Breaking the Law II, Animal Care in U.S. Labs:

Government Sanctioned Negligence

By

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Introduction

While the use of animals in laboratories has been a controversial subject for decades, virtually everyone concerned with this subject agrees that animal experimentation should be regulated. This regulation began in 1966 with the advent of the Animal Welfare Act (AWA). This law regulates many situations in which animals are used including exhibition, sale, transportation, and experimentation. The act has been amended several times in the interim to allow for things like exercise for dogs and environmental enhancement for primates. The AWA is enforced by the Animal Care division of the Animal and Plant Health Inspection Service of the United States Department of Agriculture (USDA/APHIS/AC).

The existence of this law is not in question. However, the enforcement of this law is open to discussion. A recent audit of USDA/APHIS/AC by the Office of the Inspector General (OIG) found:

“Due to a lack of clear National guidance, AC’s Eastern Region is not aggressively pursuing enforcement actions against violators of the AWA. We found that regional management significantly reduced its referrals of suspected violators to IES from an average of 209 cases in fiscal years (FYs) 2002-2003 to 82 cases in FY 2004. During this same period, regional management declined to take action against 126 of 475 violators that had been referred to IES. In contrast, the Western Region declined action against 18 of 439 violators.”

The full summary of the OIG audit is in Appendix A of this report.

This finding is cause for concern because many large and well-known laboratories are located in the Eastern Region of the U.S. This report was dated September of 2005, but it dealt with information from the 2002 – 2004 time period. The elapsed time since this report should have allowed USDA/APHIS/AC to implement changes which could improve AWA enforcement.

This report examines enforcement of the AWA since the OIG Audit of 2005. Inspection reports for 163 registered research facilities were examined which covered the nine month period from January 1, 2005 to October 3, 2005. These documents were obtained through the Freedom of Information Act.
During 2005 the number of violations of laboratory specific violations increased during 2005 (1,780 violations) by 53.7% from 2002 (1,106 violations). The majority of these violations were in the areas of Institutional Animal Care & Use Committees (1,116). For details of these violations see Appendix B.

In general the findings for the 163 laboratories used in this study were spread across a broad spectrum. 61 of these facilities either had no non-compliances during this period, or had no regulated animals when inspected, and so were not really inspected.

The remaining laboratories had a wide range of violations. 63 of the remaining 102 facilities had 3 violations or less. However, these facilities do not represent institutions where all was well. For Example, the Southern Research Institute, with only 2 violations had a very serious infraction:

***An incident occurred where two dogs were inadequately fed during a two week period. One dog lost about 38% of its body weight and the other lost about 24% of its body weight. The dramatic weight loss should have been recognized and brought to the attention of the veterinarian. It was not documented that the animal caretaker was trained to recognize conditions and illness in animals that would require the attention of the Veterinarian. All employees that handle the animals should be adequately trained and proper documentation to that effect should be maintained to insure proper handling and care of the animals. Corrective and preventive actions put in place as a result of the incident are satisfactory.

Other institutions having only a small number of violations should also be of major concern. The University of Chicago is one such facility:

Protocol #71565 (previously identified as # 71127) - Principal investigator has not followed the approved protocol. The fluid control description provided in the protocol (Supplement Form L) states that when a six percent or more decrease in weight occurs, the veterinary staff will be notified. The protocol also states that when an eleven percent or more decrease in weight occurs, that the animal will be placed immediately on “ad libitum” water for at least two days and a veterinarian will be consulted. The June 2005 records for monkey # 607923 show that this animal had a weight loss greater than 6% on 6/21, 6/22, 6/23, & 6/30 and had a weight loss greater than 11% on 6/27 and 6/29 (calculated by using the animal’s average weight while under fluid restriction during the month of May 2005). Although animal #607923 had a weight loss greater than 11% on 6/27 and 6/29 the principal investigator did not immediately place it on “ad libitum” water. The veterinarian was consulted on 30 June 2005 when the principal investigator’s staff reported an approximate 6% "weight loss" on that day. Medical record entries made by the veterinarian on 30 June 2005 indicated that the animal was observed and appeared to be clinically healthy.

