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Stephen Case <stevec@hawaii.edu>

## Follow up on requested materials for UH SA program

2 messages

Stephen Case <stevec@hawaii.edu>

Thu, Mar 2, 2017 at 3:43 PM

To: "[REDACTED]" (CDC/OPHPR/DSAT) <[REDACTED]@cdc.gov>

Cc: Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Bcc: Steve Case <stevec@hawaii.edu>

Aloha [REDACTED]

Hope all's going well with respect to the NEW Administration and hopefully they haven't been causing too many problems for your programs.

Just wanted to follow up on your email of Feb 10th regarding sending us a.....

- Summary report of all our security risk assessment (SRA)-approved and non-approved individuals at our entity and
- Summary of the entity's currently registered agents, spaces and PI's.

Also, when will we get you our "current" **Form 1** for our renewal now that it's not "required for the renewal process".....don't quit understand the thinking there? I would assume it would be during the inspection.

Will you also be requiring copies of our current Biosafety, Biosecurity and Incidence Response plans, from both our CDC and USDA labs, prior to our inspection?

Let me know.

Mahalo,

Steve

On Fri, Feb 10, 2017 at 3:23 AM, [REDACTED] ([REDACTED]) <[REDACTED]@cdc.gov> wrote:

The amendment to remove Galland was recently approved and you should receive fax confirmation in a few days.

For the renewal—this is a new process for us and since you are in the middle of those processes we will have to work something out. However, you don't need to do anything and this will work out good, since you don't have to send in a complete Form 1! Next week I will find out how to proceed, and we will likely send you the summary report for review.

I'll be in touch- have a great weekend

[REDACTED]

[REDACTED]

Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: (404) [REDACTED]

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**From:** Stephen Case [mailto:stevec@hawaii.edu]

**Sent:** Thursday, February 09, 2017 11:52 PM

**To:** [REDACTED] (CDC/OPHPR/DSAT) [REDACTED] cdc.gov>

**Cc:** Leonard Gouveia <lgouveia@hawaii.edu>; Hubert Olipares <olipares@hawaii.edu>

**Subject:** Couple of questions...UH Manoa SA prg.

Aloha again [REDACTED]

I decided to send this in a separate email to keep from muddling up the request process for addition of new staff .

Anyway, would like to know the status of amendment "**289944- Remove Galland, Designate Douglas as PI, Update personnel**". You New Years email dated Jan 18th, said it was tracked for final approval by management, and was just wondering were it stood?

Also, received today the "**\*\*SA GRAM 2/9/2017: Changes to Registration Renewal Process\*\***" which said it takes effect immediately and was wondering how this would impact our renewal process. We received our renewal notice letter on Dec. 2, 2016 but only the letter, nothing else. I was going to request you send a DB listing of our "**list of all security risk assessment (SRA)-approved and non\_approved individuals for our entity**" anyway in preparation for our renewal inspection. Your thoughts would be helpful.

Mahalo,

Steve

--

-----  
Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Alternate Responsible Official

Animal Welfare and Biosafety Programs

Office of Research Compliance  
2425 Campus Road Sinclair 10

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-----  
[REDACTED] (CDC/OPHPR/DSAT) [REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>  
Cc: Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Thu, Mar 2, 2017 at 4:11 PM

Since this is a new process for all of us, we are still working on some of the details. For you all-- don't worry about providing us any documentation at this time. The summary report and DOJ will be presented to you at the time of the inspection. The most recent biosafety, security, and incident response plans will also be requested at the time of the inspection.

The good news is-- there is no Form 1 to worry about. I don't need it, and you don't need to fill it out! We will go over the summary and DOJ together at the time of the inspection and that's pretty much it. If there is a need to update or change any information, we will discuss how to proceed with an amendment.

In short, you don't need to do anything prior to the registration renewal or the inspection --- just be prepared for us to show up

[REDACTED]

[REDACTED]  
Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

3/12/2020

University of Hawaii Mail - Follow up on requested materials for UH SA program

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: ( [REDACTED] )

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---

**From:** Stephen Case <stevec@hawaii.edu>

**Sent:** Thursday, March 2, 2017 8:43 PM

**To:** [REDACTED] (CDC/OPHPR/DSAT)

**Cc:** Leonard Gouveia; Hubert Olipares

**Subject:** Follow up on requested materials for UH SA program

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

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## Manoa and Kaka'ako Plans - Electronic copies

1 message

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Stephen Case <stevec@hawaii.edu>

Mon, Mar 13, 2017 at 11:39 AM

To: [REDACTED] cdc.gov>

Hi [REDACTED]

Find attached the pdf copies of all plans for Manoa and Kaka'ako SA labs.

Steve

---







Stephen Case, MSPH, RBP  
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### 6 attachments

-  **Biosafety\_Manual.pdf**  
2623K
-  **Biosecurity\_Manual.pdf**  
2584K
-  **Incident Response Plan.pdf**  
3431K
-  **Biosafety Manual\_Updated-Manoa.pdf**  
183K
-  **Incident Response Plan\_Updated-Manoa.pdf**  
1557K
-  **Security Plan\_Updated-Manoa.pdf**  
2274K



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Stephen Case <stevec@hawaii.edu>

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## Interview list and times....assuming 2 interviewers

2 messages

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Stephen Case <stevec@hawaii.edu>

To: [REDACTED]@cdc.gov>

Tue, Mar 14, 2017 at 7:50 PM

Hi [REDACTED]

Here's the time slots for the requested interviewees.....per your statement that some could be done at same time by 2 interviewers.

	Interviewer 1	Interviewer 2
9:00am	Zhenxin Sun	Nicole Montey
9:30am	Darlene Cabanas	Rosendo Quitazol
10:00am	Yun Kang	Alyssa Makalea
10:30am	Kurtis Murata	
1:30pm	Ian McMillen	
2:00 pm	Kent Koster	
2:30pm	Pakieli Kaufusi	

Hopes this schedule will work.

Mahalo,  
Steve

---

[REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Tue, Mar 14, 2017 at 8:17 PM

Looks great. Also, can we set up time to speak with Hugh and Dr. Hoang as well?

Thanks

[REDACTED]

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

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## Occ Hlth electronic copies

1 message

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Stephen Case <stevec@hawaii.edu>

Thu, Mar 16, 2017 at 9:19 AM

To: [REDACTED]@cdc.gov>

Aloha [REDACTED]

Find attached electronic copies of the Occ Health program for Tier 1 and also the AVS Occ Hlth plan in case you need.

I'll be back over shortly with Hoang's IBC protocols and Toxin info.

Mahalo,  
Steve

---


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### 2 attachments

 Occupational\_Health\_Program for Tier 1 BSAT January 2017.pdf  
1312K

 AVS\_OHSP\_FINAL\_rev\_4\_21\_16\_w\_attachments.pdf  
7892K



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Stephen Case <stevec@hawaii.edu>

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## Status of our BSL2 and BSL3 Facilities

1 message

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Leonard Gouveia <lgouveia@hawaii.edu>

Sat, Apr 8, 2017 at 1:16 PM

To: "[REDACTED] 9@cdc.gov"

Cc: Stephen Case <stevec@hawaii.edu>

Dear [REDACTED]

This serves to inform you that all essential UH laboratory personnel have been apprised of our suspension. There will be no further research conducted with select agents as of 4:30 pm on 4/6/2017. All select agents have been properly secured. User access cards to the BSL3 select agents have been suspended for all select agent users. All other non-select agent work is being carried on in our labs in a normal fashion, in both facilities - BSL2 (Manoa) and BSL3 (Kaka'ako). Steve Case (Alternate Responsible Official), and I (Responsible Official) inspected the BSL2 (Manoa) and BSL3 (Kaka'ako) in order to verify cessation of work. We also ensured that all of our select agents have been properly secured and locked in order to prevent theft, loss, or release. We also placed tamper-evident tape in appropriate areas, as an additional security measure.

In addition to the above, this also serves to inform you that we have autoclaved the material for PI Tung Hoang's inactivated material that were moved from the BSL3 to his BSL2 lab on campus that had previously been secured and locked down.

Please do not hesitate to contact me with any questions or concerns.

Thank you.

Lenny

Leonard R. Gouveia, Jr.

Interim Director of Research Compliance  
Manager, Office of Export Controls/Facility Security Officer  
University of Hawaii  
Office of the Vice President for Research and Innovation  
2425 Campus Road, Sinclair 10  
Honolulu, HI 96822  
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lgouveia@hawaii.edu

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Stephen Case <stevec@hawaii.edu>

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**RE: UH Removal of Staff from registration, 299717**

2 messages

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[REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Mon, Apr 10, 2017 at 10:08 AM

Please reply with a reason for removal.

Thanks

[REDACTED]  
Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: ([REDACTED])

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**From:** Stephen Case [mailto:stevec@hawaii.edu]

**Sent:** Wednesday, March 29, 2017 7:21 PM

**To:** [REDACTED]@cdc.gov>

**Cc:** Leonard Gouveia <lgouveia@hawaii.edu>; Hubert Olipares <olipares@hawaii.edu>

**Subject:** UH Removal of Staff from registration, and Amendment #296114 check

Aloha [REDACTED]

Hope all's going well and your over you VOG experience. Also hope all the potential changes coming down from the top aren't to frustrating or keeping you busier than normal.

(1) We would like to remove the following individuals from our entities registration.

- 1) Steven Chun, C-SC-042033
- 2) Terry Gerber, C-TG-042043
- 3) Caryn Hashimoto, C-CH-043264
- 4) Joe Lee, C-JL-047372
- 5) Steve Mau, C-SM-043626
- 6) Vance Mizuba, C-VM-046003
- 7) Ryan Yamauchi, C-RY-042047
- 8) Denise Yee, C-DY-043265

These listed individuals have never had access to and will never need access to or work with any Select Agents within our registered space.

(2) Could you also please check the status of **Amendment #296114**, addition of D. Clements and T. Premeaux, without Tier 1 access to our registration. We received their SRA approvals on March 6th but as yet haven't received their "Approval of Amendment" to add them to our registration.

If you should have any questions don't hesitate to contact me.

Mahalo,  
Steve

-----  
Stephen Case, MSPH, RBP  
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Stephen Case <stevec@hawaii.edu>

Tue, Apr 11, 2017 at 5:18 PM

To: "C. [REDACTED] cdc.gov"

Cc: Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Aloha [REDACTED]

Concerning previous removal of staff "**Amendment #299509**" sent 3/29/2017, Request to Amend... received dated

4/5/2017 Adding reason for removal.

We would like to remove the following individuals from our entities registration. Reason for removal access to select agents and toxins no longer required for those listed below.

- 1) Steven Chun, C-SC-042033.
- 2) Terry Gerber, C-TG-042043.
- 3) Caryn Hashimoto, C-CH-043264
- 4) Joe Lee, C-JL-047372.
- 5) Steve Mau, C-SM-043626.
- 6) Vance Mizuba, C-VM-046003.
- 7) Ryan Yamauchi, C-RY-042047.
- 8) Denise Yee, C-DY-043265.

**NOTE:** These listed individuals have never had access to and will never need access to or work with any Select Agents within our registered space.

Unclear on your reference to "Amendment #299717" for the this group. As noted above the # assigned to this amendment was #299509 on the "Request to Amend your Entity's Certification of Registration" we received 4/5/17. Did we get another Amendment # for some reason?

Mahalo,  
Steve

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

---

## RE: UH Removal of Staff from registration

4 messages

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Stephen Case <stevec@hawaii.edu>

Tue, Apr 11, 2017 at 5:23 PM

To: [REDACTED]@cdc.gov

Cc: Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Aloha [REDACTED]

Per your emails dated 4/10/201....added reason for removal.

We would like to **remove** the following individuals from our entities registration. Reason for removal, access to select agents and toxins no longer required for those listed below.

