



Inspection Report

UNIVERSITY OF CALIFORNIA, LOS ANGELES

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THE UNIVERSITY OF CALIFORNIA, LOS ANGELES

UCLA SCHOOL OF MEDICINE - D L A M

10833 LE CONTE AVENUE, ROOM 16-222 H C H S

LOS ANGELES, CA 90095

Type: ROUTINE INSPECTION

Date: Dec-16-2010

2.31 (c) (2)

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:(2) Inspect, at least once every six months, all of the research facility's animal facilities, including animal study areas, using title 9, chapter 1, subchapter A-Animal Welfare, as a basis for evaluation.

A review of IACUC semi-annual reports for the last year and a discussion with the Director of the Division of Lab Animal Medicine (DLAM) and a compliance officer of the facility reveal that whereas the multiple-room surgical suite in question had been inspected at the appropriate 6-month intervals, one of the rooms within the suite, the emergency primate surgery (EPS) room was not inspected by the IACUC in 2010. According to the compliance officer, the EPS room was not inspected because the Department of Surgery staff informed the IACUC it was being used for storage and not for surgical procedures. This was confirmed by the absence of a surgical table in the room. Failure to inspect all animal facilities, including animal study areas, can adversely affect the health and well being of the animals. A system should be in place to ensure all of the research facility's animal facilities, including animal study areas and each room that forms part of a multiple-room surgical suite approved as a surgical area, regardless of the nature of its apparent use, are inspected at least once every six months.

Correct on all subsequent inspections/reviews

2.31 (d) (1) (ix)

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:

ix) ...Major operative procedures on non-rodents will be conducted only in facilities intended for that

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purpose which shall be operated and maintained under aseptic conditions.

***The surgical scheduling board of the Department of Surgery indicates that cadaver hand dissection surgeries are being conducted in an animal surgical room. According to the Director of Surgical Services (Department of Surgery), these surgeries are being conducted aseptically in the large surgical suite that is also used for USDA-covered species. The DSS also indicated that the space is appropriately sanitized after cadaver work is conducted and prior to the conduct of surgery on USDA-covered species.

A system should be in place to ensure major operative procedures on non-rodents will be conducted only in facilities intended for that purpose which should be operated and maintained under aseptic conditions.***

Corrected during inspection

2.32

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.

(b) Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities under this section and Sec. 2.31.

(c) Training and instruction of personnel must include guidance in at least the following areas:

(1) Humane methods of animal maintenance and experimentation, including:

- (i) The basic needs of each species of animal;
- (ii) Proper handling and care for the various species of animals used by the facility;
- (iii) Proper pre-procedural and post-procedural care of animals; and
- (iv) Aseptic surgical methods and procedures;

(2) The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;

(3) Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;

***The following personnel training deficiencies were identified:

1) Animal surgery rooms in the Department of Surgery managed suite were not being used as originally designated. According to the Director of DLAM both the EPS and the rodent surgical rooms are negative pressure rooms and are ideal when performing surgical procedures on macaques to reduce the possibility of disease spread beyond the room. Since the EPS room was being used for storage, surgeries on non human primates had to be done in either the negative-pressure rodent room or in the large surgical suite, which is a positive pressure room. According to the Director of Surgical Services (Department of Surgery), he was not aware of which rooms had positive or negative pressure.

2) There were no written documents available on site to indicate the Department of Surgery surgical staff technicians were qualified and trained to perform the treatments and/or procedures conducted on the covered species. The Collaborative Institutional Training Initiative (CITI) animal research curriculum completion report was reviewed to verify basic courses were done, but records to verify species specific

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courses were completed were not available at time of inspection. According to the Director of Surgical Services, he was not certain if species specific courses have been taken by his surgical staff or if these courses were even available. According to the Director of DLAM, who was present during this discussion, species specific courses are available through DLAM.

