NOTICE TO REQUESTER

TO: request+2yfsb4kex4@foi.uipa.org
(Requester's name)

FROM: **University of Hawaii, Presley Pang, 956-2211 Presley@hawaii.edu**
(Agency, and agency contact person's name, telephone number, & email address)

DATE THAT THE RECORD REQUEST WAS RECEIVED BY AGENCY: 02-04-2020

DATE OF THIS NOTICE: _March 16, 2020

GOVERNMENT RECORDS YOU REQUESTED (attach copy of request or provide brief description below):
1.

Correspondence between the University of Hawaii and the Centers for Disease Control and Prevention from May 13, 2014 to present regarding UH's registration to possess, use, or transfer select agents and toxins, including but not limited to Registration # C20110621-1232.

See attached.

THIS NOTICE IS TO INFORM YOU THAT YOUR RECORD REQUEST:

☐ **Will be granted in its entirety.**

☐ **Cannot be granted. Agency is unable to disclose the requested records for the following reason:**

- ☐ Agency does not maintain the records. (HRS § 92F-3)
  Other agency that is believed to maintain records: _____
- ☐ Agency needs further clarification or description of the records requested. Please contact the agency and provide the following information: _____
- ☐ Request requires agency to create a summary or compilation from records, but requested information is not readily retrievable. (HRS § 92F-11(c))

X **Will be granted in part and denied in part, OR** ☐ **Is denied in its entirety**
Although the agency maintains the requested records, it is not disclosing all or part of them based on the exemptions provided in HRS § 92F-13 and/or § 92F-22 or other laws cited below.
(Describe the portions of records that the agency will not disclose.)

RECORDS OR INFORMATION WITHHELD	APPLICABLE STATUTES	AGENCY JUSTIFICATION
CDC Employee Identities and contact information	92F-13(1) and (4)	Privacy

REQUESTER'S RESPONSIBILITIES:

You are required to (1) pay any lawful fees and costs assessed; (2) make any necessary arrangements with the agency to inspect, copy or receive copies as instructed below; and (3) provide the agency any additional information requested. If you do not comply with the requirements set forth in this notice within 20 business days after the postmark date of this notice or the date the agency makes the records available, you will be presumed to have abandoned your request and the agency shall have no further duty to process your request. Once the agency begins to process your request, you may be liable for any fees and costs incurred. If you wish to cancel or modify your request, you must advise the agency upon receipt of this notice.

METHOD & TIMING OF DISCLOSURE:

Records available for public access in their entireties must be disclosed within a reasonable time, not to exceed 10 business days from the date the request was received, or after receipt of any prepayment required. Records not available in their entireties must be disclosed within 5 business days after this notice or after receipt of any prepayment required. HAR § 2-71-13(c). If incremental disclosure is authorized by HAR § 2-71-15, the first increment must be disclosed within 5 business days of this notice or after receipt of any prepayment required.

Method of Disclosure:

☐ Inspection at the following location: _____

☐ As requested, a copy of the record(s) will be provided in the following manner:

- ☐ Available for pick-up at the following location: _____
- ☐ Will be mailed to you.
- **X** Will be transmitted to you by other means requested: email to request+2yfsb4kex4@foi.uipa.org

Timing of Disclosure: All records, or the first increment if applicable, will be made available or provided to you:

x On March 16, 2020.

☐ **After prepayment** of 50% of fees and 100% of costs, as estimated below.

For incremental disclosures, each subsequent increment will be disclosed within 20 business days after:

- X The prior increment (if one prepayment of fees is required and received), or
- ☐ Receipt of each incremental prepayment, if prepayment for each increment is required.

Records will be disclosed in increments because the records are voluminous and the following extenuating circumstances exist:

- X Agency must consult with another person to determine whether the record is exempt from disclosure under HRS chapter 92F.
- X Request requires extensive agency efforts to search, review, or segregate the records or otherwise prepare the records for inspection or copying.
- X Agency requires additional time to respond to the request in order to avoid an unreasonable interference with its other statutory duties and functions.
- ☐ A natural disaster or other situation beyond agency's control prevents agency from responding to the request within 10 business days.

ESTIMATED FEES & COSTS AND PAYMENT:

FEES: For personal record requests under Part III of chapter 92F, HRS, the agency may charge you for its costs only, and fee waivers do not apply.

For public record requests under Part II of chapter 92F, HRS, the agency is authorized to charge you fees to search for, review, and segregate your request (even if a record is subsequently found to not exist or will not be disclosed in its entirety). The agency must waive the first $30 in fees assessed for general requesters, OR in the alternative, the first $60 in fees when the agency finds that the request is made in the public interest. Only one waiver is provided for each request. *See* HAR §§ 2-71-19, -31 and -32.

COSTS: For either personal or public record requests, the agency may charge you for the costs of copying and delivering records in response to your request, and other lawful fees and costs.

PREPAYMENT: The agency may require prepayment of 50% of the total estimated fees and 100% of the total estimated costs prior to processing your request. If a prepayment is required, the agency may wait to start any search for or review of the records until the prepayment is received by the agency. Additionally, if you have outstanding fees or costs from previous requests, including abandoned requests, the agency may require prepayment

of 100% of the unpaid balance from prior requests before it begins any search or review for the records you are now seeking.

