



Inspection Report

VERO SCIENCE LLC

Customer ID: **33144**

Certificate: **15-R-0020**

Site: 001

1334 MAIN ROAD

VERO SCIENCE LLC

Type: ROUTINE INSPECTION

Date: May-28-2009

TIVERTON, RI 02878

2.31 (c) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (c) (3) - "IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility.....The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations."

1. The Semi-annual Reports to the Institutional Official (IO) from the IACUC were reviewed during the inspection beginning with the 7/26/07 Report. The last Semi-annual Report from the IACUC was submitted to the IO almost 10 months ago on 8/1/08. There has not been a report submitted yet for the semi-annual reviews of the Program and Facility Inspection conducted by the IACUC on 3/9/09.

The IACUC is required to submit a Report to the IO at least once every six months upon completion of the required semi-annual evaluations of the Animal Facility Inspection and the Program for the Humane Care and Use of Animals.

A Semi-annual Report to the IO needs to be submitted to the IO for the reviews conducted by the IACUC on 3/9/09. Correct by 6/5/09.

NOTE - Record keeping requirements and continuing annual reviews of proposals for animal use were reviewed as part of the inspection.

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This was a focused inspection based on the non-compliant items that were identified during the last inspection. Facility has successfully corrected all of the non-compliant items from the last inspection.

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2.31 (c) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (c) (3) - IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (3) Prepare reports of its evaluations conducted..... the reports shall be reviewed and signed by a majority of the IACUC members."

1. The Semi-annual Report to the IO from the IACUC dated 3/29/07 for the reviews conducted on 12/11/06 was not reviewed and signed by a majority of the members of the IACUC before it was submitted to the IO as required per this Section of the Regulations. The IACUC is responsible for the evaluations and reports required by the AWA and Regulations. All IACUC members must be given the opportunity to review and sign the Report before it is sent to the IO. Correct with the next Semi-annual Report to the IO for the reviews scheduled for the Summer of 2007.

2.31 (d) (4)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (4) - "The IACUC shall notify principal investigators and the research facility in writing of its decision to approve or withhold approval of those activities related to the care and use of animals."

1. The IACUC did not notify the Principal investigator (PI) in writing of its decision regarding the annual continuing reviews of Protocols #2005-1 and #2005-4 that were conducted on 3/30/07. The IACUC is required to provide written notification to the PI of decisions concerning its review of activities related to the care and use of animals. Correct by 8/1/07.

3.25 (c)

FACILITIES, GENERAL.

3.25 (c) - "Food supplies shall be stored in containers with tightly fitting lids or covers."

1. There was an opened bag of Hamster feed in A1 was not being stored in a container with a tightly fitting lid as required per this Section. Storage of opened supplies of feed in containers with a tightly

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fitting lid protects the feed from possible contamination and spoilage. Correct by 6/28/07.

3.31 (b) **REPEAT**
SANITATION.

3.31 (b) - "Housekeeping. Premises (buildings and grounds) shall be kept clean."

1. There was spilled bedding material on the floor, shelves, and underneath the pallets in A1. Animal premises should be kept clean to facilitate proper husbandry practices.

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2.31 (d) (5)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (5) - "IACUC review of activities involving animals.....(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."

1. Protocols #2005-1 and #2005-4 were approved by the IACUC on 7/14/05 but have not undergone an annual review as prescribed per this Section of the Regulations. Correct by 4/1/07.

2.31 (c) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (c) (3) - "IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility.....The reports shall be reviewed and signed by a majority of the IACUC members.....The reports shall be updated at least once every six months upon completion of the required semiannual evaluations.....The reports must contain a description of the nature and extent of the research facility's adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A--Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies.....If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency."

1. According to the Agendas of the IACUC meetings held in 7/06 and 12/06, the IACUC reviewed some of the components of the Program for Humane Care and Use and conducted inspections of the Animal Facilities as part of those convened meetings. However, the IACUC has not prepared reports of its evaluations to submit to the IO as described in this Section of the Regulations. The IACUC needs to prepare a Semi-annual Report for the evaluations conducted in 7/06 and 12/06 and submit them to the IO. Correct by 5/1/07.

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2.33 (b) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (b) (2) - "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."

1. It was learned during the inspection that the chemical grade sodium pentobarbital manufactured by Sigma found at the facility was used for the anesthesia and euthanasia of Hamsters. Pharmaceutical grade medications should always be used in AWA covered species. Chemical grade compounds should only be used for reasons such as: (1) non-availability of a veterinary or human pharmaceutical grade product; or (2) for scientific reasons with the approval of the IACUC. The AV and IACUC need to address this issue. Correct by 4/1/07.

2.35 (a) (1)

RECORDKEEPING REQUIREMENTS.

2.35 (a) (1) - "The research facility shall maintain the following IACUC records: (1) Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations."

1. The facility is not consistently including the IACUC Committee's deliberations in the minutes that are maintained of the IACUC meetings. Correct with all meetings of the IACUC that are held from this day forward.

3.25 (c)

FACILITIES, GENERAL.

3.25 (c) - "Storage. Supplies of.....bedding shall be stored in facilities which adequately protect such supplies against spoilage or deterioration and infestation or contamination by vermin."

1. There was an opened bag of bedding material being stored in Room A1. This method of storage does not adequately protect the opened supply of bedding from possible contamination and needs to be improved. Correct by 2/13/07.

3.31 (b)

SANITATION.

3.31 (b) - "Housekeeping. Premises (buildings and grounds) shall be kept clean.....to facilitate the prescribed husbandry practices set forth in this subpart. Premises shall remain free of accumulations of trash."

1. The following Housekeeping issues were identified during the inspection. Animal premises need to be kept clean to facilitate proper husbandry practices. These areas need to be cleaned. Correct items 1a, 1b, 1c, and 1d by 2/13/07.

a. Room A1 - There was spilled bedding material present on the floor and shelves.

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- b. Room A3 - There were used paper towels present on 2 shelves that held animal enclosures.
- c. Room A8 - There was some used animal bedding material on the tops of the Cage Washers.
- d. Room A8 - The floor underneath the sink was dirty and had a dried, dark color material present.

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