

## 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

January 26, 2022

FOR EXPRESS MAIL:

Facsimile: (301) 480-3387

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

Re: Animal Welfare Assurance A3200-01 [OLAW Case 3T]

Dr. Susan Buskirk
Vice President – Chief Accountability Officer
University of Maryland School of Medicine
620 West Lexington St. (b) (4)
Baltimore, MD 21201-1559

Dear Dr. Buskirk,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 10, 2022 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the University of Maryland- Baltimore. According to the information provided, OLAW understands that a circuit on a temperature controller for a fish tank tripped which resulted in elevated water temperature. The tripping of the circuit occurred due to someone turning on another piece of equipment. The elevated temperature combined with reduced dissolved oxygen and high fish density led to the death of six rainbow trout. The temperature alarm had been switch off and no alarm was issued. This incident constitutes the third reportable event occurring in the aquatic program in the past several months.

The corrective actions consisted of relocating the surviving fish to another working system with monitors, reducing fish density, turning on all alarms, and upgrading the monitoring equipment. Due to repeated failures in the aquatic research program, multiple steps were taken to correct and prevent additional incidents. Specifically, identifying vulnerabilities, improving facilities, improving monitoring systems and tanks, hiring new staff, reinstating the internship program which will add additional staffing, minimizing working on systems containing live animals, regularly checking all alarms and tracking changes, and closely monitoring fish densities in the tanks.

Based on its assessment of these explanations, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

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

cc: IACUC Chair





OFFICE OF ANIMAL WELFARE ASSURANCE (OAWA)

655 West Baltimore Street BRB Mezzanine Ste. M023 Baltimore, MD 21201-1509 410 706 4365

iacuc@umaryland.edu www.medschool.umaryland.edu/iacuc/

January 10, 2022

Brent C. Morse, DVM, DACLAM Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, MD 20892

RE: Final Report of Reportable Situation (ACUPAQ0921)

Dear Dr. Morse,

The University of Maryland Baltimore (UMB), in accordance with Assurance No. D16-00125 (A3200-01) and PHS Policy IV.F.3., provides this final report on a reportable situation that resulted in a condition that jeopardized the health or well-being of animals. On September 27, 2021, the IACUC was promptly notified of a physical plant incident that resulted in fish fatalities on September 26<sup>th</sup>.

On Sunday afternoon September 26th, an Aquaculture Research Center (ARC) staff member found the circuit for the temperature controller on the 6-11,12 tank system tripped with a water temperature of 19°C, as measured with an infra-red temperature sensor. The ARC staff member reset the circuit and contacted the ARC manager reporting the high temperature, the dark colored water, and suspected that there may be mortalities. The reset temperature controller started cooling the system water, but at a slow rate. The ARC Manager suggested reducing the water volume by 25% to help reduce the heat load, which was done. Upon review, the system's circulation pump, filter pressures and water level in the biofilter were all operating normally. The PI and lab were notified. The lab increased aeration in both tanks and removed a total of 6 dead rainbow trout from the system later that day.

On September 27<sup>th</sup>, following an internal investigation by the ARC Manager to determine the source of the tripped circuit, it was reported the temperature in the tank system had remained consistent since April 7<sup>th</sup>. The temperature controller was on a circuit that powered the temperature controller, a Royce Dissolve Oxygen monitor, and the Royce Oxidation Reduction Potential (ORP) monitor and the protein skimmer pump. As this was a freshwater system, the protein skimmer was not being used and was switched off. The protein skimmer pump was switched on by ARC manager to see if it operated properly and was not the source of the tripped circuit. Powering of the protein skimmer pump tripped the circuit. The circuit was reset, and the pump unplugged. When the switch was turned on, the circuit remained powered. The protein skimmer pump appeared to be the likely cause of the tripped circuit used to power the temperature controller. Review of the online data / graphs for ORP and temperature showed readings for both parameters stopped on Saturday 09/25/21 approximately 8:45AM and restarted on Sunday 09/26/21 about 12:15PM. These finding suggest that the circuit was tripped on Saturday morning, likely by someone switching on the protein skimmer pump, possibly accidently. When the ARC staff member reset the circuit on Sunday afternoon, the readings started up again.

B. Morse (OLAW) – ACUPAQ0921 Final Report 01/10/22 Page 2

When the Royce monitors are off, the readings displayed on the alarm system are -99. Such a reading should trigger an alarm text and email message to go out to all ARC staff. No alarm message was received. Upon further investigation, it was found that the temperature alarm for the 6-11, 12 system was switched off. The ARC Manager tested the temperature alarm to confirm operation. The test showed that the alarm notification text and emails worked properly. How or who turned off this temperature alarm is unknown. Any additional information gathered during the investigation would be forwarded to IACUC.