- 1) Brandi Antonio, C-BA-048445.
- 2) Brad Bannister, C-BB-043187
- 3) Allexa Dow, C-AD-047620
- 4) Freddie Fernandez, C-FF-043183
- 5) Brian Haruno, C-BH-043182
- 6) Kris Koyama, C-KK-048474.
- 7) Jason Moore, C-JM-043189.
- 8) Edward Ohlson, C-EO-042119.
- 9) Sladjana Prsic, C-SP-046002
- 10) Jason Quitazol, C-JQ-041922
- 11) Ronald Remigio, C-RR-041920
- 12) Derrick Tomasa, C-DT-043489
- 13) Dien Truong, C-DT-041921
- 14) Celeste Yergin, C-CY-048914

**NOTE:** These listed individuals have never had access to and will never need access to or work with any Select Agents within our registered space.

Mahalo,  
Steve

--

---

Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Alternate Responsible Official  
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---

[REDACTED]@cdc.gov

Wed, Apr 12, 2017 at 6:05 AM

To: Stephen Case <stevec@hawaii.edu>

Cc: Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Aloha all,

Our course of action with regards to the Form 1 and registration is to continue to process and approve these and other amendments to get the registration accurate and updated.

- There are currently 2 amendments to remove personnel (below).
- Steve mentioned there are some maiden to married name changes that may need to be updated. Please send these as one new amendment to update names. It requires the request to update along with the 4A or 4B with new names. Just like when you add a new person, only those with updated names should be listed & be sure to fill out all the fields (DOJs, Bdays)
- Registration Verification & DOJ list sent 3/8/17: I need an email reply for this. I think the letter asks that you verify with the file manager that everything is accurate, or work with them and submit amendments to update things. Since we are making changes to the registration, a simple response that states you are doing the latter will suffice.
- Update PI Alvarez to Storage only. You can start this now, or wait and submit as a response to the inspection report. (if you submit before the report goes out, I will update the report to state that an amendment was received, no further action is required). Regardless, to update please send an official request and a new section 7.
- If there is anything else, please let me know

Summary of pending amendments to remove personnel.

-

#### Amendment 300212

- 1) Brandi Antonio, C-BA-048445
- 2) Brad Bannister, C-BB-043187
- 3) Allexa Dow, C-AD-047620
- 4) Freddie Fernandez, C-FF-043183
- 5) Brian Haruno, C-BH-043182
- 6) Kris Koyama, C-KK-048474
- 7) Jason Moore, C-JM-043189
- 8) Edward Ohlson, C-EO-042119
- 9) Sladjana Prsic, C-SP-046002
- 10) Jason Quitazol, C-JQ-041922
- 11) Ronald Remigio, C-RR-041920
- 12) Derrick Tomasa, C-DT-043489
- 13) Dien Truong, C-DT-041921
- 14) Celeste Yergin, C-CY-048914

#### Amendment 299509

- 1) Steven Chun, C-SC-042033
- 2) Terry Gerber, C-TG-042043
- 3) Caryn Hashimoto, C-CH-043264
- 4) Joe Lee, C-JL-047372

- 5) Steve Mau, C-SM-043626.
- 6) Vance Mizuba, C-VM-046003.
- 7) Ryan Yamauchi, C-RY-042047.
- 8) Denise Yee, C-DY-043265.

[REDACTED]  
Microbiologist

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1600 Clifton Road, NE MS A-46

Atlanta, GA 30329  
[REDACTED]

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Stephen Case <stevec@hawaii.edu>

Wed, Apr 12, 2017 at 11:58 AM

To: "[REDACTED]" <ihe9@cdc.gov>

Cc: Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Aloha [REDACTED]

This is to confirm the correctness of information sent to us on March 8, 2017 along with our letter of **Renewal of Registration Certificate for Select Agents and Toxins**, dated March 7, 2017, that the:

- **Registration Verification to Entity** listing of Agents stored or being worked with was accurate, verified and up to date for our site.
- **Individuals Listed on Registration (Entity ID: CDC112125)** was compared with our listing of approved and pending DOJ/SRA individuals for our site and was found to be in total agreement. Since receipt of this listing we have submitted two amendments, #299509 and #300212, to remove individuals from our registration who no longer require access to select agents or toxins within our registered space.

With regards to the one individual, Lisa Sato, who I thought might need a maiden to married name change, IT IS NOT NEEDED. I reviewed the DOJ approved individuals listing that accompanied our last *Certificate of Registration*, dated June 11, 2015, and it listed her as Sato (and not Ho, maiden name). **So no change needed.**

Change for Alvarez to **storage only** forthcoming in a separate email.

The reason we didn't respond to the above information was due to your email dated March 2, 2017, when I asked about the new renewal process, you stated that the Summary report and DOJ would be presented to us at the time of inspection

3/12/2020

University of Hawaii Mail - RE: UH Removal of Staff from registration

and we would go over the them together at that time. But I guess your bosses decided to send the info out earlier.

Any more questions or concerns let me know.

Mahalo,

Steve

[Quoted text hidden]

[Quoted text hidden]

[REDACTED]@cdc.gov>

Thu, Apr 13, 2017 at 2:05 AM

To: Stephen Case <stevec@hawaii.edu>

Cc: Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Excellent! This is all I need for the renewal

[REDACTED]

Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: [REDACTED]

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[Quoted text hidden]





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Stephen Case <stevec@hawaii.edu>

## Clarification on Departure 20 UH at Manoa March 2017 report

5 messages

Stephen Case <stevec@hawaii.edu>

Thu, Apr 27, 2017 at 11:43 AM

To: [REDACTED]@cdc.gov

Cc: Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Bcc: Ian Mcmillan <iamcm@hawaii.edu>

Aloha [REDACTED]

I know that you're entrenched in another inspection but we have a question that could use a little further clarification as we move forward with addressing "Departure 20" from our inspection report. I've included it below in the hopes that it will save you time in not having to look it up and further detract from your current endeavors.

As the departure noted that this was also observed in the "March 2015" report, I've also included that as reference as well to help in clarification and minimize, again, your time away from your current inspection.

Main questions for clarification....

1. What was meant by "long term storage"?
2. What should be used as "source" when material is generated in the lab; the source of all material obtained or received from outside lab is always logged (i.e from Form2 transfers)?
3. How specific/detailed should "purpose of use" be?

Mahalo,

Steve

----- References info below

**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.

### March 2015 report observation:

**Observation:** At the time of the inspection, several inventory records for the Burkholderia strains were reviewed by inspectors. The inventory record for a box labeled "Animal Study Box" indicated 48 tubes were added to the inventory on 1/22/15. Another 36 tubes were added to the inventory on 1/28/15. These 84 tubes consisted of multiple strains of Burkholderia species; however, the number of tubes (quantity) of each species was not recorded. Additionally, the source of these strains was not recorded. On three occasions, tubes were removed from inventory without indicating which Burkholderia strains were removed. Likewise, the inventory record labeled "37°C Box Permanent Inventory" indicated 20 tubes of two different Burkholderia strains were added to the collection on 1/7/15. However, the number of tubes of each

strain and the source were not recorded. Please describe the measures implemented to ensure that inventory records are complete and all information is recorded including the quantity of each select agent acquired and the source. Also, please provide an updated inventory record for the material stored in these two boxes.

-----  
Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Alternate Responsible Official  
Animal Welfare and Biosafety Programs  
Office of Research Compliance  
2425 Campus Road, Sinclair 10  
Phone: (808) 956-8009 (o), (808) 285-7545 (c)  
FAX: (808) 956-3535  
-----

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-----  
[REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>  
Cc: Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Thu, Apr 27, 2017 at 12:13 PM

Hopefully this will help. In addition, please refer to the guidance document on the website (resources/compliance assistance)

([https://www.selectagents.gov/resources/Inventory\\_Guidance.pdf](https://www.selectagents.gov/resources/Inventory_Guidance.pdf))

Long term storage is basically anything not part of an ongoing experiment.

Source: details that link to the origin of that material: for material transferred, the transfer information is good—as long as it can be tracked back to that Form 2 (use the CEA # for example). For in house generated material, you need something that makes it clear it was generated in-house (example- decide on common language everyone will use). The source for animal samples, old sera, could be animal tissues from experiment #xxxx or historical sera from 1972. This should be for ALL inventory that is currently possessed- old and new.

Purpose of use. There are lots of ways to meet this requirement, but it should be descriptive enough to know the intent of the work performed. For example, "removed" and "experiment" do not any actual purpose for that material. These are just examples: streak plate for DNA extraction, preparation of new stock, plaque assay, — all give a little more detail and the actual purpose of removing that tube from the freezer.

[REDACTED]  
[Quoted text hidden]

---

Stephen Case <stevec@hawaii.edu>

To: "[REDACTED]" <ihe9@cdc.gov>

Thu, Apr 27, 2017 at 12:30 PM

Thanks [REDACTED] appreciate your quick response.

Mahalo,  
Steve

[Quoted text hidden]

---

Stephen Case <stevec@hawaii.edu>

To: Ian Mcmillan <iamcm@hawaii.edu>, Tung Hoang <tongh@hawaii.edu>, Yun Kang <yunkang@hawaii.edu>

Thu, Apr 27, 2017 at 12:36 PM

Ian...response from [REDACTED] regarding clarification...hope this helps.

Steve

[Quoted text hidden]

---

Ian McMillan <ian.andrew.mcmillan@gmail.com>

To: Stephen Case <stevec@hawaii.edu>

Cc: Ian Mcmillan <iamcm@hawaii.edu>, Tung Hoang <tongh@hawaii.edu>, Yun Kang <yunkang@hawaii.edu>

Thu, Apr 27, 2017 at 12:42 PM

Thanks Steve!

Ian

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

---

## Clarifications on renewal inspection report needed

4 messages

---

Stephen Case <stevec@hawaii.edu>

Mon, May 1, 2017 at 1:04 PM

To: [REDACTED]@cdc.gov

Cc: Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Bcc: Ian Mcmillan <iamcm@hawaii.edu>

Aloha [REDACTED]

Hope all's well and you back home following last weeks inspection.

We still need a little more detail on our **Departure #20** in order to properly address...

More clarity is needed to address the "**Quantity (e.g., number of containers), date of acquisition**" missing from from of Hoang's inventory records. They are unclear as to where or what specific records are being refereed to where these particular entries are missing. Await your response.

We will be consolidating our responses to the various departures on our inspections report this week before we submit by our 14 day deadline. As such there might be a need for your clarifying input on other issues should they arise. Will try to keep things to a minimum as I know your busy and we appreciate you time.

Mahalo,  
Steve

--

---

Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Alternate Responsible Official  
Animal Welfare and Biosafety Programs  
Office of Research Compliance  
2425 Campus Road, Sinclair 10  
Phone: (808) 956-8009 (o), (808) 285-7545 (c)  
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---

[REDACTED]@cdc.gov

Tue, May 2, 2017 at 2:51 AM

To: Stephen Case <stevec@hawaii.edu>

Cc: Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

This applies to every inventory record of material that is currently possessed—both old stored material and any new material made or acquired.

Quantity- original number of vials (generated a stock of 40 vials, received 2 vials)

The idea here is that you have the starting number of vials, then tracking usage you use 1 here, 1 there—and have an accurate count of current vials & know how many have been used.

The date of acquisition could be the date received or the date the material was generated.

Note: the new regulations Section 17(b) include a new phrase regarding records "accurate and legible." Based on the binders we reviewed, there was definitely room for improvement on the legible part—please keep this in mind when updating the records.

Don't hesitate to contact me this week—I'll be around to answer any questions!

[REDACTED]

[REDACTED]

Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: [REDACTED]

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[Quoted text hidden]

Stephen Case <stevec@hawaii.edu>

To: Ian Mcmillan <iamcm@hawaii.edu>

Cc: Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Tue, May 2, 2017 at 9:31 AM

Hey Ian,

See below [REDACTED] response... it does not sound very "specific" in nature more of a very general "guideline". Not sure if this helps or not...do your best

Steve

[Quoted text hidden]

3/12/2020

University of Hawaii Mail - Clarifications on renewal inspection report needed

Ian McMillan <ian.andrew.mcmillan@gmail.com>

Tue, May 2, 2017 at 9:42 AM

To: Stephen Case <stevec@hawaii.edu>, Tung Hoang <tongh@hawaii.edu>

Cc: Ian McMillan <iamcm@hawaii.edu>, Leonard Gouveia <lgouveia@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Hey Steve

Thanks for getting that "clarification". It is not specific at all and seems that they are dinging us on the "legible" part. I will write something but in terms of "quantity" and "date of acquisition", it doesn't seem that there are specific problems with our inventory. I will put this in the report.

