



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: Mar-03-2016

2.33 (a) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The attending veterinarian has not been given the appropriate authority by the research facility to ensure that adequate veterinary care is provided to the animals. The attending veterinarian's instructions on animal care to include the use of deworming medications have not been followed. In addition, instructions on disease prevention to include biosecurity and the separation of newly acquired animals have not been followed. The attending veterinarian also advised the facility to have three animal care staff to facilitate appropriate care. Finally, the attending veterinarian has not recently visited the facility in order to oversee the adequacy of all other aspects of animal care and use. Without appropriate authority for the attending veterinarian, animal care and disease prevention is compromised leading to significant animal health issues and undue pain and suffering.

To be corrected by: immediately

2.33 (a) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The attending veterinarian is not a voting member of the IACUC. And although the IACUC has a veterinarian on the committee, he is not affiliated with the research facility. The attending veterinarian's function on the committee is to provide expertise in the care and use of the animals. The input of the attending veterinarian is critical to prevent inappropriate procedures and to ensure that any pain, distress or discomfort to the animals is avoided or minimized.

To be corrected by: April 8, 2016

2.33 (b) (1)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Based on the numerous medical ailments and severe health issues observed in the goats on this inspection, the research facility does not have an adequate number of staff to provide care for the animals. In addition, based on the extremely poor state of sanitation of the goat/sheep barn and the repairs

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Title: VETERINARY MEDICAL OFFICER Inspector 5053

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needed for barn and the outdoor shelters in the pasture, the research facility does not have adequate staffing for cleaning and maintenance. The facility also lacks bedding for the animals and the appropriate equipment to remove the manure of 46 animals. Although the facility has a power washer, someone had come and taken it to use at a facility elsewhere when the staff wanted to use it to clean the restraint and bleeding area. Equipment for cleaning and disinfection must be available at all times. Finally, the facility lacks a separate enclosure to house ill animals to facilitate their care and prevent the spread of disease.

Lack of adequate staffing, equipment, and facilities has adversely affected the care and well-being of the animals, prevented proper biosecurity, and has led to severe discomfort and pain and suffering in these animals.

To be corrected by: April 8, 2016

2.33 (b) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

****Non-Direct NCI**** Expired medications were found in the refrigerator during the inspection. These included a bottle of Panacur (expiration 11-2015) and a bottle of Cydectin (expiration 3-2015).

Expired medications should not be used in the treatment of regulated animals as they may have lost potency or do not function as intended. It is the responsibility of the IACUC to ensure that the methods utilized in the prevention and treatment of diseases or injuries are in accordance with established standard veterinary practices.

To be corrected by: March 18, 2016

2.33 (b) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

****Non-Direct NCI**** The research facility must perform daily observations of all animals to assess their health and well-being. According to the USDA inspection conducted on 9/10/14, the animal inventory indicated the facility had 60 goats and 5 sheep. For the USDA inspection on 11/20/14, the animal inventory showed the facility had 43 goats and 5 sheep. Based on the facility records for 02/13/15, they had 46 goats and 5 sheep. On today's inspection, they had 42 goats and 4 sheep. The facility cannot account for the animals that are missing nor explain the discrepancy in the number of animals.

The facility must perform daily observations which includes keeping track of the animals and what happens to them, and have the documentation available for review by APHIS officials. In addition, a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.

To be corrected by: March 18, 2016

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3.125 (a)

FACILITIES, GENERAL.

**The goat/sheep barn is a very large structure divided into several different areas: sleeping, hay feeding, and grain feeding areas. The barn had a large sliding door on the south side that is now missing. There are also broken and missing boards, and boards with holes along the sides of the structure. This has allowed rain and wind to enter the facility contributing to the extremely wet conditions within the barn. In addition, the concrete walkway on the north side of barn slopes sharply towards the structure, so that as it rains the water runs down the walkway directly into the hay feeding area for the animals. The adjacent barn north of the goat/sheep barn functions as a fence for the walkway, and it has broken and damaged boards. There is also a support pole in the sleeping area of the barn that has a metal wrap around at the base that is rusted.

