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

April 23, 2021

Re: Animal Welfare Assurance
A4051-01 [OLAW Case 1A]
Reference Case 1B

Dr. Wayne E. Cascio
Deputy Director, National Health and
Environment Effects Research Laboratory
U.S. Environmental Protection Agency
EPA-MD-B305-01, 109 T.W. Alexander Drive
Research Triangle Park, NC 27709

Dear Dr. Cascio,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 15, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the US Environmental Protection Agency, following up on an initial telephone report on April 12, 2021. According to the information provided, OLAW understands that a soiled rack was taken to cage wash with one cage containing a live rat. The incident was attributed to an animal caretaker who had been involved in previous noncompliance.

The immediate action taken upon discovery by the cagewash personnel was to have the rat euthanized due to biosecurity concerns. Tissue from the animal was used for the sentinel pathogen program. The contract animal caretaker responsible was terminated and all aspects of performance under this contract will be evaluated.

Based on its assessment of this explanation, OLAW understands that measures are underway to prevent recurrence of this problem. We note that OLAW was subsequently notified that a similar issue occurred again and that this will be included in the current contract review, with another final report to be filed with this Office. OLAW concurs with the actions being taken by the institution to comply with the PHS Policy and we await the next report. Thank you for keeping OLAW apprised on this matter.

Sincerely,

Axel Wolff, MS, DVM

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

A4051-1A

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
CENTER FOR PUBLIC HEALTH AND ENVIRONMENTAL ASSESSMENT
Research Triangle Park, NC 27711

OFFICE OF
RESEARCH AND DEVELOPMENT

April 15, 2021

Axel Wolff, M.S., D.V.M
Deputy Director
Office of Laboratory Animal Welfare
National Institutes of Health

Dear Dr. Wolff;

The purpose of this letter is to report an adverse event at the US EPA Research Triangle Park research program (Assurance # D16-00569, A4051-01) and to report on the measures taken by the program to ensure that such an event will not be repeated. A preliminary report of this event was originally called in to you at OLAW by the IACUC Chair on Monday, April 12, 2021.

Routine cage changes were performed on pair-housed rats used in an investigator training protocol by an animal care contractor staff member on the morning of April 12. In this process rats are transferred from used, soiled bedding and cages on one rack to a new rack with clean cages containing new bedding and enrichment, and the cage card and its holder are transferred with the rats. However, on this occasion one pair of rats was separated: one rat and its cage card were moved to a clean cage on its new rack, but the other adult female rat was left behind in the dirty cage along with other empty dirty cages on its rack, and the entire rack with one rat was rolled to the cage wash room on a different floor of the animal facility. The rat was discovered in her home cage prior to dumping the bedding and retained in that cage. The rat could not be returned to the colony because it had travelled from a clean holding room to a locale outside the clean area (the cage wash area), and consequently she was humanely euthanized. Some of the rat's tissues were utilized for the sentinel pathogen program. The loss of this female rat from the training program is significant since it was one of the training colony's long-term socialized rats used to build confidence and competence in new handlers.

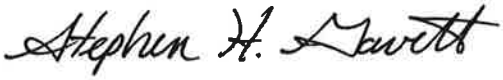
Following investigation into the incident, the contractor providing animal care to the US EPA RTP animal care and use program elected to dismiss the individual responsible for sending the rat down to the cage wash. Further discussion with the Facility Manager indicates that this was not the first problem with this long-time animal care staff member but rather one in a series of recent events. As prior corrective measures had not been effective, the dismissal was agreed upon by both the prime contractor and the subcontractor who has employed this individual over the last 30 years. As federal employees of the US EPA, we are not allowed to influence personnel issues on the contract, nor were we privy to corrective actions that may have been taken prior to this final incident with this contract employee.

The US EPA Contracting Officer (CO) who has oversight for the contract has requested an in-depth review of all parts of this contract's performance, inclusive of terrestrial animal care, aquatic animal care, veterinary care, facility maintenance, and provisioning of the facility. The US EPA Animal Resources Program Office will be working on this review over the next several days and will be consulting with the CO following its completion to ensure that the quality of animal care meets contractual requirements.

We hope these measures satisfactorily address the issues raised by this incident. Please contact Steve Gavett (919-541-2555, Gavett.steve@epa.gov) or Jaimie Graff (919-541-0690, Graff.jaimie@epa.gov), Animal Resources Program Office, if you have further questions.

Sincerely,

Wayne E. Cascio, M.D.
Director, CPHEA
Institutional Official



Stephen H. Gavett, Ph.D., D.A.B.T.
CPHEA / PHITD / CIB
IACUC Chair

Walker, Keri (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, April 19, 2021 8:21 AM
To: Graff, Jaimie
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: final report adverse event RTP program Assurance # D16-00569, A4051-01

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

Keri

Keri Walker
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Dr., Suite 2500
Bethesda, MD 20892
301-435-2390
keri.walker@nih.gov

From: Graff, Jaimie <Graff.Jaimie@epa.gov>
Sent: Friday, April 16, 2021 11:44 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Gavett, Stephen <Gavett.Stephen@epa.gov>; Cascio, Wayne <Cascio.Wayne@epa.gov>
Subject: final report adverse event RTP program Assurance # D16-00569, A4051-01

Dear Dr. Wolff:

The purpose of this letter is to report an adverse event at the US EPA Research Triangle Park research program (Assurance # D16-00569, A4051-01) and to report on the measures taken by the program to ensure that such an event will not be repeated. A preliminary report of this event was originally called in to you at OLAW by the IACUC Chair on Monday, April 12, 2021. I am sending you this report on behalf of our institution while our IACUC Chair is on leave.

The attached final report from our Institutional Official Dr. Wayne Cascio provides the details of the incident and the corrective actions which are being implemented.

Please let us know if you need any further information. We look forward to your response.

Sincerely,

Jaimie Graff

Jaimie Graff, MA, CPIA | Director, Animal Resources Program Office | US EPA/ORM/RSCD/FRCB | Phone: 919-541-0690 | Cell: 984-484-0332

A4051-1A

Office of Laboratory Animal Welfare

OLAW

Initial Report of Noncompliance

By: aw

Date: 4/12/21

Time: 12:30

Name of Person reporting: Steve Gravett
Telephone #: 919-541-2555
Fax #:
Email:

Name of Institution: EPA
Assurance number: A4051

Did incident involve PHS funded activity? _____
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?
Rat left in cage after changing + sent to cage wash, staff found it but still euthanized after leaving vivarium.
Species involved: Rat
Personnel involved:
Dates and times:
Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____
Will use carcass for sentinel purposes.
Counsel caretakers

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____