

Attachment 1:

**APHIS Inspection Report
July 20, 2021**



Inspection Report

ENVIGO RMS LLC
8520 Allison Pointe Blvd., Suite 400
INDIANAPOLIS, IN 46250

Customer ID: **506554**
Certificate: **32-A-0774**
Site: 005
ENVIGO RMS LLC

Type: FOCUSED INSPECTION
Date: 20-JUL-2021

2.40(b)(2) Critical

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

Mortality records show that during the time period from 01/01/2021 to 07/22/2021 over 300 puppy deaths were attributed to unknown causes, however, the facility has not taken additional steps to determine the causes of death in order prevent similar deaths of other puppies in the future. Current guidance from the attending veterinarian is that she should be notified when adult dogs are found dead, however, when puppies are found dead she may or may not be notified. Instead, the animal care staff (who have significant additional responsibilities) are permitted to make the decision of whether the body is disposed of without examination or if they perform a gross necropsy examination. When a gross necropsy has been conducted, the medical records recording those results are incomplete. The lack of consistently applied methods to accurately diagnose the cause of deaths for these animals and complete record-keeping when tests are performed limits the ability to determine causes of deaths and implement changes that would prevent the deaths of additional animals.

***165 puppies under 5 weeks of age were found dead and the cause of death is identified as "unknown" in the medical records. Individual medical records are not recorded for puppies less than 5 weeks old, instead litter records are maintained. The medical records that were evaluated did not have any recorded information indicating abnormalities observed prior to death and did not include any information regarding a potential cause of death, investigation of death, or

Prepared By: DIANA CARE
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

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body condition when found.

***5 puppies (CMBCGY, a 7 week-old female; CLLCFK, a 7.4 week-old female; CMDCHW, a 7.4 week-old male; CMBCHN, a 6.9 week-old male; CLLCMY, a 6.3 week-old male) were found dead in building G2 and the cause of death identified in the medical records is “unknown”. These deaths occurred in February, April, and June of 2021. The individual medical records for these animals were evaluated and there were no notations of any abnormalities observed prior to being found dead. There were no post-mortem examination results recorded and no record of any attempt made to determine the cause of death for these animals.

***16 dogs over 5 weeks of age and 157 puppies under 5 weeks of age were found dead and postmortem change (“PMCH”) was recorded as the cause of death. According to the attending veterinarian, this code is generally used to indicate that postmortem decomposition (autolysis) was present and no other causes of death could be identified. Individual medical records were only maintained for those puppies over 5 weeks old while “litter records” were maintained for those under 5 weeks old. The subset of records checked did not include any recorded information indicating abnormalities observed prior to death, how long bodies were stored before post mortem examination, or body condition when found.

Adequate veterinary care is essential for preventing, identifying, controlling, and treating animal health issues all stages of life. Due to their immature body systems and small size, young puppies are especially vulnerable to stress, infection, and illness. Failure to provide adequate veterinary care including both adequate observations to recognize subtle signs of illness in live animals (as required by section 2.40(b)(3)) and appropriate methods to diagnose disease post mortem when unexpected deaths occur may result in a failure to implement measures to prevent or control disease for the remaining animals.

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Correct by August 7th, 2021 by providing adequate veterinary care to include the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of after hours and emergency care.

2.50(a)(1)

Time and method of identification.

Weaned puppies and adult dogs are individually identified by a tattoo placed on the inside of the ear when dogs are approximately 5 weeks old. The use of tattoos for official identification must be approved in writing by the APHIS Administrator. Approvals for the use of tattoos typically specify the location of application as well as a standard prefix which will be applied to all animals from the particular licensee or registrant. The tattoos currently in use by the licensee do not appear to conform to the standard tattooing conventions approved by the administrator. Additionally, Animal Care has no record of a tattoo request on file from this licensee and no records of any approval for the use of tattoos as official identification.

Accurate identification of all live dogs is important for animal identification, traceability of animals, and investigation of disease outbreaks or animal theft.

Correct by August 30th, 2021 by obtaining approval from the Administrator for the use of tattoos as dog identification, or by using an alternative method of identification that does not require written approval by the Administrator.

2.75(a)(1)

Records: Dealers and exhibitors.

The facility is currently missing disposition records for several of their dogs and puppies.

Disposition records show that there are three adult dogs whose disposition is recorded as 'missing':

- 1) CLICEE, 9 months old, missing on 7/2/21
- 2) CLGCKD, 1 year old, missing on 7/2/21
- 3) CLJCDN, 4.7 months old, missing on 2/25/21

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Disposition records show that 21 puppies were recorded "miss" during the time frame 01/01/2021 to 07/22/2021.

The attending veterinarian stated that these dispositions, recorded as "miss", are likely due to data collection, data entry or administrative error, and will be corrected when dogs are identified.

Accurate and complete recordkeeping of all acquisitions (including births) and dispositions is important for animal identification, traceability of animals, and investigation of disease outbreaks or animal theft.

Correct by August 30th, 2021 by maintaining records that fully and accurately record the disposition of animals in accordance with 2.75(a)(1).

2.75(a)(2)

Records: Dealers and exhibitors.

The facility is not using official APHIS Forms 7005 and 7006 to record acquisitions and dispositions of dogs and cats. Instead, the facility is maintaining electronic records for acquisition and disposition information. There is currently no approved variance is on file from the APHIS Administrator regarding electronic record keeping.

Recordkeeping is important for animal identification, traceability of animal movement, search for missing animals, and investigation of disease outbreaks or animal theft.

Correct by August 30th, 2021 by using official APHIS Forms 7005 and 7006 for recording acquisition and disposition records, or by requesting a variance from the APHIS Administrator to use electronic records.

3.1(c)(1)

Housing facilities, general.

The facility has widespread problems with maintenance of primary enclosures, dog toys, and dog-contact surfaces:

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*** There are plastic hanging doors in most of the sheltered housing runs in Buildings G1, G2, and G3. Approximately 90% of the plastic hanging doors have badly chewed edges with dirt and grime embedded in the edges. Some of the flaps have been chewed so much that they are completely missing and the metal flashing around the doors is also damaged or missing.

*** Dog toys such as rubber 'Kongs' and plastic dumbbells are provided for many of the dogs. Approximately 75% of the toys are severely worn resulting in irregular, pitted, flaking, and worn plastic surfaces. One Kong was found in an enclosure located in Building G3, Room 1 that was missing a large chunk of rubber; small pieces of rubber were present in the waste trough under the plastic coated metal grate flooring.

*** In Building 96, Room 6, approximately 50% of the solid-floored whelping kennels had areas of chipped and peeling paint and exposed concrete on the back wall of the kennel. The kennels have a nesting area in the rear by the wall with bedding where the puppies stay. The areas of flaking paint are low on the wall and adjacent to the area used by the animals.

*** Throughout Buildings G1, G2, and G3 there are several areas of chipped concrete around the edge of the hole that provides access between the inside and outside areas of each kennel. Some of the chipped concrete creates gaps about 1/2 inch to 1 inch in size between the concrete and the metal flashing of the door frame. Areas with chunks of concrete missing have an underlying irregular, unsealed, and uneven surface.

*** Metal kennel walls, gates, metal flashing surrounding the dog door flaps, heat lamps, and metal grates covering the waste troughs have excessive accumulations of rust and deterioration. Buildings G1-3 have approximately 5-10% of their kennel walls, gates, or metal flashing surrounding the dog door flaps affected by rust. The rust on the metal kennels leaves a residue on hands and flakes off when touched. The remaining metal has pitting on the surface. In Building G3, Room 2, the metal heating unit suspended above the dog kennels has accumulations of rust on the underside of the

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metal tubing and on supporting brackets. In Building G2 each room has an outdoor waste trough running underneath the raised, plastic-coated metal grate flooring. At one end there is a metal grate covering an access point to the trough. Closest to the kennels there is an accumulation of flaking rust on the grate covering approximately 5-10% of the surface area.

*** Plastic whelping trays are present in some of the enclosures containing dams and nursing puppies. Approximately 10% of the whelping trays have edges and/or corners that are badly chewed and worn. In some cases, pieces of the plastic are missing altogether. A white plastic board (approximately 2 inches tall) is used as a divider in some solid-floored kennels containing dams and nursing puppies in building 96/97. Approximately 10% of the dividers have deep bite marks, chewed edges, and many of these chewed areas contain organic debris and hair. In Building 97, many of the metal cages containing dams and nursing puppies contain a white plastic board (approximately 2 inches tall) across the base of the door inside the front of the cage. Approximately 10% of these plastic boards were chewed and worn. Surfaces that are worn, chewed, or in poor repair may harbor organic matter or bacteria that can cause illness, injury, or poor health in dogs. Surfaces and structures in poor repair may trap, cut, or otherwise injure animals.

Correct by August 31, 2021 by maintaining enclosures, toys, and other surfaces in good repair.

3.6(a)(2)(ii) Critical

Primary enclosures.

Records show that during the time frame January 1, 2021 to July 22, 2021, 71 dogs were injured when a body part (such as an ear or tail) was pulled through the wall of the kennel by a dog in an adjacent kennel and bitten. The exact injury varied in each case, however substantial or minor, the dogs were subsequently euthanized. Although some enclosures had solid walls separating animals from the adjacent enclosure, the majority of kennels in the facility are constructed

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using either metal wire or mesh to separate animals in adjacent enclosures. Dogs with body parts pulled through cage walls have experienced physical harm and unnecessary pain.