3) According to a DLAM clinical veterinarian, the surgical staff often makes medical decisions about the care and treatments of the covered animals without consulting with the DLAM. The Principal Investigators (PIs) and their staff will consult with the Department of Surgery surgical staff technicians for surgical and pre and post-procedural monitoring. Some investigators are not aware that consulting with the surgical staff is not the same as consulting with the DLAM veterinary staff.

4) The DLAM is not notified by the Department of Surgery if there are unscheduled surgeries performed on covered species and/or if there are surgical complications. The surgical staff and /or the PIs using the Department of Surgery suite often fail to notify DLAM if there are surgical complications

5) Research personnel mentioned in citation 2.38 (b)(1)(iv) were not familiar with the following regulation: Each research facility shall, during business hours, allow APHIS officials 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.

6) Department of Surgery technicians occasionally failed to verify if procedures were approved by the IACUC prior to allowing an activity to proceed. This indicates inadequate communication between PIs and the surgical staff or deficient oversight by the surgery technicians.

Departure from the above regulations can adversely affect the health and well being of the animals. A system should be in place to ensure and document that that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties.***

Corrected during inspection

2.33 (a) (2) DIRECT NCI

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

(a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section: (2) Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

*** The animal surgery area where surgical procedures are performed on covered species is currently under the management and direct supervision of the Department of Surgery, as opposed to DLAM. Although there are three surgical technicians available to assist with surgery and pre and post-procedural care, they are not qualified veterinarians. Principal Investigators (PI) and their staff typically consult with the Department of Surgery technicians for surgical and pre and post-procedural monitoring instead of consulting with a DLAM veterinarian. According to a DLAM clinical veterinarian, the DLAM is not always notified if there are unscheduled surgeries performed on covered species and/or if their are surgical complications. Even though the IACUC has an established notification procedure in place between the Department of Surgery surgical staff and the DLAM, regular communications among the surgical staff, the PIs and DLAM have occasionally failed.

This notification mechanism should be consistently observed to ensure the attending veterinarian is being informed, in a timely manner, of any problems related to the care and use of animals at the facility. Failure to comply with the regulations above may adversely affect the health and well being of the animals. Each

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procedures are regularly performed had an accumulation of dust on the procedure table and surrounding equipment. An unlabeled syringe with an unknown substance was observed on the procedure table. The floor had an accumulation of debris and dirt.

Failure to comply with the regulations above may have adverse affects on the health and well being of the animals. A system should be in place to ensure that the research facility establishes and maintains programs of adequate veterinary care ***

Corrected during inspection

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.

***In an animal surgery area overseen by the Department of Surgery, while accompanied by the Director of the Division of Laboratory Animal Medicine(DLAM) (who identified us as USDA inspectors), we were told by the Director of Surgical Services (DSS) we could not enter the large surgical suite because there was an "intellectual property issue" concerning a surgery being conducted at the time. The Director of DLAM emphasized we were federal inspectors and asked him to call the PI of the project. The DSS went into the surgery suite and returned to allow us into the surgical area. Although the situation was resolved within 5 minutes, the actions of the DSS indicated he was not familiar with inspection procedures.

At a USDA-covered rodent species study area, the Director of DLAM was recognized and greeted by the lab personnel. The Director identified us as USDA inspectors and asked to inspect the lab. The lab personnel stood in the doorway to block our entry. The lab personnel said that they did not perform surgeries on covered species in this area, only mice were used. Notwithstanding, the Director entered the study area and proceeded to inspect the lab space. A restraint device to fit the covered species in question was present on the procedure table. The Director of DLAM asked to speak with the PI of the project and we were directed next door. The PI of the project confirmed procedures on USDA-covered rodents were being performed in the lab area and the inspection proceeded.

Intentionally misleading by giving false information and denying USDA Animal Care inspectors access to inspect the facilities, property, and animals is a violation of the Animal Welfare Act. Each research facility shall, during business hours, allow APHIS officials 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. ***

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An exit interview was conducted with the facility representative.

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