In other words, one primate had as much as an 11% loss of body weight due to being deprived of water. This is similar to a 150 lb human losing 17 lbs due to thirst. Clearly, this is a very significant situation.

Another such situation existed at Penn. State University:

Animal activity proposal #20562 describes withholding food for up to 2.5 months to induce hibernation. The principal investigator provided justification for withholding the food but did not acknowledge that the animals will experience unrelieved distress. Food deprivation is considered unrelieved distress. The proposal also does not include a description of how the animals will be monitored during the food deprivation to ensure their health. The principal investigator must address the unrelieved distress caused by food deprivation and describe how the animals will be monitored to assure their health is maintained. This proposal may not be funded.

The 103 laboratories within the study group violated the Animal Welfare Act a total of 487 times, an average of 6.3 times per year. The majority of the violations took place in the areas of Institutional Animal Care & Use Committees (176), Housing/Facilities (166 – this category is a combination of several areas) and Veterinary care (75). Collectively these three categories accounted for 417 (85.6%) of the violations.
The Top 20 AWA Violators

The top 20 violators of those used in this report are listed in Appendix C. The top 20 labs violated the AWA 271 times in nine months, averaging 13.6 violations per facility. These 20 labs accounted for 55.6% of all the violations recorded by 103 facilities. It is interesting to note that 19 of the top 20 were in the Eastern Region of the United States, including all of the top ten facilities. The top 10 facilities average 17.7 AWA violations per 9 months, or 1 infraction every two weeks. It is significant that none of these facilities have had enforcement actions taken against them by the USDA.

Additionally, the USDA FOIA office did not provide inspection reports due to open investigations, preliminary to enforcement actions, for 5 registered research facilities. These facilities were: the University of Colorado (Denver), the University of Hawaii (Manoa), the University of Louisiana (Lafayette), Lovelace Respiratory Research Institute, and SNBL. It is very significant to note that these five laboratories are all located in the Western Region of the U.S.

The top twenty violators discussed in this report cover a broad spectrum of entities. They include twelve universities (Harvard is mentioned twice because there are two registrations at Harvard – the Medical School and the University), a private research institute, a pharmaceuticals company, and several private testing laboratories. Details of all violations for the top 20 facilities are available on the SAEN website in the facilities reports and information section at: http://www.all-creatures.org/saen/res-fr.html. This next section of this report will focus on the most egregious violations at the top 10 labs.
Specific Facilities

The Covance (PA) amassed 27 violations in the areas of veterinary care, IACUC, and Housing. Incidents at this Covance facility caused intense suffering to rabbits and dogs. These violations included incidents such as (8/15/05):

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33(b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter.

Section 2.33 (b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

1. Since June 10, 2004, the research facility has failed to ensure that a doctor of veterinary medicine was available to provide adequate veterinary care to the rabbits and other animals which have undergone surgical procedures and/or have been housed in Building 4.

2. Building 4, Animal Facility, Animal room 107, housing 60 rabbits.
   a. Rabbit DV58, involved in a surgical procedure on June 16, 2005, was observed by the APHIS official to exhibit signs of discomfort, repeatedly licking at the right flank surgical area. Available information failed to provide evidence that the rabbit had been examined or evaluated by a doctor of veterinary medicine for possible postoperative discomfort, pain and/or distress since the procedure was conducted.
   b. Rabbit DV84, involved in a surgical procedure on July 21, 2005, was observed by the APHIS official to be wearing an Elizabethan collar with signs of possible bleeding and delayed healing beneath a clear bandage. Available information failed to provide evidence that the rabbit had been examined or evaluated by a doctor of veterinary medicine for wound healing and possible postoperative discomfort, pain and/or distress since the procedure was conducted.

