



## Inspection Report

UNIVERSITY OF KANSAS MEDICAL CENTER

Customer ID: **1460**

3901 RAINBOW BLVD

Certificate: **48-R-0003**

1040 WESCOE PAVILION - MS 2014

Site: 001

UNIVERSITY OF KSMENTAL

KANSAS CITY, KS 66160

Type: ROUTINE INSPECTION

Date: Mar-10-2009

**2.31** (d) (2) (iv) (B) **DIRECT NCI**  
**INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).**

(d) IACUC review of activities involving animals.

(1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Provided, however, That field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (iv) Procedures that may cause more than momentary or slight pain or distress to the animals will: (B) Involve, in their planning, consultation with the attending veterinarian or his or her designee  
\*\*\*\*\*

Protocol 2007:1688 describes the analgesic plan for a protocol in which nonhuman primates undergo craniotomies. Their description states that "The surgical and anesthetic procedures discussed her have been used safely and effectively for many yearsIt is acknowledged that the use of alternative analgesic agents, such as narcotic opiates, in the early post-surgical period might provide greater pain relief than the proposed combination of local anesthetic and systemic Tylenol. However, it has been our experience that such analgesics are contraindicated after the prolonged anesthetic regimens used in these studies. Often, we have found narcotic agents to produce severe respiratory suppression and extended durations for complete anesthetic recovery by several hours-to-days, thereby requiring substantially greater care by lab and animal care staff." The protocol acknowledges that animals experience some symptoms that could be related to pain and/or distress immediately following the craniotomies. It states "some symptoms of distress are usually apparent in the first days after the procedure, including lethargy, limited locomotion or climbing in cage, huddling, touching of incision, and/or reduced food consumption." When appropriate analgesics are withheld, it must be justified for scientific reason, not due to the increased care the animals would require. The attending veterinarian stated that he was not consulted in the planning of this protocol. The failure of the investigator to consult with the attending veterinarian in the development of this protocol contributed to circumstances that caused animals to experience inadequate analgesia, causing unnecessary pain and distress as documented in animal surgical records and the investigators description of "normal" animal behavior post-surgery in the protocol.

The IACUC must ensure that when proposed involve procedures that may cause more than momentary or slight pain

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or distress to the animals that the investigator involves in their planning, consultation with the attending veterinarian or his or her designee in order to protect the welfare of the animals.

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TO BE CORRECTED IMMEDIATELY

**2.31** (d) (1) (x)

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

No animal will be used in more than one major operative procedure from which it is allowed to recover, unless: (A) Justified for scientific reasons by the principal investigator, in writing; (B) Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or (C) In other special circumstances as determined by the Administrator on an individual basis. Written requests and supporting data should be sent to the Animal and Plant Health Inspection Service, Animal Care, 4700 River Road, Unit 84, Riverdale, Maryland 20737-1234;

\*\*\*\*\*

Protocol 2007:1688 states that nonhuman primates will undergo multiple major survival surgeries. The protocol is not specific how many major survival surgeries each animal will undergo prior to euthanasia. Approximately 5 surgical animal records were examined; one record indicated that an animal underwent three major survival surgeries. The attending veterinarian stated that neither he nor the IACUC was aware that animals on this protocol underwent more than one multiple major survival surgery. The IACUC, therefore, did not conduct an effective and thorough review of this protocol that was sufficient in order to ensure the investigator provided an adequate scientific justification to use animals in more than one major operative procedure from which they are allowed to recover.

In order to protect the welfare of the animals, the IACUC must ensure that no animal will be used in more than one major operative procedure from which it is allowed to recover unless justified for scientific reasons by the principal investigator in writing, required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian, or in other special circumstances as determined by the APHIS Administrator.

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TO BE CORRECTED IMMEDIATELY.

**2.31** (d) (1) (iv) (A)

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

(d) IACUC review of activities involving animals.

(1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Provided, however, That field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements: (iv) Procedures that may cause more than momentary or slight pain or

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distress to the animals will: (A) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;

\*\*\*\*\*

Protocol 2007:1688 describes the analgesic plan for a protocol in which nonhuman primates undergo craniotomies. Their description states that "It is acknowledged that the use of alternative analgesic agents, such as narcotic opiates, in the early post-surgical period might provide greater pain relief than the proposed combination of local anesthetic and systemic Tylenol. However, it has been our experience that such analgesics are contraindicated after the prolonged anesthetic regimens used in these studies. Often, we have found narcotic agents to produce severe respiratory suppression and extended durations for complete anesthetic recovery by several hours-to-days, thereby requiring substantially greater care by lab and animal care staff." The protocol acknowledges that animals experience some symptoms that could be related to pain and/or distress immediately following the craniotomies. It states "some symptoms of distress are usually apparent in the first days after the procedure, including lethargy, limited locomotion or climbing in cage, huddling, touching of incision, and/or reduced food consumption." When appropriate analgesics are withheld, it must be justified for scientific reason, not due to the increased care the animals would require.

In its review of animal activities, the IACUC must ensure that all procedures that may cause more than momentary or slight pain or distress to the animals are performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time.

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TO BE CORRECTED IMMEDIATELY

### 2.31 (d) (5)

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

(d) IACUC review of activities involving animals. (5) The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually;

\*\*\*\*\*

Nonhuman primates on protocol 2007:1688 have been exempted from manipulative environment enhancement. Twenty-four squirrel monkeys had hair loss varying from partial to full loss of hair on the tail to patchy hair loss on the body, which can be a sign of psychological distress. Approximately 7 animals were actively plucking or stripping hair from their bodies or exhibiting stereotypic behaviors such as flipping, swaying, bouncing or self-clasping which could be signs of psychological distress. The IACUC has not conducted an appropriate review of animal activities to ensure that the exemption has not had a negative impact on the welfare of the animals.

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Protocol 2007:1688 states that after nonhuman primates are transferred from the surgical table to the incubator, they will be monitored every 10-30 minutes until sitting up. Approximately 5 surgical records were examined, and inspectors found that in one animal record observation of the squirrel monkey was only documented at 47 and 45 minute intervals before the record indicated that the animal was sitting up. The IACUC has not conducted appropriate review of animal activities to ensure that investigators are following the approved protocols.

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The IACUC must conduct continuing review of activities in order to ensure that all animal activities are conducted in compliance with these regulations in order to protect the health and welfare of the animals.

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TO BE CORRECTED IMMEDIATELY

### 2.31 (c)

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

(c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (5) Make recommendations to the Institutional Official regarding any aspect of the research facility's animal program, facilities, or personnel training;

\*\*\*\*\*

IACUC meeting minutes from March 24, 2008 indicated that "increased research activity has exceeded the existing infrastructure creating a need for additional support for the LAR. The committee believes animal welfare could be jeopardized if action is not taken soon." The Committee agreed to draft a letter to send to the administration. April 14, 2008 meeting minutes again stated the need to "draft a letter to administration from the IACUC outlining the committee's concerns regarding administrative support for the infrastructure sustaining research with laboratory animals at KUMC" and expressed the same need at the May 20, 2008 meeting. The June 17, 2008 meeting minutes then stated that "the committee determined that it will not be necessary to write a letter KUMC Administration requesting additional funding be allocated to support the LAR and infrastructure supporting the animal research enterprise at KUMC." However in the August 19, 2008 minutes the IACUC stated that "decreased mouse per diem rates, the current hiring freeze, increased fuel costs, PPE costs, and decreased financial support from KUMC Administration have negatively affected the LAR budget."

The IACUC must ensure that the facility meets the standards of care described in the regulations in order to protect the health and welfare of the animals. When any aspect of the research facility's animal program, facilities, or personnel training prevents these standards to be met, the IACUC must make recommendations to the Institutional Official regarding these conditions.

TO BE CORRECTED BY: April 20, 2009

### 2.31 (d) (1) (ii)

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

(d) IACUC review of activities involving animals.

