

UH IBC: Isolation of Select Agent (SA) in a non-Federal certified UH Facility

Guideline 1.0 Version 1.0

Effective Date 8/6/06, 6/5/20

1. The Laboratory Supervisor shall notify:

Biosafety Officer, except CTHAR CTAHR notifies their Responsible Official, Campus Security Chair, Dean, Unit Supervisor

2, CTAHR Responsible Officer shall notify (Biosafety Notification Tree Activated)

Assistant RO Police, FBI and Homeland Security USDA (Local) Hawaii Department of Agriculture

2. The Laboratory Supervisor shall complete APHIS/CDC form 4, "Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory":

https://www.selectagents.gov/form4.html

Fax or Scan and forward original, to RO and Biosafety Program, ORC, Honolulu HI 96822-2320). **DO NOT SEND to USDA**.

- 4. Secure SA under lock and key all equipment that is storing SA.
- 5. Use the following procedures depending on intended disposition of the SA
 - a. TRANSFER.

Transfer to a secure federally authorized site. Form APHIS/CDC Form 2. "Transfer SelectAgents and Toxins" must be completed and faxed to RO and Biosafety Program.

A federal permit to transport is also required either: (a) USDA-APHIS VS Form 16-3, "Import Controlled Material or Transport Organisms or Vectors" for High Consequence Livestock Pathogens and Toxins/Select Agents (Overlap agents) or (b) PPQ Form 526, "Application to Move Live Plant Pests or Noxious Weeds."

Once the permit to transfer is issued, the RO will notify facility's Laboratory Supervisor. BSP-2 form must be completed after notification and faxed to Biosafety Program. The

package must meet IATA and DOT specifications. As this is a dangerous goods shipment, a "Dangerous Goods Declaration" is needed. Use a parcel courier, no hand carrying on public transportation. Parcel must be shipped "registered" and "certified" with insurance.

User must be "Category A Biological Material Transport" trained.

b. RETAIN

All provisions of USDA and Health and Human Services (HHS) rules for the possession, use, and transfer of select agents and toxins (42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121) must be followed.

An IBC review must be conducted. Please submit appropriate Biosafety Program forms.

c. DESTROY

Notify RO of date of expected destruction.

Arrange for witness destruction by securing representatives from Biosafety, Police, FBI, Homeland Security, HDOA and USDA.

All agency representatives must sign the BSP-2 form acknowledging total destruction. Quality Controls (Biological Indicators, Chemical Indicator) must be run during the autoclave destruction.

Copies of the BSP-2 form with witnesses' signatures must be forwarded to RO and Biosafety Program.

RO will notify appropriate agencies that the select agents have been destroyed.