



Inspection Report

SOUTHERN RESEARCH INSTITUTE

Customer ID: 878

Certificate: 64-R-0001

Site: 001

2000 NINTH AVENUE SOUTH

SOUTHERN RESEARCH INSTITUTE

P.O. BOX 55305

Type: ROUTINE INSPECTION

BIRMINGHAM, AL 35255

Date: May-15-2009

2.31 (c) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(c)(3) IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall prepare reports of its evaluations conducted. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency.

***I reviewed the Facility findings report for April 2008 as well as the facility semiannual reports. There are several deficiency items listed as still open. There are some facility noncompliances that date back as far as October of 2006 and 2007 (ie. 171, 174, 666, etc.). These items and others do not list a specific plan for correction or expected completion date. Although these items are designated as minor noncompliances they should be corrected within a reasonable timeframe. A specific plan and schedule for correction must be developed and maintained. Correct by August 15, 2009.

3.1 (c) (3)

HOUSING FACILITIES, GENERAL.

(3) Cleaning. . 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 using any of the methods provided in Sec. 3.11(b)(3) for primary enclosures.

***Several light shields in CCP in animal rooms and in the hallways contain debris and or dead insects. The shields should be cleaned on a regular basis to aid in proper lighting and minimize the possibility of pest control issues. Correct by June 15, 2009.

3.25 (c)

FACILITIES, GENERAL.

(c) Storage. Supplies of food and bedding shall be stored in facilities which adequately protect such supplies against spoilage or deterioration and infestation or contamination by vermin. Food supplies shall be stored in containers with tightly fitting lids or covers or in the original containers as received from the commercial sources of supply.

Prepared By:

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Date:

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Refrigeration shall be provided for supplies of perishable food.

***The small refrigerator in Skipper 223 is currently empty but has not been cleaned. There is dried residue in the bottom and door of the refrigerator. The refrigerator shall be cleaned and sanitized to prevent possible contamination of any food items stored within. Correct by May 20, 2009.

3.26 (d)

FACILITIES, INDOOR.

(d) Interior surfaces. The interior building surfaces of indoor housing facilities shall be constructed and maintained so that they are substantially impervious to moisture and may be readily sanitized.

***The ceiling in skipper 223 around one of the light shield has chipping and peeling paint. There are currently hamsters housed in the room. The chipping and peeling paint reveals surfaces that are not impervious to moisture and therefore cannot be adequately sanitized. All interior surfaces shall be maintained so that they may be readily sanitized. Correct by August 15, 2009.

Prepared By:

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Title: VETERINARY MEDICAL OFFICER Inspector 2028

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Type: ROUTINE INSPECTION

Date: Oct-10-2007

This inspection conducted as a follow-up for the following noncompliances documented on the previous inspection:

- Section 2.32(a)
- Section 2.33(b)(3)
- Section 3.50 (c)
- Section 3.51 (b)
- Section 3.75 (e)
- Section 3.126 (a)

All items have been corrected.

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BIRMINGHAM, AL 35255

Date: Aug-28-2007

2.32

DIRECT NCI

PERSONNEL QUALIFICATIONS.

(a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.

***The incident involving the exposure of the beagle to Coverage indicates that the veterinary staff on day one was delayed in providing medication to the beagle while awaiting approval from the client. On the fourth day of the incident records indicate the daily observation was made by the animal care technician who noted the dog was bright, alert and responsive. He also noted there was a wound on the right ear. He was instructed to contact the on-call veterinarian. The attempt was made by email and the veterinarian attempted to make contact by phone but was unable to. The dog continued without further veterinary care throughout the night. By the next morning the dog's condition had seriously deteriorated. There was a lack in follow-up between the animal care staff and veterinary staff to make certain that contact was made and the dog was evaluated by the appropriate veterinary staff. Training shall be provided to re-enforce the responsibilities at each level to permit proper performance of duties. Correct by September 3, 2007.

