

EXHIBIT B –
July 2021 Inspection Report
Part 2



United States Department of Agriculture
Animal and Plant Health Inspection Service

DCARE
2016090000739000 Insp_id

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

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United States Department of Agriculture
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DCARE
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Inspection Report

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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United States Department of Agriculture
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DCARE
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Inspection Report

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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Inspection Report

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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Inspection Report

*** 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 ½ 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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Inspection Report

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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DCARE
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Inspection Report

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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Inspection Report

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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Inspection Report

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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Inspection Report

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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Inspection Report

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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Inspection Report

*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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Inspection Report

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	