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INDEPENDENT REGULATORY  
REVIEW COMMISSION

Merck & Co., Inc.  
770 Sumneytown Pike  
P.O. Box 4  
West Point, PA 19486



14 March 2007

Ms. Mary Bender  
Bureau of Dog Law Enforcement  
Pennsylvania Department of Agriculture  
2301 North Cameron Street, Room 102  
Harrisburg, PA 17110-9408

Re: Dog Law Enforcement, Proposed Regulation #2-152 (#2559) Pennsylvania Dept of  
Agriculture

Dear Ms. Bender:

I am writing on behalf of Merck Research Laboratories, a Division of Merck and Co., Inc. which is located in West Point, Pennsylvania in Montgomery County. We are writing to provide comments on the proposed regulations promulgated under the Pennsylvania Dog Law and published in the Pennsylvania bulletin on 16 December, 2006. Merck is a multinational ethical pharmaceutical company headquartered in Whitehouse Station, N.J. with one of its major research and development sites located in West Point, PA. The West Point, PA site conducts research and safety testing utilizing purpose-bred canines and has operated in full compliance with U.S. Department of Agriculture (USDA), U.S. Food and Drug Administration (FDA), and Pennsylvania Dog Law regulations. The animal care and use program, of which dogs are a part, is in full conformance with the standards for animal care as set forth in the Guide for the Care and Use of Laboratory Animals (ILAR, 1996). As such, the program is overseen and directed by nationally and internationally recognized veterinary specialists known as laboratory animal veterinarians who are board certified by both the American College of Laboratory Animal Medicine (ACLAM) and the European College of Laboratory Animal Medicine (ECLAM).

We commend Governor Rendell, his staff, and the Department of Agriculture for their efforts to ensure the humane, responsible care and use of canines in our Commonwealth. The welfare of all animals under our care should be a concern for all citizens of Pennsylvania. We assure you that providing for the responsible and humane care and use

of all animals, including dogs, in concert with the principles of the 3R's is a matter of policy and part of our culture at Merck Research Laboratories worldwide.

Merck Research Laboratories has utilized canines in a biomedical research setting to successfully discover and develop medicine and vaccines to benefit both humans and animals. Two recent examples where dogs contributed significantly to demonstrating efficacy and safety to FDA were Fosamax® (a drug to treat osteoporosis) and Gardasil® (a vaccine for cervical cancer/HPV). We are concerned, however, about creating regulations that may have limited value in improving the welfare of dogs in a laboratory setting while adding more regulatory and enforcement burden.

Biomedical Research Facilities, defined as "Research Kennels" in the P.A. Dog Law (P.L. 28 No. 255), represent less than 1% of all licensed kennels in Pennsylvania and are unique in their nature and housing requirements in comparison to other kennels used for dog breeding or for boarding.

In most cases, due to the requirements of scientific protocols and regulatory requirements (e.g., USDA, FDA-GLP), "a one size fits all" singular engineering standards approach will not work for research facilities.

Proper housing to assure the proper welfare and humane use of dogs at our research facility is therefore based upon peer-reviewed scientific and veterinary medical literature in addition to regulatory requirements, using a more flexible, dynamic performance standard (outcomes-driven) approach. This is done for ethical reasons as well as to assure the quality of the science derived from the use of dogs in biomedical research.

Research programs at Merck invest heavily in facility and kennel construction for dogs, maintenance of the systems, as well as in veterinary oversight, professional staffing, and personnel training well beyond the requirements of applicable regulations or Guide standards.

Biomedical research facilities and programs at Merck are registered with the USDA and the FDA, and also as a Kennel in PA. They are routinely inspected in accordance with regulations. Internal inspections are comprehensive and are conducted by qualified personnel; USDA inspections are equally comprehensive and are conducted by a trained USDA veterinarian (Veterinary Medical Officer – VMO).

The Federal regulations established for research facilities include a number of other provisions enhancing oversight for housing and care such as the requirements for an Institutional Animal Care and Use Committee (IACUC), Provisions for the Opportunity for Exercise, and Provisions for Adequate Veterinary Care. For example:

- The IACUC is charged with overseeing animal care of regulated species, such as the dog, at the institutional level and must:
  - Include a licensed, trained laboratory animal veterinarian as a member
  - Include a person not affiliated with the institute whose role as a member is to represent the general, outside interest of the community regarding the proper care and use of the regulated animals
  - Inspect the program of animal care and use and the facilities at least every six months and maintain a documented record of these inspections for review by the USDA

Federal regulations also include provisions for dog exercise and for ensuring adequate veterinary care by a licensed veterinarian trained in laboratory animal medicine.

In light of the unique research requirements and multitude of animal welfare regulations currently placed on our facilities, **we recommend that, as is done in other states, research kennels that are registered with the USDA under the Federal Animal Welfare Act and are subject to annual Federal Government inspection be exempt from Pennsylvania Dog Law Regulations, as stated in the PA Dog Law.**

- We do not believe that it is the Department's intent to regulate research kennels using the proposed regulations.
- We recommend the Department add language similar to that which has been proposed in Ohio as that state works on strengthening its kennel laws. Ohio Senate Bill 0342 of the 2005-2006 Regular Session states, "Medical kennels for dogs and research kennels for dogs are not required to obtain a license under this chapter or comply with any other requirements of this chapter and rules adopted under it."
- **Without such an exemption, the proposed regulations as published in the Pennsylvania Bulletin of December 16, 2006, will severely curtail or halt pharmaceutical research (some of which is legally required by the FDA) that benefits both animals and humans. Improvements in animal and human health will be put at risk due to the additional regulatory burden and cost of compliance.**

The optimal method to improve the standards of dog care in Pennsylvania is to have strong enforcement of regulations that benefit the animals, are workable for the regulated community, and insure a high quality program of veterinary care. Many of the proposed regulations are unnecessarily prescriptive, inflexible, overly burdensome, not based on scientific evidence, and will not achieve the outcome desired, namely improving the welfare of and humane treatment of dogs within the Commonwealth.

- Housing that provides novel environments is precluded in the proposed state regulations.
- Regulations as rigid as those proposed by the Department offer little opportunity for new scientific discoveries because of the regulatory burden and cost associated with the newly proposed regulation stipulating the manner in which dogs must be housed.
- A high quality program of veterinary care ensures animal well-being and is an integral component of any animal care program. A requirement for such a program is lacking in the Department's proposed regulations. The lack of a section on adequate veterinary care with the inclusion of rigid regulations on such items as drain size exhibits an unbalanced approach to addressing the proper care for dogs.
- Regulations exceeding the Federal Animal Welfare Act standards, such as the proposed Dog Law regulations for Pennsylvania, if enacted for research institutions, would put the Commonwealth in a position of competitive disadvantage for research funds and private biomedical and biotechnological investment.

**Thus, with respect to animals other than those in exempt research kennels, we recommend that the Pennsylvania Department of Agriculture align the regulations for the care of dogs with those established by the United States Department of Agriculture in the appropriate sections of CFR Title 9 Chapter 1 subchapter A parts 1-3.**

- By aligning with the well-established and proven Federal regulations, which include the requirement for a program of veterinary care, a program for dog exercise, and allow for acceptable variation in housing methods, the Commonwealth will:
  - Utilize proven successful and enforceable regulations.
  - Ensure consistency of definitions among the regulators, regulated community, and courts.
  - Enable the state to maximize its efforts by working with the Federal government to share information, training, and enforcement methods that will better the lives of dogs within Pennsylvania.
  - Align with other states that have recently rewritten their Dog Law regulations to improve the standard of care of kenneled dogs within their states.

In order to benefit the taxpayers of the Commonwealth, the regulated community, the Department of Agriculture, and most importantly the dogs within our Commonwealth, we urge the Department to depart from the proposed regulations and adopt instead standards consistent with those established by the United States Department of Agriculture in the appropriate sections of CFR Title 9 Chapter 1 subchapter A Parts 1-2. The Department can then focus on increasing enforcement efforts. **New regulations, without enforcement by properly trained staff and personnel, will do little to improve the welfare of dogs in Pennsylvania.**

We have carefully reviewed the proposed Dog Law regulations and have prepared comments on some of the more problematic areas of the proposed regulations. These comments are found in the appendix to this letter.

Sincerely,



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## Appendix to the letter of March 14, 2007

Because of unique research requirements and the multitude of animal welfare regulations currently placed on research facilities, we recommend that, as has been done or is being done in other states, research kennels that are registered with the USDA under the Federal Animal Welfare Act, currently under Federal Government inspection and undergo no less than one Federal Government inspection annually, be exempt from Pennsylvania Dog Law regulations. We suggest that the Department add language similar to that has been proposed in Ohio as they work on strengthening their kennel laws. Ohio Senate Bill 0342 of the 2005-2006 Regular Session states, "Medical kennels for dogs and research kennels for dogs are not required to obtain a license under this chapter or comply with any other requirements of this chapter and rules adopted under it."

