

Every research facility, exhibitor, carrier, and intermediate handler not required to be licensed under Section 3 of the Animal Welfare Act, shall register with the USDA (7 USC 2136). This application provides information for such registration.

OMB No. 0579-0036  
FORM APPROVED

U.S. DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE  
**APPLICATION FOR REGISTRATION**  
(TYPE OR PRINT)

**REGISTRATION UPDATE**

**USDA USE ONLY**

Applicant should send completed form to this address.  
USDA APHIS ANIMAL CARE  
EASTERN  
920 Main Campus Drive  
Suite 200  
Raleigh, NC 27606-5210  
(919) 855-7100

OCT 27 2017

**CERTIFICATE NO./CUST NO:**

14-R-0101

147

**RENEWAL DATE**

15-Nov-2017

Vmc.

**1. REGISTRANT (Name and permanent mailing address, including Zip Code)**

Toxikon Corporation  
15 Wiggins Ave  
Bedford, MA 01730

COUNTY: MIDDLESEX TELEPHONE (781) 275 - 3330

**3. (A) PREVIOUS USDA REGISTRATION NUMBER (IF ANY)**

N/A

**2. LOCATION (S) OF BUSINESS, EXHIBITION SITE(S), OR RESEARCH FACILITIES**  
(Use additional sheets if necessary)

15 Wiggins Ave  
Bedford, MA 01730  
County: Middlesex

(b) (7)(F)

**4. (B) ACTIVE USDA CERTIFICATE NUMBER(S) IN WHICH YOU HAVE AN INTEREST:**

N/A

**5. ARE YOU USING FEDERAL FUNDS TO CARRY OUT**

RESEARCH, TESTS, OR EXPERIMENTS

☐ Yes ☒ No

**6. TYPE OF REGISTRATION:**

☒ Class E - Exhibitor ☐ Class H - Intermediate Handler  
☒ Class R - Research Facility ☐ Class T - Carrier

**7. FEDERAL FUND TYPES:**

☒ Award ☐ Contract ☐ Grant ☐ Loan

**8. TYPE OF ORGANIZATION:**

☐ Partnership ☐ Corporation ☐ Individual  
☒ Other (Specify)

**9. IF INDIVIDUAL IDENTIFY EACH OWNER, IF PARTNERSHIP IDENTIFY EACH PARTNER OR OFFICER, IF CORPORATION, IDENTIFY PRINCIPAL OFFICERS FOR RESEARCH FACILITIES INCLUDE THE INSTITUTIONAL OFFICIAL (Use separate sheet if needed)**

A. NAME	B. TITLE	C. ADDRESS (full address, including ZIP Code)
Laxman S. Desai	President and IO	TOXIKON CORPORATION 15 WIGGINS AVE Bedford, MA 01730

**CERTIFICATION**

I hereby register as a Research Facility, Exhibitor, Carrier, or Intermediate Handler under the Animal Welfare Act, 7 U.S.C. 2131 et seq. and I certify that the information provided herein is true and correct to the best of my knowledge. I hereby acknowledge receipt of and agree to comply with all the regulations and standards contained in 9 CFR, Subpart A, parts 1, 2 and 3. I certify that all listed persons are 18 years of age or older.

**10. SIGNATURE**

**11. NAME AND TITLE (Type or Print)**

**12. DATE SIGNED**

Laxman S. Desai, President

10/24/17

ACKNOWLEDGEMENT OF RECEIPT OF REGULATIONS AND STANDARDS



Animal and Plant  
Health Inspection  
Service

August 31, 2017

Certified Mail Return Receipt:  
7017 0530 0000 3207 5064

Animal Care  
700 River Road  
Pawcatent, MD 20737

Toxikon Corporation  
15 Wiggins Ave  
Bedford, MA 01730  
Attn: Dr. Laxman S. Desai

Customer No.: 147  
Registration No.: 14-R-0101

**RE: Official Warning; Notice of Alleged Violation**

Dear Registrant:

Our agency, the Animal and Plant Health Inspection Service, is responsible for enforcing the Animal Welfare Act (7 U.S.C. § 2131 *et seq.*) (AWA), and other agricultural laws that help prevent the spread of animal and plant pests and diseases and ensure the welfare of animals. We have reason to believe that you failed to comply with the regulations issued under the AWA, as described in the enclosed attachments. Noncompliance with the regulations can have serious and costly impacts that are detrimental to animals and the public interest. You should take prompt action to correct noncompliances and establish procedures so they do not recur.

