



Inspection Report

YALE UNIVERSITY

Customer ID: 48

Certificate: 16-R-0001

Site: 001

AMITY FARM RESEARCH FACILITY

OFFICE OF THE PROVOST

OFFICE OF RESEARCH ADMINISTRATION

2 WHITNEY AVE ROOM #331

NEW HAVEN, CT 06510

Type: ROUTINE INSPECTION

Date: May-03-2010

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31 (d) (1) (ii) states - "The IACUC shall determine that the proposed activities or significant changes in ongoing 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.....used to determine that alternatives were not available."

1. Review of Protocol #10312: The written narrative of the methods and sources used to determine that alternatives were not available to the potentially painful or distressful procedures described in the proposal for animal use does not include the procedure of retro-orbital bleeding under anesthesia in Hamsters.

In order to approve proposed animal use activities, the IACUC should determine that the proposed activities meet the requirements as described in Section 2.31 (d) (1) that include that a principal investigator has considered alternatives to the potentially painful and distressful procedures described in a proposal for animal use. The IACUC needs to: (1) address this item as identified for this protocol and (2) ensure that all active proposals comply with Section 2.31 (d) (1) (ii). Correct (1) by 6/7/10 and (2) by 1/8/11.

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31 (e) (3) states - "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."

1. Review of Protocol #10312: There is an incomplete description noted in the proposal for animal use for the immunization and challenge portion of the study.

2. Review of Protocol #10692: There was an inconsistency noted in the proposal for animal use pertaining to the method of collection of tissues in Phase I animals; pg 10 describes one technique but pg 28 describes a different

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May-06-2010

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May-06-2010



Inspection Report

technique.

A proposal for animal use must contain a complete description of the proposed use of the animals. The IACUC needs to: (1) address this item as identified for these 2 protocols and (2) ensure that all active proposals comply with Section 2.31 (e) (3). Correct (1) by 6/7/10 and (2) by 1/8/11.

2.33 (b) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33 (b) (2) states - " 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."

1. A Baboon underwent general anesthesia under an approved proposal for animal use on 2/4/10. Later that same evening, laboratory personnel noted the presence of blisters on a small, localized area of the abdomen of the animal. According to the investigator, an electric heating pad had been substituted for one of their warm water circulating units that was broken at the time of general anesthesia. The AV was immediately contacted and instituted medical care for the animal. The investigator stated that he/she had also used the same electric heating pad for another Baboon during general anesthesia on 1/26/10; the AV then assessed the other animal and identified signs of earlier thermal injuries that were now healing. Both animals made a full recovery.

A research facility should use appropriate methods to prevent injuries to the animals. Immediately after the NHPs' thermal injuries were recognized, the electric heating pad was discarded and a new warm water circulating unit was obtained, the AV reviewed the appropriate technique for thermoregulatory support during general anesthesia with laboratory personnel, and the IACUC implemented new procedures to ensure that additional incidents do not occur. The Registrant has taken appropriate measures to correct this item.

2.33 (b) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

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

1. Protocol #10312 includes the study of infectious agents using Hamsters. A group of Hamsters housed in the same enclosure had been inoculated with a strain that rarely produces severe clinical signs but may result in mild signs in the animals post inoculation. At the time of inspection of F-800G on 5/3/10 the APHIS inspector noted the presence of a dead Hamster in the enclosure. It was learned that on 4/29/10 husbandry staff had found one animal dead and laboratory staff euthanized one Hamster due to illness; another Hamster was euthanized by laboratory staff due to illness 4/30/10. The remaining Hamsters in the enclosure were acting normally when evaluated again by

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Inspection Report

laboratory staff in the evening of 4/30/10. On 5/1/10 another Hamster was found dead by husbandry staff, one Hamster was found dead 5/3/10 during the inspection, and the remaining Hamsters were subsequently euthanized 5/3/10 due to clinical signs. The investigator did not inform the veterinary staff of all of the unexpected illness and deaths observed in the Hamsters on 4/29 and 4/30.

