



DEPARTMENT OF HEALTH & HUMAN SERVICES

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NATIONAL INSTITUTES OF HEALTH

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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

September 9, 2022

Re: Animal Welfare Assurance
A3029-01 [OLAW Case 1H]

Dr. Ramesh Kolluru
Vice President of Research, Innovation,
and Economic Development
University of Louisiana at Lafayette New Iberia Research Center
104 University Circle, (b) (4)
P.O. Box 43610
Lafayette, LA 70504

Dear Dr. Kolluru,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 7, 2022 letter in response to allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Louisiana at Lafayette. These allegations were received from the People for the Ethical Treatment of Animals (PETA) regarding the USDA APHIS Inspection Report dated August 26, 2021.

OLAW requested additional information regarding the incidents described in the USDA APHIS Inspection Report. The USDA APHIS Inspection Report stated an unresponsive infant was identified on July 19, 2021. The previous letter dated April 26, 2022, stated the infant was found on July 18th, and it is understood that was typographical error. The current letter states observations of animals were completed in the morning and afternoon of July 18th, and on the morning of July 19th. The infant was identified as unresponsive during an unscheduled walkthrough (10:30am) and was ultimately euthanized due to its poor prognosis. The infant was not assigned to a research protocol and was housed with its mother. The letter also states other infants and/or animals were assigned to research protocols, and research personnel observed animals specifically assigned to study.

Regarding animal observations, animals are observed twice daily throughout the Center, typically between 6:30-7:00am. On July 18th and 19th, Animal Resources staff completed animal observations in 31D by 7am. Daily observations completed on July 18th and 19th did not require the reporting of abnormalities that warranted immediate veterinary intervention.

Water bowls were placed in each cage as soon as the deficiency in the water supply was detected on July 20, 2021. Animals were checked to verify that they would drink from the bowls consistently and were offered a water bottle with sipper tube as an alternative, if required. Animal Resource personnel ensured water was available to the animals throughout the day. Food enrichment (jello cups) were placed in each cage as well by Veterinary Resources. Once the water supply was confirmed to be consistent and reliable, the Attending Veterinarian made the decision to remove the water bowls at the end of the day on July 20th.

It is understood that a manual system for monitoring/recording water pressure in modular buildings was implemented on July 21, 2021. Also, water pressure monitoring devices were installed and interfaced with the building automated control system. Regarding the supply water, New Iberia Research Center (NIRC) municipal supply water system was evaluated to determine strategic monitoring points for detection of water flow/pressure variances. Monitoring devices were installed and interfaced with the Building Automation Control System to allow immediate notification as of October 4, 2021. It is stated that while SOP M-28 was not finalized until November 30, 2021, implementation and documentation continued across the facility upon implementation and interface of each monitoring device. Per the letter, SOP training was performed after SOP implementation.

Regarding refresher trainings, the trainings were recommendations for improvement from the IACUC subcommittee. It is understood immediate implementation of visual confirmation of water flow and pressure occurred. However, a more formal and extensive training occurred later to reinforce the importance of water checks, which were corrective actions #6 and #7.

NIRC acknowledges that this incident resulted in a programmatic change for the center. While this incident was encountered for the first time, NIRC assessed all buildings to determine points of risks, regarding mechanisms to monitor water flow. In response, a system for additional monitoring extended to all animal housing, not only where the incident occurred. NIRC also acknowledges that the matter should have been reported to since the incident had the potential to affect PHS-supported animals.

Thank you for the detailed responses to each of OLAW's concerns. Based on its assessment of this explanation, OLAW understands that the University of Louisiana at Lafayette has implemented appropriate measures to correct and prevent recurrences of these problems and reported incidents to this Office as appropriate.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T. Tubbs -S

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2022.09.09
09:06:38 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

Robert M. Gibbens, DVM, Director, Animal Welfare Operations

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Friday, September 9, 2022 9:10 AM
To: Ramesh.kolluru@louisiana.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD); Robert.m.gibbens@usda.gov; iacuc@louisiana.edu; (b) (6)
Subject: OLAW Case A3029-1H
Attachments: A3029-1H.pdf

Good morning Dr. Kolluru,

Attached please find Dr. Tubbs' response to OLAW Case A3029-1H. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390



Office of the Vice President for Research,
Innovation, and Economic Development

P.O. Box 43610 • Lafayette, LA 70504-3610

Office: (337) 482-5811

Fax: (337) 482-5102

Université des Acadiciens

July 7, 2022

Re: Animal Welfare Assurance
A3029-01 [OLAW Case 1-H]

Dr. Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Dear Dr. Tubbs,

Thank you for reviewing of the summary of the incident that involved the interruption of water supply to a modular building on the UL Lafayette NIRC site. To clarify the points made in the letter dated June 27, 2022: The USDA report states, "On July 19, 2021, in modular ^{(b) (4)} there was an unresponsive infant rhesus macaque showing signs of dehydration with a poor prognosis which was euthanized." However, this letter states the infant was found on the afternoon of July 18, 2021. Please clarify the date of the initial incident.

