance document where they might be referenced by inspectors or entities as a situation may warrant a need to reference them.

Occupational Exposure. Clarification of what constitutes an exposure to a Select Agent is welcomed. Under the current language in the standard, it's unclear as to whether or not a "release" of a Select Agent also constitutes an exposure. The adoption of the Occupational Safety and Health Administration's (OSHA's) definition would limit possible exposures to Select Agents only to bloodborne pathogens and to other potentially infectious materials as noted in that standard. Many Select Agents are capable of transmitting disease through airborne transmission and other routes. It is suggested that the new definition of "occupational exposure" read, "Occupational exposure – contact with a potentially infectious agent via a specific route of infection (ingestion, inhalation, inoculation, non-intact skin, mucous membrane) that results from the performance of an employee's duties"

73.3 Select Agents and Toxins

(d)(3)(ii) and 73.16(l)(1) These sections indicate that entities must demonstrate and document that a recipient of a Select Agent has legitimate need for the material in advance of its transfer. Specifically, this new requirement is inclusive of exempt amounts of toxins.
As currently written, it is unclear if this requirement would apply to suppliers providing materials to an entity or if this requirement would apply to subsequent transfers by an entity of materials to investigators. Exempt quantities of toxins are often sought for use by investigators. Clarification or definition of the term, "legitimate need" in the definition section of the final standard would also provide better guidance to entities, especially given that they would be required to furnish documentation of this determination with little notification by the agency. For entity accountability of exempt amounts of toxins, we suggest that the "legitimate need" provisions be eliminated, but a requirement for entities to maintain an inventory of these exempt materials is included in the final rule as a means of accounting for the materials and their responsible use of these materials.

73.9 Responsible Official

(3) This section indicates that the RO is to have appropriate training and expertise to be competent to perform the duties of this position.

It is unclear what specific training and competencies would be required of any RO. Some entities designate a biological safety officer to serve in this capacity because they may feel a need for someone with applicable technical knowledge would be the best person to manage the provisions of this program. However, other entities may designate a vice chancellor or vice president in order to better establish management accountability in their organizations for the successful and proper administration of this program.
A useful point of reference could be the CDC/APHL Laboratory Biosafety Competencies if the intent of this proposed requirement is to better assure management engagement and competence.

(6) This section indicates that the RO is to have their physical duty station at the physical address of the entity.

Entities which have animal facilities remote from the duty station and with multiple registered locations on a campus may have practical issues in addressing this requirement as currently stated.

73.10 Security Risk Assessments

(e) This new provision requires a registered entity to notify the DHHS to extend a valid approval to another registered person or entity for a specific period of time.

The process by which this notification and approval is to be done is unclear. It is suggested the processes noted in the Transfers section of the standard be reviewed and adopted in this section in order to provide a specific means to accomplish this requirement, since that process is well detailed for that activity.

73.11 Security

(b) This section would require a registered entity to notify the DHHS to extend an approval status to another registered person or entity for a specific period of time.
The process by which this notification and approval is to be done is unclear. It is suggested the processes noted in the Transfers section of the standard be reviewed and adopted in this section in order to provide a specific means to accomplish this requirement, since that process is well detailed for that activity.

(c)(9)(i) This section would require entities to secure access to security systems for select agents from unauthorized individuals.

It is unclear whether the statement, "external connections to the systems which control security" refers only to security monitoring and controls, or if it is also inclusive of electrical power supplying the electrical system and controls.

(c)(10) This section indicates the need for entities to have a written response plan that is inclusive of responses to unexpected shipments.

The text of the proposal does not indicate if the "unexpected shipments" referenced are shipments of Select Agents initiated by the entity or unexpected shipments of Select Agents received by the entity. It's also assumed that the "unexpected shipments" are shipments of Select Agents. This should be clarified in the text of the final rule.

(e)(1) This section indicates the need for Tier 1 Select Agent entities to conduct a pre-access suitability assessment as part of their security plans for individuals with access to Select Agents.

