



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

January 29, 2021

Re: Animal Welfare Assurance  
A3034-01 [OLAW Case W]

Dr. Michael R. Kuhlman  
Institutional Official  
Battelle Memorial Institute - Richland  
550 King Avenue  
Columbus, OH 43201

Dear Dr. Kuhlman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 25, 2021 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Battelle, following up on an initial report on January 12, 2021. According to the information provided, OLAW understands that six mice on a training protocol died due to lack of food. Specifically, food had not been placed correctly into the feeders on this type of rack and the mice could not access it.

The corrective actions consisted of counseling and retraining the technician responsible, developing a rodent care and husbandry checklist which is posted in the animal rooms, and revising the standard operating procedure on providing food in these types of racks.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to 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.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair



January 25, 2021

Axel Wolff, MS, DVM  
Deputy Director  
Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892

Dear Dr. Wolff:

Battelle, in accordance with Assurance D16-00021 (A3034-01) and PHS Policy, provides this report of noncompliance regarding an adverse event with training mice. This incident was first reported on January 12, 2021 via email to OLAW's Division of Compliance Oversight.

This document is our Final Report relative to this incident which we identified as a deviation from the provisions of the *Guide*. This situation was not related to a PHS-funded activity.

The reportable event involved training mice. Six mice on a training protocol were found dead. It was determined that feed was not provisioned correctly by the animal technician and the mice could not access the feed that had been provided. The caging/rack in use was for training in the whole body chamber exposure system. These "cage racks" have feed troughs, and depending on the specific unit size, either drop-in feeders or placing feed in the troughs without a feeder is performed. Each feeder is a slotted, narrow, long, metal feeder designed to feed multiple animals in a row. Feed troughs are depressed spaces in a cage where the feeder will be placed, or, depending on the cage unit size, feed placed in the troughs directly.

The following corrective and preventive actions were implemented after the incident:

- Staff retraining was performed on 12/4/20 for the involved technician. The Attending Veterinarian met with the involved staff member on 12/30/20 to discuss the incident, initial and additional training, the importance of husbandry duties, and the reporting process.
- The IACUC full committee review occurred on December 21, 2020. The IACUC determined that this was an isolated incident and not a programmatic failure. The corrective and preventive actions were reviewed and accepted by the IACUC.
- On 1/11/21, a group including veterinarians, management and technical staff met to discuss additional preventive measures. A rodent care and husbandry checklist was developed and posted in the applicable rooms on 1/14/21. This checklist is for use by trainers and senior staff members who are assessing the performance of trainees.

- Standard Operating Procedure (SOP) ARF2-053 "Daily Animal Care for Whole-Body Inhalation Studies" and the "Whole Body Inhalation (WBI) Husbandry Skill Sheet" were revised to add additional detail on which cage units require feeders and which have feed added directly to the feed trough. These documents were finalized and posted on 1/20/21.

If you have any questions regarding this report, please let me know.

Respectfully,

(b) (6)

*Michael R. Kuhlman, Ph.D.*

Institutional Official

Battelle

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(c)

kuhlmanm@battelle.org

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, January 27, 2021 7:00 AM  
**To:** Kuhlman, Michael R (US)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reportable event Final Report

Thank you for this report, Dr. Kuhlman. We will send a response soon.

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

-----Original Message-----

**From:** Kuhlman, Michael R (US) <KUHLMANM@battelle.org>  
**Sent:** Monday, January 25, 2021 11:34 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** Reportable event Final Report

Dear Division of Compliance Oversight:

Attached is our Final Report for the reportable incident for which we submitted the preliminary report on January 12. Please feel free to contact me with any questions.

Respectfully,

Michael R. Kuhlman, Ph.D.  
Institutional Official  
Office: (b) (6) | Mobile: (b) (6) | Fax: (b) (6)  
kuhlmanm@battelle.org<mailto:kuhlmanm@battelle.org>

Battelle  
505 King Ave.  
Columbus, OH 43201  
<http://www.battelle.org><<http://www.battelle.org/>>

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, January 13, 2021 7:14 AM  
**To:** Kuhlman, Michael R (US)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reportable event Preliminary Report

Thank you for this preliminary report, Dr. Kuhlman. We will start a new case file.

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

-----Original Message-----

**From:** Kuhlman, Michael R (US) <KUHLMANM@battelle.org>  
**Sent:** Tuesday, January 12, 2021 12:16 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Reportable event Preliminary Report

Dear Division of Compliance Oversight:

A situation recently occurred at Battelle which the IACUC deemed reportable. Immediate corrective actions were put in place, the details of which are provided below.

Animal Welfare Assurance number: D16-00021 (A3034-01)

Funding component and if contacted: Not applicable

**Description of the incident:** Six mice on a training protocol were found dead. It was determined that feed was not provisioned correctly by the animal technician and the mice could not access the feed that had been provided. The caging/rack in use was for training in the whole body chamber exposure system. These "cage racks" have feed troughs, and depending on the specific unit size, either drop-in feeders or placing feed in the troughs without a feeder is performed. Each feeder is a slotted, narrow, long, metal feeder designed to feed multiple animals in a row. Feed troughs are depressed spaces in a cage where the feeder will be placed, or, depending on the cage unit size, feed placed in the troughs directly.

**Description of actions taken:** On 12/4/20, the staff member was retrained and sign off as being able to perform this task independently was delayed. An IACUC full committee review was held on 12/21/20 at which time it was determined that external reporting was required. The Attending Veterinarian met with the involved staff member on 12/30/20 to discuss the incident, initial and additional training, the importance of husbandry duties, and the reporting process.

Description of corrective plans include: Standard Operating Procedure (SOP) ARF2-053 "Daily Animal Care for Whole-Body Inhalation Studies" and the "Whole Body Inhalation (WBI) Husbandry Skill Sheet" were revised to add additional detail on which cage units require feeders and which have feed added directly to the feed trough. These documents are in final review as of 1/12/21.

A signed copy of the final report will be provided no later than 1/26/21.

Please contact me if you require additional information.

V/r,

Michael R. Kuhlman, Ph.D.

Institutional Official

Office: (b) (6) Mobile: (b) (6) Fax: (b) (6)  
kuhlmanm@battelle.org<mailto:kuhlmanm@battelle.org>

Battelle

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Columbus, OH 43201

<http://www.battelle.org><<http://www.battelle.org/>>