Please see clarification for the additional requested information:

1. *Were the animal observations performed in the morning and the infant was found unresponsive late afternoon on July 18th?*

The date is incorrect in the letter addressed to your office. We apologize for this typographical error. The unresponsive infant was identified on July 19, 2021 as stipulated in the USDA inspection report. Observations were done on the morning and afternoon of the day prior on July 18, 2021 and on the morning of July 19, 2021. During an unscheduled walkthrough at 10:30 AM, this infant was reported as unresponsive and was sedated at 10:40. Given its poor prognosis, the infant was subsequently euthanized in the late morning of July 19, 2021. This infant, housed with its mother, was not assigned to a research protocol.

2. *Please clarify when animals were observed prior to the discovery of the unresponsive infant (i.e., specific time frames).*

Animals are observed throughout the Center twice daily. On Sunday July 18, 2021 and Monday July 19, 2021, Animal Resources staff completed observations of the animals in 31D by 7 am (between 6:30 -7:00 am is typical observation time).

Additionally, as other infants and/or animals in (b) (4) were assigned to research protocols, Research personnel observed animals specifically assigned to study, but generally the entire room for abnormal animal behavior. During the daily observations performed on July 18, 2021 (walkthrough performed ~8:15 AM) and July 19, 2021 walkthrough performed ~11:30), abnormalities warranting immediate veterinary intervention of other non-assigned animals housed in this building were not reported.

3. *Please describe the watering devices that were temporarily implemented while the automatic watering system was being assessed.*

As soon as the deficiency in the water supply was identified, on July 20, 2021, water bowls were placed in each cage. Municipal water supply was turned off to allow controlled delivery of water to all animals housed in the building. The animals were observed to ensure that they would drink from the bowls consistently for the first 15-20 minutes. (Some animals were flipping their bowls). If an animal flipped their bowl, a water bottle device with a sipper tube was affixed to the front of the cage with zip ties. Throughout the day, Animal Resources personnel assessed the building to ensure water was available to the animals, as monkeys tend to "play" with new items, occasionally emptying watering devices. Veterinary Resources placed jello cups in each cage and continued to provide high water content produce enrichment in each cage.

The Attending Veterinarian made the decision to remove the water bowls at the end of the day (July 20, 2021) once water supply was confirmed consistent and reliable

4. *It is understood that manual water pressure readings were implemented July 21, 2021, however SOP M-28 did not become effective until November 30, 2021 regarding water supply monitoring and maintenance of NHP housing areas. Is the creation of this SOP related to training on the improved monitoring of the water supply system that permitted 24/7 notification of variance from preset limits? Please clarify.*

A manual system for reading/recording water pressure in modular buildings was immediately implemented (July 21, 2021 assigned to Physical Facilities personnel) to allow visual assessment of water pressure. This manual reading and recording system is still in effect to date. In addition, water pressure monitoring devices were installed and interfaced with the building automated control system for the five modular buildings on site. This interface allows continual monitoring against preset action limits and automated notification of physical facilities personnel if limits are exceeded (24 hours a day). M-28 was not finalized till Nov. 30, 2021.

Furthermore, the NIRC municipal supply water system from source to individual litix delivery was evaluated to identify strategic monitoring points for detection of water flow/pressure variances enabling prior to impacting non-human primate housing areas. Municipal water supply back flow preventers were identified as points of monitoring. Sixteen monitoring devices were installed downstream of municipal water system back flow preventers and interfaced with the building automated control system. These devices were installed and interfaced with the Building Automation Control System to allow

immediate notification as of Oct. 4, 2021. SOP M-28 Water Supply Monitoring and Maintenance of NHPs also addresses/ documents continual daily checks of water, water pressure readings and maintenance of water filters as applicable across NIRC. Although SOP M-28 was not finalized until Nov 30, 2021, progressive implementation and documentation across the facility progressed upon implementation and interface of each monitoring device. SOP training was conducted after SOP implementation.