Additionally, in order to benefit the taxpayers of the Commonwealth, the regulated community, the Department of Agriculture, and most importantly the dogs within our Commonwealth, we urge the Department to drop the proposed regulations and adopt the standards established by the United States Department of Agriculture in the appropriate sections of CFR Title 9 Chapter 1 subchapter A Parts 1-3 and to increase the Department's enforcement efforts.

We have carefully reviewed the proposed Dog Law regulations and have prepared comments on the more problematic areas of the proposed regulations. These comments follow below.

### **In the preamble to the proposed regulations:**

(Proposed regulations are in *italics*. Suggested revised language is in *italics* and underlined.)

### **Proposed regulation**

*Section 21.23. Space.*

*This section contains new language which is intended to address the health and welfare of dogs housed in kennels and which makes the Department's regulations more consistent with Federal regulations set forth under the Animal Welfare Act (7 U.S.C.A. §§ 2131--2159). The new language addresses space requirements and sets forth the requirements of and for an exercise program for all dogs kept in a kennel.*

### **Comment**

In fact, the new language is not consistent with the Federal Animal Welfare Act. The proposed language is actually significantly more inconsistent than the current Pennsylvania Dog Law regulations.

## **Proposed regulation**

### ***Private Sector***

*The proposed amendments to the regulations will impose additional costs on the regulated community. Licensed kennels will likely have to make some changes to comply with the lighting, ventilation and space requirements, as well as, the additional sanitation and housing requirements in these regulations. Furthermore, establishments utilizing temporary homes will now have to comply with the kennel licensure and recordkeeping requirements of the act and these regulations. The costs to the regulated community will be varied, depending on the size and condition of the existing kennel. It is estimated that the costs will range from \$5,000 to \$20,000 per existing kennel for compliance with the new standards.*

### **Comment**

The figure of \$20,000 is grossly underestimated for research kennels. In fact, our members estimate that it will cost between \$800,000 and \$18 million per research facility in construction, renovation, and equipment costs alone, depending on facility size and number of dogs housed, to comply with the proposed regulations. Utilizing the proposed regulations will also result in an additional \$100,000 to \$800,000 per year in operating costs depending again on the facility size and number of dogs housed.

Implementing the proposed regulations for research kennels will present an additional cost which will be borne by our citizens and animals. That cost will be the loss of research that benefits veterinary and human medicine. In addition to delaying much needed medical research due to the requirements for new construction and renovation, biomedical research utilizing dogs at many of our member institutions would, at a minimum, be reduced by half and, very possibly eliminated entirely. This is especially true for the Commonwealth's outstanding major academic research institutions whose finances for biomedical research is limited by grant funding.

## **Proposed regulation**

### ***Paperwork Requirements***

*The proposed amendments to the regulations will not result in a substantial increase in paperwork. The Department will not have to develop new application forms or review procedures, but in some cases may want to amend current forms.*

### **Comment**

The record keeping proposed is extensive and is substantially more burdensome than what is presently required.

**In the proposed regulations:**

(Proposed regulations are in *italics*. Suggested revised language is in *italics* and underlined.)

**Proposed regulation**

**§ 21.1. Definitions.**

*Licensed veterinarian--A licensed doctor of veterinary medicine as defined [in section 901-A of the act (35 P. S. § 459-901-A)] by the Veterinary Medicine Practice Act (63 P. S. §§ 485.1--485.33).*

**Comment**

Veterinarians in biomedical research facilities are not covered by the Veterinary Practice Act and some veterinarians employed by research facilities may have multi-state responsibilities and may, therefore, not be licensed in Pennsylvania. We suggest using the following language found in the section 1.1 of the Federal regulations.

*Licensed veterinarian means a person who has graduated from an accredited school of veterinary medicine or has received equivalent formal education as determined by the Administrator, and who has a valid license to practice veterinary medicine in some State.*

**Proposed regulation**

*Sanitize--To make physically clean and to remove, neutralize and destroy, to a practical minimum, agents, vectors of disease, bacteria and all infective and deleterious elements injurious to the health of a dog.*

**Comment**

This definition of sanitize is not technically or scientifically correct including but not limited to the words *deleterious elements*. We suggest using the following language found in the section 1.1 of the federal regulations.

*"Sanitize means to make physically clean and to remove and destroy, to the maximum degree that is practical, agents injurious to health."*

We also propose adding a definition of "Attending Veterinarian". We suggest using the following language found in the section 1.1 of the Federal regulations.

*Attending veterinarian means a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education, or*

has a certificate issued by the American Veterinary Medical Association's Education Commission for Foreign Veterinary Graduates, or has received equivalent formal education as determined by the Administrator; has received training and/or experience in the care and management of the species being attended; and who has direct or delegated authority for activities involving animals at a facility subject to the jurisdiction of the Secretary.

## **Proposed regulation**

### **§ 21.14. Kennel licensure provisions.**

(3) *Kennel license required.* A kennel license shall be required for any establishment upon which a cumulative total of 26 or more dogs of any age in any 1 calendar year are kept, harbored, boarded, sheltered, sold, given away or in any way transferred. The Department, based upon the application, will determine the appropriate licensure classifications.

(i) *Upon reaching the cumulative total of 26 or more dogs of any age in any 1 calendar year, the establishment in question shall be required to apply for and obtain a kennel license. The establishment shall have kennel facilities that meet the regulatory requirements for all of the dogs currently on the premises or to be kept, harbored, boarded, sheltered, sold, given away or in any way transferred by the establishment, which ever number is larger.*

## **Comment**

The language in this section needs clarification. By including the words "which ever number is larger", one would be led to believe that if one has 100 dogs throughout the year but only 10 at any one time, a kennel would be required to have facilities for 100 dogs. We do not believe that this is the Department's intent. The regulation should state that the establishment must have facilities for the maximum number of dogs housed at the establishment at any one time during the year.

## **Proposed regulation**

(5) *Kennel records.* Every kennel shall keep, for at least 2 years, a record of each dog kept at any time kept in the kennel. The records must be legible and be open to inspection and may be copied by any employee of the Department, State dog warden or police officer as defined by the act. The records must include the following information:

(i) *The breed, color, markings, sex and age of each dog.*

(ii) *The date on which each dog entered the kennel.*

(iii) *From where the dog came. The records must provide the following information:*

*(A) For Kennel Class I--Kennel Class V licensed kennels, the following information:*

*(I) The name of the kennel and kennel owner from which the dogs were acquired.*

*(II) The address of the kennel.*

*(III) The Pennsylvania kennel license number or Out-of-State dealer license number of the kennel from which the dog came.*

*(IV) The name and address of the individual breeder of the dog, when applicable.*

*(V) Where applicable the name and address of the owner or keeper of the dog.*

### **Comment**

Clarification is required as to where such records must be held. We have members who have multiple kennels with one main office where records are normally maintained.

### **Proposed regulation**

*(b) Prohibitions on dealing with unlicensed kennels. It shall be a violation of the act and this chapter for any kennel to keep, harbor, board, shelter, sell, give away or in any way accept, deal or transfer any dog from a kennel or establishment operating without a license in violation of sections 206, 207 or 209 of the act (3 P. S. §§ 459-206, 459-207 and 459-209), without the express written permission of the Department. In addition, it shall be a violation of the act and this chapter for any kennel to keep, harbor, board, shelter, sell, give away or in any way accept, deal or transfer any dog from a kennel that has had its license suspended or revoked, without the express written permission of the Department.*

### **Comment**

Some of our members have multiple sites, some of which may be out of state. In addition some academic institutions share animals which are models for specific diseases. Some of the institutions where the animals are coming from may be out of state. Our members desire to maintain compliance with regulations and believe that compliance with this proposed regulation may at some point jeopardize timely and valuable research.

### **Proposed regulation**

*(c) Health certificate requirement. A dog entering this Commonwealth from another state, commonwealth or country shall have a health certificate. A person, licensed kennel, establishment or temporary home accepting a dog from another state, commonwealth or country shall assure a health certificate accompanies each dog and copy and record the health certificate which shall become part of their records. In accordance with section 214 of the act (3 P. S. § 459-214), it shall be unlawful to transport any dog into this Commonwealth, except dogs temporarily in this Commonwealth as defined in section 212*

*of the act (3 P. S. § 459-212), without a certificate of health prepared by a licensed doctor of veterinary medicine. The health certificate or a copy thereof must accompany the dog while in this Commonwealth. The health certificate must state that the following conditions have been met:*

*(1) The dog is at least 7 weeks of age.*

#### **Comment**

Dogs less than seven weeks of age may be required for some research. For those reasons an exemption has been made in the Federal regulations and we suggest adding the following language found in section 2.130 of the Federal regulations.

