ABSA INTERNATIONAL
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February 23, 2017

Leroy A. Richardson
Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road NE., MS-D74
Atlanta, Georgia 30329

RE: Proposed Data Collection Submitted for Public Comment and Recommendations, Docket No. CDC-2016-0125

Dear Mr. Richardson,

ABSA International welcomes the opportunity to review the proposed revision of the CDC information collection project entitled "Possession, Use, and Transfer of Select Agents and Toxins" published December 30, 2016. ABSA International provides a critical expertise for this topic as many of its members are extensively involved in implementing the Federal Select Agent Program (FSAP) and fulfilling certain roles therein.

ABSA International has reviewed the draft "APHIS/CDC Form 3 Incident Notification and Reporting (Theft/Loss/Release)" and the draft "APHIS/CDC Guidance Document for Reporting Potential Theft, Loss, Release, or Occupational Exposure". The specific comments provided respond to category "(c) ways to enhance the quality, utility, and clarity of the information collected" in the Federal Register notice.

ABSA International appreciates efforts by the CDC to reduce the regulatory burden and provision of the draft information collection tool and guidance. The comments in the attached table are respectfully offered for your consideration.

Sincerely,

Maureen O'Leary, PhD, CBSP
President, ABSA International

Attachment

ABSA International Technical and Regulatory Review Committee
Comments Table

Comments on: • CDC: Proposed Data Collection Submitted for Public Comment and Recommendations. • Incident Notification and Reporting APHIS/CDC Form 3 Draft. •APHIS/CDC Guidance Document for Reporting Potential Theft, Loss, Release, or Occupational Exposure.	**Deadline: 14 February 2017**	**Document Citation/Number: 81 FR 96456** https://www.federalregister.gov/documents/2016/12/30/2016-31739/proposed-data-collection-submitted-for-public-comment-and-recommendations

Table 1: General Comments

Instructions: Use this table to make general comments about the document content or related issues. Add rows as needed.

General comment	*Comment (justification for change)*	*Proposed change*	*Proposal to address each comment submitted*

Table 2: Specific Comments

Instructions: Use this table to make comments specific to each recommendation in the document

Form 3 or Guidance Drafts, Section and Name	*Form 3 Block, or Guidance Page*	*Type of comment ge = general te = technical ed = editorial*	*Comment (justification for change)*	*Proposed change*	*Proposal to address comment submitted*
Form 3 Section A-Entity Information	Block 7	ed	Laboratory supervisor should be removed, all communication should be through the RO (or ARO) and not a lab manager. This ensures that the RO is apprised of all situations in the laboratory as they are occurring.	Name of Responsible Official (or ARO):	The Guidance document refers to listing the laboratory supervisor if the entity is not registered. Recommend adding as subtext "(see Guidance document if entity is not registered)". The term "laboratory supervisor" is too vague in how it is used across various entities. The Guidance document can explain that the person listed should be equivalent in responsibility to the RO or ARO. This person may have a different title than laboratory supervisor.

Form 3 or Guidance Drafts, Section and Name	***Form 3 Block, or Guidance Page***	***Type of comment ge = general te = technical ed = editorial***	***Comment (justification for change)***	***Proposed change***	***Proposal to address comment submitted***
Form 3 Section E - Report of Release	Block 3	ge	The list of types of PPE worn is very generic, a space is suggested for a "Description of PPE" below the list. In doing this a more specific answer can be provided such as " Tyvek suit with PAPR and double gloves", thus better assisting in the exposure risk assessment.	Add a line for Description of PPE after the list	
Form 3 Section E - Report of Release	Block 8	te	Modify question to ask if an internal incident invesigation has been initiated to identify the root cause versus only a review of procedures and policies.	Modify question to "Has an internal investigation ~~review of laboratory procedures and policies,~~ been initiated to lessen the likelihood of recurrences of incident involving the select agents and toxin at this entity?"	Change prioritizes focus on how incident occurred versus whether it was a violation of procedure or policy.
Guidance - Section E - Report of Release	Page 16, Block E8	te	Modify text in Guidance document, page 16, Block E8, to reflect proposed change above in Form 3 Section E Block 8.	Change Block E8 title from "Internal Review" to "Internal Investigation". Change first bullet to read: "Select 'yes', if an internal investigation has been initiated to identify the root cause and review laboratory procedures and policies. Otherwise, select 'no'.	