Please know that after providing you with an opportunity for a hearing, our agency may pursue civil penalties and other sanctions for each alleged violation of the AWA and regulations. Although we have authority to pursue penalties for the allegations in the attachment, we have decided not to do so in this instance, so long as you comply with the AWA and regulations in the future.

If you have any questions concerning this letter, please contact 970-494-7478.

Sincerely,

Gerald Rushin  
Assistant Deputy Administrator  
Animal Care

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

**USDA**  
**OFFICIAL WARNING**

**NOTICE OF ALLEGED VIOLATION**

**CASE NUMBER:**  
MA170012

**VIOLATOR:**  
Toxikon Corporation

**Customer#** 147  
**License#** 14-R-0101

**ADDRESS (City, State):**  
Bedford, MA

The Animal and Plant Health Inspection Service (APHIS) has evidence that on or about April 3, 2017, you failed to comply with the regulations issued under the Animal Welfare Act (7 U.S.C. § 2131 *et seq.*) (AWA), as documented in the attached inspection report(s).

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 animals and the public interest, APHIS is providing you with this Official Warning. This Official Warning is not to be construed as a final agency action or an adjudicated finding of a violation. If APHIS obtains evidence of any violation of these Federal regulations in the future, APHIS may pursue civil penalties and other sanctions for these alleged violations and for any future violations. If you have any questions concerning this Official Warning, please contact the APHIS office telephone number listed in this notice.

**APHIS OFFICIAL (Name):**  
Gerald Rushin

**OFFICE ADDRESS:**  
4700 River Road  
Riverdale, MD 30737

**APHIS OFFICIAL (TITLE):**  
Assistant Deputy Administrator  
Animal Care

<b>DATE ISSUED:</b>	<b>TELEPHONE NO:</b>
August 31, 2017	(970) 494-7478

**CERTIFIED MAIL RECEIPT NO:**  
7017 0530 0000 3207 5064





## 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.

#### Prepared By:

GLADUE PAULA, V M D USDA, APHIS, Animal Care

Date:

05-APR-2017

Title: VETERINARY MEDICAL OFFICER 1054

#### Received By:

Obtained by Rise for Animals. Uploaded 07/06/2020

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

Title: ATTENDING VETERINARIAN  
19-04198\_000006

Date:

05-APR-2017



## Inspection Report

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### 2.33(b)(5) CRITICAL

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

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

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#### Prepared By:

GLADUE PAULA, V M D      USDA, APHIS, Animal Care

Date:  
05-APR-2017

Title:      VETERINARY MEDICAL OFFICER    1054

#### Received By:

Obtained by Rise for Animals. Uploaded 07/06/2020

(b) (6), (b) (7)(C)  
Title:      ATTENDING VETERINARIAN  
19-04198\_000007

Date:  
05-APR-2017



## Inspection Report

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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.

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.

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#### Prepared By:

GLADUE PAULA, V M D      USDA, APHIS, Animal Care

**Date:**  
05-APR-2017

**Title:**      VETERINARY MEDICAL OFFICER    1054

#### Received By:

**Obtained by Rise for Animals. Uploaded 07/06/2020**

**(b) (6), (b) (7)(C)**  
**Title:**      ATTENDING VETERINARIAN  
19-04198\_000008

**Date:**  
05-APR-2017



## Inspection Report

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### 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 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

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#### **Prepared By:**

GLADUE PAULA, V M D      USDA, APHIS, Animal Care

#### **Date:**

05-APR-2017

**Title:**      VETERINARY MEDICAL OFFICER    1054

#### **Received By:**

**Obtained by Rise for Animals. Uploaded 07/06/2020**

**(b) (6), (b) (7)(C)**  
**Title:**      ATTENDING VETERINARIAN  
19-04198\_000009

#### **Date:**

05-APR-2017



## Inspection Report

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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.

