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
Date: Jul-19-2011

2.31 (d) (1) (ix)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31 (d) (1) (ix) states - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (ix) Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions."

1. W208: The room is dedicated surgical space that is used for major operative procedures on NHPs. The regulator valve of the room’s radiator that is located near the surgery table was noted to be rusty, there was flaking paint on both the valve and the water pipe for the radiator, and there were flakes of paint and rust on the floor under the radiator. The presence of rust on surfaces can interfere with effective sanitization and this could compromise the aseptic procedures performed in this room.

Per this Section of the Regulations, major operative procedures on non-rodents should be conducted in facilities that are maintained under aseptic conditions. The Registrant needs to address the presence of rust and peeling paint to maintain the surgery room under aseptic conditions.

Correct by 8/22/11.

2.32

PERSONNEL QUALIFICATIONS.

Section 2.32 states - "(a) 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; and (c) Training and instruction of personnel must include guidance in at least the following areas: (3) Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used."

1. Pertaining to Protocol #02487: In February 2011, a major operative survival procedure described in the approved
protocol was performed on an NHP. During the surgery the anesthetist, who was a member of the investigator's staff, increased the dose of anesthesia to the NHP based on a change in the NHP's monitoring parameters. However, the dose of anesthetic was not re-adjusted to the lower maintenance dose and the NHP received an overdose of the anesthetic agent that caused acute renal failure in the animal. One of the clinical veterinarians was contacted and appropriate treatment measures for acute renal failure were begun but the condition of the NHP deteriorated and the animal was euthanized.

Per this Section of the Regulations, it is the responsibility of a research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are appropriately trained and qualified to perform their duties. When those duties include the administration of anesthesia, the training and instruction must include guidance in the proper use of anesthetics, analgesics, and tranquilizers for the species of animals used to ensure the health and well-being of the animals.

Following this incident, the clinical veterinarian provided additional instruction and re-training to the investigator's staff on the proper use of anesthetics and analgesics, as well as the administration of anesthesia to ensure that another incident does not occur. The incident was also reported by the institution to the USDA.

The research facility has taken appropriate steps to address this item and at this time it is considered to be corrected.

3.75 (c) (3)

HOUSING FACILITIES, GENERAL.

Section 3.75 (c)(3) states: "Cleaning. Hard surfaces with which nonhuman primates come in contact must be spot-cleaned daily and sanitized in accordance with Sec. 3.84 of this subpart to prevent accumulation of excreta or disease hazards."

1. W205: This area is used to store clean primate chairs, personal protective equipment (PPE), and food supplies. Several of the primate chairs were noted to be dirty and had not been adequately cleaned after being used for NHPs. There was particulate residue adhered to the metal base of one chair as well as corn cob bedding residue in the corners and on the rim of the plastic pan, and there was a piece of fecal matter left in the plastic pan of another chair.

Per this Section of the Regulations, hard surfaces with which NHPs come in contact must be spot cleaned daily and sanitized to prevent accumulation of excreta or disease hazards. The primate chairs should be cleaned and sanitized daily after being used by the NHPs to minimize disease hazards and possible contamination of the other clean objects stored in the room.

Correct from this date forward.
3.75 (e) 
HOUSING FACILITIES, GENERAL.

Section 3.75 (e) states - "Trash containers in housing facilities.....must have tightly fitted lids on them at all times."

1. There were uncovered trash containers noted in several different laboratory areas in G. Trash receptacles that are covered by a lid help to minimize odors and disease hazards to both animals and facility personnel.

Per this Section of the Regulations, there must be a tightly fitting lid present on trash containers in NHP housing facilities at all times.

Correct by 8/4/11.

NOTE - This inspection was conducted 7/19/11 through 7/21/11. Exit interview held 7/21/11 on-site with facility personnel. END OF REPORT.
2.31 (c) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31 (c) (7) states - "IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities."

1. At the end of June 2011, it was discovered during the research facility’s post-approval monitoring program (PAM) that there has been more than one instance when procedures were performed on study animals that were not described in the IACUC approved proposal for animal use. The IACUC immediately formed a subcommittee to look into the issue when it was informed of the findings of the PAM and it also reported the issue to the USDA.

Per this Section of the Regulations, the IACUC must review and approve significant changes to proposals for animal use before the investigators can conduct any additional activities that were not initially described at the time of IACUC approval.

The subcommittee of the IACUC is currently in the process of investigating the extent of the non-compliant issue to determine what corrective actions are needed and to then determine an appropriate correction schedule to implement those corrective actions.

NOTE - This was a focused inspection based on the research facility’s self-reporting of the non-compliant item to the USDA. The findings documented on this inspection report are undergoing further review by the Eastern Regional Office. Exit interview held 7/21/11 on-site with facility personnel. END OF REPORT.