I'm not sure if there is any real issue here other than the legibility of the one record.

I should finish the documents to send you soon.

Ian

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

## RO paperwork

3 messages

[REDACTED] <[REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Tue, Jun 6, 2017 at 6:00 AM

Hi Steve,

Please submit a new section 1A, 1B, and 2 ASAP. Email me with any questions

[REDACTED]  
Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

Stephen Case <stevec@hawaii.edu>

Tue, Jun 6, 2017 at 5:25 PM

To: "[REDACTED]9@cdc.gov"

Aloha [REDACTED]

Please find attached the updated and signed **Form 1 Section 1A and 1B, and Section 2**, which reflects the changes to RO and ARO's for UH. I wasn't exactly sure which box to check at the top but went with the "An update to an existing registration".

Any further needs or questions let me know. Will give you a call so we can discuss these latest developments and how they impact our program.

Mahalo,

Steve

[Quoted text hidden]

-----  
Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Alternate Responsible Official  
Animal Welfare and Biosafety Programs  
Office of Research Compliance  
2425 Campus Road, Sinclair 10  
Phone: (808) 956-8009 (o). (808) 285-7545 (c)  
FAX: (808) 956-9150

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### 2 attachments

UH\_Form\_1\_Section\_1A\_1B\_Signed.pdf  
301K

UH\_Form\_1\_Section\_2\_Signed.pdf  
191K

[REDACTED] <[REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Wed, Jun 7, 2017 at 1:28 AM

Thanks Steve

I'm out of the office on inspection, so I won't be available to talk this week.

[REDACTED]

Sent from my BlackBerry 10 smartphone on the Verizon Wireless 4G LTE network.

**From:** Stephen Case

**Sent:** Tuesday, June 6, 2017 11:28 PM

**To:** [REDACTED]

**Subject:** Re: RO paperwork

[Quoted text hidden]





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Stephen Case <stevec@hawaii.edu>

## FSAP Amendment 303648

6 messages

[REDACTED]@cdc.gov>

Thu, Jun 8, 2017 at 4:33 AM

To: "lgouveia@hawaii.edu" <lgouveia@hawaii.edu>

Cc: "stevec@hawaii.edu" <stevec@hawaii.edu>, "[REDACTED]@cdc.gov>

Good morning gentlemen,

I am assisting [REDACTED] while [REDACTED] is out of the office. For the amendment to designate Stephen as RO, there are a few items that need corrections and/or clarifications. I have listed them below. If you could send me a correct page 1 of the Section 1A (I do not need all the other pages) today, then we can expedite this amendment and have it approved today or by tomorrow morning. Please do not hesitate to contact me if you have any questions.

- The Physical address and additional physical address have been flipped on the Section 1A submitted for this amendment. Was this intentional?
- Did you intend to change S. Case's fax # to (808)546-5025. Please confirm or correct.
- Please correct H. Olipares's business E-mail address.
- Please confirm the change of H. Olipares's business fax # to (808)546-5025 or correct.
- Please confirm the change of J. Olipares's emergency phone # to (808)285-7819 or correct.

Regards,

[REDACTED]

[REDACTED]  
[REDACTED]  
Division of Select Agents and Toxins (DSAT)

Office of Public Health Preparedness and Response (OPHPR)

Centers for Disease Control and Prevention (CDC)

1600 Clifton Road NE, Atlanta, Georgia 30029

Office Phone: ([REDACTED])

Work Cell Phone: ([REDACTED])

Email: [REDACTED]

DSAT Vision: To be the preeminent resource for the safety and security of biological agents and toxins.

Stephen Case <stevec@hawaii.edu>

Thu, Jun 8, 2017 at 10:00 AM

To: "[REDACTED]@cdc.gov"

Cc: "lgouveia@hawaii.edu" <lgouveia@hawaii.edu>, "[REDACTED]@cdc.gov"

Hi [REDACTED]

Find attached corrected and updated **Form 1 Sec. 1A** with corrections.

- The Physical address and additional physical address have been flipped on the Section 1A submitted for this amendment. Was this intentional? **No, addresses have been corrected to reflect correct locations of entity.**
- Did you intend to change S. Case's fax # to (808)546-5025. Please confirm or correct. **Confirmed and correct, this is our secure fax line.**
- Please correct H. Olipares's business E-mail address. **Email address for Olipares has been corrected.**
- Please confirm the change of H. Olipares's business fax # to (808)546-5025 or correct. **Confirmed and correct, again this is our secure fax line.**
- Please confirm the change of J. Olipares's emergency phone # to (808)285-7819 or correct. Not correct (typo) and **emergency phone # has been corrected to (808)285-7619.**

I think everything else should be correct. If you should have any more questions or concerns please contact me.

Mahalo

Steve

[Quoted text hidden]

-----  
Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Responsible Official  
Animal Welfare and Biosafety Programs  
Office of Research Compliance  
2425 Campus Road, Sinclair 10  
Phone: (808) 956-8009 (o), (808) 285-7545 (c)  
FAX: (808) 956-9150  
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 UH\_Form\_1\_Section\_1A\_corrected.pdf  
151K

Leonard Gouveia <lgouveia@hawaii.edu>  
To: Stephen Case <stevec@hawaii.edu>  
Cc: Victoria Rivera <riveravg@hawaii.edu>

Tue, Jun 13, 2017 at 2:44 PM

Steve,

Has this been resolved?

Thanks,

Lenny

[Quoted text hidden]

---

**Stephen Case** <stevec@hawaii.edu>  
To: Leonard Gouveia <lgouveia@hawaii.edu>  
Cc: Victoria Rivera <riveravg@hawaii.edu>

Tue, Jun 13, 2017 at 4:32 PM

Hi Lenny,

As far as I know it is. I didn't receive any further response from [REDACTED] after I sent [REDACTED] the corrected Form 1 - Sec 1A.

Steve

[Quoted text hidden]

[Quoted text hidden]

---

[REDACTED] cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Wed, Jun 14, 2017 at 7:49 AM

Hi Steve,

Our office has been trying to fax the RO approval to 808/546-5025

Is this the correct number. we are getting a disconnected notice

Thanks

[REDACTED]

Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: ([REDACTED])

*DSAT Vision: To be the preeminent resource for the safety and security of biological agents and toxins*

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[Quoted text hidden]

Stephen Case <stevec@hawaii.edu>

Wed, Jun 14, 2017 at 9:30 AM

To: "[REDACTED]@cdc.gov"

Hi [REDACTED]

No, it has the wrong prefix.....should be (808) 956-5025. This was the same # that was on the old Form 1.

I've also attached the corrected Form 1 - Sec 1A which has the Business Fax #'s for both RO and ARO corrected to read (808) 956-5025.

Any questions let me know.

Mahalo,

Steve

[Quoted text hidden]

 UH\_Form\_1\_Section\_1A\_corrected\_6-14-17.pdf  
157K



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Stephen Case <stevec@hawaii.edu>

## Couple of question of UH's followup responses

3 messages

Stephen Case <stevec@hawaii.edu>

Wed, Jul 12, 2017 at 6:23 PM

To: [REDACTED]@cdc.gov

Aloha [REDACTED],

Hope all's well and your not to busy. Couldn't recall from our last conversation whether you were going to be out of office or not this week. Got a couple of questions.

1) Still having issues with our response to the original observation for departure #12, included below as I'm not sure if you are out of office.

**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.

The wording used in our submitted response was such that had been approved in the previous inspection departure responses regarding these accidental exposure situations, hence the similar or identical wording.

Any guidance you can provide as to what we need to make this information acceptable to meet the regulation would be helpful.

2) By my reckoning our responses are due to you on July 18th COB our time....30 days from June 19th?

Our Occ Hlth program is for the most part done but we'll be unable to get everyone "enrolled" by the deadline. Should we just submit new plan and followup later with conformations of enrollment. Some individuals have already completed certain parts of the "new" plan previously (i.e. respirator med clearance and fit testing) and so integrating into new plan will take time.

We've addressed the "serious" departures first to get those done but some of the other's might take a little more time. Should we just submit what we have or is an extension possible? An additional 2 weeks would helpful.

I'll be in the office all day tomorrow and Friday if you would like give me a call to discuss and give some guidance. Much appreciated.

Mahalo,  
Steve

--

Stephen Case, MSPH, RBP

Biosafety Professional

Educational Coordinator

Responsible Official

Animal Welfare and Biosafety Programs

Office of Research Compliance

2425 Campus Road, Sinclair 10

Phone: (808) 956-8009 (o), (808) 285-7545 (c)

FAX: (808) 956-9150

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[REDACTED]@cdc.gov  
To: Stephen Case <stevec@hawaii.edu>

Fri, Jul 14, 2017 at 6:13 AM

Sorry for not responding yesterday. I am out on inspection

Please respond to All observations. What you have done, are doing, plan to do.

Accidentally exposed: steps to taken if an animal somewhere else in the vicarious or an unintended animal displays signs/symptoms of infection with a select agent.

Responses are due on the 17 th.

Please email if you have other questions. I'll be traveling back to Atlanta today.

[REDACTED]

---

[Quoted text hidden]

---

**Stephen Case** <stevec@hawaii.edu>

Fri, Jul 14, 2017 at 9:27 AM

To: Norman Magno <nmagno@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>

FYI

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

---

## Autoclaving unneeded room temp culture plates prior to facility shut down

7 messages

---

Stephen Case <stevec@hawaii.edu>

Mon, Jul 17, 2017 at 10:16 AM

To: [REDACTED]@cdc.gov>

Cc: Hubert Olipares <olipares@hawaii.edu>

Hi [REDACTED]

Per our conversation, the JBF is preparing to shut down for our annual PM and 3rd party certification. Normally as part of this all unneeded cultures and waste is autoclaved out and the facility is cleaned prior to shut down. With or current suspension Dr. Hoang's group have been unable to do complete some of these activities.

Dr. Hoang's group have some room temperature working culture plates that are currently locked down and secured in the lab. We are requesting authorization to terminate these cultures and remove them from our inventory prior to our facility shut down as there is no need to retain the cultures for any future work.

As part of our preparatory work prior to shut down we would like to terminate and remove these cultures in order to alleviate any undue concerns the contractors might have regarding active cultures present, even though secured and locked down, in areas where they might be working.

If you have any further question don't hesitate to contact me.

Mahalo,  
Steve

--

---

Stephen Case, MSPH, RBP

Biosafety Professional

Educational Coordinator

Responsible Official

Animal Welfare and Biosafety Programs

Office of Research Compliance

2425 Campus Road, Sinclair 10

Phone: (808) 956-8009 (o), (808) 285-7545 (c)

FAX: (808) 956-9150

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---

[REDACTED]@cdc.gov>

Tue, Jul 18, 2017 at 8:44 AM

To: Stephen Case <stevec@hawaii.edu>

Steve,

Under the conditions of the current suspension, any access to select agents is not permitted.

This matter will be brought to the attention of the FSAP directors, and any exception to this will be their decision.

I will let you know if I hear anything

3/12/2020

University of Hawaii Mail - Autoclaving unneeded room temp culture plates prior to facility shut down

[REDACTED]  
[REDACTED]  
Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: [REDACTED]

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[Quoted text hidden]

Stephen Case <stevec@hawaii.edu>

To: [REDACTED] <[REDACTED]@cdc.gov>

Tue, Jul 18, 2017 at 9:07 AM

Thanks [REDACTED], Steve

[Quoted text hidden]

Stephen Case <stevec@hawaii.edu>

To: Ian Mcmillan <iamcm@hawaii.edu>

Cc: Steve Case <stevec@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Tue, Jul 18, 2017 at 9:10 AM

Ian,

FYI...will let you know when I hear anything.

Steve

[Quoted text hidden]

Ian McMillan <ian.andrew.mcmillan@gmail.com>

To: Stephen Case <stevec@hawaii.edu>

Tue, Jul 18, 2017 at 9:15 AM

Thanks Steve!

Im planning on autoclaving tomorrow morning to get rid of the remainder of the trash in our suite. Let me know if I can add those plates or not.

