



Inspection Report

LYCHRON, L L C

Customer ID: **8647**

Certificate: **93-R-0448**

Site: 001

LYCHRON, L L C

2569 WYANDOTTE

Type: ROUTINE INSPECTION

MOUNTAIN VIEW, CA 94043

Date: Aug-20-2009

2.31 (c) (7)

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: (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.***

The IACUC-approved protocol # ARC 1055 involves the evaluation of tissue response to implants in pigs. The protocol is approved for approximately six implants per pig. However, a test animal was observed during the inspection to have ten implants (five on each side of the spine), including two implants in between the shoulder blades. The insufficient description of the implant locations is addressed under the appropriate section of this report.

Increasing the number of tissue implants by nearly double the number approved by the IACUC may have a significant impact on an animal's well-being. The IACUC must thoroughly review any changes to a protocol regarding the care and use of animals in ongoing activities at the institution. Following review, the IACUC may approve those changes, require modification of the proposed changes prior to approval, or withhold approval of the proposed changes. Changes must be approved before they are implemented. A system must be in place to ensure that proposed significant changes to activities involving the care and use of animals are adequately reviewed and approved by the IACUC prior to their implementation.

CORRECT BY 10-22-09

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.***

The IACUC-approved protocol # ARC 1055 involves the evaluation of tissue response to implants in pigs. The protocol is approved for approximately six implants per pig, however the protocol does not contain a complete description of how proximal or distal the implants may be placed on the backs of the pigs, or whether they may be placed in between the shoulder blades of the pigs.

Prepared By:

ANIL SHARMA, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5049

Sep-22-2009

Received By:

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

Date:

Title:

Sep-22-2009



Inspection Report

It is the responsibility of the IACUC to ensure that the investigator provides a complete description of proposed activities that involve the use of animals in order that those activities may be adequately reviewed and determined to be in accordance with the Animal Welfare Act.

CORRECT BY 03-22-10

2.31 (e) (2)

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:(2) A rationale for the appropriateness of the species and numbers of animals to be used.

Protocol ARC 1043, testing a spinal pump for analgesia delivery, was approved by the IACUC for 13 animals, including five backup animals. There was no rationale in the protocol that explained why five backup animals were needed for this activity.

Protocol ARC 889, testing implants placed in the vena cava, was approved for 20 animals. This activity also included five backup animals with no rationale that explained the need for this number of backup animals.

Justification for the number of animals to be used is important in order to ensure that the necessary information is gained using the minimum number of animals. The IACUC must ensure that proposals, renewals, and significant changes involving animals contain rationales that adequately explain the appropriateness of the species and numbers of animals to be used in those activities.

CORRECT BY 03-22-10

3.129 (b) **REPEAT**

FEEDING.

(b) Food, and food receptacles: Food receptacles shall be kept clean and sanitary at all times. If self-feeders are used, adequate measures shall be taken to prevent molding, contamination, and deterioration or caking of food.

Eleven animal feeders, which were made of synthetic fibrous material, were being used for feeding sheep and pigs. These feeders were observed to have worn surfaces at the time of the inspection. Two of the feeders also had broken rims, with apparently sharp edges. The worn and scratched surfaces of the animal feeders may be difficult to clean and thus may become contaminated. The sharp edges of the broken rims of the feeders may cause injury to the animals. The food receptacles (feeders) shall be kept clean and sanitary and in good repair. A system must be in place to monitor the sanitary conditions of food receptacles and appropriate measures should be taken in a timely manner to repair or replace the worn out or broken food receptacles.

Previous correction date: 04-08-2007

Prepared By:

ANIL SHARMA, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5049

Sep-22-2009

Received By:

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

Date:

Title:

Sep-22-2009



Inspection Report

LYCHRON, L L C

Customer ID: **8647**

Certificate: **93-R-0448**

Site: 001

LYCHRON, L L C

2569 WYANDOTTE

Type: ROUTINE INSPECTION

MOUNTAIN VIEW, CA 94043

Date: Aug-26-2008

No non-compliant items were identified during this inspection.