Correct by August 7th, 2021 by housing dogs in primary enclosures that protect the dogs from injury, including protecting animals from injury by dogs in adjacent enclosures.

3.7 Critical

Compatible grouping.

Records show that 2 female dogs were found dead from fight wounds, the first on 3/14/21 (CEJCGL) and second on 3/18/21 (CFHCUB). Additionally, on 5/26/21 an intact 6-year-old female dog (CFGCMJ) was found dead killed by a cage mate.

Records show there were 48 dogs (over 5 weeks of age) who had fight wounds during this same time period (01/01/21-07/22/21).

When asked about compatibility, the facility representative stated that following a fight, animals are relocated to a new enclosure.

Dogs injured or killed by cage mates may experience pain, distress, suffering, and death.

Correct by August 7th, 2021 by ensuring that all dogs housed in the same primary enclosure are compatible. Ensure that there is a mechanism of observation in place to ensure compatibility and prevent fighting.

3.11(a)

Cleaning, sanitization, housekeeping, and pest control.

The waste gutters below the main sheltered housing of Buildings G1, G2, and G3 contained a large accumulation of feces, urine, standing water, insects (both dead and alive) and uneaten food under the raised indoor and outdoor kennel floors. Near the outside gutters there is an overpowering ammonia and fecal odor that emanates from below the kennels.

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Inside the buildings, below the raised kennel floors there is an accumulation of feces, urine, insects (dead and alive), and food. Large numbers of cobwebs are present at the access points to the drain trough, which in some cases impede visualization of the length of the trough. There is organic matter and debris surrounding the inside access points to the drains and against the wall of the rooms. Around the entire facility are large populations live insects including house flies, drain flies, water bugs, cockroaches, and spiders with cobwebs. According to the facility operations manager, a pump in the system that cleans the gutters had broken on Thursday of the previous week and the facility had been unable to clean out the gutters since that time. The accumulation of organic material under the kennels has been present for 6 days without waste removal, and was continuing to grow. The facility operations manager stated that the gutters are typically cleaned every other day when the system is operational.

Build up of feces, urine, food waste and water waste provide breeding grounds for pests and insects, expose the dogs to unnecessary disease hazards, and cause noxious odors.

Correct by July 30th by maintaining a cleaning system that ensures excreta and other waste is removed from under primary enclosures often enough to prevent excessive accumulation of feces and food waste, and to reduce disease hazards, insects, pests, and odors. Additionally ensure that drainage and waste disposal is maintained in accordance with 3.1(f).

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3.11(b)

Cleaning, sanitization, housekeeping, and pest control.

In the Buildings 96 and 97, adult female dogs nursing litters of puppies were housed in solid-floored dog runs. There was a build up of brown organic material on the walls of the dog runs, mainly located near the front of the runs. The facility operations manager stated that the floors in the runs were cleaned daily but the walls were spot cleaned with a degreaser (GP-100) and hot water daily or on an as-needed basis. The facility operations manager stated that these kennels are power washed and sanitized between litters, but are not sanitized during the 6 weeks that the dams and puppies are housed there.

Animal enclosures in the whelping building are cleaned in accordance with two procedures. The first procedure, "Whelping building pressure washing" (EGS-SOP-PRD-6512) outlines pressure washing and application of a cold sterilant in the whelping areas, but does not specify when or at what frequency this procedure is completed. The facility operations manager stated that the animal enclosures in the whelping area are only sanitized between litters (approximately every 6 weeks). The facility operations manager stated that while cages and runs are in use, they are spot cleaned daily or as needed using a degreaser (GP-100) which does not have disinfection properties.

The second cleaning procedure, "General Husbandry of the Whelping Area" (EGS-SOP-PRD-6521) states that cages are scrubbed daily with a disinfectant. However, the facility operations manager stated that employees currently use GP-100 as a degreaser to clean cages, but this product is not a disinfectant. The water temperature used for cleaning is not specified or monitored/recorded. The facility operations manager stated that cages and runs in the whelping area are disinfected in between litters (approximately every 6 weeks).

Buildings G1, G2, and G3 are cleaned in accordance with the procedure for "Sanitation methods and frequency of indoor/outdoor facilities using the Landa stationary pressure washer" (EGS-SOP-PRD-6526). That SOP states that indoor/outdoor runs are cleaned with 180 degree Fahrenheit water at least every two weeks, but there is no detergent or

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soap utilized in this cleaning process. The facility operations manager stated that the degreaser (GP-100) used elsewhere in the facility was not used in the broodstock building (G1, which house approximately 1100 adult dogs) due to concerns about its potential impact on fertility.

Cleaning and disinfection is essential for removing waste and killing germs that can cause disease. Inadequate cleaning and disinfection may lead to animal sickness, outbreaks of disease, or proliferation of pests.

Correct by August 7th, 2021 by cleaning and disinfecting facilities in accordance with the Animal Welfare Act.

3.11(d)

Cleaning, sanitization, housekeeping, and pest control.

There is an extensive, widespread pest problem throughout all animal-housing buildings at the facility.

There are live spiders and house flies in the building G3, most abundantly in rooms 1 and 2. Live spiders and spider webs were present throughout this building on ceilings, in corners, in windows, and at the tops of dog runs containing dogs.

Spider and spiderwebs were also present in drains, on equipment, and on overhead heating lamp structures.

Building G3 also has large numbers of ants present on the floor and adjacent to self-feeders mounted on the front of kennels. Live ants were observed going in and out of self feeders containing dog food for dogs.

House flies were present throughout all animal housing buildings at the facility (G1, G2, G3, and 96/97). Live flies were present in moderate numbers on the walls, ceilings, floors, and flying in the air. Upon lifting the lid on many self-feeders containing dog food, flies often emerged or were seen crawling on food within the feeders. Flies were extremely numerous in Building G2, on the walls behind the enclosures.

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In Building G1 live black hairy worm-type insects and live black beetles were present in the metal self-feeders (which contained dog food) which were mounted to sides of kennels containing dogs. These self feeders were the only source of food for the dogs. These live black worm-type insects, along with live black beetles, were observed in amongst the dog food contained in a large silo/hopper outside building G1. In Building G2, numerous live black worm-type insects were also present in metal self-feeders, and a large bulk feed container in a food storage room.

There were a very large number of live flies ('sewer flies') in all of the whelping rooms containing live dogs in building 97 (rooms 7, 10, 11, 13). The flies were observed on the walls, ceilings, flying in the air, and in the drains in the rooms housing dogs. In Building G1, numerous 'sewer flies' were also present on the walls behind kennels.

Insects which contaminate feed can decreased nutritive value of the feed and/or result in reduced feed consumption.

Insect infestation in other areas may irritate animals and/or can spread disease.

Correct by August 15, 2021 by maintaining an effective program to control pests including insects and spiders.

3.13(b)(2)

Veterinary care for dogs.

Medical records are not complete for numerous dogs. For example:

*CLACJP, an 11-month old male, had a laceration by a leg caught in the run on 01/03/21. The location and description of the injury are not recorded.

*CMBCDM, a 4-month-old male, had a fracture on 06/10/21. The location and type of fracture is not recorded.

*CMACLK, a 4-month-old male, had a fracture on 06/04/21. The location and type of fracture is not recorded.

*CLGCTT, a 9-month old female, had a fracture on 04/23/21. The location and type of the fracture is not recorded.

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*CFEDDY, a 7-year-old female, had a fracture on 06/14/21. The location and type of the fracture is not recorded.

*In addition to these 4 animals with fractures, two other animals were identified in the mortality logs as having been euthanized due to fractures (CLGCHJ a 7-month old female beagle with a broken right rear leg identified on 2/3/2021 and CLDCAH a 1-year old male beagle identified on 4/23/2021 with a broken tail). When the attending veterinarian was asked about how 6 dogs experienced fractures during this period, she stated that she had investigated a nutritional cause, but that she hadn't been able to determine any cause with certainty. Fractures and lacerations may result from improper handling, unsafe primary enclosures, incompatibility of animals, improper nutrition, or many other causes.

Failure to maintain complete and accurate medical records for dogs prevents the attending veterinarian from determining the cause of these injuries and implementing preventive measures. Additionally, this lack of accurate complete record keeping prevents APHIS Officials from determining the facility's compliance with other regulations and standards within the Animal Welfare Act.

*CJKCGC, a 2-year-old female, is listed on the mortality log with a cause of death as "other" on 04/20/21. The animal's individual record contains no information about the animal's death; the record only contains general husbandry information.

*CLBCJF, a 1-year-old female, is listed on the mortality log with a cause of death as "other" on 04/02/21. The animal's individual record contains no information about the animal's death; the record only contains general husbandry information.

During inspection the Attending Veterinarian stated that staff is supposed to notify her when adult dogs are found dead so she can perform a necropsy examination. There is no record of the results for such necropsy examination included in the medical record for either of these two animals.

*CKHCDL, a 1-year-old female, is listed on the mortality log with a cause of death as "pull" (pull injury) on 06/24/21. The

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animal's individual record contains no information about the animal's death; the record only contains general husbandry information.

Complete and Accurate medical records are important for the ensuring provision and continuity of veterinary care, communication with the animal care team, prevention of medical errors, and analysis of animal health. Lack of complete and accurate medical records may result in failure to identify adverse trends in animal health, medical errors, and lack of medical care.

