



Inspection Report

Pi Bioscientific Inc.
8315 Lake City Way N E
Seattle, WA 98118

Customer ID: **331329**
Certificate: **91-R-0072**
Site: 001
Pi Bioscientific Inc.

Type: ROUTINE INSPECTION
Date: 08-MAR-2016

2.31(b)(3)(2) REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The public member on the IACUC is affiliated with the research facility. The unaffiliated member is intended to provide representation for the general community interests in the proper care and treatment of animals. The facility must ensure that at least one member of the IACUC is not affiliated with the facility in any way other than being a member of the Committee.

To be corrected by: April 15, 2016

2.31(c)(1)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The IACUC is not conducting a program review at least once every six months. A review was conducted in 2014, and the next review did not occur until November 5, 2015. The IACUC must review the research facility's program for humane care and use of animals to ensure that animals are utilized in a manner that minimizes pain and distress. The IACUC must review the research facility's program for humane care and use of animals at least once every six months.

Correct from this time forward for all program reviews.

2.31(c)(2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The IACUC is not conducting inspections of the research facility's animal facilities at least once every six months. IACUC records indicate an inspection occurred in 2014; however, the IACUC was not scheduled to conduct the next inspection until December 2, 2015. In addition, there is no documentation that this inspection actually took place. Inspection of the animal areas must be conducted to ensure that animals used in research activities are maintained under humane conditions and meet all of the regulatory requirements of the Animal Welfare Act.

Prepared By: DIANE FORBES, D V M USDA, APHIS, Animal Care

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The IACUC must inspect, at least every six months, all of the research facility's animal facilities including the animal study areas.

Correct from this time forward for all facility inspections.

2.31(c)(3) REPEAT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

There is no documentation that a report of the facility inspection (scheduled for December 2, 2015) was prepared or that it was submitted to the Institutional Official of the research facility. In addition, the report for the program review conducted on November 5, 2015 was not reviewed and signed by the majority of the IACUC members.

The IACUC must prepare reports of its evaluations and submit the reports to the Institutional Official. In addition, reports for the program review and the facility inspection must be reviewed and signed by the majority of the IACUC members. The research facility must ensure that reports are generated for IACUC activities and made available to APHIS officials during unannounced inspections to ensure facility compliance with the Animal Welfare Act may be evaluated.

Correct from this time forward for all reports of facility inspections and program reviews.

2.31(d)(1)(2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The protocol for the sheep and goats does not address the principal investigator's consideration of alternatives to the potentially painful and/or distressful procedures nor does it provide a written narrative of the methods to determine alternatives were not available.

It is the responsibility of the IACUC to review the protocol(s) to ensure the principal investigator has given consideration to alternatives to the potentially painful and/or distressful procedures and provided a written narrative describing the methods utilized to determine alternatives were not available.

To be corrected by: April 15, 2016

2.31(d)(1)(3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The principal investigator has not provided written assurance that the activities do not unnecessarily duplicate

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previous experiments. This statement ensures that the principal investigator has considered procedures that could prevent unintended and unnecessary duplication of research involving animals. This statement must be included in the description of proposed activities.

To be corrected by: April 15, 2016

2.32(b)

PERSONNEL QUALIFICATIONS.

There are no training records documenting instruction or capabilities of any of the staff members of the research facility, and in particular for the animal care staff. In addition, the animal care staff has not been trained on methods to assure the health status of the animals as outlined in the protocol(s). The facility's Animal Care Protocol states:

**regularly (at approximately 3 week intervals), animals will be monitored for anemia by examination of the ocular mucosa and scored on a three point scale. However, the animal care staff has not been trained on how to perform this procedure.

**animals that score low (1= poor status) will be tested for their hematocrit status. The animal care staff has not been trained on how to conduct this procedure; further, there is no equipment in the lab to do so.

The protocol also states that "the maximum volume of blood expressed in milliliters that can be drawn from an animal will be no more than ten times its body weight expressed in kilograms". Personnel are possibly taking too much blood as an employee ordered 600 ml reservoir blood collection bags, when staff should have been using 300 ml bags. The staff has also not been trained to conduct body condition scoring.

It is 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. Training and instruction must be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facilities responsibilities.

To be corrected by: April 15, 2016

2.33(b)(2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The research facility had written Programs of Veterinary Care from two veterinarians. The APHIS Form 7002 from

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the attending veterinarian is filled out on page 1 only; the rest of the form is blank. There is no indication of the species involved, vaccinations, parasite control program, emergency care or description of euthanasia for the animals. This written Program of Veterinary Care must be completed in full, and include any medications/methods used, the route of administration, and the dose of the product.

To be corrected by: April 15, 2016

2.35(f)

RECORDKEEPING REQUIREMENTS.

The research facility is not maintaining all records that relate directly to the proposed activities and proposed significant changes in ongoing activities reviewed and approved by the IACUC. These records apply directly to the proposals and include:

- weights of the sheep and goats
- blood volumes on sheep/goats with the date, animal ID number, and the amount of blood obtained
- hematocrit status of all animals at least once per year
- scoring results based on examination of the ocular mucosa to assess anemia
- crude hematocrit determination for animals that score low (1) when assessed for anemia

These records must be maintained for the duration of the activity and for an additional three years after completion of the activity. All records must be available for inspection and copying by APHIS officials.

To be corrected by: immediately

An exit interview was conducted with the facility representative, Dr. Carolyn McKinnie, SACS, and Dr. Diane Forbes, VMO.

Additional Inspectors

McKinnie Carolyn, Supervisory Animal Care Specialist

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
331329	91-R-0072	001	Pi Bioscientific Inc.	08-MAR-16

Count	Scientific Name	Common Name
000042	<i>Capra hircus</i>	DOMESTIC GOAT
000004	<i>Ovis aries aries</i>	SHEEP INCLUDING ALL DOMESTIC BREEDS
000046	Total	