The following is an itemization of what you must pay, based on the estimated fees and costs that the agency will charge you and the applicable waiver amount that will be deducted:

For public record requests only:

Fees:	Search	Estimate of time to be spent: _____ hours ($2.50 for each 15-minute period)	$
	Review & segregation	Estimate of time to be spent: _____ hours ($5.00 for each 15-minute period)	$
	Fees waived	☐ general ($30), **OR** ☐ public interest ($60) (Only one waiver per request)	<$ _____>
	Other	_____ (Pursuant to HAR §§ 2-71-19 & 2-71-31)	$
	Total Estimated Fees:		**$** To Be Determined

For public or personal record requests:

Costs:	Copying	Estimate of # of pages to be copied: _____ (@ $ ____ per page, pursuant to HRS § 92-21)	$
	Delivery	Postage	$
	Other	_____	$
	Total Estimated Costs:		**$** To be Determined

TOTAL ESTIMATED FEES AND COSTS from above: **$ TBD**

☐ **The estimated fees and costs above are for the first incremental disclosure only. Additional fees and costs, and no further fee waivers, will apply to future incremental disclosures.**

☐ **PREPAYMENT IS REQUIRED** (50% of fees + 100% of costs, as estimated above) **$**

☐ **UNPAID BALANCE FROM PRIOR REQUESTS** (100% must be paid before work begins) **$**

TOTAL AMOUNT DUE AT THIS TIME **$ TBD**

Payment may be made by: ☐ cash
☐ personal check payable to _____
☐ other _____

For questions about this notice or the records being sought, please contact the agency person named at the beginning of this form. Please note that the Office of Information Practices (OIP) does not maintain the records of other agencies, and a requester must seek records directly from the agency it believes maintains the records. If the agency denies or fails to respond to your written request for records or if you have other questions regarding compliance with the UIPA, then you may contact OIP at (808) 586-1400, oip@hawaii.gov, or 250 South Hotel Street, Suite 107, Honolulu, Hawaii 96813.

REQUEST TO ACCESS A GOVERNMENT RECORD

This is a model form that may be used by a Requester to provide sufficient information for an agency to process a record request. Although the Requester is not required to use this form or to provide any personal information, the agency needs enough information to contact the Requester with questions about this request or to provide its response. This request may not be processed if the agency has insufficient information or is unable to contact the Requester.

DATE: 02-04-2020

TO: **University of Hawaii**
Agency that Maintains the Government Record

UHUIPA@hawaii.edu
Agency's Contact Information

FROM: request+2yfsb4kex4@foi.uipa.org
Requester's Name or Alias

request+2yfsb4kex4@foi.uipa.org
Requester's Contact Information

AS THE REQUESTER, I WOULD LIKE THE FOLLOWING GOVERNMENT RECORD:

Describe the government record as specifically as possible so that it can be located. Try to provide a record name, subject matter, date, location, purpose, or names of persons to whom the record refers, or other information that could help the agency identify the record. A complete and accurate description of the requested government record will prevent delays in locating the record. Attach additional pages if needed.

Correspondence between the University of Hawaii and the Centers for Disease Control and Prevention from May 13, 2014 to present regarding UH's registration to possess, use, or transfer select agents and toxins, including but not limited to Registration # C20110621-1232.

I WOULD LIKE: (Please check one or more of the options below, as applicable)

☐ **To inspect the government record**

☒ **A copy of the government record:** (Please check only one of the options below.) See the next page for information about fees and costs that you may be required to pay for agency services to process your record request. Note: Copying and transmission charges may also apply to certain options.

- ☐ Pick up at agency (**date and time**): _____
- ☐ Mail (address): _____
- [X] E-mail (address): request+2yfsb4kex4@foi.uipa.org
- ☐ Fax (toll free and only if available; provide fax number): _____
- ☐ Other, if available (please specify): _____

Department of Health and Human Services
Centers for Disease Control and Prevention
Division of Select Agents and Toxins
Atlanta, GA

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Agriculture Select Agent Services
Riverdale, MD

April 25, 2017

Leonard Gouveia (Responsible Official)
University of Hawaii at Manoa (CDC)
2425 Campus Road, Sinclair 10
Honolulu, HI 96822
lgouveia@hawaii.edu

cc: stevec@hawaii.edu; olipares@hawaii.edu

RE: Entity Inspection Report: **University of Hawaii at Manoa (CDC)**

Pursuant to the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the United States Department of Health and Human Services (HHS) and the United States Department of Agriculture (USDA) have established regulatory requirements for the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety, animal and plant health, and animal and plant products. These requirements can be found at 42 CFR Part 73 (HHS), 7 CFR Part 331 (USDA-PPQ), and 9 CFR Part 121 (USDA-VS).

The Federal Select Agent Program (FSAP) is jointly comprised of the Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins (DSAT) and the Animal and Plant Health Inspection Service (APHIS), Agriculture Select Agent Services (AgSAS). CDC DSAT inspects entities to evaluate whether they meet the regulatory requirements set forth in 42 CFR Part 73. APHIS AgSAS inspects entities to evaluate whether they meet the regulatory requirements set forth in 7 CFR Part 331 and 9 CFR Part 121. The above referenced regulations and supporting guidance information may be found at http://www.selectagents.gov.

FSAP inspectors visited your facility located at 1960 East-West Road, Honolulu, HI 96822 from 3/13/2017 to 3/16/2017. A list of laboratories inspected on these dates is on file with this letter at CDC.

The following personnel from FSAP inspected the facility:

[redacted] Lead Inspector
[redacted]
[redacted]
[redacted]

A list of the individuals from University of Hawaii at Manoa (CDC) who were present during the inspection was provided to you at the close of the inspection.

During the inspection, departures from regulatory requirements cited above were noted. Please address each of the items described in Appendix 1 (List of Entity Departures) and include in your response the specific actions or changes to be adopted to correct these departures. **A detailed response should be received by this office not later than 14 calendar days from receipt of this letter.** An electronic copy of your response should be sent to the lead inspector, [redacted] Failure to fully respond may result in the initiation of proceedings for further compliance action.

