



## Inspection Report

Toxikon Corporation  
15 Wiggins Ave  
Bedford, MA 01730

Customer ID: 147  
Certificate: 14-R-0101

Site: 001

TOXIKON CORPORATION

Type: ROUTINE INSPECTION

Date: 03-APR-2017

### 2.32(a) CRITICAL

#### PERSONNEL QUALIFICATIONS.

Training of personnel.

\*The review of IACUC and medical records involving two adverse events in AWA covered species reported to the IACUC since October 2016 indicated that the events surrounding these adverse events were not in compliance with Section 2.33 (b) (5) as documented on this report.

Although prior instruction had been provided to laboratory staff on the institution's standards for animal use in research, for the appropriate pre and post procedural care of research animals, and the use of anesthetics, it was determined that research personnel failed to follow the IACUC approved protocols and the institution's guidelines that resulted in the adverse events.

Per this Section of the Regulations, all personnel involved in animal care and use should be qualified and appropriately trained to perform their duties. Training should include as a minimum, the research methods of animal use for the species the personnel will be using, the proper pre procedural and post procedural care, as well as the proper use of anesthetics, anesthesia, and the monitoring of animals while under anesthesia.

Properly trained personnel are vital to ensure that research animals receive proper care and optimal welfare. Although the IACUC and AV are currently reviewing the circumstances of these adverse events in order to develop procedures to avoid future incidents, the research facility needs to ensure that all personnel are qualified to perform their duties.

Correct from this date 4/5/17 forward.

### 2.33(b)(5) CRITICAL

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Prepared By: GLADUE PAULA, V M D USDA, APHIS, Animal Care

Date:  
05-APR-2017

Title: VETERINARY MEDICAL OFFICER 1054

Received by Title: ATTENDING VETERINARIAN

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Adequate pre-procedural and post-procedural care.

\*\*In February 2017, a dog was under general anesthesia as per IACUC approved protocol. According to the medical record, the initial vital signs were recorded at 10:34 AM but when the vital signs were checked again 10 minutes later the dog had expired. The AV was notified of the adverse event and conducted an investigation. It was determined that the pre-procedural respiratory rate of the dog was elevated above normal but research staff did not notify veterinary services of the problem and administered general anesthesia to the dog. Once the dog was under general anesthesia, the research staff failed to recognize that the dog's oxygen saturation was below the required 90-95% and in addition the research staff left the dog unattended and failed to continuously monitor the animal while under general anesthesia.

\*In October 2016, a rabbit was used in an IACUC approved protocol that included the weight loss of 20% from the baseline weight as a study end point criteria. On 10/10/16 laboratory staff reported to veterinary services that a rabbit had a 27% weight loss from baseline; the AV directed research personnel to euthanize the rabbit. On 10/12/16 veterinary staff discovered during rounds that the rabbit still had not been euthanized by research personnel. Veterinary staff euthanized the rabbit.

In both of these incidents, the AV met with research personnel to provide additional re-training on facility standard operating procedures and guidelines.

\*During the inspection at 1:10 PM on 4/3/17, APHIS personnel identified 2 rabbits that were in ventral recumbency with their rear legs fully extended backwards and 1 rabbit that was in right lateral recumbency. The 3 rabbits were unattended in the room and had their eyes closed. APHIS personnel requested that the rabbits be examined to determine their level of alertness. The rabbits did not respond when the doors of their enclosures were opened (unusual behavior for rabbits) and they needed to be touched in order to get a reaction. The 2 ventral recumbent rabbits lifted their heads, tried to move but their feet slid on the floor of the cage and they could not become upright. The lateral recumbent rabbit was able to get into sternal recumbency.

It was determined during a review of the animals' medical records that that the 3 rabbits had undergone an IACUC approved procedure involving the administration of injectable anesthesia at approximately 10:10 AM that morning. Notations in the records made by research personnel indicated that the animals had recovered approximately 1 ½ hrs after the anesthesia was administered and were returned to their enclosures. The condition of the 3 rabbits and their reactions to external stimuli indicated that the animals had not sufficiently recovered from anesthesia to be left unattended.

