United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Animal Care

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Animal Care Policies

Safeguarding American Agriculture

TABLE OF CONTENTS

Subject: **Denial of AWA License Applications** **Policy #1**

References: AWA Section 3
9 CFR, Part 2, Sections 2.1, 2.5, 2.10, 2.11

History: This replaces the September 3, 1992 memo entitled "Denial of AWA License Applications."

Justification: Under the Animal Welfare Act (AWA) regulations and standards, the Animal & Plant Health Inspection Service (APHIS), Animal Care (AC) can deny an AWA license application under certain restricted circumstances. This policy serves to clarify when a license application can be denied, and when and what it means for a license to be invalid.

Policy: The Investigative & Enforcement Services (IES) staff has met with the Office of General Counsel (OGC) and identified the following situations where the denial of a license is appropriate:

a. Failure of new applicant to pass three compliance inspections within 90 days of first inspection as specified in Section 2.3(b) or to comply with the regulations and standards as specified in Section 2.11(a)(3).

The Animal Care Regional Director (ACRD) will issue a letter (attached) to the applicant informing him/her of APHIS' denial of his/her license application. The denial letter will notify the applicant of his/her right to a formal administrative hearing to show why the application should not be denied as required in Section 2.11(b). The letter will also inform the applicant of the procedures required to request a hearing. The license denial will remain in effect until the final legal decision. Once a hearing is requested, IES will be responsible for compiling a case of existing evidence and submitting it through the ACRD to the IES staff within a short period of time. The IES staff will coordinate with OGC to arrange a hearing date.

b. Applicant has been fined or sentenced to jail under State or local animal cruelty laws as specified in Section 2.11(a)(4).

IES will prepare a case file documenting the evidence from the State or

local case including a copy of the court's decision and sentence levied. The ACRD will inform the applicant of APHIS' denial of license application with a letter. The letter will contain information on the applicant's right to a hearing and procedures to initiate the process. Once a hearing is requested, the ACRD will immediately submit the case to IES staff. The IES staff will coordinate with OGC to arrange a hearing date.

c. **Applicant is under investigation by State or local authorities for animal cruelty.**

IES will conduct an investigation and collect evidence to substantiate or refute the allegations. The evidence should include information collected by State or local investigators in addition to corroborating evidence from interviews and/or AC inspections. The ACRD will submit the case to the IES staff for review and forwarding to OGC. If OGC concurs with the denial, IES staff will notify the ACRD. The ACRD will issue a letter informing the applicant of the denial of license application. The letter will contain information on the applicant's right to a hearing and procedures to initiate the process. If a hearing is requested, the ACRD will submit the case to IES staff. The IES staff will coordinate with OGC to arrange a hearing date.

What is a "valid" license?

A license shall be considered valid and effective unless:

a. The license has been revoked or suspended.

b. The license is voluntarily terminated by the licensee in writing. (This may include notation of the surrendering of the license to the inspector on the APHIS inspection form.)

c. The license has expired.

d. The applicant has failed to pay the application and appropriate annual licensing fee.

Licenses are issued for specific premises and are not valid at a different location.

Dear _____:

This letter is to inform you that your application for a license under the Animal Welfare Act (7 U.S.C. § 2131 et seq.) is denied pursuant to Section 2.11 of the regulations (9 C.F.R.§ 2.1 et seq.) for the following reason(s):

_____ Failure to comply with the requirements of Section 2.1 of the regulations (9 C.F.R. § 2.11(a)(1)).

_____ Failure to comply with the requirements of Section 2.2 of the regulations (9 C.F.R. § 2.11(a)(1)).

_____ Failure to comply with the requirements of Section 2.3 of the regulations (9 C.F.R. § 2.11(a)(1)).

_____ Failure to comply with the requirements of Section 2.4 of the regulations (9 C.F. R. § 2.11(a)(1)).

_____ Failure to comply with the requirements of Section 2.6 of the regulations (9 C.F.R. § 2.11(a)(1)).

_____ License has been revoked or is currently suspended as set forth in Section 2.10 of the regulations (9 C.F.R. § 2.11(a)(3)).

_____ Has been fined, sentenced to jail, or pled nolo contendere (no contest) and paid a penalty under State or local cruelty to animal laws within 1 year of application (9 C.F.R. § 2.11(a)(4)).

_____ Has made false or fraudulent statements or has provided false or fraudulent records to the Department (9 C.F.R. § 2.11(a)(5)).

You may request a hearing in accordance with the applicable Rules of Practice for the purpose of showing why your application for a license should not be denied. You must notify this office, in writing by certified mail, within 20 days from receipt of this letter if you desire a hearing, and a hearing will be held in due course. Failure to request a hearing within 20 days from receipt of this letter will be deemed a waiver of such hearing.

If you have any questions with reference to this matter, please do not hesitate

to contact this office by mail or by phone at _____.

Sincerely,

Subject: **Submission of Traveling Exhibitor Itinerary** **Policy #2**

References: AWA Sections 10, 17
9 CFR, Part 2, Sections 2.8, 2.126

History: This is a new policy statement, to remain in effect until enacted into regulatory changes.

Justification: The Animal Plant & Health Inspection Service (APHIS), Animal Care (AC) has been provided the authority to require whatever records or reports are needed to effectively enforce the Animal Welfare Act (AWA). In order for licensed traveling facilities to comply with the requirement of readily available access to the premises by the APHIS inspector, APHIS must be kept apprised of the location of the facility.

Policy: Exhibitors who are in continuous travel status shall update their itinerary as often as necessary to ensure AC knows their whereabouts at all times.

Circuses, petting zoos, and acts with an established route shall notify AC in advance of departing their home facility and update travel information as needed.

Exhibitors who take animals from their facilities from time to time shall notify AC when any animal is gone more than four (4) consecutive days. Upon request, a licensee shall provide an itinerary of absences of less than four (4) days.

Providing notification ensures the opportunity for access for an unannounced inspection, eliminates unnecessary AC visits when a licensee has been inspected recently, and minimizes resources needed to locate the exhibitor.

The itinerary should provide the following:

1. Dates away from home facility
2. City and State for all stops
3. Site name or location of all stops

Similar information must be provided for all periods of “lay-over” while traveling.

The licensee may provide this information to AC by any of the following methods:

a. Mail information to the Regional office or inspector
b. Fax information to the Regional office or inspector
c. Voicemail information to the inspector
d. E-mail information to the Regional office

Notice must be made in advance of travel and updated as needed.

Subject: **Veterinary Care:** **Policy #3**
Expired Medical Materials
Pharmaceutical-Grade Compounds in Research
Surgery
Pre- and Post- Procedural Care
Program of Veterinary Care
Declawing and Defanging Practices in Wild or Exotic Carnivores or Nonhuman Primates
Health Records
Euthanasia

References: AWA Section 2143
9 CFR, Part 2, Sections 2.31, 2.32, 2.33, 2.40; 9 CFR, Part 3, Section 3.110

History: Provides requested guidance. Replaces memoranda dated May 31, 1990, November 29, 1991, April 6, 1992, and September 25, 1992. Replaces policies dated April 14, 1997, January 14, 2000, and August 18, 2006, to update the section regarding declawing and defanging practices used in wild or exotic carnivores or nonhuman primates.

Justification: The Animal Welfare Act (AWA) requires that all regulated animals be provided adequate veterinary care.

Policy: **Expired Medical Materials**

The use of expired medical materials such as drugs, fluids, or sutures on regulated animals is not considered to be acceptable veterinary practice and does not constitute adequate veterinary care as required by the regulations promulgated under the Animal Welfare Act. All expired medical materials found in a licensed or registered facility are to be brought to the attention of the responsible official. The facility must either dispose of all such materials or segregate them in an appropriately labeled, physically separate location from non-expired medical materials. The Animal & Plant Health Inspection Service (APHIS) has no jurisdiction over facilities using expired medical materials for non-regulated animals or non-regulated activities.

For acute terminal procedures, APHIS does not oppose the use of expired medical materials if their use does not adversely affect the animal's wellbeing or compromise the validity of the scientific study. Proper anesthesia, analgesia, and euthanasia are required for all such procedures. Drugs administered to relieve pain or distress and emergency drugs must not be used beyond their expiration date. Facilities allowing the use of expired medical materials in acute terminal procedures should have a policy

covering the use of such materials and/or require investigators to describe in their animal activity proposals the intended use of expired materials.

The attending veterinarian and the Institutional Animal Care and Use Committee (IACUC) are responsible for ensuring that proposed animal activities avoid or minimize discomfort, distress, and pain to the animal. These responsibilities cannot be met unless the veterinarian and the IACUC maintain control over the use of expired medical materials.

Pharmaceutical-Grade Compounds in Research

Investigators are expected to use pharmaceutical-grade medications whenever they are available, even in acute procedures. Non-pharmaceutical- grade chemical compounds should only be used in regulated animals after specific review and approval by the IACUC for reasons such as scientific necessity or non-availability of an acceptable veterinary or human pharmaceutical-grade product. Cost savings alone are not an adequate justification for using non-pharmaceutical-grade compounds in regulated animals.

Surgery

AWA regulations require that survival surgeries be performed using aseptic techniques and that major operative procedures on nonrodents be performed only in dedicated surgical facilities. Nonsurvival surgeries require neither aseptic techniques nor dedicated facilities if the subjects are not anesthetized long enough to show evidence of infection. Research facilities doing surgical demonstrations while traveling must use aseptic techniques and dedicated surgical facilities. Motel meeting rooms and auditoriums do not qualify as dedicated surgical facilities.

Nonsurvival surgeries not performed aseptically or in a dedicated facility must at least be performed in a clean area, free of clutter, and using acceptable veterinary sanitation practices analogous to those used in a standard examination/treatment room. Personnel present in the area must observe reasonable cleanliness practices for both themselves and the animals. Eating, drinking, or smoking are not acceptable in surgery areas, and locations used for food handling purposes do not qualify as acceptable areas for performing surgeries.

Pre- and Post-Procedural Care

All animal activity proposals involving surgery must provide specific details of pre- through post-procedural care and relief of pain and distress. The specific details must be approved by the attending veterinarian or his/her designee. However, the attending veterinarian retains the authority to change post-operative care as necessary to ensure the comfort of the animal. The

withholding of pain and/or distress relieving care must be scientifically justified in writing and approved by the IACUC. The appropriate use of drugs to relieve pain and/or distress must be specified in the animal activity proposal to avoid possible delays due to investigator concerns that a treatment regimen may interfere with the study. Furthermore, the specified drugs for relief of pain and/or distress must be readily available for use as described in the proposal.

While an animal is under post-surgical care, the ownership of the animal is not to change. If the animal is taken to an off-site location, such as a farm, for post-operative care, that location should be identified as a site of the research facility. An animal is not to be taken to an off-site location before it fully recovers from anesthesia unless justified in the animal activity proposal. Appropriate post-operative records must be maintained in accordance with professionally accepted veterinary procedures regardless of the location of the animal.

Program of Veterinary Care

Facilities which do not have a full-time attending veterinarian must have a written Program of Veterinary Care (PVC). This Program must consist of a properly completed APHIS Form 7002 or an equivalent format providing all of the information required by the APHIS form. The attending veterinarian must visit the facility on a regular basis, i.e., often enough to provide adequate oversight of the facility's care and use of animals but no less than annually. Records of visits by the attending veterinarian must be kept to include dates of the visits and comments or recommendations of the attending veterinarian or other veterinarians.

