

| Pro Sci Inc. | Customer ID: | 43309 |
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| 12170 Flint Place | Certificate: | 93-R-0521 |
| Poway, CA 92064 | Site: | 002 |
| | PRO SC | CI INC |
| | | |
| | Туре: | ROUTINE INSPECTION |
| | Date: | 13-FEB-2018 |

2.33(b)(2)

REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Several instances were identified in which the facility is not using appropriate methods to prevent, control and treat diseases and injuries.

*The Baytril 100 multi use bottle had dried medication and debris on the lid, specifically where the needle is inserted to withdraw medication to be injected into the rabbits. The kwikstop/styptic and blue-kote bottles were also sticky with residual medication and are applied to open wounds, and contamination of medication can cause infection.

*A spray bottle filled with liquid in the supply cabinet was unlabeled. Without a proper label, an employee could injure the animal using a caustic solution directly on the animal.

*The parasite control program of the Program of Vet Care specifies that "fecal material is removed from enclosures a minimum of twice weekly to minimize the attraction of flies." The big llama pen contained an excess accumulation of excreta, and there was no documentation that they had cleaned the pen twice in the last week, in accordance with their PVC.

Failure to provide appropriate methods to prevent, control and treat diseases and injuries could jeopardize the health and well-being of the animals. The facility should ensure that their program of veterinary care appropriately addresses the medical needs of all animals under their care and they are following it.

Correction date: 23 February 2018

3.30

WATERING.

All three guinea pig enclosures had dirty water bowls at time of inspection. The water in the bowls contained excreta and some shavings. Animals were observed drinking the dirty water during inspection. Water for guinea pigs must

| Prepared By: | FRANK KATHARINE, D V M FRANK KATHARINE, D V M USDA, APHIS, Animal Care | Date: 27-FEB-2018 |
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| Title: | VETERINARY MEDICAL OFFICER 6091 | 211222010 |
| Received By: | | |
| Title: | | Date: 28-FEB-2018 |



be clean and potable and provided daily unless food supplements consumed by the animals supplies their normal water requirements. The room log showed that water was checked daily, but fresh water was only provided on February 3rd, 4th, and 11th and that the cage had not been cleaned since February 2nd. The facility SOP AF-211 specifies that "animal cages are cleaned at least once per week" and it has been more than a week since cleaning.

Open containers such as water bowls must be placed in or attached to the primary enclosure as to minimize the contamination from excreta. Water that contains dirty bedding and excreta can expose the guinea pigs to disease hazards or make it unpalatable. Correct by ensuring that potable water is offered as often as necessary to ensure the health of the animals and at least daily. Additionally, ensure that watering receptacles are free from contamination and are properly sanitized when dirty.

Correction date: 23 February 2018

3.31(a)(1)

SANITATION.

Cleaning and sanitation of primary enclosures. Guinea pig enclosures are not being cleaned adequately or often enough to remove accumulations of excreta, soiled bedding, debris and stains. There were accumulations of excreta, soiled bedding, urine stains, and grime on the sides and floors of enclosures. The room log showed that the cage had not been cleaned since February 2nd. The facility SOP AF-211 specifies that "animal cages are cleaned at least once per week" and it has been more than a week since cleaning. Ineffective cleaning and sanitation exposes the animals to disease hazards such as bacteria, fungal, and parasites. Primary enclosures must be cleaned often enough to prevent accumulations of excreta, soiled bedding, dirt, urine stains and grime. Enclosures must be sanitized at least once every 2 weeks, or in accordance to the facilities SOP. Correct by ensuring that all primary enclosures are kept clean and sanitized often enough to prevent accumulation of excreta and debris.

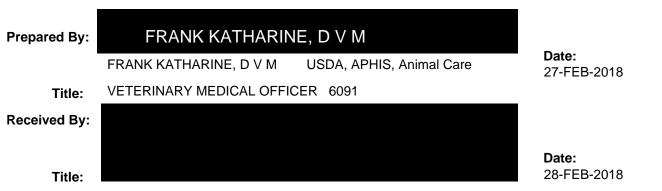
Correction date: 23 Feb 2018

3.125(a)

FACILITIES, GENERAL.

