United States Department of Agriculture
Animal and Plant Health Inspection Service

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Inspection Report

Pro Sci Inc.
12170 Flint Place
Poway, CA 92064

Customer ID: **43309**
Certificate: **93-B-0229**
Site: 002
PRO SCI, INC.

Type: ROUTINE INSPECTION
Date: 22-SEP-2016

2.31(e)(1)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Several IACUC (Institutional Care and Use Committee) approved animal care and use protocols utilizing a regulated species did not identify the approximate number of animals to be used in the study.

The protocols (1A & 5) states that "number of animals used for a project depends upon the quantity of antiserum needed" for testing or commercial quantities. For testing, two rabbits or guinea pigs will be used per antigen, but the number of antigens tested in a given time period is not identified, while for commercial quantities the number of animals depends on the quantity of antiserum requested by the company (market -driven). The protocols (1C & 8) have similar rationale, starting with 1 sheep or goat for testing, and as many as needed to produce antibodies for commercial projects. The approximate total number of animals is not identified in the protocols.

The IACUC should ensure that a proposal to conduct activities involving animals includes the appropriate information prior to approving the proposal. The approximate number of animals the study proposes to use during a specific time period is important for the IACUC to assess and approve. Additionally, any significant changes (such as the total number of animals used) to activities should have IACUC approval prior to implementation.

IACUC oversight is intended to ensure that the facility is in compliance with the Animal Welfare Act. Inadequate program oversight may be detrimental to the welfare of the animals used in the program.

Correction date 11 November, 2016 for these four protocols and in all protocols by the next routine inspection.

2.31(e)(3) **REPEAT**

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An IACUC approved protocol involving covered animals did not provide a complete description of the proposed use of the animals. The protocol specified the minimum size of the animal and the blood collection schedule (volume every two weeks), but did not ensure that the blood collection protocols do not exceed the industry standard of 7-10% of species specific total blood volume every two weeks.

Prepared By: KATHARINE FRANK, D V M USDA, APHIS, Animal Care **Date:** 27-SEP-2016

Title: VETERINARY MEDICAL OFFICER 6091

Received by Title: PRODUCT DEVELOPMENT DIRECTOR **Date:** 27-SEP-2016

For example, the IACUC protocol requires rabbits weigh 2.5 Kgs at the initiation of the protocol, and production bleeds are 20 mls and up to two bleeds in two weeks can be performed if the condition and health of the animal allow. Rabbits have a mean blood volume of 62 mls/Kg, so total blood volume for a 2.5 Kg rabbit is 155 mls and 20 mls is 13% of total blood volume.

The IACUC Goat protocol requires goats weigh 35 Kg at the initiation of the study and calls for 500 ml production bleeds typically every two weeks and up to two bleeds in two weeks can be performed if the condition and health of the animal allow. Goats have a mean blood volume of 70 mls/Kg, so a 35 Kg goat would have a total blood volume of 2,450 mls and 500 mls is 20% of total blood volume.

The IACUC protocol does not define what steps are taken to determine that the health and condition of the animal are sufficient for weekly bleeds, such as monitoring packed cell volume or weight. The facility maintains records of animal blood collection, but no record of animal weights, therefore the amount of blood drawn from an individual animals may exceed what is safe and adversely affect their health and well-being.

A complete description of activities using animals must be included in protocols prior to IACUC approval. The facility should ensure that all protocols contain complete descriptions of animal use in order to assess how the procedures will affect the animals health.

2.33(b)(2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Several llamas, goats and rabbits were observed to have excessively long hooves or nails. Specifically, approximately twenty rabbits in Barn 1 were observed with long toenails. One goat in the Quarantine pen had front hooves with splits and cracks, while the back hooves were overgrown, and several other goats had overgrown hooves. Several llamas, especially the one adjacent to the cow enclosure had overgrown feet that needed trimming. Overgrown nails and hooves can result in injury, discomfort, and/or lameness.

Appropriate methods and services should be employed in order to provide necessary maintenance of nails and hooves for all the animals.

Correction date 11 October, 2016

2.131(b)(1)

HANDLING OF ANIMALS.

