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

July 21, 2021

Re: Animal Welfare Assurance
A4051-01 [OLAW Case 1C]

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 July 19, 2021 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the US Environmental Protection Agency, following up on an initial report on June 29, 2021. According to the information provided, OLAW understands that 317 zebrafish died due to improper water quality parameters, specifically pH and conductivity. The sodium bicarbonate and salt dosing tanks were found empty and a failure of the Timed Water Exchange (TWE) unit is considered to be a probable cause.

The immediate action taken upon discovery consisted of moving the surviving juvenile fish to a different tank with normal water quality. The corrective actions consisted of taking the old housing unit out of service, ordering new fish racks which will have email/text alarm notification capability for specific water parameters, performing preventive maintenance on the TWE solenoids, and having the vendor perform preventive maintenance on all fish housing systems.

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 comprehensive actions being taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

Axel Wolff, MS, DVM

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

cc: IACUC Chair

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

OFFICE OF
RESEARCH AND DEVELOPMENT

July 19, 2021

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

Dear Dr. Wolff:

We are writing to report final resolution of an adverse animal welfare incident at the US EPA Research Triangle Park (RTP) research program (Assurance # D16-00569, A4051-01), including measures taken by the program to ensure that such events will not be repeated. A preliminary report of this event was originally emailed to OLAW by the IACUC Chair on June 29, 2021.

On Saturday morning 6/26/2021, animal care staff found that on a rack of tanks containing adult and juvenile zebrafish, all 150 adults were dead, and 160 out of 200 juvenile fish were dead. The surviving 40 juveniles were immediately transferred to another rack with normal water quality parameters, but 7 of those were found dead the next morning (6/27/2021). Total mortality for this incident was 317 zebrafish (150 adults and 167 juveniles). The surviving juvenile zebrafish now appear to be in normal health. On the original rack of tanks, pH and conductivity were outside of acceptable ranges on 6/26/2021, while temperature was normal. The sodium bicarbonate dosing tank (used to buffer rack water pH) and salt dosing tanks (used to adjust conductivity) were both depleted. Several possibilities of equipment failure have been considered. The most likely explanation is a failure of the Timed Water Exchange (TWE) unit on the rack in question. Failure of the TWE could have allowed constant influx of reverse osmosis water, causing the bicarbonate and salt dosing tanks to be depleted.
The following corrective actions have been taken:

- This older housing unit has had two serious mechanical failures and has now been taken out of service permanently.
- Our Animal Resource Program Office has begun the purchase of new replacement fish racks; the replacement for this rack has been approved and funded and is waiting with the contracts department for purchase pending IT security approvals. The new system will have email/text alarm notifications for pH and conductivity among other water parameters.
- The solenoids on other TWE units are being prophylactically serviced and monitored. A small amount of debris has been observed to accumulate in some solenoids; due to this observation routine service of these solenoids has been increased on the aquatics facility preventative maintenance schedule.

- A vendor preventative maintenance service visit for all fish housing systems from this manufacturer is taking place 7/20-21/21.
    - Vendor preventative maintenance service for other manufacturer fish housing systems is scheduled for November as usual.

We hope these measures satisfactorily address the issues raised by this incident. Please contact Stephen Gavett ([redacted] (b) (6) Gavett.stephen@epa.gov) or Jaimie Graff ([redacted] (b) (6) 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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, July 21, 2021 7:35 AM
To: Graff, Jaimie
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of noncompliance Assurance # D16-00569

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

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

From: Graff, Jaimie <Graff.Jaimie@epa.gov>
Sent: Tuesday, July 20, 2021 1:46 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Report of noncompliance Assurance # D16-00569

Good afternoon;
Attached please find a final report of noncompliance for US EPA's ORD RTP animal care and use program, Assurance D16-00569, following an initial email report on June 29,2021.
Please call or email me if you have any questions.
Thank you;
Jaimie

Jaimie Graff, MA, CPIA | Director, Animal Resources Program Office | US EPA/ORM/RSCD/FRCB | Phone: (b) (6) | Cell: (b) (6)

A4051-10

Walker, Keri (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 30, 2021 8:19 AM
To: Gavett, Stephen
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary notice of animal welfare issue

Good morning,

Thank you for this preliminary report. We will open a new case and await a final report.

Best,
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: Gavett, Stephen <Gavett.Stephen@epa.gov>
Sent: Tuesday, June 29, 2021 3:59 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Cascio, Wayne <Cascio.Wayne@epa.gov>; Graff, Jaimie <Graff.Jaimie@epa.gov>; Jarrell, Leslie <Jarrell.Leslie@epa.gov>; [redacted]
Subject: Preliminary notice of animal welfare issue

To the Division of Compliance Oversight:

As chair of our IACUC, I am writing to provide preliminary notice of an adverse event impacting animal welfare which occurred on Saturday June 26, 2021, at our institution (US EPA, Office of Research and Development, Research Triangle Park, NC; OLAW Assurance number D16-00569, A4051-01). Our attending veterinarian Dr. Leslie Jarrell left messages at the OLAW reporting phone number on this incident yesterday but has not yet received any reply.

On Saturday morning 6/26/2021, animal care staff found that in a rack of tanks containing adult and juvenile zebrafish, all 150 adults were dead, and 160 out of 200 juvenile fish were dead. The surviving 40 juveniles were immediately transferred to another rack with normal water quality parameters, but 7 of those were found dead the next morning (6/27/2021). Total mortality for this incident was 317 zebrafish (150 adults and 167 juveniles). The surviving juvenile zebrafish now appear to be in normal health. In the original rack of tanks, pH and conductivity were outside of acceptable ranges on 6/26/2021, while temperature was normal. The sodium bicarbonate dosing tank (used to buffer rack water pH) and salt dosing tanks (used to adjust conductivity) were both depleted. Several possibilities of equipment failure have been considered. At this time the most likely explanation may be a failure of the Timed Water Exchange (TWE) unit on the rack in question. Failure of the TWE may have allowed constant influx of reverse osmosis water, causing the bicarbonate and salt dosing tanks to be depleted. This older housing unit has had several mechanical failures and has now been taken out of service permanently. Our Animal Resource Program Office will begin purchasing new replacement fish racks starting in the new fiscal year. Systems with notification alarms for pH and conductivity will be purchased. We will seek to expedite the first purchase following this rack's failure.

A final report from our Institutional Official will provide more incident details and corrective actions, and will be delivered to OLAW when the necessary facts are established.

Please let me know if you need further information.

Sincerely,

Stephen Gavett, Ph.D., D.A.B.T.
Chair, EPA Health Institutional Animal Care and Use Committee

Research Biologist
Cardiopulmonary and Immunotoxicology Branch
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Mailing Address:
U.S. Environmenal Protection Agency
Attn: Stephen Gavett
Mail Code: B105-02
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