In the large animal pens, there were several pens that were not maintained in good repair and contained elements that were potentially hazardous to the animals:

*The sheep enclosure had a loose piece of wire with wool caught on it at the height of a sheep head, which could





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cause damage to the face or eyes.

*Several enclosures had loosely wrapped rusty wire on the pipe corral fence panels, including the previous cow enclosure and the new llama enclosures.

*The new llama enclosures had areas of rust on the pipe corrals that weakened the structural integrity of the enclosure and created sharp edges that could cause injury to the animals in the enclosure.

*The first new llama enclosure had a shelter area with a plywood wall that had two holes in it near the ground, creating a potential for a hoof to get caught in one of the holes.

The enclosures must be kept in good repair to protect the animals from injury, and a system of maintenance must be in place to ensure that the enclosures are kept in good repair and are structurally sound.

Correction date: 15 March 2018

Additional Inspectors

Schnell Michael, Veterinary Medical Officer

| Prepared By: | FRANK KATHARINE, D V M FRANK KATHARINE, D V M USDA, APHIS, Animal Care | Date: 27-FEB-2018 |
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| | Date: | 20-JUN-2017 |

2.31(c)(7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The Institutional Animal Care and Use Committee (IACUC) approved animal care and use protocols for covered species were changed in late 2016 to require the animals to be weighed prior to bleeding. This change was made in order to ensure that the amount of blood drawn from the animals does not exceed the protocol guidelines, yet the facility only started recording weights in June, 2017 for animals on the rabbit protocol.

Failure to weigh the animals to determine the appropriate maximum blood draw volume constitutes an unapproved significant change to the approved protocol. A system should be in place to ensure that proposed significant changes to activities involving the care and use of animals are reviewed and approved by the IACUC prior to their implementation.

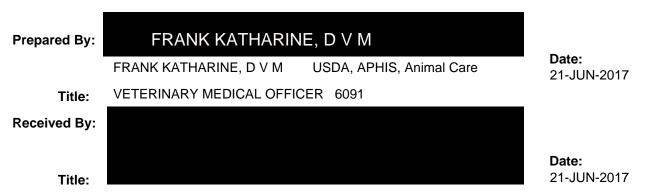
Corrected at the time of inspection.

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. Facility representatives stated that their staff received training as outlined in the protocols and SOP's, but there is no documentation of the training.

The animal care staff has no documented training regarding identifying conditions that may affect the health of the animals. Examples observed during the inspection included rabbits with long toenails, one rabbit with lesions consistent with an ear mite infection, and overgrown and cracked hooves in goats; all conditions which have the potential to adversely affect the welfare of the animals. There is no documentation of training to recognize when an animal has significant weight loss, such as for animal 8735, which was euthanized at a Body Condition Score of 1 on April 28, 2017. The animal was last handled by staff on April 18, 2017. There is also no documentation of training for animal care staff regarding wound care following routine blood collection to ensure that animals have stopped





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bleeding. Several rabbits were observed with excessive amounts dried blood on their ears and/or backs.

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.

Correction date: 31 July, 2017

2.33(b)(2) REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Two goats were observed to have overgrown hooves and three rabbits were observed to have overgrown nails. The goat hooves were misshapen and cracks were observed on the outer wall of one of the goat hooves.

Excessively long and misshapen hooves and nails are susceptible to breaking and cracking and also place abnormal stresses on joints and tendons. Cracks in hoof walls may make animals more susceptible to infections. The facility should ensure that staff members are monitoring the animals so that routine hoof and nail care may be provided when appropriate.

Correction date: 5 July, 2017

2.33(b)(3) CRITICAL

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Several rabbits had medical issues that have not been appropriately monitored through daily observation or communicated to the veterinarian for appropriate treatment in a timely manner.

During inspection, a rabbit appeared to have an ear mite infestation that the facility has not identified or treated. Another rabbit has an ongoing malocclusion, and the teeth are overgrown with no records of when the teeth were last trimmed.

Upon review of records, rabbit 8735 was euthanized by the veterinarian on April 28th, 2017. The medical records from April 28th, 2017 documented that rabbit 8735 had hemiparesis of the hindlegs and was "unable to reach food" and "has lost a great deal of weight" with a body condition score of about 1. This animal had undergone a blood collection procedure on 18 April, 2017 and the animal was not weighed and there was no documentation of any

| Prepared By: | FRANK KATHARINE, D V M FRANK KATHARINE, D V M USDA, APHIS, Animal Care | Date: 21-JUN-2017 |
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observation of weight loss or communication to the attending veterinarian until April 28th, 2017.