Prepared By:

ANIL SHARMA, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5049

Sep-02-2008

Received By:

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

Date:

Title:

Sep-02-2008



Inspection Report

LYCHRON, L L C

Customer ID: **8647**

2569 WYANDOTTE

Certificate: **93-R-0448**

Site: 001

LYCHRON - MOUNTAIN VIEW

Type: ROUTINE INSPECTION

MOUNTAIN VIEW, CA 94043

Date: Feb-06-2007

2.31 (d) (1) (ix)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(ix) Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices.

While reviewing the medical records for protocol # ARC-789, it was noted that one of the animals died due to prolonged anesthesia. Further examination of the records revealed that the procedure lasted for more than 12 hours because of complications in the device being tested and the researcher being from different facility. The procedure finished at about 1820 hrs and last check for vital signs was done at around 1855 hrs. After extubating at 1900 hrs; the animal was returned back to the cage. No documentation of further post - procedural monitoring was available in the medical records. The animal was found dead in the cage in the morning. The restraint and anesthesia SOP does cover post-procedural or post-operative care of the animals but does not specify about post-operative monitoring of the animals once the animal returns to the cage. A system must be in place that includes post-operative care of the animals after the animals placed in the cage for the activities that involve surgery, in accordance with established veterinary medical and nursing practices.

CORRECT BY 04-08-07

2.33 (b) (2)

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.

Three packs of Swan Ganz catheters; expired on 12/2006, a package of glide wires; expired on 11/2006, 2 vials (50 ml. each) of magnesium sulphate; expired on 01/2007 and Ethicon expired on 12/2006, were noted during the inspection. Besides this expired materials were commingled with non-expired materials in the same closet on the same shelf. Medical materials are often imprinted with an expiration date, beyond which the manufacturer does not guarantee the safety or stability of the item. The use of outdated medical materials is undesirable, as these materials may lose their potency or degrade to toxic byproducts if stored after the expiration date, resulting in unpredictable outcomes. These materials when commingled with non-expired materials increase the chances of health hazards to

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ANIL SHARMA, V.M.O. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5049

Feb-15-2007

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

Date:

Title:

Feb-15-2007



Inspection Report

animals.

This item was corrected during the inspection.

3.129 (b)

FEEDING.

*** (b) Food, and food receptacles: Food receptacles shall be kept clean and sanitary at all times. If self-feeders are used, adequate measures shall be taken to prevent molding, contamination, and deterioration or caking of food.***

About ten feeding troughs made of synthetic fibrous material were noted during the inspection. These troughs are used for feeding sheep and pigs. The inner surfaces of these troughs were worn out and exposing underlying fibers that can easily trap contamination and will be hard to clean as required. The rims of two troughs were broken; exposing sharp edges which can injure the animals. The food receptacles shall be kept clean and sanitary and in good repair at all times so that molding, contamination or deterioration of food shall be prevented to maintain the health of the animals. A system must be in place to monitor the sanitary conditions of food and food receptacles and means how to repair / or replace the worn out feeding receptacles in a timely manner.

CORRECT BY 04-08-2007

Prepared By:

ANIL SHARMA, V.M.O. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5049

Feb-15-2007

Received By:

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

Date:

Title:

Feb-15-2007



Inspection Report

LYCHRON, L L C

Customer ID: **8647**

Certificate: **93-R-0448**

Site: 002

2569 WYANDOTTE

LYCHRON, L L C

Type: ROUTINE INSPECTION

Date: Sep-29-2009

MOUNTAIN VIEW, CA 94043

2.31 (d) (1) (viii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Sec. 2.31 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. The IACUC shall determine that the proposed activities meet the following requirements:

(viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.