*No dog or cat shall be delivered by any person to any carrier or intermediate handler for transportation, in commerce, or shall be transported in commerce by any person, except to a registered research facility, unless such dog or cat is at least eight (8) weeks of age and has been weaned.*

In many cases, when dogs less than 8 weeks of age are needed for a research project, they are shipped with their dam. Therefore, we also suggest adding the following language found in section 3.14(f)(4) of the Federal Animal Welfare regulations.

*Weaned live puppies or kittens less than 8 weeks of age and of comparable size, or puppies [or kittens] that are less than 8 weeks of age that are littermates and are accompanied by their dam, may be transported in the same primary enclosure when shipped to research facilities, including Federal research facilities...*

#### **Proposed regulation**

*(2) The dog shows no signs or symptoms of infectious or communicable disease.*

#### **Comment**

Some research may be on infectious and/or communicable disease and, for research purposes, these dogs may need to be transferred from one research institution to another. These transfers are performed under strict containment and surveillance with appropriate veterinary oversight and proper permitting. An exemption for research kennels would be required from this provision or research that benefits animals as well as humans would be jeopardized.

#### **Proposed regulation**

*(5) The dog has been vaccinated for rabies in accordance with the Rabies Prevention and Control in Domestic Animals and Wildlife Act (3 P. S. §§ 455.1--455.12). The health certificate must show the vaccine manufacturer, the date of administration of the rabies vaccine and the rabies tag number.*

## Comment

Some research requires dogs that have not been vaccinated against any disease, including rabies. These dogs are maintained in indoor facilities and in closed colonies with strict containment procedures and veterinary oversight. They, therefore, have a near zero risk of being exposed to and contracting rabies. In order to continue with this research, research kennels will need an exemption from this proposed regulation.

## Proposed regulation

### **§ 21.21. Dog quarters.**

*(c) Adequate drains or gutters, or both, shall be provided to rapidly eliminate excess water from both indoor and outdoor housing facilities and other areas such as outdoor runs and exercise areas.*

## Comment

Some of our members maintain dogs in cages. For sanitization of the cages, the dogs are removed and placed in clean cages. The soiled cages are then moved to another area of the premises where they are sanitized. The floor in the animal holding room gets a minimal amount of water on it and may be cleaned using a mop and bucket or it may be dried using some other method such as a wet-vac. Thus a drain and/or gutter would not be needed to prevent standing water.

We suggest that, if included, the provision read, *Adequate drains or gutters, or other means [both], shall be provided to prevent standing water in [rapidly eliminate excess water from] both indoor and outdoor housing facilities and other areas such as outdoor runs and exercise areas.*

## Proposed regulation

*(e) Where the primary enclosures are stacked or set side by side, a tray, wall, partition or other device approved by the Department which does not allow for feces and urine to pass between primary enclosures or soil the primary enclosure of another dog, shall be placed under or between, or both, the primary enclosures. The tray, wall, partition or approved device must be impermeable to water, removable and able to be easily sanitized.*

## Comment

Clarification is required for this provision. It is our understanding that a "primary enclosure" includes pens and runs. This provision would exclude most currently used pens and runs whose sides are constructed of open fencing or metal bars. These pens and runs do not prevent the soiling of an adjacent pen or run, especially by male dogs. Do the proposed regulations require that pens and runs have solid sides? If this is the case, will it not limit the visual contact with other dogs and thus reduce their ability for socialization?

## **Proposed regulation**

### **§ 21.22. Housing.**

*(d) Dogs that are not acclimated to the outdoor temperatures prevalent in the area or region where they are maintained, breeds of dogs that cannot tolerate the prevalent outdoor temperatures without stress or discomfort (such as short-haired breeds in cold climates), and sick, infirm, aged or young dogs may not be kept in outdoor facilities [unless that practice is specifically approved by the attending veterinarian].*

## **Comment**

The removal of the provision for approval by the attending veterinarian removes the ability for the veterinarian to use professional judgment and does not benefit the dog. We urge that the present language remain as it is also consistent with section 3.4 of the Federal Animal Welfare regulations.

## **Proposed regulation**

*(d) Puppies not born in the receiving kennel facility or establishment, that are brought into a kennel from another kennel facility or acquired from another person shall be quarantined from other dogs and puppies in the receiving kennel facility for a minimum of 14 days or for the time period necessary to allow for treatment of any disease, prevent the spread of parasites or new strains of bacteria or viruses and to allow the puppies to acclimate to the new kennel environment, which ever is longer. Each group of puppies arriving from another kennel facility, person or establishment shall be quarantined together and kept separate from other groups of puppies arriving at the receiving kennel facility or establishment from a different kennel facility, person or establishment and shall be kept separate from the current kennel population of the receiving kennel facility or establishment.*

*(e) Adult dogs entering a kennel facility or establishment, that are brought into a kennel from another kennel facility or acquired from another person or individual, that exhibit signs of parasites or disease or that have no record of vaccinations, shall be quarantined until adequate veterinary care has been provided to arrest the parasites or disease and until proper vaccinations can be given and become effective or all of the requirements have been met, when applicable. A release from the treating licensed veterinarian shall be adequate to allow the dog to enter the kennel population.*

## Comment

Our members purchase dogs from closed colonies of known health background. These dogs therefore may not require a quarantine period. However, there may be times when quarantine is required. In addition, an acclimation period may be required for the animals. Therefore, we suggest that (d) and (e) be re-written without rigid timelines but require a plan for quarantine and/or acclimation which has been reviewed and approved by the attending veterinarian.

## Proposed regulation

### § 21.23. Space

*(a) Primary enclosures [shall] must be constructed and maintained to provide sufficient space to allow each dog to turn about freely and to stand erect, sit and lie down in a comfortable, normal position. The dog shall be able to lie in a lateral recumbence (on its side or back) with legs fully extended, without head, tail, legs, back or feet touching any side of the enclosure.*

## Comment

In the preamble to the proposed regulations, the Department states, "This section contains new language which is intended to address the health and welfare of dogs housed in kennels and which makes the Department's regulations more consistent with Federal regulations set forth under the Animal Welfare Act (7 U.S.C.A. §§ 2131--2159)." When, in fact, the proposed additional language makes the regulations less consistent with Federal regulation. In addition, this requirement will be difficult to meet for long-tailed dogs while providing no additional benefit to the dog. Existing state regulations, as well as Federal regulations, ensure that the dog can stand, sit and lie down in normal positions. We suggest removing the proposed added language. We recommend using the following language found in section 3.6(a)(2)(xi) of the Federal regulations.

*Primary enclosures must be constructed and maintained so that they provide sufficient space to allow each dog [and cat] to turn about freely, to stand, sit, and lie in a comfortable, normal position, and to walk in a normal manner.*

In addition, in the research field, we are constantly looking for ways to improve the housing of our research animals. We explore new and innovative ways by which we can benefit animal welfare. The possibility of exploring new housing methods is limited by the proposed regulations but recognized by existing Federal regulations. Any deviation from the prescribed caging size requires the approval of the Institutional Animal Care and Use Committee before it may be implemented. We suggest adding the language found in section 3.6(d) of the Federal regulations, citing the appropriate sections in the Pennsylvania regulations.

*Innovative primary enclosures not precisely meeting the floor area and height requirements provided in paragraphs [(b)(1) and (c)(1)] of this section, but that provide*

the dogs [or cats] with a sufficient volume of space and the opportunity to express species-typical behavior, may be used at research facilities when approved by the Committee, and by dealers and exhibitors when approved by the [Administrator] Secretary.

### **Proposed regulation**

*(b) Each dog housed in a primary enclosure shall be provided with [a] twice the minimum amount of floor space[, which] set forth in this subsection. The minimum amount of floor space shall be calculated according to the following procedure:*

### **Comment**

Again, this is in conflict with the Department's stated objective of making the Commonwealth's regulations more consistent with the Federal regulations. By adding the proposed language, the cage size requirement is twice that required by Federal regulation. The Federal regulations do address doubling the required cage size under exercise (section 3.8) not space requirements, and then only for dogs that are individually housed, and then only if those dogs are not provided with another means of exercise. (We will address this further under the section on exercise.) We do not believe that doubling the primary enclosure size requirement will benefit the welfare of the dogs that we work with. Research shows that, for purpose bred male laboratory beagle dogs (the most commonly used research dog), enlarging cage size over that currently require by federal regulation, has little or no effect on their activity (Hughes et. al. 1989). The addition of the proposed twice the existing cage size requirement would have the effect of immediately stopping valuable and legally required research at some facilities, reducing to one-half the amount of research at other facilities, and/or requiring a huge investment in new caging by research facilities that are currently in compliance with Federal regulations.