Daily observation of all animals to assess their well-being, appropriate documentation of those observations, and direct and frequent communication with the attending veterinarian regarding health issues are necessary to ensure that the animals at the facility receive timely and adequate veterinary care. A system should be in place to ensure that all animals are observed daily, any health problems are documented, and the attending veterinarian is notified when necessary.

Correct from this date forward.

2.33(b)(5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Adequate post-procedural care was not provided for several rabbits used under the rabbit protocol. During inspection, multiple rabbits had dried blood covering the back of the ears or staining the fur on their backs following blood collection. Dried blood can attract flies and cause skin irritation. Failure to control bleeding may also result in excessive blood loss.

Failure to ensure adequate hemostasis after blood collection and adhere to current established veterinary medical procedures may cause the animals unnecessary discomfort and pain. The facility should ensure that adequate post-procedural care is provided to all animals used in activities regulated by the Animal Welfare Act.

Correct from this day forward

3.129(a)

FEEDING.

In the hoof stock feed barn, there was contamination of both the hay and the pelleted feed. An area of mold was observed on one bale of straw that was directly adjacent to hay that was meant to be fed to hoof stock. The pelleted feed had evidence of rodent feces on the bag, and one bag of feed was chewed open with rodent feces present in the bag of feed. The rodent feces appeared to be from rats, based on the size.

Contamination of animal feed can result in disease transmission and potentially impact the health of the animals. There should be a system in place to ensure that the food shall be wholesome and free from contamination.

Correction date: 5 July, 2017

| Prepared By: | FRANK KATHARINE, D V M FRANK KATHARINE, D V M USDA, APHIS, Animal Care | Date: 21-JUN-2017 |
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3.131(d)

SANITATION.

In the small sheep and the small llama enclosure, the flies were not controlled. Flies were observed on and around several llamas and the animals were observed shaking their heads repeatedly to dislodge the flies. The flies were particularly bad in areas of damp hay on the ground in two hoof stock enclosures where they were observed clustered in and moving on the damp hay. An adhesive fly control string had been placed above one animal enclosure, however the string had not been maintained and was coated with flies and thus was ineffective at the time of the inspection.

Rodent feces (appeared to be from rats) were observed on top of and in the pelleted feed bags in the hoofstock feed barn. There was a bag of pelleted feed that had been chewed open and there were rodent feces contaminating the feed.

Flies and rodents can transmit disease and flies can be irritating to the animals. The facility must establish and maintain an effective method of pest control.

Correction date: 5 July, 2017

This inspection and exit interview were conducted with facility representatives.

Additional Inspectors

Rosendale Marcy, Veterinary Medical Officer

| Prepared By: | FRANK KATHARINE, D V M FRANK KATHARINE, D V M USDA, APHIS, Animal Care | Date: 21-JUN-2017 |
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| Title: | VETERINARY MEDICAL OFFICER 6091 | |
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| 12170 Flint Place | Certificate: | 93-B-0229 |
| Poway, CA 92064 | Site: | 001 |
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| | Туре: Date: | ROUTINE INSPECTION 22-SEP-2016 |

2.40(b)(2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE (DEALERS AND EXHIBITORS).

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

| Prepared By: | KATHARINE FRANK, D V M | Date: |
|--------------|---|-----------------------------|
| Title: | KATHARINE FRANK USDA, APHIS, Animal Care VETERINARY MEDICAL OFFICER 6091 | 27-SEP-2016 |
| Received By: | | |
| Title: | | Date: 27-SEP-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.

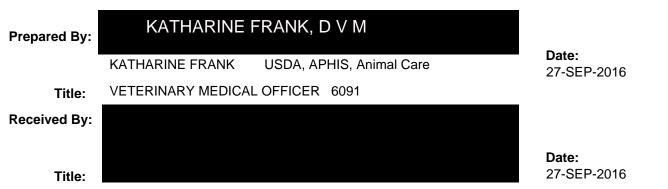
A system should be in place to ensure the removal and disposal of animal wastes on a regular schedule so as to minimize vermin infestation, odors, and disease hazards. The disposal facilities shall comply with applicable laws and regulations relating to pollution or the protection of the environment.