This report contains appendices that may list departures, additional concerns, requests for information, or issues currently under review. Please read these appendices carefully as they contain important information.

You may dispute observations within this report. Within 14 calendar days from receipt of this report, you may email your dispute request to the DSAT Operations Branch Chief (lrsat@cdc.gov). The request must specify the observations that you are disputing. Within 30 calendar days of the receipt of this report, provide a written statement that clearly states why you consider the observations are in error. You may include documentation in support of your dispute. The DSAT Operations Branch Chief will attempt to resolve the dispute with you within 30 calendar days of the receipt of the written statement. The resolution of a dispute may include discussions with the entity or additional site visits. If the resolution of a dispute results in a change to an observation or required corrective action, DSAT will issue an addendum to the inspection report.

If you have any questions concerning this correspondence please contact [redacted] or [redacted]

Sincerely,

Von McClee
Operations Branch Chief (Acting)
Division of Select Agents and Toxins
Department of Health and Human Services
Centers for Disease Control and Prevention

Charles Divan
Unit Director
Agriculture Select Agent Services
Animal and Plant Health Inspection Services
United States Department of Agriculture

Appendix 1:
List of Entity Departures

Appendix 2: General
Concerns

Appendix 3:
Concerns Related to Amendments (Not applicable to this report)

Appendix 4:
Request for Additional Information (Not applicable to this report)

Appendix 5:
Issues Under Review

Appendix 6
Entity Report Card

Appendix 1: List of Entity Departures

Departures noted from 3/13/2017 to 3/16/2017 at University of Hawaii at Manoa (CDC) (citations from 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73 specifying each requirement are given in brackets).

A detailed response to each of the following departures is due to DSAT within 14 calendar days of the receipt of this report. The departures below are presented in order of their **relative severity – highest to lowest**. Repetition of these departures, as shown on future inspections, will be considered more serious and may result in compliance actions.

Severity Level: Serious

1 **Requirement:** An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release. [Section 11(a)]

Observation:

A. The entity failed to implement written procedures regarding personnel suitability for individuals with access to Tier 1 select agents. These failures were recognized through the Responsible Official's (RO) and laboratory personnel's lack of familiarity with the written suitability assessment program and related reporting procedures during interviews.

B. The entity failed to implement effective procedures for obtaining access to the JBF containment suites. This failure was recognized after review of the university's incident reports and statements made by security and laboratory personnel. This resulted in:

- Tier 1 laboratory areas being unprotected by an intrusion detection system (IDS) when the laboratory was not physically occupied [Section 11(f)(4)(v)].
- The failure to monitor or respond to the IDS alarms [Section 11(f)(4)(vi)].
- The failure to implement after hour access controls for FSAP approved personnel entering JBF laboratory areas [Section 11(f)(4)(ii)].
- The failure to implement procedures for monitoring and responding to suspicious behavior. [Section 11(c)(6)]
- A physical security vulnerability when an interior service door (room 158) was found to be unsecured for approximately 2 weeks [Section 11(f)(4)(iv)].

Note: The failure to implement the entity's security plan, including the Tier 1 requirements, were observed during the 2014 and 2015 inspections and reflects a failure of the entity to implement or sustain past corrective actions.

Corrective Action:

A. Describe the measures taken to ensure the security plan is implemented for the security requirements described above. Provide a copy of the updated security plan if revisions are made to the plans and procedures in response to this observation.

B. Provide documentation of training for FSAP-approved personnel on the procedures described in the security plan and related SOPs. Training documentation must include the names of the individuals, date and description of the training, and the means used to ensure personnel understood the information provided.

2 **Requirement:** The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program. [Section 12(d)]

Observation: The entity failed to implement the occupational health program (OHP) described in the entity's document titled "The Biosafety Plan - Occupational Health Program for Working with Tier 1 Select Agents or Toxins". Specifically, there was no evidence that Tier 1 personnel were enrolled in the university's occupational health program or that annual medical evaluations, fit-testing for respirators, or other written requirements (as determined by the university's risk assessment) were completed in 2015 and 2016.

Note: The lack of implementation of the entity's occupational health plan was observed during the March 2014 inspection and reflects a failure of the entity to implement or sustain past corrective actions.

Corrective Action: Provide:

- Documentation that Tier 1 staff are enrolled in the OHP.
- The measures implemented to ensure the OHP is implemented and all Tier 1 staff receive the occupational health considerations as reflected in the written procedures and determined by the entity's risk assessment.
- A revised OHP for review if changes are made to the plan.
- Documentation of training for Tier 1 staff on the OHP including any revised procedures. Training documentation must include the names of the individuals, date and description of the training, and the means used to ensure personnel understood the information provided.

3 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials). [Section 17(a)(1)]

Observation: Inventory records for PI Douglas's Brucella sera (boxes 4 and 5), and PI Nerurkar's stocks of Venezuelan equine encephalitis virus and Eastern equine encephalitis virus did not meet the requirements of 17(a)(1)(i-v). The incomplete hand written notes provided are insufficient. The failure to document inventory was observed during the March 2015 inspection, and although that record was immediately created as a spreadsheet and provided to inspectors, subsequent select agent material was not properly documented at the 2017 inspection.

Note: The lack of accurate inventory records was observed during the March 2015 inspection and reflects a failure of the entity to implement or sustain past corrective actions.

Corrective Action: Provide:

- Updated inventory records for PI Douglas' Brucella sera and PI Nerurkar's Venezuelan and Eastern equine encephalitis virus stocks. The revised inventory records must meet all requirements of 17(a)(1)(i-v)
- The measures implemented to ensure that all select agents held in long term storage are documented in the inventory record.
- The measures implemented to ensure that all inventory records remain accurate.
- Documentation of training for staff on the record keeping requirements. Documentation must include the names of the individuals, date and description of the training, and the means used to ensure personnel understood the information provided.