Ian

[Quoted text hidden]

---

Stephen Case <stevec@hawaii.edu>

Wed, Sep 6, 2017 at 12:32 PM



3/12/2020

University of Hawaii Mail - Autoclaving unneeded room temp culture plates prior to facility shut down

To: [REDACTED]@cdc.gov  
Cc: Hubert Olipares <olipares@hawaii.edu>  
Bcc: Vivek Nerurkar <nerurkar@hawaii.edu>, Mukesh Kumar <mukesh@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>

Aloha [REDACTED]

Just following up with the previous request to terminate (autoclave) Tung's room temperature working cultures from his lab (room AA) for our Level 3 shutdown and re-certification. Any movement or information from the FSAP directors on this yet?

It seems no matter how hard we try and educate the contractors on the low risk of any potential exposure from these cultures in the decontaminated, secured, locked and sealed container, they are still concerned "because they're active cultures and not FROZEN samples" and it's having an impact of their scheduling and access to the area.

Another option for these RT cultures would be to relocate to the -80 freezer with the rest of Tungs organisms instead of autoclaving out....would that be a possibility? Or would that still be in violation of our suspension.....I'm guessing yes! Just trying to think of other alternatives so we can keep the contractors happy and continue in a timely fashion with our scheduled PM.

If you would like to discuss, please give me a call at 808 285-7545 or I can call you.

Your quick response would be greatly appreciated.

Mahalo,  
Steve

[Quoted text hidden]

[REDACTED]@cdc.gov  
To: Stephen Case <stevec@hawaii.edu>

Thu, Sep 7, 2017 at 10:43 AM

Hi Steve.

Nothing new- the terms of the suspension still stand. I'll bring this up to my leadership tomorrow and let you know--

[REDACTED]

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

---

## UH Responses to CDC letter dated June 19, 2017

3 messages

---

Stephen Case <stevec@hawaii.edu>

Tue, Jul 18, 2017 at 5:06 PM

To: [REDACTED]@cdc.gov

Cc: Vassilis Syrmos <syrmos@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Bcc: Steve Case <stevec@hawaii.edu>

Dear [REDACTED]

Please find attached our responses to the "Inadequate Response from University of Hawaii at Manoa" letter dated June 19, 2017

We look forward to continue working with you on this.

Sincerely,

--

Stephen Case, MSPH, RBP

Biosafety Professional

Educational Coordinator

Responsible Official

Animal Welfare and Biosafety Programs

Office of Research Compliance

2425 Campus Road, Sinclair 10

Phone: (808) 956-8009 (o), (808) 285-7545 (c)

FAX: (808) 956-9150

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### 3 attachments



Cover\_Letter\_7\_18\_17.pdf

63K



UH Second Response to CDC Inspection.pdf

186K



Attachments 1-17 UH 2nd Response.zip

8801K

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Hubert Olipares <olipares@hawaii.edu>

Thu, Jul 20, 2017 at 5:59 AM

To: Stephen Case <stevec@hawaii.edu>

Cc: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>

Will a copy be forwarded to respective PIs (Alvarez, Hoang, Nerurkar) as well as IBC (Ako & Siefried)?

Hubert

[Quoted text hidden]

<Cover\_Letter\_7\_18\_17.pdf>

<UH Second Response to CDC Inspection.pdf>

<Attachments 1-17 UH 2nd Response.zip>

---

Norman Magno <nmagno@hawaii.edu>

Thu, Jul 20, 2017 at 6:14 AM

To: Hubert Olipares <olipares@hawaii.edu>

Cc: Stephen Case <stevec@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>

Steve,

Hubert makes an excellent point. Please forward a copy to the PI and IBC officer named in Hubert's inquiry.

Thanks.

N. Magno

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

---

## UH Hawaii question on IDS

3 messages

---

Stephen Case <stevec@hawaii.edu>

Tue, Jul 25, 2017 at 9:51 AM

To: [REDACTED]@cdc.gov>

Aloha [REDACTED]

As you know from our last correspondence our Level 3 is down for annual PM and 3rd party certification. My questions is with regard to the IDS alarm for our ABLS3 area.

We do not have ANY select agents in storage anywhere in our ABLS3 and haven't had any work with SAs in the facility for more than a year. With NO agents present in our ABLS3 registered space, do we still need to continue to have the IDS active for the ABLS3 suite? My take is that we don't.

As we are going to have contractors providing PM work during the shutdown in the ABLS3, not having to arm and disarm the alarm daily would simplify the work procedures for that area. The BSL3, were we do have agents in storage, the IDS alarm will remain in use according to protocol.

Your thoughts would be appreciated. I left a message on your work phone but if you can answer here no need to give me a call. Not sure in you're in or out of the office this week.

Mahalo,  
Steve

---

Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Responsible Official  
Animal Welfare and Biosafety Programs  
Office of Research Compliance  
2425 Campus Road Sinclair 10  
Phone: (808) 956-8009 (o), (808) 285-7545 (c)  
FAX: (808) 956-9150

---

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---

To: Stephen Case <stevec@hawaii.edu>  
[REDACTED]@cdc.gov>

Tue, Jul 25, 2017 at 10:26 AM

Steve  
IDS and access requirements are for areas where select agents are used/stored.

[REDACTED]

[Quoted text hidden]

---

Stephen Case <stevec@hawaii.edu>

Tue, Jul 25, 2017 at 10:29 AM

To: [REDACTED]@cdc.gov>

Thanks [REDACTED] Steve  
[Quoted text hidden]





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Stephen Case <stevec@hawaii.edu>

---

## Updated status on UH Level 3 annual maintenance and re-certification

3 messages

---

Stephen Case <stevec@hawaii.edu>

Mon, Aug 28, 2017 at 12:09 PM

To: [REDACTED] <[REDACTED]@cdc.gov>

Cc: Vassilis Syrmos <syrmos@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

H [REDACTED]

Hope all's well.

Please find an update on the current status of our level 3 laboratory annual shutdown for maintenance and re-certifications.

Excerpt from email from JBF Director Nerurkar below, though this would be easier than me trying to summarize.

-----  
Colleagues:

As you all know BSL-3/ABSL-3 (JBF) was shut down for maintenance on July 29, 2017. JBF was supposed to reopen for conducting research by the end of August 2017. JBF Staff had a meeting with JABSOM Facilities on Wednesday August 16, 2017. Based on the discussion with JABSOM Facilities, **it appears that the JBF will not open till end of October 2017.** Attached find summary of JBF update provided by JABSOM Facilities Director.

There are two main reasons for this delay. The first is HVAC-related. The second is related to the Piller UPS

### CURRENT PROGRESS

#### Critical Path - HVAC

New static pressure (SP) sensors have been procured. JABSOM facilities is working with the building automation system (BAS) contractor to replace existing SP sensors. The old SP sensors were not tracking properly. Additional SP sensors will be installed in the exhaust ducts (4) and in the supply duct (1) following locations to help in troubleshooting efforts:

1. Return duct/tunnel duct exhaust
2. Biosafety Cabinet (BSC) exhaust duct
3. EF-2-407 and 408 L3 exhaust duct
4. EF-2-405 and 406 exhaust duct
5. On the supply-air side, Relief and Isolation damper

Once the new SP sensors are installed and wired, HES – the BAS contractor – will investigate and correct an overly complicated and convoluted BAS program that probably evolved to compensate for SP sensors that were not functioning properly.

A supply-air-side phoenix air valve was found installed backwards – the inlet and outlets are 180° off. The PAV is SAV-148 and serves AVS suite 2. This PAV will have to be re positioned before balancing continues. The repair is not trivial due to its location (11-feet off the deck) and the proximity to hot water lines, air ducts, a light fixture and a lot of conduit). The importance that supply air serves the vivarium necessitates that the work be done quickly to minimize down-time of the supply-air-side, and if JABSOM Facilities undertakes this job, they will require greater than one day.

**Piller Uninterruptible Power Supply (UPS)**

The Piller is presently out of commission (OOC)/off-line.

The fully approved Sole Source for the new maintenance contract was delivered to the UH Procurement and Real Property Management Office today (8/23). After "posting the notice for 7-days, it will be sent to the President's office for signature. Unless Piller wants to change the "terms and conditions" from last year's contract, a Purchase Order (PO) should be issued from UH to Piller around Labor Day. Assuming a PO is issued around Labor Day, the Piller should be returned to service before October 2017.

**State Boiler Pressure Vessel Inspector**

Approved placement of L3 autoclave UPS on August 17, 2017

**Wall Repairs and Painting**

Special epoxy-paint for L3 is on order. Cannot be flown to Hawaii.

**Finger Print Readers**

Security Resources is still working on getting the new equipment to work with the old equipment. Short of changing out all the readers (7) at about \$800 per reader, we may just have to wait on the switch out. The good thing is that the hand readers still work. They will eventually fail, but let's hope we find a solution to the compatibility issue before that time

**Certification**

WBHT visit scheduled for October 24, 2017

end excerpt.....

If you have any questions or concerns let me know

Mahalo,

Steve

-----  
Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Responsible Official  
Animal Welfare and Biosafety Programs  
Office of Research Compliance  
2425 Campus Road, Sinclair 10  
Phone: (808) 956-8009 (o), (808) 285-7545 (c)  
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3/12/2020

University of Hawaii Mail - Updated status on UH Level 3 annual maintenance and re-certification

[REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Fri, Sep 1, 2017 at 3:38 AM

Thanks for the update Steve,

I'm sending this to our facility specialists and I'll be in touch if we need any records associated with the HVAC issues.

[REDACTED]  
[REDACTED]  
Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: ([REDACTED])

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[Quoted text hidden]

[REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Tue, Sep 5, 2017 at 8:50 AM

Hi Steve,

Once the HVAC related issues are resolved, we will need failure testing data.

This should include the following tests;

- Single exhaust fan failure.
- Loss of normal power.
- Return to normal power.

Here is a link to the policy which outlines and gives further information on these tests.

<https://www.selectagents.gov/regBSL3ABSL3policy.html>



Let me know if you have any questions

[REDACTED]

[REDACTED]

Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: [REDACTED]

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**From:** Stephen Case [mailto:stevec@hawaii.edu]

**Sent:** Monday, August 28, 2017 6:10 PM

**To:** [REDACTED] <[REDACTED]@cdc.gov>

**Cc:** Vassilis Syrmos <syrmos@hawaii.edu>; Victoria Rivera <riveravg@hawaii.edu>; Norman Magno <nmagno@hawaii.edu>; Hubert Olipares <olipares@hawaii.edu>

**Subject:** Updated status on UH Level 3 annual maintenance and re-certification

Hi [REDACTED]

Hope all's well.

[Quoted text hidden]

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

---

## Form 5 Exclusion for Bp and Bm strains

8 messages

---

Stephen Case <stevec@hawaii.edu>

Wed, Sep 13, 2017 at 11:44 AM

To: [REDACTED]@cdc.gov

Cc: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Bcc: Tung Hoang <tongh@hawaii.edu>, Ian Mcmillan <iamcm@hawaii.edu>

Aloha [REDACTED],

Dr. Hoang would like to submit a **Form 5** and accompanying data to obtain some exclusions for several of his Bp and Bm and gene negative strains obtained from previous data generated before our program was suspended.

Can we submit under our current suspension?

Please let me know asap so we can get this going without further delays.

Mahalo,  
Steve

---

Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Responsible Official  
Animal Welfare and Biosafety Programs  
Office of Research Compliance  
2425 Campus Road Sinclair 10  
Phone: (808) 956-8009 (o), (808) 285-7545 (c)  
FAX: (808) 956-9150

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---

Tung Hoang <tongh@hawaii.edu>

Wed, Sep 13, 2017 at 12:32 PM

To: Stephen Case <stevec@hawaii.edu>

Cc: [REDACTED]@cdc.gov, Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

We are not manipulating select-agent anymore and there is no need to, to get this approved. This has to go to the ISATTAC for approval. We had 3 similar strains previously approved by the ISATTAC for exclusion from select-gent regulation that is widely used in our field.