Correction date 25 October 2016

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.

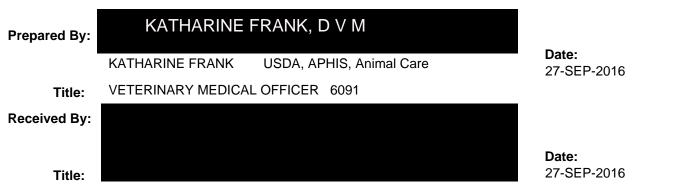
Food and food receptacles shall be kept clean and sanitary at all times and shall be placed so as to minimize contamination and accessible to all animals in the enclosure.

Correct by 25 October 2016

This inspection and exit interview were conducted with facility representatives.

Additional Inspectors

Marcy Rosendale, Veterinary Medical Officer





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| | Туре: | 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

| Prepared By: | KATHARINE FRANK, D V M | |
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| | KATHARINE FRANK USDA, APHIS, Animal Care | Date: 27-SEP-2016 |
| Title: | VETERINARY MEDICAL OFFICER 6091 | |
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| Title: | | Date: 27-SEP-2016 |



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.

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.

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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

| Prepared By: | KATHARINE FRANK, D V M | 5.4 |
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| | KATHARINE FRANK USDA, APHIS, Animal Care | Date: 27-SEP-2016 |
| Title: | VETERINARY MEDICAL OFFICER 6091 | 2. 02. 2010 |
| Received By: | | |
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| Title: | | 27-SEP-2016 |



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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.

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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.

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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.

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| l | KATHARINE FRANK USDA, APHIS, Animal Care | Date: 27-SEP-2016 |
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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

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)

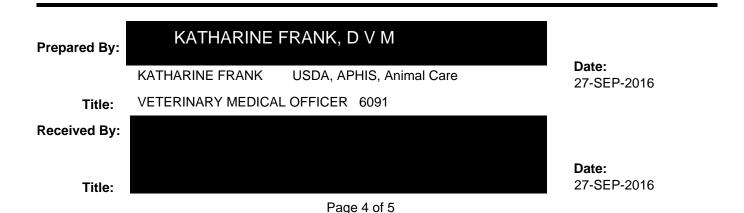
FEEDING.

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.





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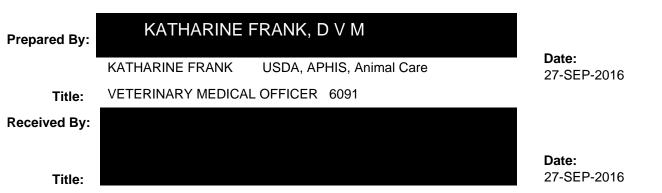
Inspection Report

Correct by 25 October 2016

This inspection and exit interview were conducted with facility representatives.

Additional Inspectors

Marcy Rosendale, Veterinary Medical Officer





Pro Sci Inc. 12170 Flint Place Poway, CA 92064

Customer ID: 43309 Certificate: 93-B-0229 Site: 001 PRO SCI, INC.

> Type: ROUTINE INSPECTION Date: Mar-23-2016

2.40 (b) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE (DEALERS AND EXHIBITORS).

The daily treatment records for the rabbits were incomplete. The facility keeps a written, daily observation log including documentation of any medications administered. According to a facility representative, the medication, Oxytetracycline has been given to sick rabbits; however there is no written documentation or instructions for the use of this medication in the records. The lack of complete and accurate documentation of the use of all medications may lead to inappropriate use on the animals. Accurate information and records should also be available in the event of communications with the attending veterinarian. A system of complete, accurate and timely information concerning animal health problems and observations must be in place.

Correct by 04/04/2016.

3.51 (d)

FACILITIES, INDOOR.

-There were several cracks from 2ft to 6 ft long in the cement flooring of the rabbit building. Some of the deeper cracks were filled with organic waste/debris which attracted several flies to these areas at time of inspection. Large cracks in the flooring are not impervious to moisture and prevent proper sanitization. Also, these areas may trap debris and bacterial organisms as well as attract flies or pests which all may pose a health risk to the animals.

