



Inspection Report

ETHOX CORP

Customer ID: **30934**

Certificate: **21-R-0209**

Site: 001

STS DUOTEK

STS DUOTEK

251 SENECA ST

Type: ROUTINE INSPECTION

Date: May-04-2010

BUFFALO, NY 14204

2.36 (b)

ANNUAL REPORT.

Section 2.36(b) Annual report: The annual report shall:

- (5) State the common names and the numbers of animals upon which research were conducted involving no pain, distress, or use of pain-relieving drugs. (e.g., injections, tattooing, blood sampling) should be reported with this group;
- (6) State the common names and the numbers of animals upon which research were conducted involving pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used;
- (7) State the common names and the numbers of animals upon which research were conducted involving pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the research. An explanation of the procedures and the reasons such drugs were not used shall be attached to the annual report.

On test T09-0024 for animal activity proposal 09-5 in September of 2009 there were four rabbits with systemic signs that were euthanized (090824, 090843, 090832 & 090836) and one rabbit (090822) from the same group that was found dead. These five rabbits were reported incorrectly on the 2009 annual report for the facility under column C; research involving no pain, no distress or use of pain-relieving drugs. Research facilities need to submit accurate annual reports to comply with the Animal Welfare regulations and to provide the correct information to APHIS, AC.

The 2009 annual report needs to be amended to report the correct number of rabbits in Columns C, D and E and submitted to the Eastern Regional Office:

Dr. Elizabeth Goldentyer
Eastern Regional Director
USDA, APHIS, Animal Care
920 Main Campus Drive, Suite 200
Raleigh, NC 27606

Correct by June 5, 2010

An exit briefing was conducted with the facility representative.

Prepared By:

MARY E GEIB, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1021

May-04-2010

Received By:

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

Date:

Title:

May-04-2010



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2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(ii) IACUC: The IACUC shall determine that 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 used to determine that alternatives were not available.

Amendment #1 for animal activity proposal 09-5 includes the addition of survival surgery with no written description of the methods and sources used by the principal investigator to determine that alternatives were not available. The principal investigator must provide the required information to the IACUC to ensure pain and distress is minimized and to comply with the Animal Welfare regulations.

Correct by July 9, 2009.

2.35 (a) (2)

RECORDKEEPING REQUIREMENTS.

Section 2.35(a)(2) Recordkeeping requirements: The research facility shall maintain the following IACUC records: Records of proposed activities involving animals and proposed significant changes in activities, and whether IACUC approval was given or withheld.

The research facility did not have a copy of the final IACUC approved animal activity proposal for proposal 08-11 available during this inspection. Animal activity proposals must be maintained by the research facility for animal work being conducted at the facility.

Correct by July 9, 2009.

Prepared By:

MARY E GEIB, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1021

Jun-08-2009

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2.31 (d) (1) (iv) (A)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(iv)(A) IACUC: The IACUC shall determine that the proposed activities meet the following requirement: procedures that may cause more than momentary pain or distress to the animals will be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time.

Animal activity proposal 08-06 was approved to treat potential pain in the animals. However, on page 9 there is a statement that if the sponsor does not approve of the analgesics then the animals would be moved to Category E on the Annual Report and not receive the analgesic treatment. The principal investigator needs to provide in writing the scientific justifications for not relieving animal pain or distress in the proposal to ensure the welfare of the animals. Correct by December 1, 2008.

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(e)(3) IACUC: A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain a complete description of the proposed use of the animals.

Animal activity proposal 08-01 is not consistent in the description of the analgesia used for the ocular procedure described on pages 11, 12, 21 and 25. The description for blood collection on page 13 is marked N/A and there is not a complete description of the blood sample collection techniques mentioned on page 11. Amendment 3 for the proposal lists numerous procedures without including a complete description of the proposed procedures and indicating when they would occur in relationship to the original proposal. The proposal and amendment need to include a complete and consistent description of the proposed use of the animals for the IACUC to review to ensure the welfare of the animals.

Correct by December 1, 2008.

Prepared By:

MARY E GEIB, D V M
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER Inspector 1021

Date:
Oct-29-2008

Received By:

Title:

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

Date:
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Date: Nov-14-2007

No non-compliances identified this inspection.

Note: Discussed what constitutes a significant change to animal proposals.

Prepared By:

MARY E GEIB, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1021

Nov-14-2007

Received By:

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

Date:

Title:

Nov-14-2007