



## Inspection Report

MCLEAN HOSPITAL CORPORATION

Customer ID: 146

Certificate: 14-R-0096

Site: 001

MC LEAN HOSPITAL

115 MILL STREET

Type: ROUTINE INSPECTION

BELMONT, MA 02478

Date: Aug-02-2011

**2.31** (e) (3)

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

A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain a complete description of the proposed use of the animals.

Protocol #095218 contains an amendment for a new procedure with the animal being placed in a closed chamber. This procedure included monitoring every 10 mins when the PI staff opened the chamber to administer test compounds and check on the animal. The first animal used in this procedure was found dead at one of the 10 minute check points. The PI staff informed the IACUC, and took many mitigating steps to prevent this problem from recurrence in future animals used for this study, one of which is to have constant access to monitor the animals. The IACUC should have considered the original monitoring procedures for an animal in a closed chamber as insufficient and the description of the amendment incomplete to ensure the safety and well-being of the animals. A proposal to be approved by the IACUC must contain a complete description of the proposed use of the animals.

This item has been corrected.

**3.76** (a) **REPEAT**

### INDOOR HOUSING FACILITIES.

Heating, cooling, and temperature. Indoor housing facilities must be sufficiently heated and cooled when necessary to protect nonhuman primates from temperature extremes and to provide for their health and well-being. The ambient temperature in the facility must not fall below 45 [deg]F (7.2 [deg]C) for more than 4 consecutive hours when nonhuman primates are present, and must not rise above 85 [deg]F (29.5 [deg]C) for more than 4 consecutive hours when nonhuman primates are present. The ambient temperature must be maintained at a level that ensures the health and well-being of the species housed, as directed by the attending veterinarian, in accordance with generally accepted professional and husbandry practices.

Prepared By:

TONYA HADJIS, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1081

Aug-04-2011

Received By:

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

Date:

Title:

Aug-04-2011



## Inspection Report

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Temperature records from rooms 2B and OP1 were reviewed from May through July 2011 and it was noted that there were several occasions when the temperatures in those rooms met or exceeded 85 deg. The temperature is logged in the am and pm daily. On four consecutive days in May in OP1 the am temperatures were 85, 85, 86, and 86 deg and the pm temperatures were 84, 84, 86, and 84 deg. In room 2B there were pm temperature readings of 88 deg on 3 consecutive evenings. Although measures were taken to decrease room temperature additional temperature readings were not documented to demonstrate a decrease to below 85 deg. The am and pm temperature readings in the record are greater than 4 hours apart. During temperature extremes increased documentation must be done to illustrate the affect of mitigating steps on the room temperatures. Temperatures >85 deg for >4 hours may have a severe affect on the health and well-being of the animals.

**3.81** (c) (1)

### ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

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 Infants and young juveniles.

There are several juvenile non-human primates (NHPs) that are not on study and are housed individually without a signed exception from the social housing requirement in the AWA Standards from the Attending Veterinarian nor does the facility's environmental enhancement plan address special considerations for the environmental enhancement needs for young juvenile NHPs. Juvenile NHPs without special consideration taken for their environmental enhancement needs may become distressed and have abnormal social development. The facility must address the special environmental enhancement and social needs of their juvenile NHPs.

Correct by 1 September 2011

Inspection conducted on 2 August with exit briefing conducted with Institutional Official and facility representatives on 3 August 2011.

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**Prepared By:**

TONYA HADJIS, D V M USDA, APHIS, Animal Care

**Date:**

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Aug-04-2011

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**Date:**

**Title:**

Aug-04-2011



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Customer ID: 146

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115 MILL STREET

Type: ROUTINE INSPECTION

BELMONT, MA 02478

Date: Mar-22-2011

### 2.31 (b) (3) (ii)

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

IACUC membership. Of the members of the Committee at least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals.

The unaffiliated member on the IACUC resigned prior to the IACUC meeting that was held in February 2011. The IACUC conducted a meeting in February and in March 2011 without a duly constituted IACUC. During this time, the IACUC approved protocols, protocol reviews, and new personnel to add to animal-use protocols. The unaffiliated member is an essential member of the IACUC in order to represent the interests of the general community. Without an unaffiliated member there is not a duly constituted IACUC and the IACUC cannot conduct activities that require the full committee. Any activities that were approved in full committee in February and March were not approved by a committee that met the requirements set in the Animal Welfare Act. The required members of an IACUC are an Attending Veterinarian, a Chair, and an Unaffiliated member. The Institutional Officer must appoint an unaffiliated member to the IACUC before any further full member IACUC activities can be conducted and ensure that an unaffiliated member is on the committee during IACUC activity.

Correct by April 30, 2011

### 2.31 (c) (3)

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

IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity.

