



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) 402-7065

February 13, 2019

Re: Animal Welfare Assurance
A3718-01 [OLAW Case C]

Dr. J. Michael Parrish
Provost, Senior Vice President for Academic Affairs
The City University of New York
College of Staten Island
2800 Victory Blvd.
Staten Island, NY 10314

Dear Dr. Parrish,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 11, 2019 letter reporting an adverse event affecting research mice at the College of Staten Island, following up on an initial report on May 8, 2018. According to the information provided, OLAW understands that nine mice died after the animal room had overheated. The cause was due to a failed thermostat and the use of a heater which was too large.

The immediate action taken upon discovery consisted of moving the surviving mice to a cooler area where they recovered. The corrective actions consisted of installing a baseboard heater, installing a programmable thermostat, having the room temperature display in the facility manager's office, and alarming the system. The animal room will be kept out of service until all the repairs have been completed.

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. Please notify OLAW if there is a change or problem with the projected corrective actions. 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



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Building 1A, Room 305
Staten Island, NY 10314
T 718.982.2440 • F 718.982.2442
www.csi.cuny.edu
J. Michael Parrish, PhD
Provost/Senior Vice President
for Academic Affairs

February 11, 2019

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Re: A3718-01 – Final report of Adverse Event reported to OLAW 05/08/2018

Dear Dr. Gopee -

On May 8, 2018, CSI submitted a preliminary report to OLAW describing an event that occurred in an animal recovery room and was discovered the previous day, Sunday, May 7, 2018. When a researcher entered the recovery room, he found that the temperature in the room had risen to 103° F; however, the thermostat was set at 74° F. Sadly, nine mice had died. The Animal Care Staff immediately removed the remaining animals to a different recovery area where they were later observed to be doing fine. The room was cleared and shut down from use.

In response to the event of 05/07/2018, a campus Engineer investigated the room and the heating system thoroughly. The Engineer's report concluded that several factors contributed to the extreme deviation in temperature. It was apparent, according to the Engineer, that the line voltage thermostat failed to turn off the unit heater at the established 74° F setpoint, resulting in the room temperature exceeding 100° F. The particular type of control device, he stated, is not fail safe, and inherently has the potential of overheating. The Engineer and his team made the suggestion that we have installed a manual reset high temperature cutout, in series with the primary control. It was the Engineering team's professional opinion that the unit heater in use at the time of the incident, which was rated at 5kW was exceptionally large for this particular application. It was recommended that the existing unit heater be replaced with an appropriate size section of electric baseboard heating. Their final suggestion was to install a form of remote annunciate in the *vivarium* to facilitate additional oversight. While the matter was quite unfortunate, they concluded, it did not appear to be the result of human intervention.



The conclusions and preliminary recommendations of CSI's Engineering Team were submitted to the IACUC, and to OLAW, on August 15, 2018. On August 27, 2018 the IACUC met to discuss the findings, and Engineers' professional recommendations for adequately heating and monitoring the post-surgery room in the Animal Care Facility. IACUC members agreed with the engineers' professional assessment, and the future installation of a monitoring device that links the Animal Facility (AF) and the Recovery Room. The report and the proposed corrective measures were unanimously approved by the IACUC at the convened meeting.

The proposal from CSI's Sr. Engineer detailing what is needed to rectify the temperature issue in the post-surgery recovery (b) (4) includes:

- Installation of a small section of electric baseboard to heat the space;
- A thermostat with programmable limits to prevent an unintended setting of a temperature out of acceptable range
- A sensor and display to give remote indication of the temperature in (b) (4) to the office of the Animal Facility Manager.
- An alarm for the Animal Facility Manager's office (indicator light and buzzer) to alert staff of temperature extremes.

The animals that make our research possible are of primary concern to the IACUC and the Animal Care staff at College of Staten Island. We are confident of the Engineers' diagnosis of the cause of the overheating problem and agree with the proposed remedy and preventive measures to be put in place. Funding has been approved and the work will commence immediately following procurement of the above items. We expect to conclude the project by March 31, 2019. This animal recovery room will not be used until the corrections described herein have been completed.

Very Sincerely.

(b) (6)

J. Michael Parish, PhD.
Institutional Official / Sr. Vice President for Academic Affairs

Gopee, Neera (NIH/OD) [E]

From: Gopee, Neera (NIH/OD) [E]
Sent: Monday, February 11, 2019 5:18 PM
To: (b) (6)
Cc: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Request for update on preliminary noncompliance report for A3718-C

Thank you for this final report (b) (6) We will send an official response soon.

Best Regards,
Neera

Neera V. Gopee, DVM, PhD, DABT, DACLAM
Acting Director, Division of Policy and Education
Office of Laboratory Animal Welfare, NIH
6700B Rockledge Drive
Bethesda, MD 20892-6910
Phone (301) 594-3657
gopeenv@od.nih.gov

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From: (b) (6)
Sent: Monday, February 11, 2019 5:03 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Cc: (b) (6)
Subject: RE: OLAW Request for update on preliminary noncompliance report for A3718-C

Dear Dr. Gopee,

Please find attached the final non-compliance report for A37718-C.