Correct by 08/30/21 by maintaining records for all dogs that include a date and description of problems identified, examination findings, test results, plans for treatment and care, and treatments performed.

This inspection was conducted with the Operations Manager and the Attending Veterinarian.

The exit interview were conducted with the Operations Manager, Attending Veterinarian, Site Director, Regional Quality Assurance Manager, Director of Quality Assurance, Senior Vice President for Veterinary Services, Chief Operations Officer, and Regional Facilities Manager.

This is a continuation of the report for the routine inspection conducted 07/20/21-7/22/2021 and contains the remaining non-compliances found during the inspection from 7/20/2021 to 7/30/2021. The exit briefing for the items included on this report was conducted on 7/30/2021.

Additional Inspectors:

Rachel Perez-Baum, VETERINARY MEDICAL OFFICER

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
506554	32-A-0774	005	ENVIGO RMS LLC	20-JUL-2021

Count	Scientific Name	Common Name
003021	<i>Canis lupus familiaris</i>	DOG ADULT
002014	<i>Canis lupus familiaris</i>	DOG PUPPY
005035	Total	

Attachment 2:

**APHIS Focused Inspection Report
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Inspection Report

ENVIGO RMS LLC
8520 Allison Pointe Blvd., Suite 400
INDIANAPOLIS, IN 46250

Customer ID: **506554**
Certificate: **32-A-0774**
Site: 005
ENVIGO RMS LLC

Type: ROUTINE INSPECTION
Date: 20-JUL-2021

2.40(b)(3) Direct

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

15 animals had medical problems that had not been identified or treated by the facility prior to the inspection.

July 20th, 2021:

***An adult female beagle (CLDCCL) had an abnormal right eye. There was a moderate amount of thick greenish yellow discharge around the edge of the eye. The membrane at the inner corner of the eye was protruding ("cherry eye"). The surface of the eye was slightly grey and there was an irregular, roughened area approximately ¼ inch diameter within this grey area near the inner corner of the eye. This eye condition was not previously identified by the facility and the dog was not receiving any treatments for the eye. The attending veterinarian examined the dog and stated that the eye condition was likely not present for more than two days, and treatment was started for the eye condition.

***An adult female beagle (CGDCEX) had severe dental disease. The back 4 upper teeth on the left side were completely covered with hard, brown tartar and the gums were red. There was hair embedded in the tartar. The right upper canine tooth was 50% covered with tartar, and the gums adjacent to the tooth were inflamed. The 2 back upper teeth on the right side were 90% covered with hard, brown tartar, and there was hair embedded in the tartar. The gums were red. The attending veterinarian examined the dog and stated that the dog had severe dental disease. The animal last had a dental cleaning in May 2019.

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***An adult female beagle (CGGCAE) was itching her right ear continuously. When the ear flap was lifted, the ear canal was thickened, reddened, and there was a brown waxy debris in the ear. The left ear canal was also thickened, reddened, and contained waxy brown debris and a small amount of clear discharge. There were small red scabs on the outside of both the right and left ears. The facility had not previously identified this dog's ear condition and the dog was not currently being treated for its ear condition, but the facility started treatment during the inspection.

***One adult female beagle (CKKCPZ) had a skin issue. The dog had patchy hair loss and a thinning coat along with some scabs affecting approximately 70% of the right side of the dog's rib cage and side. The skin appeared mildly irritated and red. According to the attending veterinarian, the dog's skin condition had not been observed previously and the dog was not being treated for this condition, and treatment was started the same day.

***One adult beagle (CNACDX) was identified with large quantities of fur stuck on the bottoms of the front paws and between the toes of these paws. On examination, an approximately 1-inch diameter area of hair loss with yellow crusts and red skin was identified at the tail base. The hair surrounding this area was crusty. According to the attending veterinarian, the dog's skin condition had not been observed previously and the dog was not being treated for this condition, but treatment was started the same day.

***One adult female beagle (CFECGS) in the broodstock area (G1, room #10) had severe dental disease. The 2 upper left back teeth were completely covered with hard brown tartar, and there were pieces of hair in the tartar. The gums above these teeth were red and bled slightly when touched. The dog was prioritized for a dental cleaning.

***One adult female beagle (CICCYS) in the broodstock area (G1, room #10) had severe dental disease. There was gingivitis, gum recession, and some hair in the tartar. The attending vet examined the dog's teeth and agreed that severe dental disease was present.

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***One adult female beagle (CLGCST) located in G2, room 2, kennel #44, had a wound on the outer surface of her left ear. The wound was approximately 1 inch long and ½ inch wide, and was covered by a dark brown scab. The scab had pulled away from the ear on the front edge and there was a small amount of red and pink milky fluid in the area. There was a small amount of patchy hair loss at the base of the ear. Facility personnel had not previously identified this lesion, and began treatment immediately.

***One male puppy (CMCCIZ) located in G2, room 3, kennel #73, was reluctant to bear weight on the right front foot. The underside of each of the middle two toes on the front right foot had a small circular red area approximately 1/3 inch in diameter. There were yellow crusts or scabs on the underside of all four toes on this foot. Facility personnel had not previously identified this lesion, and began treatment immediately.

***One adult male beagle (CKDCBZ) located in G2, Room 8, Kennel 48, was reluctant to stand and bear weight on his left rear leg. He would stand for a short period of time and then lay down, despite his cage mates jumping around excitedly. This toe was swollen, and skin in the area between this toe and the next was red. The toe nail was curved tightly against the underlying pad. The attending veterinarian further trimmed the nail on this toe and there was a depression left in the toe pad where the nail had been. Facility personnel had not previously identified this issue, and created a treatment plan immediately and was given pain medication the same day.

***One adult female beagle (CGASCD), located in G1, Room 3, Kennel #24, had severe dental disease and a skin issue. On both sides of the mouth, the upper back teeth were completely covered in a hard brown tartar, the adjacent gums were red, swollen, and had pulled back from the teeth. On the right side, there was a greyish substance along the gum line. On the left side of the dog's neck, where the neck meets the lower jaw, there was an yellowish brown scab approximately 1 inch wide and 1.5 inches long. The skin around the edges of the scab was hairless and red, and there was a small amount of clear fluid at the center of the scab. Facility personnel had not previously identified this issue, and

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created a treatment plan immediately.

***One adult female beagle (CFHCAS), located in G1, room 4, kennel 23, had severe dental disease. On the left side of the mouth, the upper back teeth were completely covered in hard brown tartar, and there was hair stuck in the tartar. The adjacent gums were red and swollen and pulling away from the teeth. On the right side of the mouth, the upper middle teeth were completely covered in hard brown tartar, and the gums were swollen and had pulled back from some of the teeth exposing the roots of the teeth. There was greyish material along the gum line. Facility personnel had not previously identified this issue. The dog was prioritized for a dental cleaning.

*** In Building G2, Room 1, an adult female beagle (CLACHJ) has a large, firm, pink and swollen area of skin between the 3rd and 4th toes of her right front paw. The cyst was approximately 1” in length and approximately 70-80% the length of the toes. She was reluctant to bear her full weight on the right front limb. According to the attending veterinarian, the condition was not previously identified by the facility and no treatments had been initiated prior to the time of observation. The dog received treatment immediately.

***In Building G2, Room 5, an adult male beagle (CMBCIA) has discharge in the left eye. The eye has milky, yellow discharge around the edges and there are crusts on the surrounding eyelid. The eye and surrounding tissues were mildly inflamed and red. The condition was not previously identified by the facility and treatment began immediately.

***In Building G1, Room 3, an adult female beagle (CHICPT) has a large amount of patchy hair loss encompassing approximately 80% of her entire coat. The hair loss is primarily over the trunk, sides, and top side of her tail. There are several small yellow scabs spread throughout the hair loss and the skin is red over the tail where the hair is missing. She was not found scratching or chewing during inspection. According to the attending veterinarian, this issue had not been observed and the dog had not been started on any medical treatment prior to the inspection. The attending veterinarian examined the dog and created a treatment plan.

Prepared By: DIANA CARE
USDA, APHIS, Animal Care
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Animals with medical conditions including eye, skin, ear, and dental problems, may suffer from pain, discomfort, infection, and stress. Daily observation of animals to identify medical problems is essential for animal health and welfare.

Correct by July 23, 2021 by observing animals on a daily basis to identify physical, medical or behavioral problems, and communicate all findings to the attending veterinarian promptly.

2.131(b)(1) Direct

Handling of animals.

***In Building 97, Room 15, at 1:36 PM on 07/20/21, a 3-week-old male puppy was found in the pan below cage # 97-11-15. The puppy was huddled, depressed and not actively vocalizing or searching for his dam. He had dried excreta in his fur. When handled he remained listless and quiet. Upon removing the puppy from the pan and replacing him into the cage above, with his dam (CHBCM), he immediately began crawling towards the rest of the litter. According to the facility operations manager, the room had been cleaned around 9 AM that morning and this puppy belonged in the cage above the tray where he was found. The facility operations manager indicated that this puppy must have fallen into the tray during the morning cleaning. There are no gaps or areas where the puppy could fall out of the cage when the cage door is closed. The puppy was immediately examined and treated by the attending veterinarian.

Young puppies who fall into trays below their cage may become distressed, cold, hungry, dehydrated, or contaminated with feces and urine.

