Inspection Report

BIOANALYTICAL SYSTEMS INC
10424 MIDDLE MT. VERNON RD
MOUNT VERNON, IN 47620

Customer ID: **784**
Certificate: **32-R-0020**
Site: 001
BIOANALYTICAL SYSTEMS, INC

Type: FOCUSED INSPECTION
Date: 26-MAY-2022

2.31(c)(3)

Institutional Animal Care and Use Committee (IACUC).

During the IACUC semi-annual inspection conducted in Oct. 2021, there were deficiencies noted that were identified as being significant. The correction date of the significant finding was to be completed by the end of Nov. 2021 but was not confirmed as being corrected until Dec. 9, 2021. The facility did not report this lapse in correction until early Jan. 2022, which was more than 15 business days past the original correction date.

If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days to APHIS and any Federal agency funding that activity.

Corrective actions taken include highlighting any significant findings in a bold red font and adding a more thorough method to track progress of completion, such as calendar reminders.

Correct by adhering to correction dates set for deficiencies noted during semi-annual inspections.

Corrected actions in place prior to inspection date.

Prepared By: REBECCA NANNEY
USDA, APHIS, Animal Care
Date: 02-JUN-2022

Title: VETERINARY MEDICAL OFFICER

Received by Title: Attending Veterinarian
Date: 02-JUN-2022

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2.38(f)(1) **Critical**

Miscellaneous.

*On Nov. 30, 2021, a male Cynomolgus macaque (~1.5-2 kg), a stock animal, was found dead in a slide style restraint chair while out for a routine cage change/sanitization. It was the second time these primates had been placed in restraint chairs. Also, during this restraint period, there was a female that had to be removed from the chair due to not acclimating well to the restraint and was placed into a slide and clip style chair with no further issues. Prior to this date, it was noted that a male had to be removed due to not acclimating well to the restraint and was placed into a slide and clip style chair with no further issues. He was persistently trying to escape from the chair and appeared to be compromising his respirations in the attempt. There were two (2) technicians present during the routine cage change/sanitization, one primarily observing the primates in the chairs and the other cleaning/sanitizing the animal room.

*On March 10, 2022, a male Cynomolgus macaque (~1.5 kg), a stock animal, was found unresponsive in a restraint chair during an animal room sanitization. He was removed from the chair and the veterinary staff was immediately notified. Upon veterinary exam, no respiratory effort or pulse was noted, and he was pronounced dead. It was the second time he had been placed in a restraint chair which was equipped with a slide style top. Shortly after this incident on the same day, a second primate began to show signs of distress in a slide style restraint chair, and he was immediately removed from the chair and given oxygen before recovering. There were at least three (3) technicians in very close proximity. Mitigation efforts were planned to modify the chairs in this building to restrain the collar only but were delayed due to a shortage of hardware. Approximately 50% of the chairs had already been modified and the remaining were modified by the end of the day.

The previous style of the primate restraint chairs (slide style), in combination with the primate collars and size of the

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primates available, did not adequately protect the animals from injury during handling.

*On Dec. 7, 2021, a male pig (5M024, repeat dose toxicity study) was evaluated due to lameness that had persisted since Dec. 6, following a toxicokinetic blood collection, during which manual restraint was used. Upon palpation of the right distal hind limb, the Attending Veterinarian noted swelling and crepitus, as well as a likely fracture of the mid-tibia. Deep palpation, further diagnostics and treatment were not performed due to the scheduled necropsy of this animal on that day. Euthanasia and necropsy occurred after the examination (on Dec. 7). Necropsy revealed fractures in both the tibia and fibula.

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.

Corrective actions already taken for the primates: the restraint chairs have been modified, additional monitoring has been instigated and there is a plan to review and implement an acclimation process.

Correct by further evaluating handling techniques and devices, conduct appropriate training or re-training as needed, and evaluate methods of monitoring, to include the importance of proper care and monitoring of all animals.

3.125(a)

Facilities, general.

A female pig (#3088782, 4F053) was witnessed on Aug 19, 2021, as being loose from her primary enclosure with a male pig (4M023). This was recorded as a potential mis-mating between the animals, as this facility does not breed animals. On Sept. 16, 2021, the female was administered inhalation anesthesia by mask for Lutalyse injections to terminate any

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potential pregnancy.

The facility must be constructed of such material and of such strength as appropriate for the animals involved. The indoor and outdoor housing facilities shall be structurally sound and shall be maintained in good repair to protect the animals from injury and to contain the animals.

Correct by evaluating all enclosures (primary and secondary) and repairing as needed to protect and contain the animals.
Correction date: June 17, 2022

This inspection was conducted with Attending Veterinarian, Team Leader of Veterinary Care, IACUC chair and other facility representatives.

This exit interview was conducted with Attending Veterinarian, Team Leader of Veterinary Care, IACUC chair, Chief Operations Officer and other facility representatives.

Additional Inspectors:

Michael Schnell, VETERINARY MEDICAL OFFICER

Prepared By: REBECCA NANNEY
USDA, APHIS, Animal Care

Date: 02-JUN-2022

Title: VETERINARY MEDICAL OFFICER

Received by Title: Attending Veterinarian

Date: 02-JUN-2022

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United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 784
Inspection Date: 26-May-2022

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
784	32-R-0020	001	BIOANALYTICAL SYSTEMS, INC	26-MAY-2022

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	

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