### **Proposed regulation**

*In addition to the space requirements, each dog shall receive 20 minutes of exercise per day. Dogs shall be observed and supervised during exercise and shall be exercised the following manner:*

*(i) Walked on a leash by a handler or put in an exercise area.*

### **Comment**

Again this is in conflict with the goal of consistency with Federal regulation as well as not showing a direct benefit to the dogs' welfare. Laboratory dogs have been shown to increase activity primarily when stimulated by human interaction and not when left alone in larger areas (Hughes et. al. 1989). Dogs receive more positive stimulation by novel environments, social interaction and human interaction than a large cage size. This is one

reason that Federal regulations do not require additional exercise for dogs housed in groups if each animal is provided 100 percent of the space required for an individual dog.

Additionally Federal regulations are not as prescriptive as those proposed by the Department. It is not at all clear on what scientific basis the 20 minute period was established. Federal regulations require an exercise program for dogs but recognize that "The opportunity for exercise may be provided in a number of ways,..." According to Federal regulation, the exercise plans must be developed, documented, and followed as well as reviewed and approved by the attending veterinarian. In addition, these plans are reviewed for concept, compliance, and animal well-being by the USDA on routine inspection. In a research facility, there are additional safeguards for the animals. In addition to the attending veterinarian, the exercise plan must be reviewed and approved by the Institutional Animal Care and Use Committee. At a minimum, the Committee insures compliance with the plan and checks for the dogs' well-being during their semi-annual inspections of the facility.

### **Proposed regulation**

*(iii) Dogs put in an exercise area shall be segregated in the following manner:*

*(A) Small dogs (35 pounds and less) shall be exercised together and may not be put in the same exercise area with medium or large dogs.*

*(B) Medium sized dogs (36 pounds but less than 60 pounds) shall be exercised together and may not be put in the same exercise area with small or large dogs.*

*(C) Large sized dogs (61 pounds but less than 90 pounds) shall be exercised together and may not be put in the same exercise area with small or medium dogs.*

*(D) Giant sized dogs (91 pounds and greater) shall be exercised together and may not be put in the same exercise area with small, medium or large dogs.*

### **Comment**

The proposed regulations on compatible groupings are arbitrary. It may or may not be advisable to group a Chihuahua with a 34 pound dog but it is acceptable under the proposed regulations. There may also be circumstances when the Chihuahua and the 34 pound dog are fine together. These proposed regulations are much too prescriptive and should be based on compatibility, rather than size. We suggest using the following language found in section 3.6(c)(2) of the Federal regulations.

*All dogs housed in the same primary enclosure must be compatible, as determined by observation. Not more than 12 adult nonconditioned dogs may be housed in the same primary enclosure. Bitches in heat may not be housed in the same primary enclosure with sexually mature males, except for breeding. Except when maintained in breeding colonies, bitches with litters may not be housed in the same primary enclosure with other adult dogs, and puppies under 4 months of age may not be housed in the same primary*

enclosure with adult dogs, other than the dam or foster dam. Dogs with a vicious or aggressive disposition must be housed separately.

### **Proposed regulation**

*(iv) The Department may exempt a dog from exercise for a period of time, if a licensed veterinarian has determined the dog has an injury or other physical condition that would cause exercise to endanger the health, safety or welfare of the dog. The determination must be in writing, be for a time period limited to the amount of time medically necessary to recover from the injury or illness, state the specific medical condition and reason for the exemption and list the time period for the exemption.*

### **Comment**

We are unsure how this exemption from exercise will work. How will a facility be able to get a timely exemption for exercise for medical reasons especially during off-hours? We suggest using the Federal regulatory concept that allows the attending veterinarian to exempt a dog from the exercise program for medical reasons.

In research we have additional and unique concerns due to some of our research. For scientific reasons, exercise may be contraindicated for a research protocol. In that case, according to Federal regulations, the Institutional Animal Care and Use Committee may exempt the dogs from exercise. There is no such provision in the Department's proposed regulations possibly endangering the research or jeopardizing the welfare of the dog. We suggest adding an opportunity for exemption from exercise using the language below found in section 3.8(d) of the Federal regulations.

(1) If, in the opinion of the attending veterinarian, it is inappropriate for certain dogs to exercise because of their health, condition, or well-being, the dealer, exhibitor, or research facility may be exempted from meeting the requirements of this section for those dogs. Such exemption must be documented by the attending veterinarian and, unless the basis for exemption is a permanent condition, must be reviewed at least every 30 days by the attending veterinarian.

(2) A research facility may be exempted from the requirements of this section if the principal investigator determines for scientific reasons set forth in the research proposal that it is inappropriate for certain dogs to exercise. Such exemption must be documented in the Committee-approved proposal and must be reviewed at appropriate intervals as determined by the Committee, but not less than annually.

(3) Records of any exemptions must be maintained and made available to [USDA] Department officials [or any pertinent funding Federal agency] upon request.

### **Proposed regulation**

*(v) Daily records of exercise shall be kept for each dog in the kennel. The records, at a minimum, must set forth:*

*(A) The breed, color, markings, sex, approximate weight and age of each dog or when applicable, the microchip number of each dog.*

*(B) The date and the time period each dog was exercised and whether the exercise was on a leash or in an exercise area.*

*(C) Any medical exemption written by a veterinarian licensed to practice in this Commonwealth.*

### **Comment**

While we believe strongly in accurate record keeping, we believe these proposed regulations are too prescriptive, especially (A). We suggest for (A) and (B), the regulations allow for group records and identifying dogs by number that can be traced back to the dog's individual information which may be maintained elsewhere. In addition (C) appears to be in conflict with (iv) that states that the Department issues the exemption from exercise. As written, the proposed regulations need clarification on this issue.

### **Proposed regulation**

## **§ 21.24. [Shelters] Shelter, housing facilities and primary enclosures.**

### **Comment**

In general we believe that this section is much too prescriptive in nature. There is a multitude of ways to house dogs that protect their welfare which would not be allowed under these proposed regulations.

Because of the number of issues generated by this section, we will address only the major problems and contradictions in the proposed regulations

### **Proposed regulation**

*Dogs that are not acclimated to the temperatures prevalent in the area or region where they are being maintained, breeds of dogs that cannot tolerate the prevalent temperatures of the area without stress or discomfort (such as short-haired breeds in cold climate or cold climate breeds--such as huskies--in warm climates), and sick, infirmed, aged or young dogs, may not be kept in outdoor facilities. When a dog's acclimation status is unknown, it may not be kept in an outdoor facility when the ambient temperature is less than 50° F.*

## **Comment**

While it appears that the Department was attempting to be consistent with the Federal regulations on this point, a key statement, "unless that practice is specifically approved by the attending veterinarian", that is found in section 3.4(a)(1) of the Federal regulations, was left out of the proposed Pennsylvania regulations. We believe that the professional judgment of the veterinarian should be employed and that appropriate language be added to the proposed regulations.

## **Proposed regulation**

*2) Dogs housed in outdoor facilities shall be provided with a flat and level surface for housing and for exercise. Outdoor facilities and exercise areas must have a slope of at least 1/8 inch per foot to provide drainage, but may not be placed on a slope of more than 6 inches per 10 feet. The slope must be situated to assure drainage away from the primary enclosure and away from any adjacent primary enclosure and run associated with that primary enclosure.*

## **Comment**

The statements made here appear to be contradictory. If a surface is flat and level, it does not have a slope. In addition, this proposed regulation is too prescriptive. If the intent is to ensure drainage, we suggest the elimination of the first two sentences and start with "The slope..." If the Department is concerned that the slope is too great for a dog, a figure, based on scientific evidence, could be added as a maximum slope.

## **Proposed regulation**

*(3) The run associated with each dog box or primary enclosure of an outdoor facility must be at least five times the length of the largest dog in that run and two times as wide as the length of the largest dog in that run, as measured from the tip of its nose to the base of its tail, and allow each dog convenient access to the primary enclosure or dog box, permanent shade area and food and water containers.*

## **Comment**

The proposed sizes for the minimum run size appear to be arbitrary and overly prescriptive. It is not clear how these sizes were determined and how such a prescriptive requirement will benefit the dog's welfare.