Two llamas were wearing halters with lead ropes attached that dragged on the ground and could wrap around their

feet. The llama adjacent to the cow pen and the llama mixed with the large herd of sheep wore long lead lines. The llama in the smaller corral with several goats had a slightly shorter lead line, but there was a lasso underfoot and tangling with the llama's feet.

Long lead lines dragging on the ground while animals are loose in their enclosures has the potential to cause trauma, physical harm or unnecessary discomfort if the lead line is caught underfoot or on something in the enclosure. Animals shall be handled in a careful manner that does not cause trauma or physical harm.

Correction date 11 October, 2016

3.50(d)

FACILITIES, GENERAL.

The waste material from the breeding barn of rabbits is flushed out of the barn via a partially open channel, through a large pipe underground and into an uncovered animal waste pile containing manure from farm animal species as well. The channel is not adequately flushed and fecal material is built up in the area where the channel transitions from open channel to underground pipe. The open channel with fecal material built up and sprawling waste pile potentially attract vermin and can result in disease hazards.

Animal waste can contribute to unsanitary conditions, vermin infestation, odors, and disease hazards The facility must ensure that animal waste is removed often enough to minimize any potential contamination, odors or disease hazards.

Correction date 25 October, 2016

3.125(d)

FACILITIES, GENERAL.

The new sheep quarantine/project pen was directly adjacent to the large and uncovered animal waste disposal area. The animal waste disposal area included the runoff from the rabbit breeding barn, as well as the collected waste from the cows, llamas, sheep and goats on the property. This material can attract a variety of pests and could impact the health and well- being of the animals in the enclosure.

A system should be in place to ensure the removal and disposal of animal wastes on a regular schedule so as to minimize vermin infestation, odors, and disease hazards. The disposal facilities shall comply with applicable laws and regulations relating to pollution or the protection of the environment.

Correction date 25 October 2016

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3.127(b)

FACILITIES, OUTDOOR.

In the new quarantine/project pen for ten sheep, the only shelter provided is shade cloth stretched over one side of the enclosure and a small cover directly over the food trough. In the larger sheep pen with approximately forty animals, the shelter covered the food trough, but all the sheep could not all comfortably fit under the shelter, and the bedding under the shelter was damp. In the rainstorm earlier this week, the sheep in the quarantine pen had no shelter provided to afford protection and prevent discomfort, and shelter in the larger pen was not sufficient for all the animals, and the uncovered portion of the ground in the enclosure was muddy.

The inability to shelter from seasonal winter rains could cause discomfort to the animals and adversely impact their health. The facility should ensure that all animals housed at the facility have access to natural or artificial shelter to adequately protect all animals from inclement weather and prevent discomfort.

Correction date 25 October, 2016

3.129(b)

FEEDING.

In the llama and goat enclosure, there was a large raised feed bin. The feed bin contained both food and feces and was tall enough that the young goats in the pen would have difficulty accessing the food.

In the cow enclosure, the hay was on the ground and intermingled with fecal matter.

Any food receptacle, hay manger, or platform used is to be sanitizable (the ground is not considered sanitizable). This feeding situation can negatively impact the health and wellbeing of the animals.

Food and food receptacles shall be kept clean and sanitary at all times and shall be placed so as to minimize contamination and accessible to all animals in the enclosure.

Correct by 25 October 2016

This inspection and exit interview were conducted with facility representatives.

Additional Inspectors

Rosendale Marcy, Veterinary Medical Officer

Prepared By: KATHARINE FRANK, D V M USDA, APHIS, Animal Care **Date:** 27-SEP-2016

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Customer: 43309
Inspection Date: 22-SEP-16

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
43309	93-B-0229	002	PRO SCI, INC.	22-SEP-16

Count	Scientific Name	Common Name
000003	*Bos taurus*	CATTLE / COW / OX / WATUSI
000016	*Capra hircus*	DOMESTIC GOAT
000019	*Lama glama*	LLAMA
001300	*Oryctolagus cuniculus*	EUROPEAN RABBIT
000080	*Ovis aries aries*	SHEEP INCLUDING ALL DOMESTIC BREEDS
001418	**Total**	