Do not hesitate to be in contact if you require further information,

Sincerely,

(b) (6)

(b) (6)

Gopee, Neera (NIH/OD) [E]

From: Gopee, Neera (NIH/OD) [E]
Sent: Thursday, December 20, 2018 12:01 PM
To: (b) (6)
Cc:
Subject: RE: OLAW Request for update on preliminary noncompliance report for A3718-C

You are correct. Happy Holidays to you too!

Neera

From: (b) (6)
Sent: Thursday, December 20, 2018 11:58 AM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Cc: (b) (6)
Subject: Re: OLAW Request for update on preliminary noncompliance report for A3718-C

Thank you, Dr. Gopee. If I understand correctly, we will submit the final report with necessary details including the planned schedule for the proposed work, signed by the IO. This report should be forthcoming; it is not necessary to wait until completion of the work. After submitting the report, the only need for follow-up with OLAW is in the event that the reported plan for remedy, or the schedule for repair should change. Correct?

Wishing you very happy holidays,
(b) (6)

(b) (6)

From: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Sent: Thursday, December 20, 2018 11:21 AM
To: (b) (6)
Cc:
Subject: RE: OLAW Request for update on preliminary noncompliance report for A3718-C

Thank you for your prompt response (b) (6) You may proceed with submitting a final report signed by the IO to OLAW. Be sure to include in the final report a description of the nature of the incident and the plan and schedule for correction. You must keep OLAW apprised only if the plan and/or schedule that was described in the final report changes.

Hope this helps. I look forward to receiving the final signed report in the near future.

Best Regards,
Neera

From: [REDACTED] (b) (6)

Sent: Wednesday, December 19, 2018 4:02 PM

To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>

Cc: [REDACTED] (b) (6)

Subject: Re: OLAW Request for update on preliminary noncompliance report for A3718-C

Hello, Dr. Gopee -

A proposal to adequately heat and monitor the post-surgery room in the Animal Care Facility has been approved by the IACUC. The work has not commenced. Should I write more detailed information about the forthcoming project; or, should I wait until it is completed to finalize a report?

Thank you for your help. It is very much appreciated.

Best regards,

[REDACTED] (b) (6)

[REDACTED] (b) (6)

From: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>

Sent: Wednesday, December 19, 2018 3:52 PM

To: [REDACTED] (b) (6)

Subject: RE: OLAW Request for update on preliminary noncompliance report for A3718-C

Dear [REDACTED] (b) (6)

I was writing with regards to an update or final report regarding the noncompliance that was initially reported to this Office on May 8, 2018 an interim report was subsequently submitted to OLAW on August 15, 2018.

If you have any questions or concerns regarding this matter, please do not hesitate to contact me.

Best Regards,
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Gopee, Neera (NIH/OD) [E]
Sent: Wednesday, August 15, 2018 6:04 AM
To: (b) (6)
Cc: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: RE: OLAW Request for update on preliminary noncompliance report for A3718-C

Thank you (b) (6) for the prompt response. This communication, along with the Engineer's assessment, will serve as an interim report for this case.

Best Regards,
Neera

From: (b) (6)
Sent: Tuesday, August 14, 2018 3:09 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Subject: Re: OLAW Request for update on preliminary noncompliance report for A3718-C

Hello, Dr. Gopee,
My apologies for not having followed up on our report of May 8, 2018 regarding a situation in which 9 mice succumbed due to excessively high temperature in the room in which they were being housed. The situation was resolved but I do not yet have a copy of the Engineer's assessment of the event. I am expecting to receive that report either today or tomorrow. The Engineer was working with the Animal Facility Manager and I did not receive a copy of the report. I have been out of the office on FMLA almost two months with a fractured foot and communications have been sporadic.

I will certainly update you tomorrow, presumably with a report from the Engineer. The IO's report will follow though I can't be certain when. Summertime is winding down so it should soon be easier to find folks in their offices. Please note that the animal facility is very closely monitored and there have been no new incidents.

I will stay in touch with you until all reporting is finalized and we have complete resolution of the event as determined by OLAW.

Best regards,
(b) (6)

(b) (6)

From: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Sent: Tuesday, August 7, 2018 2:36 PM

To: (b) (6)

Subject: OLAW Request for update on preliminary noncompliance report for A3718-C

Dear (b) (6)

I am writing with regards to the adverse event which was reported by via telephone on May 8, 2018 involving the death of 9 mice due to elevated temperatures at CUNY College of Staten Island. To date we do not have a record of receiving further information regarding this preliminary report. OLAW requests that submission of a final or interim report to the OLAW Division of Compliance Oversight (NIH/OD) olawdco@od.nih.gov at your earliest convenience.

If you have any questions or concerns regarding this matter, please do not hesitate to contact me.