This assessment needs to be included in the security risk assessment completed by the FBI. Alternatively, more specific details need to be provided in the standard or its supporting documents on how to accomplish this review. Otherwise, it should be stricken from the revised standard if neither of these options is adopted. Aspects need to be clearly stated, since Health Insurance Portability and Accountability Act (HIPPA) confidentiality provisions could be compromised with the release of personal medical information.

(3) (iv) This section details the need for three different security barriers for accessing Tier 1 Select Agents.

It is suggested that the word, "different" be dropped from the proposed standard. Some entities may chose to use three separate security systems through which Select Agents are accessed, but others may use the same security barrier in different ways in order to secure access (e.g. three different doors requiring the use of three different locks or three different security codes for passage). Doing so would maintain the spirit and intent of the new Tier 1 Select Agent security requirements while providing flexibility to entities in addressing this requirement.

73.12 Biosafety Plans

(a) This section states that a biosafety plan is to be developed commensurate of the risk for the Select Agents in use.

We suggest that the following amended text be substituted with the text in the second sentence of this section, "The biosafety plan must contain sufficient information and documentation to describe the biosafety, physical and operational containment requirements for working with the select agent or toxin including any animals or plants intentionally or accidentally exposed to or infected with a select agent." This modified text seeks to provide clarity related to features of containment infrastructure intended to facilitate biosafety of workers dealing with these materials.

73.14 Incident Response

(2) This section notes the need for the entity's plan to provide a means for notification to the FBI in the event of theft or suspicious criminal activity related to a Tier 1 Select Agent.

Clarification of what may constitute "suspicious criminal activity" would be helpful, since this would be a new requirement related to Tier 1 Select Agents. Without specific criteria on which to judge this activity, there would be significant variability in any determinations made that seek to address this requirement.

73.15 Training

(b) This section indicates that entities possessing Tier 1 agents must conduct annual threat awareness briefings on how to how to identify and report suspicious behaviors.

Clarification is needed in this proposed requirement. As written, it is unclear as to which entity employees need to participate in these briefings, much less whether or not law enforcement officials are to be participants. In absence of clarification in the text of the standard, clarification would be needed in the supporting documents issued by CDC for this standard.

(d) This section indicates requisite training that visitors to Tier 1 Select Agents facilities are to have before receiving access to the facility.

As currently written, the proposed text would require that visitors to the facility be trained in the same manner as an entity's employees. It is suggested that the amended standard to require that continuous escort of visitors by an entity's employee possessing requisite training be stated in the standard as meeting the visitor security provisions of the standard.

73.17 Records

(2) This section indicates a need to inventory, in detail, animals or plants infected by Select Agents.

The number of animals constantly changes on a daily basis at many facilities using them for research. Managing them in the manner currently detailed in the proposal is not practical, particularly to the level of detail noted in the proposal.

Accountability for the number of animals is typically an animal husbandry standard of care. Revising the proposed standard to mandate adoption and implementation of a specific standard operating procedure for tracking lost or missing animals infected with Select Agents would be more in keeping with current standards of care.

Guidance Documents

In response to the request for input regarding guidance documents, we suggest that the Select Agent Program web site be posted with templates and standard operating procedures (SOPs) reflective of the final, amended provisions of the Select Agent and Toxins standard, providing checklists to aid entities in addressing provisions of the final amended standard, as well as useful definitions and definition clarifications.
We also would like to suggest that DHHS/APIHS host a meeting or some other forum at which possible helpful templates and SOPs could be developed.

Request for a Letter of Interpretation Policy

The American Biological Safety Association (ABSA) lauds the Department of Health and Humans Services (DHHS) and United States Department of Agriculture's (USDA) proposal to adopt guidance documents to assist in the interpretation of select agent regulations.

However, ABSA believes that DHHS and USDA should augment guidance documents with a letter of interpretation policy. Specifically, ABSA believes that select agent registrants should be able to submit

written requests detailing a compliance issue and receive back a written letter of interpretation from the Centers for Disease Control (CDC) and/or the Animal Plant Health Inspection Service (APHIS) in a similar manner as employers can submit requests for interpretation to the Department of Labor (DOL) Occupational Health and Safety Administration (OSHA).