And on 1/18/05:

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(vi) Medical care for animals will be available and provided as necessary by a qualified veterinarian;

Dogs with chronic food restrictive devices implanted are transferred to a holding facility in central California. A dog on this study was identified as "CVRRIFE" when brought into the institution at 7 months of age weighed 19.3 kgs. The restrictive device was placed in the animal on October 21, 2004, and on December 2, 2004 the animal was sent to the holding facility weighing 14.4 kgs. It was returned to Covance on December 28, 2004 weighing 13.5 kg at or near the end of the study. During this inspection on January 18, 2005 the animal weighed 13.7 kgs. There was no documented medical care provided to the animal for the significant weight loss. The animal was brought back to the facility for a protocol related procedure and the significant weight loss was not indicated as a problem in the animal's record. An animal with a 30% or more weight loss must be identified as an animal in need of veterinary medical evaluation by either the holding facility or the research facility. Any significant amount of weight loss associated with this protocol must be evaluated and treated by the veterinary staff. If weight loss goes unmonitored or untreated these animals must be placed in category "E" unrelieved pain and or distress.

Other incidents occurred at Covance involving depriving dogs and pigs of food (same date):

Protocol 1152 placed food restrictive devices in dogs and pigs without adequate provisions for post-procedural care, i.e.; significant weight loss in chronic food restrictive device instrumentation. Animals had the devices implanted and within several weeks were transferred to holding facilities for 30, 60 or 90 days. The protocol did not have any descriptions of procedures designed to assure that discomfort and or distress associated with food restrictive devices. Reduction in amount of food intake would cause a loss of weight over the entire period of time the food restrictive device is in place. The significant weight loss identified in the animal described below on this study was not a factor considered or described in the protocol and provisions were not described to provide supportive care to any emaciated or abnormally thin animals after they were transferred to the holding facility.

The animal described above that went from a starting weight of 19.3 down to a low of 13.5 and was never identified or treated as an animal in distress. The condition of the animal does not appear to be a consideration described in the protocol. The animal's condition should be of a major concern to the IACUC and the institution. The protocol and/or attending veterinarian must include in the protocol some parameters for terminating the study if an animal loses a significant amount of weight.
Charles River Laboratories piled up 22 violations in the areas of veterinary care, facilities/housing, and Institutional Animal Care & Use Committee. Testing at Charles River caused unrelieved pain and distress to many animals causing killing 21 animals and forcing the killing of 20 more. These violations include (7/5/05):

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).
Section 2.31(d)(1) IACUC: The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:
(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description of the methods and sources used to determine that alternatives were not available;
(iv) Procedures that may cause more than momentary or slight pain or distress to the animals will: (A) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time.

The IACUC is still approving animal activity proposals from principal investigators that do not address the potential animal pain or distress from or as the result of the test drug and/or procedures.

(2) The following animal activity proposals reviewed during this inspection were approved by the IACUC as studies for testing drugs not causing pain or distress in animals: proposals ZPS00014, ZPS00016, VGJ00002, ARY00006, and TZE00003. The principal investigators did not address adverse reactions to the test drug, did not include pain/distress relief or provide written scientific justification for withholding treatment. The principal investigators did not provide any written narrative description of the methods and sources used to determine that there were no alternatives to the potentially painful/distressful procedures.

Proposal ZPS00014: The first portion of the proposal, part A, resulted in 3 animals found dead and 2 moribund sacrifices. The proposal was not amended by the principal investigator to address the adverse effects of the test drug and the potential animal pain and distress before the second portion of the proposal, part B, was conducted. Part B of the proposal resulted in 18 animals found dead and 18 moribund sacrifices.

And (same date):

Section 2.31(e)(4) IACUC: A proposal to conduct an activity involving animals must contain a description of procedures designed to assure that discomfort and pain to animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, including provision for the use of analgesic, anesthetic, and tranquilizing drugs where indicated and appropriate to minimize discomfort and pain to animals.