5. *Regarding corrective actions #6 and #7, when were personnel refresher trainings conducted?*

Refresher trainings were recommendations from improvement from IACUC subcommittee (sent to NIRC on Oct. 01, 2021): Immediate implementation of visual confirmation of water flow and pressure occurred. However, a more formal and extensive documented training was conducted later to reinforce the importance of water checks as outlined below:

- a. #6. Refresher training of personnel on visual assessment of water flow and pressure versus presence or absence of water flow was accomplished
Oct. 07-28, 2021 all relevant NIRC personnel (Research, Veterinary Resources, Animal Resources) were trained.
 - b. #7. Refresher training of all persons conducting observations on recognizing signs of dehydration across all NHPs and age groups was accomplished-
Oct 07-28, 2021 all relevant NIRC personnel (Research, Veterinary Resources, Animal Resources) were trained.
6. *The letter states that the incident was not considered a programmatic failure. However, it also details facility-wide implementation of corrective actions i.e., development of SOPs, refresher training for personnel on the recognition of signs of dehydration, improvements to the monitoring of the water supply system, daily recording of water pressure reading, etc. Hence, if the corrective actions were programmatic, and correctly so, why was such a serious incident not considered to be programmatic? Please clarify. Please clarify if this decision was determined by the full IACUC or based on the investigation by the subcommittee of the IACUC.*

In the interest of transparency, OLAW should have been notified of these matters regardless of funding source. Five animal deaths (including required euthanasia) occurred within a short time frame and the root cause could have affected animals associated with PHS/HHS/NSF and other funding sources that are subject to OLAW oversight. If an incident is serious enough to warrant self-reporting to one federal oversight agency, an initial brief discussion with OLAW is certainly in order. OLAW is always open for consultation regarding the reportability of an event. NOT-OD-05-034 (Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals) details examples and information that must be reported to the Office. Per the notice, OLAW must receive "a full description of any potential or actual effect on PHS-

*supported activities if the situation is not directly supported by the PHS but is in a functional, programmatic, or physical area that could affect PHS-supported activities." The events of July 2021 unequivocally meet the definition as a reportable event to OLAW. To learn of these incidents from animal rights organizations, the media, or other outside sources is very concerning when OLAW encourages self-reporting to abate negative perception of the care and use of animals in research. Self-reporting is one of the few proactive measures that institutions may take that demonstrates transparency regarding the reportable events and actions taken to prevent future recurrence. Please provide an update to this Office by **July 31, 2022**.*

As with any incident that is encountered for the first time at the Center, NIRC staff immediately reviews its entire animal care operation, and takes steps to ensure such incident is prevented in the future. Thus, as correctly pointed out in your letter, this incident prompted a programmatic change for the Center. We appreciate your direction and guidance in this matter. NIRC did assess all buildings for mechanisms to monitor water flow to identify any points of risks. NIRC did implement a system for additional monitoring extending to all animal housing.

The Center appreciates and fully accepts that this was an issue that should have been directly reported to OLAW, even though (b) (4) never housed PHS supported animals. It was self-reported by NIRC to USDA, from where PETA obtained the information via the Freedom of Information Act.

Moving forward, we will maintain an open communication for both consult and reporting with OLAW.

Sincerely,

(b) (6)

✍ Ramesh Kolluru, PhD.
Institutional Official
Vice President for Research, Innovation, and Economic Development
University of Louisiana at Lafayette

cc: IACUC contact

Tubbs, Jai (NIH/OD) [E]

From: Ward, Joan (NIH/OD) [E]
Sent: Thursday, July 7, 2022 10:10 PM
To: Tubbs, Jai (NIH/OD) [E]
Subject: FW: OLAW Case A3029-1H
Attachments: Response to OLAW - July 7, 2022.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Jai, FYI

From: Ramesh Kolluru <ramesh.kolluru@louisiana.edu>
Sent: Thursday, July 7, 2022 6:15 PM
To: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Cc: Institutional Animal Care and Use Committee <iacuc@louisiana.edu>; (b) (6)
(b) (6)
Subject: [EXTERNAL] RE: OLAW Case A3029-1H

Dear Dr. Ward,

Please find attached responses to Dr. Tubb's questions re. OLAW Case A3029-1H.

