



Inspection Report

HARVARD MEDICAL SCHOOL

Customer ID: **107**

CTR ANM RES/COMP MED 665 HUNTINGTON

Certificate: **14-R-0019**

Site: 001

ARCM/WARREN APLPERT BLDG

BOSTON, MA 02115

Type: ROUTINE INSPECTION

Date: Nov-03-2008

There were no non-compliant items identified during the inspection. Registrant was in compliance with AWA Regulations and Standards at the time of the inspection.

NOTE - This was a full facility inspection of the Main Location of the Registrant in Boston, MA conducted by USDA/APHIS/AC VMOs Paula S. Gladue, V.M.D. and Tonya Hadjis, D.V.M. from 11/3/08 through 11/5/08 with exit interview on 11/5/08.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

Nov-05-2008

Received By:

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

Date:

Title:

Nov-05-2008



Inspection Report

HARVARD MEDICAL SCHOOL

Customer ID: 107

Certificate: 14-R-0019

Site: 001

ARCM/WARREN APLPERT BLDG

CTR ANM RES/COMP MED 665 HUNTINGTON AVE

Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: Jul-09-2008

3.75 (c) (1) (i)

HOUSING FACILITIES, GENERAL.

3.75 (c) (1) (i) - " Any surfaces that come in contact with nonhuman primates must: (i) Be free of excessive rust that prevents the required cleaning and sanitization."

1. The facility uses "C" clamps to secure enrichment devices to primary enclosures. The "C" clamp attached to the front of an enclosure in 548 was noted to be rusty. The presence of rust can prevent effective cleaning and sanitization.

Facility corrected this item at the time of inspection by removing the "C" clamp from the primary enclosure.

3.75 (e) **REPEAT**

HOUSING FACILITIES, GENERAL.

3.75 (e) - "Supplies of food and bedding must be stored.....away from the walls."

1. REPEAT item: There were bags of food stored up against the wall in the food storage room located near the RB5 loading dock. This method of storage for food supplies does not allow for cleaning around the bags of stored food.

Facility corrected this item during the inspection by moving the bags of food away from the wall.

3.80 (a) (2) (i)

PRIMARY ENCLOSURES.

3.80 (a) (2) (i) - "Primary enclosures must be constructed and maintained so that they: (i) Have no sharp points or edges that could injure the nonhuman primates."

1. One water bottle in 307 was noted to be secured to the front of the primary enclosure using several heavy duty tie wraps. The ends of the tie wraps projected into the enclosure and were approximately 4 inches in length. The

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presence of the long ends of the tie wraps inside the enclosure posed a hazard to the NHP housed in the enclosure from chewing on and ingesting a piece of the tie wrap or causing an injury to the animal's eye(s).

2. There was a broken weld noted on the metal grid top of an enclosure in 400. One end of the weld was approximately 1 inch long and was noted to be sticking into the enclosure and could cause an injury to the NHP housed in the enclosure.

Primary enclosures must be maintained so there are no sharp points or edges that could result in injury to the NHP. Facility immediately corrected item 1 at the time of the inspection by trimming the excess length from the tie wraps. Facility corrected item 2 during the inspection by moving the NHP to a different enclosure.

3.80 (a) (2) (iii)

PRIMARY ENCLOSURES.

3.80 (a) (2) (iii) - "Primary enclosures must be constructed and maintained so that they: (iii) Contain the nonhuman primates securely and prevent accidental opening of the enclosure, including opening by the animal."

1. NHP #116-98 housed in 574 was discovered by personnel to be loose inside the room on the morning of 7/9/08. It was determined that the NHP was able to escape from its primary enclosure because personnel had not properly secured one of the latching mechanisms on the enclosure the previous evening. As a result of the escape, NHP #116-98 received a cut to one of its hands and another NHP in the room also sustained a minor hand injury.

Primary enclosures must be maintained to securely contain NHP and prevent accidental opening of the enclosures by the NHP. The facility added another clasp to secure the NHP's primary enclosure and also reviewed the proper procedures with personnel to secure NHP in their primary enclosures to prevent accidental opening of the enclosures by the animals. The facility has addressed this item.

3.81 (c) (2)

ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

3.81 (c) (2) - "Special considerations. Certain nonhuman primates must be provided special attention regarding enhancement of their environment, based on the needs of the individual species and in accordance with the instructions of the attending veterinarian. Nonhuman primates requiring special attention are the following: (2) Those that show signs of being in psychological distress through behavior or appearance."

1. NHP #CRA 23-08, CRA 28-08, and CRA 24-08 housed in 518 were noted by the inspector to be exhibiting abnormal behaviors compatible with psychological distress (saluting; circling; pouncing). According to their medical records, the facility had identified the abnormal behaviors in the NHP on 6/20/08. There was no documentation that the NHP were being provided special attention regarding enhancement of their environment as required by this Section.

