



Animal and Plant
Health Inspection
Service

4700 River Road
Riverdale, MD 20737

January 24, 2020

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

85-R-0003
CID 1072

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

Your December 17, 2019 appeal of citations on the USDA inspection report, dated November 19, 2019, was thoroughly reviewed by an Animal Care appeal panel consisting of two Supervisory Animal Care Specialists, an Assistant Director, and me. The appeal is addressed below.

Citation 2.32(b) will be removed from the Inspection Report:

- We accept the report from the facility attending veterinarian that a necropsy was completed by a qualified technician. However, at the time of the inspection, Dr. Sismour was told that a necropsy had not been done, constituting a failure to follow the protocol requiring a necropsy, and resulted in the citation in the inspection report.
- We recommend that steps are taken to ensure facility personnel participating in inspections have knowledge of, or access to, all relevant information regarding animal management and adherence to study protocols.

Citation 2.33(b)(3) will remain on the Inspection Report as written:

- Based on the results of the necropsy report, the macaque was severely dehydrated and malnourished, including an overall thin body condition. This condition should have been noticed during the daily observations. Although this condition may not have been due to observed social incompatibility, as suggested by your staff during the inspection, the serious body condition of the animal shows that daily monitoring failed to identify the circumstances that led to this animal's dehydration and malnutrition. Consequently, the daily observation did not adequately assess the health and well being of the animal.
- We recognize your efforts to group house your macaques and provide environmental enrichment. We encourage you to review your protocols and training program to ensure your staff can more closely observe each individual animal on a daily basis.

Citation 2.38(f)(1) will remain on the Inspection Report as written:

- Adequate handling of animals, as required by the Regulations, is not limited to the physical handling of the animals by humans or physical restraints. It requires that the conditions an animal is placed in "do not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort." Based on the circumstances surrounding the death

- of the macaque, as described by the animal technician, there were multiple conditions that potentially contributed to the animal's death, such as the technician having more animals to observe than normal, the inadequacy of the restraint chairs to fit the animals, and the faulty equipment; these are considered handling noncompliances.
- According to Dr. Sismour, your facility is addressing these issues and we encourage you to continue to ensure the well-being of the animals.

You should receive a copy of the amended inspection report within two weeks.

All decisions made by the appeal panel are final and represent Animal Care's final determination for this appeal.

Sincerely,

DANA COLE Digitally signed by DANA
COLE
Date: 2020.01.24 12:24:44
-07'00'

Dana Cole, DVM, PhD
Acting Director, Animal Welfare Operations
USDA, APHIS, Animal Care

USDA Animal Care. Ensuring humane treatment. Serving people. Doing right.



December 17, 2019

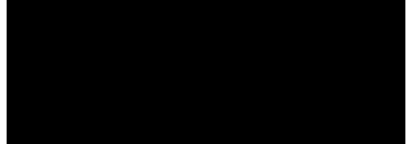
To whom it may concern

Dr. Naomi Sismour, DVM, USDA/APHIS Animal Care Veterinary Medical Officer conducted a focused inspection of our Institute on 19Nov2019. We would like to thank her for her time and thorough evaluation of two incidents that were recently self-reported to the USDA. We are always grateful for the opportunity to improve our program. We do, however, respectfully disagree and would like to clarify the incidents for which we are being cited in the attached appeal.

We ask for your consideration of this appeal and look forward to working with the USDA/APHIS to improve and refine our operations. Please contact me if you have any questions or desire additional information.

Sincerely,

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



Lovelace Respiratory Research Institute.



17Dec2019

To: (b) (6), (b) (7)(C)
Lovelace Biomedical
2425 Ridgecrest SE
Albuquerque, NM 87198

From: (b) (6), (b) (7)(C)
Lovelace Biomedical
2425 Ridgecrest SE
Albuquerque, NM 87198

Customer ID: 1072, Site: 001

Re: Appeal to USDA Inspection Report 2016082569665446 received on 27Nov2019 following inspection conducted on 19Nov2019.

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

We are submitting this appeal to the aforementioned USDA inspection report to kindly request that you forward it to the Fort Collins Animal Care Office. We thank Dr. Sismour for her thorough evaluation during a focused inspection of our facility on 19Nov2019. We are grateful for the opportunity to improve our program. We do, however, respectfully disagree with the citations and would like to clarify our position in the following appeal.

1) The first citation reads as follows: 2.32 (b)

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 oversight of a veterinary pathologist. It is the responsibility of the research facility to provide continued training and instruction to all personnel with sufficient frequency to fulfill the research facility's responsibilities.

