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 20892-7982
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) 402-7065

DATE: April 23, 2019

TO: Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH

FROM: Director
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation (ORS - DVR #03-19) - Animal Welfare Assurance A4149-01 [Case 12V]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 3, 2019 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Office of Research Services/Division of Veterinary Resources. According to the information provided, OLAW understands that during the evening of January 28, 2019 a faulty HVAC valve feeding an animal housing room at the NIH Animal Center caused the temperature in the room to reach 100 degrees Fahrenheit by the next morning. Due to a manually changed read-out of the Building Automation System (BAS) the room overheated and the alarm did not notify of the excessive temperature. At 7:30 am on January 29, 2019 an Animal Caretaker reported that the room was above the temperature range and the two racks of mice were moved into the cooler hallway. Four of the cages contained 13 dead mice. All cages were examined by a veterinarian and affected animals were provided treatment.

Corrective and preventive actions included repairing and resetting the BAS and retraining all maintenance staff. Rights have been removed from maintenance staff so that they would not have the ability to change read-out temperatures.

The actions taken to resolve the issues and prevent recurrence were appropriate and accepted by OLAW. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: Dr. Stephen Denny
Dr. Richard Wyatt
Mr. Scott Green, Chair, ORS ACUC

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TO: Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH

FROM: Director
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation (NIAID-RML #03-19) - Animal Welfare Assurance A4149-01 [Case 12V]

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(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: Dr. Stephen Denny
Dr. Richard Wyatt
Mr. Scott Green, Chair, ORS ACUC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

April 3, 2019

TO: Brent C. Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Animal Welfare Investigations - Assurance A4149-01 (ORS-DVR #03-19)

This correspondence conveys the results of an adverse event investigation by the Office of Research Services (ORS) ACUC, in accordance with Assurance A4149-01 and PHS Policy IV.F.3. The adverse event involved the mechanical failure of an animal room's ventilation system which resulted in the death of several mice.

As noted in the attached ORS ACUC memorandum, the event was first reported to the NIH Office of Animal Care and Use by the ORS-Division of Veterinary Resources Director on January 29, 2019.

Please contact me or Dr. Stephen Denny, Acting Director, Office of Animal Care and Use, if additional information or clarifications are required.

(b) (6)

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt
Mr. Green
Dr. Denny

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

Date: March 29, 2019

To: Michael M. Gottesman, MD
Deputy Director for Intramural Research, NIH

From: Scott Green,
Chair, ORS Animal Care and Use Committee

Subject: NIH Animal Center (Poolesville) Building 110A Incident Summary
NIH Animal Welfare Assurance # A4149-01

This memorandum summarizes findings regarding a report of high temperatures in Building 110A at the NIH Animal Center which resulted in the death of 13 mice. The incident occurred during the evening of Monday, January 28th, 2019 although it was first observed by the animal care staff on the morning of Tuesday, January 29th. On the afternoon of Tuesday, January 29, the ORS ACUC Chair was notified of the incident by the DVR Director. The incident was discussed during the February ACUC meeting and an ACUC Subcommittee was formed to investigate the event.

This report is necessitated due to non-compliance with the Guide, which recommends that dry-bulb macro-environmental temperatures for mice be maintained between 68-79ºF

The DVR ACUC Subcommittee met with or received information from the following individuals as part of their investigation: NIH Animal Center (NIHAC) DVR Government Facility Manager, NIHAC DVR Facility Veterinarian, NIHAC Contract Project Manager, ORF NIHAC Contract Manager, and the ORF General Engineer, Accreditation Services Branch.

Incident Summary:

The incident occurred during the evening (after PM checks) of January 28, 2019. At 7:30 am on January 29, an Animal Caretaker reported to the contract facility manger (CFM) that animal room 1A118 was above the temperature range at approximately 100 ºF. The CFM informed the government facility manager (GFM) that there were several cages with dead mice. The two racks of mice were moved out of the room into the cooler hallway. At 7:45am, the ORF NIHAC facility contractor found a faulty HVAC valve feeding into the room and closed it off. The GFM then checked all cages and found 4 cages with 13 dead mice and three survivors. All affected cages were located on the top two shelves of the rack. The Facility Veterinarian examined all the cages, provided treatment to the affected animals, and submitted a memo to the affected investigators informing them of the high temperatures in the room which resulted in fatalities. In the memo, the Veterinarian explained that despite the room-level thermostat reading 100 ºF, the Building Automation System (BAS) failed to correctly measure the high temperature and

thus did not send an alarm notification. While the room was noted with a normal temperature reading the previous day, it reached the high temperatures at some point overnight which was not discovered until physical inspection earlier that morning. In addition to the 13 fatalities, several other moribund mice were resuscitated upon cooling. The Veterinarian checked all the mice after they were able to cool down and observed that they all seemed to be doing fine. Staff also added oral hydration gel packages to all cages. As the room was still at 84 ºF at 10am, the colony was temporarily moved from the hallway into room 1A111 until the temperature stabilized. It was requested that the ORF facility contractor manually check temperatures overnight to ensure the temperatures remained at normal range until the problem was resolved. While the situation was resolved swiftly, the BAS had not registered the dangerously hot room temperature. The DVR FMB Chief and GFM met with ORF leadership to discuss this incident, including repairing and resetting the BAS for it to function properly.

In a conference call on March 18th, DVR management was told that the ORF operator had manually changed the room read-out to 74°F which caused the system to continually call for heat. We were told that this should never be done and because the read-out stated the temperature was 74°F there was no alarm notification.

Corrective actions taken:

DVR management has been informed that all maintenance staff have undergone retraining and rights have been removed from maintenance staff so that they would not have the ability to change read-out temperatures in the future.

The ORS ACUC reviewed the findings of the subcommittee at its March 19, 2019 meeting and believes the corrective actions taken will significantly minimize the possibility of a similar incident occurring in the future.

The Committee voted unanimously that this incident is a reportable incident.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 10, 2019 1:58 PM
To: Denny, Stephen (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A4149-01 Animal Incident Final Report: NIH-ORS (03-19)

Thank you for this final report Dr. Denny. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: Denny, Stephen (NIH/OD) [E]
Sent: Friday, April 05, 2019 10:50 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: A4149-01 Animal Incident Final Report: NIH-ORS (03-19)

Dear OLAW/DCO,

The final NIH IO memo and ORS ACUC report regarding the animal incident referenced in the messages below are attached.

If you have any questions please contact me at the phone number or email listed below. Thanks, Steve

STEPHEN L DENNY, DVM, MS, DACLAM, DACVPM | Acting Director, NIH Office of Animal Care and Use| Phone: (301) 496-5424

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, February 04, 2019 7:39 AM
To: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: A4149-01 Reportable Incident: NIH-ORS (03-19)

Thank you for this prompt report Dr. Denny. We will open a compliance case file and await further information.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: Denny, Stephen (NIH/OD) [E]
Sent: Friday, February 01, 2019 3:41 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: A4149-01 Reportable Incident: NIH-ORS (03-19)

Dear OLAW/DCO,

On January 29, 2019, the Attending Veterinarian for the NIH Office of Research Services-Division of Veterinary Resources (ORS-DVR) animal program informed this office of a reportable animal incident involving the apparent mechanical failure of an animal room's ventilation system. The failure resulted in the death of several mice.

The ORS-DVR ACUC will perform a full investigation, propose corrective actions, and render a report in the near future. Sincerely, Steve

STEPHEN L DENNY, DVM, MS, DACLAM | Acting Director, NIH Office of Animal Care and Use| Phone: (301) 496-5424