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We would like to clarify that all technical personnel working on the study involving this incident had documented training and experience in the relevant procedures, including nonhuman primate necropsy. Although the technician failed to follow the directive to include a pathologist in the necropsy, a full necropsy was indeed performed by the technician, who is fully trained in this procedure. Post-life instructions contained within study protocols are usually not included in our IACUC protocols as they do not impact animal welfare. The study protocol is a document that is independent of the IACUC protocol and the AWA, and serves as a part of the scientific contract between the institute and our client.

Because the Animal Welfare Regulations do not contain any specific directive for necropsy of nonhuman primates, we feel that this citation falls outside the jurisdiction of the USDA. Failure of a technician to follow a *study* protocol-directed procedure is a separate issue that should be able to be dealt with internally at our Institute, and we ask that this citation be retracted.

2) The second citation reads as follows: 2.33(b)(3) CRITICAL

A 2.5-year-old male cynomolgus macaque was found dead in his enclosure where he was housed with 5 other male cynomolgus macaques of the same age. Daily observations are recorded per enclosure and not per animal unless there is a health concern. Prior to his death the facility stated this animal did not appear unhealthy and was active with a healthy hair coat. After the animal's death the facility raised potential compatibility issues between this same group of macaques. According to the necropsy report, the animal was found to have marked dehydration, little to no visceral fat, and an overall thin body condition. Observations for compatibility within primate groups is necessary to prevent situations where individual animals are not allowed access to food, water, or shelter by other animals.

Response

We would like to clarify that there were no observed signs of social incompatibility within this group of nonhuman primates. In accordance with our environmental enhancement plan, group housed animals are observed twice daily for activity, including aggressive behaviors, none of which had been documented within this enclosure. Social incompatibility as a potential contributor to the death of this animal is, therefore, entirely speculative. In fact, necropsy revealed no evidence of superficial trauma to suggest conspecific aggression, and other underlying disease cannot be ruled out.

Animals in this enclosure were observed twice daily by trained technicians, and nothing abnormal had been noted to trigger more detailed examination or behavioral consult. Furthermore, animals were housed in accordance with our social housing policies which state that group-housed nonhuman primates in enclosures receive access to food and

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water in multiple locations to ensure subordinate animals have sufficient opportunity for food/water intake. Accurate estimation of body condition score in group-housed nonhuman primates is often not possible, as was noted by Dr. Sismour during the focused inspection, and confirmed by our veterinary pathologist. Moreover, in consultation with multiple recognized experts in nonhuman primate behavior (see enclosed letter of support), animals can establish a hierarchy at any point in time, even years after animals have otherwise been perfectly compatible. It is difficult to notice a hierarchy developing without any warning signs. The animal that died was scheduled for a weight check the following day and we would have noted the weight loss at that time and acted accordingly.

While we are always striving to improve our animal care program to reduce incidents such as this, at this time, we have no reason to believe that this specific instance was preventable by any refinement of our social housing plan for nonhuman primates. Further, all procedures and observations followed our approved social housing plan and were compliant with the approved IACUC protocol.

For the reasons stated above, we respectfully ask that this citation be retracted.

3) The third citation reads as follows: 2.38 (f)(1) CRITICAL

A 2.5-year-old male cynomolgus macaque died unexpectedly during a face-mask inhalation to test the effects of a substance. During this procedure one animal technician was monitoring the 5 cynomolgus macaques. It was stated that this was beyond the usual number of animals monitored per technician. It was stated that during the procedure, the arm restraints on the chairs where the animals were held were too large for some of these animals. This allowed the animals to maneuver their arms to bypass the arm restraints and move around in the chair and get entangled in the equipment. In addition, according to the technician, the monitoring equipment was producing many false error alarms making it difficult to monitor the animal's condition. Near the end of the procedure, the technician found this animal to be non-responsive. The incident was immediately reported to a veterinary technician who examined the animal but was unable to resuscitate it and the animal died.
Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

Response

We disagree with the assumption that this animal was mishandled. Prior to the animal being reported to veterinary staff, he never showed signs of trauma, overheating, cooling, behavioral stress, harm or discomfort, as noted in this citation. In contrast, the animal was reported to be comfortable and resting during exposure. The self-identified

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corrective action from this incident is to keep animals alert and responsive during exposure by periodic stimulation. This corrective action is not related to any mishandling of animals; instead, it is a refinement of our monitoring procedures to prevent this from happening again. Therefore, we respectfully disagree that the animal was being handled in a way that caused any sort of distress or trauma and ask that the citation be retracted.