<https://www.selectagents.gov/exclusions-overlap.html>

- *Burkholderia pseudomalleis* strain B0011, a  $\Delta$ *asd* mutant of *B. pseudomallei* strain 1026b (effective 12-07-2011)

This strain contains a deletion in the aspartate-B-semialdehyde dehydrogenase ( *asd* ) gene, which is auxotrophic for diaminopimelate (DAP). The  $\Delta$  *asd* mutant was found to be avirulent in mice and unable to replicate in HeLa or RAW 264.7 cells.

#### Reference(s):

1. Norris MH, Propst KL, Kang Y, Dow SW, Schweizer HP, Hoang TT. The *Burkholderia pseudomallei*  $\Delta$  *asd* mutant exhibits attenuated intracellular infectivity and imparts protection against acute inhalation melioidosis in mice. *Infect Immun.* 2011 Oct; 79(10):4010-8.
2. Norris MH, Kang Y, Lu D, Wilcox BA, Hoang TT. Glyphosate resistance as a novel select-agent-compliant, non-antibiotic-selectable marker in chromosomal mutagenesis of the essential genes *asrI* and *dapB* of *Burkholderia pseudomallei*. *Appl Environ Microbiol.* 2009 Oct; 75(19):6062-75.

With regard to this new application for select-agent exclusion, we have previously purified these new cultures, which we intend to get select-agent exclusion for, a few times and had validated them in mice studies (see mice data).

On another note, we have generated a huge amount of data before the shutdown that we will publish several papers on. So, please don't be concern/surprise to see future publications a couple of years from now involving select-agent from our lab, since we already have the data generated before the shutdown, but are writing them up for publications now and soon.

Tung

Tung T Hoang, PhD (Professor)  
2538 McCarthy Mall/Snyder Hall Rm 310  
Department of Microbiology  
University of Hawaii at Manoa  
Honolulu, HI 96822  
Tel: (808) 956-3522  
Fax: (808) 956-5339  
<http://www.hawaii.edu/microbiology/faculty/tunghoang.html>  
[Quoted text hidden]

Stephen Case <stevec@hawaii.edu>

Wed, Sep 13, 2017 at 1:11 PM

To: Tung Hoang <tongh@hawaii.edu>

Cc: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Hi Tung,

Understand, but the request needs to go through our "file manager" and FSAP first then....." *FSAP reviews requests for exclusions and may seek input from CDC'S Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC), which is comprised of employees from CDC, NIH, FDA, USDA/Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/Center for Veterinary Biologics (CVB) and the Department of Defense (DOD). The ISATTAC reviews requests for the exclusion of attenuated strains and modified toxins of HHS only or overlap select agents and toxins.*" (From the Exclusion Guidance Doc, March 2107)

Please don't cc [REDACTED] on our in house communications or email directly. Any communication with our "file manager" needs to go through me (RO) or Hurbert (ARO) only.....FSAP policy.

Mahalo,  
Steve

[Quoted text hidden]

Tung Hoang <tongh@hawaii.edu>

Wed, Sep 13, 2017 at 1:35 PM

To: Stephen Case <stevec@hawaii.edu>

Cc: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Hi Steve,

Having done this a few times before with 5 other ROs at UH before you came along, I am fully aware of the process. I was emailing you, so you are aware of what we have been approved for a few times by the by the ISATTAC and have done, so there is no surprise. I am not in direct communication with [REDACTED] and have never communicated with [REDACTED] directly.

Tung

Tung T. Hoang, PhD (Professor)  
2538 McCarthy Mall/Snyder Hall, Rm 310  
Department of Microbiology  
University of Hawaii at Manoa  
Honolulu, HI 96822  
Tel: (808) 956-3522  
Fax: (808) 956-5339  
<http://www.hawaii.edu/microbiology/faculty/tunghoang.html>

On Sep 13, 2017, at 1:11 PM, Stephen Case <stevec@hawaii.edu> wrote:

Hi Tung,

Understand, but the request needs to go through our "file manager" and FSAP first then....." *FSAP reviews requests for exclusions and may seek input from CDC'S Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC), which is comprised of employees from CDC, NIH, FDA, USDA/Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/Center for Veterinary Biologics (CVB) and the Department of Defense (DOD). The ISATTAC reviews requests for the exclusion of attenuated strains and modified toxins of HHS only or overlap select agents and toxins.*" (From the Exclusion Guidance Doc, March 2107)

Please don't cc [REDACTED] on our in house communications or email directly. Any communication with our "file manager" needs to go through me (RO) or Hurbert (ARO) only.....FSAP policy.

Mahalo,  
Steve

On Wed, Sep 13, 2017 at 12:32 PM, Tung Hoang <tongh@hawaii.edu> wrote:

We are not manipulating select-agent anymore and there is no need to, to get this approved. This has to go to the ISATTAC for approval. We had 3 similar strains previously approved by the ISATTAC for exclusion from select-gent regulation that is widely used in our field.

<https://www.selectagents.gov/exclusions-overlap.html>  
<PastedGraphic-2.png>

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[Quoted text hidden]

---

**Stephen Case** <stevec@hawaii.edu>  
To: Tung Hoang <tongh@hawaii.edu>

Wed, Sep 13, 2017 at 1:42 PM

Thanks Tung, appreciate the background.....Steve  
[Quoted text hidden]

---

**Tung Hoang** <tongh@hawaii.edu>  
To: Stephen Case <stevec@hawaii.edu>

Wed, Sep 13, 2017 at 1:45 PM

Thanks Steve for helping out.

Tung

3/12/2020

University of Hawaii Mail - Form 5 Exclusion for Bp and Bm strains

Tung T. Hoang PhD (Professor)  
2538 McCarthy Mall/Snyder Hall, Rm 310  
Department of Microbiology  
University of Hawaii at Manoa  
Honolulu, HI 96822  
Tel: (808) 956-3522  
Fax: (808) 956-5339  
<http://www.hawaii.edu/microbiology/faculty/tunghoang.html>

[Quoted text hidden]

[REDACTED]@cdc.gov>

Mon, Sep 18, 2017 at 3:28 AM

To: Tung Hoang <tongh@hawaii.edu>, Stephen Case <stevec@hawaii.edu>

Cc: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

This does not meet the criteria for a Form 5, however, if you would like to submit these strains to be excluded, please send me the applicable data, and I will forward to our science group to consider and take to the ISATTAC.

Thanks

[REDACTED]

[REDACTED]

Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: (404) [REDACTED]

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[Quoted text hidden]

Tung Hoang <tongh@hawaii.edu>

Mon, Sep 18, 2017 at 8:40 AM

Cc: Stephen Case <stevec@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Hi Steve,

Please send in the data that Ian has given you, as [REDACTED] suggested for approval. Thanks.

Tung

Sent from my iPhone

On Sep 18, 2017, at 3:28 AM, Gustin, Kortney M. (CDC/OPHPR/DSAT) <ihe9@cdc.gov> wrote:

This does not meet the criteria for a Form 5, however, if you would like to submit these strains to be excluded, please send me the applicable data, and I will forward to our science group to consider and take to the ISATTAC.

Thanks

[REDACTED]  
[REDACTED]  
[REDACTED]  
Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: ([REDACTED]) 405

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**From:** Tung Hoang [mailto:tongh@hawaii.edu]

**Sent:** Wednesday, September 13, 2017 6:32 PM

**To:** Stephen Case <stevec@hawaii.edu>

**Cc:** [REDACTED] <ihe9@cdc.gov>; Victoria Rivera <riveravg@hawaii.edu>;

Norman Magno <nmagno@hawaii.edu>; Hubert Olipares <olipares@hawaii.edu>

**Subject:** Re: Form 5 Exclusion for Bp and Bm strains

We are not manipulating select-agent anymore and there is no need to, to get this approved. This has to go to the ISATTAC for approval. We had 3 similar strains previously approved by the ISATTAC for exclusion from select-gent regulation that is widely used in our field.

<https://www.selectagents.gov/exclusions-overlap.html>

<image001.png>

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

---

## UH Manoa SA program....moving forward

1 message

---

Stephen Case <stevec@hawaii.edu>

Fri, Oct 20, 2017 at 3:35 PM

To: [REDACTED]@cdc.gov

Cc: Hubert Olipares <olipares@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>

Aloha [REDACTED]

I would like to set up a quick conference call with you on Tuesday next week, Oct 24th, sometime between 2 - 4pm your time, just let me know when would be a good time for you. I'm assuming you'll be back in the office next week as this week you said you would be out on inspections. In attendance would be Hubert (ARO), Norman Magno, our supervisor, Ms. Victoria Rivera, Interim Director of the Office of Research Compliance and myself.

We would like to discuss how to move forward with the shutdown of our SA program. We've already discussed this a little already but as things become more "formal" there's going to be things that need to be done on your end so we can proceed here and I know these things take time to process. Hopefully our discussion will give us a better feel for a time line to accomplish our shutdown goal.

If Tuesday doesn't work for you, just let me know and we can reschedule for another date and time.

Hope all's well, and look forward to hearing back from you.

Mahalo,  
Steve

---

Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Responsible Official  
Animal Welfare and Biosafety Programs  
Office of Research Compliance / OVPRI  
2425 Campus Road, Sinclair 10  
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Stephen Case <stevec@hawaii.edu>

---

## Question regarding APHIS/USDA portion of registration

3 messages

---

Stephen Case <stevec@hawaii.edu>

Tue, Oct 24, 2017 at 5:02 PM

To: [REDACTED]@cdc.gov>

Cc: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Aloha Kortney,

During my conversations with our APHIS/USDA PI's this morning after our conference call the question arose as to the possibility of maintaining their portion of the registration dealing with the USDA agents and keeping it active. Would this be even possible and if so what would it require?

Just making the inquiry as to possibilities and alternatives to total withdrawal on behalf of the PI's. I realize if this did occur we would have to change oversight agencies as we would then fall totally under USDA.

I also wish our administration might have been a little more transparent as to their intentions and motivations for withdrawing from the Select agent program, in which case we might have been able to address this issue in a more timely fashion.

You thoughts would be greatly appreciated.

Mahalo,  
Steve

---

Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Responsible Official  
Animal Welfare and Biosafety Programs  
Office of Research Compliance / OVPRI  
2425 Campus Road Sinclair 10  
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---

To: Stephen Case <stevec@hawaii.edu> [REDACTED]@cdc.gov>

Wed, Oct 25, 2017 at 10:06 AM

Hi Steve,

I think you would still have to adequately address the inspection report findings and re-vamp the program into compliance—to have the suspension lifted. The regulations for PPQ agents would be the same, as would the requirements.

For now, we are still expecting the intent to withdraw letter. If this is not the case, we will need to know sooner—rather than later. I'm guessing it might initiate another leadership conference call?

[REDACTED]  
[REDACTED]  
Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: [REDACTED]

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[Quoted text hidden]

Stephen Case <stevec@hawaii.edu>

Wed, Oct 25, 2017 at 10:20 AM

To: [REDACTED]@cdc.gov

Cc: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Aloha [REDACTED]

Thanks for your quick response to inquires regarding our PPQ agents.

We are currently working on our intent to withdraw letter and putting together the accompanying plans of action for all our agents.

If you should have any further questions arise on your end please let me know.

Mahalo,  
Steve

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

## Moving forward with UH's withdrawal process from FSAP

4 messages

Stephen Case <stevec@hawaii.edu>

Fri, Nov 3, 2017 at 2:51 PM

To: [REDACTED]@cdc.gov

Cc: Hubert Olipares <olipares@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>

Dear [REDACTED]

Yesterday, Nov. 2nd, we officially received notice from our administration to cease all select agent work on UH campus' and officially withdraw our registration from the FSAP. This included both CDC and USDA agents currently listed on our registration. If your office would like a copy of the memorandum for program closure, I will forward it to you

During our conference call on Oct. 24th, we went over the basic procedures for our withdrawal. Because of our suspension from accessing or working with any of the agents, there are several questions that have surfaced regarding the actual process "for us" with withdraw.

First, our letter of intent to withdraw from the program along with an explanation of reasons in being drafted now that we have received the official notice from above. Couple of questions regarding this....