**The roof of the goat/sheep barn is composed of metal panels. The panels on the eastern side of the roof are rusted away allowing precipitation to fall inside of the barn below, thus soaking the feeding and sleeping areas for the animals.

Poor maintenance of the goat/sheep barn has resulted in extremely wet conditions inside the structure. This has contributed to the numerous and severe health issues seen in the goats, and resulted in pain and discomfort for these animals.

**The outdoor shelters have boards that have fallen from the structures and are lying on the ground. There is also a broken picnic table next to one of the shelters that is now just loose boards with nails. The boards contain nails that are protruding upward, are easily accessed by the animals, and can cause injury.

**There are missing and damaged tiles on the roofs of the outdoor shelters. This compromises the ability of the structure to provide adequate shelter and shade.

**Areas of wire fencing in the pasture are loose and have fallen down. This compromises the strength of the fencing and animals could become entangled in the wire.

**The ladder that leads to the hay storage on the top of the barn is missing a rung. This compromises the ability of both employees and APHIS officials to safely access the hay storage area.

To be corrected by: April 8, 2016

3.133

SEPARATION.

One of the goats (animal #28) is particularly combative with the other animals and was reported by staff to have caused numerous injuries in the other goats. Personnel described the goat as ramming the other animals and lifting them into the air. In addition, this goat has horns while others do not, allowing for more injuries. Animals shall not be housed with other animals if they are not compatible, as they can cause injury, interfere with feeding or cause them discomfort. Any animals that are not compatible must

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not be housed in the same enclosure.

To be corrected by: March 18, 2016

Note: This is the inspection report for all non-compliances on March 3, 2016 that were not cited as direct non-compliances. In addition, a record review was not conducted at that time.

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

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3.131 (a) REPEAT SANITATION.

The sheep/goat barn has been divided into five areas by the research facility. The following areas have been cleaned and provided with fresh bedding: #1(ill animal area), #4 (sleeping area) and #5 (feeding area). However, two remaining areas of the barn have not been cleaned. These are areas #2 and #3; with area #3 being used for feeding sheep and goats the pelleted ration. These areas still need the remaining manure removed and the floors washed.

This was a focused inspection for the direct non-compliances documented on March 3, 2016. The following animals were examined, diagnosed and treated by the attending veterinarian on March 4, 2016: Animal ID #: 45, 35, 15, 19, 14, 40, 29, 32, and 23.

In addition, the following animals were examined, diagnosed and treated by the attending veterinarian on March 7, 2016: Animal ID #: 28, 41, 8, 9, 5, 34, 22, 44, 2, 47, 30, 4, 33, and 21.

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

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2.31 (b) (3) (ii) **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.

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

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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) (ii)

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) (iii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

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

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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 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.

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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.

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2.33 (b) (2) **DIRECT NCI**
ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Over half of the goat herd (24 out of 42 animals) was afflicted with various ailments and severe medical problems to include emaciation, diarrhea, lameness, overgrown hooves, coughing and upper respiratory disease. Low body weight and emaciation can indicate a parasite problem, dental issues or overall poor health. Diarrhea can also indicate a parasite problem or other diseases. Overgrown hooves can lead to lameness and make movement difficult and extremely painful. It can stress ligaments and joints from the abnormal movement. Coughing may indicate respiratory disease, parasites or other diseases.

*** Goat #45, a female Nubian, is emaciated with a body score of 1 out of 5 with protruding hip bones and spinal processes. The animal was coughing and had mucoid discharge around the nostrils and eyes. In addition, she was observed holding the left rear leg up and walking stiffly in the rear legs. All hooves were overgrown.

*** Goat #19, a female Nubian, is emaciated with jutting hip bones and spinal processes and a body score of 1 out of 5. The animal also has diarrhea with dried feces in the tail area and down the rear legs.