## **Proposed regulation**

*(10) Outdoor facilities must be constructed and maintained in a manner and in an area that assures adequate and proper drainage and elimination of standing water, pooled water and mud--even in times of severe weather conditions. The outdoor facility and drainage system must be constructed to insure the animals stay dry and are not subjected to wet, muddy or unsanitary conditions. Outdoor facilities shall be cleaned of all feces*

*and sanitized to wash away urine, and kill all parasites, fungus and other disease causing elements. The facilities shall be cleaned and sanitized every 24 hours and in a manner consistent with this chapter.*

## **Comment**

This is another section in the proposed regulations where scientifically and technically incorrect language is used. Sanitizing is not the same as cleaning. Federal regulations require that excreta and food waste be removed from primary enclosures daily, and from under primary enclosures as often as necessary to prevent an excessive accumulation of feces and food waste, to prevent soiling of the dogs contained in the primary enclosures, and to reduce disease hazards, insects, pests and odors. The aforementioned is cleaning. Federal regulations require sanitization of the primary enclosure occur a minimum of once every two weeks (unless new dogs are put in the enclosure). Sanitizing a primary enclosure daily would be over burdensome and the existing Federal requirements have proven to be adequate to maintain the health of the dogs within the enclosure.

The killing of all parasites, fungus and other disease causing elements is by definition "sterilization". This would be highly impractical, if not impossible, for outdoor runs. We suggest that the Department review the language used so that it correctly matches the intent of the regulations. In the alternative and a better solution would be to use the language (minus the language for cats) below that is found in section 3.11 of the Federal regulations.

*Cleaning of primary enclosures. Excreta and food waste must be removed from primary enclosures daily, and from under primary enclosures as often as necessary to prevent an excessive accumulation of feces and food waste, to prevent soiling of the dogs [or cats] contained in the primary enclosures, and to reduce disease hazards, insects, pests and odors. When steam or water is used to clean the primary enclosure, whether by hosing, flushing, or other methods, dogs [and cats] must be removed, unless the enclosure is large enough to ensure the animals would not be harmed, wetted, or distressed in the process. Standing water must be removed from the primary enclosure and animals in other primary enclosures must be protected from being contaminated with water and other wastes during the cleaning. The pans under primary enclosures with grill-type floors and the ground areas under raised runs with mesh or slatted floors must be cleaned as often as necessary to prevent accumulation of feces and food waste and to reduce disease hazards pests, insects and odors.*

*(b) Sanitization of primary enclosures and food and water receptacles.*

*(1) Used primary enclosures and food and water receptacles must be cleaned and sanitized in accordance with this section before they can be used to house, feed, or water another dog or cat, or social grouping of dogs [or cats].*

*(2) Used primary enclosures and food and water receptacles for dogs [and cats] must be sanitized at least once every 2 weeks using one of the methods prescribed in paragraph (b)(3) of this section, and more often if necessary to prevent an accumulation of dirt, debris, food waste, excreta, and other disease hazards.*

*(3) Hard surfaces of primary enclosures and food and water receptacles must be sanitized using one of the following methods:*

- (i) Live steam under pressure;  
(ii) Washing with hot water (at least 180 [deg]F (82.2 [deg]C)) and soap or detergent, as with a mechanical cage washer; or  
(iii) Washing all soiled surfaces with appropriate detergent solutions and disinfectants, or by using a combination detergent/disinfectant product that accomplishes the same purpose, with a thorough cleaning of the surfaces to remove organic material, so as to remove all organic material and mineral buildup, and to provide sanitization followed by a clean water rinse.  
(4) Pens, runs, and outdoor housing areas using material that cannot be sanitized using the methods provided in paragraph (b)(3) of this section, such as gravel, sand, grass, earth, or absorbent bedding, must be sanitized by removing the contaminated material as necessary to prevent odors, diseases, pests, insects, and vermin infestation.

### **Proposed regulation**

*(f) Housing facilities--general. The following criteria apply to both indoor and outdoor facilities:*

*(5) Housing facilities and areas used to store food or bedding must be free of any accumulation of trash, waste, garbage or other discarded material.*

*(7) Animal waste including bodily fluids, food waste, soiled bedding, dead animals, garbage and water that is dirty and no longer potable shall be removed from all areas of the housing facility and disposed of on a daily basis to minimize or prevent contamination and disease risks to the dogs. Where water is removed, the operator shall immediately provide new potable water to the dog.*

### **Comment**

Many facilities hold trash, waste, and dead animals in designated areas or rooms, including cold rooms and freezers, awaiting proper disposal. These areas or rooms, which are separated from animal holding areas, may be within the "housing facility". They may be emptied on an as-needed basis and not necessarily emptied every day. This appears to be prohibited by the proposed regulations and is unnecessary and would be overly costly and burdensome. If the intent is to keep possibly contaminated materials separated from the dogs, it appears that more accurate language than "housing facility" must be used.

### **Proposed regulation**

*(8) Records shall be kept in accordance with the act and §§ 21.14(a)(5) and 21.41 (relating to kennel licensure provisions; and general requirements) must evidence, among the other provisions, the date and time of day following conditions were met:*

- (i) The housing facility was cleaned.*  
*(ii) The housing facility was sanitized.*

*(iii) Each individual cage, dog box or primary enclosure was cleaned.*

*(iv) Each food and water bowl was sanitized.*

*(v) New food and potable water was provided each dog.*

### **Comment**

Again, we believe that the word "sanitized" is used incorrectly. In addition the use of "housing facility" needs clarification. Does the Department intend it to mean the immediate area in which the dogs are housed or the entire facility? We believe that it is practically impossible to "sanitize" the "housing facility" as defined in the proposed regulations.

In addition, this record keeping is overly prescriptive and burdensome without benefit. Records on the maintenance of animal holding areas should be kept but can be done so in other manners such as referencing Standard Operating Procedures with the use of check-off lists. Record keeping is an integral part to a quality husbandry program but does not have to be as prescriptive as proposed in order ensure proper animal care.

### **Proposed regulation**

*(9) The housing facility must have and be equipped to provide potable water for all the dogs' drinking needs and for all other animal husbandry requirements.*

### **Comment**

Clarification is required for this proposed regulation. Does the Department intend that all husbandry requirements that use water use "potable" water? This would be an extreme waste of potable water and environmentally unfriendly. Municipalities are starting to require that businesses have both potable and non-potable water sources with the idea that the non-potable water is to be used for certain purposes such as some animal husbandry procedures. Some of our facilities now use grey water for husbandry procedures where the use of potable water would be wasteful. Would the above provision in the proposed regulations prohibit this use of grey water?

### **Proposed regulation**

*(i) Where the kennel is an indoor kennel with no outside runs, a gutter and drain shall be provided for sluicing waste waters during kennel cleaning. The kennels must have adequate holding facilities to allow a dog to be outside its primary enclosure during the washing of that primary enclosure and until there has been adequate drying of the primary enclosure.*

## **Comment**

We believe that there are other ways to clean indoor kennels without the use of excessive water and therefore drains and gutters should not be required. This was discussed previously by us under section 21.21 (c) "Dog Quarters".

We believe that having holding facilities to allow a dog to be outside its primary enclosure during the washing of that primary enclosure and until there has been adequate drying of the primary enclosure is unnecessary if the primary enclosure has an area to allow for the dog to escape the water. We suggest using the language below found in section 3.11(a) of the federal regulations.

*When steam or water is used to clean the primary enclosure, whether by hosing, flushing, or other methods, dogs [and cats] must be removed, unless the enclosure is large enough to ensure the animals would not be harmed, wetted, or distressed in the process.*

## **Proposed regulation**

*(ii) Floor or surface drains and gutters must be at least 6 inches in diameter.*

## **Comment**

This is overly prescriptive. While 6 inch drains may be needed in some instances, they are not needed for all cases where dogs are held. The size of the drain should be determined by the material that is to flow into it and the flow rate of sewage through it. For example, if excrement were to be picked up prior to washing to the drain, a smaller diameter drain can be used. In addition, if the primary enclosures are cages with pans, there would not be any excrement of the floor so smaller drains, if installed, would suffice. Imposing this regulation would require major renovations to our members' facilities without any benefit to the dogs.

Additionally, there is no mention of covers for these drains. An open drain would meet the requirements but would endanger both the dogs and the animal care staff.

