



Inspection Report

HARVARD MEDICAL SCHOOL

Customer ID: 107

Certificate: 14-R-0019

Site: 002

NEW ENGLAND REGIONAL PRIMATE CENTER

CTR ANM RES/COMP MED 665 HUNTINGTON AVE

Type: ROUTINE INSPECTION

Date: Jun-29-2010

BOSTON, MA 02115

2.32 (a) DIRECT NCI PERSONNEL QUALIFICATIONS.

Section 2.32 (a) states - "It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel."

1. The non-compliant items identified under Sections 2.33 (b) (3) and 3.84 (a) on this inspection report pertaining to the 6/9/10 incident when the body of an NHP was found on the floor of an enclosure of a quad cage unit that had just completed a sanitization cycle in a mechanical cage washer have the potential to have direct and adverse effects on the health of the animals. Results of gross and microscopic examinations of the body are consistent with the conclusion that the NHP had died before the enclosure was put into the cage washer. This affected 1 NHP.

It is the responsibility of a research facility to ensure that all personnel involved in animal care, treatment, and use are qualified and adequately trained to perform their duties. Inadequate training in any aspects of animal care and use can result in harm to the animals and negatively affect the animals' welfare. The research facility needs to take appropriate steps to ensure that all personnel are adequately trained in the requirements of these Sections for the health and safety of the animals. Correct immediately.

2. The non-compliant item identified under Section 3.84 (b) (2) on this inspection report pertaining to (a) the changing and sanitization of used primary enclosures at a schedule other than 14 days or less and (b) the failure of personnel to document and record on the Husbandry Room Logs the research facility's compliance with the sanitization schedule as prescribed per Section 3.84 indicates a lack of familiarity with the required husbandry procedures by personnel at the research facility.

It is the responsibility of a research facility to ensure that all personnel involved in animal care, treatment, and use are adequately trained to perform their duties. The research facility needs to ensure that all personnel are instructed in: (1) the prescribed sanitization schedule for used primary enclosures and (2) the appropriate record keeping procedures for the documentation of the research facility's compliance with Section 3.84. Correct (1) and (2) by 7/8/10.

Prepared By:

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Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1054

Jul-01-2010

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2.33 (b) (3) DIRECT NCI

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33 (b) (3) states - "Each research facility shall establish and maintain programs of adequate veterinary care that include: (3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian."

1. The 6/9/10 morning health check of the NHPs in 552 was completed by personnel. A rolling quad cage unit in 552 was scheduled to be changed out following the AM health check. The NHPs housed in the 4 separate primary enclosures in the unit were moved to a new clean quad cage unit. The dirty quad cage unit was then moved to the cage wash room for sanitization. Following the completion of the sanitization cycle in the mechanical cage washer, the quad cage unit was removed from the cage washer and it was at that time that personnel discovered the body of an NHP on the floor inside one of the enclosures in the quad cage unit. Results of gross and microscopic examinations of the body are consistent with the conclusion that the NHP had died before the enclosure was put into the cage washer. This affected 1 NHP.

It is evident from the details of this incident that on 6/9/10 personnel failed to do the following procedures: (1) observe that this NHP was not exhibiting normal behavior during the morning health check; (2) recognize that all of the NHPs that were housed in the quad cage unit did not transfer to the new clean quad cage unit; (3) notice that an NHP was still inside the dirty quad cage unit when it was being taken to the cage wash room; and (4) notice that an NHP was still inside the dirty quad cage unit when it was put inside the mechanical cage washer. This affected 1 NHP.

The daily observation of all animals to assess their health and well-being to identify any problems of animal health and behavior should be done by all personnel involved with animal care. The failure of personnel to observe all animals to assess their health and well-being can have direct and adverse effects on the animals. The research facility needs to take appropriate steps to ensure that all personnel are instructed in the requirements of this Section for the health and safety of the animals. Correct immediately.

3.84 (a) DIRECT NCI

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

Section 3.84 (a) states - "Cleaning of primary enclosures.....When steam or water is used to clean the primary enclosure, whether by hosing, flushing, or other methods, nonhuman primates must be removed, unless the enclosure is large enough to ensure the animals will not be harmed, wetted, or distressed in the process."

1. A rolling quad cage unit was changed out on 6/9/10 and the NHPs housed in the 4 separate primary enclosures in the unit were moved to a new clean quad cage unit. The dirty quad cage unit was then moved to the cage wash room for sanitization. Following the completion of the sanitization cycle in the mechanical cage washer, the quad cage unit was removed from the cage washer and it was at that time that personnel discovered the body of an NHP on the floor inside one of the enclosures in the quad cage unit. Results of gross and microscopic examinations of the

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body are consistent with the conclusion that the NHP had died before the enclosure was put into the cage washer. This affected 1 NHP.

Whenever primary enclosures are cleaned using steam, NHPs must be removed to ensure the animals are not harmed, wetted, or distressed in the process. The failure of personnel to remove an NHP from a primary enclosure prior to cleaning by steam in a mechanical cage washer has direct and adverse effects on the health and well being of the animal. The research facility needs to take appropriate steps to ensure that all personnel are instructed in the requirements of this Section for the health and safety of the animals. Correct immediately.

3.84 (b) (2)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

Section 3.84 (b) (2) states - "Sanitization of primary enclosures and food and water receptacles. (2) Indoor primary enclosures must be sanitized at least once every 2 weeks and as often as necessary to prevent an excessive accumulation of dirt, debris, waste, food waste, excreta, or disease hazard."

1. The Husbandry Room Logs for several rooms were selected at random and reviewed. The following instances of a sanitization schedule associated with complete cage changes at other than the 14 day prescribed interval were noted.

a. 552: Cage change dates of 5/11/09 and 5/27/09 - 16 days; 3/16/10 and 4/1/10 - 16 days; 5/12/10 and 5/28/10 - 16 days.

b. 518 and 547: Husbandry Room Logs from 2/2009 through 5/2010 were reviewed. There were instances noted in the logs for each room when there was no documentation recorded that the cages were in fact changed at the 14 day interval as prescribed per this Section. Specifically, there were 7 instances noted for 518, and 5 instances noted for 547.

Indoor primary enclosures must be sanitized at least once every 2 weeks and as often as necessary to prevent an excessive accumulation of dirt, debris, waste, food waste, excreta, or disease hazards for the NHPs. The research facility needs to: (1) ensure that enclosures are changed and sanitized at no more than the 14 day prescribed interval; (2) ensure that all personnel are instructed in the prescribed sanitization schedule for used primary enclosures; and (3) ensure that all personnel are instructed in the appropriate record keeping procedures for the documentation of the research facility's compliance with this Section. Correct (1), (2), and (3) by 7/8/10.

NOTE - This was a focused inspection conducted in response to a complaint that was received by the Eastern Regional Office (ERO). The details of the complaint are undergoing further review by ERO.

NOTE - Exit interview held 7/1/10 with facility personnel. END OF REPORT.

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