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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### Prepared By:

GLADUE PAULA, V M D      USDA, APHIS, Animal Care

**Date:**  
05-APR-2017

**Title:**      VETERINARY MEDICAL OFFICER    1054

### Received By:

**Obtained by Rise for Animals. Uploaded 07/06/2020**

**Title:**      (b) (6), (b) (7)(C)  
ATTENDING VETERINARIAN  
19-04198\_000010

**Date:**  
05-APR-2017





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

Count	Species
000006	SYRIAN HAMSTER (GOLDEN HAMSTER)
000009	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000017	CRAB-EATING MACAQUE / LONG-TAILED MACAQUE / CYNOMOLGUS MONKEY
000090	DOG ADULT
000628	EUROPEAN RABBIT
000838	DOMESTIC GUINEA PIG
<b>001588</b>	<b>Total</b>

MAY 04 2017

Research Facility Protocol Selection Worksheet<sup>\*</sup>Legal Name : Toxikon CorporationCustomer Number: 147Certificate Number: 14-R-0101Inspection Date: 4/3/17 thru 4/5/17Site Number: 001Inspector: VMOs PGladue & JLopinto

Reasons Protocols Were Selected for Review :	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	0
2. Column E protocols ( select all)	0
3. Protocols with IACUC-approved exemptions/exceptions (select all)	0
4. Protocols cited as noncompliant and not corrected during the last inspection (select all)	0
5. Additional Protocols Selected: a. If <5 remaining protocols, select all remaining:  b. If >5 remaining protocols, select 5 additional protocols: 1) Protocol for each regulated species and/or, 2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance):	7
<b>Total Protocols Selected and Reviewed</b>	7

\*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.



## 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: 30-OCT-2017

There were no non-compliant items identified during the inspection..

NOTE - Inspection conducted 10/30/17 and 10/31/17. Exit briefing held 10/31/17 on-site with facility representatives.

\*END OF REPORT\*

### Additional Inspectors

Lopinto John, Veterinary Medical Officer

### Prepared By:

GLADUE PAULA, V M D USDA, APHIS, Animal Care

Date:  
31-OCT-2017

Title: VETERINARY MEDICAL OFFICER 1054

### Received By:

Obtained by Rise for Animals. Uploaded 07/06/2020

Title:  
19-04198\_000013

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

Date:  
31-OCT-2017



Cust No	Cert No	Site	Site Name	Inspection
147	14-R-0101	001	TOXIKON CORPORATION	30-OCT-17

Count	Species
000001	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000001	SYRIAN HAMSTER / GOLDEN HAMSTER (INCLUDES COMMON NON-DWARF PET STORE VARIETIES)
000005	CRAB-EATING MACAQUE / LONG-TAILED MACAQUE / CYNOMOLGUS MONKEY
000044	DOG ADULT
000446	DOMESTIC RABBIT / EUROPEAN RABBIT
000802	DOMESTIC GUINEA PIG
<b>001299</b>	<b>Total</b>



## 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: 26-MAR-2018

### 2.33(b)(3)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

In Nov 2017 a medical emergency developed with an animal on study following the administration of a test article. Study personnel contacted a non-veterinarian who rendered emergency care but the condition of the animal declined and was euthanized. Although there was a qualified veterinarian available on-site, study personnel did not contact him/her directly to provide information on the emergency condition that developed in the animal.

Per this Section of the Regulations, daily observation of animals may be accomplished by someone other than the attending veterinarian but a mechanism of direct and frequent communication to the veterinarian is required so that timely and accurate information on problems of animal health is conveyed to the veterinarian. Failure to contact a veterinarian when problems of animal health develop can compromise animal welfare.

Correct from this date forward 3/28/18.

Inspection conducted 3/26/18 thru 3/28/18 with facility personnel. Exit briefing held 3/28/18 with facility personnel.