## **Proposed regulation**

*(iii) Where an indoor kennel has outside runs attached, drains or gutters shall be installed between the indoor and outdoor section of the kennel for sanitation and drainage purposes. Half round pipe shall be installed in these areas to permit the dog to walk through.*

## **Comment**

This section requires clarification. If half round pipe is installed within a run, it will allow urine and feces to flow into the run from adjacent runs, contrary to the intent of the

proposed regulations. In addition, this would be extremely costly to install in existing facilities while showing no clear cut benefit to the dogs. We believe this requirement to be contrary to the dogs' welfare and unnecessarily prescriptive.

#### **Proposed regulation**

*(iv) Outdoor kennel runs must be sloped to a gutter located immediately outside of the end fence of each run and shall meet the criteria established in subsection (b)(1)--(3) and (6)--(9). Indoor kennels with outdoor runs must also have indoor drains or gutters.*

#### **Comment**

Again we believe that this proposed regulation is too prescriptive. There are other designs and engineering methods that will allow the runs to be readily cleaned and sanitized. We believe that the broader language below from section 3.6(a)(2) of the Federal regulations should be used.

*Primary enclosures must be constructed and maintained so that they:  
Enable the dogs [and cats] to remain dry and clean;  
Enable all surfaces in contact with the dogs [and cats] to be readily cleaned and  
sanitized [in accordance with Sec. 3.11(b) of this subpart,] or be replaceable when worn  
or soiled;*

#### **Proposed regulation**

*(v) Drains and gutters shall be sanitized at least once daily and flushed immediately after cleaning with potable water to prevent sanitation problems.*

#### **Comment**

We believe that the word "sanitized" is again used incorrectly and would like the Department to clarify the intent of this proposed regulation. Daily sanitization of drains is overly burdensome and not required to maintain the health of the animals. We are unclear as to the reason for flushing only with potable water. It is our understanding that using some no-potable sources of water, including but not limited to grey water, is effective and more environmentally friendly.

#### **Proposed regulation**

*(vii) The floor or surface of the indoor or outdoor kennel must be sloped, situated and constructed in a manner which assures the urine and feces are eliminated from the areas occupied by the dog or dogs housed in that enclosure and in a manner to assure the urine and feces do not wash into the area occupied by another dog. The kennel floor or surface must be sloped (at least 1/8-inch per foot) to the gutter or drain to allow for quick water drainage and drying.*

## Comment

We believe that specifying the slope at a minimum of 1/8-inch per foot is overly prescriptive. We have cited examples above where there are housing conditions, such as caging with pans, that would not require drains for adequate cleaning and sanitization. In addition we may specify 1/8-inch slope per foot to the contractor but the end construction may be a little more or less due to the variability in the manner in which floors are poured. Will the Department require that we tear up existing floors that do not have this slope? We suggest that the last sentence should be deleted.

## Proposed regulation

*(18) Kennel facilities shall be cleaned and sanitized once every 24 hours in a manner consistent with this chapter.*

## Comment

We question the use of the word "sanitized" here as well. We would like the Department to clarify what they would like "sanitized" daily. Would walls, ceilings, lights, feed rooms, hallways, etc. be required to be "sanitized" daily. This proposed regulation is much too broadly written and/or overly burdensome with no real benefit to the dogs. If the Department is referring to the premises, we suggest using the language below found in section 3.11(c) of the Federal regulations.

*Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair to protect the animals from injury, to facilitate the husbandry practices required in this subpart, and to reduce or eliminate breeding and living areas for rodents and other pests and vermin.*

## Proposed regulation

### § 21.25. Temperature control.

*(c) Auxiliary temperature control and air movement from fans, blowers or air conditioners shall be provided when the ambient temperature is 85° F (29.5° C) or higher.*

## Comment

We believe that the words "temperature control" should be replaced with the word "ventilation". This would make the regulation consistent with Federal regulations and the Department's proposed regulation in Section 21.26 (b).

### **Proposed regulation**

*(d) Indoor kennels shall have a heating source sufficient to assure a slab temperature of not less than 35° F and not more than 55° F during heating season.*

### **Comment**

We believe that the “55 degrees” is incorrect. We also believe that this should be deleted and that the focus should be on ambient temperature as in the Federal requirements cited in our comments below.

### **Proposed regulation**

*(2) Cooling. The ambient temperature in the facility may not rise above 85° F.*

### **Comment**

We believe that the Commonwealth should use the language below found in section 3.2(a) of the Federal regulations.

*The ambient temperature must not fall below 45 [deg]F (7.2 [deg]C) for more than 4 consecutive hours when dogs or cats are present, and must not rise above 85 [deg]F (29.5 [deg]C) for more than 4 consecutive hours when dogs or cats are present.*

The inclusion of the words “for more than 4 consecutive hours” is extremely important. Without these words, every kennel in Pennsylvania that is not fully air conditioned will, at some time, be in violation of the proposed regulations.

### **Proposed regulation**

#### **§ 21.26. Ventilation in [indoor] housing facilities.**

*(1) Kennels must be equipped and meet the minimum air flow required for control of moisture condensation under severe conditions, which is 0.8 to 1.0 cubic feet per minute per square foot of floor area.*

*(2) The ventilation system in the kennel building shall provide at least six air changes per hour.*

*(3) The kennel building must include ground level ventilation to assure dry kennel run floors during cold weather.*

### **Comment**

Again, these proposed regulations are overly prescriptive and arbitrary. For example, humidity may be reduced by means, including engineering methods, other than ventilation. In addition, the air changes required to maintain a healthy environment will

depend on the number of dogs and the size of the space. The heat loads, size and number of animals, frequency of bedding changes and efficiency of air distribution to the primary enclosure need to be considered. One can more accurately determine the required ventilation rate using an average-total-heat-gain formula published by the American Society of Heating, Refrigeration, and Air-Conditioning Engineers. For many facilities, such strict engineering may not be required and may be overly burdensome. Therefore, for the purpose of the regulations we recommend the deletion of the proposed requirements (1), (2), and (3) above.

Additionally, complying with (3) would require major renovations to many of our member's facilities when dry kennel floors may be achieved by other means than ground level ventilation.

### **Proposed regulation**

*(4) The ventilation system for latrines and support buildings must be separate from the ventilation system for the kennel building. Kennel support buildings, such as supply buildings, must have a ventilation system that provides at least one air exchange per hour.*

### **Comment**

The Department needs to clarify this proposed regulation. We believe that the intent is to avoid having unfiltered air from an animal holding room exhausted to personnel and other clean areas. This is a concept that we agree with. However, the way the regulation reads, the entire ventilation systems must be separate. Does the Department mean completely separate air handlers must be used? The same air handler can be engineered to bring 100% fresh air into all rooms of a facility and then exhaust 100% of that air from all rooms. Completely separate air handling systems would not be required to accomplish this. In addition, HEPA filtration of re-circulated air is not considered in this proposed regulation.

We suggest rewriting this proposed regulation to state that unfiltered air may not be exhausted from animal holding rooms into personnel areas or dropping the regulation entirely.

We also do not understand why a building that is used to store equipment such as clean caging would be required to have a ventilation system and recommend deleting the second sentence.

### **Proposed regulation**

*(5) The ventilation requirements may be achieved through design of the building shell and natural air flow or by means of auxiliary air movement systems. Where auxiliary air movement systems are required or utilized to achieve the required air exchanges, the kennel must still have doors and windows which can be opened to allow air flow in the event of a system malfunction.*

## **Comment**

We have concerns with the second sentence of this proposed regulation. Research facilities typically do not design windows into animal holding rooms. This is for security, biosecurity, and scientific reasons. Our colonies are very often closed colonies with high health standards. Opening a window could allow in pathogens, contaminating our colony and jeopardizing the dogs' health and the research project. In addition, there are times when, for research purposes, we house dogs that have infectious diseases. These are maintained under strict barrier conditions. We would not want the possibility of having an infectious agent escape through an opened window.

We do understand that systems will malfunction and preparations need to be made for this. Therefore, we use redundant or partially redundant systems such as generators and back up HVAC systems. We also have written emergency plans should these fail as well.

The regulations proposed here will not work for research facilities and possibly other facilities and should be rewritten to include other means of back-up in case of system malfunctions.

## **Proposed regulation**

### **§ 21.27. Lighting [in indoor housing facilities] and electrical systems.**

*(1) Dogs housed in [these] indoor and sheltered kennel facilities shall be provided a regular diurnal lighting cycle. The lighting must be uniformly diffused throughout the animal facility. Primary enclosures must be placed to protect the dogs from excessive light. Lighting in the kennel building and area containing the primary enclosures must be at least 10-foot candles. At least 20-foot candles of light must be provided in all bathing, grooming and toilet areas and 70-foot candles of light shall be provided in support buildings, including food preparation and storage areas.*

## **Comment**

Obtaining total uniformity in diffusion of light is very difficult to obtain. Therefore, if the regulations are to require physical measurements, they need to specify where in the room the measurements will be taken. Typically, these measurements are taken about one meter from the floor.