Response



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

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



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 through 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,

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

Memo

To: To whom it may concern

From: (b) (6), (b) (7)(C)

cc: (b) (6), (b) (7)(C)

Date: December 17, 2019

Re: Citation appeal

As an attending veterinarian with recognized expertise in nonhuman primate behavior, I would like to express my support for the Lovelace Respiratory Research Institute as they appeal a citation related to presumed inadequate observations leading up to a primate found dead in his social enclosure. Like most of our laboratory species, evolution has programmed NHPs to disguise when they are ill. This ability to hide illness, coupled with the laboratory animal field's much needed emphasis on social housing, can make it difficult to assess the body condition of some animals by cage side observation. I have no direct experience with LRRI's NHP monitoring, or this animal in particular. I can state that, for animals housed in long term social groups, twice daily cage-side observations with brief removal every two weeks for weighing and closer examination is a plan that I and the vast majority of my colleagues would consider more than reasonable. More frequent capture events are unrealistic and can be more stressful to the animals. It is extremely unfortunate any time an animal succumbs to illness, but it is also important that laboratories be encouraged to pursue the social housing of non-human primates despite the risk of such incidents.

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



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 personnel 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

Date:

27-NOV-2019

Title: VETERINARY MEDICAL OFFICER 6121

Received By: 33_000120

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 12/24/2020

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

Date:



Inspection Report

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: 33_000121

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 12/24/2020

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

Date:

Amended Report Letter



United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Services

Animal Care

920 Main Campus Drive
Suite 200
Raleigh, NC 27606

Tel No. 919-855-7100
Fax No. 919-855-7123


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

February 5, 2020

This amended inspection report, dated February 5, 2020 by the signature block, replaces the previous inspection report dated November 27, 2020 by the signature block. The previous inspection report is no longer valid.

Respectfully,

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



Animal Care is a part of the Department of Agriculture's Animal and Plant Health Inspection Service.

An Equal Opportunity Provider and Employer

Figure A-30 Amended Report Letter



Inspection Report

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

Customer ID: 1072

Certificate: 85-R-0003

Site: 001

LOVELACE BIOMEDICAL RESEARCH INSTITUTE

Type: FOCUSED INSPECTION

Date: 19-NOV-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.

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

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

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

Title: VETERINARY MEDICAL OFFICER 6121

Date:
05-FEB-2020

Received By: 16-05763_000123

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 12/24/2020

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

Date:



Inspection Report

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.

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

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

Date:
05-FEB-2020

Title: VETERINARY MEDICAL OFFICER 6121

Received By: 16-05763_000124

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 12/24/2020

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

Date:



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1072	85-R-0003	001	LOVELACE BIOMEDICAL RESEARCH INSTITUTE	19-NOV-19

No Animals were Inspected.

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	

Sismour, Naomi K - APHIS

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

@lovelacebiomedical.org>

Sent: Thursday, February 6, 2020 6:38 AM

To: Sismour, Naomi K - APHIS

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

Subject: RE: USDA Inspection Report Please Respond CID: 1072

Attachments: Amended report letter 2-5-20.pdf; Lovelace Respiratory Research Institute.pdf

Thanks Dr. Sismour. I'm confirming receipt of your edited inspection report. I'm also copying

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

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

Thanks,

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

(b) (6), (b) (7)(C)@lovelacebiomedical.org

Phone: 505-348-9662

Lovelace Biomedical

www.lovelacebiomedical.org



From: Sismour, Naomi K - APHIS <naomi.k.sismour@usda.gov>

Sent: Wednesday, February 5, 2020 7:11 PM

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

@lrri.org>

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

Subject: USDA Inspection Report Please Respond CID: 1072

WARNING: This is an external email. Use Caution responding, opening attachments and following links.

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

Here is the edited inspection report and amended letter from the focused inspection conducted on 11/19 and 11/20.

I have sent the report in a PDF format. *****Please acknowledge that you successfully received the inspection report via a return e-mail to me.***** The return e-mail takes the place of a "received by" signature on the report.

If you are having any difficulty sending an e-mail response, please let me know and I can send the report to you by a different method.

Please let me know if you have any questions. Thank you for reporting these incidences and doing your best for caring for all the animals under your supervision. I truly appreciate how fast corrections are made! Have a Happy Thanksgiving!

Dr. Sismour

Naomi Kirby Sismour, DVM, MS
Veterinary Medical Officer
USDA, APHIS, Animal Care
Arizona
Cell: (424) 397-3579
Email: naomi.k.sismour@usda.gov

This electronic message contains information generated by the USDA solely for the intended recipients. Any unauthorized interception of this message or the use or disclosure of the information it contains may violate the law and subject the violator to civil or criminal penalties. If you believe you have received this message in error, please notify the sender and delete the email immediately.