



ABSA INTERNATIONAL

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August 23, 2017

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RE: SA Gram August 3, 2017 "Updated Draft Biosafety/Biocontainment
Guidance Document Available for Comment"

Dear Dr. Isaac and Dr. Edwin,

ABSA International welcomes the opportunity to comment on the updated draft Biosafety/Biocontainment Plan Guidance document released in the August 3, 2017 SA Gram. ABSA International provides critical expertise in this field as many of its members are extensively involved in implementing the Federal Select Agent Program for their entities and fulfilling certain roles therein.

ABSA International appreciates the overall responsiveness to comments submitted for the Biosafety/Biocontainment Plan Template version reviewed in April 2017 and additional changes reflected in the updated draft Biosafety/Biocontainment Plan Guidance document. General and specific comments for the August 2017 updated draft are provided in the attached Comments Table. These comments are respectfully offered for your consideration.

Sincerely,


Maureen O'Leary, PhD, CBSP
President, American Biological Safety Association

**ABSA International
Technical and Regulatory Review Committee**

<p>Comments on: Federal Select Agent Program (FSAP) Selects Agents and Toxins Biosafety/Biocontainment Plan Guidance, Updated Draft Document</p>		<p>Document Citation/Number: 7 CFR Part 331.12, 9 CFR Part 121.12, 42 CFR Part 73.12</p>
<p>Deadline: August 25, 2017</p>		
<p>Table 1: General Comments</p>		
<p><i>General comment</i></p>	<p><i>Comment (justification for change)</i></p>	<p><i>Proposed change</i></p>
<p>Document format; Table of Contents (TOC) doesn't match the text.</p>	<p>The TOC does not align with the layout of the document. Recommend keeping capitalization pattern and indentations in consistent format throughout. Titles in the TOC were not consistent as listed in the text. Titles for two text sections are omitted in TOC. See below for added title.</p>	<p>Numbering sections may provide clarity to TOC organization. TOC under <i>Proposed change</i> column matches Guidance document. Changes are in bold or underlined. Order of sections under 4.B. corrected as seen in text. Omitted rest of title for "Engineering Controls" section to match in text. Capitalization among titles in TOC and in text varies. Presented consistently as proposed. "Secondary containment", "Administrative Controls" and "Work Practices" section titles added to match text. Title for Section 4.C. Disinfection.... uses the singular form of Agent and Toxin. This may be intended so no change is included.</p>

Technical and Regulatory Review Committee
Document Review

Table 1: General Comments				
General comment	Comment (justification for change)	Proposed change		
TOC section omitted from document	Risk Management Process Controls is in the TOC but not in the document	Proposed to address each comment submitted		
Table 2: Specific Comments				
Section Name and/or Section Number (e.g. Introduction, 331.9 Responsible Official)	Page/Paragraph/Figure/Table (e.g. 121.14(f))	Comment (justification for change)	Proposed change	Proposal to address each comment submitted
Introduction	Page 3: bulleted resources list	References are incomplete for the first 3 bullets.		It is understandable that the text is incomplete assuming the references versions to be used will be the most current at the time of release. The caution is to ensure that information included is still consistent with that contained in the updated versions, if the versions change.
Definitions	Page 4: Definitions	Including a definition of select agents and Tier One select agents would be useful in this section, and in the introduction in general.		Add definitions for Select Agents and Tier one select agents in definitions section
Appendix I: Disinfection	Page 12	There are other factors that can alter the effectiveness of a disinfectant. It might be a good idea to mention a few others, to make the list more complete.		Along with temperature, disinfection can be affected by time, pH, water hardness, other chemicals used (e.g., mixing with certain detergents), etc.
Appendix I	Page 12: citation in footer	Citation #3 is incomplete.		Caution only to ensure the page number in the citation is the same for the reference when it is completely listed. Recommend including the appendix title as well.