The proposed regulations are extremely prescriptive when describing minimum levels of lighting but broad when describing excessive levels. Excessive light may be injurious to humans and other animals, particularly those who are photosensitive.

The National Institutes of Health design guidelines for the construction of research animal facilities are:

| <u>Space</u>      | <u>Lighting levels (footcandles)</u> |
|-------------------|--------------------------------------|
| Animal Facilities | 25-74 (variable through dimming)     |
| Offices           | 49-74                                |
| Corridors         | 30-49                                |
| General Storage   | 19-30                                |

In addition, we have found a reference for the lighting levels for kitchens in schools of 50-75 foot candles (The Need Project) and dishwashing areas in schools of 20-30 foot candles. NIH design specifications for research animal facilities call for 19-30 foot candles for storage areas and we found a reference with a recommendation as low as 9 foot candles for storage in offices (megavolt.co.il). **Therefore, we do not understand why a level of 70 foot candles would be required for all support buildings including storage areas and believe that this proposed requirement is wasteful of energy.**

If the Department requires additional guidance on this subject, information may be found in the National Research Council publication, *Guide for the Care and Use of Laboratory Animals* and the Illuminating Engineering Society of North America handbook.

We suggest deleting the proposed language and replacing it with the language below that is found in section 3.2(c) of the Federal regulations.

*Indoor housing facilities for dogs and cats must be lighted well enough to permit routine inspection and cleaning of the facility, and observation of the dogs and cats. Animal areas must be provided a regular diurnal lighting cycle of either natural or artificial light. Lighting must be uniformly diffused throughout animal facilities and provide sufficient illumination to aid in maintaining good housekeeping practices, adequate cleaning, adequate inspection of animals, and for the well-being of the animals. Primary enclosures must be placed so as to protect the dogs and cats from excessive light.*

Additionally, for research facilities, this proposed regulation provides other concerns. There may be times when, for scientific reasons including but not limited to vision research, the visible light level in the animal room will need to be less than 10 foot candles. The National Institutes of Health design guidelines for the construction of research animal facilities recognizes this issue and states, "The numbers listed are target values and shall be adjusted to meet the research requirements." Therefore, some form of exemption from the Commonwealth's proposed regulations in this section will be required for research kennels.

### **Proposed regulation**

*(b) Electrical systems. Receptacle circuits in areas to be washed down or subjected to spraying shall be provided with ground fault circuit interrupters. Electrical sockets (inside and out) must be the all-weather type with a spring cover.*

## Comment

We believe that the facility should be held to the requirements of the existing building code at the time of construction or major renovation. To rewire many of our facilities to accept GFCI receptacles would not be feasible. In addition, the proposed regulations do not address the possibility of the use of ground fault circuit breakers. We also suggest that all-weather type outlets not be required for indoor facilities. A spring cover should be sufficient.

## Proposed regulation

### § 21.28. Food, water and bedding.

*[(a)] (1) Dogs kept in kennels shall be fed at least once each day unless otherwise directed by a veterinarian. The food [shall] must be free from contamination [or], mold and disease, and [shall] be of sufficient quantity and nutritive value to maintain the health of the dogs. Wet, moldy, soiled or inedible food shall be disposed of promptly--meaning within 2 hours of feeding--and feeding bowls shall be cleaned with detergent and hot water at least daily and always prior to the next feeding. Water bowls shall be cleaned with detergent and hot water on at least a daily basis or whenever urine, stools or vomit are present in the bowl, whichever is more frequent.*

## Comment

We have concerns with several parts of this proposed regulation and believe that it should be rewritten. First, we agree that feed that is moldy should not be used. Therefore, we do not understand how feed that is not moldy to begin with can become moldy within two hours. We also do not believe that it is necessary to wash feed and water bowls with detergent daily. Research facilities are very concerned about the health status of their dogs. They have been operating under Federal regulations for many years and have found the regime dictated by those regulations to work quite well for maintaining healthy dogs. We recommend using the language below and found in section 3.11(b) of the Federal regulations.

(1) Used primary enclosures and food and water receptacles must be cleaned and sanitized in accordance with this section before they can be used to house, feed, or water another dog [or cat], or social grouping of dogs [or cats].

(2) Used primary enclosures and food and water receptacles for dogs [and cats] must be sanitized at least once every 2 weeks using one of the methods prescribed in paragraph (b)(3) of this section, and more often if necessary to prevent an accumulation of dirt, debris, food waste, excreta, and other disease hazards.

(3) Hard surfaces of primary enclosures and food and water receptacles must be sanitized using one of the following methods:

(i) Live steam under pressure;

(ii) Washing with hot water (at least 180 [deg]F (82.2 [deg]C)) and soap or detergent, as with a mechanical cage washer; or

(iii) Washing all soiled surfaces with appropriate detergent solutions and disinfectants, or by using a combination detergent/disinfectant product that accomplishes the same purpose, with a thorough cleaning of the surfaces to remove organic material, so as to remove all organic material and mineral buildup, and to provide sanitization followed by a clean water rinse.

### **Proposed regulation**

*[(b) If potable water is not accessible to the dogs in their primary enclosures, potable fluids shall be offered to the dogs at least 6 hours daily] (2) Potable water shall be available to the dogs at all times unless otherwise directed by a veterinarian. The water must be free of stools, urine, vomit and other contaminants at all times.*

### **Comment**

We believe that, even with the best intentions, this regulation is impossible to comply with. First, if a dog spills the water from its dish, the regulated entity is in violation of the proposed regulation. Secondly, if a dog vomits or defecates in its water dish, the facility is again immediately in violation of the proposed regulation. This is also contradictory with (a) (1) which states, "water bowls shall be cleaned... whenever urine, stools or vomit are present in the bowl, whichever is more frequent." Why would they need to be cleaned for these reasons if it is a violation for the stools, urine, or vomit to be in the water bowl at all?

We suggest that more appropriate language is shown below and may be found in section 3.10 of the Federal regulations.

*If potable water is not continually available to the dogs [and cats], it must be offered to the dogs and cats as often as necessary to ensure their health and well-being, but not less than twice daily for at least 1 hour each time, unless restricted by the attending veterinarian. Water receptacles must be kept clean and sanitized in accordance with Sec. 3.11(b) of this subpart, and before being used to water a different dog [or cat] or social grouping of dogs [or cats].*

Note that the language in Sec 3.11(b) can be found above in our comments on 21.28 (1).

### **Proposed regulation**

*[(c)] (3) Food and water receptacles shall be accessible to dogs kept in the kennel and shall be located to avoid contamination by excreta. The receptacles [shall] must be durable, meaning a dog cannot destroy or ingest parts of the receptacle, and shall be kept clean and sanitized in accordance with this section. Self-feeders and waterers may be used but shall be sanitized [regularly] on a daily basis to prevent [molding] mold, deterioration, contamination or caking of feed.*

## **Comment**

Self-waterers are routinely used in research facilities. The waters are not sanitized daily but maintained by passing the water through UV lights and/or chlorinating the water. This has proven to maintain the research dogs at a high health standard required by the institutions. Daily sanitization of the self-waterers is not required and over burdensome. This regulation should be modified or deleted.

## **Proposed regulation**

### **§ 21.29. Sanitation.**

*(1) Kennels, including the kennel building, areas in which dogs are housed, all interior surfaces, the primary enclosure of each dog, outdoor runs associated with both indoor and outdoor kennels, and drains and gutters shall be sanitized and disinfected daily (every 24 hours), using only those disinfecting products approved by a licensed veterinarian.*

## **Comment**

We question the use of the words “sanitized and disinfected” here as well. We would like the Department to clarify what they would like “sanitized and disinfected” daily. Would walls, ceilings, lights, feed rooms, hallways, *etc.* be required to be “sanitized” daily? This proposed regulation is much too broadly written and/or overly burdensome with no real benefit. If the Department is referring to the premises, we suggest using the language below and found in section 3.11(c) of the Federal regulations.

*Premises where housing facilities are located, including buildings and surrounding grounds, must be kept clean and in good repair to protect the animals from injury, to facilitate the husbandry practices required in this subpart, and to reduce or eliminate breeding and living areas for rodents and other pests and vermin.*

If the Department is referring to the primary enclosure, then we recommend using the language from the Federal regulations that we provided in our comments on 21.28 (1) and (2).