The literature reports temperature tolerances for rainbow trout as high as 24-25°C. During the loss of power, the measured temperature in the 6-11, 12 system reached 19°C, which makes it unlikely that it was the sole cause of the animal losses. Tank densities were 45 & 48 kg/m³ using average weights from June 2021. The actual tank densities were likely slightly greater than this due to increased growth since the last weighing. These densities are considered moderately high. At higher temperatures, the oxygen availability in the water would have been reduced and could have been a contributing factor in the losses. The system did not have a functional dissolved oxygen monitor. These findings suggest the rainbow trout losses were due to a combination of stresses from elevated temperatures, reduce dissolved oxygen and moderately high densities.

The ARC Manager reported pursing the following corrective actions as result of this incident:

- Relocating the rainbow trout to another system with a functional dissolve oxygen and monitoring system.
- 2. Reduce density by moving to a larger system and/or reducing animals, as research work allows.
- 3. Ensure all alarms are turned on.
- 4. Upgrade the monitoring equipment on the 6-11,12 system.

## ACTIONS TAKEN, COMMITTEE DELIBERATIONS AND OUTCOME

The IACUC Chair, Attending Veterinarian (AV) and IO were notified of this incident on September 27th. The IACUC Chair and AV noted that this incident was result of human error and the third such incident since May 2021. A meeting was scheduled with the Director, Institute of Marine and Environmental Technology (IMET), the ARC Director, ARC Manager and ARC Veterinarian on October 12th to review the last three incidents and discuss any ongoing efforts to improve monitoring that could prevent future losses. IMET / ARC Leadership reported they have reviewed the last three incidents, have identified vulnerabilities, and summarized the corrective steps taken in the last six months. IMET Leadership also highlighted planned improvements for the facility. The IACUC Chair and AV were satisfied with IMET's internal review and response to date.

The IACUC discussed this incident at its meeting on October 15<sup>th</sup>. It was noted that human error seems to be the cause of the last three incidents; there appears to be a chronic problem of alarms being turned off. The IACUC Chair and AV summarized the results of the October 12<sup>th</sup> meeting with IMET and ARC Leadership. New staff have been hired and improvements have been made to the monitoring system and tanks. The committee agreed it seems IMET has taken the appropriate steps to prevent these types of incidents from occurring in the future, however, IMET should formalize in a response the results of their review of the last three incidents, i.e., what were the vulnerabilities, what steps were taken to mitigate them (personnel, equipment, and process improvements) and any future planned enhancements. Upon receipt and IACUC review, this incident can be closed. The IACUC Letter of Determination was sent to the ARC Manager on October 18<sup>th</sup>.

On October 27th, the ARC response was submitted for IACUC review.

The IACUC reviewed ARC's report summarizing the results of their review of the last three incidents, i.e., what were the vulnerabilities, what steps were taken to mitigate them (personnel, equipment, and process

improvements) and any future planned enhancements at its meeting on November 22<sup>nd</sup>. All requested information was thoroughly and satisfactory addressed, including:

- 1. ARC is now fully staffed.
- 2. The ARC Internship Program is being reinstated. Once trained, interims will assist ARC facility staff with various tasks such as feedings, pH control, animal movements, etc.
- 3. Minimize working on systems with animals. If necessary, ensure adherence to a new SOP that dedicates staff to animal monitoring and different staff to tank repair / upgrade.
- 4. A designated staff member has been assigned to review all alarm set points at least weekly and document that setpoints were confirmed.
- Pursuing the development of 'journaling' for ARC's alarm system software to track and record the individual, date and time alarm changes are made. At present, all staff utilize the same login. Individual logins will establish accountability.
- 6. Upgrading all monitoring equipment on all systems from the Royce monitoring units to the new standard YSI monitors.
- 7. Working with investigators to improve density monitoring and density reductions, when necessary. ARC staff will ensure the lab member, the investigator and the ARC Veterinarian are notified of density concerns to ensure timely resolution.

The committee concurred it seems IMET has taken the appropriate steps to prevent these types of incidents from occurring in the future. IMET's review and response was appropriate, and this case could be closed. The AV noted that AAALACi reviewed the ARC late October and identified no concerns regarding their operations or animal care.

The UMB is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please do not hesitate to contact my office or the (b) (6)

Thank you for your consideration of this matter.

Sincerely,



Susan C. Buskirk, DM, MS, CCEP Vice President Chief Accountability Officer Institutional Official for Animal Research University of Maryland, Baltimore

SCB:ap

cc: IACUC File

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

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Wednesday, January 12, 2022 8:25 AM

To:

(b) (6)

Cc: Subject: OLAW Division of Compliance Oversight (NIH/OD) RE: UMB # D16-00125 (A3200-01): Final Report

Thank you for this report,

(b) (6) We'll send a reply soon.

Axel Wolff

From:

(b) (6)

Sent: Wednesday, January 12, 2022 8:05 AM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Buskirk, Susan <sbuskirk@umaryland.edu>;

(b) (6)

Subject: [EXTERNAL] UMB # D16-00125 (A3200-01): Final Report

Importance: High

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 OLAW Division of Compliance Oversight,

Please find attached a PDF copy of the final report signed by our Institutional Official for incident ACUPAQ0921

If you have any questions or require any additional information, please do not hesitate to contact me directly.

Sincerely,

(b) (6)