Ramesh

Ramesh "Hon. Cajun" Kolluru, Ph.D.
Associate Provost & Vice President for Research, Innovation, and Economic Development
University of Louisiana at Lafayette - A Carnegie R1 Research University
PO Box 42570
Lafayette, LA 70504
(b) (6)
Ramesh.Kolluru@louisiana.edu

#FullSteamAhead

Université des Acadiens

From: Ward, Joan (NIH/OD) [E] <wardjoa@od.nih.gov>
Sent: Tuesday, June 28, 2022 6:02 AM
To: Ramesh Kolluru <Ramesh.kolluru@louisiana.edu>
Cc: Institutional Animal Care and Use Committee <iacuc@louisiana.edu>
Subject: FW: OLAW Case A3029-1H

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Dear Dr. Kolluru,

Attached please find Dr. Tubb's additional response to OLAW case A3029-1H.

If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,

Joan

Joan Ward
Program Specialist
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Dr., Suite 2500
Bethesda, MD 20892
301-496-7163
wardjoa@od.nih.gov

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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

June 27, 2022

Re: Animal Welfare Assurance
A3029-01 [OLAW Case 1H]

Dr. Ramesh Kolluru
Vice President of Research, Innovation,
And Economic Development
University of Louisiana at Lafayette New Iberia Research Center
104 University Circle, (b) (4)
Lafayette, LA 70504

Dear Dr. Kolluru,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 26, 2022 letter in response to allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Louisiana at Lafayette. These allegations were received from People for the Ethical Treatment of Animals (PETA) regarding the USDA APHIS Inspection report dated August 26, 2021.

This Office requested additional information regarding an event involving a rhesus infant discovered with severe dehydration and required euthanasia. The following day, two infant rhesus macaques were found dead; another two infant rhesus macaques were reported unresponsive. Also, a third infant was reported for dehydration. The Attending Veterinarian (AV) treated all 3 animals, but euthanasia was required for two animals. A malfunctioning pressure regulator was identified as the cause for these events. This Office requested a summary of these incidents, subsequent corrective actions, and funding sources for the animals (and if any animals on known PHS-funded projects were identified for dehydration).

The letter states on July 20, 2021, the New Iberia Research Center discovered (NIRC) a mechanical failure in the inline water pressure regulator. This failure resulted in an intermittent reduction of water supply to the animals via lixits. It is understood that non-PHS/NSF/DHHS research was housed in this building. Daily animal observations occurred on Monday, July 18th without any observation of clinical issues. Later that afternoon there was report of an infant rhesus macaque as unresponsive with signs of dehydration. Due to a poor prognosis the animal was euthanized the same day. On July 20, 2021, Animal Resources personnel identified 2 dead infants, 2 unresponsive infants, and 1 infant exhibiting signs of dehydration. The AV was contacted, and emergency care was initiated. Simultaneously, lixits were confirmed to be functional but in an intermittent manner, which led to a thorough assessment of the system. It is understood that manual watering devices were provided temporarily for use. Replacement of the regulator permitted the return to use of the automatic watering supply via lixit by the afternoon of July 20th. It is stated the inconsistencies in automatic watering supply impacted the younger juveniles more significantly than the adults and nursing infants kept with their mother.

The letter notes the animal deaths were self-reported to the USDA on July 28, 2021 when the root cause was identified, and remediation measures were planned facility wide. The USDA completed a focused inspection on August 26, 2021. Also, recommendations to prevent future recurrence were provided by an IACUC subcommittee following an investigation. The IACUC received a progress report from NIRC with corrective actions that were implemented, and the committee determined the incident was not a programmatic failure. The corrective actions implemented include the following:

- All other modular buildings' pressure regulators were inspected immediately. Acceptable function of water pressure regulators in the 4 remaining modular buildings was confirmed on July 21, 2021.
- Manual water pressure readings were implemented July 21, 2021 and are recorded daily in each modular building. Manufacturer recommendation of ~15 psi from a newly installed modular building was used as the optimal pressure (starting July 21, 2021). Automated water pressure sensors for the 5 modular buildings including interface with Building Automated Control System were installed September 28, 2021. Alarms were verified October 29, 2021.
- All Research infant studies now include twice daily observations done by Research Staff in addition to twice daily Animal Resources observations (standard procedure) to enable earliest detection of potential clinical issues.
- Facility wide, NIRC improved the monitoring of the water supply system for designated primate housing areas to enable around the clock notification of variance from preset limits. Interface of back flow regulators and the Building Automated Control System provides the ability to set acceptable limits, detect deviation from set limits and notify on call personnel of such deviations 24/7.
- Building Automation Control System interfaces were installed October 04, 2021 on all backflow preventers associated with animal rooms. This will alert personnel of reduced pressure (below 25 psi) at individual buildings being monitored 24/7.
- Standard Operating Procedure (SOP) M-28 "Water Supply Monitoring and Maintenance of NHP housing areas" was implemented effective November 30, 2021. SOP M-28 enforces the following documentation: continual daily building water pressure log, monthly building water flow tests log, quarterly building water filter replacement log as applicable across NIRC. All applicable personnel have been notified and trained on the SOP.
- A refresher training of personnel on visual assessment of water flow and pressure versus presence or absence of flow was accomplished.
- A refresher training of all persons conducting observations on recognizing signs of dehydration across all nonhuman primate species and age groups was accomplished.

