



Inspection Report

UNIV OF TENNESSEE KNOXVILLE OFF LAB AN CARE

Customer ID: **843**

Certificate: **63-R-0105**

Site: 001

UNIV. OF TN - KNOXVILLE

336 ELLINGTON PLANT SCIENCE

Type: ROUTINE INSPECTION

KNOXVILLE, TN 37996

Date: Apr-06-2011

2.31 (d) (5)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(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;

Protocol 1862 was approved by the IACUC in Nov. 2009. An annual renewal form that the IACUC approved in Aug. 2010 stated that there were no adverse effects reported yet the records reviewed of three dogs (C10006, C10005 and C10001) which received drug infused pellets under the skin in Feb. and Mar. 2010 all developed draining lesions and swelling in the affected area several days after the procedure and required multiday treatments. The IACUC must conduct adequate reviews of activities covered by the Animal Welfare Act & Regulations to ensure the health and welfare of the animals. Correct from this day forward.

2.32 (c) (5) (iv)

PERSONNEL QUALIFICATIONS.

(c) Training and instruction of personnel must include guidance in at least the following areas: (5) Utilization of services...available to provide information: (iv) Regarding the intent and requirements of the Act.

A researcher on protocol (1862) performed a surgical implant (not described in the approved protocol) of drug infused pellets instead of the approved trochar method. The dog became ill from the drug later the same day and required emergency surgery to remove the pellets. The researcher stated to the IACUC that he knew the surgical method was not in the approved protocol but that he was unaware that an amendment needed to be filed to make a change to a protocol. Adequate training of personnel to include training on the requirements of the Animal Welfare Act and Regulations is required to ensure the humane care and use of research animals. The researcher involved has completed IACUC mandated retraining and the IACUC is in the process of setting up annual required training for all animal users at the facility. Correct by ensuring from this day forward that all personnel receive guidance on the requirements of the Act.

Prepared By:

SUSANNE BRUNKHORST, V M O USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1076

Apr-06-2011

Received By:

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

Date:

Title:

Apr-07-2011



Inspection Report

2.33 (b) (5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

In the absence of written documentation of procedures performed along with associated pre- and post-procedural care, it cannot be determined if care was provided in accordance with current established veterinary medical and nursing procedures. This documentation is critical in conveying critical information to all people involved in an animal's care.

*Three dogs developed reactions with draining lesions and swelling after their first insertion of nicotine pellets. The records available for review do not show what dosage or how these pellets were inserted in Feb./Mar. 2010. One of these dogs later developed severe clinical signs post another pellet insertion procedure requiring emergency surgery to remove the pellets and overnight treatment in the ICU. The available records for this dog do not indicate how the pellets were implanted. The protocol requires daily body condition scoring as part of post-procedural monitoring but the available records for the dogs do not include any body condition score documentation. All three dogs were euthanized as part of the protocol but the available documentation does not state how this euthanasia was conducted.

*Protocol 1964 states that cats are to be given one of three experimental drugs two of which are radioactive hazards. Three cat records reviewed stated that the cats were given drug C but did not state which protocol the cats were on. Without this information, all people involved in the animal's care cannot determine what the proper post-procedural care is supposed to be.

To ensure adequate veterinary care, the facility must establish and maintain programs of adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures which include documentation of the care. Correct from this day forward.

2.38 (f) (1)

MISCELLANEOUS.

(f) 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.

IACUC records show that an internal complaint revolved around a cat that was physically restrained for an IV drug injection procedure and became very distressed. The study personnel continued to restrain the distressed cat in order to allow the remainder of the injection to be completed to the point that the cat was open mouth breathing. The study protocol contains multiple pre-anesthetic and anesthetic drugs approved for use but none were administered. To ensure the health and welfare of the animals, all handling must be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, behavioral stress, physical harm or unnecessary discomfort. The IACUC mandated additional required training for the personnel involved. Correct from this day forward.

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SUSANNE BRUNKHORST, V M O USDA, APHIS, Animal Care

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3.1 (c) (1) (i)

HOUSING FACILITIES, GENERAL.

(c) Surfaces--(1) General requirements. The surfaces of housing facilities...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. Interior surfaces and any surfaces that come in contact with dogs or cats must: (i) Be free of excessive rust that prevents the required cleaning and sanitization, or that affects the structural strength of the surface;

Room J contains 11 dog runs with concrete walls and doors constructed of metal pipe and metal chain link. Each of the doors has rust at the lower left corner of the door (corner at which door is hinged to wall) where four metal pipes converge (two vertical and two horizontal pipes). The rust on the door of the second run has affected the structural strength of the metal seam between one of the vertical and one of the horizontal pipes such that the horizontal pipe has come loose from the vertical pipe. This creates a movable loose horizontal pipe which protrudes into the run. The dog in the run may injure itself if it comes in contact with the loose end. In addition, the rust prevents adequate cleaning and sanitation of the surface. A finger wiped across the rusty area showed dirt while the non-rusty portion did not. Interior surfaces and any surfaces that come in contact with dogs must be free of rust that prevents the required cleaning and sanitization or that affects the structural strength of the surface. Dog was removed from damaged run on the day of inspection. Correct damage to door of second run prior to using the run to house dogs. Correct rust issue on all runs by 10/6/11.

3.11 (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 to protect the animals from injury, to facilitate the husbandry practices required in this subpart, and to reduce or eliminate breeding and living areas for rodents and other pests and vermin.