Correct by July 23rd, 2021 by ensuring all puppies are handled expeditiously and carefully in a manner that does not cause excessive cooling, behavioral stress, or unnecessary discomfort. This noncompliance was discussed with facility management and the facility took steps to address this issue immediately.

***13 nursing adult female beagles, housed in individual cages with their litters of 6-week old puppies (78 total), were fasted for 42 hours. The facility representatives stated that this reduces milk production and is part of their current standard operating procedure for weaning which they believe reduces the risk of mastitis. This was conducted in

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accordance with the facility's "Weaning of puppies" procedure (EGS-SOP-PRD-6616). Metal automatic food dispensers (self-feeders) which were normally mounted on the doors of each cage were turned around and left on the doors of the cage, so that the dogs could see and smell the food but could not eat it. Many of these self-feeders did not have lids, so the dog food was visible through the uncovered top of the feeders. Food access was removed on Monday (07/19/21) after noon, and food access was returned to the dogs on Wednesday (07/21/21) beginning around 6AM when the females were separated from their litters and moved to a different housing area. The inspectors initially observed the dogs at approximately 12PM on Tuesday, 7/20/21. Three dams were observed to be reaching their front paws through the doors of the cages to reach the food in the top of their feeders, these dogs were seen trying to scoop or dig out food from the feeders but could only retrieve the occasional piece of kibble. One dam was observed to be vigorously licking the back of the self-feeder, another was observed intently smelling the side of the feeder.

Deprivation of food causes stress, hunger, and anxiety. Placing the food where it can be seen, smelled, and in some cases touched by dogs while the dogs are fasting is causing unnecessary distress and anxiety.

Correct by July 23rd, 2021 by ensuring that dogs are handled in a manner that does not cause unnecessary discomfort and/or behavioral stress. This noncompliance was discussed with facility management at the time of initial observation on Tuesday 7/20/2021.

3.3(a) Direct

Sheltered housing facilities.

Puppies and adult dogs were housed in sheltered housing facilities in which the temperature inside the sheltered area exceeded 85 degrees Fahrenheit for at least 5 hours.

The temperature was measured in multiple locations in the following rooms:

Building G2, Room 3 (contains 543 puppies and 21 adults including some that are currently receiving medical treatment for minor conditions):

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USDA, APHIS, Animal Care

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86.4F, 86.1F, and 86.0F at 11:40AM

89.4F, 89.1F, and 89.2F at 1:30PM

90.5F, 90.3F, 90.2F at 2:36PM

90.8F, 90.7F, 90.8F at 3:42PM

91.3F, 91.2F, 91.0F at 4:55PM

Building G2, Room 2 (contains 112 adult dogs, 219 puppies)

86.4F, 86.2F, and 86.2F at 11:42AM

88.7F, 89.0F, 89.1F at 1:33PM

90.2F, 90.1F, 90.2F at 2:33PM

90.7F, 90.8F, 90.7F at 3:39PM

92.3F, 92.2F, 91.8F at 4:53PM

Building G2, Room 1 (contains 319 dogs)

86F at 11:45AM

88.7F, 88.8F, and 88.9F at 1:36PM

90.0F, 89.1F, 90.1F at 2:31PM

92.0F, 91.8F, 91.9F at 3:37PM

92.3, 92.1, 92.0 at 4:49PM

The outdoor ambient temperature taken mainly in shaded areas were 89F at 11:48AM, 91F at 2PM, 92.3F at 2:30PM, and 92.7F at 4:15PM.

Other buildings, which are constructed in the same way and in which the temperature is managed in the same way, were of similar ambient temperatures in their sheltered areas throughout the day. G2 building, room 8 was 89.0F at 1:18PM.

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G1 building, room 1 was 89.9F at 3:03PM. G1 building, room 4 was 90.1F inside at 4:11PM. G1 building, room 5 (which contained a very small number of dogs) was 88.4F at 4:20PM.

Each room had a large fan at one end and two exhaust fans at the other end. There is no air conditioning or other mechanism in place for cooling this building. The facility stated that they typically monitor temperatures once daily at approximately 7 AM. The adult dogs within the buildings were easily excited by the presence of USDA personnel, and were usually jumping, barking, and panting excitedly when inspectors were present. When USDA personnel returned to the rooms throughout the afternoon as temperatures increased, both dogs and puppies were observed to be sleeping. When sleeping, the dogs were avoiding contact and were splayed out not touching each other. Puppies were frequently observed sleeping on the cinderblock at the bottom of the door between the inside and outside of the kennel. Dogs that were awake and not barking or overly excited were often observed to be panting.

Dogs who are hot may experience discomfort, lethargy, or stress. Puppies and dogs with medical problems are especially vulnerable to the effects of hot weather.

Correct by July 26th, 2021 by providing additional / alternate cooling mechanisms that ensure ambient temperatures that do not exceed 85F for more than 4 consecutive hours when dogs are present, and that adequately provides for animal comfort and wellbeing.

3.6(a)(2)(x) Direct

Primary enclosures.

In the G3 building, Rooms 1 and 2, the floors in the cages have a grid pattern with openings large enough for young puppies feet to pass through. There are approximately 200 puppies housed with their respective dams in indoor housing comprised of raised plastic-coated metal grate-type flooring. The grid pattern openings in the flooring allow the puppies feet to fall through the flooring up to their shoulders. Three puppies were observed with their limbs through the floor, and these puppies were able to remove their limbs and move around the cage.

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In the sheltered area of kennels in G2, Room 3, there were two kennels with a total of 13 puppies. In one kennel, two puppies were sleeping at the front of the sheltered area of the kennel. The puppies were leaning against the front gate and their front paws were passing down through a gap between the raised grate floor and the bottom of the gate. In the second kennel, three puppies were up at the front gate and walking back and forth. At least four times their back limb and front limbs fell down between the raised grate floor and the gate. Puppies whose limbs passed through this gap between the floor and the bottom of the gate would sink down to their shoulders or hips and could touch the edge of the cement slab below.

In Building G1, Room 3, an adult female beagle (CJICFN) was standing on the outside of the kennel. The dog's left front paw was caught in the raised plastic-coated grate flooring. Her two middle toes were caught in a thin rectangular opening in the grate floor and she was unable to free her foot. She was standing on her other three feet while panting rapidly and making small movements, as the other 3 dogs in the kennel jumped around her excitedly. It took two facility personnel approximately 3 minutes to free the dog's toes from the opening in the floor. Once the toes were free, the dog was examined more closely and the two toes were red and swollen. The facility provided immediate veterinary care. Facility personnel did not know how long the dog's toes had been stuck in the floor. Medical records indicated that the animal was mildly dehydrated.

Raised mesh or slatted flooring that contains openings that are wide enough for a limb, paw, or digit to pass through can lead to an animal becoming trapped or injured. When an animal becomes entrapped as described above, they can become distressed, dehydrated, or may suffer additional injuries.

Correct by 07/30/21 by ensuring that mesh or slat flooring does not allow the animals' feet or legs to pass through and that all flooring is constructed in a manner that protects their feet and legs from injury.

3.6(c)(1)(ii) Direct

Primary enclosures.

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Inspection Report

62 nursing female dogs (and a total of 393 puppies) in the whelping building (building 97) were housed in cages that did not provide the minimum amount of floor space for the dam and her litter as required by the Animal Welfare Act.

Room 7 has dams housed with their litters in cages that measure 33 inches by 36 inches providing a total floor space of 1,188 square inches. The following dams were identified and measured from nose to base of tail:

CJKCNN measured 28" and has 7 puppies

CIHCLC measured 26" and has 7 puppies

CIJCCF measured 25" and has 5 puppies

CJGCAU measured 28" and has 4 puppies

CKICGJ measured 25" and has 6 puppies

CLDCDA measured 26" and has 6 puppies

CGDCEX measured 25" and has 6 puppies

Additional dams with litters who did have enough floor space were identified in Room 7, Room 10, Room 11, and Room 13. The facility staff stated that the dogs are a consistent size (average female is 25-28 inches). Each of these 62 female dogs had 5 to 9 puppies.

CJKCNN with her seven puppies, requires a minimum floor space of 1560.6 sq.in. The enclosure requires an additional 372 sq.in. of space for compliance with the AWA. CIJCCF, with her five puppies, requires a minimum floor space of 1201.25 sq.in. The enclosure requires an additional 13 sq.in. of space for compliance with the AWA.

Dams and puppies without the minimum amount of floor space may suffer from distress, discomfort, crowding, poor sanitation, increased trauma and mortality.

Correct by July 30th, 2021 by ensuring that all dams and litters are provided with at least the amount of floor space required under the Animal Welfare Act. This issue was identified to the facility during inspection on 7/20/21.

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USDA, APHIS, Animal Care

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Inspection Report

3.9(a) Direct

Feeding

***13 litters of 6-week-old beagle puppies were kept with their mothers (dams) while the dams were fasted (did not have food) for 42 hours. Facility representatives stated the purpose of the fast was to decrease milk production and reduce the risk of mastitis for the mother dogs. This was conducted in accordance with the facility’s “Weaning of puppies” procedure (EGS-SOP-PRD-6616). The puppies only source of food was to nurse on the mother dogs, who were experiencing decreased milk production. Puppies were observed vocalizing and nursing on their mothers, while the mothers stood and tried to gain access to the food outside their cage.

