



ABSA INTERNATIONAL

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Adis Dijab and Samuel Edwin
Directors
Federal Select Agent Program

Dear Dr. Dijab and Dr. Edwin,

ABSA International (American Biological Safety Association) welcomes the opportunity to review the **draft Federal Select Agent Program (FSAP) Policy Statement: Registration and Inspection of Effluent Decontamination Systems** released June 19, 2018. ABSA International provides a critical expertise for this topic as many of its members are extensively involved in implementing the FSAP at their entities and fulfilling certain roles therein.

The comments below are respectfully offered for your consideration.

Policy Statement: "It is the policy of the FSAP that an area containing an Effluent Decontamination System is not required to be listed on an entity's registration so long as:"

- **Concern:** If the EDS is not to be included in the entity's registration, what method will be used to ensure that the EDS meets containment requirements prior to use?
- Will the EDS be required to be included the containment facility commission or certification process?
- If the EDS is not included in the containment facility commission or certification process, what validation documents, test reports, and other materials will be reviewed by the authorities prior to use?

Item #2:

"2. The entity's plans (i.e., incident response, biosafety, and security) must address the entity's Effluent Decontamination System."

- **Recommendation:** The FSAP to include detail on what must be addressed in the entity's three plans.
- Does the condition to address the EDS in the entity's listed plans include addressing the EDS in each plan, and to what detail; or does it meet the intent of policy if the entity addresses the EDS in

- only one of the three listed plans (incident response, biosafety, and security) as long as it is inclusive with incident response, biosafety, and security FSAP regulations?
- What *specific information* is required to be in the entity's incident response, biosafety, and security plans regarding the entity's Effluent Decontamination System?

For example:

Incident Response & Biosecurity Plans

- Are EDS leaks to be addressed in the incident response and biosecurity plan?
- Do leaks require a Form 3 to be filed?

Biosafety Plan

- Validation of the EDS to demonstrate operation at the decontamination parameters effective for the select agents and toxins for which it is intended to decontaminate.
- Verification to be conducted to ensure validated measures are working.
- Periodicity of the required testing to ensure effluent is properly decontaminated.

- *Grammar:* Item #2 of the policy statement does not grammatically follow the initial portion of the policy statement. It is recommended to change the statement *from:*

“It is the policy of the FSAP that an area containing an Effluent Decontamination System is not required to be listed on an entity's registration so long as:

1. The entity's plans (i.e., incident response, biosafety, and security) **must** address the entity's Effluent Decontamination System.”

to:

2. The entity's plans (i.e., incident response, biosafety, and security) **clearly** address the entity's Effluent Decontamination System.”

Paragraph #3: “FSAP reserves the right to inspect an entity's entire Effluent Decontamination System, including those sections of an Effluent Decontamination System that may be in an area not listed on an entity's registration, to verify that treatment process is effective to protect entity personnel, the public, and the environment.”

- Will FSAP inspect the EDS and verify that the treatment process is effective prior to the facility participating in the FSAP or receiving select agents?
 - *Recommendation:* A consistent FSAP inspection of the EDS for all FSAP facilities prior to use.

Guidance and/or Standards

- What guidance documents and standards are to be followed for the EDS? Are the FSAP inspection checklists and information in the BMBL sufficient to guide entities on what should be addressed in their plans with regard to EDS?
- What specific criteria or regulations for EDS systems, commercial and developed in-house, must be followed to ensure that the EDS meets containment requirements? Examples:

- USDA ARS Facilities Design Standards Manual 242.1
- NIH Design Requirements Manual
- Canadian Biosafety Standard, Chapter 3.8. CBS does not require the EDS to be in the containment zone but it must meet containment requirements.

ABSA International appreciates the opportunity provided by FSAP to review the **draft FSAP Policy Statement: Registration and Inspection of Effluent Decontamination Systems**. We recognize and appreciate the work involved in maximizing program safety and efficiency, and efforts to reduce the regulatory burden. Please contact me with any questions or to request clarification.

Respectfully,

A handwritten signature in black ink, appearing to read 'Patrick Condreay', with a stylized flourish at the end.

Patrick Condreay, PhD, RBP
President, ABSA International