The daily observation of all animals to assess their health and well-being to identify any problems of animal health and behavior should be done by all personnel involved with animal care. The research facility needs to ensure that accurate and timely information on problems of animal health are communicated to the AV by all personnel involved with animal care to ensure the provision of adequate veterinary care to the animals. Correct from this date forward.

2.38 (f) (1)

MISCELLANEOUS.

Section 2.38 (f) (1) states - "Handling. (1) 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."

1. Two laboratory personnel were observed while removing an NHP from its home cage to a restraint chair using the pole and collar technique on 5/4/10. According to personnel, the NHP is still learning the chairing procedure. The chair was not appropriately stabilized by laboratory personnel during the chairing procedure so that whenever the NHP attempted to enter the chair, the chair would move and the NHP would not climb onto it. Once laboratory personnel stabilized the chair to prevent it from moving, the NHP then went into the chair.

All animals should be handled as expeditiously as possible in a manner that does not cause behavioral stress or unnecessary discomfort. The facility needs to address this item for the health and well-being of the animals. Correct by 6/7/10.

3.8

EXERCISE FOR DOGS.

Section 3.8 states - "Research facilities must develop, document, and follow an appropriate plan to provide dogs with the opportunity for exercise."

1. The research facility has developed an appropriate plan to provide Dogs with the opportunity for exercise and states that personnel will provide additional human contact time with each Dog twice a day. The Dog Log and Enrichment Sheet for the one Dog housed at K was reviewed. Although personnel were providing the twice a day contact time to the Dogs, it was only being documented once a day.

A research facility must follow the plan developed to provide dogs with the opportunity for exercise and document that the plan is being followed. The Registrant corrected this item during the inspection by modifying the Dog Husbandry Log and Enrichment Sheet to include provision for twice daily documentation of the enrichment provided to the Dogs.

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May-06-2010



Inspection Report

3.75 (e)

HOUSING FACILITIES, GENERAL.

Section 3.75 (e) states - "Storage. Supplies of food and bedding must be stored in a manner that protects the supplies from spoilage, contamination, and vermin infestation..... 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."

1. There was an opened bag of wooden shavings identified in I-54C that was not stored in a leakproof container with a tightly fitting lid to protect against spoilage and contamination as required per this Section. Correct by 5/14/10.

3.80 (a) (2) (iii)

PRIMARY ENCLOSURES.

Section 3.80 (a) (2) (iii) states - " Primary enclosures must be constructed and maintained so that they: (iii) Contain the nonhuman primates securely and prevent accidental opening of the enclosure, including opening by the animal."

1. There were 5 separate incidents of escapes of NHPs from either the primary enclosure or restraint chair that took place from January 2010 through March 2010. The NHPs were loose inside their housing room in 4 of the incidents, and in one incident the NHP was loose in a procedure room. The NHPs escaped due to one of three circumstances: (1) a failure of personnel to properly secure the latching mechanisms on the enclosure when the animal was being returned to its home cage; (2) when there was a gap between the tunnel mounted on the outside of the enclosure and the enclosure itself that afforded the NHP a means to escape; or (3) when an adjustable part of the restraint chair was not adequately secured when the NHP was chaired. During one of the escape incidents, two NHPs received minor injuries; both animals received medical care and fully recovered.

Primary enclosures must be maintained to securely contain the NHPs and prevent accidental opening of the enclosures by the NHPs. Following these incidents, the IACUC and AV undertook several measures and safeguards to ensure that additional escape incidents do not occur. The Registrant has taken appropriate measures to correct this item.

3.81 (b)

ENVIRONMENT ENHANCEMENT TO PROMOTE PSYCHOLOGICAL WELL-BEING.

Section 3.81 (b) states - "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"

1. One NHP housed in I-423 was provided with a swing for enrichment of the environment. The swing was

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suspended from the top of the enclosure using sections of chain each approximately 24 inches long that were attached to either end of the swing's plastic seat. The manner in which the swing was constructed has the potential to cause injury to the NHP from entrapment of a limb or other body.

The physical environment of NHP must be provided with means of expressing non-injurious species-typical activities. The Registrant needs to address the environmental enrichment objects provided to the NHP to ensure they provide means of expressing non-injurious species-typical activities. Correct from this date forward.