(1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Provided, however, That field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities or significant changes in ongoing

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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, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available;

\*\*\*\*\*

In protocol 2007:1688 nonhuman primates undergo craniotomies, which are surgical procedures in which an opening is made into the skull. The keywords used in the investigators search for alternatives did not include terms that relate to the procedures that may cause more than momentary or slight pain or distress to the animals. Search words included: motor cortex, stroke, rehabilitation, hand function, ischemia, recovery, physical therapy, axonal sprouting, anesthesia, and analgesia. The inadequate search contributed to circumstances that caused animals to experience inadequate analgesia, causing unnecessary pain and distress as documented in animal surgical records and the investigators description of "normal" animal behavior post-surgery in the protocol.

In protocol 2007-1686 nonhuman primates also undergo craniotomies. The keywords used in this investigators search for alternatives also did not include terms that relate to the procedures that may cause more than momentary or slight pain or distress to the animals. Search words included: capsular infarct and white matter infarct.

The IACUC must ensure that the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals in order to protect the welfare of the animals.

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TO BE CORRECTED IMMEDIATELY

### 2.31 (e) (4)

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

(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:

(4) A description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals; and

\*\*\*\*\*

Protocol 2007:1688 states that ketamine will be used as a pre-anesthetic, gas anesthesia for the craniotomy, and intravenous ketamine supplemented with diazepam will be used for the neurophysiological mapping portion of the protocol. Intravenous doses of ketamine are not included in this protocol. Conflicting information is provided concerning the use of "childrens liquid Tylenol" (acetaminophen) after the craniotomy. In one section it states that "childrens liquid Tylenol" will be given "2-3 times during the first 24 hours post-op as needed." In another section of the document, the investigator states that the "childrens liquid Tylenol" will be given "2-3 times within 24 hours, then as needed." These statements do not clearly indicate whether the "childrens liquid Tylenol" will be given to every animal after the surgical procedure or only those animals that have been determined to require it by the investigator.

The IACUC must ensure that all protocols describe procedures designed to assure that discomfort and pain to

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animals are limited in sufficient detail for the IACUC to determine whether or not the procedures are adequate in order to protect the welfare of the animals.

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TO BE CORRECTED BY: April 3, 2009

### 2.31 (e) (3)

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

(e) 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;

\*\*\*\*\*

Protocol 2007:1688 states that nonhuman primates will undergo multiple major survival surgeries. The protocol is not specific how many major survival surgeries each animal will undergo prior to euthanasia. Approximately 5 surgical animal records were examined; one record indicated that an animal underwent three major survival surgeries.

The IACUC must ensure that all proposals to conduct animal activities contain a complete description of the proposed use of the animals including the number of major operative procedures an animal will undergo and a rationale for each in order to protect the health welfare of the animals.

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TO BE CORRECTED BY: April 3, 2009

### 2.33 (b) (2)

#### REPEAT DIRECT NCI

#### 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;

\*\*\*\*\*

An investigator cart in procedure room 3020 contained expired drugs 8 vials of ketamine (expiration date 6/08) and one bottle of Nembutal Sodium Solution/Pentobarbital 50 mg/ml (expiration date 1 Sep 2008). Expired medications may no longer work as expected and could harm the animals. These medications were intermingled with other pharmaceuticals that are currently being used in the facility and were therefore ready for use. The program of veterinary care must include the use of appropriate methods to treat diseases in order to protect the health of the animals. The registrant must develop a program of monitoring and maintenance to ensure that all medications utilized for regulated species are within date. The registrant must ensure that all medications used in the facility are not expired and labeled properly in accordance with standard veterinary practices and manufacturer's recommendations.

\*\*\*\*\*

In room 3025, housing 4 macaques, a bottle of "children's chewable vitamins" was stored immediately adjacent to cleaning solutions, which could contaminate the medications. In room 1048, used to house a rabbit, an oral pill dispenser was being stored in a container with grooming supplies including nail clippers and a comb, which could

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contaminate the tip of the pill popper. A significant accumulation of hair and debris was on the tip of the tool. If used to medicate the rabbit, this tool could introduce a contaminant into the mouth of the animal potentially causing medical problems or distress. In room 3022, used to house 3 macaques, an oral dispensing tube of "Panacur" (Fenbendazole) was stored on a soap dispenser adjacent to cleaning chemicals. This medication and/or dispenser could be contaminated by these chemical agents and could harm the animals. An investigator cart located in procedure room 3020 contained butterfly catheters (used to catheterize veins) that were stored in a drawer with an aerosol can of "Clipperside" spray (a disinfectant for hair clippers). Storage of drugs, tools used for administration of oral medication, and medical supplies used to gain venous access in an animal with or near chemicals or soiled equipment could result in contamination of the items and negatively impact the health of the animals.

\*\*\*

In room 1048 a large, white rabbit (ID unknown) had a persistent, abnormal head tilt to the right. Head tilts in this species are indicative of a possible medical condition such as a bacterial or parasitic infection that could be painful or distressful to the animal. The veterinary staff was not aware of this condition, and there was no documentation that the animal caretakers had recognized the problem. The registrant must ensure that the rabbit is examined by a veterinarian in order to obtain an accurate diagnosis and appropriate treatment plan.

\*\*\*

A macaque (ID# RQ3787) had a red to brown colored crusty discharge around the resin on his surgically placed acrylic head cap. This could indicate the presence of infection, inflammation or other medical conditions that could be painful. The veterinary staff was not aware of this condition, and there was no documentation that the animal caretakers had recognized the condition. This animal must be examined by a veterinarian in order to ensure that an accurate diagnosis is obtained and an appropriate treatment plan is developed.

\*\*\*

Twenty six nonhuman primates had hair loss and/or excessive scratching (see list below). Hair loss can be self-induced by psychological distress, or indicative of a medical or environmental condition. None of the animal caretaker staff had documented the problems or communicated to the veterinary staff that the animals were scratching excessively or had hair loss. These animals must be evaluated by a veterinarian in order to determine if a medical cause for the excessive scratching and/or hair loss is present and to evaluate their psychological well-being in order to ensure that the animals receive an accurate diagnosis and an appropriate treatment plan:

Squirrel monkeys included ID# 1929 (rm 3026, tail hair loss), ID# 88C (rm 3026, tail hair loss), ID# 1930 (rm 3026, tail hair loss), ID# 88D (rm 3026, tail hair loss, left flank hair loss; inspectors observed this animal plucking out its hair), ID# 1926 (rm 3026, tail hair loss to the point the tail was bare), ID unknown (location left side, bottom row, second from left in room 3026, tail hair loss), ID# 1910 (rm 3026, tail hair loss), ID# 88B (rm 3026, tail hair loss to the point that the tail was bare), ID# 1927 (rm 3026, tail hair loss to the point that the tail was bare), ID# 1928 (rm 3026, tail hair loss to the point that the tail was bare), ID# 060 or 73A (rm 3029, tail hair loss), ID# 729 (rm 3029, tail hair loss), ID# 735 or 947 (rm 3029, tail hair loss), ID# 36B or C4B (rm 3029, tail hair loss with a patchy haircoat on its body). ID unknown (rm 3029, tail hair loss), ID# 335 (rm 3029, hair loss on right knee), ID# 10B (rm 5019A, tail hair loss), ID# 19B (rm 5019A, tail hair loss; animal was in a hunched over posture actively stripping his tail as well as excessively

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scratching), ID# 615 (rm 5009, tail base hair loss; inspectors animal was excessively scratching), ID# 1906 (rm 5009, tail base hair loss), ID# 1911 (rm 5009, tail base hair loss), ID# 94B (rm 5009, tail hair loss, flank hair loss, thin appearance), ID# 796D (rm 5009, tail base hair loss; animal was excessively scratching and rubbing its back on its cage), and ID unknown (located under 796D in rm 5009, tail hair loss).

Macaques included ID# CL8R (hair loss on forearms and shins; plucking hair from his arms) and ID# RQ3787 (hair loss on back of neck and shoulders).

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This is a repeat non-compliant item. It was also not in compliance on August 27, 2008.

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

(b) 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; 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;

\*\*\*\*\*

A facility representative stated that animal caretaker staff members "sometimes notice that guinea pigs are no longer present in their cage". The representative stated that the animals will then reappear in the room in a couple of days. When asked how an animal caretaker would know if an animal had escaped or was missing from its enclosure, the facility representative stated that animal caretakers do not document nor have access to census information while completing daily husbandry tasks. In the gerbil room, two gerbils were present in a cage, but the cage card stated "Total Qty: 12." Caretakers must be informed of the number of animals present in each enclosure to prevent or report possible animal escapes that could result in injury or death.

