



Inspection Report

DIOSYNTH RTP INC

Customer ID: **33163**

Certificate: **14-R-0175**

Site: 001

DIOSYNTH RTP INC

ORGANON RESEARCH CENTER

245 FIRST ST 6TH FLOOR

Type: ROUTINE INSPECTION

Date: Jan-23-2008

CAMBRIDGE, MA 02145

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 updated at least once every six months upon completion of the required semiannual evaluations."

1. The IACUC has still not submitted a Report to the IO for the Program Review and Facility Inspection that were conducted on 9/10/07. The Report should be submitted to the IO in a timely manner following completion of the required reviews in order to provide the IO with a report of the status of the Program and Animal Facility. Correct by 2/6/08.

2.31 (d) (1) (viii) REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (1) (viii) - The IACUC shall determine that the proposed activities or significant changes in ongoing 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."

1. REPEAT item - There is no documentation that the IACUC has addressed the issue identified during the last inspection pertaining to qualifications of the personnel listed on Protocol #05-02 who will be conducting procedures on Hamsters.

2. NEW item - Protocol #05-03 uses Hamsters and was approved during the 9/10/07 convened meeting of the IACUC. According to information in the protocol available for review by the IACUC, all of the personnel had prior experience with Mice only. There is no indication as to how the personnel will be provided training for this species.

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The IACUC must determine that all personnel conducting procedures on the species of animal under study are appropriately qualified and trained as part of the review of activities involving animals. The IACUC must address this issue for these approved protocols.

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 is not notifying principal investigators in writing of its decisions regarding the review of protocols as required by this Section of the Regulations. Correct from this date forward.

2.31 (d) (5)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (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. There was no documentation available for review that Protocol #05-02 has undergone an annual review since 11/30/06 as required by this Section of the Regulations. Correct by 3/1/08.

2.31 (e) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (e) (2) - "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 involving animals, and for the appropriateness of the species and numbers of animals to be used."

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (e) (3) - "A proposal to conduct an activity involving animals, or to make a significant change in an ongoing

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activity involving animals, must contain the following: (3) A complete description of the proposed use of the animals."

1. Review of Protocol #05-03:

a. [2.31 (e) (2)] - There is no rationale for the appropriateness of the species (Hamster) or for the number of animals requested (Hamsters) included in the proposal for animal use.

b. [2.31 (e) (3)] - There are incomplete details for Procedure 1 provided in the proposal for animal use. Specifically:

- i. The number of times blood is collected is not specified.
- ii. The interval between blood collections is not specified.
- iii. The time of euthanasia is not specified.

A proposal for animal use must contain a rationale for the appropriateness of the species and the numbers of animals used, as well as a complete description of the proposed use of the animals. The IACUC must address these issues for this protocol. Correct by 3/1/08.

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2.31 (c) (1) **REPEAT**

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (c) (1) - "IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (1) Review, at least once every six months, the research facility's program for humane care and use of animals, using title 9, chapter I, subchapter A--Animal Welfare, as a basis for evaluation."

1. There is no documentation available for review that the research facility's Program for Humane Care and Use of Animals has been reviewed by the IACUC since the research facility received its USDA registration approval on 9/12/05. The Program for Humane Care and Use of Animals must be reviewed by the IACUC at least once every 6 months.

2.31 (c) (2) **REPEAT**

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (c) (2) - "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 I, subchapter A-Animal Welfare, as a basis for evaluation."

1. According to the minutes of the 11/30/06 IACUC meeting, the IACUC conducted an inspection of the animal facilities as part of that meeting. There was no documentation available for review that the IACUC has inspected the animal facilities within 6 months of the 11/30/06 as required by the Regulations.

The IACUC is responsible for conducting an inspection of the animal facilities at least once every 6 months.

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2.31 (c) (3) **REPEAT**

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 IACUC remains responsible for the evaluations and reports as required by the Act and regulations. 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 and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. 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. There is no documentation available for review that the IACUC has prepared and sent a Semi-annual Report to the Institutional Official (IO) as required per this Section of the Regulations since the research facility received its USDA registration approval on 9/12/05.

The IACUC is required to submit a Semi-annual Report to the IO at least once every 6 months regarding its evaluations of the research facility's Program for Humane Care and Use of Animals and Animal Facility Inspection.

2.31 (d) (1) (viii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

2.31 (d) (1) (viii) - "IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities.....the IACUC shall determine that the proposed activities or significant changes in ongoing 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."

1. Protocol #05-02 uses Hamsters and was approved during the 11/30/06 convened meeting of the IACUC. The protocol lists the personnel, protocol responsibilities of personnel, and the prior experience of personnel who will be conducting procedures on the Hamsters. According to information in the protocol available for review by the IACUC, all of the personnel had prior experience with Mice but none of them had prior experience with Hamsters. There is no indication in either the protocol or in the minutes of the 11/30/06 convened meeting of the IACUC how the necessary training for this species of animal will be provided to the personnel.

The IACUC must determine that all personnel conducting procedures on the species of animal under study

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are appropriately qualified and trained. The IACUC must address this issue for this approved protocol. Correct by 9/1/07.

2.33 (a) (1) REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33 (a) (1) - "Each research facility shall employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility.

1. The Program of Veterinary Care dated 3/1/06 still does not include a description of the frequency of regularly scheduled visits by the attending veterinarian as was previously identified during the 7/11/06 USDA inspection.

2.35 (a) (1) REPEAT

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. There are no minutes available for review of the IACUC meeting convened on 3/22/07. Minutes of IACUC meetings must be kept by the facility and must be available for review by USDA inspectors.

NOTE - There has been no AWA Regulated Activity conducted by the Registrant since the registration was issued by the Eastern Regional Office on 9/12/05. There were no AWA covered species at the time of the 7/16/07 inspection. The Registrant plans to cancel its registration. Written notification of the change in operation and a request to cancel the registration should be sent by certified mail addressed to:

Eastern Regional Director
Dr. Elizabeth Goldentyer
USDA/APHIS/AC
920 Main Campus Drive
Suite 200 Unit 340
Raleigh, NC 27606
Phone: 919-855-7100

NOTE - The Registrant was informed that an Annual Report for FY 2007 will need to be submitted to the Eastern Regional Office on or before 12/1/07 as per Section 2.35 (a).

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