



Inspection Report

ROCHE PALO ALTO, L.L.C.

Customer ID: **1180**

Certificate: **93-R-0029**

Site: 001

ROCHE PALO ALTO, L.L.C.

3431 HILLVIEW AVENUE

Type: ROUTINE INSPECTION

PALO ALTO, CA 94304

Date: Dec-08-2009

This is a partial inspection. All previously identified DIRECT non-compliant items have been corrected. No regulated species were present during this inspection.

Prepared By:

ANIL SHARMA, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5049

Dec-08-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Dec-08-2009



Inspection Report

ROCHE PALO ALTO, L.L.C.

Customer ID: 1180

Certificate: 93-R-0029

Site: 001

ROCHE PALO ALTO, L.L.C.

3431 HILLVIEW AVENUE

Type: ROUTINE INSPECTION

PALO ALTO, CA 94304

Date: Sep-02-2009

2.31 (e) (4) DIRECT NCI

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

*** (e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals.***

The IACUC-approved protocol 2005-53, "Airway Inflammation and Bronchial Hyperactivity in Oval albumin-Sensitized Guinea Pigs", had a significant deviation involved in which surgically modified animals (Jugular Vein Catheterization) were purchased from an approved vendor. The protocol had no description and /or justification for the use, creation or acquisition of conscious catheterized animals. The lack of description for the animals with intact jugular catheter exposed the animals to the potential of serious injury due to chewing of catheters, infection and death resulting from loss of blood through a damaged catheter port. Lack of adequate description in the protocol for the proper housing of the catheterized animals, created misunderstanding among the animal handlers and hence, exposed the animals to undue sufferings. The protocol also lacked neither provision for maintenance of catheters and potential for complications that may arise because of the surgical modification (jugular catheterization) nor of the additional animal welfare oversight that is required to ensure the health of the animals.

The IACUC did not have approval for any of the activities involved in this significant deviation, therefore descriptions of procedures did not fulfill the requirements of the regulation cited above, that would have assured that discomfort and pain to the animals will be limited to that which is unavoidable. In order to approve proposed activities or proposed significant changes in ongoing activities involving animals, the proposal must contain a description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs. A system is needed which would ensure that proposal to conduct significant changes to activities involving the animals must have complete description of procedures designed to assure that discomfort and pain to animals will be limited and the proposals are reviewed and approved by the IACUC prior to being implemented.

Prepared By:

ANIL SHARMA, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5049

Nov-06-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Nov-06-2009



Inspection Report

Additional training and procedures have been put in place and necessary amendments have been made to protocol since the incident to ensure that re-occurrence of this nature may be avoided in future. All protocols are to be corrected before any covered use of covered species.

2.31 (d) (1) (vi) DIRECT NCI

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

***(d) IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this sub-chapter unless acceptable justification for a departure is presented in writing; Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (vi) The animals' living conditions will be appropriate for their species in accordance with part 3 of this sub-chapter, and contribute to their health and comfort. The housing, feeding, and non-medical care of the animals will be directed by the attending veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied. ***

The IACUC approved protocol 2005-53, "Airway Inflammation and Bronchial Hyperactivity in Oval albumin-Sensitized Guinea Pigs", had a significant deviation involved in which surgically modified animals (Jugular Vein Catheterization) were purchased from an approved vendor. The animals were group-housed after arrival because the protocol did not have any provision and /or justification for the use, creation or acquisition of conscious catheterized animals. Because of the altered living conditions, the animals chewed on the catheters and wound clips of their cage-mates, causing significant threat to their health. The animals were exposed to the potential of serious injury, including infection and death, resulting from loss of blood through a damaged catheter port. The single-housing, which is necessary for catheterized animals, could not be provided because of inadequate provisions in the protocol. After the approval of a protocol, the IACUC has a responsibility to ensure that procedures are carried out as described in the protocol. In order to approve proposed activities or significant proposed changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine whether the proposed activities are in accordance with this sub-chapter. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the requirement that the animals' living conditions will be appropriate for their species in accordance with part 3 of this sub-chapter, and contribute to their health and comfort. Due to the Principal Investigator's significant deviation in this protocol, the IACUC failed to adhere to the requirement to provide appropriate living conditions for the species in accordance with Part 3 of this sub-chapter that contribute to the health and comfort of the animals. A system is needed which would ensure that significant proposed changes to activities involving the care and use of the animals are reviewed and approved by the IACUC prior to being implemented. Proper preventive measures, including retraining of the employees involved and revisions in the present protocol were immediately taken to avoid any future harm to the animals.