\*\*\*

Several animals in the facility had medical problems that had not been documented by animal caretakers nor communicated to the veterinary staff including a rabbit (white, ID unknown, room 1048, persistent, abnormal head tilt to the right); 26 nonhuman primates with varying amounts of hair loss and excessive scratching, including one animal that was thin; approximately 7 nonhuman primates plucking or stripping hair from their bodies or exhibiting stereotypic behaviors such as flipping or swaying; and a macaque (ID #RQ3787) with a red to brown colored crusty discharge around the resin around his acrylic head cap.

\*\*\*

Checklists used by the nonhuman primate animal caretaker staff to document completion of husbandry tasks and daily health observations revealed that completion of the daily health check was not documented on multiple occasions; all except for one of these dates fell on the weekend: Room 5019A (Saturday February 21- Sunday February 22; no husbandry or the daily health check documented); Room 3018 (no daily health check documented Friday March 6 through Sunday March 8, 2009); Room 3025 (no daily health check documented Sunday February 1, 2009); Room 3022 (no daily health check documented Sunday February 8, 2009); Room 3024 (no daily health check documented Sunday February 8, 2009).

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The registrant must develop and follow an effective program to ensure that effective daily of observation of the animals to assess their health and well-being occurs at all times. Additionally, the registrant must ensure that when this observation is accomplished by someone other than the attending veterinarian that timely and accurately information is communicated when problems concerning animal health, behavior, and well-being are detected.

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TO BE CORRECTED IMMEDIATELY

### 2.36 (b) (7)

#### ANNUAL REPORT.

(b) The annual report shall: (7) State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report;

\*\*\*\*\*

In Protocol 2007:1688 nonhuman primates undergo a craniotomy during which a stroke, resulting in loss of function in one arm, is induced. The investigator stated that "the use of alternative analgesic agents, such as narcotic opiates, in the early post-surgical period might provide greater pain relief than the proposed combination of local anesthetics and systemic Tylenol." The local anesthetic is only applied to the incision after closure. In the protocol the investigator also stated that "some symptoms of distress are usually apparent in the first days after the procedure, including lethargy, limited locomotion or climbing in the cage, huddling, touch of incision, and/or reduced food consumption." Additionally, the investigator stated in the protocol that the same general surgical and analgesic procedures are used in the squirrel monkeys as in rats. However, an IACUC veterinarian confirmed that the rat portion of the protocol was recently changed to the category pain or distress for which no treatment is offered.

\*\*\*

The registrant did not report any nonhuman primates on the annual report upon which experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. The registrant must ensure that the annual report fully and accurately discloses all of the required information.

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TO BE CORRECTED BY: April 3, 2009

### 2.36 (b) (8)

#### ANNUAL REPORT.

(b) The annual report shall: (8) State the common names and the numbers of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.

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At least thirty two squirrel monkeys were being held to be used in future research. According to the facility representative these animals arrived at the facility August 2008. The registrant did not report any nonhuman primates on the annual report as being bred, conditioned, or held. The registrant must ensure that the annual report fully and accurately discloses all of the required information.

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TO BE CORRECTED BY: April 3, 2009

**2.38** (b) (1) (iv)

### MISCELLANEOUS.

(b) Access and inspection of records and property. (1) Each research facility shall, during business hours, allow APHIS officials: (iv) To inspect the facilities, property, and animals, as the APHIS officials consider necessary to enforce the provisions of the Act, the regulations, and the standards in this subchapter;

\*\*\*\*\*

Both inspectors made multiple direct requests for the facility representatives to accompany the inspectors into the nonhuman primate rooms during the inspection but the representatives refused. Inspectors were not able to show the facility representatives areas of non-compliance. The registrant must ensure that facility representatives allow APHIS officials to inspect the facilities as the officials consider necessary to enforce the provisions of the Act in order to protect the health and welfare of the animals.

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TO BE CORRECTED IMMEDIATELY

**2.38** (k) (1)

### MISCELLANEOUS.

(k) Compliance with standards and prohibitions. (1) Each research facility shall comply in all respects with the regulations set forth in subpart C of this part and the standards set forth in part 3 of this subchapter for the humane handling, care, treatment, housing, and transportation of animals; Provided, however, That exceptions to the standards in part 3 and the provisions of subpart C of this part may be made only when such exceptions are specified and justified in the proposal to conduct the activity and are approved by the IACUC.

\*\*\*\*\*

The registrant reported in an amendment its 2008 Annual Report that the IACUC approved an exemption to housing standards to allow one nonhuman primate to be housed in an enclosure that did not meet minimum height requirements in order to allow the investigator to make modifications to the pole and collar system because the research assistant was unable to capture the animal in an enclosure that met the minimum requirements. The facility told the inspector that this macaque could not fully stand up in the enclosure. The amendment to the annual report stated that the exemption was in effect for approximately one month; IACUC meeting minutes review the approval as being in effect for 5 months.

The registrant must ensure that exceptions to the standards in part 3 and the provisions of subpart C are made only

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when such exceptions are specified and justified in the proposal to conduct the activity and are approved by the IACUC.

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TO BE CORRECTED IMMEDIATELY

### 3.25 (a)

#### FACILITIES, GENERAL.

(a) Structural strength. Indoor and outdoor housing facilities for guinea pigs or hamsters shall be structurally sound and shall be maintained in good repair, to protect the animals from injury, to contain the animals, and to restrict the entrance of other animals.

\*\*\*\*\*

In room 5007C, housing approximately 6 guinea pigs, the drain cover was off. A facility representative stated that animal caretaker staff members "sometimes notice that guinea pigs are no longer present in their cage." The representative stated that the animals will then reappear in the room in a couple of days. If an animal escaped from its enclosure, it could become entrapped in this large opening which could cause injury or lead to death. Facilities for guinea pigs must be maintained in good repair to protect the animals from injury. The registrant must develop a program of monitoring and maintenance to ensure that all facilities for guinea pigs are structurally sound, maintained in good repair, protect the animals from injury, and contain the animals at all times.

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TO BE CORRECTED BY: March 23, 2009

### 3.56 (c)

#### REPEAT

#### SANITATION.

(c) Housekeeping. Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart. Premises shall remain free of accumulations of trash.

\*\*\*\*\*

The receiving room had an excessive accumulation of non-husbandry related items including 9 boxes of filters and other materials. A delivery of rabbits was expected in the next two days. Excessive accumulations of materials could prevent completion of the required husbandry practices and could provide breeding grounds for mammalian and insect pests, which could harm the health and welfare of the animals.

\*\*\*

The refrigerator in room 2015, used to store husbandry materials for rabbits and other animals, had a thick layer of brown to tan dusty material on top. A large quantity of spilled bedding was also present on the floor of this room. The lack of housekeeping could result in contamination of supplies or attract mammalian and insect pests, which could contaminate the supplies and negatively impact the health of the animals.

\*\*\*

In room 3030, the clean side of the cage wash used for rabbit enclosures, an uncovered trashcan containing waste materials was present, which could create odors or attract vermin that could contaminate the clean, stored supplies.

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The clothes dryer in this area had an excessive accumulation of towels, clothing and other materials, some of which had fallen off the dryer and onto the floor between the dryer and the wall. This accumulation of materials could provide breeding grounds for mammalian or insect pests and could prevent completion of the required husbandry tasks. At least 2 dirty ceramic food/water receptacles with a layer of white to tan scaly material on their interior surface were identified on the shelf with clean supplies. These dirty food/water receptacles stored with clean supplies could contaminate the supplies, negatively impacting the health and welfare of the animals.

\*\*\*

The registrant must develop and follow a program of monitoring and maintenance to ensure that all premises for rabbits are kept clean and in good repair in order to protect the animals and to facilitate the prescribed husbandry practices.

\*\*\*

This is a repeat non-compliant item. It was also not in compliance on August 27, 2008.

### 3.56 (d)

#### SANITATION.

(d) Pest control. An effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained.

\*\*\*\*\*

The receiving room had several dead insects on the floor. The facility representative stated that a delivery of rabbits was expected in the next two days. Pests can contaminate supplies and enclosures and negatively impact the health and welfare of the animals. The registrant must develop and follow an effective program for the control of insects, ectoparasites, and avian and mammalian pests.