The PVC must be reviewed and updated whenever necessary (e.g., as a new species of animal or a new attending veterinarian is obtained, or the preventive medical program changes). It must be initialed and dated by both the attending veterinarian and the facility representative whenever it is changed or reviewed without change. The preventive medical program described in the PVC is expected to be in accordance with common good veterinary practices (e.g., appropriate vaccinations, diagnostic testing). It should include zoonotic disease prevention measures and, if necessary, special dietary prescriptions

Declawing and Defanging Practices in Wild or Exotic Carnivores or Nonhuman Primates

Declawing of wild and exotic carnivores and the removal or reduction of canine teeth in nonhuman primates and wild and exotic carnivores have been used in the past in an attempt to minimize dangers presented to humans and other members of these species. These procedures are not innocuous and can

cause ongoing pain, discomfort, or other pathological conditions in the animals. In addition, they do not prevent predatory behaviors, safeguard the general public, nor prevent biting in nonhuman primates and carnivores.

The declawing of any wild or exotic carnivore does not constitute appropriate veterinary care. Any medical treatment of a paw should be limited to the affected digit(s) or area and would not require bilateral declawing.

The removal of the canine teeth of a nonhuman primate, unless for the immediate medical needs of the animal, does not constitute appropriate veterinary care.

We are adopting the position statements of the American Veterinary Medical Association (AVMA) on these practices because these positions reflect the generally accepted veterinary standards. Not everyone has access to the AVMA information, so we are including the position statements of the AVMA (2005 and 2007).

"Declawing Captive Exotic and Wild (Indigenous) Cats

The AVMA opposes declawing captive exotic and other wild (indigenous) cats for nonmedical reasons."

"Removal or Reduction of Canine Teeth in Captive Nonhuman Primates or Exotic and Wild (Indigenous) Carnivores

The AVMA is opposed to removal of canine teeth in captive nonhuman primates or exotic and wild (indigenous) carnivores, except when required for medical treatment or scientific research approved by an Institutional Animal Care and Use Committee. Reduction of canine teeth may be necessary to address medical and approved scientific research needs, or animal or human safety concerns. If reductions expose the pulp cavity, endodontic procedures must be performed by a qualified person.

To minimize bite wounds, recommended alternatives to dental surgery include behavioral modification, environmental enrichment, and changes in group composition."

Health Records

Health records are meant to convey necessary information to all people involved in an animal's care. Every facility is expected to have a system of health records sufficiently comprehensive to demonstrate the delivery of adequate health care. For those facilities that employ one or more full-time veterinarians, it is expected there will be an established health records system consistent with professional standards that meets and probably exceeds, the minimum requirements set forth in this policy. For facilities that do not

employ a full-time veterinarian, it is suggested the health records system be explained as part of the written PVC, to ensure involvement of the attending veterinarian in developing the system. For all facilities, health records must be current, legible, and include, at a minimum, the following information:

- Identity of the animal.
- Descriptions of any illness, injury, distress, and/or behavioral abnormalities and the resolution of any noted problem.
- Dates, details, and results (if appropriate) of all medically-related observations, examinations, tests, and other such procedures.
- Dates and other details of all treatments, including the name, dose, route, frequency, and duration of treatment with drugs or other medications. (A "check-off" system to record when treatment is given each day may be beneficial.)

Treatment plans should include a diagnosis and prognosis, when appropriate. They must also detail the type, frequency, and duration of any treatment and the criteria and/or schedule for re-evaluation(s) by the attending veterinarian. In addition, it must include the attending veterinarian's recommendation concerning activity level or restrictions of the animal.

Examples of procedures which should be adequately documented in health records include, but are not limited to, vaccinations, fecal examinations, radiographs, surgeries, and necropsies. Routine husbandry and preventive medical procedures (e.g., vaccinations and dewormings) performed on a group of animals may be recorded on herd-health-type records. However, individual treatment of an animal must be on an entry specific to that animal. As long as all required information is readily available, records may be kept in any format convenient to the licensee/registrant (e.g., on cage cards for rodents).

Health records may be held by the licensee/registrant (including, but not limited to, the investigators at research facilities) or the attending veterinarian or divided between both (if appropriately cross-referenced), but it is the responsibility of the licensee/registrant to ensure that all components of the records are readily available and that the record as a whole meets the requirements listed above.

An animal's health records must be held for at least 1 year after its disposition or death. (Note: Some records may need to be held longer to comply with other applicable laws or policies.) When an animal is transferred to another party or location, a copy of the animal's health record must be transferred with the animal. The transferred record should contain the animal's individual medical history, information on any chronic or ongoing health problems, and information on the most current preventive medical procedures (for example, the most recent vaccinations and dewormings). For traveling exhibitors,

information on any chronic or ongoing health problems and information on the most current preventive medical procedures must accompany any traveling animals, but the individual medical history records may be maintained at the home site.

Euthanasia

The method of euthanasia must be consistent with the current Report of the AVMA Panel on Euthanasia. Gunshot is not an acceptable method of routine euthanasia for any animal. Gunshot as a routine method of euthanasia not only endangers surrounding animals, buildings, and personnel, but it is likely to cause distress to other animals. It should only be used in situations where other forms of acceptable euthanasia cannot be used (such as emergency or field conditions where the animal cannot be appropriately restrained) or in cases where gunshot will reduce danger to other animals or humans. Only personnel skilled in the use of firearms, using appropriate firearms, and familiar with the "kill point" of an animal should perform the euthanasia. If the firearm is not aimed so that the projectile enters the brain and causes rapid unconsciousness and subsequent death without evidence of pain or distress, this method does not meet the definition of euthanasia. (All State and local laws relevant to gunshot must also be met.)

Subject: **Use of Leased Animals by Licensees** **Policy #4**

References: AWA Sections 12, 13
9 CFR, Part 2, Section 2.6

History: This replaces the March 6, 1992 memo entitled "Use of Leased or Rented Animals by Licensees."

Justification: When leased animals are used by another licensee, the responsible party or parties need(s) to be consistently identified in the event of alleged Animal Welfare Act (AWA) violations involving those animals. This policy serves to clarify this issue.

Policy: Animals are subject to AWA jurisdiction when they are used in regulated activities. Animals that are leased are still regulated, even if they are not in the custody of their owners.

Both lessee and lessor must be licensed, as indicated in 9 CFR, Section 2.6, which describes that lessee and lessor shall both pay a fee as dealer, or lessee and lessor shall both include the animals held when calculating the required fees as an exhibitor.

Exhibitors and dealers must keep records which identify animals they own, hold for others, or keep in their possession or under their control.

The Regional Director is authorized to grant an exemption from licensing when issuing a license would not effectuate the purposes of the Animal Welfare Act, e.g., one-time use of a non-performing animal for the purpose of making an advertisement.

4.1

Subject: **Licensing of Exotic Animal Auction Markets** **Policy #5**

References: AWA Section 12
9 CFR, Part 2, Section 2.1, 2.6
9 CFR, Part 3, Subpart F

History: This replaces the February 1, 1991 memo entitled "Licensing of Exotic Animal Auction Markets."

Justification: Until the proposed exotic animal auction regulations are cleared and published, guidelines are needed to address these growing markets.

Policy: All auction markets that sell exotic or wild animals are required to be licensed.

The market operator is responsible for compliance with all regulations and standards, including transportation standards, once the animals are accepted by the auction market.

If the consignor is licensed, compliance will be the responsibility of both the licensee and the market.

The standards for recordkeeping, transportation, cleaning, sanitation, and general animal health and well-being will be monitored and enforced.

Incompatible animals are not to be held in the same enclosure or close to other animals that may cause them stress.

All caged and/or dangerous animals must be held in a manner that ensures the safety of the animals and the public.

A species-appropriate containment area is required around the loading and unloading areas to prevent the escape of animals.

Subject: **Space and Exercise Requirements for Traveling Exhibitors** **Policy #6**

References: AWA Section 13
9 CFR, Part 3 Sections 3.6, 3.8, 3.28, 3.53, 3.80, 3.104, 3.128

History: This replaces the June 6, 1984, memo entitled "Traveling Animal Acts-Cage Spaces for Dogs, Cats, and Nonhuman Primates." It expands and clarifies enclosure space and exercise requirements for traveling exhibitors. The previous version of this policy released on March 5, 1998, has been modified to provide better clarification of the requirements regarding space for vertical posturing.

Justification: Some traveling exhibitors maintain animals long term in transport cages during "travel status." This policy clarifies when the licensee is required to meet full primary enclosure space requirements and/or provide sufficient exercise space and time for animals in traveling exhibits.

Policy: Animals exhibited in traveling shows may be kept in enclosures that meet the space requirements for transport enclosures as specified in Sections 3.14, 3.36, 3.61, 3.87, 3.113, and 3.137 **ONLY** during actual transport, i.e., movement in a conveyance between temporary locations. At all other times, they must be provided with space as described below.

- Dogs, cats, rabbits, guinea pigs, hamsters, nonhuman primates, and marine mammals must be housed in primary enclosures that meet the space requirements described in Sections 3.6, 3.28, 3.53, 3.80, and 3.104, respectively.

- Primary enclosures for all other animals must allow space for each animal to express all species-typical postures, social adjustments, behaviors, and movements. For example, animals must be able to lie down with limbs extended in a normal manner without obstruction from enclosure sides or having to extend feet through feeder doors or bars. Animals that normally engage in occasional vertical postures, such as bears and many felines, must have sufficient vertical space available to accommodate these postures. For example, bears often stand upright on their rear legs and must be allowed sufficient vertical space within their housing enclosure to do so. Many felines also stand on their rear legs, for example, when using scratching posts. However, if enclosures used while "on the road" (i.e., when away from permanent quarters but not actually in transit) do not provide adequate height for animals that occasionally exhibit vertical postures to

engage in such activities, this requirement can be satisfied through release of the affected animals into an exercise pen or equivalent. If a pen is used for this purpose, animals should be released at least once per day and allowed to remain for a reasonable length of time unless otherwise justified. These periods will be in addition to regular performance and practice time.

- When elephants are housed on chains while not in transport, chains must be of sufficient length and arrangement so as to permit each elephant to comfortably lie down, get up, self-groom, and move about within a reasonable range. If elephants are kept unchained in a truck or railway car, each elephant must have enough space to make these postural adjustments as well. These same requirements apply to tethered hoofstock.

- When more than one animal is kept in an enclosure at one time, all animals must simultaneously have sufficient space to accommodate the postures and movements as described above.

- Subpart F animals (for example, elephants, hoofstock, and exotic cats) are required to have "sufficient space to allow each animal to make normal postural and social adjustments with adequate freedom of movement." Enclosures that allow only postural adjustments are inadequate to meet this requirement. "Adequate freedom of movement" includes the ability to exercise. Since it is sometimes difficult for a traveling exhibitor to provide a primary enclosure large enough to allow an animal sufficient exercise, an enclosure that allows only "normal postural and social adjustments" will be considered acceptable if the animal contained therein is released regularly from the primary enclosure (or tether) into a secure space, such as a ring or corral, that provides the opportunity for species-appropriate exercise. This release must occur at least once per day for an appropriate length of time unless otherwise justified. These periods will be in addition to regular performance and practice time. For some species, an area enclosed by an electrical fence is acceptable for this purpose if monitored at all times. Trained elephants and domestic hoofstock may be walked by a qualified handler for this purpose. These provisions apply only to the need for additional space for exercise. Other than to satisfy the vertical posturing needs of animals that occasionally exhibit such movement, the requirement for "sufficient space to allow each animal to make normal postural and social adjustments" cannot be met by periodic release into a larger enclosure. When a traveling exhibitor is not actually in transit (i.e., when he/she is set up for a show or in a holding location), animals must be kept in enclosures which allow them to express postural adjustments typical of their species.