*** Goat #15, a female Boer, was observed lying down, depressed and reluctant to move. Once she began to walk, she held up the left foreleg and limped as she moved forward painfully. The animal also has diarrhea and the hooves are overgrown.

*** Goat #35, a female Boer, is lame with severely overgrown hooves, especially in the right foreleg where the hoof is widened and flattened like a plate. The hoof on the left foreleg is overgrown and the goat was observed chewing on the foot.

*** Goat #14, a female Boer, has severely overgrown hooves especially in the rear feet. The hooves are curved and twisted and approximately 5 inches in length.

*** Goat #40, a female Saanen, is severely lame. The animal is holding the left rear leg up and struggling to move as it limps forward. She has diarrhea with dried, caked feces around tail area.

*** Goat #29, a white Angora mix, is severely lame with non-weight bearing lameness in right rear leg.

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The animal is holding the leg up at rest and limping as it walks forward.

*** Goat #32, a Boer wether, has severe diarrhea with feces covering the tail, hind end and rear legs. The animal is extremely emaciated with a body score of 0 out of 5. In addition, he has overgrown hooves on all four legs.

*** Goat #23, a Toggenburg mix female, was emaciated with a body score of 2 out of 5. The animal had diarrhea with greenish liquid stool present under and around the tail and the hooves were overgrown.

All of the goats above (#45, #35, #15, #19, #14, #40, #29, #32, #23) must be seen, diagnosed and treated by the attending veterinarian no later than March 4th, 2016 at 1:00 pm. All veterinary documentation must be made available to APHIS personnel upon request.

Goat #28, a female Alpine mix, has overgrown hooves.

Goat #41, a female LaMancha, has overgrown hooves.

Goat #8, a wether, has diarrhea with dried, caked feces on rear legs.

Goat #9, a female Boer, has diarrhea with dried, caked feces on rear legs.

Goat #5, a female Boer, has overgrown hooves on all four feet.

Goat #34, a female Boer, has severely overgrown hooves that are broken and twisted.

Goat #22, a female Boer, has severely overgrown hooves, especially in the right front leg. This animal high steps while walking as hooves appear to get in the way of normal movement.

Goat #44, an Alpine female, has overgrown front hooves.

Goat #2 has diarrhea with dried fecal material present and the anal area appears swollen from irritation.

Goat #47 has diarrhea with fecal debris dried around tail area.

Goat #30, an Alpine female, is coughing.

Goat #4, a Boer female, is coughing.

Goat #33, a female Boer mix, has diarrhea and overgrown hooves.

Goat #21, a white mixed breed, has overgrown hooves on all four feet.

All of the following goats (28, 41, 8, 9, 5, 34, 22, 44, 2, 47, 30, 4, 33, 21) must be seen, diagnosed and treated by the attending veterinarian no later than March 7th, 2016 at close of business. All veterinary documentation must be made available to APHIS personnel upon request.

2.33 (b) (3) DIRECT NCI

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Over half of the goat herd (24 out of 42 animals) was afflicted with various ailments and severe medical problems. These medical issues were not reported to the attending veterinarian. Prompt reporting and discussion of animal health issues with the attending veterinarian is essential and must occur to prevent diseases and other medical issues from worsening, thus leading to undue suffering by the animals. A mechanism of direct and frequent communication must be established and maintained so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending

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veterinarian. To be corrected immediately.

3.131 (a)

DIRECT NCI

SANITATION.

The barn for the animals was full of fecal material and wet throughout, so that none of the animals had a clean or dry area they could access. Lack of a clean, dry facility will lead to severe discomfort and disease in the animals. Areas included the sleeping and feeding areas, and also the walkways for the animals. To be corrected by close of business on March 7, 2016.

Note: This inspection report includes only the direct non-compliances. A subsequent report will be prepared to document all other non-compliances noted at the time of inspection.

An exit interview was conducted on March 4, 2016 with the facility representative, Dr. Carolyn McKinnie, SACS, and Dr. Diane Forbes, VMO.

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