3.125 (c)

FACILITIES, GENERAL.

Section 3.125 (c) states - "Refrigeration shall be provided for supplies of perishable food."

1. There was an opened can of KMR powder identified on a cart in E-101. According to the label instructions, opened cans must be stored under refrigeration for up to 3 months or frozen for up to 6 months. In addition, there was no date recorded on the label to indicate the date the can was opened.

Perishable food supplies should be refrigerated to adequately protect against deterioration, molding, or contamination. Registrant immediately corrected this item at the time of the inspection by discarding the opened can of KMR powder.

NOTE - This was a full facility inspection conducted from 5/3/10 through 5/6/10. Exit interview held with facility personnel on 5/6/10. END OF REPORT.

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May-06-2010

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May-06-2010



Inspection Report

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Customer ID: **48**
Certificate: **16-R-0001**
Site: 001
AMITY FARM RESEARCH FACILITY

Type: ROUTINE INSPECTION
Date: Mar-09-2009

2.31 (c) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (c) (3) - "IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility..The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure."

1. The Semi-annual Report to the Institutional Official (IO) dated 12/9/08 did not specifically identify and state the reasons for the departures from the provisions of the Animal Welfare Act that were approved by the the IACUC pertaining to Feeding and Watering Standards for Non-Human Primates, and Multiple Major Operative Procedures as is required by this Section.

The Semi-annual Report to the IO must contain a description of a research facility's adherence to this subchapter and specifically identify any departures and state the reasons for those departures. Correct with the next Semi-annual Report to the IO to be prepared by the IACUC for the year 2009.

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (e) (3) - "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."

1. Protocol #11227 states that all of the Does are euthanized at the conclusion of the study. It was learned during the inspection that some of the Does were not euthanized at the end of the study but were adopted out to private homes.

A proposal for animal use must contain a complete description of the proposed use of the animals. The IACUC must address the inconsistency identified for this protocol. Correct by 4/13/09.

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Title: VETERINARY MEDICAL OFFICER Inspector 1054

Mar-11-2009

Received By:

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Date:

Title:

Mar-11-2009



Inspection Report

2.33 (b) (2) REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (2) - "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."

1. The following outdated medications or medical supplies were identified during the inspection. The use of outdated medications and/or medical supplies may not be safe or efficacious and is not considered an acceptable standard of veterinary practice. Registrant corrected this item at the time of the inspection by discarding the outdated materials.

a. I-417: Betadine solution, 16 oz bottle, #1, exp 2/09; Triple Antibiotic ointment, tube, #1, exp 2/09

3.50 (c)

FACILITIES, GENERAL.

3.50 (c) - "Refrigeration shall be provided for supplies of perishable food."

1. F-800G: Fruit juice is being used to dilute the doses of Doxycycline that are being administered to a Rabbit housed in the room. There was an opened bottle of fruit juice found in the room that laboratory staff confirmed was currently being used to dilute the Doxycycline. The label on the juice states "refrigerate unused portion".

Perishable food must be refrigerated. The Registrant corrected this item at the time of the inspection by discarding the bottle of opened juice.

3.54 (a)

FEEDING.

3.54 (a) - "The food shall be free from contamination, wholesome, palatable and of sufficient quantity and nutritive value to meet the normal daily requirements."

1. D-2027: There was a clear plastic bag containing animal chow located on a shelf in the store room. There was no label on the bag to identify the kind of feed or the mill date in order to determine that the feed was wholesome and of sufficient nutritive value to meet normal daily requirements. Personnel stated that the feed in the clear plastic bag was Rabbit stix that had just been transferred from a larger bag and the Rabbit feed was in current dating.

All food should be wholesome and of sufficient nutritive value. Whenever feed is transferred from a bulk bag to a secondary container, a label should be affixed that states the mill date and type of feed to document that the feed is wholesome and has sufficient nutritive value. Registrant corrected this item during the inspection by putting a label on the bag of feed stating the type of feed and mill date.