2.33

DIRECT NCI

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b)(3) Each research facility shall establish and maintain programs of adequate veterinary care that include 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;

On July 12, 2007 there were dogs being exercised in accordance with the facility's written exercise plan. One of the dogs became stuck in the exercise gate. In an attempt to free the dog from the gate; the

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animal care technician sprayed the dog with a detergent (Coverage Plus NPM) for lubrication. The dog was freed, lightly rinsed off and returned to its enclosure. Further observation and care continued throughout the weekend. Communication was conducted primarily by email. There were delays in response and follow-up on recommended treatments. It was determined that the compound applied was caustic and resulted in toxicity. The dog was eventually euthanized. There was a breakdown in communication between the animal care staff and the veterinary staff throughout the incident. The investigation indicated there was insufficient training provided to some employees on the use of chemicals and emergency response to exposure of chemicals. Additionally, the reporting of observations by the animal caretaker and the follow-up on recommended treatment by the study technician was incomplete. The delayed response to communications from the staff observing the animals and the waiting on the client approval before applying medications to alleviate any pain or inflammation that might occur added to an extended period of time the dog went without medication. All employees responsible for animal care and handling shall be adequately trained in chemical usage, emergency response to exposure, communication procedures, and completeness of follow-up. The veterinary staff shall be trained on their responsibility and authority pertaining to the welfare of the animals. All training provided shall be documented and records maintained indicating the employees are trained to perform their duties. Correct by September 3, 2007.

3.50 (c)

FACILITIES, GENERAL.

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

***There is rabbit feed currently stored in containers with lids in the rabbit rooms. In CCP I observed lids of feed storage containers with labels indicating the feed in the containers had expired. The nutritional value of expired feed may decrease or the feed may become moldy or contaminated. If fed to the rabbits it may result in malnutrition and illness. I am told that the feed containers are filled frequently and that it is probable that the lid labels were not updated. The feed appeared to be fine. In addition, in one room the feed was stored on an old "hooded" table. There was hair and dust from the feed accumulating on the table surface and vent. Feed prepared on this table may become contaminated by these accumulations. Measures shall be taken to ensure only feed that is within the manufacturers specified usage period is being used for the rabbits and that all tables, and utensils shall be properly cleaned and sanitized to prevent contamination of the food. To be corrected by September 15, 2007.

3.51 (b)

FACILITIES, INDOOR.

(b) Ventilation. Indoor housing facilities for rabbits shall be adequately ventilated to provide for the health and comfort of the animals at all times. Such facilities shall be provided with fresh air either by means of windows, doors, vents, or air conditioning and shall be ventilated so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans and vents or air conditioning, shall be provided when the ambient temperature is 85 °F. or higher.

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***There is condensation dripping from the ceiling vent in room 105 CCP. The condensation or water in the ceiling has resulted in the ceiling paint peeling away leaving a large pocket which may fall from the ceiling. There is a rack of cages housing rabbits very close to the dripping condensation. The cages shall be moved away from the condensation to prevent the rabbits from coming in contact with it. Measures shall be taken to adequately control the ventilation and condensation thereby providing for the health and comfort of the rabbits. The rack was moved during the inspection. Correct by September 30, 2007.

Note: This noncompliance was corrected prior to exit conference.

3.75

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.

***I observed a food storage container containing food for the non human primates with the label on the lid indicating the food had expired in July 2007. Expired food may have decreased nutritive value which may lead to malnutrition or illness if fed to the non-human primates. There was a feed bag in the room with a current expiration date indicating the food being used was within date and perhaps the lid labels were not being changed. Only food that is within the manufacturers recommended usage period shall be fed to the non human primates thereby protecting their health and well being. Corrected prior to the end of this inspection.

3.126 (a)

FACILITIES, INDOOR.

(a) Ambient temperatures. Temperature in indoor housing facilities shall be sufficiently regulated by heating or cooling to protect the animals from the extremes of temperature, to provide for their health and to prevent their discomfort. The ambient temperature shall not be allowed to fall below nor rise above temperatures compatible with the health and comfort of the animal.