Puppies who have no food source aside from a dam that is on a program to reduce (and eventually halt) milk production may not get enough nutrition, causing the puppies to experience hunger, dehydration, stress, increased susceptibility to infections, and low blood sugar.

Correct by July 23rd, 2021 by ensuring that puppies and dogs are fed in a manner that provides a sufficient amount of wholesome food and nutrition for their age and condition.

***Food in the self-feeders and feed silo in G1 building, and food in self feeders and storage areas in the G2 building were contaminated with a variety of live insects. Live small black worm-type insects were observed in the feed silo and in four self-feeders. Approximately 5 feeders contained live small black beetle-type insects. Flies were present inside many of the self feeders, and were observed landing on the feed in those feeders. Facility operations management stated that feed is added to the feeders every other day, or when food levels were low, and that the self feeders were sanitized every 2 weeks. Facility operations management stated that currently the hopper is cleaned at least twice a year.

Feed infested with insects is not considered wholesome and palatable and may lead to reduced feed consumption or poor nutrition. Correct by July 23, 2021 by ensuring that all feed offered to dogs is uncontaminated, wholesome, palatable, and of sufficient quantity and nutritive value. The following day the facility provided alternative, uncontaminated feed to the

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USDA, APHIS, Animal Care

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dogs in G1.

This noncompliance was discussed with facility management at the time of inspection.

3.12 Direct

Employees

Daily observation failed to identify 15 dogs with medical issues prior to the inspection. A treatment plan was created for each of these dogs following identification by APHIS inspectors, however, there are currently not sufficient employees to recognize these issues effectively. Daily observations regarding veterinary care are made by 6 trained staff members who conduct daily observation in addition to other duties including treatments and husbandry; 3-4 of these employees conduct daily observations each day.

Several animals were found in need of critical care. This included the puppy found by inspectors under the enclosure in the tray used for urine and feces collection and the adult dog with the toes entrapped in the slat flooring. Although both animals received care immediately, they were not identified by animal care staff responsible for providing husbandry care. Two cage cards, and one puppy, were missing from nursery cages. Sheltered housing facilities were not being managed in accordance with the written temperature SOP. The facility currently employs 39 personnel for over 5000 dogs, and there are 5 vacancies which remain unfilled.

Only one attending veterinarian is employed to oversee care for all of the dogs and cats well as assisting in research projects.

Adequate staffing is essential for carrying out the level of husbandry and care required to maintain animal health, welfare, and facility maintenance and sanitation.

Correct by August 31, 2021 by maintaining enough personnel to carry out the level of husbandry practices and care required by the Animal Welfare Act and to assure animal health and wellbeing.

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USDA, APHIS, Animal Care

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Inspection Report

A complete routine inspection was conducted starting on 7/20/2021. This inspection report is limited to the Direct non-compliances identified during that inspection. An additional inspection report will be delivered with the other issues identified during this inspection.

This inspection was conducted with the Manager of Operations and Attending Veterinarian. The exit briefing was conducted on July 22nd, 2021 with the Manager of Operations, the Attending Veterinarian, the Senior Vice President for Vet Services, the Director of Quality Assurance, the Regional Quality Assurance Manager, the Regional Facilities Manager, the Vice President of North American Operations, and the Chief Operating Officer.

Additional Inspectors:

Rachel Perez-Baum, VETERINARY MEDICAL OFFICER

Prepared By: DIANA CARE
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
506554	32-A-0774	005	ENVIGO RMS LLC	20-JUL-2021

Count	Scientific Name	Common Name
003021	<i>Canis lupus familiaris</i>	DOG ADULT
002014	<i>Canis lupus familiaris</i>	DOG PUPPY
005035	Total	

Attachment 3:

**APHIS Inspection Report
October 25, 2021**



Inspection Report

ENVIGO RMS LLC
8520 Allison Pointe Blvd., Suite 400
INDIANAPOLIS, IN 46250

Customer ID: **506554**
Certificate: **32-A-0774**
Site: 005
ENVIGO RMS LLC

Type: FOCUSED INSPECTION
Date: 25-OCT-2021

2.40(a)(2) Direct

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

The facility failed to provide adequate authority to the attending veterinarian by treating three animals with medication not approved by the attending veterinarian (AV). The medical treatment records for 26 Oct 2021 showed that caretaker staff had identified three dogs as being too thin (CGDDBN, CJFCLZ, CLHCHF). These records also indicated that a medication (later identified by the attending veterinarian as Cefpodoxime) had been given to these dogs that day. Medical records did not show that a veterinarian had been consulted regarding the diagnosis of thin body condition or prescription of medications to these dogs. There was no guidance in the program of veterinary care allowing caretaker staff to start this medication on dogs they perceived as too thin. The AV verified that she did not prescribe this medication for these dogs nor would she prescribe this for a dog with only a thin body condition. When APHIS officials brought this to the attention of the AV, she completed an examination on these dogs and directed the antibiotics be stopped. Employees who diagnose and prescribe treatment for animals without consulting the AV are undermining the authority of the AV to ensure the provision of adequate veterinary care for the animals. Correct by ensuring that the AV has adequate authority to ensure the provision of veterinary care and to oversee all other aspects of animal care and use. Additionally, ensure that timely and accurate information concerning health of the dogs is communicated to the attending veterinarian in

Prepared By: RACHEL PEREZ-BAUM
USDA, APHIS, Animal Care
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accordance with section 2.40(b)(3) so that appropriate methods are used to diagnose and treat all diseases and injuries as required by section 2.40(b)(2). Correct by November 5, 2021

2.40(b)(2) Direct Repeat

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

Adult, female beagle (CIACNG) was squinting her right eye and had extensive tear staining and clear discharge around and under her right eye. There were small eyelashes pointing down from the upper lid toward the surface of her eye. This dog received a physical exam on 4 Oct 2021. The physical exam findings documented at that time were consistent with the eye problems seen during the inspection. The veterinarian documented on the physical exam form that the action for this dog was "cull". The facility was unable to provide any documentation showing that this dog had received any kind of treatment since the diagnosis was made during the physical exam on 4 Oct and, as of the time of the inspection, had not been "culled" or otherwise disposed of through either adoption, sale, or euthanasia. This dog's symptoms are consistent with untreated conditions resulting in eye pain. While the condition was diagnosed by the veterinarian, the disease was not treated. The licensee must use appropriate methods to prevent, control, diagnose, and treat diseases and injuries.

2.40(b)(3) Direct Repeat

Attending veterinarian and adequate veterinary care (dealers and exhibitors).

Three dogs had medical conditions that had not been identified or treated by the facility prior to the inspection.

October 25, 2021:

*** A male beagle puppy (CMHCKL) has an abnormal left eye. There was yellow-green discharge present at the corner of the eye with dried discharge surrounding the eye. The membrane at the inner corner of the eye was extended slightly and there was increased tearing present. This eye condition was not previously identified by the facility and the dog was not receiving any treatments for the eye. The facility examined the dog and immediately began treatment for an eye infection.

Prepared By: RACHEL PEREZ-BAUM
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

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*** An adult female beagle (CKJCAZ) has a medium firm, pink, and swollen area of tissue between the 4th and 5th toes of her right rear paw. The swelling was approximately 1/3” in diameter and the inflamed tissue was easy to visualize from a distance. The condition was not previously identified by the facility and the dog was not receiving any treatments for the foot. The facility examined the dog and immediately began treatment for an interdigital cyst.

October 26, 2021:

*** An adult female beagle (CGHCAC) has multiple skin lesions on all four feet. The hair between all four feet was discolored red, commonly seen with licking/chewing due to the presence of saliva. On the left front paw there was a small firm and swollen area of tissue between digits 3+4, and a large firm, swollen, and pink area of tissue between digits 2+3. The larger swelling also has a scab present closest to the toe. On the right front paw there is thickening present in the crevice of skin between the 4th + 5th toes with pink skin and a small scab. There is a medium firm, pink, and swollen area of tissue between digits 3+4 with yellow crusts attached and an oozing sore on the top surface. There is also thickening and inflammation of the skin on the 5th digit between digits 4+5 with two more scabs present. On the left rear paw there is swelling of the skin on digit 4 between digits 4+5 with an open wound on the top surface and partial scabbing. In between digits 3+4 there is a lot of inflamed, pink, and thickened skin with numerous crusts/scabs on the front edge of the toe and an exposed raw area of skin. Between digits 2+3 there is a medium firm, swollen, and pink area of tissue with a scab on the top surface. On the right rear paw there is a small firm, swollen, and dark pink area of tissue with white flaking crusts between digits 2+3. The condition was not previously identified by the facility and the dog was not receiving any treatments for her feet. The facility examined the dog and began treatment.

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USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

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Animals with medical conditions including eye and skin problems may suffer from pain, discomfort, infection, and stress. Daily observations of animals to identify medical problems is essential for animal health and welfare. The licensee must observe all animals at least daily to identify physical, medical, or behavioral problems. Additionally, ensure that all findings are communicated in a timely manner to the attending veterinarian so that they can examine animals and ensure that appropriate treatment is provided as required by section 2.40(b)(2) and further, that the findings are documented in accordance with section 3.13.

2.75(a)(1) **Repeat**

Records: Dealers and exhibitors.