-Several rabbit cages are moderately covered in rust. The presence of rust may prevent the required cleaning and sanitization of the enclosures, which may adversely affect the health and well-being of the animals. There are improvements being made which include sections of new cages and feeders that have replaced older ones.

The interior building surfaces of indoor housing facilities shall be constructed and maintained so that they are substantially impervious to moisture and may be readily sanitized.

Correct by 09/30/2016.

| Prepared By: | TYLER FIELDS, D V M | | |
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| - | TYLER W FIELDS, V.M.O. | USDA, APHIS, Animal Care | Date: |
| Title: | VETERINARY MEDICAL OFFIC | CER Inspector 6082 | Mar-31-2016 |
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| Title: | | | Date: Mar-31-2016 |



3.53 (c) (2)

PRIMARY ENCLOSURES.

Several, primary enclosures housing adult rabbits did not provide the minimum amount of floor space as required. The rabbit cages were 2 ft. X 1.5 ft. which provides a total of 3 square feet which is the minimum floor space for adult rabbits between 4.4-8.8 lbs. Several rabbits in the facility at time of inspection weighed greater than 8.8 lbs, therefore requiring more than the 3 square feet provided by the cages.

Enclosures with insufficient space may have a negative impact on the health and well-being of the animals being maintained within them. A sufficient amount of floor space for rabbits is necessary in order to ensure that they have enough space to make normal postural adjustments and adequate freedom of movement. The facility should ensure that the cages housing their rabbits meet the required minimum floor space set forth in the regulations.

Correct by 09/30/2016

Exit interview was conducted with facility representative, Dr. Alexandra Andricos, VMO and Dr. Tyler Fields, VMO.

| Prepared By: | TYLER FIELDS, D V | Μ | |
|--------------|---------------------------|--------------------------|-------------|
| _ | TYLER W FIELDS, V.M.O. | USDA, APHIS, Animal Care | Date: |
| Title: | VETERINARY MEDICAL OFFICE | R Inspector 6082 | Mar-31-2016 |
| Received By: | | | |
| | | | Date: |
| Title: | | | Mar-31-2016 |



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Customer ID: 43309 Certificate: 93-R-0521 Site: 002 PRO SCI, INC.

Type: ROUTINE INSPECTION Date: Mar-23-2016

2.31 (e) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An IACUC approved protocol involving cows did not contain an adequate rationale for the numbers of these animals to be used. The protocol stated that for commercial applications, larger numbers of cows may be required for these larger projects. There is no quantity or range provided which corresponds to how many more numbers of the animals this would require.

The rationale approved by the IACUC should provide assurances that the appropriate number of animals is being used to obtain the information the activity is designed to provide.

It is the responsibility of the IACUC to ensure that proposals to conduct activities involving animals contain an adequate rationale for the number of animals to be used in those activities.

Correct by 05/15/2016.

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

An IACUC approved protocol involving cows did not provide a complete description of the proposed use of the animals.

- The protocol does not provide a description of the chemical restraint methods for the cows. According to facility representatives, chemical restraint may occasionally be administered to the cows.

-The protocol states, up to two bleeds may be taken within a two-week period if the condition and health of the animal allow. There is no information or parameters provided in the protocol which would consider an animal to have an acceptable health status to remain on the study.

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.

Correct by 05/15/2016.

| Prepared By: | TYLER FIELDS, D V M | | |
|--------------|------------------------------|--------------------------|-------------|
| | TYLER W FIELDS, V.M.O. L | JSDA, APHIS, Animal Care | Date: |
| Title: | VETERINARY MEDICAL OFFICER I | nspector 6082 | Mar-31-2016 |
| Received By: | | | |
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2.33 (b) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The daily treatment records for the rabbits were incomplete. The facility keeps a written, daily observation log including documentation of any medications administered. According to a facility representative, the medication, Oxytetracycline has been given to sick rabbits; however there is no written documentation or instructions for the use of this medication in the records. The lack of complete and accurate documentation of the use of all medications may lead to inappropriate use on the animals. Accurate information and records should also be available in the event of communications with the attending veterinarian. A system of complete, accurate and timely information concerning animal health problems and observations must be in place.

Correct by 04/04/2016.

3.51 (d) **REPEAT**

FACILITIES, INDOOR.