4 **Requirement:** Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application. The Responsible Official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of the amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part. No change may be made without such approval. [Section 7]

Observation: The work objectives described on the entity's registration for PI Alvarez include *in vitro* diagnostic development and detection assays in Room 315C. This area is not equipped with primary containment measures and the facility standards of a BSL-2 laboratory commensurate with the risk of working with *Ralstonia solanacearum* race 3 biovar 2. Additionally, entity personnel stated experiments with plants were also conducted in Room 315C. These work objectives are not reflected in PI Alvarez's current work objectives.

Corrective Action: An amendment was submitted to FSAP on April 13, 2017 to update PI Alvarez's work objectives to storage only. If the entity would like to resume active work with *Ralstonia solanacearum*:

- Submit an amendment to the registration.
- Provide the measures implemented to ensure work areas meet the BSL-2 facility standards commensurate with the risk of work with this agent. These facility requirements are listed in the approved PPQ Form 526 permits for plant pathogen select agents P526P-15-03136; P526P-15-03137 (7 CFR part 330).

5 **Requirement:** An individual or entity required to register under this part must designate an individual to be the Responsible Official. The Responsible Official must be familiar with the requirements of this part. The Responsible Official must ensure compliance with the requirements of this part. [Section 9(a)(2), 9(a)(4)]

Observation: The RO stated he is unfamiliar with the requirements of 42 CFR Part 73. Additionally, current and past ROs appointed by the entity have not ensured compliance with the select agent regulations. The regulatory departures from sections 7, 9, 11, 12, 14, 15, and 17 described in this report, the entity's failure to maintain past corrective actions, and the stated lack of familiarity by the RO with the regulations highlight the serious lack of administrative oversight at leadership levels within the entity.

Note: The failure of the entity's RO to ensure compliance was previously observed during the March 2014 inspection.

Corrective Action:

- Provide the administrative measures implemented to increase familiarity of the RO with the select agent regulations.
- Describe the administrative efforts to ensure that oversight of the program by the RO will achieve and maintain compliance with the requirements of the select agent regulations.

6 **Requirement:** An entity may designate one or more individuals to serve as an alternate Responsible Official, who acts for the Responsible Official in his/her absence. These individuals must have the authority and control to ensure compliance with the regulations when acting as the Responsible Official. [Section 9(b)]

Observation: The designated alternate Responsible Officials (ARO) did not act for the RO in his absence to ensure compliance with the select agent regulations. This departure was identified by FSAP inspectors through onsite interviews with the AROs. It is unclear if the AROs failures to act on behalf of the RO was due to a lack of familiarity with the select agent regulatory requirements or a lack of control over the university's select agent activities.

Note: This observation was observed during the 2012 and March 2014 inspections and reflects a failure of the entity to implement or sustain past corrective actions.

Corrective Action:

- Provide the administrative measures implemented to increase familiarity of the AROs with the select agent regulations.
- Provide the measures implemented to ensure individuals designated as an ARO have the authority and responsibility to ensure compliance with the select agent regulations when acting as the RO.

Severity Level: Moderate

7 **Requirement:** An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). [Section 12(a/b)]

Observation: The written procedure for the inactivation of *Burkholderia pseudomallei* material with paraformaldehyde was not followed as stated by laboratory personnel. This material was subsequently transferred from the JABSOM BSL-3 laboratory to an unregistered BSL-2 laboratory on at least three occasions.

Note: Additional requirements on inactivation of select agents became effective on March 21, 2017. University of Hawaii at Manoa is responsible for complying with the new requirements for the inactivation of select agents. Information on compliance with these requirements can be found at https://www.selectagents.gov/irg-intro.html.

Corrective Action: The material was secured in place during the inspection and FSAP received notification from the RO on April 8, 2017 that the material was destroyed. Provide the measures implemented to ensure inactivation procedures meet the requirements of the amended select agent regulations and are followed by laboratory personnel prior to removing material from the registered laboratories.

8 **Requirement:** The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). [Section 12(b)]

Observation:

A. The entity did not provide evidence of enrollment for FSAP approved non-Tier 1 personnel in an appropriate medical surveillance program or respiratory protection program for 2015 and 2016. *[BMBL: (BSL-3) B2; (ABSL-3) A4]*

Note: This observation was observed during the March 2014 inspection and reflects a failure of the entity to implement or sustain past corrective actions.

B. The St. John autoclave used to decontaminate select agent waste had not been validated to be an effective means of waste decontamination by the entity. Autoclave based decontamination methods are widely accepted as an effective means to decontaminate infectious materials, but the specific parameters employed for this method (i.e. temperature, time, pressure), type of materials being autoclaved (i.e. liquid, dry) and the amount of materials loaded into the autoclave for each use can affect the decontamination results. Failure to achieve effective decontamination under all circumstances can lead to a loss of select agent containment. *[BMBL: (BSL-2) D11]*

Corrective Action:

A. Provide the measures implemented to ensure personnel complete the requirements for the medical surveillance or respiratory protection programs.

B. Provide the procedures used to validate the autoclave-based methods for decontamination of select agent waste.

9 **Requirement:** The Responsible Official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (e.eg. laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training. [Section 15(d)]

Observation: The entity failed to ensure that effective training was provided annually to individuals. These failures were recognized through staff and laboratorians' lack of familiarity and knowledge of procedures during interviews, indicating the entity's means used to verify personnel understood the training provided was not effective. Specifically:

- FSAP approved personnel with access to Tier 1 agents stated they were unfamiliar with pre-access and ongoing suitability procedures, and the occupational health plan requirements.
- Training on the security procedures, including arming and disarming of the IDS by FSAP approved personnel and security guards, was not effective, demonstrated by the high volume of "false alarm" incident reports documenting the failure to follow procedures.