\*\*\*

TO BE CORRECTED BY: April 3, 2009

### 3.57

#### EMPLOYEES.

A sufficient number of employees shall be utilized to maintain the prescribed level of husbandry practices set forth in this subpart. Such practices shall be under the supervision of an animal caretaker who has a background in animal husbandry or care.

\*\*\*\*\*

In room 3030, the clean side cage wash used for rabbit enclosures, at least 2 dirty ceramic food/water receptacles with a layer of white to tan scaly material on their interior surface were identified on the shelf with clean supplies. These dirty food/water receptacles stored with clean supplies could contaminate the supplies, negatively impacting the health and welfare of the animals. The facility representative stated that the employees are trained to survey the area and return dirty materials to the dirty side to be re-cleaned but that this is not currently happening since the facility is short staffed.

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The registrant must ensure that a sufficient number of appropriately trained employees are utilized in order to maintain the prescribed level of husbandry practices set forth in this subpart in order to protect the health and welfare of the animals.

\*\*\*

TO BE CORRECTED BY: April 3, 2009

**3.75 (a) REPEAT DIRECT NCI**  
**HOUSING FACILITIES, GENERAL.**

(a) Structure: construction. Housing facilities for nonhuman primates must be designed and constructed so that they are structurally sound for the species of nonhuman primates housed in them. They must be kept in good repair, and they must protect the animals from injury, contain the animals securely, and restrict other animals from entering.

\*\*\*\*\*

At least 18 squirrel monkey cages located in room 5009 had a two inch by four inch opening at the front of the enclosure. This opening was large enough that an animals head and/or body could pass through it leading to possible injury, entrapment, or escape. Some of these openings had protruding metal points around the edges of the opening, which could injure the animals. A facility representative told inspectors that a baby squirrel monkey previously escaped from its enclosure through this opening; when it attempted to return to its mother, it entered the wrong enclosure and was killed. The facility representative stated that the staff was instructed to place zip ties on the opening, to prevent squirrel monkeys from escaping. Inspectors observed zip ties on three enclosures; none of these zip ties were positioned in a manner that effectively reduced the size of the opening.

\*\*\*

Inspectors observed several nonhuman primate rooms in which the drain covers had been removed for cleaning and not replaced. These openings were large enough that if an animal escaped, as has been reported in this facility, it could become injured or trapped in the opening. Rooms with drains that were completely or partially uncovered included: 3024 (2 squirrel monkeys), 3025 (4 macaques), 3029 (17 squirrel monkeys), 5019 (11 squirrel monkeys in first area, 11 in back area), 5009 (18 squirrel monkeys).

The registrant must develop and follow a program of monitoring and maintenance to ensure that all buildings used to house animals are kept clean and in good repair in order to facilitate the required cleaning and sanitization and to protect the animals from injury.

\*\*\*

This is a repeat non-compliant item. It was also not in compliance on August 27, 2008.

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

(c) Surfaces (1) General requirements. The surfaces of housing facilities -- including perches, shelves, swings, boxes, houses, dens, and other furniture-type fixtures or objects within the facility -- must be constructed in a manner and made of materials that allow them to be readily cleaned and sanitized, or removed or replaced when worn or soiled. Furniture-type fixtures or objects must be sturdily constructed and must be strong enough to provide for the safe

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activity and welfare of nonhuman primates. Floors may be made of dirt, absorbent bedding, sand, gravel, grass, or other similar material that can be readily cleaned, or can be removed or replaced whenever cleaning does not eliminate odors, diseases, pests, insects, or vermin.

\*\*\*\*\*

In room 3028, housing 10 macaques, the drywall behind the hose was bowing out and had a roughened surface with peeling paint. This area of the wall is no longer impervious to moisture and can no longer be effectively cleaned and sanitized. In room 3029, housing 17 squirrel monkeys, the paneling in the back left corner of the room was broken on the corner creating an approximately 6 inch by 1 inch gap. The surface underneath can not be effectively cleaned and sanitized. In the back part of room 5019, housing 11 squirrel monkeys, there were areas of chipping and peeling paint causing the cinder blocks underneath to be exposed on two walls of the room. In the dirty side of the cagewash inspected last, on two walls there were areas of peeling and cracked paint exposing the underlying cinder blocks. The largest of these exposed areas was approximately 12 by 6 inches.

\*\*\*

All surfaces within housing facilities must be constructed in a manner that allows them to be readily cleaned and sanitized in order to protect the health of the animals. The registrant must repair the aforementioned areas and develop a program of monitoring and maintenance to ensure that all surfaces of housing facilities are constructed in a manner that allows them to be readily cleaned and sanitized at all times.

\*\*\*

This is a repeat non-compliant item. It was also not in compliance on August 27, 2008.

### 3.75 (e)

#### HOUSING FACILITIES, GENERAL.

e) Storage. Supplies of food and bedding must be stored in a manner that protects the supplies from spoilage, contamination, and vermin infestation. The supplies must be stored off the floor and away from the walls, to allow cleaning underneath and around the supplies. Food requiring refrigeration must be stored accordingly, and all food must be stored in a manner that prevents contamination and deterioration of its nutritive value. Only the food and bedding currently being used may be kept in animal areas, and when not in actual use, open food and bedding supplies must be kept in leakproof containers with tightly fitting lids to prevent spoilage and contamination. Substances that are toxic to the nonhuman primates but that are required for normal husbandry practices must not be stored in food storage and preparation areas, but may be stored in cabinets in the animal areas.

\*\*\*\*\*

An open bottle of Pedialyte was not marked with the date it was opened. The label states that it is only supposed to be used for a limited period of time after being opened, in order to ensure that it does not become contaminated or deteriorate. Bags of sunflower nuts and peanuts were also observed that were open at the top, making it possible for the contents to become contaminated or deteriorate.

\*\*\*

In room 3017, a food storage room, "Foot Rot & Ringworm Spray" and WD40 were stored above food treat items used for nonhuman primates including Fig Newtons, Gatorade, other treats, and vitamins. A bag of peanuts located in this area was open at the top and not sealed or protected from contamination or spoilage.

\*\*\*

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In room 3005, a nonhuman primate neurobehavior lab that is currently being used to store materials, Pine-sol and glass cleaner were stored above or adjacent to "Precision Pellets," a treat item for nonhuman primates. In a cabinet mirror cleaner and Lysol were stored adjacent to a bag of Gourmet Dried Fruit: Nutty Bananas. Storage of food items near chemicals could result in contamination of the items, which could negatively impact the health of the nonhuman primates.

\*\*\*

The registrant must develop and follow a program of monitoring and maintenance to ensure that supplies of food and bedding are stored in a manner that protects the supplies from spoilage, contamination, and vermin infestation. Additionally, the registrant must ensure that open food and bedding supplies are kept in leakproof containers with tightly fitting lids to prevent spoilage and contamination and that substances that are toxic to the nonhuman primates (but that are required for normal husbandry practices) are not stored in food storage and preparation areas.

\*\*\*

TO BE CORRECTED BY: March 27, 2009

### 3.75 (f) REPEAT

#### HOUSING FACILITIES, GENERAL.

(f) Drainage and waste disposal. Housing facility operators must provide for regular and frequent collection, removal, and disposal of animal and food wastes, bedding, dead animals, debris, garbage, water, and any other fluids and wastes, in a manner that minimizes contamination and disease risk. Housing facilities must be equipped with disposal facilities and drainage systems that are constructed and operated so that animal wastes and water are rapidly eliminated and the animals stay dry. Disposal and drainage systems must minimize vermin and pest infestation, insects, odors, and disease hazards. All drains must be properly constructed, installed, and maintained. If closed drainage systems are used, they must be equipped with traps and prevent the backflow of gases and the backup of sewage onto the floor. If the facility uses sump ponds, settlement ponds, or other similar systems for drainage and animal waste disposal, the system must be located far enough away from the animal area of the housing facility to prevent odors, diseases, insects, pests, and vermin infestation. If drip or constant flow watering devices are used to provide water to the animals, excess water must be rapidly drained out of the animal areas by gutters or pipes so that the animals stay dry. Standing puddles of water in animal areas must be mopped up or drained so that the animals remain dry. Trash containers in housing facilities and in food storage and food preparation areas must be leakproof and must have tightly fitted lids on them at all times. Dead animals, animal parts, and animal waste must not be kept in food storage or food preparation areas, food freezers, food refrigerators, and animal areas.