## **Proposed regulation**

*(2) A dog may not be placed in a primary enclosure previously occupied unless the enclosure has been sanitized and disinfected. The primary enclosure and runs associated with that primary enclosure shall be sanitized and disinfected whenever an animal is removed from that primary enclosure and prior to being occupied by another animal. Exercise areas shall be sanitized and all stools removed prior to the next group of dogs being exercised in that area.*

## Comment

Again, we question the use of the word "disinfected". We suggest using the following language which is found in section 3.11(b)(1) of the Federal regulations.

Used primary enclosures and food and water receptacles must be cleaned and sanitized before they can be used to house, feed, or water another dog [or cat], or social grouping of dogs [or cats].

In addition, we believe that time constraints will make it impossible for most facilities to sanitize an exercise area between groups of dogs. We recommend that the word "sanitized" in the last sentence of 21.29 (2) be changed to "cleaned".

## Proposed regulation

*(3) Dogs shall be removed from their enclosures while the enclosure is being sanitized and washed down.*

## Comment

Washing down an enclosure and sanitizing it are two completely separate procedures. We agree that dogs should be removed from the enclosure during the sanitization process. However, as stated previously, for washing down the enclosure, this should not be a requirement where there is space in the primary enclosure for the dog to escape the water from the hose. The requirement that the dog be removed for washing the enclosure is also inconsistent with Federal regulations. We suggest using the following language which is found in section 3.11(a) of the Federal regulations.

When steam or water is used to clean the primary enclosure, whether by hosing, flushing, or other methods, dogs [and cats] must be removed, unless the enclosure is large enough to ensure the animals would not be harmed, wetted, or distressed in the process.

## Proposed regulation

*(4) Excreta shall be removed from the primary enclosure, including any floor area or ground surface beneath the primary enclosure, on at least a daily basis. Stools are a common source of infection and shall be removed from the runs as often as necessary. Before washing down concrete runs, stools shall be removed with a shovel to prevent them from splashing into adjacent runs, on the walls of the kennel, or on the dog. The method of disposing of stools depends on local conditions and the type of sewage system present. If stools must be carried from the area in cans, the cans shall be cleaned and disinfected on a daily basis.*

## **Comment**

We believe that the third and fourth sentences are too prescriptive. There is a multitude of ways in which to adequately remove the stools from the primary enclosure and only one is permitted under this proposed regulation. We question whether this regulation intends for stools that have fallen through from dogs maintained on vinyl coat grates be picked up prior to washing down. Typically, a hose is placed underneath the grate in order to wash these stools to a drain without picking up the grate. This housing system is designed to be cleaned this way and it would be very difficult to remove the grates every time one is to wash down the enclosure.

Additionally, there is no provision for putting a liner in the cans for the stools. This would eliminate the need for "disinfecting" the can daily and it can then be sanitized on an as-needed basis.

## **Proposed regulation**

*(5) One of the causes of bacterial skin infections and bacterial ear infections in kennels is the high humidity in the kennels. For this reason, when cleaning or sanitizing the kennels animals shall be removed from their primary enclosure and runs prior to cleaning or sanitizing the primary enclosure or run. The runs and floor areas associated with the primary enclosure shall be squeegee dried and the primary enclosure shall be dried prior to putting the animal back in the run or primary enclosure.*

## **Comment**

The premise for this proposed regulation is flawed. High humidity is not caused by wet dogs but rather lack of proper humidity controls and/or improper ventilation. As stated previously, this section should be consistent with the Federal regulations and the dogs should not have to be removed if the enclosure is large enough to ensure the animals will not be harmed, wetted, or distressed in the process.

This regulation is also very prescriptive. Wet-vacs and mop and bucket, routinely used in research facilities, would work satisfactorily for drying the enclosure but are excluded by this proposed regulation. In addition, it would be over burdensome to dry every enclosure before the animal returns to it. How dry is dry? We suggest that this proposed regulation be broadened and brought into consistency with Federal regulations which require the removal of standing water rather than the enclosure being dried.

## **Proposed regulation**

*(6) The buildings and grounds of kennels, as well as the primary enclosures, runs, fencing and food and water receptacles shall be maintained, kept clean and in good repair to protect the animal from injury and to facilitate practices required by this chapter. The entire kennel area must be free of refuse and garbage that could attract rats, vermin, insects and other vectors of disease.*

## Comment

The last sentence must be clarified as to what is meant by the "entire kennel area". It would be impossible to store refuse and garbage awaiting pick up by a waste hauler under this proposed regulation. We suggest that the regulation should read, "The entire kennel area must be free of an accumulation of refuse and garbage that could attract rats, vermin, insects and other vectors of disease." While making this workable, this would make the regulation consistent with Federal regulation.

## Proposed regulation

### § 21.30. Condition of dog.

*[An employe] A State dog warden or other employee of the Department [may] entering or inspecting a kennel or entering onto the premises of a kennel or a person or individual dog owner or keeper for the purpose of enforcing the act, shall visually observe the physical condition of [a] each dog sheltered at [a] the kennel or on the premises of the person or individual. A dog sheltered at a kennel shall be free of infectious and contagious diseases, and shall be in general good health. If a dog exhibits signs of an infectious or contagious disease, parasites or appears to be in poor health, the kennel owner shall [have] provide the State dog warden or employee of the Department with proof of adequate veterinary care for the dog. A State dog warden or employee of the Department may order a veterinary check on any dog that exhibits signs of an infectious or contagious disease, parasites or the appearance of poor health. When a veterinary check is ordered, the kennel owner, person or individual who is the owner or keeper of the dog shall provide the Department, within 72 hours of the order, with proof that the veterinary check has been carried out and with documentation concerning the veterinary recommendation or protocol for treatment of the dog.*

## Comment

This section has a lack of relevancy for research facilities. There are times when a dog may have an infectious or contagious disease, parasites or be in poor health due to the required research protocol studying these conditions, vaccine studies for example. According to Federal law, these protocols must be approved by the Institutional Care and Use Committee and monitored by the attending veterinarian under an extensive program of veterinary care as described below and found in the section 2.33 of the Federal regulations.

Attending veterinarian and adequate veterinary care.

- (a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section:
  - (1) Each research facility shall employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant

- arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility;
- (2) Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use; and
  - (3) The attending veterinarian shall be a voting member of the IACUC; Provided, however, That a research facility with more than one Doctor of Veterinary Medicine (DVM) may appoint to the IACUC another DVM with delegated program responsibility for activities involving animals at the research facility.
- (b) Each research facility shall establish and maintain programs of adequate veterinary care that include:
- (1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;
  - (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;
  - (3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian;
  - (4) Guidance to principal investigators and other personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia; and
  - (5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

We would also believe that the term "employee of the Department" should be narrowed so that only properly trained individuals can represent the Department in this regard.

#### Proposed regulation

### **KENNELS--RECORDS**

#### **§ 21.41. General requirements.**

*(e) In addition to the records required under section 207 of the act, every keeper of a kennel shall keep a record of the following for each dog housed in the facility:*

- (1) The date, time and detail of daily feedings, cleaning of kennel, and changing and refreshing potable water.*
- (2) The date, time and detail of exercise activity of the dog.*
- (3) The date, time and detail of any medication administered to a dog.*

- (4) *Any accident or incident in which the dog is injured.*
- (5) *The date and time of any veterinary care administered.*
- (6) *Records of veterinary care for each dog.*
- (7) *Any veterinary ordered or voluntary protocol for vaccination, medication or other recommendation for medical treatment of the dogs.*

### **Comment**

While we are in agreement that good record keeping is essential for a quality animal care program, the records required by this proposed regulation are too prescriptive. There are other methods by which accurate and complete records may be kept but they are not allowed under this proposed regulation. For example, establishment of standard operating procedures with the use check-off sheets.

The time of medication is not typically noted in veterinary care records except for certain medications such as analgesics. The time of veterinary care is not typically noted as well. In addition, (3), (4), (5) and (7) are all part of the veterinary record and are therefore not needed as separate items.

### **Proposed regulation**

#### **§ 21.42. Bills of sale.**

*(b) It shall be a violation of the act and this chapter for a kennel owner, operator or agent to purchase, accept, sell on behalf of or transport a dog from a kennel required to be, but not licensed under section 207 or 209 of the act (3 P. S. §§ 459-207 and 459-209) without written permission from the Department.*

### **Comment**

Some of our members have multiple sites, some of which may be out of state. In addition some academic institutions share animals which are models for specific diseases. Some of the institutions where the animals are coming from may be out of state. Our members desire to maintain compliance with regulations and believe that compliance with this proposed regulation may at some point jeopardize timely and valuable research.