Corrective Action: Describe the measures implemented to ensure effective means are used to verify FSAP approved personnel understand the required training.

10 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: An accurate, current accounting of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition). [Section 17(a)(2)]

Observation: The entity did not account for animals infected with *Burkholderia pseudomallei* through final disposition. Animals are tracked from the time they enter the ABSL-3 through final disposition in the tissue digester. However, there are no means to reconcile the number of animals or carcasses infected with a select agent from the time of infection through disposition in the records.

Corrective Action: Provide the measures implemented to ensure animals infected with select agents are accurately accounted for from the date of infection through final disposition.

Severity Level: Low

11 **Requirement:** The security plan must contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including documented procedures for receiving, monitoring, and shipping of all select agents and toxins. These provisions must provide that an entity will properly secure containers on site and have a written contingency plan for unexpected shipments. [Section 11(c)(10)]

Observation: The St. John laboratory security plan did not describe procedures for unexpected shipments.

Corrective Action: Provide an updated section of the security plan that contains provisions for unexpected shipments.

12 **Requirement:** The security plan must contain provisions for the control of access to select agents and toxins including the safeguarding of animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release. [Section 11(c)(2)]

Requirement: An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. [Section 12(a)]

Requirement: The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. [Section 14(c)]

Observation: The JABSOM and St. John security, biosafety, and incident response plans did not contain procedures for responding to animals or plants that have been accidentally exposed to or infected with a select agent.

Note: The security observation was previously observed during the March 2015 inspection and reflects a failure of the entity to implement or sustain past corrective actions.

Corrective Action: Provide an updated section of the security, biosafety, and incident response plans that contains this information.

13 **Requirement:** The security plan must describe procedures for how the Responsible Official will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins; and describe procedures for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of such activity. [Section 11(c)(8)]

Observation: The St. John laboratory security plan did not contain procedures for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of suspicious activity that may be criminal in nature and related to the entity, its personnel, or it select agents or toxins.

Corrective Action: Provide an updated section of the security plan that contains this information.

14 **Requirement:** Entities with Tier 1 select agents and toxins must prescribe the following security enhancements: For powered access control systems, describe procedures to ensure that security is

maintained in the event of the failure of access control systems due to power disruption affecting registered space. [Section 11(f)(4)(vii)]

Observation: The JABSOM security plan does not include procedures for maintaining security in the event of a failure of the Edstrom Watchdog System that controls access to rooms 158A and 158B in the ABSL3 laboratory.

Corrective Action: Provide the revised sections of the security plan that contain this information.

15 **Requirement:** The incident response plan must also contain decontamination procedures. [Section 14(d)(12)]

Observation: The decontamination procedures in the JABSOM incident response plan did not contain or reference specific disinfectants, the concentrations of these disinfectants, or appropriate contact times for spills involving select agents.

Corrective Action: Provide:

- An updated section of the incident response plan that contains this information.
- Provide documentation of training for personnel on the updated procedures. Training documentation must include the names of the individuals, date and description of the training, and the means used to ensure personnel understood the information provided.

16 **Requirement:** An individual or entity required to register under this part must provide information and training on biosafety, security (including security awareness), and incident response to: Each individual with access approval from the HHS Secretary or Administrator before that individual has such access to select agents and toxins. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. [Section 15(a)(1)]

Observation:

A. The training curriculum for FSAP approved personnel did not include agent specific information on the risks posed by the select agents on the entity's registration. Training on select agents includes the agent(s) each individual may work with, but not all the select agents and associated risks present in the JABSOM, BSL-3, or ABSL-3 laboratory suites.

B. The entity failed to ensure training is provided to FSAP approved individuals in isolated instances resulting in approximately 5% of the required personnel missing training in 2015 and 2016.

Corrective Action:

A. Provide an updated training curriculum that includes all select agent risk based considerations.

B. Describe the measures implemented to ensure comprehensive training is provided to all FSAP approved individuals.

17 **Requirement:** An individual or entity required to register under this part must provide information and training on biosafety, security (including security awareness), and incident response to: Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas where select agents or toxins are handled or stored (e.g., laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas,

production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. [Section 15(a)(2)]

Observation: The JABSOM Biocontainment Facility visitor training curriculum did not describe the risks associated with accessing areas where select agents are used or stored.

Corrective Action: Provide an updated visitor training curriculum that includes the above information. These procedures should include agent specific information and the procedures to follow in event of a potential exposure or illness.

18 **Requirement:** Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors. [Section 15(b)]

Observation: Insider threat awareness briefing was not provided to all personnel in 2016.

Corrective Action: Describe the measures implemented to ensure that all FSAP approved personnel receive insider threat awareness briefings annually.

19 **Requirement:** Refresher training must be provided annually for individuals with access approval from the HHS Secretary or Administrator or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans. [Section 15(c)]

Observation: In isolated instances in both 2015 and 2016, there was no record of annual refresher training for FSAP approved personnel.

Note: The failure to provide refresher training to all personnel was observed during the March 2014 and 2015 inspections and reflects a failure of the entity to implement or sustain past corrective actions.

Corrective Action: Describe the measures implemented to ensure that all FSAP approved personnel receive annual refresher training.

