3.80 (a) (2) (ii)

PRIMARY ENCLOSURES.

The IACUC minutes dated 10/20/2015 include discussion regarding an animal that died as a result of entrapment associated with a chain securing an enrichment device. It was found that a device with an obsolete design had been used in the animals primary enclosure. That device had enough unprotected chain length for an entrapment accident to occur. Immediate changes to the enrichment plan were to include fastener length in the maximum chain length left unprotected by a PVC sleeve, and to make the enrichment storage area accessible to only the behavioral sciences group to ensure that only approved toys and other enrichment devices are dispensed for animal use.

Environmental enrichment is an important part of housing non-human primates. Design of enrichment devices must involve careful scrutiny for safety for use with these animals; they can cause harm if not carefully constructed and monitored with use to ensure they have not become unsafe.

The facility must ensure that all enrichment devices are safely constructed and maintained in order to protect the non-human primates from injury. This NCI was corrected prior to the time of inspection.

A progress report on the comprehensive alopecia study was reviewed.

The inspection was conducted by Drs. Gwynn Hallberg and Heather Cole on January 12-14, 2016 and was accompanied by facility personnel. The exit briefing was conducted on 1/14/2016 with facility personnel.
United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 1046  
Inspection Date: 14-JAN-16

Animal Inspected at Last Inspection

<table>
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<tr>
<th>Cust No</th>
<th>Cert No</th>
<th>Site</th>
<th>Site Name</th>
<th>Inspection</th>
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<tr>
<td>1046</td>
<td>92-R-0001</td>
<td>002</td>
<td>OREGON HEALTH &amp; SCIENCE UNIVERSITY</td>
<td>14-JAN-16</td>
</tr>
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</table>

Count  Species
000078  Crab-eating/long-tailed macaque/cynomolgus monkey
000109  Japanese macaque
000008  Olive Baboon
000207  Japanese macaque *Male
000014  Hamadryas baboon
002619  Rhesus macaque *Male
001740  Rhesus macaque
000000  European rabbit
004775  Total
2.31 (c) (7)
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A macaque was found to have necrotic lesions at three of six subcutaneous injection sites of an experimental substance. The facility’s follow-up to this incident determined that the animal received a series of six subcutaneous injections instead of a single intramuscular injection as was described in the approved protocol. An additional departure from the approved protocol was that the injection sites were not shaved. Shaving the area was to allow observation of the site post-injection.

The protocol also states that the clinical veterinary staff was to be notified when the injections were given and the IACUC was to be notified regarding the results of the study at 72 hours post-injection. A facility representative stated that the veterinary staff was not notified until 3-4 days post-injection and the IACUC was not notified until four days post-injection.

This incident resulted in injury to the animal and delay in evaluation and treatment. The facility must ensure that from this day forward all significant changes to protocols are reviewed and approved by the IACUC prior to implementation by the Principal Investigator and research staff.

Correction date: The facility corrected the NCI prior to the time of inspection by retraining all personnel involved in the incident on the importance of following a protocol exactly, as well as on the chain of communication for working within and between departments to ensure all experimental procedures are conducted according to approved protocols. This adverse event was self-reported to OLAW.

A high incidence of alopecia was reported on a previous inspection report. The facility’s alopecia incidence was reviewed as well as supporting documentation regarding their extremely comprehensive investigation into potential causes and, therefore, remedies for the cases of alopecia at the facility.

The inspection was conducted on March 24-26, 2015, accompanied by facility representatives.

The exit briefing was conducted on March 26 with facility representatives.
ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

An adverse outcome was reported in the IACUC minutes: A female Japanese macaque was undergoing an imaging procedure under anesthesia. The procedure was necessarily conducted in a darkened room. The animal was noted to have respiratory distress and the veterinarian was notified, but the animal expired in spite of resuscitation efforts. It was found that the pop-off valve on the anesthesia machine was left closed and went unnoticed in the darkened room. This was the first of several animals scheduled to be imaged, but the remainder of the studies that day were cancelled.

Since the event and prior to resumption of study activities, the anesthesia machines have been modified so that the pop off valve cannot be left closed - it must be held closed for pressure checking the machine, and it automatically returns to the open state when the operator releases hold on the fitting.

Correct by: This non-compliance was corrected as described prior to the time of inspection.

An adverse outcome was reported in early July 2013. On June 27, 2013, a total of twenty-one rhesus macaques were hospitalized and six animals died or were euthanized from a previously stable breeding group of 260 animals housed outdoors in a one-acre corral. All of the animals were injured as a result of fighting within the group. They concluded that the event was likely the result of displaced aggression triggered by construction activity - noise and vibration - on land near the corral. This new construction involved frequent heavy trucks passing around the end of the row of corrals. The affected corral was the last in that row, with the trucks passing just outside, along the exterior wall.

The Center responded by halting construction that day and relocating the remaining 233 rhesus macaques to another outdoor corral further from the construction site. Additional enrichment was added - swimming tubs, branches, treats - as well as additional monitoring by the Behavioral Services Unit, which studied behavioral trends and compared them to readings from five noise and vibration monitors placed around the areas of construction and animal housing. They also developed housing modifications to allow for better social interaction or avoidance as needed by the animals.

Correct by: This was corrected by responding to the event, as described, prior to the time of inspection. Additionally, the facility must develop comprehensive plans to address the impact on the animals for all future construction. These plans must include logistics for animal relocation in relation to construction activity if necessary, increased monitoring of the animals, and intervention to address any escalation of
stress activity in the animals.

