



## 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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