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Subject: **GROUP Classifications for Nonhuman Primates** **Policy #7**

References: AWA Section 13
9 CFR, Part 3, Section 3.80.

History: Replaces July 31, 1991 policy entitled "Clarification of Owl Monkey as a Group 2 Species," and June 30, 1992, letter regarding classification of tree shrews.

Justification: Clarification is needed to specify group classifications for various species of nonhuman primates in order to determine proper space requirements.

Policy: In reference to space requirements under Section 3.80, the following will apply:

- Group 2 will include adult owl monkeys *(Aotus* spp.*)* and squirrel monkeys *(Saimiri spp.)* regardless of adult weight.

- Group 3 will include adult crab-eating macaques *(Macaca fascicularis)* regardless of adult weight. They are also known as cynomolgus macaques.

- Group 6 will include adult:

  a. spider monkeys *(Ateles* spp.*)*
  b. woolly spider monkeys (*Brachyteles* spp.*)*
  c. woolly monkeys (*Lagothrix* spp.*)*
  d. gibbons and siamangs *(Hylobates* spp.*)*

  These species have been designated as brachiating since this term applies to any primate whose form of locomotion involves using its arms, legs, and/or tail while its body is suspended. The intent of the space regulations is to provide sufficient space for all species-typical postural and locomotive behaviors. Since each of these species engages in brachiating-type movement, they require the larger space provided for Group 6 primates.

Tree Shrews-The scientific community has removed tree shrews from the

Suborder Prosimii. Therefore, they are no longer classified as primates and are not required to meet space or environmental enrichment requirements for primates.

Policy #8

Subject: **Guidelines for the Confiscation of Animals**

References: AWA Section 16, Section 19
9 CFR, Part 2, Section 2.38(e) and 2.129

History: This replaces Policy #8 dated April 14, 1997.

Justification: Under the Animal Welfare Act (AWA), the Animal and Plant Health Inspection Service (APHIS), Animal Care (AC) is authorized to confiscate and destroy regulated animals if they are suffering. This guideline specifies the protocol for such action.

Policy: Animals (as defined in 9 CFR, Subchapter A, Part 1, Section 1.1) shall be confiscated in accordance with Section 2.38(e) and Section 2.129, if they are found to be suffering and relief has not been provided by the licensee or registrant. This policy established procedures to:

a. Require the licensee or registrant to provide proper care and relief to a suffering animal as soon as possible, but typically not to exceed 24 hours.

b. Confiscate the animal and/or make arrangements for relief, relocation or euthanasia, as appropriate, if the licensee or registrant does not provide the needed relief from suffering.

Recognition of Suffering by AC

Animals can be found to be suffering from any condition which causes pain or distress if action is not taken to alleviate the condition. Examples of conditions which can cause suffering include, without limitation: animals with serious medical problems that are not receiving adequate veterinary care; animals without adequate food or water; animals exposed to temperature extremes without adequate shelter or bedding; and animals held in enclosures that are filthy. Animals do not need to be in jeopardy of dying to be in a state of suffering. Veterinary Medical Officers (VMO) and Animal Care Inspectors (ACI) are qualified to recognize a suffering animal.

Responsible Person Agrees that an Animal is Suffering

The facility owner, manager, or responsible person, hereafter referred to as "responsible person," should provide the necessary relief, veterinary care, or euthanasia, within the time frame specified by AC personnel. Typically, this time frame should not exceed 24 hours, and it may be considerable less depending on the circumstances. If the animal is an endangered species or a marine mammal, the AC representative should also comply with the requirements of the responsible government agencies. Euthanized animals may be disposed of on the licensee's premises or the registrant's facility, provided such disposal complies with all applicable local, State and Federal laws.

Follow-up by the AC inspector is essential to verify all the necessary relief and/or euthanasia has been accomplished and the matter is satisfactorily resolved. The inspector will document all noncompliant items in accordance with established procedures and initiate enforcement action as appropriate.

Responsible Person is Unavailable

When the AC and Investigative Enforcement Services'(IES) representatives have reason to believe that an animal is suffering and the responsible person for the animal cannot be found after a reasonable time (24 hours or less), the IES investigator shall contact local law enforcement for assistance, and the AC veterinarian shall contact a qualified private veterinarian to accompany them to the premises. The veterinarian and the AC representative shall determine whether or not the animal is suffering, diagnose the problem and probable cause, and document the findings and recommendations in writing. The AC representative shall ensure that adequate care is provided to the animal. If the condition of the animal cannot be corrected by this temporary care, the AC representative shall confiscate the animal in accordance with this policy.

Responsible Person Disagrees that an Animal is Suffering

If the inspector determines that an animal is suffering and the responsible person disagrees, that determination should be confirmed by a second VMO or ACI whenever possible. If the suffering is caused by a medical condition and there has been inadequate veterinary care, the confirmation must be made by at least one, and preferably two, VMOs. The determination must be documented with a complete inspection to include photographs and/or other physical evidence as may be available. A private veterinarian, or a veterinarian from another government agency, may also be requested by AC to examine the animal to confirm a state of suffering.

Similarly, the responsible person may call upon a qualified veterinarian for a second opinion. This will be at the licensee's or registrant's expense and must be done as soon as possible within the specified correction time frame (typically less than 24 hours) so as not to unduly jeopardize the health and well-being of the animal. The second opinion will be considered only if the veterinarian provides a signed written statement to the responsible person and to the AC representative indicating the following:

1. Time and place of examination
2. Number and species of animal(s) examined
3. Examination findings and tentative diagnosis
4. Recommended treatment of course of action, including euthanasia if indicated
5. Time and method of treatment of euthanasia administered, or, a statement that the animal(s) is healthy and sound and that veterinary treatment or euthanasia is not required
6. Any recommended follow-up treatment or action

If AC disagrees with the veterinarian's findings, the Animal Care Regional Director (ACRD) may obtain the assistance of a non-APHIS veterinarian with expertise with the species of animal involved. The final decision in determining if an animal is suffering shall be made by the ACRD based upon all of the relevant findings. The ACRD shall maintain contact with the responsible person until the matter is resolved.

Suffering Not Confirmed or Is Relieved

If the ACRD determines that the animal is not suffering, or if the condition causing the suffering is adequately remedied within the prescribed time period, the inspector will document any noncompliant items in accordance with established procedures and initiate enforcement action, as appropriate. Reinspections will be conducted as needed by the AC inspector.

Notification to Owner of Intent to Confiscate

If it is determined that an animal is suffering and in need of veterinary care or other form of relief, the AC inspector should contact IES for assistance if an IES investigator is not already involved. The IES investigator should assist in documentation of violations and suffering during the examination and inspection by AC personnel.

If confiscation of an animal is being considered, the AC inspectors should immediately notify the responsible person (with the approval of the ACRD),

both verbally and in writing, and request correction of the problem causing the suffering. Correspondence to the responsible person should include the "Notice of Intent to Confiscate" (Appendix A) and an inspection report or other document that includes all of the following specific information:

1. Number and species of animal(s) found to be suffering and individual identification number (for dogs or cats) or brief description of each animal.
2. Identification of deficiencies or conditions causing the suffering.
3. Steps that must be taken to correct the problem and alleviate the suffering; e.g., examination and treatment by a qualified veterinarian.
4. The time period in which the animal is to be given relief and adequate care. This time period must be as soon as possible after determining the animal is suffering, but typically no more than 24 hours
5. Current location of the premises or transport conveyance holding the affected animal.
6. A statement that the animal(s) shall not be removed from the premises or location without prior approval from AC.
7. The signature of the responsible person receiving this notification. (If the responsible person refuses to sign, the AC representative must document the issuance of this notification by a sworn statement.) Follow-up notification will be accomplished by the ACRD.

Confiscation Authorization

Copies of all relevant correspondence should immediately be forwarded by the AC inspector to the AC Regional Office. Notification will be forwarded from the Regional Office to the Animal Care Deputy Administrator (DA) as soon as possible, via fax to (301) 734-4993. The DA shall seek written authorization from the APHIS Administrator for confiscation of the animal under the authority of Section 16(a) of the Act, and as provided in Sections 2. 38 and 2.129 of the regulations. To expedite approval, the ACRD shall provide the DA with the most current information, to include a summary memo listing the number and species of animals to be confiscated, the location of the animals, and the reason(s) for the confiscation action. If at all possible, digital photographs of the conditions should be forwarded electronically to the DA along with the summary memo. The ACRD will also prepare the "Notice of Confiscation of Animals" letter (Appendix B) for the Administrator's signature as well as the list of animals to be confiscated. These will ordinarily be forwarded by e-mail to the DA. The DA will seek any necessary legal counsel from the Office of the General Counsel (OGC) and then obtain the Administrator's signature, as appropriate.

Arranging for Facility to Hold Confiscated Animal

In rare circumstances, the confiscated animal may be held by AC on the premises, provided that the premises complies with AWA standards and regulations. AC shall maintain constant supervision of the confiscated animal if they are left on the premises.

If the confiscated animal will not be held on the premises, the ACRD should arrange for transportation and transfer of the animal to an appropriate facility capable of providing the necessary care and housing consistent with the requirements of the AWA and regulations. Back-up plans for animal placement should also be considered. The ACRD must ensure proper care, holding, treatment or euthanasia of the animal at the facility receiving the confiscated animal.

The ACRD shall arrange for the following provisions as needed:

1. Transportation of the confiscated animal which meets all standards as required for that species of animal, including trained animal handlers and tranquilization or sedation, if required.
2. A premises, kennel, staging area, or other facility which meets the standards and which may house or contain the confiscated animal until it is permanently placed or euthanized.
3. The services of a veterinarian knowledgeable in the species involved, caretakers, handlers or truck drivers, as required.
4. Feeding, watering, veterinary treatment, euthanasia, or other care as may be indicated.
5. Assist inspector in providing equipment, such as a table or shade tent, etc., needed to facilitate the confiscation.
6. Identification and record of each animal confiscated, including ID tags and a record of any tattoos found on the animals.

Any services provided will be at the expense of the responsible person, although APHIS will assume responsibility for such expenses subject to reimbursement from the responsible person. (See sample memo at Appendix C) Whenever possible, written estimates of the cost of all contracted services should be obtained by the ACRD prior to the confiscation and prior to actually incurring the expenses. The ACRD may seek the cooperation of local humane organizations, industry associations, zoos, and shelters for the use of their transportation, personnel, and other facilities. The ACRD will seek to procure the most appropriate and cost effective transport and placement of the animals. An animal that does not require euthanasia will be placed in another facility at

no cost to APHIS whenever possible. If it cannot be placed after a reasonable time, it will be euthanized.

When working with outside organizations, the ACRD should be in direct contact with those people who will actually be assisting with the confiscation. A clear list of responsibilities for each participant should be developed.