The USDA report states, "On July 19, 2021 in modular (b) (4) there was an unresponsive infant rhesus macaque showing signs of dehydration with a poor prognosis which was euthanized." However, this letter states the infant was found on the afternoon of July 18, 2021. Please clarify the date of the initial incident. Please see the additional requested information below:

- Were the animal observations performed in the morning and the infant was found unresponsive late afternoon on July 18th?
- Please clarify when animals were observed prior to the discovery of the unresponsive infant (i.e., specific time frames).
- Please describe the watering devices that were temporarily implemented while the automatic watering system was being assessed.
- Please describe how long these devices were in use, and when it was confirmed that the automatic water system was safe for use by animals.
- It is understood that manual water pressure readings were implemented July 21, 2021, however SOP M-28 did not become effective until November 30, 2021 regarding water supply monitoring and maintenance of NHP housing areas. Is the creation of this SOP related to training on the improved monitoring of the water supply system that permitted 24/7 notification of variance from preset limits? Please clarify.
- Regarding corrective actions #6 and #7, when were personnel refresher trainings conducted?

The letter states that the incident was not considered a programmatic failure. However, it also details facility-wide implementation of corrective actions i.e., development of SOPs, refresher training for personnel on the recognition of signs of dehydration, improvements to the monitoring of the water supply system, daily recording of water pressure reading, etc. Hence, if the corrective actions were programmatic, and correctly so, why was such a serious incident not considered to be programmatic? Please clarify. Please clarify if this decision was determined by the full IACUC or based on the investigation by the subcommittee of the IACUC.

In the interest of transparency, OLAW should have been notified of these matters regardless of funding source. Five animal deaths (including required euthanasia) occurred within a short time frame and the root cause could have affected animals associated with PHS/HHS/NSF and other funding sources that are subject to OLAW oversight. If an incident is serious enough to warrant self-reporting to one federal oversight agency, an initial brief discussion with OLAW is certainly in order. OLAW is always open for consultation regarding the reportability of an event. NOT-OD-05-034 (Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals) details examples and information that must be reported to the Office. Per the notice, OLAW must receive *"a full description of any potential or actual affect on PHS-supported activities if the situation is not directly supported by the PHS but is in a functional, programmatic, or physical area that could affect PHS-supported activities."* The events of July 2021 unequivocally meet the definition as a reportable event to OLAW. To learn of these incidents from animal rights organizations, the media, or other outside sources is very concerning when OLAW encourages self-reporting to abate negative perception of the care and use of animals in research. Self-reporting is one of the few pro-active measures that institutions may take that demonstrates transparency regarding the reportable events and actions taken to prevent future recurrence. Please provide an update to this Office by **July 31, 2022**.

Sincerely,

Jacquelyn
T. Tubbs -S

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2022.06.27
11:40:43 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



**Office of the Vice President for Research,
Innovation, and Economic Development**

P.O. Box 43610 • Lafayette, LA 70504-3610

Office: (337) 482-5811

Fax: (337) 482-5102

Université des Acadiens

April 26, 2022

Re: Animal Welfare Assurance
A3029-01 [OLAW Case 1H]

Dr. Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Dear Dr. Tubbs,

On July 20, 2021 the New Iberia Research Center (NIRC) identified a mechanical failure in the inline water pressure regulator in modular (b) (4) resulting in an intermittent reduction of water supply to the animals via lixits. The program housed in the building was a non-PHS/NSF/DHHS funded program. Daily animal observations were accomplished the day prior, on Monday July 18, 2021 without any observation of clinical issues. However later that afternoon, an infant rhesus was reported unresponsive with signs of dehydration. The infant's prognosis was poor and therefore, it was humanely euthanized that afternoon. The following day (July 20, 2021), the Animal Resources personnel found 2 infants dead, 2 infants unresponsive, and 1 showing signs of dehydration. This was immediately reported to the Attending Veterinarian. Simultaneous with initiation of emergency care to the animals by the Attending Veterinarian, lixits were verified as functional but in an intermittent fashion, leading to a thorough assessment of the system by Facility Maintenance personnel. While assessing the automated watering supply system, manual watering devices were implemented temporarily. The water pressure regulator failure was detected upon attempting to transition back to the automatic watering system. Replacement of the regulator allowed returning to use of the automatic watering supply via lixit by the afternoon of July 20, 2021. The inconsistencies in automatic watering supply impacted the younger juveniles more dramatically than adults and nursing infants housed with their mothers. To this end, two juvenile rhesus macaques died and 2 subsequently required euthanasia after intense medical intervention.

