I. Purpose

This standard operating procedure (SOP) describes the procedures for intra-entity transfer of select agents and toxins discovered in unregistered locations on NIH Campuses.

II. Scope

The document applies to all NIH Campuses and all NIH Select Agent Programs (SAP).

III. Roles and Responsibilities

NIH SAP personnel are responsible for following this SOP.

IV. Special Practices

- Select agent(s)/toxin(s) must be transferred in a triple-packaging system designed to prevent leakage of materials.
- Packages must have a biohazard symbol on the outside.
- Select agent(s)/toxin(s) must be transferred with a chain-of-custody form (Appendix A) to ensure that they will not be left unattended.
- NIH SAP may seize select agent materials at any time. In such circumstances, the seizure of materials shall be documented using a chain-of-custody form.
- The RO/ARO will collect all the necessary information for filing a Form 3.

V. Procedures

A. How to conduct an intra-entity transfer of select agents and toxins discovered in unregistered locations on NIH Campuses.

1. If an ARO is first notified of the discovery of the select agent(s)/toxin(s) in an unregistered location, the ARO must notify the RO immediately.

2. The RO/ARO will instruct the individual(s) to secure the select agent(s)/toxin(s) and wait for the RO/ARO to arrive at the location.

3. Upon arrival, the RO/ARO will assess the circumstances surrounding the discovery of the select agent(s)/toxin(s) in the unregistered location and will collect all the necessary information for filing a Form 3.

4. If the assessment reveals that individual(s) were exposed to the select agent(s)/toxin(s), the RO/ARO will instruct the individual(s) to report to Occupational Medical Service immediately.

5. Following the procedures in the RO/ARO's incident response plan, the RO/ARO will notify CDC/DSAT or USDA/AgSAS File Manager about the discovery (phone, fax, email). The RO/ARO will document all non-email notifications with a follow-up email as soon as practically possible.

6. If a decision is made to remove the select agent(s)/toxin(s) from the premises, the RO/ARO will triple-package the select agent(s)/toxin(s) in a safe and secure manner and will complete a chain-of-custody form prior to transporting the select agent(s)/toxin(s).

7. The RO/ARO will transfer the select agent(s)/toxin(s) in a safe and secure manner to a registered select agent location. If a Form 2 is required, the RO/ARO will communicate with their File Manager to secure the necessary approvals.

8. Upon arrival, the RO/ARO will securely store the select agent(s)/toxin(s) or will make a decision to destroy them utilizing appropriate methods based on the agent(s)/toxin(s).

9. If a decision is made to destroy the select agent at the site of discovery, the RO/ARO will witness the destruction of the select agent(s)/toxin(s) and will document this destruction on the chain-of-custody form. An appropriate destruction method will be utilized based on the agent(s)/toxin(s) discovered.

10. When applicable, a biological indicator (BI) will be included with the destruction to validate the destruction method.

B. Notifications

1. The RO/ARO will make initial notifications to their File Manager following the procedures in the RO/ARO's incident response plan.

2. The RO/ARO will complete a Form 3 and submit it within 7 calendar days.

3. The RO/ARO will make the appropriate notifications up the chain-of-command as soon as possible.

VI. References

- 7 CFR 331
- 9 CFR 121
- 42 CFR 73
- Form 2 Instructions on FSAP website
- Form 3 Instructions on FSAP website

VII. Appendices

A. Chain-of-Custody

Appendix A

NIH SELECT AGENT PROGRAM

Chain of Custody

Material Description: _____

_____

From (print): _____

ID#: _____

Organization: _____

Authorization Signature: _____

Date (mm/dd/yyyy): _____ Time: _____

To (print): _____

ID#: _____

Organization: _____

Authorization Signature: _____

Date (mm/dd/yyyy): _____ Time: _____

From (print): _____

ID#: _____

Organization: _____

Authorization Signature: _____

Date (mm/dd/yyyy): _____ Time: _____

To (print): _____

ID#: _____

Organization: _____

Authorization Signature: _____

Date (mm/dd/yyyy): _____ Time: _____

Make additional blank copies as needed.

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