Seizure of Animal

If it is deemed necessary prior to the seizure of an animal, the IES investigator shall request the local police, sheriff, U.S. Marshal, or other appropriate law enforcement personnel to accompany him/her and the AC representatives to the premises for the purpose of providing security to APHIS personnel. The IES representative shall serve oral and written notice to the responsible person that AC is seizing the animal under the provisions of the AWA, Section 16(a), and the regulations, Sections 2.38 and/or 2.129. The IES representative shall read these sections of the regulations and serve a copy to the responsible person. If agreeable, the responsible person shall sign a statement surrendering the custody and rights of the animal to APHIS for disposition. If the responsible person will not sign a statement surrendering the animal (See sample at Appendix D), the IES investigator will provide the responsible person the "Notice of Confiscation of Animal" letter signed by the Administrator, and the confiscation of the animal will proceed as planned.

Summary Suspension of License and Injunctive Relief

An injunction against further violations or an immediate summary suspension of the license, as provided in Section 19 of the AWA, may be recommended by the ACRD at the time of confiscation proceedings. This would be especially prudent if there are on-going conditions which may affect other animals remaining at the facility. Such a request should be made immediately by the ACRD by telephone to the Director of IES. The request would need to be supported by a preliminary report prepared by IES, documenting evidence that there have been flagrant violations of the AWA, regulations, and/or standards. The report shall be submitted by the ACRD as an alleged violation to the IES staff and coordinated with the Animal Care DA.

Guidelines for Billing and Reimbursement for Confiscation of Animal

The following procedure is to be used to recover expenses from the responsible person for the costs associated with the confiscation of animals (veterinary care, transportation, housing, feeding, handlers and other related expenses). This should not include salary, travel expenses, etc., APHIS personnel.

1. Regional offices will prepare a memo to the Marketing and Regulatory Programs - Business Services Office (MRP-BS), Accounting Section, with a copy to Resource Management Staff (RMS) in Riverdale, Maryland, requesting that payment be made for expenses incurred in connection with the confiscation of animals. The memo must include either a taxpayer i.d. or social security number of business/individual receiving the reimbursement. If multiple parties will be receiving payment, contact RMS for guidance. This memo will also seek reimbursement of costs from the responsible person. (see Appendix C, "Billing and Collection for Confiscated Animals")

2. MRP-BS has the responsibility of billing and collecting reimbursement from responsible persons and for making payment to veterinarians, transporters, handlers, etc., for care of the animal.

INDIVIDUAL RESPONSIBILITIES IN CONFISCATION ACTIONS

AC Inspector Responsibilities

- Promptly recognize animal suffering and initiate confiscations procedures in accordance with the regulations and this policy.

- Clearly communicate to the responsible person, verbally and in writing, all conditions that are causing animal suffering and the actions necessary for providing relief of that suffering.

- Clearly communicate to the responsible person AC's authority and intent to confiscate animals if the suffering is not relieved within the prescribed time frame.

- Early in confiscation efforts, involve and coordinate all on-site efforts with an IES Investigator.

- Keep the ACRD informed of the situation and current on all pertinent facts and issues. This includes providing inspection reports, photographs, and other relevant documents.

- If negotiating with owners, be clear about what can and cannot be agreed upon prior to the actual confiscation or voluntary relinquishing of the animals. Any agreements should be put in writing and signed by the responsible person.

- If the suffering animal subject to confiscation is an endangered species or

a marine mammal, notify the ACRD, who will then ensure coordination with appropriate government agencies.

- Should any injury or illness occur during the course of a confiscation ensure delivery of pompt emergency care as needed. Refer to the AC Occupational Health and Safety Manual or contact the Collateral Duty Safety and Health Officer (CDSHO) for assistance. Also promptly notify your supervisor and/or the ACRD.

- Consider weather conditions and have available a tarp/canopy for shelter, tables, and chairs and other equipment as needed during the actual confiscation or in the staging area.

AC Regional Director Responsibilities

- Promptly notify the DA that confiscation procedures have, or will be, initiated.

- If it is deemed necessary, obtain the opinion of a second AC VMO or a private veterinarian with appropriate expertise with the species involved.

- Provide the DA with the most current information, to include a summary memo listing the number and species of animals to be confiscated, the location of the animals, and the reason(s) for the confiscation action. If at all possible, digital photographs of the conditions should be forwarded to the DA to include with the memo.

- Advise the DA if the suffering animal subject to confiscation is an endangered species or a marine mammal so that coordination with the appropriate government agencies can be initiated.

- Request assistance and coordinate confiscation procedures with the IES Regional Director (IESRD).

- Coordinate all proposed legal actions (subpoenas, etc.) with the IESRD.

- Notify Legislative and Public Affairs (LPA) and provide information for the press releases and arrange media assistance on site, if indicated (This may be especially important if animals will be euthanized.).

- Document anticipated expenses in advance and send written estimates of costs for products or services to AC Headquarters.

- When working with animals with contagious diseases, e.g., dogs infected

with or exposed to canine brucellosis, establish a plan to deal with the disease. Determine APHIS' financial responsibility to test or treat any infected or exposed animals.

- Consider a temporary staging area to triage process large numbers of animals.

- Promptly review and forwarded the IES investigative report to the IES Headquarters' Staff.

Deputy Administrator Responsibilities

- Seek authorization from the Administrator for all confiscation actions.

- Contact OGC to arrange for legal assistance with the confiscation and provide the contact information to the ACRD.

- If the suffering animal subject to confiscation is an endangered species or a marine mammal, inform the Department of the Interior, the Department of Commerce, and/or other appropriate cooperating services as required and consistent with any functioning interagency agreement.

IES Investigator Responsibilities

- Contact and coordinate with local law enforcement officials, the U.S. Marshal, or other appropriate law enforcement officials as needed with the confiscation or to protect APHIS employees.

- Maintain a complete list of all participants in the confiscation including name and contact information. The investigator should inform participants that APHIS will coordinate security but does not assume liability for non-APHIS personnel in the case of injury or illness.

- Develop a plan to report and handle injuries or possible adverse after effects.

- During and after the confiscation, document all apparent violations of the AWA which led to the suffering of the animal. This may include videotaping the facility and/or confiscation for accurate documentation. Back-up cameras should be available.

- Submit an investigative report to the ACRD as an alleged violation within 15 calendar days after the completion of the confiscation procedures.

Appendix A

Notice of Intent to Confiscate Animals

Date:

TO: _____

Notice is hereby given that the animals identified on the attached inspection report dated_____, are subject to confiscation by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, and may be confiscated unless the instructions given in the report are followed.

Such action is authorized by Section 16 of the Animal Welfare Act (7 U.S.C. § 2146) and Title 9, Code of Federal Regulations, Section 2.129 (9 C.F.R. § 2.129).

Should you need further information, you may contact_____ at_____(phone number).

Animal Care
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

By:_____

Appendix B

Notice of Confiscation of Animals

Date:

TO:_____

Notice is hereby given that the following animals (list attached) are hereby confiscated by the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, pursuant to the authority of Section 16 of the Animal Welfare Act (7 U.S.C. § 2146) and Title 9, Code of Federal Regulations, Section 2.129 (9 C.F.R. § 2.129), for failure to provide necessary care for the animals.

Animal Care
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

By:_____

S A M P L E

Appendix C

Date:

Subject: Billing and Collection for Confiscated Animals

To : Accounting Section
Marketing and Regulatory Programs
Business Services, MRPBS
Minneapolis, MN

Please make payment to John Doe, File No. 12345, City, State, in the amount of $999.99 (bill enclosed), and charge accounting code 1596101500. Dr. Doe's taxpayer i.d. is 34-12345.

John Doe provided examination, evaluation, euthanasia, and necropsy services on June 1-4, 1992, for the animal(s) confiscated from Jack Smith, 1234 Main Street, City, State. Refer to 9 CFR, Animal Welfare, Section 2.129 (a), (b), and (c).

Also, please bill for collection Jack Smith at the above address using the following statement of charges:

> All costs for providing care, treatment, euthanasia, or disposition of confiscated animals (as provided in Section 2.129 (a), (b), and (c) of the 9 CFR) shall be reimbursed by the person responsible for the animal(s).

When funds are received, please deposit them back to Accounting Code 1596101500. If you have any questions regarding the payment, please contact Terry Schneider at (301) 734-5015.

Name
Director
Regional Office, Animal Care

Enclosure

cc:
AC, RMS, Riverdale, MD

S A M P L E

Appendix D

We, _____ and _____voluntarily agree to

donate _____ dogs to the _____.

I understand that this donation is permanent and I have no further claims or interests in these animals or their offspring.

_____	_____
Signature	Signature
_____	_____
Date	Date

Subject: **Barrier Facility** **Policy #9**
SPF Colony Inspection

References: AWA Section 16 (a)
9 CFR, Part 2, Sections 2.38(b), 2.1

History: Provides requested guidance. Replaces letter dated July 5, 1991.

Justification: The Animal & Plant Health Inspection Service (APHIS) must have access to inspect all covered animals at a regulated facility to ensure compliance with the Animal Welfare Act (AWA).

Policy: Animals housed in barrier facilities are required to be maintained in accordance with the AWA's regulations and standards.

In some cases, APHIS inspections of **bonafide** barrier facilities may be performed by analysis of environmental records, visual inspection through an adequate viewing window, and random selection of animals to be visually inspected. Various non-entry methods, such as video viewing from outside the barrier room, may substitute for an inadequate viewing window.

If the APHIS inspector determines it is necessary to enter a barrier room to adequately complete an inspection or to resolve a suspected problem, the inspector may, by following entry procedures normally used by facility personnel, enter and complete the inspection. The inspector cannot be expected to comply with procedures not used by facility employees. The facility must supply a copy of their barrier entry procedures upon request. The facility will need to provide the inspector with protective clothing and items needed to complete the inspection (pens, paper, tape measure, flashlight, etc.).

Prior to an inspection of a barrier facility, the facility may ask the inspector (as part of the standard entry procedure) to verify that he/she has not been in contact with, or exposed to, certain animals for a specified time period. Such verification is acceptable. Generally, barrier facilities require a period of no animal or specific species contact for 72 hours.

The APHIS inspector **will not** sign any statement in which he or she accepts responsibility for the health of the animals in that barrier facility.

Animal Care Resource Guide
Policies
Barrier Facilities

Subject: **Licensing and Registration Guidelines for Producers of Antibodies, Sera and/or Other Animal Parts, Producers of Genetically Engineered and Cloned Animals, Licensed Exhibitors, and Producers of Pregnant Mare Urine (PMU)** **Policy #10**

References: 9 CFR, Part 1, Section 1.1
9 CFR, Part 2, Section 2.6(c)

History: Replaces Policy #10 dated April 14, 1997.

Justification: Clarification of the licensing and/or registration of producers of antibodies, sera or other animal parts, producers of genetically engineered and cloned animals, and licensed exhibitors. Production of PMU is not covered by the Animal Welfare Act (AWA).

Policy: Producers of Antibodies, Sera and/or Other Animal Parts

A facility that produces antibodies or antisera is "testing" animals for their immune response and selects animals for production based on the results of this testing. Therefore, the facility must be **registered** as a research facility.

A facility which harvests or produces only normal blood or sera for regulated purposes is not testing. The facility is selling parts of the animal which is maintained for this purpose. Therefore, the facility meets the definition of a dealer and must be **licensed** as such.

A research facility selling antibodies, antisera, or other body parts for research, teaching, testing, or experimentation, would require a dealer's **license** in addition to its registration. This is not intended to apply to legitimate collaboration between researchers and their exchange and/or transfer of body parts, antibodies, and antisera.