The facility still does not have complete acquisition or disposition records for their animals. Facility records, known as Inventory Change Notices, are used to record newborn puppy numbers, procedures performed, and changes in puppy numbers due to euthanasia or death. The facility continues to have animals which are no longer present for unknown reasons that they have stated to be clerical errors.

***Records indicate that a female puppy born on 9-27-2021, from the dam CIICMP, was not present during a litter count conducted on 10-14-2021. The original litter count was 4 males and 5 females. On 10-14 there were only 4 males and 4 females. There was no record of this puppy dying or being euthanized which would account for its absence. When the facility was asked as to the status of the missing female puppy, they were unable to determine if the original puppy count was wrong (i.e., there were only 4 males and 4 females at birth) or if a female puppy has truly been lost. If the puppy has been lost, the facility does not know how or when.

***On 4 November the facility's Manager of Operations disclosed that she recalled a neonate puppy was found in the drain under an enclosure on 13 October 2021. The puppy was removed from the drain and subsequently died later that

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day. This puppy had not been given an acquisition number and was not included in the acquisition records provided earlier to inspectors. There was no record of this puppy included in the “mortality logs” or other disposition records provided by the facility to inspectors. When asked, the Operations Manager stated that that she was not sure why it had not been included, but perhaps the employees were “not sure how to code it”.

Accurate and complete recordkeeping of all acquisitions and dispositions is important for animal identification, traceability or animals, animal loss, and investigation of disease outbreaks or animal theft. Correct by maintaining records that fully and accurately document all dogs and cats acquired by the facility (through birth, purchase, or other method) and all animals that are disposed of (by sale, death, euthanasia, or other method) including all information required in this section.

2.131(b)(1) **Critical** **Repeat**

Handling of animals.

Animals have not been handled as carefully and expeditiously as possible leading to subsequent death.

*** According to the manager of operations, a newborn puppy was found in the drains below the kennels on 10-13-2021. The Manager of Operations explained that the facility had recently laid down a new type of flooring on top of the existing kennel grate to enhance puppy safety. The manager believes that the puppy fell into the drain because one dam (CKJCCT) had shifted a piece of the flooring, exposing a gap, and whelped on top of the old flooring. The puppy was found between 1-2 pm and immediately brought to the clinic for a bath and was returned to the above dam who had recently whelped near where the puppy was found. The puppy was also provided supplemental heat but died later that day. The Manager of Operations stated that in response to this incident, employees replaced the flooring and added paper to the back of the kennels to prevent another occurrence.

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USDA, APHIS, Animal Care
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*** Mortality records show that a 7-week-old puppy (CLICBE) was found deceased on 21 Oct 2020 with its head stuck in the swinging kennel door of a bedded whelping run. Facility representatives state that an investigation of the incident was completed at the time, but they do not have access to the files from previous management. It was determined that the entrapment and subsequent death was a result of employee error. The employee has since been terminated. Failure to handle animals as carefully and expeditiously as possible can lead to injury or death. Employees must take special care when working with small puppies as they are more easily overlooked and seriously injured. The licensee must ensure all animals are handled expeditiously and carefully in a manner that does not cause physical harm, trauma, or unnecessary discomfort.

Failure to handle animals as carefully and expeditiously as possible can lead to injury or death. Employees must take special care when working with small puppies as they are more easily overlooked and seriously injured. The licensee must ensure all animals are handled expeditiously and carefully in a manner that does not cause physical harm, trauma, or unnecessary discomfort.

3.1(c)(3)

Housing facilities, general.

The facility has surfaces in contact with the dogs that are not being spot-cleaned frequently enough to prevent the buildup of grime and dirt and to reduce disease hazards. In multiple enclosures, the outer cement walls housing the dog doors have brown dirt/grime built up. According to the facility, the outdoor enclosures are hosed down once per day with either a pressure washer or a routine hose. Every two weeks the enclosures are sanitized using a product called "Intervention." Due to the accumulations of dirt and debris on the walls, it is evident that the facility is not spot-cleaning or sanitizing effectively to prevent accumulations or to reduce disease hazards.

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The facility must ensure that floors of primary enclosures are constructed and maintained in such a manner that does not allow dogs' feet and legs to pass through any openings.

3.7 **Direct** **Repeat**

Compatible grouping.

The facility is still having compatibility issues between dogs housed in groups.

October 26, 2021:

***Two adult female beagles (CIBCTG and CJACNF) being housed together had scabs covering multiple small puncture wounds/scrapses. CIBCTG had hair loss present on her back midline and wounds located on her right nose, right ear, left ear, and left cheek. After replacing CIBCTG in the kennel, she began biting and chasing her kennel mate (CJACNF). CJACNF had scabs/wounds on her right knee and inner left thigh. The biting and wounds had not been previously identified by the facility. When questioned, the facility stated that CIBCTG is currently in heat and may be picking fights with her kennel mates. When inspectors identified this issue, the facility representatives removed CIBCTG and placed her in a separate kennel. No steps have been implemented at the facility to prevent potential compatibility issues.

***Two adult female beagles were currently being treated for fight wounds that occurred on 10/25/2021. An adult female beagle (CJACRI) had fight wounds on her chest and left ear. The other adult female beagle (CGFCFA) had fight wounds on her rear end and right front shoulder. These dogs were removed from two different kennels subsequent to fights which resulted in these injuries. According to the facility representative, following a fight, the injured animal is removed and treated medically. Once they are healed, the animal is relocated to a new enclosure in the attempt to find more compatible kennel mates. If one dog is found to be involved in multiple fights and thought to be the aggressor, they may elect to euthanize due to temperament. There is currently no systematic pro-active attempt to identify incompatible animals

Prepared By: RACHEL PEREZ-BAUM
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

Date:
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through behavioral observation; rather, dogs are moved only after injuries are sustained.

***Facility records also show on 10/14/2021, a female dog CMHCAC was found dead. The mortality log and mortality record sheet from October 14th attributed the dog’s death to evisceration (EVIS). CMHCAC was being cohoused with 9 other dogs approximately the same age (10 weeks old). According to the facility, the dog was found dead and the “littermates had chewed on it.” The facility was unable to provide additional information when asked. There is no description of the lesions identified other than the facility code “EVIS” and no record of post-mortem examination findings. When inspectors asked to talk to the employee that found this puppy dead, they were informed she was unreachable due to leave. Dogs attacking/chewing on another dog, whether alive or deceased, is an uncommon behavior for dogs with adequate nutrition and likely indicates a compatibility issue.

Even though this facility continues to have compatibility problems in their group housed animals, there has been no action taken by the facility to proactively identify and potentially house separately those dogs that are incompatible or have an aggressive disposition. Failure to maintain compatible groups of dogs can lead to injuries, pain, and even death in the dogs. Correct this by ensuring all dogs are maintained in compatible groups.

**3.11(a) Repeat
Cleaning, sanitization, housekeeping, and pest control.**

The facility continues to have general sanitation problems with cleaning of enclosures, waste gutters, and odor control.

***At least two enclosures had old, dried, and moldy feces still present in the outdoor section. According to the facility, the lactating females inside do not currently have outdoor access. Additionally, an enclosure in Building G1 housing an adult male beagle contained at least nine to ten piles of feces in the outdoor portion, preventing him from accessing a majority of the outside run without stepping in his own waste and creating a disease hazard. Due to the presence of mold on some

Prepared By: RACHEL PEREZ-BAUM
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

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feces and the excessive number of feces in with the male, it is apparent that some of the enclosures are not being cleaned, at a minimum, daily.

*** In at least 50% of the rooms being used within Buildings G1 and G2 there are still accumulations of waste and an overpowering fecal odor that emanates from below the kennels. Significant accumulations of animal waste and fur on top of 2 pulley systems used to scrape solid waste underneath enclosures are contributing to the excessive odor in the facility. One waste gutter found in Building G2, outside Room 7 had a pile of feces stacked on top of the pulley system approximately 5-6" high. According to the facility, this happens when the gutters are drained and flushed prior to the facility power-washing the enclosures. Another waste gutter found in Building G1, inside Room 8 had a very large collection of fur and fecal matter piled on top of a pipe and the surrounding floor just in front of the pulley mechanism. The waste in the gutters below the main sheltered housing buildings of G1, G2, and G3 have been flushed out since the last inspection and, although the gutters contain much less waste, several waste gutters throughout the facility still had accumulations of feces and urine sitting under the kennels. According to the facility, the waste gutters are limited to being flushed once every other day due to water supply and storage on site.

***Throughout the facility there are areas where a strong sewage odor emanates from the waste gutters surrounding the rooms. The odor is not present at all rooms in a building, but every building has at least one or more rooms with a strong odor. The facility is aware of this issue and has been looking into possible causes and potential solutions.

Buildup of feces, urine, food waste and wastewater provide a breeding grounds for pests and insects and exposes the dogs to unnecessary disease hazards and noxious odors. The licensee must ensure that excreta and food waste is

Prepared By: RACHEL PEREZ-BAUM
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

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removed from and under primary enclosures as often as necessary and with a functioning system that reduces disease hazard, insects, pests, and odors.

3.11(d) Repeat
Cleaning, sanitization, housekeeping, and pest control.

There are still large numbers of dead flies and spiders noted throughout the facility especially in the corners of buildings, near drains, and in the storage areas. Additionally, some areas near drains have populations of small live black flies. The facility has changed pest control companies and there is an improvement in the number of pests found during this inspection. However, failure to remove dead pests makes it impossible to properly monitor the effectiveness of the pest control program. Correct by ensuring an effective pest control program is established and maintained.