NIRC self-reported the animal deaths to the USDA on July 28, 2021 once the root cause was identified and remediation measures were planned facility wide. The USDA conducted a focused inspection on August 26, 2021. Additionally, the University of Louisiana at Lafayette Institutional Animal Care and Use Committee conducted a subcommittee investigation and made recommendations to assist in preventing future failures. A progress report was sent to the IACUC October 28, 2021 from NIRC with corrective actions implemented. Due to the nature of the failure and lack of occurrence over decades of operation, this incident was not deemed to be a programmatic failure.

Corrective Actions taken:

1. All other modular buildings' pressure regulators were inspected immediately, even though such a failure had never before been encountered in over 2 decades of NIRC operation. Acceptable function of water pressure regulators in the 4 remaining modular buildings was confirmed on July 21, 2021.
2. Manual water pressure readings were implemented July 21, 2021 and are recorded daily in each modular building. Manufacturer recommendation of ~15 psi from a newly installed modular building was used as the optimal pressure (starting July 21, 2021). Automated water pressure sensors for the 5 modular buildings including interface with Building Automated Control System were installed September 28, 2021. Alarms were verified October 29, 2021.
3. All Research infant studies now include twice daily observations (once daily research observations were being conducted at the time of the incident) done by Research Staff in addition to twice daily Animal Resources observations (standard procedure) to enable earliest detection of potential clinical issues.
4. Facility wide, NIRC improved the monitoring of the water supply system for designated primate housing areas to enable around the clock notification of variance from preset limits. Interface of back flow regulators and the Building Automated Control System provides the ability to set acceptable limits, detect deviation from set limits and notify on call personnel of such deviations 24/7.
Building Automation Control System interfaces were (16 devices were implemented for the purposes of automatic pressure monitoring and alarming when psi is outside preset limits) installed October 04, 2021 on all backflow preventers associated with animal rooms. This will alert personnel of reduced pressure (below 25 psi) at individual buildings being monitored 24/7.
5. Standard Operating Procedure (SOP) M-28 "Water Supply Monitoring and Maintenance of NHP housing areas" was implemented with associated attachments effective November 30, 2021. SOP M-28 enforces the following documentation: continual daily building water pressure log, monthly building water flow tests log, quarterly building water filter replacement log as applicable across NIRC. All applicable personnel have been notified and trained on the SOP.
6. A refresher training of personnel on visual assessment of water flow and pressure versus presence or absence of flow was accomplished.
7. A refresher training of all persons conducting observations on recognizing signs of dehydration across all nonhuman primate species and age groups was accomplished.

Sincerely,

(b) (6)

Ramesh Kolluru, PhD.
Institutional Official
Vice President for Research, Innovation, and Economic Development
University of Louisiana at Lafayette

Enclosures
Cc: IACUC contact

Tubbs, Jai (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 29, 2022 9:42 AM
To: Tubbs, Jai (NIH/OD) [E]
Subject: FW: OLAW response Case ULA-L 3029-1H
Attachments: OLAWresponseCase1H.pdf

Follow Up Flag: Follow up
Flag Status: Completed

From: Ramesh Kolluru <ramesh.kolluru@louisiana.edu>
Sent: Friday, April 29, 2022 9:35 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Institutional Animal Care and Use Committee <iacuc@louisiana.edu>
Subject: [EXTERNAL] FW: OLAW response Case ULA-L 3029-1H

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Dear Dr. Tubbs:

Please find attached a letter with information from inspection report along with a summary of the incident and corrective actions you requested on March 16, 2022, related to OLAW Case 1H. Please let me know if you need further information.

Best regards,

Ramesh "Hon. Cajun" Kolluru, Ph.D.
Associate Provost & Vice President for Research, Innovation, and Economic Development
University of Louisiana at Lafayette - A Carnegie R1 Research University
PO Box 42570
Lafayette, LA 70504
(b) (6)
Ramesh.Kolluru@louisiana.edu

#FullSteamAhead

Université des Acadiens

From: (b) (6)
Sent: Thursday, April 28, 2022 8:47 AM
To: Ramesh Kolluru <ramesh.kolluru@louisiana.edu>
Subject: OLAW response Case 1H

Good morning,

(b) (6) would like to know if you want to send out this letter or should IACUC?

