



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

January 28, 2022

Re: Animal Welfare Assurance
A3638-01 [OLAW Case C]

Dr. Marcia Baroni
Senior Director
Emergent BioDefense Operations Lansing
3500 North Martin Luther King Boulevard
Lansing, MI 48906

Dear Ms. Baroni,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 20, 2022 letter reporting an adverse event involving guinea pigs at Emergent BioSolutions, following up on an initial report on January 14, 2022. According to the information provided, OLAW understands that a malfunction in a fire suppression system resulted in release of a suppression chemical into a guinea pig housing room. Although no animals were harmed and the chemical was quickly removed by the air handling system, the incident introduced a significant variable to the anthrax vaccine study in progress. The animals had access to food/water and were briefly exposed to a minor drop in temperature.

The corrective actions consisted of euthanizing the 159 impacted guinea pigs due to the failure of the study. The room was thoroughly disinfected and checked for anthrax spores. The fire suppression system was examined and a faulty actuator was identified as a cause of the failure and was replaced. Additional tests will be performed by the vendor on the system and may require additional preventive measures.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair
Robert Gibbens, D.V.M., USDA-APHIS-AC

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A 3638 - C

EMERGENT

MEMO

Emergent BioSolutions

To: **Dr Axel Wolff**
Office of laboratory Animal Welfare
From: F. Claire Hankerson, DVM, MS
Marcia Baroni, BS, MBA
CC:
Date: 20 January 2022
Re: Report of FM200 failure in (b) (4)

Dear Dr. Wolff,

On 06JAN22 at 2:04pm, the fire suppression mechanism for the biocontainment area in (b) (4) (b) (4) was undergoing scheduled maintenance and discharged unexpectedly, leading to a release of suppression chemical into the housing room. The chemical was rapidly removed by the air handling system yet introduced a significant variable that required the animals in the room to be removed from the vaccine test. No animals were injured, and food and water remained accessible throughout the occurrence. Review of room parameters indicated that temperature and humidity values dropped briefly to 64°F (allowable range 68-79°F) and 33% (allowable range 30-70%) respectively, during the incident. These values for temperature returned to allowable range (per Guide for the Care and Use of Animals) within 10 minutes as the building HVAC responded after the (b) (4) release.

Due to the time of the suppression release, guinea pigs were not able to be assessed for a second check of husbandry on 06JAN22. The Attending Veterinarian verified that the animals could be left with their remaining food and water until such time on 07JAN22 that the animals could be accessed.

On 07JAN22, the facility was thoroughly disinfected (via a 3X cleaning, using diluted SporKlenz RTU with a 30-min wet contact time per site procedures). Environmental Monitoring (EM) was conducted before and after the three cleanings and no B. anthracis was detected by the pre-disinfection and post-disinfection environmental monitoring. Animals were then able to be assessed by Laboratory Resources staff: all animals had remaining food and water, with no evidence of disruption to the cage environments. The remaining test animals (n=159) were humanely euthanized utilizing the Euthanex system by 6:00pm.

At conclusion of the internal investigation, it was confirmed that the actuator on the fire suppression chemical tank was the definitive root cause, as it was found in the engaged position accompanied with a full tank discharge. Failure analysis will be conducted on the suspected faulty actuator by a certified vendor to characterize the cause of failure. These findings may warrant a supplemental

corrective action dependent on the failure tests. The immediate corrective action to replace the faulty actuator and recharge of the depleted (b) (4) tank will be executed under work order 4234915. Details and conclusions of the full investigation report, root cause analysis, corrective and preventative actions will be documented in quality system as deviation DEV-002746 within Emergent.

(b) (6)

F. Claire Hankenson, DVM, MS, DACLAM
Attending Veterinarian, Emergent BioSolutions

(b) (6)

Marcia Baroni, BS, MBA (IO)
Interim Head of Global Quality

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, January 21, 2022 1:15 PM
To: Hankenson, F. Claire
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW report

Follow Up Flag: Follow up
Flag Status: Flagged

Thank you, Dr. Hankenson. This looks good and we will send an official response shortly.
Axel Wolff

From: Hankenson, F. Claire <fclaire@upenn.edu>
Sent: Friday, January 21, 2022 10:59 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Baroni, Marcia <baronim@ebsi.com>; (b) (6)
Subject: [EXTERNAL] RE: OLAW report

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Wolff,
Here is the final report, we needed to await an assessment of the fire suppression system to include this information for you. Please let me know if you need anything further, thank you.
Claire

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Wednesday, January 19, 2022 7:14 AM
To: Hankenson, F. Claire <fclaire@upenn.edu>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: OLAW report

Thank you for this preliminary report, Dr. Hankenson. I will start a new case file and am requesting an official final report signed by the IO, on company letterhead. The description of what happened is fine but is there anything that can be added regarding preventive measures with the fire suppression system?

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Hankenson, F. Claire <fclaire@upenn.edu>
Sent: Friday, January 14, 2022 10:58 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Baroni, Marcia <baronim@ebsi.com>; (b) (6)
Subject: [EXTERNAL] OLAW report

Dear Dr. Wolff,

I am writing to inform you of a recent adverse animal event in our facility, for which I serve as the Attending Veterinarian. I am including our IO and our Manager of Lab Resources as well on this message.

- Name of institution
 - Emergent BioSolutions
- Assurance number
 - A3638-01
- Funding component
 - Not grant funded
- Brief description of incident
 - Our program is responsible for performing relative potency testing of our anthrax vaccine, Biothrax. Our institution experienced an adverse facility event related to a malfunction of the (b) (4) fire suppression system within the (b) (4) facility in which anthrax-challenged guinea pigs are housed. On 1/6/22 at 2:04pm, the fire suppression mechanism was undergoing scheduled maintenance and discharged unexpectedly, leading to a release of suppression chemical into the housing room. The chemical was rapidly removed by the air handling system yet introduced a significant variable that led to immediately ending the test phase. Importantly, no animals were injured, and food and water remained accessible throughout the occurrence; however, once the vaccine test was invalidated, the decision was made to euthanize the remaining animals. This has also been reported to our USDA veterinary medical officer.

Please let us know if you would like further information on this matter, thank you.

Claire

F. Claire Hankenson, DVM, MS, DACLAM

Attending Veterinarian, Emergent BioSolutions