-There were several cracks from 2ft. up to 6 ft. in length in the cement flooring of the rabbit building. Some of the deeper cracks were filled with organic waste/debris which attracted several flies to these areas at time of inspection. Large cracks in the flooring are not impervious to moisture and prevent proper sanitization. Also, these areas may trap debris and bacterial organisms as well as attract flies or pests which all may pose a health risk to the animals.

-Several rabbit cages are moderately covered in rust. The presence of rust may prevent the required cleaning and sanitization of the enclosures, which may adversely affect the health and well-being of the animals. There are improvements being made which include sections of new cages and feeders that have replaced older ones.

The interior building surfaces of indoor housing facilities shall be constructed and maintained so that they are substantially impervious to moisture and may be readily sanitized.

Original Correction date of 12/31/2015.

3.53 (c) (2)

PRIMARY ENCLOSURES.

Several, primary enclosures housing adult rabbits did not provide the minimum amount of floor space as required. The rabbit cages were 2 ft. X 1.5 ft. which provides a total of 3 square feet which is the minimum floor space for adult rabbits between 4.4-8.8 lbs. Several rabbits in the facility at time of

| Prepared By: | TYLER FIELDS, D V M | | |
|--------------|-------------------------|--------------------------|-------------|
| - | TYLER W FIELDS, V.M.O. | USDA, APHIS, Animal Care | Date: |
| Title: | VETERINARY MEDICAL OFFI | CER Inspector 6082 | Mar-31-2016 |
| Received By: | | | Date: |
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inspection weighed greater than 8.8lbs, therefore requiring more than the 3 square feet provided by the cages.

Enclosures with insufficient space may have a negative impact on the health and well-being of the animals being maintained within them. A sufficient amount of floor space for rabbits is necessary in order to ensure that they have enough space to make normal postural adjustments and adequate freedom of movement. The facility should ensure that the cages housing their rabbits meet the required minimum floor space set forth in the regulations.

Correct by 09/30/2016.

3.127 (a)

FACILITIES, OUTDOOR.

In the cow enclosure, there was one shade structure (approximately 3ft X 6ft) provided for the four cows. This is not a sufficiently sized shaded area provided to comfortably protect all animals in this enclosure from the direct rays of the sun.

Failure to provide sufficient shade to allow all the animals kept outdoors to protect themselves from direct sunlight could cause overheating or discomfort to the animals. Additional shade for the animals is required to be in compliance.

Correct by 04/21/2016.

Exit interview was conducted with facility representative, Dr. Alexandra Andricos, VMO and Dr. Tyler Fields, VMO.

| Prepared By: | TYLER FIELDS, D V M | |
|--------------|---|-------------|
| | TYLER W FIELDS, V.M.O. USDA, APHIS, Animal Care | Date: |
| Title: | VETERINARY MEDICAL OFFICER Inspector 6082 | Mar-31-2016 |
| Received By: | | Defe |
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| Title: | | Mar-31-2016 |
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Type: ROUTINE INSPECTION

Date: Sep-10-2015

2.33 (b) (2) REPEAT

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

According to the documentation provided, Rabbit number 16979 was euthanized on 8/19/2015. There was no documentation provided to show the animal was seen by a qualified veterinarian and/or was treated during the previous 20 days.

Failure to provide veterinary care to a rabbit in need of medical care could lead to unnecessary pain and discomfort for the animal. A system should be in place to ensure rabbits requiring medical attention are evaluated by a qualified veterinarian in a timely manner and documentation maintained.

Original correction date: July 31, 2015

This was a focused inspection of 2 Direct non-compliance items noted on the previous inspection report.

An exit briefing was conducted with the facility representative.

| Prepared By: | JEFFREY LEE, D V N | 1 | |
|--------------|----------------------------|--------------------------|-------------|
| | JEFFREY A LEE, D.V.M. | USDA, APHIS, Animal Care | Date: |
| Title: | VETERINARY MEDICAL OFFICER | R Inspector 6032 | Sep-24-2015 |
| Received By: | | | Date: |
| Title: | | | Sep-24-2015 |



Pro Sci Inc. 12170 Flint Place Poway, CA 92064

Customer ID: **43309** Certificate: **93-R-0521** Site: 002 PRO SCI, INC.