Thanks,

(b) (6)

Tubbs, Jai (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 29, 2022 9:42 AM
To: Tubbs, Jai (NIH/OD) [E]
Subject: FW: OLAW response Case ULA-L 3029-1H
Attachments: OLAWresponseCase1H.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

From: Ramesh Kolluru <ramesh.kolluru@louisiana.edu>
Sent: Friday, April 29, 2022 9:35 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Institutional Animal Care and Use Committee <iacuc@louisiana.edu>
Subject: [EXTERNAL] FW: OLAW response Case ULA-L 3029-1H

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 Dr. Tubbs:

Please find attached a letter with information from inspection report along with a summary of the incident and corrective actions you requested on March 16, 2022, related to OLAW Case 1H. Please let me know if you need further information.

Best regards,

Ramesh "Hon. Cajun" Kolluru, Ph.D.
Associate Provost & Vice President for Research, Innovation, and Economic Development
University of Louisiana at Lafayette - A Carnegie R1 Research University
PO Box 42570
Lafayette, LA 70504
(b) (6)
Ramesh.Kolluru@louisiana.edu

#FullSteamAhead

Université des Acadiens

From: (b) (6)
Sent: Thursday, April 28, 2022 8:47 AM
To: Ramesh Kolluru <ramesh.kolluru@louisiana.edu>
Subject: OLAW response Case 1H

Good morning,

(b) (6) would like to know if you want to send out this letter or should IACUC?

Thanks,

(b) (6)

A3029-1H

AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

PETA



February 3, 2022

Brent C. Morse, D.V.M.
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Via e-mail: MorseB@mail.nih.gov

Dear Dr. Morse:

We believe that the federal Animal Welfare Act violation documented in the attached U.S. Department of Agriculture inspection report and official warning posted against the University of Louisiana at Lafayette (UL Lafayette) constitutes a violation of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). Last year, UL Lafayette received \$9,576,874 from the National Institutes of Health (NIH), and according to NIH, an estimated 47% of those funds supported projects that involved experiments on animals.

In 1985, members of Congress from both sides of the aisle worked together to strengthen protections for animals in laboratories in order to address deep-seated ethical concerns held by the American public regarding the use of animals in experiments. Polling by the Pew Research Center found that more than 50% of U.S. adults oppose the use of animals in experiments, and other surveys suggest that the support of the shrinking group that continues to accept animal experimentation is contingent on the existence and enforcement of stringent regulations aimed at protecting animals.

As you know, institutions that receive funding from Public Health Service agencies—including NIH—are required to comply with PHS Policy. Failure to comply violates not only federal animal welfare guidelines and policies but also public expectations that facilities receiving tax dollars to use animals—who are capable of experiencing pain, distress, love, and companionship and value their lives just as we value ours—at the very least, comply with minimal standards aimed at ensuring some modicum of animal welfare.

We ask that your office investigate the incidents outlined in the attached reports.

Thank you for your time and consideration.

Sincerely,

(b) (6)

PEOPLE FOR
THE ETHICAL
TREATMENT
OF ANIMALS

Washington
1536 16th St. N.W.
Washington, DC 20036
202-483-PETA

Los Angeles
2154 W. Sunset Blvd.
Los Angeles, CA 90026
323-644-PETA

Norfolk
501 Front St.
Norfolk, VA 23510
757-622-PETA

Info@peta.org
PETA.org

Entities:

- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Switzerland
- PETA Netherlands
- PETA Foundation (U.K.)



Inspection Report

UNIVERSITY OF LOUISIANA AT LAFAYETTE
P.O. BOX 41008
LAFAYETTE, LA 70504

Customer ID: 1451

Certificate: 72-R-0007

Site: 001

UNIVERSITY OF LOUISIANA AT
LAFAYETTE

Type: FOCUSED INSPECTION

Date: 26-AUG-2021

3.75(d) Critical

Housing facilities, general.