\*\*\*\*\*

Inspectors observed several rooms housing nonhuman primates in which the trashcans were not covered. Uncovered trashcans can create odors, attract vermin, and be a disease hazard to the animals. Rooms with uncovered or partially covered trashcans included: 3025 (4 macaques), 3028 (10 macaques), 3018 (6 macaques), and two trashcans on the dirty side of a cagewash used to clean nonhuman primate enclosures.

\*\*\*

In room 3026 (housing 16 squirrel monkeys), room 5009 (housing 18 squirrel monkeys), and room 3028 (housing 10 macaques) standing water was present on the floor. In room 3022 (housing 3 macaques) standing water was present on the bottom shelf of the television cart.

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\*\*\*

Wash water from room 3021, the dirty side of the cage wash for nonhuman primate enclosures, flows under the door and into the hallway used to travel between animal rooms. A large amount of water was present in the hallway, making it difficult for inspectors to avoid walking through it. This dirty wash water could contaminate the hallway, materials moved through the hallway, and animal caretakers that walk through the hallway and into animal rooms. Drainage for waste water must be constructed in a manner that waste water is rapidly eliminated and does not contaminate the animal rooms in order to protect the health of the animals.

\*\*\*

Facilities must provide for the regular and frequent removal of water and other fluid wastes in order to minimize contamination/disease risk and to protect the health of the animals. The registrant must ensure that all waste water and other standing water in animal areas are regularly and frequently removed and that drainage is constructed in a manner that minimizes contamination and disease hazard.

\*\*\*

This is a repeat non-compliant item. It was also not in compliance on August 27, 2008.

### 3.75 (c) (3)

#### HOUSING FACILITIES, GENERAL.

(c) Surfaces (3) Cleaning. Hard surfaces with which nonhuman primates come in contact must be spot-cleaned daily and sanitized in accordance with §3.84 of this subpart to prevent accumulation of excreta or disease hazards. If the species scent mark, the surfaces must be sanitized or replaced at regular intervals as determined by the attending veterinarian in accordance with generally accepted professional and husbandry practices. Floors made of dirt, absorbent bedding, sand, gravel, grass, or other similar material, and planted enclosures must be raked or spot-cleaned with sufficient frequency to ensure all animals the freedom to avoid contact with excreta. Contaminated material must be removed or replaced whenever raking and spot cleaning does not eliminate odors, diseases, insects, pests, or vermin infestation. All other surfaces of housing facilities must be cleaned and sanitized when necessary to satisfy generally accepted husbandry standards and practices. Sanitization may be done by any of the methods provided in §3.84(b)(3) of this subpart for primary enclosures.

\*\*\*\*\*

A nonhuman primate chair, in a room housing 6 macaques, contained an excessive accumulation of fecal material in the tray at the bottom. This chair was located immediately adjacent to a clean chair and animal enclosures.

\*\*\*

The television carts and televisions in several nonhuman primate rooms were covered in a general layer of white to gray grimy material and/or brown colored material that appeared to be food residue. With a gloved hand the inspector was able to easily rub off this white to gray material. Rooms with soiled televisions and carts included: 3022 (3 macaques), 3025 (4 macaques), 3027 (3 macaques), 3029 (17 squirrel monkeys).

\*\*\*

In room 3024, used to house 2 squirrel monkeys, the door and radio were covered with a general layer of scaly and grimy material.

\*\*\*

In room 3026, housing 16 squirrel monkeys, the wall around the sink area was streaked with drip marks of black to

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gray material. The sink was coated in some areas with a white to gray scaly material.

\*\*\*

In room 3028, housing 10 macaques, discarded toys and old food material was present in the corner of the room.

\*\*\*

In room 3029, housing 17 squirrel monkeys, the area above and behind the hose was covered with red to brown colored streaky material.

\*\*\*

An enclosure in room 3029 housing a squirrel monkey had crusty brown material present on the water bottle holder. In room 5009, an enclosure housing one squirrel monkey had dry, brownish colored crusty material present on it.

\*\*\*

In room G010, an investigator lab, the chamber used for nonhuman primates had brownish colored sticky material present on the walls, particularly in the corner. The inspector was able to easily remove this material with a tongue depressor. The floor also had a dirty appearance.

\*\*\*

The registrant must develop and follow a program of monitoring and maintenance to ensure that all hard surfaces with which nonhuman primates come into contact with are spot cleaned daily and sanitized as prescribed in this subpart and to ensure that all other surfaces of housing facilities must be cleaned and sanitized when necessary to satisfy generally accepted husbandry standards and practices.

\*\*\*

TO BE CORRECTED BY: March 27, 2009

### 3.75 (c) (1) (ii)

#### HOUSING FACILITIES, GENERAL.

(c) Surfaces (1) General requirements. The surfaces of housing facilities -- including perches, shelves, swings, boxes, houses, dens, and other furniture-type fixtures or objects within the facility -- must be constructed in a manner and made of materials that allow them to be readily cleaned and sanitized, or removed or replaced when worn or soiled. Furniture-type fixtures or objects must be sturdily constructed and must be strong enough to provide for the safe activity and welfare of nonhuman primates. Floors may be made of dirt, absorbent bedding, sand, gravel, grass, or other similar material that can be readily cleaned, or can be removed or replaced whenever cleaning does not eliminate odors, diseases, pests, insects, or vermin. Any surfaces that come in contact with nonhuman primates must: (i) Be free of excessive rust that prevents the required cleaning and sanitization, or that affects the structural strength of the surface;

\*\*\*\*\*

In the back part of room 5019, the metal hooks on at least 5 of the black rubber straps used to secure the perches in the cages of the squirrel monkeys had rusted to the point that they no longer can be effectively cleaned and sanitized. In room 3029, housing 17 squirrel monkeys, the vent on the wall had an area of exposed metal that was rusted to the point that it can no longer be effectively cleaned and sanitized. The area was on the bottom left-hand corner and was L shaped, approximately 4 inches tall and 2 inches wide.

The registrant must develop and follow a program of monitoring and maintenance to ensure that all surfaces are free

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of excessive rust that prevents the required cleaning and sanitization or affects the structural strength.

\*\*\*

TO BE CORRECTED BY: April 3, 2009

### 3.80 (b) (2) (i)

#### PRIMARY ENCLOSURES.

Primary enclosures for nonhuman primates must meet the following minimum requirements: (b) Minimum space requirements. Primary enclosures must meet the minimum space requirements provided in this subpart. These minimum space requirements must be met even if perches, ledges, swings, or other suspended fixtures are placed in the enclosure. Low perches and ledges that do not allow the space underneath them to be comfortably occupied by the animal will be counted as part of the floor space. (2) On and after February 15, 1994: (i) The minimum space that must be provided to each nonhuman primate, whether housed individually or with other nonhuman primates, will be determined by the typical weight of animals of its species, except for brachiating species and great apes /3/ and will be calculated by using the table provided in this sub section.

\*\*\*\*\*

A human infant incubator in room 2010, an investigator lab, is used to house adult squirrel monkeys after craniotomies. The nonhuman primates are then kept in the incubator overnight before returning to their primary enclosures. Surgical records were examined and showed that animals remain in the incubator for as long as 12, 13, 15 or up to 18 hours after surgery. The incubator is 33 inches long and 16 inches deep, providing 3.67 square feet of floor space. It is 18 inches high. Squirrel monkeys are considered Group 2 nonhuman primates and require 3 square feet with an enclosure height of 30 inches. The incubator provides 12 inches less height. This human infant incubator is not an adequate enclosure for this species.

\*\*\*

The registrant must develop a program of monitoring and maintenance to ensure that all enclosures used to house nonhuman primates meet or exceed the minimum requirements described in the regulations.

\*\*\*

TO BE CORRECTED IMMEDIATELY

### 3.81 (a)

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

(a) Social grouping. The environment enhancement plan must include specific provisions to address the social needs of nonhuman primates of species known to exist in social groups in nature. Such specific provisions must be in accordance with currently accepted professional standards, as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian.