Type: ROUTINE INSPECTION

Date: Jul-29-2015

2.33 (a) (1)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The current written program of veterinary care does not include the guinea pigs and hamsters. The PVC should include all the covered animals to ensure the facility has a written guide to follow concerning the health and care of the animals. A system should be in place and maintained to ensure the PVC reflects the current inventory of covered animals.

To be corrected by August 7, 2015

2.33 (b) (2) **DIRECT NCI**

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The following veterinary care issues were noted at the facility:

Rabbits numbered 16979, 17313, 17681 and 17329 had head tilts. Rabbits numbered 17665 (squinting and clear discharge was observed), 16627 (thick yellowish discharge was observed), and 17576 (squinting and clear discharge was observed) had eye problems which included heavy discharge. Rabbit #1309 was underweight, depressed, and soiled.

According to the facility representative, these animals had not been seen by the attending veterinarian. Failure to provide veterinary care to the rabbits could lead to unnecessary pain and discomfort. The rabbits should be evaluated by a qualified veterinarian.

To be corrected by close of business July 31, 2015

Numerous rabbits had overgrown nails. An excessive nail length can cause an animal to stand abnormally. Abnormal posture may cause strain on joints and may be accompanied by possible pain and/or discomfort and joint damage. In addition, long nails can get caught on the wire mesh floors of their primary enclosures. A system should be in place to identify animals that are in need of nail trimming and provide trimming in a timely manner.

To be corrected by August 3, 2015

| Prepared By: | JEFFREY LEE, D V I | N | |
|--------------|---------------------------|--------------------------|-------------|
| | JEFFREY A LEE, D.V.M. | USDA, APHIS, Animal Care | Date: |
| Title: | VETERINARY MEDICAL OFFICE | R Inspector 6032 | Jul-31-2015 |
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3.26 (b)

DIRECT NCI

FACILITIES, INDOOR.

In the guinea pig and hamster room, the ambient temperature was observed to be 93 degrees F. According to the facility representative, the air conditioner was not functioning and there was not a back up system available. This animal room did not have any windows or vents to provide ventilation for the health and comfort of the animals. A system should be in place to ensure that the ambient temperature in indoor housing facilities is not allowed to rise above 85 degrees F.

Indoor housing facilities for guinea pigs or hamsters shall be adequately ventilated to provide for the health and comfort of the animals at all times. Such facilities shall be provided with fresh air either by means of windows, doors, vents, or air conditioning, and shall be ventilated so as to minimize drafts, odors, and moisture condensation. The ambient temperature shall not be allowed to rise above 85 [deg]F.

To be corrected by close of business July 31, 2015.

3.28 (c) (1) (ii)

PRIMARY ENCLOSURES.

The interior height of at least one guinea pig enclosure is not 7 inches and does not meet our minimum requirements. Insufficient interior height of the primary enclosure does not allow the guinea pigs to make normal postural adjustments with adequate freedom of movement. A system should be in place and maintained to ensure this requirement is met.

To be corrected by August 3, 2015

3.28 (c) (1) (iii)

PRIMARY ENCLOSURES.

The available floor space provided in the enclosure housing 2 guinea pigs does not meet our minimum space requirements. Each guinea pig shall be provided a minimum amount of floor space to make normal postural adjustments with adequate freedom of movement. A system should be in place and maintained to ensure this requirement is met.

To be corrected by August 7, 2015

| Prepared By: | JEFFREY LEE, D V M | | |
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| _ | JEFFREY A LEE, D.V.M. | USDA, APHIS, Animal Care | Date: |
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DIRECT NCI

3.30 WATERING.

Potable water was not available to the guinea pigs being housed in plastic enclosures. The water receptacles are open containers and were contaminated with excreta, bedding, and other debris. This contaminated water may prevent the guinea pigs from receiving their normal daily water requirements. Failure to provide potable water may lead to dehydration and other health issues. A system should be in place and maintained to ensure potable water is made available to the animals.

Open containers used for dispensing water to guinea pigs shall be so placed in or attached to the primary enclosure as to minimize contamination from excreta.

To be corrected by July 29, 2015

3.51 (b)

FACILITIES, INDOOR.

The thermometer in the rabbit barn read 86 degrees F and there was not a source of auxiliary ventilation provided to the animals. A system should be in place and maintained to ensure auxiliary ventilation is provided for the rabbits when the ambient temperature is 85 degrees F or higher.

