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 10, 2022

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

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 7, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Maryland- Baltimore, following up on an initial report on June 22, 2021. According to the information provided, OLAW understands that 16 trout fish died when the tank drain was inadvertently left open by a new employee and all the water emptied. The tank alarm had been turned off and the float switch was in the lowest position.

The immediate action taken upon discovery consisted of refilling the tank and attempting to revive weak fish. The corrective actions consisted of turning on the alarm and placing the float switch in the proper position. The other fish systems and alarms were checked and found to be working properly. The Institutional Animal Care and Use Committee (IACUC) was concerned about the level of training and oversight of the Aquaculture Research Center (ARC) facility staff and requested additional information. The ARC responded and provided the following information:

- New ARC staff are trained and assessed for proficiency prior to working independently.
- The ARC manager counseled all staff to remain with the system when draining and refilling tanks. The individual responsible was deemed competent to perform the procedure but was performing too many tasks at the same time.
- Efforts will be made to ensure ARC staff perform tank water exchanges correctly.
- ARC is not full staffed due to COVID restrictions and there is on unfilled slot which has been posted. The ARC internship program will be reinstated when it can be safely done.
- Alarms and float switches will now be checked regularly.

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 actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair

UNIVERSITY of MARYLAND
BALTIMORE

OFFICE OF ANIMAL WELFARE ASSURANCE (OAWA)

655 West Baltimore Street
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Baltimore, MD 21201-1509
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January 7, 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 (ACUPAQ0621)

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. This incident was first reported to OLAW Division of Compliance Oversight on June 22, 2021 by the OAWA Director.

On June 15, 2021, the IACUC was promptly notified of a physical plant incident that resulted in fish fatalities earlier that day. The aquatic tanks affected housed large rainbow trout. An Aquaculture Research Center (ARC) facility staff member was performing a water change on a tank system and left the system to attend a meeting, forgetting the system was still draining. The tanks appeared to have drained almost completely before being found by another ARC staff member who informed a part time staff member to inform the ARC Facility Manager while he started refilling the system. All ARC staff responded to the incident. The system was filled completely. Struggling fish were moved back and forth in the water to get water passing over their gills to revive them. This continued for about an hour. The action did seem to help. At the time of the report to the IACUC only two fish had died, but 12-15 other fish were in distress. Since several fish were still recovering, a report on the total loss would be provided to the IACUC in 24-48 hours. The ARC Facility Manager counseled the responsible staff member and emphasized that the animals in the ARC Facility are always the priority and their life-support systems must be confirmed to be in proper operation before leaving. The responsible ARC staff member was relatively new (2.5 months on job) and was leaving to attend the weekly ARC staff meeting.

ACTIONS TAKEN, COMMITTEE DELIBERATIONS AND OUTCOME

The IACUC Chair, *Interim* Attending Veterinarian (AV) and IO were notified of this incident on June 15th. On June 17th, ARC facility staff reported there were 16 fish fatalities as result of this incident. Upon further internal investigation, the ARC Manager also reported that the tank system was fitted with a level alarm, but the alarm was found turned off and the float switch was found at its lowest possible position. It was unclear when and who turned off the level alarm and why the float switch was in this position. The float switch was returned to the proper position, the alarm was turned back on and checked for proper operation. All ARC systems with level alarms and fish were reviewed and confirmed to be operational.

The IACUC discussed this incident at its meeting on June 21st. The committee was extremely concerned with the second ARC incident in a little over a month resulting in fish fatalities due to ARC operations. This incident was a direct result of operational errors by personnel. The committee determined that the following information must be addressed prior to further IACUC review:

- Please describe the training provided to the responsible staff member upon hiring and the level of oversight provided by ARC Managers.
  - How is it determined new personnel are technically proficient to perform duties independently?
  - What level of QA is being performed by ARC Managers to ensure personnel are performing their duties as assigned?
- Has the responsible staff member been retrained following this incident?
- Performing a water change on a system seems like a routine responsibility of ARC staff.
  - Is there an SOP for performing this task that ARC staff can access?
  - Is there a checklist available to ARC staff to ensure this task is appropriately completed? If not, should one be created?
- Given the nature of the last two incidents, what is the current staffing levels within the ARC?
  - Is the ARC understaffed? If so, please briefly discuss why, e.g., insufficient staffing, position vacancies, personnel absences, etc.
  - If understaffed, what is the proposed corrective action? Has this been discussed with IMET Leadership?
- Regarding the additional details provided on June 17th: Level alarm was turned off on this system. When and by whom is unknown. The float switch was found at its lowest possible position. Explanation is unknown.
  - Has this concern been discussed with ARC staff and the investigator to determine a possible explanation for these findings? If so, what was the outcome. If not, this discussion should occur.
  - What level of QA is being performed by ARC Managers to ensure tanks and monitoring equipment is properly functioning to ensure animal health and welfare?

The IACUC letter of determination was sent to the ARC Manager on June 22nd.

On July 12th, the ARC response was submitted for IACUC review.

The IACUC reviewed ARC's response to the above queries at its meeting on July 16th. All requested information was thoroughly and satisfactory addressed, including:

1. A detailed description of how new personnel are trained and determined to be proficient prior to working independently.
2. Directly after the incident, the ARC Manager reinforced to all staff the need to stay by the system and closely watch during water exchanges and refills. The responsible staff member had performed backwashes, water exchanges and filled systems likely hundreds of times since his hire without incident. Retraining was not necessary. In this case, a highly competent employee made a mistake because he tried to accomplish too many tasks simultaneously.
3. There is no SOP or checklist for doing water exchanges. This is a very simple task; effort will be placed on doing the water change properly and ensuring the system is operating properly before walking away from it.
4. ARC has experienced staffing fluctuations over the last two years being staffed at 75% for 50% of the time compounded by limitations as result of the COVID-19 pandemic, e.g., retaining staff, refilling positions, staff illness and quarantine, etc. The ARC Internship Program was also halted as result of COVID-19 pandemic. A vacant position is currently posted; once filled, the ARC will return to full staffing. The ARC Internship Program will be re-instated as soon as it is safe to do so.

5. A detailed description of how alarms are checked and how float switches are secured was provided. Both were checked randomly by the ARC Manager once systems were started / brought online. As result of this incident, the ARC Manager will routinely check all alarms every Monday and Friday.

The committee found the response and corrective actions taken to be acceptable and determined this case could be closed.

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,

DocuSigned by:
(b) (6)
C4DDF08CEF09458...

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: Friday, January 7, 2022 9:25 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UMB # D16-00125 (A3200-01): Final Report

Thank you for this report, (b) (6) We'll reply soon.
Axel Wolff

From: (b) (6)
Sent: Friday, January 7, 2022 8:13 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

Dear OLAW Division of Compliance Oversight,

Please find attached a PDF copy of the final report signed by our Institutional Official for incident ACUPAQ0621 (*initially reported via email on 06/22/21*).

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

(b) (6)

A3200 - 3N

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 23, 2021 7:08 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UMB # D16-00125 (A3200-01) - Preliminary Notification of Reportable Incident

Thanks for this preliminary report, (b) (6) We'll open a new case file.
Axel Wolff

From: (b) (6)
Sent: Tuesday, June 22, 2021 1:43 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Buskirk, Susan <sbuskirk@umaryland.edu>; (b) (6)
Subject: UMB # D16-00125 (A3200-01) - Preliminary Notification of Reportable Incident
Importance: High

Dear OLAW Division of Compliance Oversight,

Please accept the following preliminary notification of an event reportable per NIH Notice NOT-OD-05-034:

1. ACUPAQ0621: Aquatic tank maintenance (water change) performed by facility staff resulted in fish fatalities. Species: Fish (rainbow trout). Date of Findings: 06/15/21

A final report will be forthcoming upon completion of the IACUC's investigation. If you have any questions, please do not hesitate to contact me at 410-706-4365.

Thank you!

(b) (6)