\*\*\*\*\*

SOP PROG 8 Promotion of Psychological Well-Being states that "Efforts will be made to advance a program of social grouping." A facility representative stated that animals are pair housed, if they come in together, but there is no active program in place to introduce singly housed animals into a program of social grouping. Protocol 2007:1688 states that "monkeys should be individually-housed in standard primate cages...Exceptions can be made in situation of

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limited available caging (in which case pair-housing would be preferred) or during the post-arrival quarantine period (for which group-housing of 3-6 monkeys in larger, gang caging would be acceptable)." This exception is permitted by the investigator only when space prevents singly housing, not based on the psychological needs of the animals or scientific necessity.

The registrant must ensure that the facility plan for environmental enrichment concerning social grouping is followed and documented in order to protect the psychological well-being of the nonhuman primates.

\*\*\*

TO BE CORRECTED BY: April 3, 2009

### 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.

\*\*\*\*\*

In room 3005, a nonhuman primate neurobehavior lab that is currently being used to store materials, Pine sol and glass cleaner were stored above enrichment toys on slatted shelves. These chemicals could lead to contamination of the toys, which could negatively impact the health of the animals.

\*\*\*

At least 12 metal circular discs, which are supposed to be reflective and act as mirrors to provide enrichment for the nonhuman primates were scratched to the point that the surface was no longer reflective. At least 4 "chew toys" for nonhuman primates were observed that had been chewed to the point that the surface was extremely grooved and pitted. These toys had been cleaned and disinfected by the facility but brown to tan grimy material was visible in some of these roughened surfaces. This accumulation of dirt and grime could result in transmission of diseases between the animals since the roughened surface of these worn toys prevents effective cleaning and sanitization. All enrichment items must be kept in good repair to ensure that they effectively provide enrichment to the animals and can be effectively cleaned and sanitized.

\*\*\*

The registrant must develop and follow a program of monitoring and maintenance to ensure that all enrichment items for nonhuman primates are kept in good repair so that they can be effectively cleaned and sanitized and that all enrichment items are protected from contamination.

\*\*\*

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### 3.81

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

Dealers, exhibitors, and research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates. The plan must be in accordance with the currently accepted professional standards as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian. This plan must be made available to APHIS upon request, and, in the case of research facilities, to officials of any pertinent funding agency.

\*\*\*\*\*

The SOP for Promotion of Psychological Well-Being states that "treats alone or in puzzle feeders or complex feeders requiring manipulation" will be provided, however inspectors did not observe any puzzle feeders; a facility representative stated that the facility did not possess any working puzzle feeders or complex feeders. The SOP also states that "Animals may be exempted from the Program of Psychological Well-Being for valid medical or experimental reasons" and that "the IACUC shall review exemption on a monthly basis." Nonhuman primates on protocol 2007:1688 were exempted from environmental enrichment as the PI stated manipulative enrichment items would interfere with the protocol; however a facility representative reported that one study animal that was chewing on its perch was allowed to have a toy to prevent the destructive behavior.

\*\*\*

The registrant must ensure that the facility plan for environmental enrichment is followed and documented in order to protect the psychological well-being of the nonhuman primates.

\*\*\*

TO BE CORRECTED BY: April 3, 2009

### 3.81 (c) (4)

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

(c) 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: (4) Individually housed nonhuman primates that are unable to see and hear nonhuman primates of their own or compatible species;

\*\*\*\*\*

The facility's SOP concerning the psychological well-being of nonhuman primates states that "Animals will be housed in rooms so that cages face one another for visual and vocal interaction of singly housed animals." The 4 macaques housed in room 3025 and the 3 macaques housed in room 3027 had no visual contact with other nonhuman primates.

The registrant must ensure that the facility plan for environmental enrichment is followed and documented in order to protect the psychological well-being of the nonhuman primates.

\*\*\*

TO BE CORRECTED BY: April 3, 2009

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**3.81** (e) (2) **DIRECT NCI**

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

(e) Exemptions. (2) For a research facility, the Committee may exempt an individual nonhuman primate from participation in some or all of the otherwise required environment enhancement plans for scientific reasons set forth in the research proposal. The basis of the exemption shall be documented in the approved proposal and must be reviewed at appropriate intervals as determined by the Committee, but not less than annually.

\*\*\*\*\*

The Committee approved an exemption to environment enhancement for squirrel monkeys on protocol 2007:1688, as the investigator stated that these items would interfere with the protocol. For 13 months, IACUC meeting minutes reflect that the IACUC approves that there be "no toys in cages because it interferes with manipulation studies" on a protocol level, but the IACUC has not approved this exemption on an individual animal basis. Despite stating in the protocol that manipulative toys would interfere with the protocol, the investigator allowed one study animal that was chewing on its perch to have a toy to prevent the destructive behavior. Additionally, 24 squirrel monkeys had variable degrees of hair loss, which can be a sign of psychological distress. Other animals were observed to be actively plucking or stripping hair from their bodies or exhibiting stereotypic behaviors such as flipping or swaying that can also be signs of psychological distress.

IACUC Meeting Minutes examined between March 2008 and February 2009 indicated that each month the IACUC reviewed an exemption to environment enhancement for new monkeys in quarantine. The exemption states that toys will not be given to these animals, as the toys could interfere with the ability to squeeze the cage in order to force them to move into new cages. This exemption has been approved as a generic exemption by the IACUC, not on an individual animal basis, and is not required for scientific reasons and is not part of a protocol as required by the regulations. When inspectors asked animal caretaker staff about the exemption, they stated that it is neither necessary nor done as they can successfully train animals to switch cages even with toys present.

When the IACUC excuses individual nonhuman primates from participation in some or all of the environment enhancement plan for scientific reasons, the Committee must review this at an appropriate interval, but not less than annually.

\*\*\*

TO BE CORRECTED IMMEDIATELY

**3.81** (c) (2) **DIRECT NCI**

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

(c) 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;

\*\*\*\*\*

Twenty six nonhuman primates had variable degrees of hair loss ranging from partial to full loss of hair on the tail to

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patchy hair loss on the body, which can be a sign of psychological distress. Approximately 7 nonhuman primates were observed to be actively plucking or stripping hair from their bodies or exhibiting stereotypic behaviors such as flipping or swaying that can also be signs of psychological distress. The 24 squirrel monkeys showing these signs were exempted from manipulative enrichment by the IACUC, but the facility had not provided them with any special attention, such as, but not limited to, non-manipulative environmental enhancements.

Primate Enrichment Worksheets, used to evaluate the nonhuman primate use of enrichment and score any observed abnormal behaviors, revealed that animals assigned to the protocol that the IACUC exempted from environmental enrichment were not evaluated, despite the high level of abnormal behavior noted by the inspectors. During this time period none of the animals exhibiting abnormal behaviors or hair loss noted by the inspectors were documented in these worksheets. The worksheets evaluated a total of 113 nonhuman primates, and abnormal behavior was only identified for two animals.

The registrant must develop and follow a plan to ensure that those nonhuman primates that show signs of being in psychological distress through behavior or appearance receive special considerations with regard to enhancement of their environment, in order to protect the health and welfare of the animals.

\*\*\*

TO BE CORRECTED BY: April 3, 2009

### 3.82 (a) REPEAT FEEDING.

(a) The diet for nonhuman primates must be appropriate for the species, size, age, and condition of the animal, and for the conditions in which the nonhuman primate is maintained, according to generally accepted professional and husbandry practices and nutritional standards. The food must be clean, wholesome, and palatable to the animals. It must be of sufficient quantity and have sufficient nutritive value to maintain a healthful condition and weight range of the animal and to meet its normal daily nutritional requirements.

\*\*\*\*\*

Three containers of baby food used as treats for nonhuman primates were located in the investigator lab located in room G010. These containers of food expired 17May08, 19Feb08, and 02Apr08.

\*\*\*

Food that is used past its expiration date may no longer be wholesome, palatable, or meet the nutritional needs of the animals. All feed must be must be wholesome, palatable, and of sufficient nutritive value to maintain the health of the animals. The registrant must develop a program of monitoring and maintenance to ensure that all feed is free from contamination, wholesome, palatable, and of sufficient quantity and nutritive value to meet the normal daily requirements of the animals.