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Mar-11-2009

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Mar-11-2009



Inspection Report

3.84 (c) REPEAT

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

3.84 (c) - "Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair."

1. The following Housekeeping items were identified during the inspection in the areas as noted. Housing facilities must be kept clean and maintained in good repair to facilitate the prescribed husbandry practices. The Registrant needs to address these items.

a. I-54C: Peanuts are stored in a bin that is mounted on a cart. The shelf underneath the peanut bin was dirty due to an accumulation of peanut skins and needed to be cleaned.

b. I-425: The two refrigerators in the room were dirty and needed to be cleaned. There was a dark colored residue on the handles and the shelves inside the refrigerators had particulate debris.

c. G-505D: The outer laminate layer of the door and shelves of the testing chamber had chipped areas on the edges that exposed the underlying particle board. The exposed particle board is porous and not impervious to water and can not be readily sanitized.

d. E-B123: The painted surfaces of the wall and ceiling directly opposite the door of the cage washer were starting to crack and there were areas of peeling paint present.

3.126 (d)

FACILITIES, INDOOR.

3.126 (d) - "Drainage. A suitable sanitary method shall be provided to eliminate rapidly, excess water from indoor housing facilities."

1. G-B25: Wooden shavings were used as bedding material to cover the entire floor of an enclosure housing one Pig. It was noted at the time of the inspection that that all of the bedding material in the enclosure was saturated with water and the Pig had to stand in wet bedding because there no dry area inside the pen. It was learned that personnel had placed a second water receptacle inside the enclosure to provide the Pig with access to sufficient water. The Pig reportedly regularly overturned and emptied the water receptacle.

Excess water should be rapidly eliminated from indoor housing to provide for the comfort and well-being of the animals. Registrant corrected this item at the time of the inspection by moving the Pig to a different enclosure equipped with a larger water receptacle that was securely attached to one wall of the enclosure and could not be overturned by the Pig.

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Mar-11-2009

Received By:

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Date:

Title:

Mar-11-2009



Inspection Report

NOTE - This was a full facility inspection conducted from 3/9/09 through 3/11/09 with the exit interview 3/11/09.

NOTE - This is the electronic ACIS version of the Word format inspection report that was delivered to the Registrant at the time of the exit interview on 3/11/09 inspection. Word format inspection report has signature.

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Title: VETERINARY MEDICAL OFFICER Inspector 1054

Mar-11-2009

Received By:

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

Date:

Title:

Mar-11-2009



Inspection Report

YALE UNIVERSITY

Customer ID: 48

Certificate: 16-R-0001

Site: 001

AMITY FARM RESEARCH FACILITY

OFFICE OF THE PROVOST

DEPUTY PROVOST FOR SCIENCE AND

Type: ROUTINE INSPECTION

Date: Jul-21-2008

NEW HAVEN, CT 06520

2.33 (b) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (2) - "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."

1. The following outdated medications or medical supplies were identified during the inspection. The use of outdated medications and/or medical supplies may not be safe or efficacious. Correct by 7/28/08.

- a. G-B15F: Povidone iodine solution, gallon, #1, exp 6/08
- b. G-B24 : Lactated Ringers, 500 ml, #1, exp 6/1/08.
- c. E-B110: Nolvassan solution, gallon, #1, exp 1/08
- d. E-114: Acepromazine, 50 ml bottle, #1, exp 5/08; Motrin 100 mg tablets, exp 6/08; Glycopyrrolate, 2 ml vial; #1, exp 11/07

2. Unlabelled items were identified in the following areas during the inspection. Syringes and bottles should have a label identifying the contents to avoid improper use and ensure current dating. Correct by 7/28/08.

- a. G-B24: 30 cc syringe containing a light blue substance.
- b. O-313: 10 cc syringe containing a light blue substance.
- c. G-500: Plastic spray bottle under the sink containing a blue liquid.

3. There was an opened 20 ml bottle of Propofol identified in E-114. The date and time the bottle was opened was not recorded on the label. According to the package insert, Propofol is a single-use parenteral product that should be discarded 12 hours after opening.

Medications should be handled according to manufacturer's instructions to ensure appropriate use. Correct by 7/28/08.

