



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

August 23, 2021

Re: Animal Welfare Assurance
A3205-01 [OLAW Case N]

Ms. Sheila Garrity
Executive Director
Research Integrity and Compliance
George Washington University
2121 Eye Street, N.W., (b) (4)
Washington, DC 20052

Dear Ms. Garrity,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 18, 2021 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at George Washington University, following up on an initial telephone report on March 8, 2021. According to the information provided, OLAW understands that 35 zebrafish required euthanasia after being exposed to cold water temperature following a power outage. The outage caused a failure in the reverse osmosis system which stopped water circulation, caused a drop in water temperature, and led to cold shock in the fish. The Office of Animal Research (OAR) failed to notify the laboratory of the outage and did not have adequate training to monitor the system properly. There was also no communication between OAR and the physical plant staff regarding the incident.

The action taken upon discovery consisted of transferring the fish to another tank with heaters and slowly warming the surviving fish. The corrective actions consisted of improving communication between OAR and physical plant staff, updating the emergency response plan to include contact information for laboratory staff in satellite facilities or those using special equipment, having the laboratory staff take over complete responsibility for the fish facility, having air temperature in the fish room monitored by an alarmed system which can notify staff of temperature drops, and taking the former holding room out of commission for animal housing. Fish water temperature is monitored by staff checking thermometers twice daily.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and reduce the likelihood of a 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 and recommends evaluating use of alarmed water temperature sensors which are able to notify staff when temperatures are outside of acceptable parameters. 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

August 18, 2021

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Wolff:

The George Washington University (GW), in accordance with Assurance D16-00128 (formerly A3205-01) and the Public Health Service (PHS) Policy IV.F.3., provides this report of non-compliance regarding an incident involving a power outage that resulted in a decrease in water temperature in a flow-through aquatic system and the subsequent euthanasia of 35 zebrafish.

The animals affected in this incident were not associated with any PHS-funded activities.

On February 16th, 2021, two buildings on the GW campus experienced an unexpected power outage from approximately 11:15-11:45am. Most of the animal use areas within these buildings are managed directly by the Office of Animal Research (OAR), however, some are managed directly by the Principal Investigators (PIs) and their staff. Immediately following the outage, the Animal Care Technicians (ACTs) were dispatched to all of the animal use areas managed by the OAR to ensure that all electrical equipment was running properly. No issues were noted at this time.

One area maintained by a PI contained a flow-through aquatic system for a breeding colony of zebrafish. Since the start of the pandemic in March 2020, the OAR assumed responsibility of performing daily health observations and feeding of the fish in this area, due to limited access to campus for students and laboratory staff as per GW COVID-19 guidelines. However, the OAR staff were unfamiliar with the specifics of the system, including general maintenance, and alarms.

On February 19th, 2021, at 7:30am, an ACT reported an abnormal noise originating from the water pump at the base of the aquatic rack and contacted the lab member responsible for maintaining the system. The lab member told the ACT to unplug the pump immediately, and noted that he would come to campus in the afternoon to check the system. When the lab member arrived at 4:00pm, he noted that the reverse osmosis (RO) system had malfunctioned, causing failure of the pump to circulate water through the tanks. It was determined that the power outage on February 16th, 2021, had caused the malfunction in the RO system. Without the flow of water, the system could not maintain the water temperature within the tanks. The lab member noted the temperature in the

tanks was 22.1°C (71.78°F), and the fish were displaying symptoms of cold-shock and stress (i.e. redness of the skin, slow swimming). The lab member immediately notified the veterinary staff from the OAR and asked for assistance in transferring the entire colony of 105 zebrafish to an alternate IACUC approved location with static tanks. The fish were safely and securely transported to another aquatic suite by 5:00pm. The fish were placed in static tanks with heaters, and the temperature was raised at a slow, controlled rate overnight. The laboratory staff also monitored the fish every few hours throughout the night and the following day.

On February 20th, 2021, 35 of the zebrafish had not recovered from the cold-shock and were humanely euthanized in accordance with the 2020 AVMA Euthanasia Guidelines.

The IACUC performed an initial investigation of this incident to identify the issues resulting in the adverse event. The issues were identified as follows:

- A recent change in personnel within the Facilities department resulted in the lack of communication between the OAR and physical plant regarding significant events (i.e. power outages) that may affect the research animals.
- The OAR did not notify the PI or lab member responsible for the zebrafish of the power outage. Due to the pandemic, most laboratory staff were working remotely, and were therefore unaware of the outage.
- OAR did not have adequate training to monitor the system properly. Following the incident, the lab indicated that the aquatic system has features that display the reservoir water level, and visual alarms indicating low tank temperature. The OAR staff were unaware of these indicators and alarms.
- The thermostat in the holding room was set to 26.7°C (80°F), but the air temperature of the room ranged from 23.3-24.4°C (74-76°F) during the week of the incident. Air temperatures are monitored via a virtual system to allow continuous monitoring of the temperature. Alarms were in place to notify the OAR Director of fluctuations outside of the 20-26.7°C (68-80°F).

The following corrective action plan has been implemented:

1. The OAR Director has met with the representatives from physical plant to stress the need for strong communication regarding planned (and unplanned) power outages, HVAC failures, etc.
2. The Emergency Preparedness and Response Plan has been updated to include the contact information of PIs and/or lab members responsible for all satellite housing locations, and animal use areas with special equipment within the core facility. These individuals will be contacted by OAR management immediately following power outages or other similar emergencies, to notify them of the situation and ensure that their equipment is functioning properly, and the animals are safe and healthy.

3. Since the fish have been relocated, the lab has taken sole responsibility of the care of the animals.
4. The air temperature within the new holding room is monitored via a virtual system to allow continuous monitoring of the temperature. An alarm is in place to notify the lab contact if the temperature drops below 24°C (75.2°F). The water temperature within the tanks is measured via individual thermometers. The water temperatures are checked and documented twice a day by the laboratory staff.
5. The old holding room is no longer being used as a housing location for vertebrate species.

The George Washington University is committed to protecting the welfare of animals used in research, as well as the individuals that work directly with these animals, and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact (b) (6) for the IACUC, at iacuc@gwu.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Sheila Garrity, JD, MPH, MBA
Institutional Official
Associate Vice President for Research Integrity
The George Washington University

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 20, 2021 7:11 AM
To: IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00128 GWU - Adverse Event

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

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

From: IACUC <iacuc@email.gwu.edu>
Sent: Wednesday, August 18, 2021 1:05 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Walker, Keri (NIH/OD) [E] <keri.walker@nih.gov>
Cc: Sheila Garrity <srgarrity@email.gwu.edu>; (b) (6)
Subject: D16-00128 GWU - Adverse Event

Dear Dr. Wolff,

The George Washington University (GW), in accordance with Assurance D16-00128 (formerly A3205-01) and the Public Health Service (PHS) Policy IV.F.3., provides this report of non-compliance regarding an incident involving a power outage that resulted in a decrease in water temperature in a flow-through aquatic system and the subsequent euthanasia of 35 zebrafish.

Please acknowledge receipt of this report.

Sincerely,

(b) (6)



Initial Report of Noncompliance

By: (b) (6)

Date: 3/8/21

Time: 3:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: George Washington UAssurance number: A3205Did incident involve PHS funded activity? NO

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Power outage, R.O. water not working, water quality affected. Attempted to move fish but 35 of 100 died/euthanized.

Species involved: Fish

Personnel involved:

Dates and times:

Animal deaths: 35

Projected plan and schedule for correction/prevention (if known): _____

Re do disaster plans, better communication w/ maintenance staff, install alarms

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____