\*\*\*

This is a repeat non-compliant item. It was also not in compliance on August 27, 2008.

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## Inspection Report

**3.84** (b) (3)

### **CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.**

(b) Sanitization of primary enclosures and food and water receptacles. (3) Hard surfaces of primary enclosures and food and water receptacles must be sanitized using one of the following methods: (i) Live steam under pressure; (ii) Washing with hot water (at least 180 °F (82.2 °C)) and soap or detergent, such as in a mechanical cage washer; (iii) Washing all soiled surfaces with appropriate detergent solutions or disinfectants, or by using a combination detergent/disinfectant product that accomplishes the same purpose, with a thorough cleaning of the surfaces to remove organic material, so as to remove all organic material and mineral buildup, and to provide sanitization followed by a clean water rinse.

\*\*\*\*\*

The logbook for the cagewash used to clean nonhuman primate enclosures in room 5014 was examined. Test strips on multiple dates indicated that the cagewash had failed to reach the required temperature of 180 degrees F. Dates with test strips indicating that the cagewash did not reach required temperatures included 11/30, 12/5 (three strips), 12/18, and 12/22.

\*\*\*

The registrant must develop and follow an effective program of monitoring and maintenance to ensure that all primary enclosures and food and water receptacles are cleaned and sanitized as required by the regulations in order to protect the health of the animals.

\*\*\*

TO BE CORRECTED BY: March 27, 2009

**3.84** (c)

### **CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.**

(c) Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair in order to protect the nonhuman primates from injury, to facilitate the husbandry practices required in this subpart, and to reduce or eliminate breeding and living areas for rodents, pests, and vermin. Premises must be kept free of accumulations of trash, junk, waste, and discarded matter. Weeds, grass, and bushes must be controlled so as to facilitate cleaning of the premises and pest control.

\*\*\*\*\*

In room 3020 (a procedure room used for nonhuman primates) many areas were not clean, despite the fact that the daily checklist stated that the room had been cleaned for the day. The counters, front of the base cabinets, sink, faucets, and handles were covered with a white to gray colored crusty material. Yellow to brown colored material was also present on the drain of the sink. The procedure table had several areas with reddish colored dried material that appeared to be dried blood.

\*\*\*

In room 3030, the clean side cage wash used for nonhuman primate enclosures, an uncovered trashcan containing waste materials was present, could create odors or attract vermin that could contaminate the clean, stored supplies. The dryer in this area had an excessive accumulation of towels, clothing and other materials, some of which had fallen off and onto the floor between the dryer and the wall. This accumulation of materials could provide breeding grounds for mammalian or insect pests and could interfere with the facility's ability to complete the required

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husbandry tasks. At least 2 dirty ceramic food/water receptacles with a layer of white to tan scaly material on their interior surface were on the shelf with clean supplies. These dirty food/water receptacles stored with clean supplies could contaminate the supplies, negatively impacting the health and welfare of the animals.

\*\*\*

Room 3023 is used to euthanize and then necropsy nonhuman primates. The counters were covered with a general layer of white to gray colored scaly material and a buildup of old soap was present underneath the soap dispenser.

\*\*\*

In the dirty side of the last cagewash inspected, used to clean nonhuman primate enclosures, the tops of two chemical barrels were covered with fecal material, bottles containing standing water, and black colored liquid. A cart in this area had brown liquid on its surface, discarded feed, goggles, a wrench, and clean trash bags.

\*\*\*

The registrant must develop and follow a program of monitoring and maintenance to ensure that all premises are kept clean and in good repair in order to protect the nonhuman primates from injury, to facilitate the husbandry practices required in this subpart, and to reduce or eliminate breeding and living areas for rodents, pests, and vermin. Registrant must also ensure that premises must be kept free of accumulations of trash, junk, waste, and discarded matter.

\*\*\*

TO BE CORRECTED BY: March 27, 2009

### 3.84 (d)

#### CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

(d) Pest control. An effective program for control of insects, external parasites affecting nonhuman primates, and birds and mammals that are pests, must be established and maintained so as to promote the health and well-being of the animals and reduce contamination by pests in animal areas.

\*\*\*\*\*

In room 3027, housing 3 macaques, the box style rodent trap was located on the shelf of the television cart rather than on the floor. Effective programs for the control of mammalian, avian, and insect pests are required in order to prevent contamination in animal areas and to protect the health of the animals

The registrant must develop and follow an effective program of pest control.

\*\*\*

TO BE CORRECTED BY: April 3, 2009

### 3.85

#### EMPLOYEES.

Every person subject to the Animal Welfare regulations (9 CFR parts 1, 2, and 3) maintaining nonhuman primates must have enough employees to carry out the level of husbandry practices and care required in this subpart. The employees who provide husbandry practices and care, or handle nonhuman primates, must be trained and supervised by an individual who has the knowledge, background, and experience in proper husbandry and care of nonhuman primates to supervise others. The employer must be certain that the supervisor can perform to these

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standards.

\*\*\*\*\*

Training records were requested for several facility employees. One employee whose training records were examined performs daily husbandry tasks and performs daily health checks for the nonhuman primates. The folder was labeled with her name and the year 2007 and contained one document labeled "Master Training Document" that was completely blank, with the exception of the words "Goats" and "Dogs" added to the list of Training Sets on the first page. The employee's name was not written on the form; none of the training tasks for any skill were marked as completed. The document states that "All training records should be reviewed by the director, associate director or departmental HR (senior coordinator)" with an area for a signature and a date. This was not completed. The only documented training for this employee was: Animal Welfare Resources On-Line Training for Investigator-Technician Staff (3/14/08) and ARPP Refresher (1/30/09).

Training records for 5 additional staff members who perform daily tasks for the nonhuman primates, including husbandry tasks and daily health checks, were examined. The area in the document that states the training records will be reviewed by the facility with a location for a signature and date was not completed for any of these employees.

\*\*\*

Daily checklists for husbandry tasks and observation of nonhuman primates were examined that covered activities between March 1 and March 10, 2009. Thirteen rooms of nonhuman primates were cared for over the course of this time period. In 67 out of 130 times (52%) rooms were serviced, the staff members spent 10 minutes or less in the rooms. The daily checklists include tasks such as checking the temperature/humidity, straightening/organizing room, washing down racks and floors, feeding vitamins, and performing daily health checks on the animals. Some technicians spent as little as 3 to 5 minutes in the room to complete these tasks.

On days when rooms were disinfected during this time period, technicians spent a total of 11 minutes or less in the room on four occasions (11, 10, 10, and 7 minutes). The disinfectant utilized by the facility, "Tec-Quat-128", requires a contact time of 10 minutes in order to effectively disinfect according to the label instructions. On other occasions during the examined time period, some technicians took 34 minutes or 1 hr 10 minutes to complete the daily tasks and disinfection of the room. Despite being listed as a weekly task, in three rooms no disinfection was documented during the 10 day time period that was examined.

\*\*\*

In room 5019A, a room used to house squirrel monkeys, the daily task list did not document that any of the daily tasks were completed (husbandry or daily observation of the animals) on one weekend in February.

\*\*\*

In room 3030, the clean side cage wash used for nonhuman primate enclosures, at least 2 dirty ceramic food/water receptacles with a layer of white to tan scaly material on their interior surface were identified on the shelf with clean supplies. These dirty food/water receptacles stored with clean supplies could contaminate the supplies, negatively impacting the health and welfare of the animals. The facility representative stated that the employees are trained to survey the area and return dirty materials to the dirty side to be re-cleaned but that this is not currently happening

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since the facility is short staffed.

\*\*\*

In room 3020, a procedure room used for nonhuman primates, many areas were present that were not clean, despite the fact that the daily checklist stated that the room had been cleaned for the day. The counters, front of the base cabinets, sink, faucets, and handles were covered with a white to gray colored crusty material. Yellow to brown colored material was also present on the drain of the sink. The procedure table had several areas with reddish colored dried material that appeared to be dried blood.

\*\*\*

In room 3026, housing 16 squirrel monkeys, the wall around the sink area was streaked with drips of black to gray material, the sink was coated in some areas with a white to gray scaly material, and standing water was present on the floor. When the inspectors brought these problems to the attention of the facility representative, she stated that the room was like this because the regular tech was on vacation.