#### Additional Inspectors

Lopinto John, Veterinary Medical Officer  
Gladue Paula, Veterinary Medical Officer

#### Prepared By:

KARR EILIS USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 6127

Date:  
28-MAR-2018

#### Received By:

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

Title: IACUC CHAIR  
19-04198\_000015

Obtained by Rise for Animals. Uploaded 07/06/2020

Date:  
28-MAR-2018





## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
147	14-R-0101	001	TOXIKON CORPORATION	26-MAR-18

Count	Scientific Name	Common Name
000088	<i>Canis lupus familiaris</i>	DOG ADULT
001232	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000003	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000001	<i>Mesocricetus auratus</i>	SYRIAN / GOLDEN HAMSTER (COMMON PET/RESEARCH TYPE)
000523	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000014	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
<b>001861</b>	<b>Total</b>	

## Research Facility Protocol Selection Worksheet <sup>\*</sup>

Legal Name : Toxikon Corporation

Customer Number: 147

Certificate Number: 14-R-0101

Inspection Date: 3/26/18 thru 3/28/18

Site Number: 001

Inspector: EKarr, PGladue & JLopinto

Reasons Protocols Were Selected for Review :	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	0
2. Column E protocols ( select all)	1
3. Protocols with IACUC-approved exemptions/exceptions (select all)	0
4. Protocols cited as noncompliant and not corrected during the last inspection (select all)	0
5. Additional Protocols Selected: a. If <5 remaining protocols, select all remaining:  b. If >5 remaining protocols, select 5 additional protocols: 1) Protocol for each regulated species and/or, 2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance):	7
<b>Total Protocols Selected and Reviewed</b>	<b>8</b>

\*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.



## 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: 15-OCT-2018

### 2.31(c)(4)

#### INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

In April of 2018, the escape of several rabbits from their enclosures was reported to the IACUC. Additional training on rabbit caging was provided to personnel. Three days after the training was conducted, two more rabbits escaped. No additional corrective action was taken at that time. From August to September 2018, six additional rabbits escaped from their enclosures. These incidents were all reported to the IACUC by facility personnel. No further action has been taken.

The enclosures at this facility are elevated off the floor on a rack system, and there is a substantial risk of injury to the rabbits upon escape from these enclosures. These incidents are recurrent despite the additional training provided by the facility in April. Further investigation of the underlying cause of the escapes is warranted to protect the animals from potential injury. It is the function of the IACUC to review and investigate reported concerns involving the care of animals.

To be corrected by: November 16th, 2018

### 2.32(a) CRITICAL

#### PERSONNEL QUALIFICATIONS.

On August 24, 2018, an animal was anesthetized for a study procedure. Two research associates were present to administer and monitor anesthesia. One was a senior employee who was training a junior employee in anesthetic procedures. The junior employee was responsible for pressure checking the anesthesia machine prior to the procedure.

The animal was intubated and its vitals were recorded. Eight minutes later, the animal's heart rate was noted to decline rapidly. The machine was checked and it was discovered that the pop-off valve had remained closed after the initial pressure check, leading to breathing complications. The veterinarian was immediately notified and

#### Prepared By:

KARR EILIS USDA, APHIS, Animal Care

#### Date:

22-OCT-2018

Title: VETERINARY MEDICAL OFFICER 6127

#### Received By:

Obtained by Rise for Animals. Uploaded 07/06/2020

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

Title: IACUC CHAIR  
19-04198\_000018

#### Date:

23-OCT-2018



## Inspection Report

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resuscitation was attempted but was unsuccessful.

The anesthetic complications and subsequent death of the animal were the result of failure of personnel to correctly configure the anesthetic machine after the initial pressure check. It is the responsibility of the research facility to ensure that personnel involved in animal care, treatment, and use are qualified to perform their duties.

In response to this incident, the facility immediately conducted additional training on anesthetic machine use and there have been no additional related incidents. Corrected prior to inspection.

This inspection was conducted from 10/15 - 10/16/18. An initial exit interview was conducted on site on 10/16/18. A supplemental exit interview was conducted on site on 10/23/18.