1. To whom should the letter and plan of disposition of our registered agents be addressed?
2. How detailed does the plan need to be for all the agents disposition. Through earlier discussions with some of the PI's, some agents will be transferred to other registered entities, via Form 2. Other agents will be destroyed by autoclaving. Some are still in the process of trying to find "new homes" for some of their inventories, understanding that should this fail they would be destroyed.
3. What would be the time frame for modification of our suspension to allow access to proceed with disposition once letter of intent is received. Keeping in mind that we are entering the "holiday session", which can have an impact on transfers, both from the sender and receiving ends. If possible, we would appreciate consideration that an administrative decision be determined on our current registration, which expires on Dec. 6th, to be extended into the first of the new year.

At the moment, these are the most over riding concerns and questions. Your response will be a great help in moving us forward.

Mahalo,  
Steve

-----  
Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Responsible Official  
Animal Welfare and Biosafety Programs  
Office of Research Compliance / OVPR  
2425 Campus Road, Sinclair 10  
Phone: (808) 956-8009 (o), (808) 285-7545 (c)  
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-----

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[REDACTED]@cdc.gov  
To: Stephen Case <stevec@hawaii.edu>

Mon, Nov 6, 2017 at 12:23 PM

Hi Steve,

1. You may address the letter to [REDACTED].
2. For the initial letter the disposition of agents can be more general. It is preferred that you give us as much detail as possible. Of course we will be requesting the actual autoclave records and have the approved Form 2s to confirm everything later.
3. We do have a process to not let you expire, but not renew you either—since you will be in the process of withdrawing. No need to worry about that. We are working on our own letter to send you to explain and to give you permission to access the inventory (please don't do so until you get the letter)

And, I'm in California this week, so if you have any questions, I'll still be working!

[REDACTED]

From: Stephen Case [mailto:stevec@hawaii.edu]

Sent: Friday, November 3, 2017 8:51 PM

To: [REDACTED]@cdc.gov>

Cc: Hubert Olipares <olipares@hawaii.edu>; Victoria Rivera <riveravg@hawaii.edu>; Norman Magno <nmagno@hawaii.edu>

Subject: Moving forward with UH's withdrawal process from FSAP

Dear [REDACTED],

Yesterday, Nov. 2nd, we officially received notice from our administration to cease all select agent work on UH campus' and officially withdraw our registration from the FSAP. This included both CDC and USDA agents currently listed on our registration. If your office would like a copy of the memorandum for program closure, I will forward it to you

During our conference call on Oct. 24th, we went over the basic procedures for our withdrawal. Because of our suspension from accessing or working with any of the agents, there are several questions that have surfaced regarding the actual process "for us" with withdraw.

First, our letter of intent to withdraw from the program along with an explanation of reasons in being drafted now that we have received the official notice from above. Couple of questions regarding this....

1. To whom should the letter and plan of disposition of our registered agents be addressed?
2. How detailed does the **plan** need to be for all the agents disposition. Through earlier discussions with some of the PI's, some agents will be transferred to other registered entities, via Form 2. Other agents will be destroyed by autoclaving. Some are still in the process of trying to find "new homes" for some of their inventories, understanding that should this fail they would be destroyed.
3. What would be the time frame for modification of our suspension to allow access to proceed with disposition once letter of intent is received. Keeping in mind that we are entering the "holiday session", which can have an impact on transfers, both from the sender and receiving ends. If possible, we would appreciate consideration that an administrative decision be determined on our current registration, which expires on Dec. 6th, to be extended into the first of the new year.

[Quoted text hidden]

---

Stephen Case <stevec@hawaii.edu>

Mon, Nov 6, 2017 at 12:51 PM

To: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

3/12/2020

University of Hawaii Mail - Moving forward with UH's withdrawal process from FSAP

FYI, and working on letter of Intent....Steve

[Quoted text hidden]

---

Stephen Case <stevec@hawaii.edu>

To: [REDACTED]@cdc.gov>

Mon. Nov 6, 2017 at 1:45 PM

Thanks [REDACTED]... Steve

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

---

## UH Intent to withdraw from FSAP registration

2 messages

---

Stephen Case <stevec@hawaii.edu>

Mon, Nov 13, 2017 at 10:44 AM

To: [REDACTED]@cdc.gov

Cc: Vassilis Syrmos <syrmos@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>

Aloha [REDACTED]

Please find attached our official letter of intent to withdraw the University of Hawaii's registration from the Federal Select Agent Program.

We look forward to working with you as we develop our plan of action and work toward our final disposition of our registered agents and closure of our SA program.

If you should have any questions or concerns as we move forward please don't hesitate to contact me.

Mahalo,  
Steve

---

Stephen Case, MSPH RBP  
Biosafety Professional  
Educational Coordinator  
Responsible Official  
Animal Welfare and Biosafety Programs  
Office of Research Compliance / OVPRI  
2425 Campus Road Sinclair 10  
Phone: (808) 956-8009 (o), (808) 285-7545 (c)  
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---

 UH\_Intent\_of\_Withdrawal\_from-FSAP\_Registration\_11-13-17.pdf  
180K

---

To: Stephen Case <stevec@hawaii.edu> [REDACTED]@cdc.gov

Mon, Nov 13, 2017 at 11:59 AM

Thanks Steve

---

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

---

## Current status of UH Withdrawal process and time line

2 messages

---

Stephen Case <stevec@hawaii.edu>

Tue, Nov 28, 2017 at 5:30 PM

To: [REDACTED]@cdc.gov>

Cc: Victoria Rivera <riveravg@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>

Hi [REDACTED],

Just checking in to see what the status is regarding our withdrawal process from the Select agent program and any time lines that might have been worked out for disposition of our agents. I know that you're aware that our current registration expires next week Wednesday, Dec. 6th, and the holiday's are quickly approaching.

Also any word on the "exclusion" status of those *Burkholderia* sp. strains of Dr. Hoang?

I'll be out of the office tomorrow, 11/29, with training's and IBC meeting but would be available for a phone consult on Thursday between 9 and 12noon my time (2-4pm your time) if you'd prefer something other than email.

Looking forward to your response.

Mahalo.  
Steve

---

Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Responsible Official  
Animal Welfare and Biosafety Programs  
Office of Research Compliance / OVRP  
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[REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Wed, Nov 29, 2017 at 7:47 AM

Hi Steve,

We do have a plan that includes extending the registration, getting the exclusion approved, and finalizing the letter authorizing you to access inventory.

Let's talk tomorrow. I'll give you a call around 9am HI /2pm EST ?

[REDACTED]  
Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: ([REDACTED])

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[Quoted text hidden]





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Stephen Case <stevec@hawaii.edu>

---

## Withdrawing

7 messages

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[REDACTED]@cdc.gov  
To: Stephen Case <stevec@hawaii.edu>

Tue, Dec 5, 2017 at 10:59 AM

Hi Steve,

You should have the letter by now. Let me know if you have any questions. Also, please keep me in the loop on the destruction/transfer progress.

Thanks

[REDACTED]  
Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: [REDACTED]

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---

Stephen Case <stevec@hawaii.edu>

Tue, Dec 5, 2017 at 2:38 PM

To: [REDACTED]@cdc.gov

Bcc: Norman Magno <nmagno@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>

Hi [REDACTED],

Yes, we received letter yesterday (12/4). Will keep you posted as we progress. PI's are now trying to finalize disposition.

PI Douglas is trying to find a home for his sera, says he might have some receptive candidates, will let you know any findings.

PI Hoang, is looking at transferring some to CSU and maybe somewhere in Florida (?). Rest will be destroyed.

PI Alvarez just returned from 2 mo. away and haven't had a chance to speak with her on specifics. She is aware that the program is being closed.

PI Nerurkar might want to transfer (?). He has a colleague in Singapore (where samples originally came from, EEE and VEE) who might want. What would be the process for International transfer? Just checking, not sure it's going to happen but want to be prepared with answer if we can or can't.

Will keep you apprised of any further developments.

Mahalo,  
Steve

[Quoted text hidden]

-----  
Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Responsible Official  
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Office of Research Compliance / OVPR  
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[REDACTED] 9@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Thu, Dec 7, 2017 at 7:41 AM

Hi Steve. I copied the below information regarding international shipments of select agents from our website. We do not require a Form 2 or otherwise authorize, however there are Department of Commerce requirements. I'm not familiar with these requirements, hopefully the link will have useful information.

Information may be obtained by calling the DOC Bureau of Export Administration at (202) 482-4811, or at <http://www.access.gpo.gov/bis/index.html> or <http://www.bis.doc.gov/>.

Let me know if you have any other questions

[REDACTED]  
[Quoted text hidden]

-----  
Stephen Case <stevec@hawaii.edu>  
To: "[REDACTED] 9@cdc.gov"<[REDACTED] 9@cdc.gov>  
Cc: Hubert Olipares <olipares@hawaii.edu>  
Bcc: Norman Magno <nmagno@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>

Thu, Dec 7, 2017 at 5:13 PM

Hi [REDACTED]

Thanks for the info on any potential Export Control regs. we might need to meet if we go international on any transfers.... I don't think we will, but was informed that for the EEE and VEE would need a license to export.

Anyway another question. When Dr. Douglas' *Brucella* materials were moved to registered space there was no quarter given as to what exactly was being moved other than it had the word "*Brucella*...." written on it. As a result some of his *Brucella* "vaccine" strains were moved over and put on inventory. In my discussion with him and passing along what we discussed regarding needing some form of documentation showing/listing by name that they were vaccine strains, he sent me the attached reference. I've highlighted the listed strains that he has.

His listed vaccine strains on inventory:

*B. abortus* 45/20 USDA Ames Iowa 1972

*B. melitensis* Rev 6/22/1966

*B. melitensis* Rev 1 Smooth Lot 102, 1972

Please note that there was a transcription error for the *B. melitensis* Rev 1 6/22/1966, the "1" was inadvertently omitted during transcription and it is listed on the inventory record as "*B. melitensis* Rev 6/22/1966". Also Ames should be Ames.

So, finally to my question, is this sufficient documentation to drop them off our inventory as not SAs? If so how do we go about documenting it and if not what else would we need?

Mahalo,  
Steve

[Quoted text hidden]

 **Brucella Vaccine Review paper.pdf**  
1207K

[REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>  
Cc: Hubert Olipares <olipares@hawaii.edu>

Fri, Dec 8, 2017 at 8:05 AM

Hi Steve,

The *Brucella* strains are not excluded and would be considered Select Agents. Although these may be considered vaccine strains in some countries, Rev 1 is not a licensed US vaccine. Additionally, there is apparently strain to strain variation in Rev1, from avirulent to completely virulent. For the other strain, the information provided isn't enough to say it would be excluded.

For these 3 to be excluded, I think you would have to do a formal exclusion request with data to support like with the Burk strains.

[Quoted text hidden]

**Stephen Case** <stevec@hawaii.edu>  
To: [REDACTED] <[REDACTED]@cdc.gov>

Fri, Dec 8, 2017 at 9:39 AM

Thanks [REDACTED]

Steve

[Quoted text hidden]

**Stephen Case** <stevec@hawaii.edu>  
To: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>  
Bcc: Steve Case <stevec@hawaii.edu>

Mon, Dec 11, 2017 at 12:19 PM

FYI on [REDACTED] response.

Steve

[Quoted text hidden]





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Stephen Case <stevec@hawaii.edu>

## UH Manoa Status of withdrawal from SAP

5 messages

Stephen Case <stevec@hawaii.edu>

Mon, Dec 18, 2017 at 1:20 PM

To: [REDACTED]@cdc.gov

Cc: Hubert Olipares <olipares@hawaii.edu>

Bcc: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>

Aloha [REDACTED]

Quick update of how things are progressing with our withdrawal process from the SAP.

**PI Nerurkar** - Has decided that all the EEE and VEE will be destroyed and not transferred.

**PI Douglas** - Still trying to find takers for his organisms and sera. Nothing definite yet. He has been made aware, per your email, that his vaccine strains of *Brucella* are NOT excluded from the SA designation.

**PI Hoang** - Some of his *Burkholderia* inventory will be transferred to CSU and possibly some to Florida (where??) remaining inventory will be destroyed. His *Brucella* inventory will all be destroyed.

With the strains that were recently "excluded", what is needed for their documentation and subsequent removal from his inventory?