\*\*\*

During the course of the inspection, the facility manager (who oversees the facility and the husbandry staff) and a husbandry supervisor who supervise the nonhuman primate husbandry staff stated that they did not know what was going on in the nonhuman primate rooms when asked questions by the inspectors. When training records for these two individuals were examined, the records did not document any instruction or training in the area of nonhuman primates. According to facility representatives, one supervisor had no nonhuman primate experience prior to being hired by the facility while the other supervisor had a background in nonhuman primate handling but not husbandry.

\*\*\*

The registrant reported in an amendment its 2008 Annual Report that the IACUC approved an exemption to housing standards to allow one nonhuman primate to be housed in an enclosure that did not meet minimum height requirements in order to allow the investigator to make modifications to the pole and collar system because the research assistant was unable to capture the animal in an enclosure that met the minimum requirements. The Director of the Office of Compliance told the inspector that this macaque could not fully stand up in the enclosure. The amendment to the annual report stated that the exemption was in effect for approximately one month; however IACUC meeting minutes review the approval as being in effect for 5 months. Due to inadequate training of the research assistant, a nonhuman primate was kept in housing that did not meet the minimum height requirements for an extended period of time.

\*\*\*

A large number of housekeeping and husbandry problems were present throughout the nonhuman primate facilities. Several facility representatives expressed concern about the current staffing levels at the facility. Training records provided by the facility do not document adequate training of supervisors or animal caretakers in the husbandry practices or care of the animals. The registrant must ensure that the employees who provide husbandry practices and care, or handle nonhuman primates, are trained and supervised by an individual who has the knowledge, background, and experience in proper husbandry and care of nonhuman primates to supervise others. The employer must be certain that the supervisor can perform to these standards and ensure that an adequate number of properly trained employees are utilized in order to carry out the level of husbandry practices and care required in this subpart.

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TO BE CORRECTED BY: April 3, 2009

### 3.125 (c)

#### FACILITIES, GENERAL.

(c) Storage. Supplies of food and bedding shall be stored in facilities which adequately protect such supplies against deterioration, molding, or contamination by vermin. Refrigeration shall be provided for supplies of perishable food.

\*\*\*\*\*

An uncovered container of hay was located in room 2015. The facility representative did not know the age of the feed. When stored without a cover, the hay could become contaminated by vermin or deteriorate, decreasing its nutritional value and potentially harming the health of the animals.

\*\*\*

On the clean side of the cagewash in room G082 used to clean the gerbil enclosure, clean bedding that was not being actively used by an employee was stored in an uncovered container, which could result in contamination of the bedding. Additionally, a trashcan containing waste materials was not covered, which could attract pests, create odors, and could result in contamination of the clean animal caging and supplies stored in this room.

\*\*\*

The registrant must develop and follow a program that ensures that all supplies of food and bedding are stored in facilities which adequately protect such supplies against deterioration, molding, or contamination by vermin.

\*\*\*

TO BE CORRECTED BY: March 27, 2009

### 3.131 (b)

#### SANITATION.

(b) Sanitation of enclosures. Subsequent to the presence of an animal with an infectious or transmissible disease, cages, rooms, and hard-surfaced pens or runs shall be sanitized either by washing them with hot water (180 F. at source) and soap or detergent, as in a mechanical washer, or by washing all soiled surfaces with a detergent solution followed by a safe and effective disinfectant, or by cleaning all soiled surfaces with saturated live steam under pressure. Pens or runs using gravel, sand, or dirt, shall be sanitized when necessary as directed by the attending veterinarian.

\*\*\*\*\*

The facility representative stated that the water softener for the cagewash in room G082 had been down for three weeks, causing the cagewash to be unable to reach the desired temperature, which was confirmed when test strips for the cage wash were examined. Inspectors observed that the cagewash test strips failed to reach 180 degrees F on 3/5/09, 3/6/09 (2 strips), and 3/9/09.

\*\*\*

A plastic cage, containing two gerbils, had flakey, white to gray colored material covering part on its interior and exterior surfaces. Enclosures must be effectively cleaned and sanitized in order to protect the health of the animals.

\*\*\*

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The registrant must develop a system of monitoring and maintenance to ensure that all cages are effectively cleaned and sanitized as required by the regulations.

\*\*\*

TO BE CORRECTED BY: March 27, 2009.

### 3.131 (d)

#### SANITATION.

(d) Pest control. A safe and effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained.

\*\*\*\*\*

Room G025, used to store bedding for the gerbils, contained a large amount of discarded construction materials including an old, large sink that had previously been used on the dirty side of the cagewash, paint, vent covers, and other discarded materials. The facility representative stated that the discarded materials had been present in this room since November 2008. Rodent dropping were observed on the ground, underneath these materials. Five discarded box style rodent traps were also stacked in this room. Rodents and other pests could contaminate the stored supplies and transmit disease to the animals.

\*\*\*

The registrant must develop and follow an effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained.

\*\*\*

TO BE CORRECTED BY: March 27, 2009

### 3.131 (c)

#### SANITATION.

(c) Housekeeping. Premises (buildings and grounds) shall be kept clean and in good repair in order to protect the animals from injury and to facilitate the prescribed husbandry practices set forth in this subpart. Accumulations of trash shall be placed in designated areas and cleared as necessary to protect the health of the animals.

\*\*\*\*\*

An accumulation of discarded construction materials was present in G025, the room used to store bedding for the gerbils. The accumulated materials included an old, large sink with attached counters that was previously located in the dirty side of the cagewash, paint, vent covers, and a plastic storage container with black soil like material on it. A general layer of dust and dirt was present on and around these materials. The facility representative stated that these materials had been present since November 2008. Five discarded box style rodent traps were also present in this area. The dirt and grime associated with this accumulated trash could contaminate the bedding material and the large accumulation of non-husbandry materials could create breeding grounds for mammalian and rodent pests and interfere with the required cleaning and sanitization.

\*\*\*

The refrigerator in room 2015, used to store husbandry materials for rabbits, gerbils, and other animals, had a thick layer of brown to tan dusty material on top of it. A large quantity of spilled bedding was also present on the floor of this room.

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\*\*\*  
A layer of brown to tan dust was present on surfaces in room G082, the dirty side of the cagewash used to clean gerbil enclosures, including the rubber bumper on the wall and the machinery.  
\*\*\*

In room G078, the dirty side of the cagewash used to clean gerbil enclosures, dirt and other materials had accumulated in the corner behind red trashcan. Two trashcans in this room containing waste materials were uncovered. An accumulation of gray to white material was present on the sink, counters, faucet, and faucet handles.  
\*\*\*

A large accumulation of spilled, moist bedding was present under the pallets in room G082, the clean side of the cage wash used to clean the gerbil enclosure. The moist, spilled bedding could attract pests/feral rodents and could support the growth of mold and/or bacteria that could contaminate the clean materials stored in the room. The SOP concerning the cagewash states that the pallets will be rotated weekly, as did the checklist outside the room, but cleaning records indicated that the task had not been completed since 2/20/2009.  
\*\*\*

The registrant must ensure that all premises are kept clean and in good repair in order to protect the animals and to facilitate the prescribed husbandry practices set forth in this subpart.  
\*\*\*

TO BE CORRECTED BY: March 27, 2009

### 3.132 EMPLOYEES.

A sufficient number of adequately trained employees shall be utilized to maintain the professionally acceptable level of husbandry practices set forth in this subpart. Such practices shall be under a supervisor who has a background in animal care.  
\*\*\*\*\*

A large accumulation of spilled, moist bedding was present under the pallets in room G082, the clean side of the cage wash used to clean the gerbil enclosure. The SOP concerning the cagewash states that the pallets will be rotated weekly, as did the checklist outside the room, but cleaning records indicated that the task had not been completed since 2/20/2009.

The registrant must ensure that a sufficient number of adequately trained employees are utilized to maintain the professionally acceptable level of husbandry practices set forth in this subpart.  
\*\*\*

TO BE CORRECTED BY: April 3, 2009

This routine inspection was conducted by Katheryn Ziegerer, VMO, and Tanya Tims, SVMO, with the Facility Manager and the Director of the Office of Compliance March 10-12, 2009.

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