3.12 Direct Repeat
Employees

The facility continues to have insufficient numbers of employees to successfully care for the animals. There continue to be severe staffing shortages and currently there are approximately 32 employees at the facility, with only 17 staff members directly responsible for all husbandry, daily observations, and medical treatments for almost 5000 dogs. Four dogs were identified by APHIS inspectors with medical conditions that required treatment and should have been found by staff during their daily observations. There are also numerous dogs that have been identified with severe periodontal disease by veterinarians and still require prescribed dental cleanings. Additionally, basic husbandry such as cleaning out kennels daily to remove feces, cleaning contact surfaces to prevent buildup of debris, and general housekeeping including dead pest removal is not being performed in accordance with the AWA regulations. The employees who are responsible for assessing animals for medical problems are also responsible for assisting with husbandry and cleaning. While the facility brought in temporary, visiting veterinary staff following the last inspection to assist in preventive medicine duties such as dentals and physical exams, the facility still has not completed all the needed procedures identified on those exams.

Prepared By: RACHEL PEREZ-BAUM
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

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There is still only one full-time veterinarian to oversee the daily medical care of all the animals as well as assisting with research projects. The facility must ensure that there are sufficient employees to carry out the level of husbandry practices and care required in this subpart.

3.13(b)(2) Repeat

Veterinary care for dogs.

Veterinary medical records are incomplete for at least 7 dogs. This includes:

*** Mortality records from August 14th and 15th, 2021 shows a list of three puppies coded as deceased from FALV (fatty liver) - CMGCAE, CMGCCZ, and CMGCAU, and two puppies as deceased from ENTE (enteritis) - CMFCYE and CMGCFA. All puppies were approximately 5-6 weeks old. When the complete medical record was requested for these animals, it only listed the facility's code for fatty liver and/or enteritis, respectively. Records indicate necropsies were performed on all these puppies however, there are no exam findings, description of lesions observed, or test results recorded. Additionally, there are no description of symptoms leading up to these animals' deaths. These are diagnoses that can't be made without either a history of symptoms or further diagnostic testing such as histopathology. There are no descriptions in the medical records of problems, daily observation of symptoms leading up to the death, examination findings, or test results listed for these puppies.

*** The mortality records for October 21, 2021 lists a puppy (CMICFA) coded deceased from FALV (fatty liver) and PNEU (pneumonia). The medical record for this puppy lists a mortality code of HPNE (hemorrhagic pneumonia) and FALV (fatty liver). Although, the record indicates a necropsy was performed on the puppy, descriptions of necropsy findings, specific observation, and descriptions of symptoms leading up to the animal's death are not present.

Prepared By: RACHEL PEREZ-BAUM
USDA, APHIS, Animal Care
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*** The inventory change sheet and medical record for a puppy (210801001C) shows that it was euthanized due to DMGB (damage by bitch), a broken jaw on August 17, 2021. However, the medical record does not have physical exam findings, such as the location or severity of the fracture of the jaw, type of fracture, diagnostics performed, or test results.

*** Medical records and a treatment form for a 6-week-old puppy (CMFCPH) on August 5, 2021 indicate that the dog was "lame on all four legs" had a "broken left femur" but failed to contain additional physical examination findings, diagnostics, or test results. The facility representative who found the dog told inspectors that they observed a head tilt and the puppy's balance seemed off, but there was no obvious limping on any specific leg. The manager of operations stated that when the Attending Veterinarian examined the dog, she felt a "pop" in the puppy's left femur and suspected a fracture. The AV recommended euthanasia and the dog was subsequently euthanized. The medical records did not include any of the attending veterinarian's examination findings but rather a presumptive diagnosis.

***On 4 November 2021, the facility's Manager of Operations disclosed that a neonate puppy (less than 1 day old) was found in the drain under an enclosure on 13 October 2021. She stated that the puppy was retrieved and was provided a warming pad and was cleaned before being returned to an enclosure. The puppy died later that day. There is no medical record for this animal documenting an examination, treatment, or death of this puppy.

The presumptive diagnoses listed on the medical records are an incomplete record of all findings/lesions on physical exam, necropsy, diagnostic testing, or results. Due to incomplete records, the facility cannot determine the exact cause of death and therefore ensure the health of the entire colony. Additionally, these animals are coded with problems that present with clinical signs prior to death such as weakness, lethargy, coughing, heavy breathing, inappetence, diarrhea,

Prepared By: RACHEL PEREZ-BAUM
USDA, APHIS, Animal Care
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and vomiting. The facility appears to have missed these clinical signs during daily observations as there are no records indicating problems found prior to death or treatments initiated.

Incomplete medical records do not allow the attending veterinarian to adequately assess the needs of individual animals as well as the medical needs of the colony as a whole. The licensee must ensure that if a problem is identified in a dog (such as disease, injury, or illness), the date and description of the problem, examination findings, test results, plan for treatment and care, and treatment procedures performed are recorded in the medical records. Additionally, daily observations must be made in accordance with 2.40(b)(3) to prevent unnecessary suffering and death in animals.

This inspection was conducted with the Site Director, Manager of Operations, Attending Veterinarian, and Supporting Veterinarian. The exit briefing was conducted with the Site Director, Manager of Operations, Attending Veterinarian, Supporting Veterinarian, Senior Vice President for Vet Services, the Director of Quality Assurance, the Regional Quality Assurance Manager, the Vice President of North American Operations, and the Chief Operating Officer.

Additional Inspectors:

RANDALL COLEMAN, ANIMAL CARE INSPECTOR

MARGARET SHAVER, VETERINARY MEDICAL OFFICER

Prepared By: RACHEL PEREZ-BAUM
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
506554	32-A-0774	005	ENVIGO RMS LLC	25-OCT-2021

Count	Scientific Name	Common Name
003283	<i>Canis lupus familiaris</i>	DOG ADULT
001646	<i>Canis lupus familiaris</i>	DOG PUPPY
004929	Total	

Attachment 4:

**APHIS Inspection Report
July 20, 2021
for License Number 23-R-0187**



Inspection Report

ENVIGO GLOBAL SERVICES INC
310 Swamp Bridge Road
DENVER, PA 17517

Customer ID: **506556**
Certificate: **23-R-0187**
Site: 002
ENVIGO GLOBAL SERVICES INC

Type: ROUTINE INSPECTION
Date: 20-JUL-2021

2.31(c)(7)

Institutional Animal Care and Use Committee (IACUC).

Study data from Protocol 03-21 was reviewed for 2 dogs on the protocol. The protocol states "body weights will be taken on Monday, Wednesday, and Friday." This protocol involves withholding food/fasting dogs.

Neither of these dogs had body weights recorded. The attending veterinarian stated that animals had not been weighed as stated in this protocol.

Significant changes to protocols, including changes to how animals are monitored, must be approved in order to assure IACUC oversight of animal activities and procedures.

Correct by ensuring that the IACUC requires modifications be made to protocols in writing when there are proposed significant changes to on-going activities involving animals. And further by ensuring that such modifications are evaluated by the IACUC and approved or approval is withheld in accordance with the Animal Welfare Act regulations. Any protocols for which significant modifications to ongoing activities are occurring without such approval at this time, must be resubmitted to the IACUC for review no later than 8/30/2021.

Prepared By: DIANA CARE
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

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2.31(d)(1)(i) Critical

Institutional Animal Care and Use Committee (IACUC).

Protocol 003-21 describes a study in which lactating female dogs and their puppies undergo different manipulations of their diet to determine the effects on prevention of mastitis post-weaning. One experimental group in this study is subjected to a 48-hour fast (abrupt removal of food completely from an ad libitum feeding schedule) and the second experimental group has their total daily food ration severely decreased. The abrupt nature of this transition is expected to cause more than momentary or slight distress not only to the nursing dam, but also to the puppies as their food supply will also decline during that period (female’s negative energy balance from lack of food is intended to decrease her milk supply). The principal investigator did not address this as a source of distress for the female dogs or the puppies in the approved written protocol; as such, the protocol neither describes any means to alleviate this distress, nor scientifically justifies in writing the withholding of any such means.

The lack of this required information in the written protocol (reviewed and approved by the IACUC) prevents the IACUC from ensuring that the proposed activities related to the care and use of the animals will avoid or minimize discomfort and distress to the dogs and puppies.

Correct by ensuring that the IACUC, for all future proposals, is able to determine that all proposed activities will avoid or minimize discomfort, pain, and distress when conducting a review of the activities related to the care and use of animals in order to approve the proposed activities. To be corrected by 08/03/21.

2.31(d)(2)

Institutional Animal Care and Use Committee (IACUC)

One protocol had a conflict of interest during its review and approval processes:

Protocol 003-21: lists the attending veterinarian as a co-principal investigator. The same attending veterinarian conducted

Prepared By: DIANA CARE
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

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the veterinary consultation as required by section 2.31(d)(1)(iv)(B) of this subpart. However, since the attending veterinarian is also the co-PI, she should not have participated in the review or approval process for this protocol, as she has a conflict of interest.

Allowing individuals with a conflict of interest to participate in the review and approval process interferes with the integrity and neutrality of that process aimed to ensure optimal animal welfare and the judicious use of animals in study activities. Correct by ensuring that no member contributes to a quorum nor participates in an IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC. Correct by 08/03/21.