Indoor housing facilities for rabbits shall be adequately ventilated to provide for the health and comfort of the animals at all times. Such facilities shall be provided with fresh air either by means of windows, doors, vents, or air conditioning and shall be ventilated so as to minimize drafts, odors, and moisture condensation. Auxiliary ventilation, such as exhaust fans and vents or air conditioning, shall be provided when the ambient temperature is 85 degrees F or higher.

To be corrected by August 7, 2015

3.51 (d)

FACILITIES, INDOOR.

Two rows of rabbit enclosures are moderately covered in rust. On at least one rabbit enclosure, the wire mesh forming the ceiling has rusted through, creating a hole in the mesh. The presence of rust may prevent the required cleaning and sanitizing of the enclosures, which may adversely affect the health and well-being of the animals. The interior surfaces of indoor housing facilities shall be constructed and maintained so that they are impervious to moisture and may be readily sanitized.

To be corrected by December 31, 2015

| Prepared By: | JEFFREY LEE, D V M | | |
|--------------|-------------------------|--------------------------|-------------|
| | JEFFREY A LEE, D.V.M. | USDA, APHIS, Animal Care | Date: |
| Title: | VETERINARY MEDICAL OFFI | CER Inspector 6032 | Jul-31-2015 |
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3.53 (a) (2)

PRIMARY ENCLOSURES.

In one rabbit enclosure, a water nozzle is leaking into the primary enclosure. The rabbit was observed to be wet from the dripping water. Wet hair coats may lead to irritation of the skin and/or dermatitis. A system should be in place and maintained to ensure rabbits remain dry in their primary enclosures.

Primary enclosures shall be constructed and maintained so as to enable the rabbits to remain dry and clean.

To be corrected by August 3, 2015

3.56 (a) (1)

SANITATION.

There is a moderate build up of hair and excreta observed along the edges of numerous rabbit enclosure. A cleaning schedule should be in place to keep primary enclosures reasonably free of excreta, hair and other debris.

To be corrected by August 7, 2015

3.56 (b)

SANITATION.

Rabbit enclosures are not being sanitized at least once every 30 days. According to the facility representative, the enclosures are being sanitized prior to the introduction of new rabbits, but not every 30 days as required. Failure to sanitize rabbit enclosures on a regular schedule could lead to unsanitary conditions. A system should be in place to ensure rabbit enclosures are being sanitized as required.

Primary enclosures for rabbits shall be sanitized at least once every 30 days by washing them with hot water (180 [deg]F.) and soap or detergent as in a mechanical cage washer, or by washing all soiled surfaces with a detergent solution followed by a safe and effective disinfectant, or by cleaning all soiled surfaces with live steam or flame.

To be corrected from this day forward

3.56 (c)

SANITATION.

The floors in the rabbit barn have areas of standing liquid containing excreta and water used to wash down the barn. The majority of the liquid is around the periphery of the barn. Standing liquid can attract flies and other flying pests increasing disease hazards to animal areas. A system should be in place and

| Prepared By: | JEFFREY LEE, D V I | M | |
|--------------|---------------------------|--------------------------|-------------|
| | JEFFREY A LEE, D.V.M. | USDA, APHIS, Animal Care | Date: |
| Title: | VETERINARY MEDICAL OFFICE | R Inspector 6032 | Jul-31-2015 |
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maintained to keep the premises clean in order to facilitate the prescribed husbandry practices set forth in this subpart.

To be corrected by August 7, 2015.

3.56 (d)

SANITATION.

In the rabbit barn, there was a moderate amount of flies. Although there is some pest control present, additional measures should be taken to minimize the fly populations in these areas. The presence of pests can increase disease hazards in animal areas.

An effective program for the control of insects, ectoparasites, and avian and mammalian pests shall be established and maintained.

To be corrected by August 7, 2015

An exit briefing was conducted with the facility representative.

Accompanied on inspection by Dr. Tyler Fields, Veterinary Medical Officer

| Prepared By: | JEFFREY LEE, D V M | | |
|--------------|--------------------------|--------------------------|-------------|
| | JEFFREY A LEE, D.V.M. | USDA, APHIS, Animal Care | Date: |
| Title: | VETERINARY MEDICAL OFFIC | CER Inspector 6032 | Jul-31-2015 |
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