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Title: VETERINARY MEDICAL OFFICER Inspector 1054

Jul-24-2008

Received By:

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

Date:

Title:

Jul-24-2008



Inspection Report

3.6 (a) (2) (ii)

PRIMARY ENCLOSURES.

3.6 (a) (2) (ii) - "Primary enclosures must be constructed and maintained so that they: (ii) Protect the dogs and cats from injury."

1. K-112 is used to house Cats which are allowed full access to the entire room for extended periods of time during the day. There were several cleaning implements hanging on the wall (broom, squeegee, small brush and dust pan) and a trash container with a swinging type of lid located inside the room. These items were readily accessible to the Cats and could pose a hazard to the animals.

Primary enclosures for Cats should be maintained to protect the Cats from injury. Trash containers and husbandry items should not be stored in the animal room when the animals are allowed full access to the entire room. Facility corrected this non-compliant item during the inspection by removing the husbandry items from the animal room.

3.11 (c)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

3.11 (c) - "Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean."

1. There was a metal cart located in G-B24 that was noted to be dirty and had dried white residue and particulate matter on the shelves. Housing facilities should be kept clean to facilitate prescribed husbandry practices. The cart needs to be cleaned. Correct by 7/28/08.

3.75 (e)

HOUSING FACILITIES, GENERAL.

3.75 (e) - "All food must be stored in a manner that prevents contamination and deterioration of its nutritive value.....open food and bedding supplies must be kept in leakproof containers with tightly fitting lids to prevent spoilage and contamination."

1. There were opened bags of cereal located in E-B110 (#1) and G-505B (#1) that were not being stored in a container with a tightly fitting lid to protect against spoilage and contamination as required per this Section. Correct by 7/28/08.

3.84 (c)

CLEANING, SANITIZATION, HOUSEKEEPING, AND PEST CONTROL.

3.84 (c) - "Housekeeping for premises. Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair."

1. There was a small area of the wall in I-B405 where the outer surface had peeled off and the underlying wallboard was exposed. This exposed wall surface was porous and not impervious to moisture. The wall needs to be

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Jul-24-2008

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Jul-24-2008



Inspection Report

addressed to maintain the facility in good repair and to ensure that the wall can be readily sanitized. Correct by 10/1/08.

2. The sink in I-B405 was noted to be dirty and had residue and particulate matter present. Premises should be kept clean to facilitate prescribed husbandry practices. The sink needs to be cleaned. Correct by 7/28/08.

NOTE - This was a full facility inspection conducted from 7/21/08 - 7/24/08 with the exit interview on 7/24/08.

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Title: VETERINARY MEDICAL OFFICER Inspector 1054

Jul-24-2008

Received By:

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

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Title:

Jul-24-2008



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Customer ID: **48**

Certificate: **16-R-0001**

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AMITY FARM RESEARCH FACILITY

OFFICE OF THE PROVOST

OFFICE OF RESEARCH ADMINISTRATION

2 WHITNEY AVE ROOM #331

NEW HAVEN, CT 06510

Type: ROUTINE INSPECTION

Date: Aug-06-2007

2.38 (f) (1)

MISCELLANEOUS.

2.38 (f) (1) - "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."

1. Dog #2107 underwent an operative procedure on 12/4/06 under Protocol #10271. Laboratory personnel used a heat lamp in addition to a circulating warm water pad as a supplemental heat source to assist the thermoregulation of the animal. Personnel noted later in the day on 12/4/06 that the Dog had sustained a burn to the skin of the lateral thorax that was attributed to the use of the heat lamp.

As a result of this incident, Veterinary staff instructed laboratory personnel to discontinue the use of a heat lamp to assist thermoregulation in anesthetized animals in order to prevent the occurrence of any additional incidents. The facility has undertaken corrective actions and has addressed this item.

NOTE - This was a focused inspection based on the non-compliant items that were identified during the last inspection, and also included the review of IACUC documents and selected protocols.

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Title: VETERINARY MEDICAL OFFICER Inspector 1054

Aug-07-2007

Received By:

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Date:

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Aug-07-2007