On July 19, 2021 in modular (b) (4) there was an unresponsive infant rhesus macaque showing signs of dehydration with a poor prognosis which was euthanized. However, the dam was slightly underconditioned with adequate hydration and was placed on conservative treatment. The facility conducted daily study observations mid to late Monday morning with no indication of dehydration in any of the animals in the building. On July 20, 2021 two infant rhesus macaque deaths were reported and two infant rhesus macaques were reported unresponsive, and a third was reported dehydrated, but aware of it's surroundings. The attending veterinarian was notified of the water issue and treated all 3 animals. By the end of the day one macaque responded well to treatment while the others did not, and they were euthanized. Animal Resources confirmed that the lixits were working properly on Monday, but it was determined on Tuesday that there was a reduction in water pressure to the lixits. At this point, the water was shut off to prevent bloat, and all animals housed in the building were supplemented with water until the water supply was deemed functional. Upon further investigation, it was determined by the Physical Facility personnel that the pressure regulator to the the housing room/lixits was not working properly, thus reducing the water pressure to the animal room excessively. The housing facility must provide reliable running potable water for a nonhuman primates' drinking needs to prevent dehydration. The facility has implemented several corrective actions including daily manual checks and records of water pressure, monthly water flow confirmation

Prepared By:

Title:

(b) (6)
Date:
26-AUG-2021

Received by Title: Facility Representative

Date:
26-AUG-2021



Inspection Report

checks, water flow monitoring plan and facility water system evaluations to identify points of risk for additional monitoring. The Center is offering the animals more high-water content supplements and all infant studies will consistently include twice daily observations. The facility is in the process of utilizing a Building Automation System based automatic pressure monitoring and alarm system to receive alerts for pressure values outside of acceptable ranges. Correct from this day forward.

This inspection and exit interview were conducted with the facility representative.

Prepared By:

Title:

(b) (6)

Date:
26-AUG-2021

Received by Title: Facility Representative

Date:
26-AUG-2021



United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1451
Inspection Date: 26-Aug-2021

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1451	72-R-0007	001	UNIVERSITY OF LOUISIANA AT LAFAYETTE	26-AUG-2021

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	



United States Department of Agriculture

<p>UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE</p> <p>USDA</p> <p>OFFICIAL WARNING</p> <p>NOTICE OF ALLEGED VIOLATION</p>	<p>CASE NUMBER: LA220001-AC</p>
	<p>ALLEGED VIOLATOR: UNIVERSITY OF LOUISIANA AT LAFAYETTE</p>
	<p>ADDRESS (City, State, ZIP Code): LAFAYETTE, LA 70504</p>
<p>The U.S. Department of Agriculture has evidence that on or about the date(s) listed below, you or your organization committed the following alleged violation(s) of Federal laws:</p> <p>Date of Alleged Violation: August 26, 2021</p> <p>9 C.F.R. § 3.75(d) Housing facilities, general.</p> <p>Water and electric power. The housing facility must have reliable electric power adequate for heating, cooling, ventilation, and lighting, and for carrying out other husbandry requirements in accordance with the regulations in this subpart. The housing facility must provide running potable water for the nonhuman primates' drinking needs. It must be adequate for cleaning and for carrying out other husbandry requirements.</p>	

The Animal and Plant Health Inspection Service (APHIS) published federal regulations to ensure the welfare of animals and help prevent the spread of animal and plant pests and diseases. Since violations of the regulations can have serious and costly impacts that are detrimental to the public interest, APHIS is providing you with an Official Warning for the alleged violation(s) described above. This Official Warning is not to be construed as a final agency action, or as an adjudicated finding of a violation. If APHIS obtains evidence of any future violation of these federal regulations, APHIS may pursue civil penalties, criminal prosecution, or other sanctions for this alleged violation(s) and for any future violation(s). If you have any questions concerning this Official Warning or alleged violation(s), please contact the APHIS official listed in this notice.

APHIS OFFICIAL (Name): Dr. Elizabeth Goldentyer, D.V.M.	OFFICE ADDRESS: 4700 River Road, (b) (4) Riverdale, MD 20737	
APHIS OFFICIAL (Title): Deputy Administrator, APHIS, Animal Care	DATE ISSUED: January 14, 2022	TELEPHONE NUMBER: (b) (6)

APHIS FORM 7060

Previous editions may be used

Rev. 4-23-21

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, February 7, 2022 10:13 AM
To: (b) (6)
Subject: RE: Concerns from PETA re treatment of animals at University of Louisiana at Lafayette:

Dear (b) (6)

OLAW will review the issues you have forwarded and investigate any, as required by the PHS Policy. Thank you for your interest in animal welfare.

Sincerely, Brent Morse

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

From: (b) (6)
Sent: Thursday, February 3, 2022 1:56 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: [EXTERNAL] Concerns from PETA re treatment of animals at University of Louisiana at Lafayette:

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 Dr. Morse,

Please see the attached letter from PETA.

Thank you very much for your time and consideration.

Sincerely,

(b) (6)