The class B dealer's license fee will be based on the total amount of blood product sales in a year. The cost of the animals will not be deducted from this figure, unless new animals are obtained for every batch of blood products. The table in 9 CFR, Part 2, Section 2.6(c) determines the correct fee.

A license **would not** be required if the research facility only produces antibodies/antisera on a contract basis for particular investigators, not for resale.

Producers of Genetically Engineered and Cloned Animals

A facility that produces genetically engineered animals is using such animals in research, tests or experiments to determine the effect of the unconventional introduction of synthetic, species-foreign, or other such genetic material on the phenotype of the animal. Therefore, the facility must be **registered** as a research facility.

A facility which produces cloned animals for regulated purposes utilizing standard veterinary medical practices is considered to be breeding animals, and must be **licensed** as a dealer. Other activities conducted by cloning companies will be reviewed on a case-by-case basis to determine whether they are covered by the AWA.

Activities at Licensed Exhibitors

Licensed exhibitors occasionally collect information on their animals with the intent to improve the nutrition, breeding, management, or care of such animals. These programs may be exempted from the registration requirements of the regulations as long as the collection methods:

- are performed as an adjunct to normal husbandry or veterinary procedures for the benefit of the animal or species (e.g., routine veterinary care, embryo transfer, artificial insemination, electroejaculation); or
- are not invasive (feed studies); or
- do not cause pain or distress to the animal (behavioral observations).

However, if the licensed exhibitor is conducting biomedical research (using the animals as models for human applications), conducting invasive or painful/distressful procedures for nonhusbandry purposes or if the research involves domestic dogs or cats, then the licensee is **not** exempt from the need for registration.

Producers of Pregnant Mare Urine

Horses used for the production of PMU are not covered by the AWA. This activity is not defined as research, teaching, or testing. People who deal in horses or horse parts are not required to be licensed.

Subject: **Painful Procedures** **Policy #11**

References: AWA Sections 13(a)(3), 13(a)(7), 13(e)(2, 3)
9 CFR, Part 2, Sections 2.31(d)(1)(i,ii,iii,iv), 2.31(e)(4), 2.33(b)(4)
9 CFR, Part 3, Section 3.6(b)(5,6,7)

History:

Replaces letters dated May 8, 1992, November 7, 1991, November 9, 1990, and March 1, 1990.

Justification: Provides requested guidance. Procedures involving animals will avoid or minimize discomfort, distress and/or pain.

Policy: A painful procedure is defined as any procedure that would reasonably be expected to cause more than slight or momentary pain and/or distress in a human being to which that procedure is applied. The Institutional Animal Care and Use Committee (IACUC) is responsible for ensuring that investigators have appropriately considered alternatives to any procedures that may cause more than slight or momentary pain or distress. A written narrative description of the methods and sources used to search for alternatives must be provided. Where specific testing procedures are required by Federal law, the CFR references or other legal guidelines requiring them should be noted.

Examples of procedures that can be expected to cause more than momentary or slight pain include, but are not limited to, the following:

- **Terminal Surgery** is considered a painful procedure which is alleviated by anesthesia.
- **Freund's Complete Adjuvant** used for antibody production may cause results ranging from momentary or slight pain to severe pain depending on the product, procedure, and species.
- **Ocular and Skin Irritancy Testing.** The dosing procedure itself is generally not painful but the reaction caused by the product being tested may cause pain.

Examples of procedures that may cause more than momentary or slight distress include, but are not limited to, the following:

- **Food or water deprivation** beyond that necessary for normal presurgical preparation.

- **Noxious electrical shock** that is not immediately escapable.

- **Paralysis or immobility** in a conscious animal.

Many procedures, including any of those in the lists above, may cause both pain and distress. An example of a procedure that can be expected to cause more than momentary or slight pain as well as distress would be a study involving extensive irradiation.

Animals exhibiting signs of pain, discomfort, or distress such as decreased appetite/activity level, adverse reactions to touching inoculated areas, open sores/necrotic skin lesions, abscesses, lameness, conjunctivitis, corneal edema, and photophobia are expected to receive appropriate relief unless written scientific justification is provided in the animal activity proposal and approved by the IACUC.

Research facilities must have a mechanism in place for ensuring that animals are reported in the appropriate pain category on the annual report (APHIS Form 7023). Individual animals that do not experience pain/distress from testing procedures should be reported in column C. Individual animals experiencing pain/distress which is alleviated with anesthetics, analgesics, sedatives and/or tranquilizers should be reported in column D. This category includes terminal surgery under anesthesia. Individual animals in which needed anesthetics, analgesics, sedatives, and/or tranquilizers are withheld should be reported in column E. For all column E animals, a written justification, approved by the IACUC, must be provided, including CFR references or other guidelines if appropriate.

Subject: **Consideration of Alternatives to Painful/Distressful Procedures** **Policy #12**

References: AWA Section 13(a)(3)(B)
9 CFR, Part 2, Section 2.31 (d)(1)(ii)and (e)
9 CFR, Part 2, Section 2.32 (c)(2) and (5)(ii)
Animal Welfare Information Center

History: Provides guidance on the requirement to provide a written narrative of the consideration of alternatives to painful and distressful procedures. Replaces Policy #12 dated April 14, 1997.

Justification: The Animal Welfare Act (AWA) regulations require principal investigators to consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and provide a written narrative of the methods used and sources consulted to determine the availability of alternatives, including refinements, reductions, and replacements.

Policy: *Alternatives or alternative methods* are generally regarded as those that incorporate some aspect of replacement, reduction, or refinement of animal use in pursuit of the minimization of animal pain and distress consistent with the goals of the research. These include methods that use non-animal systems or less sentient animal species to partially or fully *replace* animals (for example, the use of an in vitro or insect model to replace a mammalian model), methods that *reduce* the number of animals to the minimum required to obtain scientifically valid data, and methods that *refine* animal use by lessening or eliminating pain or distress and, thereby, enhancing animal well-being. Potential alternatives that do not allow the attainment of the goals of the research are not, by definition, alternatives.

A fundamental goal of the AWA and the accompanying regulations is the minimization of animal pain and distress via the consideration of alternatives and alternative methods. Toward this end, the regulations state that any proposed animal activity, or significant changes to an ongoing animal activity, must include:

1. a rationale for involving animals, the appropriateness of the species, and the number of animals to be used;

2. a description of procedures or methods designed to assure that discomfort and pain to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals;

3. a written narrative description of the methods and sources used to consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals; and

4. the written assurance that the activities do not unnecessarily duplicate previous experiments.

We believe that the performance of a database search remains the most effective and efficient method for demonstrating compliance with the requirement to consider alternatives to painful/distressful procedures. However, in some circumstances (as in highly specialized fields of study), conferences, colloquia, subject expert consultants, or other sources may provide relevant and up-to-date information regarding alternatives in lieu of, or in addition to, a database search. When other sources are the primary means of considering alternatives, the Institutional Animal Care and Use Committee (IACUC) and the inspecting Veterinary Medical Officer should closely scrutinize the results. Sufficient documentation, such as the consultant's name and qualifications and the date and content of the consult, should be provided to the IACUC to demonstrate the expert's knowledge of the availability of alternatives in the specific field of study. For example, an immunologist cited as a subject expert may or may not possess expertise concerning alternatives to *in vivo* antibody production.

When a database search is the primary means of meeting this requirement, the narrative must, at a minimum, include:

1. the names of the databases searched;
2. the date the search was performed;
3. the
period covered by the search; and
4. the key words and/or the search strategy used.

The Animal Welfare Information Center (AWIC) is an information service of the National Agricultural Library specifically established to provide information about alternatives. AWIC offers expertise in formulation of the search strategy and selection of key words and databases, access to unique databases, on- and off-site training of institute personnel in conducting effective alternatives

searches, and is able to perform no-cost or low-cost electronic database searches. AWIC can be contacted at (301) 504-6212, via E-mail at *awic@nal.usda.gov*, or via its web site at *http://www.nal.usda.gov/awic*. Other excellent resources for assistance with alternative searches are available and may be equally acceptable.

Regardless of the alternatives sources(s) used, the written narrative should include adequate information for the IACUC to assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods. If a database search or other source identifies a *bona fide* alternative method (one that could be used to accomplish the goals of the animal use proposal), the written narrative should justify why this alternative was not used.

The written narrative for federally-mandated animal testing (for example, testing product safety/efficacy/potency) needs only to include a citation of the appropriate government agency's regulation and guidance documents. Mandating agency guidelines should be consulted since they may provide alternatives (for example, refinements such as humane endpoints or replacements such as the Murine Local Lymph Node Assay) that are not included in the Code of Federal Regulations. If a mandating agency-accepted alternative is not used, the principal investigator should explain the reason in the written narrative.

Alternatives should be considered in the planning phase of the animal use proposal. When a proposal is modified during its performance, significant changes are subject to prior review by the IACUC, including the review of the implications of those changes concerning the availability of alternatives. Although additional attempts to identify alternatives or alternative methods are not required by Animal Care at the time of each annual review of the animal protocol, Animal Care would normally expect the principal investigator to reconsider alternatives at least once every 3 years, consistent with the triennial review requirements of the Public Health Service Policy (IV,C,5).

Subject: **Microchip Implants** **Policy #13**

References: AWA Section 11
9 CFR, Part 2, Sections 2.38(g), 2.35(b), 2.50, 2.75(a)

History: Provides requested guidance. Replaces letters dated December 23, 1991, and February 5, 1991. Replaces Policy #13 dated April 14, 1997.

Justification: All dogs and cats must be identified.

Policy: For Animal Care to grant approval for a microchip implantation identification system in breeding stock or research animals, the following requirements must be met:

a. The microchip must be placed in a standard anatomical location.

b. The microchip scanner device must be readily available to the Animal and Plant Health Inspection Service (APHIS) representative and/or facility employee accompanying the APHIS representative.

c. The animal identification records must indicate the microchip number, the location on the animal, and the name of the microchip manufacturer.

d. Any animal with a microchip that goes to another licensee/registrant must have a tag/tattoo if a compatible scanner is not available at the receiving facility.

If the above conditions are met, then approval to utilize a microchip identification system can be granted by the USDA Animal Care inspector or the regional office.

The Animal Care Regional Director can revoke an approval if the system is found to be ineffective and corrections are not made promptly.

13.2

Subject: **Major Survival Surgery** **Policy #14**
Single vs. Multiple Procedures

References: AWA Section 13(a)(3)(D,E)
9 CFR, Part 2, Section 2.31 (d)(1)(x)

History: Provides requested guidance. Replaces letters dated April 21, 1992 and June 5, 1990.

Justification: No animal is to be used in more than one major survival operative procedure except in cases of scientific necessity or veterinary care.

Policy: No animal assigned to a proposal is to be used in more than one major survival operative procedure unless the multiple procedures are included within one proposal, justified for scientific reasons by the Principal Investigator, and preapproved by the Institutional Animal Care and Use Committee (IACUC). However, an animal that has an emergency major operative procedure as part of proper veterinary care may still be used in a proposal that requires a major survival operative procedure.

A major survival operative procedure must not be performed a second time on an animal in a separate proposal. In order to comply with the intent of the Animal Welfare Act (AWA), animals surviving a major operative procedure must be identified (written documentation) to prevent their use in a second major survival operative procedure.