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NHP exhibiting signs of being in psychological distress must be provided with special attention regarding enhancement of their environment. Facility addressed this item during the inspection by one of the clinical veterinarians performing an assessment of the NHPs and providing special attention.

NOTE - This inspection was of the New England Regional Primate Research Center, a separate location of Site 001 of 14-R-0019 and was conducted on 7/9/08 and 7/10/08 with the exit on 7/10/08. IACUC records and documents are reviewed at the Main Location of Registrant in Boston, MA.

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Site: 001

ARCM/WARREN APLPERT BLDG

CTR ANM RES/COMP MED 665 HUNTINGTON AVE

Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: Jan-28-2008

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (e) (3) - "A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (3) A complete description of the proposed use of the animals."

1. Review of Protocol #2440:

a. The chart on page 8 provides a summary of the number of Cats to be used in each procedure described in the protocol. According to the chart, Cats are only used in procedures that are categorized as USDA "D". The number of Cats to be used in the USDA "D" procedures is listed as "X"; the same number "X" is given as the total number of Cats to be used in the protocol.

It was noted that page 21 of the protocol describes the use of Cats in USDA "B" procedures; however the number of Cats used in the USDA "B" procedures is not included in the summary chart on page 8. It is not clear if the number of Cats to be used in the USDA "B" procedures is included in the total number "X" of Cats to be used in the protocol.

b. Euthanasia is the only method of disposition described on page 21 for the adult Cats that are used for breeding; however it was learned that some Cats have been adopted out and at least one Cat was used in a surgical procedure (#4920 on 1/22/08).

A proposal to conduct activities involving animals must contain a complete description of the proposed use of the animals. The IACUC needs to address the items identified for this approved protocol. Correct by 3/1/08.

Prepared By:

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Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

Jan-30-2008

Received By:

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

Date:

Title:

Jan-30-2008



Inspection Report

NOTE - This was a full facility inspection of the Main Location of the Registrant in Boston, MA that was conducted from 1/28/08 through 1/30/08 with the exit interview on 1/30/08.

Prepared By:

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Date:

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Jan-30-2008

Received By:

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

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HARVARD MEDICAL SCHOOL

Customer ID: **107**

Certificate: **14-R-0019**

Site: 001

ARCM/WARREN APLPERT BLDG

CTR ANM RES/COMP MED 665 HUNTINGTON AVE

Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: Jul-23-2007

This was a focused inspection based on the non-compliant items that were identified during the last inspection. Facility has successfully corrected all of the non-compliant items from the last inspection.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

Jul-23-2007

Received By:

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

Date:

Title:

Jul-23-2007



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Site: 001

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Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: Jun-11-2007

2.31 (d) (1) (ii) REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (1) (ii) - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources.....used to determine that alternatives were not available."

1. Review of Protocol #02317:

a. The written narrative of the methods and sources used to determine that alternatives were not available to the potentially painful or distressful procedures described in the proposal for animal use does not include the procedure of water control that is described in the proposal. A principal investigator is required to consider alternatives to all potentially painful and distressful procedures described in a proposal for animal use. The IACUC needs to address this issue for this proposal.

2.33 (b) (2) REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (2) - "Each research facility shall establish and maintain programs of adequate veterinary care that include: (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries."

1. REPEAT ITEM: The following outdated medical supply was identified in WA-213: Betadine Solution, 1 gallon bottle, #1, exp 8/06. All medications should be in current dating.

2. REPEAT ITEM: There was no exp date written on the labels of surgical solutions that had been transferred to secondary containers from stock bottle supplies in the following areas. The exp date of a stock bottle should be recorded on the secondary container to ensure that the product is in current

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Jun-14-2007

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Date:

Title:

Jun-14-2007



Inspection Report

dating.

- a. WA-213: Plastic spray bottle of Betadine.
- b. WA-204 and WA-207: Plastic squirt bottles of Nolvasan; Canisters of 2x2 gauze squares with Betadine Solution; and Canisters of 2x2 gauze squares with Betadine Scrub.

2.33 (b) (5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (5) - "Each research facility shall establish and maintain programs of adequate veterinary care that include:
(5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures."

1. Review of Protocol #02317 and NHP #377-05 Medical Record:

a. The protocol includes a major operative procedure of several hours duration under general anesthesia. NHP #377-05 underwent surgery on 5/22/07. The protocol states that following recovery from general anesthesia, the NHP will be monitored every 30 minutes for 6 hours. There was no documentation in the NHP's medical record that this post-operative monitoring took place.

b. The protocol states that Buprenorphine will be administered post-operatively every 12 hours for 48 hours. According to the medical record for NHP #377-05, Buprenorphine was administered from 5/22/07 through 5/24/07 in the "AM" and "PM", but the time of administration is not specified. It is not clear from the medical record that the analgesic was administered at appropriate therapeutic intervals.