20 **Requirement:** An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include: An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including: The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source, when moved from storage and by whom and when returned to storage and by whom, the select agent used and purpose of use. [Section 17(a)(1)(ii)(iv-v)]

Observation: A check of PI Hoang's inventory records identified incomplete records for select agents held in long term storage. The following information was not recorded:

- Quantity (*e.g.*, number of containers), date of acquisition, and source of material.
- Returned by whom and date.
- Purpose of use.

Note: These observations were noted during the March 2015 inspection and reflects a failure of the entity to implement or sustain past corrective actions.

Corrective Action:

- Provide the measures implemented to ensure that inventory records include the required information described above.
- Provide documentation of training for relevant personnel on any updated procedures for inventory record keeping practices.

21 **Requirement:** All records created under this part must be maintained for three years and promptly produced upon request. [Section 17(c)]

Observation: The entity failed to maintain annual inspection records for the JABSOM facility for 3 years.

Corrective Action: Provide the measures implemented to ensure that all records created will be maintained for 3 years and promptly produced upon request.

Appendix 2: General Concerns

The information below represents concerns noted by the inspectors that fall outside the select agent regulations but may be important consideration for the entity. Responses to these concerns do not need to be provided as part of the 14-day detailed response to the departures noted in Appendix 1.

1 PPE donning and doffing procedures in the ABSL3 are complex and may not be consistently followed by personnel who do not enter and exit the suite on a regular basis. Simplified procedures or additional refresher training following an extended absence from the laboratory for personnel will ensure procedures are consistently followed and reduce the potential for exposure of laboratory personnel from contaminated PPE.

2 The entity's biosafety plan, occupational health plan, and posted signage in the BSL3 include procedures for the reuse of N95 respirators. Entity staff stated N95 respirators are no longer used for select agent work and reuse is not allowed for select agent work. However, the current written and posted procedures for respirators when performing select agent work are inconsistent with NIOSH guidelines for use of a respirator in a biosafety lab (https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource.html).

3 Entry and exit procedures, including the donning and doffing of PPE, were not posted in the ABSL-3. *[BMBL: (ABSL-3) A5].* Signage is only required to be posted when select agent infected animals are housed or manipulated. The lack of signage was previously observed during the March 2015 inspection, and would have been a repeat observation if select agent infected animals were present.

4 Drills conducted by the entity included inaccurate information and in some instances were not documented as stated in the entity's plans. For example, an exercise conducted in 2016 included incorrect reporting procedures for a select agent spill outside of primary containment and referenced incorrect select agent reporting forms to be used in the event of a theft, loss, or release.

Additional regulatory requirements for the documentation of drills and exercises became effective on March 21, 2017, and must include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of the registered entity personnel participants.

5 There was no system in place to ensure the records used to fulfill the select agent record keeping requirements are accurate. Entity personnel were able to locate the majority of records required by Section 17 but failed to have a system in place to identify or verify that the records were accurate and complete.

Appendix 3: Concerns Related to Amendment(s)

Appendix 3 is not applicable to this inspection report.

Appendix 4: Request for Additional Information

Appendix 4 is not applicable to this inspection report.

Appendix 5: Issues Under Review

The information below represents issues that are under review. Review of these documents may result in additional departures that will be sent to you under separate cover.

1 **Requirement:** The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program. [Section 12(d)]

Observation: The revised version of "The Biosafety Plan- Occupational Health Program for Working with Tier 1 Select Agents or Toxins," as referenced in the biosafety plan, has not been reviewed by FSAP. A FSAP specialist will contact you regarding the revised program.

2 **Requirement:** Entities with Tier 1 select agents and toxins must prescribe the following security enhancements: [Section 11(f)]

(1) Describe procedures for conducting a pre-access suitability assessment of persons who will have access to a Tier 1 select agent or toxin;

(2) Describe procedures for how an entity's Responsible Official will coordinate their efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents and toxins and share, as appropriate, relevant information; and

(3) Describe procedures for the ongoing assessment of the suitability of personnel with access to a Tier 1 select agent or toxin. The procedures must include:

i. Self- and peer-reporting of incidents or conditions that could affect an individual's ability to safely have access to or work with select agents and toxins, or to safeguard select agents and toxins from theft, loss, or release;

ii. The training of employees with access to Tier 1 select agents and toxins on entity policies and procedures for reporting, evaluation, and corrective actions concerning the assessment of personnel suitability; and

iii. The ongoing suitability monitoring of individuals with access to Tier 1 select agents and toxins.

(4) Entities with Tier 1 select agents and toxins must prescribe the following security enhancements:

i. Procedures that will limit access to a Tier 1 select agent or toxin to only those individuals who are approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General, have had an entity-conducted pre-access suitability assessment, and are subject to the entity's procedures for ongoing suitability assessment;

ii. Procedures that limit access to laboratory and storage facilities outside of normal business hours to only those specifically approved by the Responsible Official or designee;
iii. Procedures for allowing visitors, their property, and vehicles at the entry and exit points to the registered space, or at other designated points of entry to the building, facility, or compound that are based on the entity's site-specific risk assessment;
iv. A minimum of three security barriers where each security barrier adds to the delay in reaching secured areas where select agents and toxins are used or stored. One of the security barriers must be monitored in such a way as to detect intentional and unintentional circumventing of established access control measures under all conditions (day/night, severe weather, etc.) The final barrier must limit access to the select agent or toxin to personnel approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General.
v. All registered space or areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS) unless physically occupied;
vi. Personnel monitoring the IDS must be capable of evaluating and interpreting the alarm and alerting the designated security response force or law enforcement;
vii. For powered access control systems, describe procedures to ensure that security is maintained in the event of the failure of access control systems due to power disruption affecting registered space.

Observation: The 2016 JABSOM security plan, specifically the Tier 1 requirements in Section 11(f)(1-4), has not been reviewed by FSAP. Your file manager will contact you regarding this plan.