Per this Section of the Regulations, each research facility shall establish and maintain programs of adequate veterinary care that includes adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

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Animals under general anesthesia need to be continuously monitored so that any changes in vital signs are promptly identified and addressed. Animals that have met endpoint criteria must be humanely euthanized as soon as possible to minimize discomfort, pain, or distress. Animals recovering from anesthesia need to be observed until fully recovered. These guidelines are important to ensure the health and well-being of the animals.

The research facility needs to ensure that all personnel involved in the care and use of animals are appropriately trained in and follow the components of the facility's program of veterinary care.

Correct from this date 4/5/17 forward.

### 3.53(a)(4)

#### PRIMARY ENCLOSURES.

Primary Enclosure Flooring.

\*There were at least 40 smaller sized rabbits that were housed in enclosures that had floors with narrow metal slatted construction. The metal slats in the floor were approximately 1/8 inch in diameter and the spaces between the slats were approximately 1/2 inch in diameter. At the time of the inspection, APHIS personnel observed the feet and or toes of these rabbits passing through the spaces between the slats.

Per this Section of the Regulations, the floors of primary enclosures shall be constructed so as to protect the rabbits' feet and legs from injury. Housing small sized rabbits in enclosures that have floors with this sized spacing between the slats can cause injury to the feet, toes, and toenails of the animals from entrapment.

The facility needs to ensure that the floors in rabbit enclosures used to house smaller sized animals are of construction that provides support for the feet and toes that does not permit the passing of toes or feet through the spaces in the floor.

Correct by 4/14/17.

### 3.56(a)(1)

#### SANITATION.

Cleaning of Primary Enclosures.

\*At the time of inspection it was noted in one rabbit's enclosure that there was an excessive accumulation of compacted fecal material 6-8 inches in diameter that was covering the floor directly in front of the feed hopper. The

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rabbit had to stand on the fecal material in order to access the food. Although husbandry care staff had already serviced the room, the presence of the excessive fecal material had not been recognized nor removed from the enclosure.

Per this Section of the Regulations, primary enclosures shall be kept reasonably free of excreta and other debris by periodic cleaning. The enclosures should be cleaned with sufficient frequency to ensure all animals the freedom to avoid contact with excreta. In addition, when fecal material is in close proximity to the feed hopper, there is an increased risk in secondary contamination of the food supplies.

The facility needs to review its cleaning and sanitization schedule and ensure that all staff are familiar with these practices to ensure that primary enclosures are free of excessive fecal material.

Correct from this date forward 4/5/17.

### 3.56(c)

#### **SANITATION.**

Housekeeping.

\*The following housekeeping issues were identified in rabbit housing areas. There was a rabbit restraining device ready for use that had dried fecal material on its surface; there were several spots of dried blood on the shelf of a metal cart and on a blood tube holder; the Elizabethan collars of 3 rabbits had fecal material wedged between the edges of the collar at the closure snaps; and there was dried blood inside the autoclave sterilization pouch that was being used to store syringes filled with saline.

Per this Section of the Regulations, premises shall be kept clean in order to facilitate prescribed husbandry practices. The presence of dried fecal material and or blood on equipment does not constitute good housekeeping and husbandry practices.

The facility needs to review its housekeeping practices and ensure that all staff are familiar with these practices in order to maintain the cleanliness of the premises.

Correct from this date forward 4/5/17.

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NOTE – Inspection conducted 4/3/17 thru 4/5/17. Exit briefing held on-site 4/5/17 with facility personnel.

\*END OF REPORT\*

### Additional Inspectors

Lopinto John, Veterinary Medical Officer

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## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
147	14-R-0101	001	TOXIKON CORPORATION	03-APR-17

Count	Scientific Name	Common Name
000090	<i>Canis lupus familiaris</i>	DOG ADULT
000838	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000017	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000006	<i>Mesocricetus auratus</i>	SYRIAN HAMSTER (GOLDEN HAMSTER)
000628	<i>Oryctolagus cuniculus</i>	EUROPEAN RABBIT
000009	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
<b>001588</b>	<b>Total</b>	