The AWA and its regulations allow an exemption to limiting animals from being used in only one proposal with a major survival operative procedure. The Institutional Official of the research facility should make the exemption request to the appropriate Animal Care Regional Director, who forwards it to the Animal Care Assistant Deputy Administrator for review and recommendation to the Deputy Administrator. The request for exemption should include the following information:

a. An outline of the research proposals for which the procedure is requested

b. The species and the approximate number of animals involved in the exemption request

c. The time frame for the proposed exempt procedure

d. The number of major operative procedures to be performed on a given animal, the frequency of such procedures, and the period of time between each major operative procedure

e. Measures to be taken to ensure that pain/distress are minimized

f. A complete justification for the exemption in which cost is not normally a major criterion

g. An assurance that all other stipulated requirements of the AWA and regulations will be met in consideration of this exemption

h. An assurance that the facility's IACUC has approved the exemption.

The Animal & Plant Health Inspection Service (APHIS) may respond to the formal request by approving the request as written, granting a portion of the request, imposing additional limitations, or denying the request. An annual IACUC evaluation of the exemption is required, which consists of an IACUC assessment of the animals and the effectiveness and soundness of the methods and procedures used. This information is to be included in the report of the IACUC functions. Considerations for the renewal or continuation of the exemption will be based on the IACUC's recommendations following their review. The exemption must be included in the Annual Report (APHIS Form 7023).

Subject: **IACUC Membership** **Policy #15**

References: AWA Section 2143(b)(1) and (d)
9 CFR, Part 2, Section 2.31(a), (b)(2,3)
9 CFR, Part 2, Section 2.32(a)

History: Provides requested guidance. Replaces Policy #15 dated April 14, 1997.

Justification: To provide clarification of specified individual roles in the Animal Care and Use Program at research facilities.

Policy: For Animal Welfare Act (AWA) enforcement purposes, the nonaffiliated member of the Insitutional Animal Care and Use Committee (IACUC) is to "provide representation for general community interests." The outside nonaffiliated member cannot be a laboratory animal user at any research facility. Compensation of the nonaffiliated member is permissable only when it does not jeopardize the member's status as a nonaffiliated member. Compensation varies but is normally limited to payment for travel and related expenses, such as parking and meals, to modest monetary payments for participation. The dollar amount of compensation, if any, should not be so substantial as to be considered an important source of income or to influence voting on the IACUC.

The regulations provide for four specific roles within the Animal Care and Use Program:

1. Institutional Official
2. IACUC Chairperson
3. Attending Veterinarian
4. Nonaffiliated Member

These positions are meant to provide a system of checks and balances which is not normally achieved if any one person fills more than one of these roles. While the regulations do not specifically prohibit one person from filling more than one role, the Animal and Plant Health Inspection Service (APHIS) strongly discourages such assignments because of the potential for conflicts of interest and/or undue influence by one person over the facility's

program. However, a veterinarian who is not the attending veterinarian may assume any one of the other program positions.

IACUC members must be qualified to assess the research facility's animal program, facilities and procedures. The research facility is responsible for ensuring their qualification, and this responsibility is filled in part through the provision of training and instruction. For example, IACUC members should be trained in understanding the Animal Welfare Act, protocol review, and facility inspections.

No IACUC member can review his/her own proposal.

Subject: **Dealers Selling Surgically-Altered Animals to Research** **Policy #16**

References: AWA Section 13(a)(3)(A,B,C,D,E)
9 CFR, Part 2, Section 2.31 (d)(1)(i,ii,iv,viii,ix,x)

History: Provides requested guidance.

Justification: No animal is to be used in more than one major survival operative procedure except in cases of scientific necessity or veterinary care. The Institutional Animal Care and Use Committee (IACUC) is to ensure that survival surgery will avoid or minimize pain and is aseptically performed by qualified personnel.

Policy: A dealer performing surgery on animals as a necessary part of a proposed animal activity at a research facility must also register as a research facility and/or be a site of the research facility requesting the altered animals.

Dealers that register as research facilities will comply with all the regulations pertaining to research facilities. Their IACUCs must ensure that all requirements are met before approving the activities associated with the surgical alteration of the animal. If the alteration involves a major operative procedure, the animal must be identified to prevent its use in another major survival operative procedure.

Research facilities that list dealers' premises as sites under their registration are responsible for the animals at the dealers' facilities which are covered under their proposals. The IACUC must inspect all dealers' sites housing animals covered under their proposals. The research facility must also ensure that the person(s) at the dealers' sites performing the proposal procedures is qualified.

Dealers performing routine veterinary care or animal husbandry that involves surgery not required for a research proposal are not required to register as a research facility. Examples include, but are not limited to, neutering, dehorning, and debarking.

Subject: **Annual Report for Research Facilities** **Policy #17**

References: AWA Section 2143(a)(7)(A)
9 CFR, Part 2, Section 2.36

History: Replaces Policy #17 dated March 17, 1999. Provides requested guidance, deletes obsolete information related to the forms distribution process, and adds information regarding electronic submission of the annual report.

Justification: To further explain the Animal Welfare Act (AWA) and regulations regarding completion and submission of the "Annual Report of Research Facility" form.

Policy: As required by Section 2143 of the AWA and further explained in 9 CFR, Part 2, Section 2.36, each reporting research facility shall submit an annual report (APHIS Forms 7023 and 7023-A) to the Animal Care (AC) Regional office responsible for the State in which the facility is located. This report is due in the Regional office on or before **December 1** of each year.

These forms shall be signed and certified as correct by the Chief Executive Officer (CEO) or legally responsible Institutional Official (IO), and must include all species covered by the AWA **used** in research, tests, experiments, or for teaching and **being held for use** at the end of the U.S. Department of Agriculture's (USDA) fiscal year (FY) **(**October 1 through September 30). By signing the report, the CEO or IO is also certifying that the institution has adhered to the assurance statements at the bottom of the APHIS Form 7023.

Reporting of animals used (see forms) is based on the USDA FY (October 1 through September 30). Animals are to be counted only once, regardless of the number of proposals in which they were used. If an animal was used in more than one proposal, it must be counted in the most painful category. Animals used in multi-year studies will be counted once each fiscal year, regardless of when they were acquired.

Animals counted and listed in Column E must have a detailed statement explaining the procedure(s) and the basis for withholding pain-relieving medications.

Each research facility shall certify that the animal usage information submitted is true, correct and complete. It is recommended that every facility develop an animal accounting method sufficient to support this submission. USDA inspectors will verify the accuracy of these numbers during their inspection.

I. Distribution

On or before **September 15** of each year, the AC Regional office will send a packet via regular mail to the IO at each USDA registered and Federal research facility containing a notification letter, APHIS Form 7023, Column B and E explanation forms and other guidance documents, and instructions regarding the optional electronic submission process.

II. Instructions for Completing APHIS Forms 7023 and 7023-A

A. APHIS Forms

General instructions for completing the forms are included in the packet.

APHIS Form 7023: Items 1 through 3 completed by all facilities. Items 4 through 13 completed where applicable.

APHIS Form 7023-A (Continuation Sheet): Use only if needed to list additional species. Complete items 1, 2, 12, and/or 13.

B. Special Instructions for Column E

Entries in Column E must be explained in detail and attached to APHIS Form 7023. At a minimum, these statements should address the following:

1. A complete description of the procedure(s) producing pain and/or distress in the animal(s). For Federally mandated testing, this explanation should include, as appropriate, the name of the agency and specific reference citation from the Code of Federal Regulations or other relevant guidelines.
2. A complete explanation for withholding drugs for relieving pain and/or distress. For example, provide scientific justification that such drugs would adversely affect the test/study results, or cite all regulation(s) and/or Federal Agency policies that prohibit the use of these drugs.
3. An optional “Column E Explanation” form is included in the packet. Research facilities may find it useful to complete this form to provide the necessary information.

C. Exceptions to the Regulations and Standards

A summary of any Institutional Animal Care and Use Committee (IACUC) - approved exceptions to the regulations or standards must be submitted in hard copy to the appropriate Regional office. At a minimum, this summary should include the following:

1. Identify IACUC-approved exception(s) to the regulations or standards, including exemptions to the dog exercise plan and/or the nonhuman primate plan for environmental enhancement.

2. Describe the IACUC-approved exception(s).

3. Identify the species and number of animals affected.

D. Other Information

Column F contains only the total number of animals listed in Columns C, D and E. Do not include animals from Column B.

It is not necessary to report birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, or any other animals not defined as animal by 9 CFR, Part 1- Definitions of Terms, Section 1.1. This includes fish, amphibians and livestock or poultry used in agricultural research.

Wild rats and mice **are** covered and must be reported.

State the **common names** of the animals in Column A if they are not already listed.

"Other Farm Animals": List farm animals other than pigs and sheep such as goats, cattle, llamas, etc.

"Other Animals" refers to other covered animals (not farm animals). This would include, but not be limited to, animals such as gerbils, ferrets, seals, tigers, opossums, raccoons, wolves, and bobcats.

Incomplete forms or inaccurate data will be returned to the issuing facility at the discretion of the Regional office.

III. Routing of Completed APHIS Forms 7023 and 7023-A

Annual report forms from all facilities must be returned to the appropriate Regional office by **December 1** of each year. Enforcement action may be initiated if the reports are not submitted by this required deadline.

Facilities with multiple sites should collect and combine their annual reports into one report before submitting.

Electronic Submission

1. This system is only available on the USDA-APHIS-Animal Care website from **September 15** to **December 1** each year.
2. A password must be requested via e-mail by the CEO or IO, and will be mailed to them hard-copy from the appropriate Regional office. Information on how to obtain the password is included in the packet mailed to each institution in September.
3. Only animal numbers and species for each category, and Column E explanations may be entered. IACUC-exception information must be submitted in hard copy to the Regional office.

Original submissions of APHIS Forms 7023 and 7023-A will be retained by the Regional office.

INSTRUCTIONS FOR COMPLETION OF APHIS FORM 7023

(Refer to 9 CFR Part 2, Subpart C, Section 2.33 and 2.36)

ITEM 1 - Enter registration number as assigned to the Research Facility by United States Department of Agriculture (USDA).

ITEM 2 - Enter the complete name and address of the Headquarters Research Facility as registered with USDA.

ITEM 3 - List Location of each Facility or Site where animals were housed or used in actual research, testing, teaching, or experimentation, or held for those purposes. *(Attached additional sheets if necessary.)*

ITEM 4 -13 - DO NOT enter numbers in Column A. **DO NOT** add numbers enterd in Column B into the total in Column F. **Column F** is to show total of numbers entered in Columns **C + D + E.** Entries in Column E must be explained on attached sheet(s).

ITEM 12 - List by common name all other farm animal species.

ITEM 13 - Other: List, by common name, all other warm blooded animal species covered by the Regulations. *(This will include all wild or exotic species.)* Attach additional sheets if necessary or use APHIS Form 7023A.

CERTIFICATIONS: Must be signed by the Chief Executive Officer (C.E.O.) of the Registered Research Facility or other Institutional Official (I.O.) having authority to legally commit on the behalf of the Registered Research Facility. Sign, Print or type Name and Title, and Date.

RETURN COMPLETED FORM WITH AN ORIGINAL SIGNATURE OF C.E.O. OR I.O. TO APPROPRIATE REGIONAL OFFICE.