Summary:

In summary, we thank you for your time and review of our processes. We are committed to a culture of continuous improvement and transparency with the USDA. We strive to implement timely refinements to our processes that mitigate risks and improve our animal care program. We have investigated both of these incidents internally and have implemented refinements to processes to reduce the chances of similar events occurring in the future. That said, this does not mean that previous processes were inadequate or unnecessarily put animal welfare at risk. There are inherent risks involved in performing animal research. Group housing nonhuman primates has obvious benefits for this social species, however it does not come without risk. Working with nonhuman primates is a challenge and neither of these situations could have been predicted and, thus, prevented.

Furthermore, the citations in 2.32(b) and 2.38 (f)(1) are referencing the same incident. The Animal Welfare Inspection Guide section 2.4.4 states that if a noncompliant item falls into more than one section or subsection, only the most applicable section will be cited.

We intend to address the cited incidents though refinements in our procedures, but we disagree that these events resulted from any non-compliance with the Animal Welfare Regulations, and we respectfully appeal these citations. We appreciate your thoughtful review of our animal care program and consideration of this request, and we look forward to your response.

Respectfully,

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United States Department of Agriculture
Animal and Plant Health Inspection Service

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Inspection Report

Lovelace Respiratory Research Institute
2425 Ridgecrest S E
Albuquerque, NM 87108

Customer ID: **1072**
Certificate: **85-R-0003**
Site: 001
LOVELACE RESPIRATORY RESEARCH INSTITUTE

Type: FOCUSED INSPECTION
Date: 19-NOV-2019

2.32(b)

PERSONNEL QUALIFICATIONS.

There was an incident involving a 2.5 year old male cynomolgus macaque that died unexpectedly during a face-mask inhalation procedure. The incident was immediately reported to a veterinary technician who examined the animal but was unable to resuscitate it. A full necropsy was not done on this animal since the necropsy technician failed to properly read the entire study protocol that called for a full necropsy with the presence of a veterinary pathologist.

It is the responsibility of the research facility to provide continued training and instruction to all personal with sufficient frequency to fulfill the research facility's responsibilities.

To be corrected by November 28, 2019

2.33(b)(3) **CRITICAL**

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

A 2.5 year old male cynomolgus macaque was found dead in his enclosure where he was housed with 5 other male cynomolgus macaques of the same age. Daily observations are recorded per enclosure and not per animal unless there is a health concern. Prior to his death the facility stated this animal did not appear unhealthy and was active with a healthy hair coat. After the animal's death the facility raised potential compatibility issues between this same group of macaques.

According to the necropsy report, the animal was found to have marked dehydration, little to no visceral fat, and an overall thin body condition. Observations for compatibility within primate groups is necessary to prevent situations where individual animals are not allowed access to food, water, or shelter by other animals.

Prepared By:

SISMOUR NAOMI, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 6121

Date: 27-NOV-2019

Received By:

(b) (6), (b) (7)(C)

Title: SENT VIA EMAIL

Date: 27-NOV-2019

Observations regarding problems of animal health, behavior and well-being may be accomplished by someone other than the attending veterinarian but all such issues must be conveyed to the attending veterinarian in a timely manner to ensure that all animals receive appropriate veterinary care.

To be corrected by November 28, 2019

2.38(f)(1) CRITICAL

MISCELLANEOUS.

A 2.5 year old male cynomolgus macaque died unexpectedly during a face-mask inhalation to test the effects of a substance. During this procedure one animal technician was monitoring the 5 cynomolgus macaques. It was stated that this was beyond the usual number of animals monitored per technician. It was stated that during the procedure, the arm restraints on the chairs where the animals were held were too large for some of these animals. This allowed the animals to maneuver their arms to bypass the arm restraints and move around in the chair and get entangled in the equipment. In addition, according to the technician, the monitoring equipment was producing many false error alarms making it difficult to monitor the animal's condition. Near the end of the procedure, the technician found this animal to be non-responsive. The incident was immediately reported to a veterinary technician who examined the animal but was unable to resuscitate it and the animal died.

Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

To be corrected by November 28, 2019

This inspection was conducted with facility representatives on November 19-20 and the exit interview was conducted with facility representatives on November 20th.

Prepared By:

SISMOUR NAOMI, D V M USDA, APHIS, Animal Care

Date: 27-NOV-2019

Title: VETERINARY MEDICAL OFFICER 6121

Received By:

(b) (6), (b) (7)(C)

Title: SENT VIA EMAIL

Date: 27-NOV-2019