#### Prepared By:

TONYA HADJIS, D V M                      USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1081

Mar-24-2011

#### Received By:

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

Date:

Title:

Mar-24-2011



## Inspection Report

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There was a program deficiency the IACUC identified in both of the semiannual program reviews that were conducted in April and November 2010. This was the same deficiency at both reviews and was marked as minor by the IACUC. There was a general plan for correction but no correction date was scheduled. A correction date gives the IACUC a point in time to return to the identified deficiency to evaluate progress or completion of the program, otherwise, important programmatic functions may remain uncorrected and may result in a minor deficiency becoming a significant deficiency. The IACUC must ensure that the semi-annual report to the Institutional Official contains a specific plan and schedule for correction for every deficiency identified during their evaluations.

Correct from this point forward.

**3.81** (c) (4)

### ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

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 individually housed nonhuman primates that are unable to see and hear nonhuman primates of their own or compatible species.

There were 3 non-human primates (NHP) that were individually housed and were not able to see other primates of their own or compatible species and they were on the facility's routine enrichment plan. NHPs that are singly housed and cannot see and hear other NHPs of their own or compatible species require special enrichment to compensate for the decrease in social interaction that in a social animal can cause stress. The facility must correct the housing situation with these 3 animals and develop a plan to ensure that all individually housed NHPs either have the ability to see and hear other animals of their own or compatible species or are provided special attention regarding enhancement of their environment.

Correct by April 8, 2011

Inspection conducted on March 22-23, 2011 with exit briefing conducted on March 24, 2011 with the Institutional Official and an IACUC representative.

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**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1081

Mar-24-2011

**Received By:**

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

**Date:**

**Title:**

Mar-24-2011





## Inspection Report

MCLEAN HOSPITAL CORPORATION

Customer ID: 146

Certificate: 14-R-0096

Site: 001

115 MILL STREET

MC LEAN HOSPITAL

Type: ROUTINE INSPECTION

Date: Mar-24-2010

BELMONT, MA 02478

### 2.33 (b) (5)

#### ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

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.

Animal # 97C002 was treated post-operatively with analgesics and antibiotics that were to be given BID. The interval of medication administration between the pm and am doses was 16 hours which is greater than the established standard of care. Medications need to be administered based on established dosing intervals in order to be effective and to maintain blood levels for the health and well being of the animals.

Correct by May 21, 2010

### 3.76 (a)

#### INDOOR HOUSING FACILITIES.

Heating, cooling, and temperature. Indoor housing facilities must be sufficiently heated and cooled when necessary to protect nonhuman primates from temperature extremes and to provide for their health and well-being. The ambient temperature in the facility must not rise above 85 °F (29.5 °C) for more than 4 consecutive hours when nonhuman primates are present. The ambient temperature must be maintained at a level that ensures the health and well-being of the species housed, as directed by the attending veterinarian, in accordance with generally accepted professional and husbandry practices.

The temperature and humidity log for Room 2B during the month of August revealed that the temperature is recorded every 24 hours in the morning. The morning temperatures were recorded as high as 82 degrees, although steps were taken to decrease room temperature, additional temperature readings were not documented to demonstrate change throughout the day. During temperature extremes, increased documentation should be done to reveal affect of mitigating steps and increased afternoon heat on room temperature. This is for the health of the animals as temperatures >85 degrees for >4 hours can have a severe effect on the animals.

Correct by May 21, 2010

#### Prepared By:

TONYA HADJIS, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1081

Mar-24-2010

#### Received By:

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

Date:

Title:

Mar-24-2010



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MCLEAN HOSPITAL CORPORATION

Customer ID: 146

Certificate: 14-R-0096

Site: 001

115 MILL STREET

MC LEAN HOSPITAL

Type: ROUTINE INSPECTION

Date: Aug-25-2009

BELMONT, MA 02478

### 3.81 (b)

#### ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

Environmental enrichment. The physical environment in the primary enclosures must be enriched by providing means of expressing noninjurious species-typical activities. Species differences should be considered when determining the type or methods of enrichment. Examples of environmental enrichments include providing perches, swings, mirrors, and other increased cage complexities; providing objects to manipulate; varied food items; using foraging or task-oriented feeding methods; and providing interaction with the care giver or other familiar and knowledgeable person consistent with personnel safety precautions.

Several of the macaques were provided plastic enrichment items that were worn and damaged. These items could pose a hazard to the macaques and should be replaced for the health and enrichment of the animal.

Correct by September 1, 2009

#### Prepared By:

TONYA HADJIS, D.V.M. USDA, APHIS, Animal Care

#### Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1081

Aug-26-2009

#### Received By:

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#### Date:

Title:

Aug-26-2009



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115 MILL STREET

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MC LEAN HOSPITAL

BELMONT, MA 02478

Type: ROUTINE INSPECTION

Date: Jan-27-2009

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Facility is in compliance with AWA Regulations and Standards at the time of inspection.

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**Prepared By:**

TONYA HADJIS, V.M.O. USDA, APHIS, Animal Care

**Date:**

**Title:** VETERINARY MEDICAL OFFICER Inspector 1081

Jan-27-2009

**Received By:**

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

**Date:**

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