Appropriate post-operative records should be maintained to document that the animals received the prescribed post-procedural care as specified in the IACUC approved proposal for animal use. The IACUC and AV need to address the items identified for this protocol. Correct by 6/22/07.

3.81 (a) (3)

ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

3.81 (a) (3) - "Individually housed nonhuman primates must be able to see and hear nonhuman primates of their own or compatible species."

1. The Environmental Enrichment Plan for NHP (EEP) states that the configuration of cages housing individual Squirrel Monkeys will permit the NHP to have visual contact with other NHP. Squirrel NHPs #256-06 and #255-06 in SM-B027 were individually housed in enclosures positioned one above the other in a quad cage rack. There was no mirror present on either enclosure. This configuration did not allow the 2 NHP to have visual contact with each other as specified in the EEP and this Section of the Regulations. The facility needs to address this issue for these 2 NHP. Correct by 6/20/07.

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Jun-14-2007



Inspection Report

3.81

ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

3.81 - "Research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates."

1. The June 2007 Enrichment Log for NHP #256-06 and #255-06 housed in SM-B027 was reviewed on 6/11/07. There was no documentation in the log that any type of enrichment had been provided to the NHPs during the month. According to personnel, the 2 NHPs were provided with some form of environmental enrichment during that month as specified in the research facility's Environmental Enrichment Plan.

A research facility must follow and document a plan for the environment enhancement to promote the psychological well-being of NHP. Correct from this date forward.

NOTE - This was a full facility inspection conducted from 6/11/07 through 6/14/07 with the exit interview on 6/14/07.

Prepared By:

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Site: 001

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CTR ANM RES/COMP MED 665 HUNTINGTON AVE

Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: May-29-2007

3.75 (a)

HOUSING FACILITIES, GENERAL.

3.75 (a) - "Housing facilities for nonhuman primates must be?..be kept in good repair."

1. One of the ceiling mounted light fixtures in 273 - Cage wash was noted to be coming away from the ceiling at one end. Facility immediately corrected at the time of the inspection by re-securing the light cover to the fixture.

3.75 (e)

HOUSING FACILITIES, GENERAL.

3.75 (e) - "Storage. Supplies of food and bedding must be stored?....away from the walls."

1. There were bags of bedding stored up against the wall in 608. This method of storage does not allow for cleaning around the bags of stored bedding. The facility immediately corrected this item at the time of the inspection by moving the bags of bedding away from the wall.

3.80 (a) (2) (ii)

PRIMARY ENCLOSURES.

3.80 (a) (2) (ii) - "Primary enclosures must be constructed and maintained so that they: (ii) Protect the nonhuman primates from injury."

1. The metal grid panel on the front of one enclosure in 270 was noted to have a broken weld. One end of the broken weld was sticking into the enclosure and could cause an injury to the NHP. Primary enclosures must be maintained to protect an NHP from injury. Facility corrected this item during the inspection by moving the NHP into another enclosure.

Prepared By:

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May-30-2007

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May-30-2007



Inspection Report

NOTE - This inspection was of the New England Regional Primate Center, a separate location of Site 001 of Registrant 14-R-0019 and was conducted on 5/29/07 and 5/30/07 with the exit on 5/30/07. The IACUC records are reviewed at the Main Location of the Registrant.

Prepared By:

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Title: VETERINARY MEDICAL OFFICER Inspector 1054

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

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Site: 001

ARCM/WARREN APLPERT BLDG

CTR ANM RES/COMP MED 665 HUNTINGTON AVE

Type: ROUTINE INSPECTION

BOSTON, MA 02115

Date: May-10-2007

There were no non-compliant items identified during this focused inspection. Facility was in compliance with AWA Regulations and Standards.

Prepared By:

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May-10-2007

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Inspection Report

HARVARD MEDICAL SCHOOL

Customer ID: **107**

CTR ANM RES/COMP MED 665 HUNTINGTON

Certificate: **14-R-0019**

Site: 002

NEW ENGLAND REGIONAL PRIMATE

BOSTON, MA 02115

Type: ROUTINE INSPECTION

Date: Apr-21-2009

3.84

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

3.84 (c) - "Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean."

1. The wall mounted exhaust vent in 312 was noted to have a build up of dust and dirt. Housing facilities must be kept clean to facilitate the prescribed husbandry practices and provide for the health and well-being of the animals. The vent needs to be cleaned.

Registrant corrected this item during the inspection by cleaning the dirty exhaust vent.

NOTE - The inspection was conducted on 4/21/09 and 4/22/09 with the exit interview on 4/22/09. IACUC records and documents are reviewed at the main site of Registrant in Boston, MA.

Prepared By:

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Title: VETERINARY MEDICAL OFFICER Inspector 1054

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