Correct for all covered use of covered species. All other animal use protocols are to be corrected before any procedures can be done on any covered species.

Prepared By:

ANIL SHARMA, D.V.M. USDA, APHIS, Animal Care

Date:

Nov-06-2009

Title: VETERINARY MEDICAL OFFICER Inspector 5049

Received By:

(b)(6), (b)(7)(c)

Date:

Nov-06-2009

Title:



Inspection Report

2.131 (b) (1) **DIRECT NCI**

HANDLING OF ANIMALS.

(b)(1) 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.

Two non-human primates escaped from their cages. One animal escaped during the scheduled cage change and the other animal broke an access panel in a transfer tunnel. As per IACUC minutes, "both animals received minor injuries before recapture."

In another incident, twenty guinea pigs were received from the vendor with jugular vein catheterization. While the vendor provided an instruction sheet advising that the animals should be housed individually, the animal handlers, including the PI, failed to follow the vendor's instructions and group-housed the animals. The animals were exposed to the potential of serious injuries including infection and death resulting from loss of blood through a damaged catheter port due to the handling of the animals in this fashion. Animal handling should be done as expeditiously and carefully as possible, and in a manner that does not cause trauma, behavioral stress, physical harm or unnecessary discomfort.

Additional training and procedures have been put in place since the incident to ensure that re-occurrence of this nature may be avoided. A system needs to be in place to prevent escapes, as well as injuries (for all species) due to inadequate care and handling by November 12, 2009.

3.75 (a) **DIRECT NCI**

HOUSING FACILITIES, GENERAL.

(a) Structure: construction. Housing facilities for nonhuman primates must be designed and constructed so that they are structurally sound for the species of nonhuman primates housed in them. They must be kept in good repair, and they must protect the animals from injury, contain the animals securely, and restrict other animals from entering.

One non-human primate escaped from the cage by breaking the access panel in a transfer tunnel. "The animal suffered minor injuries before it was captured". All housing facilities for non-human primates must be designed and constructed so that they are structurally sound for the species. The housing facilities, including cages, must be kept in good repair to protect the animals from injury, contain the animals securely, and restrict other animals from entering. A system must be in place that assures proper monitoring and timely repairs of the structures of the housing facilities including cages, so that any injuries to the animals could be prevented.

This is already corrected. A system needs to be in place to prevent escapes, injuries (for all species) by November 12, 2009.

Prepared By:

ANIL SHARMA, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5049

Nov-06-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Nov-06-2009



Inspection Report

ROCHE PALO ALTO, L.L.C.

Customer ID: **1180**

Certificate: **93-R-0029**

Site: 001

ROCHE PALO ALTO, L.L.C.

3431 HILLVIEW AVENUE

Type: ROUTINE INSPECTION

PALO ALTO, CA 94304

Date: Sep-16-2008

No non-compliant items were identified during this inspection.

Prepared By:

ANIL SHARMA, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5049

Sep-16-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Sep-17-2008



Inspection Report

ROCHE PALO ALTO, L.L.C.

Customer ID: **1180**

Certificate: **93-R-0029**

Site: 001

ROCHE PALO ALTO, L.L.C.

3431 HILLVIEW AVENUE

Type: ROUTINE INSPECTION

PALO ALTO, CA 94304

Date: May-30-2007

No non-compliant items were identified during this inspection.

Prepared By:

ANIL SHARMA, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5049

May-30-2007

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

May-30-2007