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. **CUSTOMER NO.**

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS *(sites)*

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic,analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO. OF ANIMALS **(Cols. C + D + E)**
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. **CUSTOMER NO.**

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

A. Animals Covered By The Animal Welfare Regulations	**B.** Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	**C.** Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	**D.** Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	**E.** Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic,analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	**F.** TOTAL NO. OF ANIMALS **(Cols. C + D + E)**

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	**NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL** *(Type or Print)*	**DATE SIGNED**

Subject: **Health Certificate for Dogs, Cats, and Nonhuman Primates** **Policy #18**

References: 9 CFR, Part 2, Section 2.78

History: Replaces letter dated March 6, 1992.

Justification: Most dogs and cats transported by a dealer are usually moved for short distances and require only short periods of time in the dealer's private vehicle.

Policy: A health certificate issued within 10 days of shipment must accompany any dog, cat, or nonhuman primate that is transported in commerce by a licensee or registrant. Regulated dogs, cats, and nonhuman primates transported intrastate by commercial carrier, transported interstate, or in foreign commerce, are required to have properly executed health certificates. However, dogs, cats, and nonhuman primates transported within the State and in the licensee's/registrant's private vehicle may be transported without a health certificate.

Subject: **Tattoo Identification of Dogs and Cats** **Policy #19**

References: 9 CFR, Part 2, Sections 2.50(a)(1) and (e)(iii)

History: Replaces REAC Memorandum 430 dated July 20, 1992.

Justification: This policy is to clarify the procedure used in approving tattoo identification of dogs and cats for dealers under the authority of the Animal Welfare Act.

Policy: Each licensee who wishes to use a tattoo to identify his/her animals will be assigned a code for identification to include the type of business (Class A or Class B) and the State in which he/she is licensed. Examples of the system are as follows:

Class A dealer from Maryland:	MDAA through MDAZZ
Class B dealer from Maryland:	MDBAA through MDBZZ

In addition to the dealer's code assigned, the dealer will be required to add the necessary numbers to uniquely identify each animal. Dealers of purpose-bred dogs and cats sold only for research purposes may have special tattoos approved by the Administrator.

Subject: **Identification of Puppies Less than 16 Weeks of Age** **Policy #20**

References: AWA Sections 1 and 12
9CFR, Part 2, Sections 2.50(a)(2) and (b)(3)

History: Replaces memorandum dated December 30, 1993, "Identification of Puppies Under 16 Weeks of Age."

Justification: The Animal Care staff has been made aware of problems from using plastic collars to identify puppies that are less than 16 weeks of age.

Policy: After reviewing the Animal Welfare Act (AWA) and its intent, puppies under 16 weeks of age can be exempt from individual identification if the following requirements are met:

1. The puppies remain housed at the facility where they were whelped and are maintained as a litter.

2. The enclosure containing the puppies is identified with the information required by 9 CFR Section 2.50 until the puppies are sold or moved from the facility where they were whelped or reach the age of 16 weeks, which ever comes first.

Subject: **Control of Tuberculosis in Regulated Elephants** **Policy #21**

References: AWA Section 13
9 CFR, Part 2, Section 2.40(b)(2)

History: This is a new policy statement.

Justification: Tuberculosis is a contagious disease that affects elephants, other animals, and humans. If left untreated or if treated improperly, it can cause death. Several elephants owned by licensed exhibitors have either tested culture positive for tuberculosis or have died due to this disease. In addition, elephants with tuberculosis can transmit the disease to other elephants, other animals, and, potentially, to humans. The Animal Plant & Health Inspection Service (APHIS), Animal Care (AC) is requiring the periodic testing of all Animal Welfare Act regulated elephants. Testing will help us to identify those elephants that are infected and ensure that appropriate quarantine and/or treatment measures are instituted.

Policy: As part of the adequate veterinary care standard in the U. S. Department of Agriculture's (USDA) animal welfare regulations, all captive elephants in the United States must be periodically tested for tubercuslosis. Any animals found positive on culture will be required to undergo quarantine and/or treatment.

In conjunction with this policy, USDA, APHIS, AC is offering a protocol, *The Guidelines for the Control of Tuberculosis in Elephants*, that specifies criteria for the testing, surveillance, and treatment of elephants for tuberculosis. Copies of this protocol are available from all AC Regional Offices and on the AC homepage at *www.aphis.usda.gov/ac*.

Licensees must either follow the recommended guidelines or provide a comparable testing and monitoring program that is consistent with AC's goals of ensuring the welfare of captive elephants and minimizing the potential spread of tuberculosis.

Any protocol other than the recommended guidelines must be reviewed and approved by AC prior to implementation. Alternate plans should be submitted to the appropriate AC Regional Office.

During the course of routine inspections, AC inspectors will review

documentation that assures that elephants are being tested, and, if the animals test positive or are diseased, are treated according to the recommended guidelines or other APHIS approved protocol.

In addition, in order to protect the health of elephants that have not been exposed to the disease from humans who may be infected with tuberculosis, AC is requiring that all attendants, handlers, and/or trainees which have direct contact with elephants be tested for tuberculosis on at least an annual basis. It is the responsibility of each licensee, in consultation with a physician or other appropriate medical authority, to determine how this requirement will be satisfied.

Subject: **Necropsy Requirements** **Policy #22**

References: AWA Section 13
9 CFR, Part 2, Section 2.33 and 2.40(b)(2)

History: This is a new policy statement.

Justification: Current regulatory and policy requirements for the performance of a necropsy have focused on elephants and marine mammals. Notwithstanding these requirements, there are times when the performance of one or more necropsies is necessary to provide adequate veterinary care for a facility by providing diagnoses of conditions, thereby allowing for adequate prevention, control, and treatment of the disease.

Policy: When warranted by circumstances including--but not limited to--the list below, and at the discretion of the attending veterinarian, regulated facilities should perform necropsies as part of providing adequate veterinary care. Similarly, the Animal and Plant Health Inspection Service (APHIS) inspector, in consultation with their Regional office supervisor, may require a facility to perform necropsies on selected regulated animals which die (including euthanasia) at that licensed or registered facility. Necropsy records, like other medical information, will be maintained at the facility for at least 1 year or as otherwise specified in the Animal Welfare Act (AWA) regulations and standards, and be made available on request to APHIS personnel. Necropsies should be conducted within an appropriate interval after the death, and/or the body should be kept at appropriate refrigerated temperatures to ensure a meaningful examination. All necropsy reports must be signed and dated by the veterinarian preparing the report.

Circumstances which may warrant necropsy performance:

-The facility is undergoing a high death loss.
-There is a significant number of unexplained deaths at the facility.
-There exists a strong chance that an undiagnosed infectious disease is present at the facility (with or without potential zoonoses).
-Circumstances around a death indicate a violation of the AWA may have contributed to the situation.

For the purposes of this policy, a “necropsy” means an appropriate post-mortem examination (which complies with currently acceptable professional standards) of the animal performed by or under the direct supervision of a

veterinarian experienced with that species which may include, but not limited to, a systemic gross pathology examination (internal and external), appropriate microbiological culture and histopathology of lesions, and other indicated testing. All results are to be recorded in the animal's medical record.

Subject: **Criteria for Licensing Hoofstock Dealers** **Policy #23**

References:
AWA Section 3
9 CFR, Part 1, Section 1.1
9 CFR, Part 2, Section 2.1

History:
Replaces six previous policies:
1. Feb. 6, 1991 - Criteria for Licensing an Exotic Animal Breeder
2. April 4, 1991 - Policy for Licensing an Exotic Animal Breeder
3. June 19, 1991 - Agriculturally Used Animals and the Animal Welfare Act
4. July 1, 1991 - Licensing of Exotic or Wild Animal Breeders
5. Sept. 26, 1994 - Farm Animal Issue
6. Oct. 13, 1998 - Criteria for Licensing Hoofstock Dealers

Justification:
The policies listed above were in need of consolidation, coordination, and clarification.

Policy:
This policy covers all hoofstock. "Hoofstock" is defined to mean any hoofed animal; e.g., deer, llama, sheep, pig, etc.

Persons selling hoofstock may or may not require licensing as dealers. The following criteria should be used to determine whether a dealer's license is required:

- The sale must be for regulated purposes.
- Sales of wild/exotic hoofstock for biomedical research, exhibition or as a pet are considered to be regulated.
- Sales of wild/exotic hoofstock to game ranches, or to private collectors for breeding purposes only, are not regulated.
- Sale/Consignment of wild/exotic hoofstock to exotic animal markets is not regulated unless final disposition of the animal is known to be for a regulated purpose at the time of consignment.
- Sales for agricultural purposes or to improve food and fiber production are exempt.

- Persons selling farm animals (e.g. sheep, goats, pigs, cattle, llamas) must be licensed as dealers if two criteria are met: First, they must have sold more than 10 animals in a 12-month period for regulated purposes. Second, the animals sold for regulated purposes must represent a majority of all of the animals they have sold in that 12-month period.

- Generally, farm animals are regulated only for purposes of biomedical research, nonagricultural exhibit, or dealing as defined above. Horses are regulated only when used for biomedical research.

Subject: **Adequate Enclosures for Flying Species and Aquatic Species** **Policy #24**

References: AWA Section 13
9 CFR, Part 3, Section 3.128

History: Regulated flying species and aquatic or semi-aquatic species are covered under Subpart F.

Justification: The unique biological and physiological needs of these species require clarification of their space requirements as set forth under the general language of Section 3.128.

Policy: Subpart F species that fly (i.e., bats) must be provided with sufficient unobstructed enclosure volume to enable movement by flying and sufficient roosting space to allow all individuals to rest simultaneously.

For Subpart F species that, under natural conditions, spend a significant portion of their time in water (such as capybaras, beavers, river otters, hippopotami, tapirs, etc.,), compliance with space requirements will necessitate both dry and aquatic portions of the primary enclosure, each of which must, at a minimum, provide sufficient space to allow each animal therein to make "normal postural and social adjustments with adequate freedom of movement."

"Normal postural and social adjustments" and "adequate freedom of movement" are to be determined according to what is normal for that species under natural conditions. The spaces provided must, within each enclosure portion, comfortably accommodate species-typical postures, postural adjustments, and movement.

For example, hippopotami are known to be aquatic during daylight hours and often submerge completely for long periods, sometimes walking underwater, often floating without standing. However, at night, they become terrestrial and graze on the ground. Thus, an amount of space that permits "adequate freedom of movement" and "normal postural and social adjustments" must consist of dry and aquatic areas that each allow for at least minimal locomotion of the kind that hippos would normally engage in within that medium.

Aquatic areas of primary enclosures shall not contain water which would be detrimental to the health of the animals in those enclosures.

This policy is not meant to cover marine mammals, whose requirements are delineated in Subpart E.

Subject: **Proper Diets for Large Felids** **Policy #25**

References: AWA Section 13
9 CFR, Subpart F, Section 3.129

History: This is a new policy statement.

Justification: To clarify what is considered acceptable nutritious food for large felids (lions, tigers, cougars, pumas, jaguars, leopards, snow leopards, clouded leopards, and cheetahs).

Policy: The diet for large felids must be wholesome, palatable, and free from contamination. A number of commercially prepared diets are available which are appropriate for the varying needs of large exotic felids. If such diets are not used, the attending veterinarian--preferably in consultation with a nutritionist--must approve, in writing, a nutritionally complete alternative diet. The written diet is to specify the type, quantity, and frequency of any nutritional supplements. A diet composed exclusively of poultry necks or red muscle meat is not nutritionally complete, and will result in metabolic disease and severe structural damage, if not the death of the animal. A diet based on muscle meat alone will result in a vitamin A deficiency.