Regards,
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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Fw: 6S/335 report/recommendations

(b) (6)

Wed 8/15/2018 11:20 AM

(b) (6)

See below for the Chief Engineer's report on the incident in (b) (4)

(b) (6)

From: (b) (6)

Sent: Wednesday, August 15, 2018 10:55 AM

To: (b) (6)

Cc: (b) (6)

Subject: (b) (4) report/recommendations

(b) (6)

In response to the event that occurred in (b) (4) on 7 May 2018, our investigation concluded that several factors contributed to the extreme deviation in temperature. It is apparent that the line voltage thermostat failed to turn off the unit heater at the established 74°F setpoint, resulting in the room temperature exceeding 100°F. This particular type of control device is normally closed, opens on temperature rise. This means the system is not fail safe, and inherently has the potential of over heating. It is our suggestion to install a manual reset high temperature cutout in series with the primary control. It is also our professional opinion that the unit heater, rated at 5kW is exceptionally large for this application. We recommend replacing the existing unit heater with a proper sized section of electric baseboard. It is our final suggestion to install a form of remote annunciation the (b) (4) Vivarium to facilitate additional oversight. While the matter is unfortunate, it does not appear to be the result of human intervention.

Thanks,

(b) (6)

Morse, Brent (NIH/OD) [E]

From: Gopee, Neera (NIH/OD) [E]
Sent: Thursday, August 16, 2018 5:39 PM
To: (b) (6)
Cc: Morse, Brent (NIH/OD) [E]; Wolff, Axel (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Update on preliminary noncompliance report for A3718-C

Thank you (b) (6) for this interim report. We look forward to receiving the final report once the IACUC has completed its assessment of the incident.

Best Regards,
Neera

From: (b) (6)
Sent: Thursday, August 16, 2018 3:21 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Subject: Update on preliminary noncompliance report for A3718-C

Help again, Dr. Gopee;

Please find attached the report from the Chief Engineer at the College of Staten Island. In addition to his evaluation of the circumstances which led to the excessive overheating of a room housing mice and causing the death of nine of the mice, the Engineer has made specific recommendations for equipment necessary to prevent such an occurrence from happening in the future. The report is being forwarded to the IACUC and to the IO.

After the IO has had an opportunity to review the report and the recommendations, and when the IACUC assesses all that is known, a corrective action plan will be formulated. The IO will communicate the actions taken upon completion.

Very sincerely,

(b) (6)

(b) (6)

(b) (6)

Gopee, Neera (NIH/OD) [E]

From: Gopee, Neera (NIH/OD) [E]
Sent: Wednesday, August 15, 2018 6:04 AM
To: (b) (6)
Cc: Morse, Brent (NIH/OD) [E]
Subject: RE: OLAW Request for update on preliminary noncompliance report for A3718-C

Thank you (b) (6) for the prompt response. This communication, along with the Engineer's assessment, will serve as an interim report for this case.

Best Regards,
Neera

From: (b) (6)
Sent: Tuesday, August 14, 2018 3:09 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Subject: Re: OLAW Request for update on preliminary noncompliance report for A3718-C

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I will certainly update you tomorrow, presumably with a report from the Engineer. The IO's report will follow though I can't be certain when. Summertime is winding down so it should soon be easier to find folks in their offices. Please note that the animal facility is very closely monitored and there have been no new incidents.

I will stay in touch with you until all reporting is finalized and we have complete resolution of the event as determined by OLAW.

Best regards,

(b) (6)

(b) (6)

From: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>

Sent: Tuesday, August 7, 2018 2:36 PM

To: (b) (6)

Subject: OLAW Request for update on preliminary noncompliance report for A3718-C

Dear (b) (6)

I am writing with regards to the adverse event which was reported by via telephone on May 8, 2018 involving the death of 9 mice due to elevated temperatures at CUNY College of Staten Island. To date we do not have a record of receiving further information regarding this preliminary report. OLAW requests that submission of a final or interim report to the OLAW Division of Compliance Oversight (NIH/OD) olawdco@od.nih.gov at your earliest convenience.

If you have any questions or concerns regarding this matter, please do not hesitate to contact me.

Regards,
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 09, 2018 7:22 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable event from College of Staten Island, Assurance # A3718

Thank you for this report, (b) (6). We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

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

From: (b) (6)
Sent: Tuesday, May 08, 2018 3:26 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
(b) (6)
Subject: Reportable event from College of Staten Island, Assurance # A3718

Hello –

We are writing to provide a preliminary report of an event that occurred in an animal recovery room and was discovered yesterday afternoon, 05/07/2018. When a researcher entered the recovery room, he found that the temperature in the room had risen to 103F; however, the thermostat was set at 74 degrees F. Sadly, nine mice had died. The Animal Care Staff immediately removed the remaining animals and as of this afternoon, all appeared to be doing fine. The room has been cleared and shut down from use. We are waiting for the Engineering Department to diagnose the cause of the problem so that a remedy and preventive measures can be determined.

I will send updated information as quickly as possible. The IO will submit a thorough report when all the facts are known and plans to prevent such an incident from occurring in the future have been formulated.

Please let me know if you need additional information immediately.

Thank you.

(b) (6)