2.31(d)(4)

Institutional Animal Care and Use Committee (IACUC).

The IACUC has not notified the principal investigators (PI) and the research facility in writing of its decision to approve the submitted protocols. According to the attending veterinarian, once the protocols are approved by DMR the principal investigator signs the official protocol. The IACUC did not notify the PI in writing, by its process of adding the date of IACUC approval on the several protocols reviewed at the time of inspection.

Written notification of IACUC approval for proposed activities involving animals is important to maintain records regarding which protocols and their amendments have been approved and the date of their approval. IACUC functions as an oversight committee to help monitor animal welfare in research and written records confirm the IACUC is functioning as required by the Animal Welfare Act.

Correct by 08/03/21 by ensuring all IACUC decisions regarding approval of proposed activities involving animals are provided in writing to the principal investigators and the research facility. This written notification must include the approval, the decision to withhold approval, and/or the decision to require modifications of proposed animal activities.

Prepared By: DIANA CARE
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

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2.31(e)(2)

Institutional Animal Care and Use Committee (IACUC).

The following protocols, 02-19, 03-19, 002-20, 001-21, 002-21, and 003-21, simply state the number of animals to be used. No rationale for the appropriateness of the number stated is provided.

***Protocol 02-19 states that 16 dogs are to be used per year for the study but provides no explanation for why 16 dogs are needed.

***Protocol 03-19 states that 20 cats will be used per year for the study but also provides no explanation for why 20 cats are needed.

***Protocol 002-20 states that 100 female dogs will be used per year for the study and that a minimum of 50 dams and their litters must be evaluated on each of the diets. However, there is no rationale provided for the number of female dogs such as statistical calculations for statistically significant results, based on scientific literature, etc.

***Protocol 001-21 states that 4 adult dogs are needed for the training protocol. Although the protocol states that 4 animals are the minimum needed to practice on various sizes of beagles and temperaments, there is no rationale for the number of dogs based on the number of students/animal and/or the number of attempts on each animal.

***Protocol 002-21 states that 3 adult male dogs will be used per year for a study on pharmacokinetics but provides no rationale for the request of 3 dogs. The only rationale provided is that canines are the intended use for the compound being studied.

***Protocol 003-21 states that 400 adult female dogs will be used per year for the study and this is based on past production. However, in the justification for the number of animals in the study, it states that 400 dogs is the maximum number of bitches and puppies to be used in the study. The protocol has two different number requests with no rationale provided such as statistical calculations for statistically significant results, based on scientific literature or past experience, etc.

Prepared By: DIANA CARE
USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER

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Protocols submitted for IACUC review are required to contain a rationale for the use of live animals and for the numbers of animals to be used in the study. If no rationales are provided, the IACUC cannot complete a thorough review of the proposed activities using animals and ensure animals are not unnecessarily subjected to experimental designs.

Correct by the IACUC ensuring all new protocols submitted for review have a complete, written rationale for the use of live animals, the appropriateness of the species and the numbers of animals to be used in the study design. Correct by 09/30/2021.

2.31(e)(3)

Institutional Animal Care and Use Committee (IACUC).

Several protocols lack complete descriptions of the proposed use of the animals.

***02-19 and 03-19 are similar studies conducted in parallel on dogs and cats, respectively. The protocol states that animals will be vaccinated and blood collected. There is no mention of any other relevant details such as vaccine to be administered or the number and time points of blood draws. The approved protocol does not include any discussion of what is being studied/measured.

***004-21 is a study in which dogs have their liver perfused and subsequently harvested during a non-survival procedure. The surgical description does not include details such as the use of aseptic techniques/conditions, volume and type of perfusion fluid, and the specific steps taken to remove the liver. The anesthetic regiment does not include details such as whether inhalant anesthesia will be provided via an endotracheal tube, or if the induction agent will be given via an IV catheter (protocol states this will be given "to effect," which indicates the potential need for multiple injections if not administered through a catheter).

***002-20 is a diet trial for gestating and lactating dams with puppies. The protocol indicates two experimental diets, 1B/3B and 5L3U, which differ from the established diet of 5LL9. For the 1B/3B diet, it is not specified what the transition period will consist of or how long it will last. The stated experimental objective is to determine each diet's effects "on

Prepared By: DIANA CARE
USDA, APHIS, Animal Care

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gestation, lactation, whelping/weaning, post-weaning weight gain;" however, the protocol does not mention any objective measures such as empiric body weights will be taken, only a body condition score (BCS). No details are provided on the scoring system used to assign BCS, such as the scale (1-5 vs. 1-9), or specific observations that may help the scorer to assign a numeric value (e.g., visible ribs and hip bones, protruding vertebral spinous processes, etc.).

***002-21 is a pharmacokinetic study assessing concentrations of an experimental drug in urine and blood samples taken at various times following drug administration. The protocol provides explicit detail regarding sampling of urine via ultrasound-guided cystocentesis; however, similar details regarding blood sampling procedures are missing (location of venous access, whether a venous access portal such as a catheter will be utilized or if multiple venipunctures will be performed, and volume of blood sampled).

***001-21 is a teaching protocol to practice intravenous infusions via IV catheter. The protocol states 4 dogs will be used, but there is no information regarding the following: if a dog may undergo repeat iterations of such practice; if so, how many; the rest period between repeat uses; and the method and location(s) in which the IV catheter will be placed.

These important details are required for the IACUC to be able to make an informed determination whether the proposed activities ensure the humane and judicious use of animals in research. Correct by ensuring proposals to conduct activities involving animals contain a complete description, in lay terms and in detail, of the proposed use of the animals.

Additionally, ensure that any of the protocols listed above for which activities are still occurring or may occur in the future are amended to add a complete description of activities and resubmitted to the IACUC for review and approval. Correct by 08/30/2021.

2.35

Recordkeeping requirements.

The research facility is closely affiliated with a separate business that is licensed as an "A" dealer under the Animal Welfare Act. However, the research facility does not maintain records that disclose the acquisition or disposition of dogs

Prepared By: DIANA CARE
USDA, APHIS, Animal Care

Date:
18-OCT-2021

Title: VETERINARY MEDICAL
OFFICER

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and cats coming from and going to the Class “A” dealer. Their recordkeeping system is such that it only reflects the current use of the animals (research or breeding), but does not show the information required to be maintained of transfers between animal uses. Failure to keep and maintain records regarding transfers of animal use can lead to confusion in possession and responsibility or liability to maintain good animal health and welfare. Additionally, in the case for research animals, it may be unclear if an animal has undergone previous procedures that may compromise the integrity of ongoing research.

Correct by making and keeping records which fully and correctly disclose all pertinent information of ownership, possession, control, transport, euthanasia, sale, or other disposition, including all offspring born while in the facility's possession or under its control, as required in parts (b) and (c) of this subsection. Correct by August 30th, 2021.

2.38(a) Critical

Miscellaneous.

Medical and study data/study records for 2 animals used on each of 8 research protocols from the last year were requested from the facility on July 22nd, 2021 (records for a total of 16 animals). On July 23rd the facility provided printed medical records from their computerized system along with some handwritten surgical logs. The majority of these records do not contain any information regarding protocol-specific procedures performed on animals. On July 26th and 27th, further clarifying emails requesting study data/study records for animals were submitted to the facility. Per phone conversations, the attending veterinarian explained that notes and records generated during protocols were kept as “study data” and not included in an animal's official medical record in the electronic system. The attending veterinarian stated that according to the facility's legal department, she was not allowed to share study data with USDA personnel. These study data records were requested again, by email, on July 28th with a due date of July 29th by 9 AM. As of 9 AM on July 30th, the facility refused to provide full copies of the study records which include the procedures performed on dogs while they are on a study. At 10:30AM on July 30th, 2.5 hours before the scheduled exit briefing, USDA personnel were able to

Prepared By: DIANA CARE
USDA, APHIS, Animal Care

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OFFICER

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briefly remotely view some of the study data that had been previously requested. This review did not allow for a complete and thorough assessment of the facility's compliance with AWA regulations.

APHIS Officials must be permitted to evaluate study records that describe the procedures and exam findings from dogs participating in research studies in order to evaluate the facility's adherence to the IACUC approved protocol and to ensure compliance with the AWA regulations and standards.

Correct by furnishing any information requested by APHIS officials within a reasonable time and as may be specified in the request for such information. To be corrected: August 3rd, 2021.

This inspection was conducted with the Operations Manager and the Attending Veterinarian. The exit interview was conducted with the Operations Manager, Attending Veterinarian, Site Director, Regional Quality Assurance Manager, Director of Quality Assurance, Senior Vice President for Veterinary Services, Chief Operations Officer, and Regional Facilities Manager.

Additional Inspectors:

Rachel Perez-Baum, VETERINARY MEDICAL OFFICER

KATHRYN CAMPITELLI, VETERINARY MEDICAL OFFICER

SUSANNE BRUNKHORST, VETERINARY MEDICAL OFFICER

Prepared By: DIANA CARE
USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL OFFICER

Date:
18-OCT-2021

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
506556	23-R-0187	002	ENVIGO GLOBAL SERVICES INC	20-JUL-2021

Count	Scientific Name	Common Name
000020	<i>Canis lupus familiaris</i>	DOG ADULT
000033	<i>Felis silvestris catus</i>	CAT ADULT
000053	Total	