The feeding of road kills should be discouraged. If they are used, they must be fresh, wholesome, and fed as soon as possible. The carcass must be removed when spoilage begins, or 12 hours after it has been placed into the enclosure. If not immediately fed, it must be processed into smaller pieces and frozen for future use. Sick animals, or animals that have died of illness or unknown causes, must not be used for food. Animals euthanized with chemical euthanizing agents must not be used for food because of the danger of poisoning. When food animals have been euthanized by gunshot, the lead shot should be removed to prevent lead poisoning from ingestion of the pellets. Downer animals exhibiting signs of central nervous system disorders, including dairy and beef cows, horses, other livestock (particularly sheep), and wildlife species, must not be used for food because of the risk of transmissible spongiform encephalopathies. This includes animals suffering from scrapie and any chronic wasting disease. If the downer animals were clearly harvested because of physical injuries only, they may be used for food when properly processed. In addition, animals known or suspected of being affected with Johne's disease should not be fed to large felids.

Adherence to a strict feeding schedule is strongly recommended. Scheduled feedings will result in the animals consuming the meal more quickly, decreasing the time for potential spoilage. Meals should be of proper proportions, to facilitate consumption before they spoil or become contaminated. If spoilage does not require earlier removal, food not consumed within 12 hours must be removed and disposed of properly. Stored meat must be refrigerated, or wrapped and frozen. Frozen meats must be handled appropriately to prevent contamination; i.e., thawed under refrigeration. Bakery products are not to be fed since felids do not have the enzymes necessary to digest food with a high carbohydrate content. Outdated meats from grocery stores may be fed if kept refrigerated or frozen until used. If fish are provided as a part of the diet, appropriate vitamin E and thiamine supplementation is required to compensate for thiaminase and high polyunsaturated fatty acid content.

In order to mimic natural feeding behaviors and when approved by the attending veterinarian, animals may be fasted for 1 or 2 nonconsecutive days per week. During fasting, long femur bones, oxtails, horsetails, or rawhides should be fed in order to promote periodontal health and provide an opportunity for the animals to engage in more natural feeding behaviors. This is a good practice even when the animals are not fasted.

If young felids are not kept with the dam until weaned, a balanced formula and an appropriate feeding schedule should be approved in writing by the attending veterinarian.

Subject: **Regulation of Agricultural Animals** **Policy #26**

References: AWA Section 13
9 CFR, Part 3, Subpart F

History: Clarifies existing internal policy.

Justification: The Animal Welfare Act (AWA) regulations cover farm animals that are used in activities that are regulated by the AWA.

Policy:

Farm animals, such as domestic cattle, horses, sheep, swine, and goats that are used for traditional, production agricultural purposes are exempt from coverage by the AWA. Traditional production agricultural purposes includes use as food and fiber, for improvement of animal nutrition, breeding, management, or production efficiency, or for improvement of the quality of food or fiber.

Farm animals that are used to manufacture and test veterinary biological products intended for use in the diagnosis, treatment, or prevention of diseases in agricultural animals are, therefore, exempt from U.S. Department of Agriculture's (USDA) regulatory authority under the AWA. USDA considers this use to be agricultural research, thus, not a regulated activity.

Farm animals that are used to test and produce biologicals for nonagricultural or nonproduction animals are covered by Part 3, Subpart F of the regulations. We consider this to be nonagricultural research and testing that is covered by the AWA and the regulations. As such, when farm animals are used to test or manufacture vaccines, bacterins, toxoids, and other related veterinary biologicals that will be used exclusively in nonproduction animals such as dogs and cats and other pet animals, or in both nonproduction, as well as, farm animals, they are regulated and monitored for compliance with the regulations. An example of the latter may include rabies vaccine or other product that has a multi-species label recommendation.

Farm animals that are used as models for human subjects in order to test or manufacture biologicals that will ultimately be used in humans are also regulated. USDA considers this to be biomedical research which is a regulated activity.

Subject: **Capture Methods of Prairie Dogs** **Policy #27**

References: AWA Section 13
9 CFR, Part 2, Section 2.131(a)(1), and Section 2.126

History: Provides requested guidance. Replaces Policy #27 dated February 9, 2001. Policy #27 dated February 9, 2001 corrected typographical error in the first sentence under Policy: from "9 CFR, Part 2, Section 2.13(a)(1), to 9 CFR, Part 2, Section 2.131(a)(1)." Policy #27, dated November 17, 2000, replaced previous Policy #27 dated February 23, 1999.

Justification: Additions to this policy clarify the use of water and alternative methods for capturing prairie dogs, and adds the requirement for an itinerary. Methods used to capture prairie dogs from natural habitats for covered purposes must be done in a humane manner.

Policy: As required by Section 13 of the Animal Welfare Act (AWA) and further explained in 9 CFR, Part 2, Section 2.131(a)(1), handling of animals must be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort. The introduction of chemicals or noxious gas into prairie dog burrows will be considered a violation of Section 2.131(a)(1).

Capture methods for prairie dogs must be approved by the Animal Care Regional Director. The licensee or applicant must request approval by providing a detailed written description of the methods of capture. Changes in the capture method used by a licensee will also require approval. An Animal Care Inspector or Veterinary Medical Officer must validate that the described method does not cause unnecessary discomfort, harm or behavioral stress to the animal. Possible signs of distress with any capture method may include agitation, sneezing, coughing or difficulty breathing. The animal should remain bright, alert and free from any injuries after capture. Normal behaviors should be displayed by the animal soon after capture.

The use of water is not necessarily prohibited by this policy if such use complies with Section 2.131(a)(1). The water must be natural water (without added chemicals or noxious gas) that is introduced into a burrow at a temperature, volume, and speed that does not harm or distress the prairie dogs.

The use of certain vacuum equipment is not necessarily prohibited by this policy if such use complies with Section 2.131(a)(1). The vacuum method

must assure that minimal suction pressure is used and the animal travels a short distance from the burrow to catch basket and is quickly removed from the catch basket upon capture.

Live trapping of prairie dogs must only be done with humane traps that do not injure the prairie dog upon capture. The traps must be checked with sufficient frequency to assure that the animal does not go without food, water or shelter for a unnecessary period of time.

To comply with 9 CFR, Section 2.126, an itinerary of capture dates and sites must be provided to the appropriate Animal Care Regional Office at least two days prior to collection.

Subject: **Licensing Sales of Dead Animals** **Policy #28**

References: AWA Section 1(b)
9 CFR, Part 1

History: This is a new policy statement.

Justification: The definition of "dealer" in the Animal Welfare Act (AWA) states that a dealer "is any person who . . . buys or sells . . . any dog or other animal whether alive or dead for research, teaching, exhibition, or use as a pet . . . ." Some confusion has arisen concerning when sales of dead animals should be regulated to meet Congressional intent. Section 1(b) of the AWA clearly states that the intent of the Act is:

(1) to ensure that animals intended for use in research facilities or for exhibition purposes or for use as pets are provided humane care and treatment.

(2) to protect the owners of animals from the theft of their animals by preventing the sale or use of animals which have been stolen.

In order to meet these goals, we must ensure humane euthanasia of all covered live animals. Therefore, persons who acquire live animals, kill them, and then sell them for covered purposes must be licensed. Regulatory coverage of animals that are already dead when obtained is aimed at preventing stolen pets from being sold for covered purposes. Since pounds are an unlikely source of stolen animals, persons who obtain dead dogs/cats from pounds do not need to be regulated. Likewise, dead animals obtained from USDA licensed dealers come from a documented source and requiring further regulation would serve no purpose. This policy is to clarify when persons who sell dead animals or animal parts need to be licensed.

Policy: The following persons who sell dead animals or animal parts **do** require a license:

(1) Any person who acquires any live covered animal that subsequently dies and is then sold for research, teaching, or exhibition.

(2) Any person who acquires a dead dog/cat (or parts) from any source

other than:

a) a USDA licensed dealer

b) a municipal, county, or state pound/shelter and then sells the dog/cat for research, teaching, or exhibition.

Any person who acquires a dead dog or cat from a private, unlicensed source is required to obtain a USDA license to sell that animal for covered purposes.

The following persons who sell dead animals **do not** require a license:

(1) Any person who acquires an animal (other than a dog or cat) that is already dead and then sells it.

(2) Any person who acquires a dead dog or cat from a USDA licensed dealer or municipal, county, or state pound/shelter and then sells it.

Subject: **Farm Animals Used for Nonagricultural Purposes** **Policy #29**

References: AWA Section 2, 13
9 CFR, Part 3, Subpart F

History: This is a new policy. Farm animals used in activities regulated under the AWA are maintained in both agricultural and nonagricultural environments. Animal Care inspectors, the research and exhibition communities, as well as other members of the public, have requested that we provide more specific guidance than what the regulations contain for the humane care of farm animals used in regulated activities.

Justification: The AWA authorizes APHIS to regulate farm animals, such as cattle, sheep, pigs, and goats, when the animals are used for biomedical or other nonagricultural research or nonagricultural exhibition. In light of the increased use of farm animals for covered purposes and because the needs of farm animals can be different from other kinds of animals typically used in research and exhibition, we developed this policy.

Policy: This policy offers guidance on how regulated entities can comply with the standards in the regulations as they apply to farm animals. Animal Care has adopted two guides, the "Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching," published by the Federation of Animal Science Societies, and the "Guide for the Care and Use of Laboratory Animals," published by the Institute for Laboratory Animal Research (ILAR). The two publications are commonly known as the "Ag Guide" and the "ILAR Guide," respectively.

We adopted these two specific guides because they represent the most current scientific information available on handling, housing, care, treatment, and transportation of farm animals for nonagricultural purposes. They are widely used, are the most complete guides available, are relatively inexpensive and easily obtained, and are being used by most institutions that receive funding from the Public Health Service or are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International).

The Ag Guide contains recommendations to ensure the humane care of farm animals that are maintained in agricultural or typical farm-like settings. It contains principles that apply to all farm animals, as well as species specific recommendations. The ILAR Guide is a general guide that recommends practices that may be applied to the care and use of farm animals when they are housed in typical laboratory settings.

Regulated entities may use applicable sections of the guides to supplement their understanding of how to meet the standards in the regulations. Use of these guides should help ensure consistent enforcement by Animal Care inspectors

Adoption of these guides is intended only as additional guidance on how to meet the already existing standards in the regulations. They are to be used only to supplement or interpret the regulations. Both guides contain recommendations concerning animals such as poultry and areas such as environmental enhancement and individual animal identification that are not covered or required under the regulations. Those portions of the guides that do not relate to or support the current standards in the regulations cannot be enforced by Animal Care inspectors. At the same time, nothing in the guides will be used to reduce or lessen any of the requirements in the current regulations.

As there are other published guides, as well as other sources of information that provide recommendations on the humane care of farm animals in various settings, licensees and registrants may use recommendations from other sources, as long as the chosen practice satisfies the standards in the regulations.

All Animal Care inspectors have been provided these guides; however, since they are not published by APHIS, we cannot provide copies to the public. To obtain a copy of the Ag Guide and ILAR Guide contact the the following:

Ag Guide
Federation of Animal Science Societies
111 North Dunlap Avenue
Savory, IL 61874
217-356-3182
($10 per copy)
3313

ILAR Guide
National Academy Press
2101 Constitution Avenue NW.
Lock Box 285
Washington, DC 20055
1-800-624-6242 or 202-334-
($9.95 per copy)