Appendix 6: Entity Report Card

Appendix 6 attached.

Department of Health and Human Services
Centers for Disease Control and Prevention
Division of Select Agents and Toxins
Atlanta, GA

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Agriculture Select Agent Services
Riverdale, MD

University of Hawaii at Manoa (CDC)
Inspection Report Card

Entity Complexity Category

- Low ☐
- Moderate ☐
- High ☑
- Super ☐

Inspection Compliance Performance Category

- No Action Required ☐
- Minor Actions Required ☐
- Increased Monitoring ☐
- Corrective Action Plan ☐
- Suspension ☑

Inspection Description

Inspection Type:

Announced ☐ Unannounced ☑

Renewal ☑ Verification ☐ Maximum Containment ☐

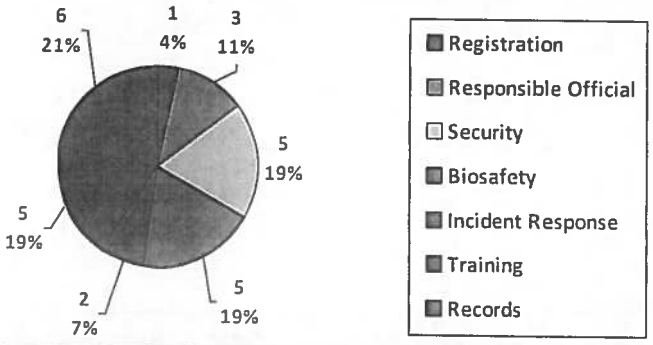
Date of Inspection: 3/13/2017

Inspection Results

Overview of Departures

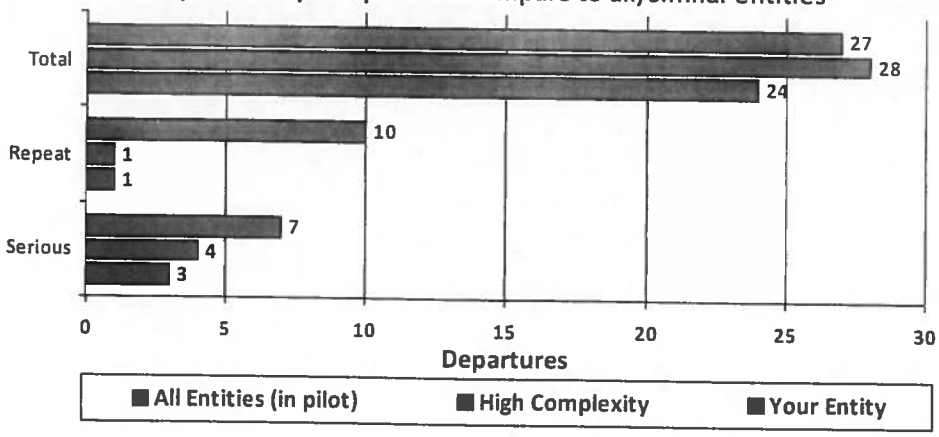
Serious:	7
Moderate:	5
Low:	15
Total Number of Departures	27
Repeat Departures	*10*

Departures by Section



Comparison to Other Entities

How your entity's departures compare to all/similar entities



Your Entity = the number of departures for your entity in the attached inspection report.

Similar Entities in Complexity = the average number of departures for entities that share your entity complexity category (i.e., low, moderate, high)

All entities (pilot) = the average number of departures for registered entities, with all complexity category combined, from a historical analysis of inspection report departures (2012-2015) (N-89).

Inspection Summary/Report Card: Each registered entity is provided an inspection summary/report card with the inspection report to illustrate the entity's regulatory departures and its compliance performance.

Entity Compliance Performance Category: CDC/DSAT will use a standardized process of assigning a score of low, moderate, or serious to each inspection departure in an entity's inspection report to generate data for the entity's compliance performance category (No further Action, Actions Required, Increased Monitoring, Corrective Action Plan, or Suspension).

Entity Complexity Category: FSAP regulates select agent and toxin programs that vary in mission, size and complexity. In order to share aggregate comparative data with our registered entities, CDC/DSAT has established a complexity score for each registered entity, based upon the relative risk of the work approved on the entity's APHIS/CDC Form 1 registration. These scores are used to group entities into super, high, moderate, and low complexity ratings.

Inspection Type: Inspections may be announced (an entity receives prior notification regarding the inspection) or unannounced. FSAP will not issue inspection summaries for new entity applications, new areas requested to be added to a registration, and/or compliance inspections.

Laboratories or Storage Areas Inspected: FSAP inspects physical locations for the possession, use or transfer of select agents and toxins. The locations assessed during an inspection are itemized on the inspection summary.

Number of Serious Departures: A serious departure is considered a departure from the select agent and toxin regulations that is an immediate threat to human, plant, or animal health, animal or plant products, and/or security of BSAT. The number of serious departures will influence the enforcement action taken by FSAP.

Number of Repeat Departures: A repeat departure is the same departure from the select agent and toxin regulations previously observed by FSAP that the entity has either not fully addressed and/or failed to implement corrective actions sufficient to prevent reoccurrence of the departure. Repeat departures may reflect systemic problems and are more likely to result in enforcement actions by FSAP.

Total Number of Departures: The aggregate number of departures cited during the inspection, including repeat departures.

Departures by Section: The pie chart shows the percent of the entity's inspection departures by section of the select agent and toxin regulations (e.g., security, biosafety, registration, Responsible Official, etc.). Note, an entity may not have departures from a particular section of the regulations either due to compliance with that section or FSAP did not assess all sections of the select agent and toxin regulations during the inspection.