Room LL contains the cage wash machine used to clean and sanitize dog and cat food/water bowls, litter pans and enrichment items. The concrete floor on the side of the room in front of the single opening of the cagewash was recently repaired to allow proper drainage but was not resealed. There was a large (approximately 6-8 sq ft) irregularly shaped wet area of concrete floor in front of the opening to the cage wash with a rim of dry white material at the leading edge indicating this problem is ongoing. Since the concrete floor is not impervious to moisture, it cannot be adequately cleaned and sanitized. The cage wash room must be kept clean and in good repair to facilitate husbandry practices. Correct by 7/6/11.

Exit conducted by undersigned VMO and Attending Veterinarian, plus several other facility representatives

Prepared By:

SUSANNE BRUNKHORST, V M O USDA, APHIS, Animal Care

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Apr-06-2011

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Inspection Report

UNIV OF TENNESSEE KNOXVILLE OFF LAB AN CARE

Customer ID: **843**

Certificate: **63-R-0105**

Site: 001

UNIV. OF TN - KNOXVILLE

2621 MORGAN CIRCLE DR

Type: ROUTINE INSPECTION

KNOXVILLE, TN 37996

Date: May-04-2010

2.31 (c) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

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

Changes regarding the care and use of animals in ongoing activities are not always being reported to the IACUC so that the IACUC can perform the required review and evaluation to determine whether it can approve the proposed change in the activity. Review of dog records for protocol 1798 and a conversation with the Principal Investigator (PI) reveal that the PI has changed the anesthesia induction drug regimen and the drug formulations and treatment procedures regarding the experimental drug compound use from what is in the currently approved protocol. Rabbit records reviewed on protocol 1118 which involves antibody production showed that both protein antigen injections to induce antibody production and blood collections are performed at more frequent intervals than approved. The IACUC must be notified of and review any changes in protocols regarding the care and use of animals before they are instituted to ensure that the changes meet the requirements of the Animal Welfare Act, Standards and Regulations and to ensure the health and well-being of the animals. The IACUC must review and approve, require modification in (to secure approval) or withhold approval of proposed changes regarding the care and use of animals in ongoing activities. Correct from this day forward.

2.38 (g) (1) (ii)

MISCELLANEOUS.

2.38(g) Identification of dogs and cats. (1) All live dogs or cats, including those from any exempt source, delivered for transportation, transported, purchased or otherwise acquired, sold, or disposed of by a research facility, shall be identified at the time of such delivery for transportation, purchase, sale, disposal, or acquisition in one of the following ways: (ii) By a tag, tattoo, or collar, applied to the live dog or cat by the research facility and which individually identifies the dog or cat by number.

Prepared By:

SUSANNE BRUNKHORST, V M O USDA, APHIS, Animal Care

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Five adult cats were not identified by tag, tattoo, collar or microchip. The inspector was told that the cats were identified by physical characteristics. Cats at this facility are housed communally in rooms so the unidentified cats are co-mingled with other each other and with identified cats. All cats should be individually identified in order to trace their legal and medical histories and to assure that the correct animals are used in approved protocols. All cats and weaned kittens shall be identified by a tag, tattoo, collar or approved microchip. Corrected during the inspection.

Records reviewed: Annual Report FY 09; Acquisition/disposition records; dog, cat and rabbit records; IACUC Meeting Minutes March 2009 through March 2010; Semiannual Evaluations and reports to IO dated Jun. 16, 2009 and Dec. 22, 2009; Protocols 1067, 1862, 1798, 1118, 1885, 1740, and 1788.

An exit briefing was conducted with the attending veterinarian.

Prepared By:

SUSANNE BRUNKHORST, V M O USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector 1076

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2621 MORGAN CIRCLE DR

Certificate: **63-R-0105**

Site: 001

UNIV. OF TN - KNOXVILLE

KNOXVILLE, TN 37996

Type: ROUTINE INSPECTION

Date: Mar-13-2009

2.33 (b) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Sec. 2.33 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;

During the inspection, one dog was noted to have a one inch round pedunculated mass protruding from its ventral thorax. The mass was red and irritated looking. No records were available to determine that the mass had been observed and its presence communicated to the attending veterinarian. All health and well-being issues need to be observed and conveyed to the veterinarian in a timely manner so that the health and well-being of the animals can be maintained. The facility must maintain a mechanism by which all health and well-being related problems observed during daily observations by someone other than the attending veterinarian are conveyed to the attending veterinarian. Correct from this day forward.

Records reviewed: Dog and cat acquisition and disposition records, Fiscal year 2008 annual report, IACUC meeting minutes dated 11/6/07, 12/4/07, 1/8/08, 2/4/08, 2/20/08, 3/4/08, 4/1/08, 5/6/08, 6/3/08, 7/1/08, 8/5/08, 9/2/08, 10/7/08, 11/4/08, 12/4/08; Semiannual evaluation letters to IO dated 12/4/07, 6/3/08 and 12/9/08; dog and cat health records; Protocols 1320, 1345, 443, 1626 and 1720.

Inspection conducted by undersigned VMO and attending veterinarian, an additional VMO, one additional OLAC veterinarian and facility managers.

Exit interview conducted by undersigned VMO and attending veterinarian, an addition OLAC veterinarian, facility managers and IACUC members.

Prepared By:

SUSANNE BRUNKHORST, V M O USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1076

Mar-13-2009

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