2.33 (b) (3)
ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

A large percentage (>50%) of rhesus macaques in all different housing types have significant, non-pruritic hair loss. Recent response to animals with alopecia has been largely through the Behavior Sciences Unit (BSU). While studies to identify potential causes in the past have been done, there is not evidence of a comprehensive clinical diagnostic plan to determine underlying physical causes. The semi-annual physical examination of all of the non-human primates (NHPs) at the facility was adjusted recently to include alopecia scoring; once they complete a full year's data set, analysis can begin to analyze incidence by location and season to help with diagnoses.

Hair loss in NHPs is multifactorial. Physical as well as psychological components need to be considered to try and determine treatable causes. Hormonal influences are currently at their peak since it is birthing season, however animals of all ages and both genders are affected. Hair loss can be a problem in that it negatively influences the skin protection and thermoregulation abilities of the affected animals.

Correct by: May 15, 2014. The NHP Resource Veterinarian stated they will have a comprehensive colony plan in place in 30 days to diagnose and develop a therapy plan for treatable physical causes, to continue the behavioral therapy, and to implement more complex diagnostics such as food trials or other "response to therapy" modalities. The most severely affected must be evaluated and treated first.

3.75 (c) (1)
HOUSING FACILITIES, GENERAL.

The bedding in the calf hutch in corral 5, and the two corrals set away from the others (Japanese macaque and a rhesus corral) is dirty. The weather has been very wet, so the bedding has quickly become soiled. High traffic areas are muddy, such as around the calf hutch, under play equipment, and at the doors to the indoor feeding area in the rhesus corral adjacent to the Japanese macaque corral. Animals must be able to avoid muddy areas. Clean bedding is necessary to ensure the animals can stay clean and dry to better thermoregulate.

The calf hutches are placed in the corrals to provide shelter in addition to the indoor feeding areas which are cleaned daily. Bedding straw is placed in the calf hutches and is changed every two weeks from October through March, and every four weeks for the remainder of the year.

Bedding changes should be done as needed rather than on a scheduled basis. Additionally, there must special attention to mud control in areas at entrances to shelters and near food and water access.

Correct by: This was corrected at the time of inspection by replacing straw bedding in the hutches and laying fresh straw over the affected traffic areas.

Prepared By:  
GWYNN HALLBERG, D.V.M.  USDA, APHIS, Animal Care  
Date:  Apr-16-2014

Title:  VETERINARY MEDICAL OFFICER Inspector  5036

Received By:  
DR KIRK ANDREWS  
Date:  Apr-16-2014

Title:  NHP RESOURCE PROJECT VETERINARIAN
3.75 (c) (2)

HOUSING FACILITIES, GENERAL.

There are cracks in the wall surface and areas of picked paint on walls and defects in the floor coating in four animal rooms in the colony building (1A, 2A, 3A, 4A) and in runs 5 and 8 in the Harem building. These cracks and defects make it difficult to clean and disinfect properly.

Correct by: April 25, 2014. The Colony building rooms and Harem run 8 were corrected at the time of inspection by moving the animals to other locations. Repairs will be made before any animals are placed in the rooms. The room that still contains animals, Harem run 5, is scheduled to be vacated and repaired by the correction date.

The inspection was conducted April 2-4, 2014 and was accompanied by the NHP Resource Veterinarian and personnel from the various areas. Records inspection was facilitated by IACUC office staff. Exit briefing with facility personnel on April 16, 2014.

Prepared By: GWYNN HALLBERG, D.V.M. USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER Inspector 5036

Received By: DR KIRK ANDREWS
Title: NHP RESOURCE PROJECT VETERINARIAN

Date: Apr-16-2014
Date: Apr-16-2014
Sec. 2.33 Attending veterinarian and adequate veterinary care.
(b) 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, and the availability of emergency, weekend, and holiday care;”

A baboon, 16249, had surgery as part of a research protocol. On necropsy as part of that protocol, a previously identified abdominal mass turned out to be a surgical sponge. The animal had been monitored due to the mass and weight loss, but had no other symptoms noted.

Prior to the time of this inspection, the IACUC reviewed the protocol and made recommendations to the investigators and veterinary staff to minimize the chances of recurrence.

“ (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; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian;

(4) Guidance to principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquillization, and euthanasia; and

(5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.”
Monkey 16212 died as a result of sepsis resulting from prolonged labor and fetal demise. The researcher did not recognize the signs of distress and, therefore, failed to communicate with the veterinarian in order to provide timely care to the animal.

Prior to the time of this inspection, the IACUC reviewed the incident and set up a plan including additional training to ensure such a failure does not recur. Neither the primary nor the co-investigator are involved in animal research at this time.

"Sec. 2.38 Miscellaneous.
(6) Handling. (l) 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."

In November of 2007, a laparoscopy was performed on the cage mate of the intended subject. Prior to the time of inspection, the incident was reported to the IACUC and corrective measures had been instituted.

Prepared by: Gayynn Hallberg, VMO, USDA APHS Animal Care  
Date: 11/19/2008

Title: Veterinary Medical Officer  
Inspector ID: 5030

Received by: Dr CJ Doane, via e-mail  
Date: 11/21/2008

Title: Department of Animal Resources Director