Comparison to Other Entities: A bar graph to show the entity's number of serious, repeat, and total departures in comparison to other entities with the same complexity rating. The comparison group is derived from a sample of 89 inspections from 2012-2015 scored for development of this report card method. Validation of the method used 36 inspections from 2014-2016 and each new inspection completed will add to the comparison group following the pilot study.

UNIVERSITY of HAWAI'I SYSTEM

Office of Research Compliance
Animal Welfare and Biosafety Programs

November 13, 2017

[redacted]
File Manager
Centers of Disease Control and Prevention
Office of Public Health Preparedness and Prevention
Division of Select Agents and Toxin
1600 Clifton Road, NE, Mailstop A-46
Atlanta, GA 30333

Re: Notice of Intent to Withdraw Registration from FASP, University of Hawaii at Manoa (Registration #C20170609-1916)

By this letter, the University of Hawaii at Manoa (UHM) is officially submitting its intent to withdraw its registration from the Federal Select Agent Program. As a result of the withdrawal, UHM will be seeking the permission of CDC to dispose of all registered agents listed on our Form 1, through either transfer of the agents to other organizations/research institutions or complete destruction.

UHM's decision to withdraw was precipitated by the previous CDC inspection conducted during March 2017. Upon receiving the inspection report, an administrative assessment of the University's Select Agent program was undertaken. Over the course of several months, a composite review of the UHM program was conducted, which included evaluations of human and plant pathogen select agent usage, as well as, the operational costs associated with the select agent/Tier 1 program, including the costs to maintain the John A. Burns School of Medicine (JABSOM) BSL-3/ABSL-3 laboratories and the College of Tropical Agriculture and Human Resources (CTAHR) select agent plant pathogen research laboratory. Upon conclusion of this review, the decision was made to withdraw the university's registration with the Federal Select Agent Program as soon as possible.

Discussions have been initiated with UHM Investigators as to the final disposition of their registered agents. Currently, some Investigators are in the process of identifying registered entities that may have an interest accepting some or their entire existing inventory. The Inventory of *Burkholderia* sp. will be partly transferred and the remainder will be destroyed. The inventories of *Brucella* sp. for several investigators will either be transferred or destroyed. The inventory of Venezuelan Equine Encephalitis virus (VEE) and Eastern Equine Encephalitis virus (EEE) will be destroyed. Some or all of our listed USDA agents, *Ralsontia* sp. and *Xanthomonas* sp. will either be sent to *Agdia*, Inc., or they will be destroyed. Appropriate and authorized Form 2s will be maintained for all

2425 Campus Road, Sinclair 10
Honolulu, Hawai'i 96822
Telephone: 808 956-4446 • Fax: (808) 956-9150
An Equal Opportunity/Affirmative Action Institution

transferred agents and witnessed documents of destruction will be recorded for those agents that will be destroyed.

Upon the completion of either transfer or destruction of all agents on our registration, all laboratories and registered spaces where these agents were stored or manipulated will be thoroughly decontaminated with the methods of decontamination documented and kept for review by the CDC closeout inspection team.

It is understood that during the process of program closure, our registration remains under suspension and that no access to any of the agents will occur until authorization has been granted in writing by CDC. If you should have any further question or require further clarification on any aspect of our withdrawal plan please don't hesitated to contact me at (808) 956-8009 or by email stevec@hawaii.edu.

Thank you for your assistance as we finalize our proposed plan to withdraw our registration.

Sincerely,

Stephen E. Case

Stephen E. Case, MSPH, RBP
Responsible Official

c: Vassilis Syrmos, Vice President for Research and Innovation
Victoria Rivera, Interim Director, Office of Research Compliance

Department of Health and Human Services
Centers for Disease Control and Prevention
Division of Select Agents and Toxins
Atlanta, GA

U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Agriculture Select Agent Services
Riverdale, MD

March 1, 2018

Stephen Case, Responsible Official
University of Hawaii at Manoa (Registration #C20170609-1916)
2425 Campus Road, Sinclair 10
Honolulu, HI 96822
stevec@hawaii.edu

cc: olipares@hawaii.edu; syrmos@hawaii.edu; david@hawaii.edu; jerris@hawaii.edu

FROM: Federal Select Agent Program (FSAP)

Re: **Withdrawal of Registration for the Possession, Use, and Transfer of Select Agents or Toxins** with the Department of Health and Human Services, Division of Select Agents and Toxins

Dear Mr. Case:

This letter is in response to the University of Hawaii at Manoa's request, dated November 13, 2017, to withdraw its registration for the possession, use and transfer of select agents and toxins.

This letter serves as formal notice that effective 3/1/2018 the University of Hawaii at Manoa is no longer registered to possess, use, and transfer select agents and toxins.

We acknowledge that the University of Hawaii at Manoa has provided written certification confirming that all agents and toxins listed under 42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 121 in University of Hawaii at Manoa's possession have been destroyed or transferred prior to 2/28/2018.

The University of Hawaii at Manoa is reminded that an entity or individual may not possess, use, transfer, or receive a select agent or toxin unless such activities are conducted for a lawful purpose and in accordance with the provisions of 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121.

You may contact [redacted], Lead Microbiologist, CDC Division of Select Agents and Toxins, at ([redacted]) [redacted] or [redacted] with any questions regarding this correspondence.

Sincerely,

Samuel S. Edwin

Samuel S. Edwin, Ph.D.
Director
Division of Select Agents and Toxins
Department of Health and Human Services
Centers for Disease Control and Prevention

Keith D. Wiggins, DVM
Acting National Director
Agriculture Select Agent Services
Animal and Plant Health Inspection Service
United States Department of Agriculture