### Additional Inspectors

Gladue Paula, Veterinary Medical Officer

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### Prepared By:

KARR EILIS      USDA, APHIS, Animal Care

**Date:**  
22-OCT-2018

**Title:**      VETERINARY MEDICAL OFFICER    6127

### Received By:

**Obtained by Rise for Animals. Uploaded 07/06/2020**

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

**Title:**      IACUC CHAIR  
19-04198\_000019

**Date:**  
23-OCT-2018



## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
147	14-R-0101	001	TOXIKON CORPORATION	15-OCT-18

Count	Scientific Name	Common Name
000042	<i>Canis lupus familiaris</i>	DOG ADULT
002160	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000009	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000414	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000014	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
<b>002639</b>	<b>Total</b>	



\*

## Research Facility Protocol Selection Worksheet

Legal Name : Toxikon Corporation

Customer Number: 147

Certificate Number: 14-R-0101

Inspection Date: 10/15/18

Site Number: 001

Inspector: Eilis Karr

Reasons Protocols Were Selected for Review :	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	
2. Column E protocols ( select all)	0
3. Protocols with IACUC-approved exemptions/exceptions (select all)	1
4. Protocols cited as noncompliant and not corrected during the last inspection (select all)	0
5. Additional Protocols Selected: a. If <5 remaining protocols, select all remaining:  b. If >5 remaining protocols, select 5 additional protocols: 1) Protocol for each regulated species and/or, 2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance):	5
<b>Total Protocols Selected and Reviewed</b>	6

\*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.



## 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: 08-APR-2019

### 2.38(f)(1) CRITICAL

#### MISCELLANEOUS.

On 3/8/19, a rabbit was placed in a restraint device on top of a counter prior to the induction of anesthesia. During induction, the rabbit escaped from the restraint device onto the counter and ended up in the sink that was set into the counter. Research staff re-restrained the rabbit and proceeded with induction of anesthesia. During anesthetic recovery, the animal vocalized and attempted to right itself from recumbency. Veterinary staff was immediately contacted to assess the animal. On examination, a spinal fracture was identified and the animal was humanely euthanized. Veterinary staff determined that the fracture occurred between pre-anesthetic assessment of the animal and its recovery from anesthesia. Inspection of the restraint device by facility personnel revealed a damaged latch that prevented secure closure of the device. The damaged restraint device did not allow for safe handling of the animal. Per this section of the regulations, handling shall be done as carefully as possible in a manner that does not cause trauma or physical harm.

This item has been corrected, as the facility has inspected all restraint devices and replaced them as necessary. This event was self-reported to the USDA.

This inspection was conducted from 4/8/19 - 4/9/19. This exit briefing was conducted on site with facility personnel on 4/9/19.

#### Additional Inspectors

Gladue Paula, Veterinary Medical Officer

#### Prepared By:

KARR EILIS, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 6127

Date:  
09-APR-2019

#### Received By:

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

Title: IACUC CHAIR  
19-04198\_000022

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Date:  
09-APR-2019



## Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
147	14-R-0101	001	TOXIKON CORPORATION	08-APR-19

Count	Scientific Name	Common Name
000054	<i>Canis lupus familiaris</i>	DOG ADULT
001427	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000014	<i>Macaca fascicularis</i>	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000525	<i>Oryctolagus cuniculus</i>	DOMESTIC RABBIT / EUROPEAN RABBIT
000024	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
<b>002044</b>	<b>Total</b>	

## Research Facility Protocol Selection Worksheet<sup>\*</sup>

Legal Name: Toxikon

Customer Number: 147

Certificate Number: 14-R-0101

Site Number: 001

Inspection Date: 4/8/19

Inspection Type: Routine ☒ Focused ☐ (list areas inspected)

Inspector: Ellis Karr and Paula Gladue

Reasons Protocols Were Selected for Review :	How Many Protocols Were Selected
1. Protocols identified during inspection of concern (select all)	0
2. Column E protocols ( select all)	1
3. Protocols with IACUC-approved exemptions/exceptions (select all)	0
4. Protocols cited as noncompliant and not corrected during the last inspection (select all)	0
5. Additional Protocols Selected: a. If <5 remaining protocols, select all remaining:  b. If >5 remaining protocols, select 5 additional protocols: 1) Protocol for each regulated species and/or, 2) Protocols involving high risk procedures (see Chapter 7, Animal Welfare Inspection Guide for guidance):	4
<b>Total Protocols Selected and Reviewed</b>	5

\*Note: Protocol selection guidance applies to protocols which have been initially approved, or have had significant changes approved, since the last inspection. For protocols reviewed by an Animal Care Veterinary Medical Officer within the last year, professional judgment should be used in determining whether another review is necessary.

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