**PI Alvarez** - Just returned from 2 mo. in Argentina and as such missed all the decisions to withdraw from the SAP. Her inventory that was due to go to Agdia Inc., had some qualifiers under their contract and her NSF grant. Samples must be shown to be viable and pure. Have been in discussion with her on options, knowing that our suspension and extension doesn't allow any active manipulation, regarding any transfer. Will elaborate and seek your guidance in another email.

I've also attached an copy of our "documentation of destruction" form to be use when we destroy inventory. It's modeled after UTMB's form. Let me know if there is anything else we might need to add or is this sufficient.

Any questions feel free to contact me via phone or email.

Mahalo,  
Steve

---

Stephen Case, MSPH, RBP  
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Educational Coordinator  
Responsible Official  
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UH Destruction of Select Agent Biological Material.pdf  
13K

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To: Stephen Case <stevec@hawaii.edu>  
[REDACTED]@cdc.gov

Tue, Dec 19, 2017 at 8:14 AM

Hi Steve,

Glad things are moving along. The destruction record will be fine. Just be sure you can match every destruction record with every item in the inventory. For example, we will look at one of the inventory sheets and ask for the destruction record of that specific material. Therefore I would recommend keeping the inventory record and destruction record together for samples, or have some other system to cross reference.

For the excluded strains, just pull those out of the inventory and note on the inventory record that these are excluded and removed, date/initials.

Let me know about the PPQ agents.

[REDACTED]

[REDACTED]

Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

[REDACTED]

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[Quoted text hidden]

[REDACTED] 9@cdc.gov>

Mon, Jan 8, 2018 at 9:03 AM

To: Stephen Case <stevec@hawaii.edu>

Cc: Hubert Olipares <olipares@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>, "syrmos@hawaii.edu" <syrmos@hawaii.edu>, "david@hawaii.edu" <david@hawaii.edu>, "jerris@hawaii.edu" <jerris@hawaii.edu>

Happy New Year Steve,

Would you mind providing another update on the progress of your plans to destroy and/or transfer the select agents listed below? The Registration expiration date is March 6, 2018 – so we are approximately at a 2 month countdown.

Thanks and please contact me with any questions,

[REDACTED]  
[REDACTED]  
Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: ([REDACTED])

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**From:** Stephen Case [mailto:stevec@hawaii.edu]

**Sent:** Monday, December 18, 2017 6:21 PM

**To:** [REDACTED]@cdc.gov>

**Cc:** Hubert Olipares <olipares@hawaii.edu>

**Subject:** UH Manoa Status of withdrawal from SAP

Aloha Kortney,

[Quoted text hidden]

[Quoted text hidden]

[Quoted text hidden]

[Quoted text hidden]

[Quoted text hidden]

[Quoted text hidden]

Mahalo,

[Quoted text hidden]

Stephen Case <stevec@hawaii.edu>

Mon, Jan 15, 2018 at 6:04 PM

To: '[REDACTED]@cdc.gov'

Cc: Hubert Olipares <olipares@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>

Aloha [REDACTED]

Quick update of how things are progressing with our withdrawal process from the SAP as of Jan. 15, 2018.

**PI Nerurkar** - Dr. Kumar has just returned from holiday vacation and we will be destroying the EEE and VEE in inventory either this week (1/15) or next (1/23) and will be maintaining the destitution records for CDCs closeout inspection.

**PI Douglas** - Has been in communication with Texas A&M and they have expressed an interest in taking on his *Brucella* inventory, both his strains and sera. A Form 2 is being prepared and going to be sent to them to begin the process of transfer once the Courier has been determined (cost??).. This being said there still is the possibility that we will end up destroying his inventory. Will keep you updated.

**PI Hoang** - Has gotten the OK from CSU to transfer several of his *Burkholderia* strains to them with a target date of Feb. 5th for shipment. Remaining *Burkholderia* strains and all of his *Brucella* strains will be destroyed. World Courier has been tasked with the transfer and initial quote for the transfer is \$4,600+. Once quote is accepted and CSU has OKed the acceptance of the various strains a Form 2 will be processed for the transfer probably this week (1/15).

**PI Alvarez** - Dr. Alvarez along with the Dean of the College of Tropical Agriculture will be meeting with UH administration later this week (1/15) in attempts to try and keep the PPQ side of the SAP viable. The new lab, which was looked at in Dr. Arifs lab during your last inspection, is ready to go and can be inspected anytime if needed. This new lab has addressed all the departures from our last inspection report relating to conditions needed for manipulation. If there is a positive outcome from the meeting then we will need to evaluate various options for her maintaining her inventory and the change over to PPQ, but we'll cross that bridge if we ever get to it. Will keep you apprised of the outcome of their meeting with UH administration.

Dr. Alvarez has also been in contact with Agdia, Inc. and they have agreed to take her entire collection, even though she won't be able to curate the collection for viability and purity if it comes down to destroying 40 years of data and samples. If talks with administration are not positive and they want to proceed with the withdrawal, then we will begin the process of transfer to Agdia, Inc., beginning with the submission of a Form 2. Should know the outcome by weeks end.

As we move forward will keep you informed with our progress. If you have any questions don't hesitate to contact me either by phone or email.

Mahalo,  
Steve

[Quoted text hidden]

[REDACTED]@cdc.gov

Wed, Jan 17, 2018 at 11:55 AM

To: Stephen Case <stevec@hawaii.edu>

Hi Steve. Thanks for the update.

We'll talk again next week.

[REDACTED]

[Quoted text hidden]





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Stephen Case <stevec@hawaii.edu>

## Inventory transcription error

2 messages

Stephen Case <stevec@hawaii.edu>

Mon, Jan 22, 2018 at 5:20 PM

To: [REDACTED]@cdc.gov

Cc: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>

Aloha [REDACTED]

Welcome back! I assume you're probably back to work now that the govn. has been funded again for at least a couple of more weeks.

I have a quick question for you regarding our "listed" inventory for PI Nerurkar.

In preparation for destruction of PI Nerurkar's EEE and VEE and verifying the inventory, a transcription error was noted and I wanted to bring it to your attention before we went ahead with our destruction of the materials.

Listed on his inventory spreadsheet that was developed, and sent to you, after our last inspection we inadvertently under recorded during our transcription of VEE. The original written inventory listed 4 vials of VEE (M20894) and we only transcribed 2 vials over on to the spreadsheet (??). During today's check there are indeed 4 vials in storage. So total vials of VEE on hand should read 8 instead of 6, as listed on the spreadsheet.

**Question:** How should we document? Doesn't meet any of the criteria for submission of a Form 3 as there is no "lost, theft or release".

Didn't want to go ahead with the destruction, scheduled for today 1/23, until we get the paperwork properly corrected, so your guidance would be greatly appreciated.

Look forward to your response so we can move forward with our withdrawal and destruction of the EEE and VEE inventories.

Mahalo,  
Steve

-----  
Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Responsible Official  
Animal Welfare and Biosafety Programs  
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[REDACTED]@cdc.gov  
To: Stephen Case <stevec@hawaii.edu>

Tue, Jan 23, 2018 at 8:34 AM

Hi Steve,

It looks like you just have a records discrepancy. Your actual inventory is correct—and that is your record.

You can make a note of the discrepancy and the change (who, what, why) on the spreadsheet

[REDACTED]  
[REDACTED]  
Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: [REDACTED]

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[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

---

## Form 2s for UH transfers

8 messages

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Stephen Case <stevec@hawaii.edu>

Tue, Jan 30, 2018 at 6:34 PM

To: [REDACTED]

Cc: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>

Aloha [REDACTED],

Just a quick note. To date we've only received one (1) transfer authorization and that was for transfer of B. mellitensis to NAU. Could you check on the other two, CSU and Texas A&M? Especially the one from CSU as we were planning on shipping Monday Feb. 5th.

Mahalo,  
Steve

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Stephen Case, MSPH, RBP  
Biosafety Professional  
Educational Coordinator  
Responsible Official

Animal Welfare and Biosafety Programs  
Office of Research Compliance / OVPRI  
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---

[REDACTED] <[REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Wed, Jan 31, 2018 at 8:31 AM

Hi Steve,

Looks like Texas A&M still has some corrections to make before approval and NAU has been approved. CSU has not submitted anything yet. My Sources tell me, they are planning on doing it this week, but haven't yet...

[REDACTED]

[REDACTED]

CDC/DSAT

Tel: [REDACTED]

Telework: Monday & Thursday

[Quoted text hidden]

---

Stephen Case <stevec@hawaii.edu>

Wed, Jan 31, 2018 at 10:08 AM

To: Ian McMillan &lt;iamcm@hawaii.edu&gt;

Cc: Yun Kang &lt;yunkang@hawaii.edu&gt;, Tung Hoang &lt;tongh@hawaii.edu&gt;, Victoria Rivera &lt;riveravg@hawaii.edu&gt;, Norman Magno &lt;nmagno@hawaii.edu&gt;

Hi Ian,

Current status of **Form 2 from CSU**. Unless things get processed really fast, 2/5 might not be viable date for transfer. Will keep you posted. Information from Kortney below.

Steve

[Quoted text hidden]

---

Ian McMillan <ian.andrew.mcmillan@gmail.com>

Wed, Jan 31, 2018 at 10:12 AM

To: Stephen Case &lt;stevec@hawaii.edu&gt;

Cc: Ian McMillan &lt;iamcm@hawaii.edu&gt;, Yun Kang &lt;yunkang@hawaii.edu&gt;, Tung Hoang &lt;tongh@hawaii.edu&gt;, Victoria Rivera &lt;riveravg@hawaii.edu&gt;, Norman Magno &lt;nmagno@hawaii.edu&gt;

Thanks for the update Steve. I will coordinate with World Courier and CSU to move the shipping date back one week to Feb. 12, 2018.

Would that work for you Steve?

Aloha,

Ian

[Quoted text hidden]

---

Stephen Case <stevec@hawaii.edu>

Wed, Jan 31, 2018 at 10:46 AM

To: Ian McMillan &lt;ian.andrew.mcmillan@gmail.com&gt;

Cc: Ian McMillan &lt;iamcm@hawaii.edu&gt;, Yun Kang &lt;yunkang@hawaii.edu&gt;, Tung Hoang &lt;tongh@hawaii.edu&gt;, Victoria Rivera &lt;riveravg@hawaii.edu&gt;, Norman Magno &lt;nmagno@hawaii.edu&gt;

Hi Ian,

Works for me, best we can do under the circumstances. Are you still planning of destroying inventory strains not being transferred this friday?

Mahalo,

Steve

[Quoted text hidden]

---

Ian McMillan <ian.andrew.mcmillan@gmail.com>

Wed, Jan 31, 2018 at 2:02 PM

To: Stephen Case &lt;stevec@hawaii.edu&gt;, Yun Kang &lt;yunkang@hawaii.edu&gt;

Hey Steve,

Lets move the destruction date closer to the shipment date. I am waiting to hear back from CSU about a different shipment date. Once confirmed lets do the destruction next week.

Any days that you prefer for doing the destruction next week?

Aloha,

Ian

[Quoted text hidden]

---

Ian McMillan <ian.andrew.mcmillan@gmail.com>

Thu, Feb 1, 2018 at 10:32 AM

To: Stephen Case &lt;stevec@hawaii.edu&gt;, Yun Kang &lt;yunkang@hawaii.edu&gt;

Hey Steve,

What day next week works for you to destroy our samples?

Ian

[Quoted text hidden]

---

**Stephen Case** <stevec@hawaii.edu>

Thu, Feb 1, 2018 at 12:43 PM

To: Ian McMillan <ian.andrew.mcmillan@gmail.com>

Cc: Yun Kang <yunkang@hawaii.edu>

Hi Ian,

I'm pretty open anytime and day next week.....whenever Eileen can reserve autoclave and have BI's ready for use.

Mahalo,

Steve

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

## Letter of Intent to register under AgSAS for UH USDA agents

3 messages

Stephen Case <stevec@hawaii.edu>

Mon, Feb 5, 2018 at 5:18 PM

To: [REDACTED]@cdc.gov>

Cc: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>, Hubert Olipares <olipares@hawaii.edu>

Aloha [REDACTED],

Find attached our letter of Intent to register our PPQ agents under AgSAS. Also find attached the completed application **FORM 1** (complete in a zip file) for our registration with them so you can forward to Aimee..

