DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
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Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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June 27, 2018

Re: Animal Welfare Assurance
#A4189-01 (OLAW Case A)

Dr. John Chicca
President
Molecular Diagnostic Services
4204 Sorrento Valley Blvd., (b) (4)
San Diego, CA 92121

Dear Dr. Chicca,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of the June 22, 2018 letter submitted by (b) (6) reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Molecular Diagnostic Services. According to the information provided, OLAW understands that 45 mice died due to excessive heat in the animal room caused by a malfunctioning thermostat.

The immediate action taken upon discovery consisted of removing the surviving mice from the room and placing them in a cooler environment. These mice were subsequently euthanized due to potential effects on the research study. The thermostat was replaced, the room temperature returned to normal, and the room temperature was tracked over several days and remained stable. The electrical and mechanical systems were examined and found to be working normally. A monitoring system was installed in all animal rooms which will notify staff when temperatures deviate from the set parameters.

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 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
(b) (6)

A4189-A

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
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6705 Rockledge Drive
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To whom it may concern,

I would like to report an unexpected event that occurred at our facility which resulted in animal deaths. Our OLAW Assurance number is: A4189-01. This event did not occur on any activity that is being funded by OLAW. Below is the description of the event, cause and corrective actions we have taken/are planning to take in regards to this event.

We were currently performing a vaccine stability mouse study under IACUC protocol #17-007. During the morning animal check on 6/7/18, the temperature in the room where animals were housed (J3) reached as high as 33°C, well outside the acceptable range of 23°C±3°. As a result of this temperature variation, numerous animals had expired and all remaining animals showed signs of heat stress (lethargy, ruffled coat, abnormal grooming). Forty five animals were found dead, all of which were found on the top shelf of the racks. The remaining surviving study animals were immediately removed from the room to cool their temperature. These animals recovered and appeared normal.

Upon observing the elevated temperature in the room, the thermostat controlling the room was examined. The temperature was displayed as 93°F but the thermostat was set at the normal 74°F and the program indicator was confirmed to be in cooling mode (both on the display and on the control switch). Nonetheless, the fan was running and hot air was being pumped through the system. The thermostat was immediately turned off to avoid further damage to the system and (b) (4) (b) (4) (our contracted HVAC company) was called and an emergency appointment was set up. Upon examination of the issue, the heat pump unit on the roof and the thermostat, the (b) (4) technician determined the event was caused by a malfunction in the thermostat unit (probably electronic), causing the thermostat to miscommunicate with the heat pump unit. The technician replaced the thermostat and the air conditioning resumed function. Temperatures were tracked in this room over June 8-11. Temperatures remained in the normal operating range throughout this period (June 8-11) and the problem appears to be resolved.

It was the opinion of the (b) (4) technician that the malfunction was likely a result of an electronic failure in the thermostat. The integrity of the electrical and mechanical systems was examined and was confirmed to operating within normal parameters.

All vivarium rooms have temperature monitoring thermometers in them that continuously monitor the temperature as well as record minimum and maximum temperatures. These thermometers have an audible alarm incorporated into them that notify the technicians of temperature deviations by way of an audible beep. The vivarium rooms are not connected to any other notification system that automatically prompts anyone offsite if the excursions occur in the off hours. We have never had a catastrophic failure of this nature that resulted in such extreme excursions. In order to avoid this in the future, we are installing and validating a temperature notification system throughout the vivarium.

The animals in this study were euthanized since 45 of the 150 treated animals were found dead initially and it's unclear what adverse effects will be seen from the extreme stress of the heat on the remaining animals. Additional animals will need to be ordered once the new monitoring system is in place. The IACUC has been notified and no additional actions other than setting up the remote notification system have been requested from its members.

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 25, 2018 7:36 AM
To: accounting
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident Report

Follow Up Flag: Follow up
Flag Status: Flagged

Thank you (b) (6) for your report. Dr. Morse will respond soon.

Regards,
Joan

From: accounting [mailto:accounting@mds-usa.com]
Sent: Friday, June 22, 2018 12:37 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Incident Report

Attached is an incident report for our facility. Our OLAW assurance # is : A4189-01. Please let me know if you need any additional information about this incident.

(b) (6)