***A power failure occurred in BSL 3 on August 14, 2007. An emergency back-up generator was able to continue the electrical power to the rooms. The generator is not large enough to run the air chillers that provide the air-conditioning in the units which results in external air being brought in directly from the outside without cooling, it remains for three minutes and then the air is exhausted. During the month's of July and August external environmental temperatures were in the high 90's to low hundreds. There were

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ferrets housed in BSL 3 during this event. The power failure occurred at approximately 3:00 pm on the 14th and the generator was used to provide the power over night. Power was not restored until the next morning. During this time period there was no air-conditioning. The temperature charts for BSL 3 indicate the room temperatures are normally held at around 65 - 68 degrees F with humidity at 50 to 55 %. During the outage the temperatures increased to as high as 96 degrees (the temperatures sensors are located above actual animal level) by 5:00 PM and remained in the 90's through the night with humidity dropping to the 30's. There were three ferrets that died during the outage from the excessive environmental conditions. The current generator is not able to adequately maintain a comfortable environment providing for the health of animals housed in the rooms during power failures. Power failures can occur at anytime and an adequate emergency back-up system must be in place to insure that the animals can be properly maintained in emergency situations. Correct by September 30, 2007.

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Customer ID: 878

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2000 NINTH AVENUE SOUTH

Type: ATTEMPTED INSPECTION

BIRMINGHAM, AL 35255

Date: Jul-19-2007

2.126 (a)

ACCESS AND INSPECTION OF RECORDS AND PROPERTY.

(a) Each dealer, exhibitor, intermediate handler, or carrier, shall, during business hours, allow APHIS officials:

- (1) To enter its place of business;
- (2) To examine records required to be kept by the Act and the regulations in this part;
- (3) To make copies of the records;
- (4) To inspect and photograph 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; and
- (5) To document, by the taking of photographs and other means, conditions and areas of noncompliance.

***I arrived at the facility at 10:50 am. The front desk attempted to notify the Corporate Veterinarian. The Animal Care staff returned the call and said the veterinarian was taking care of something but someone would come down to meet me. After waiting for an hour no one had arrived. I left a message with the desk to let them know I would return another time. Personnel shall be made available to accompany APHIS Officials on unannounced inspections.

Prepared By:

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Inspection Report

SOUTHERN RESEARCH INSTITUTE

Customer ID: **878**

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Site: 002

FREDERICK RESEARCH CENTER

2000 NINTH AVENUE SOUTH

P.O. BOX 55305

Type: ROUTINE INSPECTION

Date: May-27-2009

BIRMINGHAM, AL 35255

2.31 (e) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain a rationale for the numbers of animals to be used.

***Protocol 07-04-013: The justification of numbers states "number of animals was specified by the client." The rationale of numbers should include a clear and detailed description of why a particular number of animals are needed. The rationale should include references to the current and previous study designs and may include statistical analysis programs. The protocol must be amended to include an appropriate rationale for the proposed number of animals to ensure animals are not used unnecessarily. Correct by June 25, 2009.

Prepared By:

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Date: Jul-10-2008

NO NON-COMPLIANT ITEMS IDENTIFIED THIS INSPECTION.
IACUC records and protocols were reviewed for this inspection.

Prepared By:

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Date:

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Type: ROUTINE INSPECTION

Date: Sep-11-2007

2.31 (d) (1) (iii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

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:

-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.

***Study 07-05-025: An alternative search was completed. However, there is no written narrative to explain why available alternatives were not considered, i.e. other species.

***Study 06-04-022F: The study was designed by experts in the field, but the specific information regarding the individuals and their previous work is not included as part of the literature search.

The written narrative is an important aspect of the literature as it provides the justification for why other alternatives are not appropriate for the study. If a database search or other source identifies a bona fide alternative method (one that could be used to accomplish the goals of the animal use proposal), the written narrative should justify why this alternative was not used. Additionally, if an expert source is used, the experts name and detailed credentials should be included as part of the written narrative. A written narrative must be written to include adequate information to assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods. Correct by September 30, 2007.

Prepared By:

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