I've also attached the list of UH personnel that are being requested to be removed from our program that no longer require access to select agents and toxins. I haven't included any of the individuals who will be part of the AgSAS program application as well as myself.

Please let me know if I missed anything or need to change something on any of the FORM 1 sections.

After you've had the opportunity to review this materiel I'd like to get together for a phone conversation to see what else we might need to complete in order finalize our withdrawal or the new registration.

Mahalo.

Steve

---

Stephen Case, MSPH, RBP

Biosafety Professional

Educational Coordinator

Responsible Official

Animal Welfare and Biosafety Programs

Office of Research Compliance / OVPRI

2425 Campus Road Sinclair 10

Phone: (808) 956-8009 (o). (808) 285-7545 (c)

FAX: (808) 956-9150

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### 3 attachments

UH Letter of Intent to register with AgSAS\_2-1-18.pdf  
375K

UH Staff Removal from CDC registration.pdf  
27K

APHIS-CDC\_Form\_1\_Section\_1\_thru-7\_\_COMPLETE\_New\_UH.zip  
8086K

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Stephen Case <stevec@hawaii.edu>

Thu, Feb 8, 2018 at 10:22 AM

To: [REDACTED]@cdc.gov>

Hi [REDACTED],

Find attached the information for removal of current **ARO, Hubert Olipares C-HO-041914**. He no longer requires access to Select agents and toxins due to withdrawal of the HHS agents from the FSAP.

3/12/2020

University of Hawaii Mail - Letter of Intent to register under AgSAS for UH USDA agents


Not sure why he wasn't on the previous listing.

Mahalo,  
Steve

[Quoted text hidden]



**UH Staff Removal from CDC registration\_Olipares.pdf**  
25K

@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Thu, Feb 8, 2018 at 10:32 AM

Thanks Steve,

For the Form 2s—

Be sure and send the section 2s to the Form 2 mailbox when you are ready to ship.

Northern Arizona—is approved as is but if they are adding another agent they will have to redo it. – If it will be edited, they should submit this ASAP--

Texas A & M- haven't made their corrections yet. You may want to contact them directly to get this moving along.

  
CDC/DSAT

Tel: ()

Telework: Monday & Thursday

[Quoted text hidden]



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Stephen Case <stevec@hawaii.edu>

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**APHIS-CDC\_Form\_1\_Section\_1A\_1B\_New\_UH (002).pdf**

5 messages

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[REDACTED]@aphis.usda.gov>

Fri, Feb 9, 2018 at 7:15 AM

To: Stephen Case <stevec@hawaii.edu>

Cc: [REDACTED]@cdc.gov>, Anne Alvarez <alvarez@hawaii.edu>

Hi Steve, can you please resubmit the Form 1 section 1A 1B with Asoka's correct email address.

Thanks,

[REDACTED]

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 **APHIS-CDC\_Form\_1\_Section\_1A\_1B\_New\_UH (002).pdf**  
758K

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Stephen Case <stevec@hawaii.edu>

Fri, Feb 9, 2018 at 11:17 AM

To: [REDACTED]@aphis.usda.gov>

Hi [REDACTED]

Sorry about that, I rearranged the ARO order on the 1A and forgot to re-change a couple of fields.

Corrected **Asoka's email** address and noticed that my mailing address was incorrect so updated that. Also added new RO Jinzeng Yang's **Emergency Telephone #**.

Find corrected **FORM 1 - Section 1A, 1B** attached.

Let me know if you need anything else.

FYI Dr. Yang mentioned that he'd received his SAMS access application yesterday and is working on that.

Mahalo,

Steve

[Quoted text hidden]

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Stephen Case, MSPH, RBP

Biosafety Professional

Educational Coordinator

Responsible Official

Animal Welfare and Biosafety Programs

Office of Research Compliance / OVPRI

2425 Campus Road Sinclair 10



3/12/2020

University of Hawaii Mail - APHIS-CDC\_Form\_1\_Section\_1A\_1B\_New\_UH (002).pdf

Phone: (808) 956-8009 (o), (808) 285-7545 (c)

FAX: (808) 956-9150

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 **APHIS-CDC\_Form\_1\_Section\_1A\_1B\_New\_UH.pdf**  
761K

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[REDACTED]@aphis.usda.gov>  
To: Stephen Case <stevec@hawaii.edu>

Fri, Feb 9, 2018 at 12:34 PM

Hey Steve, please be sure to fill out all the fields in the sect 1A-1B.

Thanks,

Aimee

-----  
From: [REDACTED]  
Sent: Friday, February 09, 2018 11:15 AM  
To: 'Stephen Case' <stevec@hawaii.edu>  
Cc: '[REDACTED] cdc.gov'; 'Anne Alvarez' <alvarez@hawaii.edu>  
Subject: APHIS-CDC\_Form\_1\_Section\_1A\_1B\_New\_UH (002).pdf

Hi Steve, can you please resubmit the Form 1 section 1A-1B with Asoka's correct email address.

Thanks,

[REDACTED]

[Quoted text hidden]

 **APHIS-CDC\_Form\_1\_Section\_1A\_1B\_New\_UH (002).pdf**  
758K

-----  
Stephen Case <stevec@hawaii.edu>

To: [REDACTED]@aphis.usda.gov>

Fri, Feb 9, 2018 at 3:00 PM

Hi [REDACTED]

Attached find the updated **FORM 1 Section 1A1B** with all fields filled in that I have information on. Can't fill in **Entity Application Number, Current Registration Number** or **RO's DOJ #**. Otherwise everything should be good. I forgot how much fun it was to fill out these forms.

Mahalo,  
Steve

[Quoted text hidden]

[Quoted text hidden]

 APHIS-CDC\_Form\_1\_Section\_1A\_1B\_New\_UH.pdf  
763K

Stephen Case <stevec@hawaii.edu>

Fri, Feb 9, 2018 at 3:31 PM

To: "[REDACTED]" <[REDACTED]@aphis.usda.gov>

Hi again [REDACTED]

Just when I thought I had everything Jinzeng Yang called me with his DOJ # JY-070881. I've added it to the **FORM 1 - Sect. 1A1B** which is attached (third time's the charm).

He's getting his fingerprints done today and I will send those in along with his FD961 to FBI/BRAG, probably on Monday or Tuesday next week to get his SRA started.

Hopefully this should be it for these Sections (1A and 1B). Let me know if you need any corrections or additions to other sections as we move forward.

Mahalo,  
Steve

[Quoted text hidden]

 APHIS-CDC\_Form\_1\_Section\_1A\_1B\_New\_UH.pdf  
763K



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Stephen Case <stevec@hawaii.edu>

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## Transfers

8 messages

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[REDACTED]@cdc.gov  
To: Stephen Case <stevec@hawaii.edu>

Fri, Feb 16, 2018 at 6:55 AM

Hi Steve,

I see all the transfers have been approved. Can you please update me on when these were or will be shipped?

Thanks

[REDACTED]

[REDACTED]

Microbiologist

Division of Select Agents and Toxins

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Tel: (404) [REDACTED]

---

Stephen Case <stevec@hawaii.edu>

Fri, Feb 16, 2018 at 10:02 AM

To: "[REDACTED]@cdc.gov"

Cc: Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>

Hi [REDACTED],

All approved Form 2s received and we are prepping to ship. We are having some issues accessing local couriers, will go into more detail when I finish giving training this a.m. However, one way or another all deadlines will be met and all agents will be gone and room deconed by your visit Feb. 26th.

Steve

[Quoted text hidden]

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Stephen Case, MSPH, RBP

Biosafety Professional

Educational Coordinator

Responsible Official

Animal Welfare and Biosafety Programs

Office of Research Compliance / OVPRI

2425 Campus Road, Sinclair 10

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FAX: (808) 956-9150

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[REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Fri, Feb 16, 2018 at 10:40 AM

Steve thanks for the update and I received your voicemail. I apologize for the wrong address. I'm pretty sure we aren't going to Ohio. We will get it corrected, but probably on Tuesday since it's the end of the day here, and a holiday weekend.

[Quoted text hidden]

Stephen Case <stevec@hawaii.edu>

Fri, Feb 16, 2018 at 3:23 PM

To: "[REDACTED]" <[REDACTED]@cdc.gov>

Cc: [REDACTED]@usda.gov, Victoria Rivera <riveravg@hawaii.edu>, Norman Magno <nmagno@hawaii.edu>

Aloha [REDACTED]

A little more information regarding status of our transfers.

**PI Dr. Hoang** - Have destroyed all inventory NOT being transferred, included some *B. mallai*, *B. pseudomallei* and ALL *Brucella* sp. on inventory.

Currently due to ship remainder of *B.m* and *B.p* out this coming Tuesday 2/20 with World Courier to CSU. We were to ship 2/12, then 2/14 and now it looks like a go for 2/20. I guess World Courier was having some issues with finding a bonded courier locally who could handle SAs.

**PI Dr. Douglas** - Got two approved Form 2s to ship *B. melitensis* to Texas A&M and Northern Arizona University (NAU). Then needed to amend for NAU form to be able to send *B. abortus* and *B. susi* (sera) which we now have and are prepping for shipment with USA Courier, hopefully by first of next week. *B. melitensis* also, hopefully to Texas A&M same time frame. They have been given a deadline of ALL out or destroyed by Wed. Feb. 21st.

After all is gone we are planning on VHPing the room, IF all the bubble tight dampers work to isolate the room for decon. If can't VHP for some reason will surface decon entire room. There has been NO active manipulation of ANY BIOLOGICALS in the room for almost a year and it's been deconed several times for construction/renovations and re-certification.

**PI Alvarez** - You've been in loop with [REDACTED] regarding her AgSAS application for her agents and things seem to be progressing well.

Will keep you updated as things progress and if you should have any further questions let me know.

Also, noticed on the NOI, besides the wrong address, it was for the entire week rather than just the 3 days as mentioned during our phone conference. Just wondering in order to secure rooms for your staffs stuff as needed. With six member on the team, are you planning on splitting up and some do JBF and some Ag side and conduct inspections simultaneously?

Mahalo,  
Steve

[Quoted text hidden]

Stephen Case <stevec@hawaii.edu>

Fri, Feb 16, 2018 at 3:29 PM

To: A [REDACTED]@aphis.usda.gov>

Hi [REDACTED]

When first putting you email address in my contacts I misspelled your first name as [REDACTED], and if I'm not careful when I select I choose the wrong one and it get kicked back ..... which happened here. Hence the Foreward. Anyway, have

now deleted wrong contact address so shouldn't happen again.

Steve

[Quoted text hidden]

---

From: [REDACTED] <[REDACTED]@aphis.usda.gov>  
To: Stephen Case <stevec@hawaii.edu>

Mon, Feb 19, 2018 at 12:43 PM

Hi Steve, the CDC will be there Mon- Friday. The AgSAS team will be there Mon- Thursday.

Sorry for the confusion.

[REDACTED]

[Quoted text hidden]

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From: [REDACTED] <[REDACTED]@cdc.gov>  
To: Stephen Case <stevec@hawaii.edu>

Tue, Feb 20, 2018 at 9:37 AM

Hi Steve,

We re-issued the NOI, sorry again for the incorrect information. We scheduled the whole week to give some "just in case" flexibility. Ideally the inspection will be Monday-Wednesday. Thursday-Friday will be any extra PPQ items on Aimee's side- if needed.

I'm waiting to talk to her about more definitive plans, so I will email you as soon as I can.

Let me know how those transfers are coming along

Thanks

[REDACTED]

[REDACTED]

Microbiologist

Division of Select Agents and Toxins

3/12/2020

University of Hawaii Mail - Transfers

Office of Public Health Preparedness and Response

Centers for Disease Control and Prevention

1600 Clifton Road, NE MS A-46

Atlanta, GA 30329

Te [REDACTED]

*DSAT Vision: To be the preeminent resource for the safety and security of biological agents and toxins*

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[Quoted text hidden]

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**Stephen Case** <stevec@hawaii.edu>

To: Norman Magno <nmagno@hawaii.edu>, Victoria Rivera <riveravg@hawaii.edu>

Tue, Feb 20, 2018 at 12:44 PM

FYI... Steve

[Quoted text hidden]