Protocol 969 was approved by the IACUC without determining that the personnel conducting procedures described in the protocol were appropriately qualified and trained in those procedures. Under the section of the protocol: "Provide a Brief Description of Previous Experience with the Procedures in this species," the only urology experience described for the three "operators" was with human cadavers. The experience listed for two of the three operators was described as being primarily in placing cardiovascular catheters, while the third operator was a medical student nearing graduation. There was no reference to any of the individuals responsible for placing the device being studied as having specific experience or training in using the device, only the notation that the individuals had performed "urologic procedures" or conducted "urology experiments" on human cadavers. Additionally, the two species being used under this protocol were not mentioned in any of the activities listed in the provided experience of any of the three operators.

The IACUC is responsible for reviewing all aspects of animal care and use, and evaluating protocols in order to ensure compliance with the Animal Welfare Act. In order to properly accomplish this function, the IACUC must ascertain that personnel conducting procedures on regulated species are appropriately qualified and trained in those procedures. A system should be in place to ensure that the IACUC is provided required information in order that it may ascertain that personnel conducting procedures on the species being maintained or studied are appropriately qualified and trained in those procedures.

Correct on all current and future protocols by January 29, 2009.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Oct-02-2009

Received By:

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

Date:

Title:

Oct-29-2009



Inspection Report

2.31 (d) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(d)(2) No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum.

The individual responsible for the renewal of protocol 969 by designated review was also the assigned Study Director for this protocol. The individual in question approved the protocol with their own name listed as Study Director.

The IACUC is responsible for reviewing all aspects of animal care and use, including evaluating protocols in order to ensure compliance with the Animal Welfare Act. A member of the IACUC that is personally involved in an activity may be unable to objectively evaluate that activity and should not take part in the review or approval process of that activity in order to avoid the appearance of impropriety. A system should be in place to ensure that personnel are not involved in activities that may result in a potential conflict of interest.

Correct on all current and future protocols by January 29, 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.

IACUC approved protocol 969 did not contain an adequate description of the devices or location of implants being placed in the musculature of swine. The protocol stated that up to 10 implants may be placed in the "musculature" of swine, but there is no description of the size of the devices, exactly which muscles are appropriate for use, depth of placement, or distance between devices.

The IACUC is responsible for reviewing all aspects of animal care and use, including evaluating protocols in order to ensure compliance with the Animal Welfare Act. It is the responsibility of the IACUC to ensure that the investigator provides a complete description of proposed activities that involve the use of animals in order that those activities may be adequately reviewed and determined to be in accordance with the Animal Welfare Act. A system should be in place to ensure that a complete description of each procedure is provided to the IACUC for review.

Correct on all current and future protocols by January 29, 2009.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Oct-02-2009

Received By:

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

Date:

Title:

Oct-29-2009



Inspection Report

2.32 (a) DIRECT NCI

PERSONNEL QUALIFICATIONS.

Sec. 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.

Animal 2890 was observed during the inspection to have an area on the dorsum that was devoid of hair. Review of the medical record revealed that the hair loss was secondary to a burn thought to be caused by a heating pad used during a surgical procedure on April 16, 2009.

Personnel involved in animal care should be trained and qualified to perform their duties, including the monitoring of animals placed on heating pads or utilizing other thermal heating devices. A system should be in place to ensure that all pertinent personnel be trained to monitor animals when using heating devices in order to prevent burns to the animals.

Correct immediately.

2.33 (b) (2) DIRECT NCI

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:

(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries.

Animal 2890 was observed during the inspection to have an area on the dorsum that was devoid of hair. Review of the medical record revealed that the hair loss was secondary to a burn thought to be caused by a heating pad used during a surgical procedure on April 16, 2009. The burn was first noted in the medical record on April 20, 2009, however there was only a notation that there was a "3 cm in diameter lesion on the dorsum" with no further description of the burn, estimation of severity, or any treatment beyond a total of two applications of triple antibiotic ointment. There are no further assessments of the burn or any treatment administered in the medical records until May 06, 2009, when it was noted that the scab was scraped off and the second dose of triple antibiotic ointment was applied. The third notation regarding the burn was on May 12, "burn site on back appears moist - will notify DVM" but there was no assessment by the DVM in the records, or any notation of further treatment. The fourth and last entry regarding the burn was on May 15, when it was noted that the burn "continues to heal well." The animal was transferred to a satellite holding facility on May 18, 2009.