ABSA believes a letter of interpretation process is critical for the successful and efficient administration of the proposed amended regulations because: 1) some guidance documents will be too vague for use in the biosafety field, and 2) letters of interpretation will alleviate disparate inspection results.

I. Site-specific interpretation letters will be needed for some biosafety lab issues.

ABSA believes that while guidance documents will be helpful to registered entities, guidance documents alone will be too vague to cover many nuances that exist in biosafety labs. The need for a letter of interpretation process is best illustrated in the areas of BSL-2 and BSL-3 design, construction, and operation, and microbiological techniques (where site-specific and lab-specific questions often arise).

The need for site-specific answers based on site-specific characteristics or processes is best exemplified in the area of BSL-2 and BSL-3 construction, renovation, and operation, where entities constantly seek to improve safety, reduce costs, lessen environmental impacts, and decrease burdens on workers. Entities have almost limitless choices for improving their labs through new decontamination equipment and techniques, enhanced technology, and new construction materials. Entities seeking both major and minor changes at their facilities cannot invest and then hope for the best at inspection time. And, while an amended Form 1 and other procedures afford entities some pre-approval protection, not every nuance is covered. Stated simply, in today's ever changing technological world, a letter of interpretation policy is critical because registered entities need to know if they can pursue advances before expending the money to do so. Guidance documents do not offer the same security as letters of interpretation in these situations.

Another area where letters of interpretation are superior to guidance documents is in the area of microbiological technique. In most labs, Responsible Officials (ROs) set the standard for biological safety. However, Principal Investigators (PIs) are tasked with day to day research. Often times, a PI would like to attempt different research methods, or employ different techniques. ROs may not have the technical experience to answer the PI about microbiology, or may disagree with the PI over what is acceptable under the select agent regulations or guidance documents. A letter of interpretation policy will enable ROs to reach out to CDC and APHIS directly for a definitive answer that will satisfy both the RO and the PI.

In sum, BSL-2 and BSL-3 design, construction and operation, as well as microbiological techniques are just two specific examples of why a letter of interpretation policy should be incorporated along with guidance documents. Many other examples exist, but for brevity ABSA highlights these two examples only.

II. A letter of interpretation policy will reduce inconsistent inspection results:

ABSA believes that inspector turnover, as well as employee turnover at registered entities, is inevitable. When inspectors change, or employees change, a critical knowledgebase is lost, and inconsistent inspections become more likely.

The Executive Order Working Group perhaps best summed up the issue of contradictory inspections when it said:

> Although oversight agencies make concerted efforts to be as consistent as possible in their interpretations of the select agent and related regulations, there are, and will probably always be, subjective differences in guidance provided by different inspection teams. These differences in guidance come from multiple sources, including differences in backgrounds and experience levels of

individual inspectors as well as differences in regulations and/or policies of the inspecting organizations.

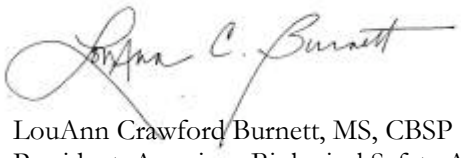
Report of the Working Group on Strengthening the Biosecurity of the United States (January 2010) at 27-28.

While guidance documents and standard operating procedures for inspections will alleviate some inconsistent inspection issues, ABSA believes written letters of interpretation are essential because they will: 1) allow registered entities to explain site-specific nuances as they relate to regulations; 2) provide entities an opportunity to identify relevant biosafety treatises such as the BMBL, FAQs, and guidance documents to support their position; 3) memorialize CDC and APHIS decisions about site-specific issues; and, 4) streamline compliance because inspectors and registered entities will not need to reanalyze a given compliance situation.

In sum, because of the multiple benefits to be gained by letters of interpretation for eliminating inconsistent inspections, ABSA encourages a letter of interpretation policy as a supplement to planned guidance documents.

We appreciate the opportunity to have provided this information in response to this proposed rulemaking.

Sincerely



LouAnn Crawford Burnett, MS, CBSP
President, American Biological Safety Association