Treatment of any burn should include an adequate description of the lesion in order that an appropriate treatment plan may be designed and implemented. Additionally, documentation of the daily observations of burns should be maintained in order to evaluate the status of the lesions and any need to alter treatment. The fact that the site had not

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

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Date:

Title:

Oct-29-2009



Inspection Report

healed in more than four weeks is an indication that the burn was not superficial and thus appropriate treatment would have been expected to be much more extensive that what was provided in this case.

The facility should ensure that an adequate program of veterinary care is in place in order that appropriate methods are used to document, diagnose, and treat injuries that occur at the facility.

Correct immediately.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Date:

Oct-02-2009

Received By:

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

Date:

Oct-29-2009

Title:



Inspection Report

LYCHRON, L L C

Customer ID: **8647**

Certificate: **93-R-0448**

Site: 002

LYCHRON, L L C - TURLOCK

2569 WYANDOTTE

Type: ROUTINE INSPECTION

MOUNTAIN VIEW, CA 94043

Date: Jun-11-2009

No noncompliant items were identified during this inspection.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Jun-12-2009

Received By:

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

Date:

Title:

Jun-12-2009



Inspection Report

LYCHRON, L L C

Customer ID: **8647**

Certificate: **93-R-0448**

Site: 002

LYCHRON, L L C

2569 WYANDOTTE

Type: ROUTINE INSPECTION

MOUNTAIN VIEW, CA 94043

Date: Jun-12-2008

No noncompliant items were identified during this inspection.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Jun-13-2008

Received By:

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

Date:

Title:

Jun-16-2008



Inspection Report

LYCHRON, L L C

Customer ID: **8647**

Certificate: **93-R-0448**

Site: 002

LYCHRON, L L C

2569 WYANDOTTE

Type: ROUTINE INSPECTION

MOUNTAIN VIEW, CA 94043

Date: Jul-17-2007

No noncompliant items were identified during this inspection.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Jul-18-2007

Received By:

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

Date:

Title:

Jul-18-2007



Inspection Report

LYCHRON, L L C

Customer ID: **8647**

Certificate: **93-R-0448**

Site: 003

LYCHRON, L L C

2569 WYANDOTTE

Type: ROUTINE INSPECTION

MOUNTAIN VIEW, CA 94043

Date: Aug-13-2008

No noncompliances identified on this inspection.

Inspection and exit interview conducted with Director.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Aug-13-2008

Received By:

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

Date:

Title:

Aug-13-2008



Inspection Report

LYCHRON, L L C

Customer ID: **8647**

Certificate: **93-R-0448**

Site: 003

LYCHRON, L L C

2569 WYANDOTTE

Type: ROUTINE INSPECTION

MOUNTAIN VIEW, CA 94043

Date: Jun-26-2007

No noncompliances identified on this inspection.

Inspection and exit interview conducted with Chief Veterinarian.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Jun-26-2007

Received By:

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

Date:

Title:

Jun-26-2007



Inspection Report

LYCHRON, L L C

Customer ID: **8647**

2569 WYANDOTTE

Certificate: **93-R-0448**

Site: 004

LYCHRON - UNIV. OF MN

MOUNTAIN VIEW, CA 94043

Type: ROUTINE INSPECTION

Date: May-05-2008

No covered animals at the time of inspection.

No noncompliances identified on this inspection.

Inspection conducted with RAR Veterinarian.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

May-05-2008

Received By:

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

Date:

Title:

May-05-2008



Inspection Report

LYCHRON, L L C

Customer ID: **8647**

Certificate: **93-R-0448**

Site: 004

LYCHRON, L L C

2569 WYANDOTTE

Type: ROUTINE INSPECTION

MOUNTAIN VIEW, CA 94043

Date: Jul-05-2007

No noncompliances identified on this inspection.

Inspection conducted with Area Veterinarian.

End of report.

Prepared By:

DEBRA M SIME, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1072

Jul-05-2007

Received By:

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

Date:

Title:

Jul-05-2007