The principal investigator for animal activity proposal OJA00014 indicated that animal pain and distress would be relieved by stoppage of treatment and/or sacrifice of the animal. Animals #1736 and #1737 were noted by the veterinarian on 6/15/05 to have the following clinical signs: in lateral recumbency; lost righting reflex; oculo-palpebral corneal and pupil reflexes present; respiration irregular and tachypneic; forelimbs, thorax and neck muscles hypertonic; hyper-reacting to palpation with twitches and opisthotonus; cold extremities and red congested conjunctiva mucous membranes.

Animals with these signs would be expected to be experiencing at least more than momentary or slight distress. This was suspected to be a drug effect and the animals received no treatment and continued on the study. A review of the summary of the clinical observations showed other animals exhibited similar signs. There was only 1 moribund sacrifice.

Principal investigator must follow their approved animal activity proposal. Animal pain/distress must be relieved as indicated in the proposal. Unrelieved animal pain/distress must be justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time.
Violations in the area of inadequate veterinary care included an untreated broken leg in a rabbit and another rabbit who had a 16.5% weight loss in 9 days (same date):

The following animals did not receive adequate veterinary care.

(1) Rabbit #9565 was suspected of fracturing its leg on Sunday, January 9, 2005. No treatment was administered and the veterinarian was not informed until Monday, January 10, 2005. The animal was diagnosed with a fractured leg and euthanized within the hour.

IACUC paper work reviewing the incident indicated that the rabbit was not in pain or distress; was properly cared for and no other action was required.

(2) Rabbit #1595 was not brought to the attention of the veterinarian until Monday, June 20, 2005. The rabbit had the following clinical signs: a 16.5% weight loss over 9 days, no food consumption for 5 days, the rabbit was thin, sits facing the rear of the cage, and perinasal fur appears uncombed.

This animal was not brought to the attention of the veterinarian until after the weekend. This rabbit has significant clinical signs and the veterinarian should have been informed more promptly.

This facility is also cited for inadequate enclosures which caused serious injuries to dogs (7/21/05):

- Many of the animals in room 505 had interdigital lesions consisting of redness, swelling, and fluid drainage. Eight out of ten observed had varying degrees of these lesions -- one dog had only a slight swelling on one frontlimb, while dog #4008453 had all four paws affected with a mucopurulent material draining from a enlarged lesion on the left rear paw. There was a total of 48 animals in this room. These animals were housed on an expanded wire covered with rubber or hard plastic commonly known as hog flooring or tenderfoot flooring. Resting boards were placed in two of the enclosures but were not helping the situation -- all four animals in these two enclosures had interdigital lesions. All enclosures must be constructed so the floor protects the animals feet from injury. These animals must be placed on a surface that does not cause these interdigital lesions.
The University of Wisconsin accumulated 20 violations in the areas of veterinary care, housing and IACUC. This laboratory tied for the most repeat violations (7) of any facility in the study group. A dog at the UW went untreated until he/she became almost skeletal and died. These infractions included (7/19/05):

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

............(3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian;............

**At 7:00 a.m. on July 5 in Building G, dog #458783 was found dead in the kennel by animal care staff. According to the necropsy report dated 7/5/05, the cause of death was severe end stage renal disease with uremia. The gross necropsy findings indicated the animal weighed 10.89kg (24.5lb),"showing prominent skeletal structure and sunken in eyes, with little to no subcutaneous fat." Upon review of the clinical records for #458783, several discrepancies were apparent:

*3/18, 5/4, 5/7 and 5/15/05 - notifications were made indicating vomit being present in the kennel.
*5/10/05 - a notation was made indicating vomiting and weight loss (18.5 kg to 17.2 kg).
*5/19/05 - although blood was drawn by the research staff which showed abnormal kidney values (BUN 178 mg/dl) no notation was made in the clinical record. Neither the principal investigator nor the attending veterinarian were notified of the health status of the animal.
*6/12, 6/30/05 - clinical records indicate the dog was still "vomiting, not eating and appeared dehydrated and thin." No notation by animal care staff to contact the attending veterinarian and/or research staff.
*7/4/05 - a notation was made by animal care staff at 10:30 a.m. indicating the dog was in distress; "panting heavily, unresponsive to sound and movement, vomit present in kennel, appearance that of skin and bones." 11:30 a.m. - research staff noted "animal lethargic, weighed 14.8 kg, will consult attending veterinarian and bloodwork." There is no notation in the clinical records indicating a veterinarian was contacted to examine the animal.
*7/5/05 - 7:00 a.m. dog #458783 was found dead in kennel.

And on 5/26/05 UW staff caused severe pain to a primate instead of calling for veterinary help:

(f) Handling.

(1) Handling of all animals shall 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..........................

***In Building L, the USDA inspector observed animal care staff attempting to release an animal #r04046's arm through the front of its enclosure. After the lead technician was located and came to the site, he applied lube and started to manipulate the arm in an attempt to free the animal. The arm was obviously swollen and within a few seconds of manipulation, the animal began to vocalize. The lead technician persisted in manipulating the arm until the USDA inspector asked him to stop and call for assistance from the attending veterinarian. Handling of all animals shall be done in a manner that does not cause trauma, physical harm or unnecessary discomfort. The attending veterinarian anesthetized the animal and bolt cutters were used to release the arm.
(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

....(3) Daily observation of all animals to assess their health and well-being: Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian;

***In Building L, upon entering an animal room this USDA inspector noted animal #04046 appeared to have its arm stuck through the front of its enclosure. Upon further investigation, it was determined that the animal was unable to free its arm. A later review of the animal’s medical records revealed that the right arm had been trapped outside the enclosure on at least 5 previous occasions. The animal has been treated for swelling and/or trauma to the right arm and/or hand since 8/21/04. Although the veterinary staff had been treating the animal, the attending veterinarian was unaware of the persistence of the problem and no plans had been discussed to address the problem. Mechanism of direct and frequent communication is

Housing for animals was also an issue (same date):

**HOUSING FACILITIES, GENERAL.**

(a) Structure: construction. Housing facilities for nonhuman primates must be designed and constructed so that they are structurally sound for the species of nonhuman primates housed in them. They must be kept in good repair, and they must protect the animals from injury, contain the animals securely, and restrict other animals from entering.

***Building M: several rooms (Socializing room, Big Socializing Room, Basement Wash Area), had pipes with exposed insulation; Room 250: one animal enclosure had exposed insulation directly over it. Numerous rooms (Rooms 41,45) had air intake filters in need of cleaning. Upon further inquiry, the staff indicated the filters were to be cleaned weekly though that was not indicated on the log. Room 51: the automatic flush system had not been operational for over a month resulting in increased amounts of fecal material in the pans under the animal enclosures. Room 41: several pipes over animal enclosures contained peeling paint which could result in paint chips falling into the enclosure.

Animal(s) affected: (15) Rhesus macaques
The Boehringer Ingelheim pharmaceutical company had 19 violations in the areas of veterinary care, housing, IACUC, etc. These violations include incidents wherein a dog on study lost 27% of his/her body weight in 35 days with a fever of 103 – 106 degrees (5/4/05):

2.31 (d) (1) (iv) (A) - "the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements....(iv) Procedures that may cause more than momentary or slight pain or distress to the animals will.....(A) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time."

1. Dog #1654 was on study under Protocol #01-66-D during the time of the inspection. The inspector observed the animal recumbent and shivering in its enclosure on 5/4/05. According to personnel, the animals run a fever at this stage of the study and the fever is managed with supportive measures including ice packs and the application of rubbing alcohol to ears and foot pads. According to the dog's medical record, the dog's weight was 12.9 kg when the study began on 4/5/05 and the dog weighed 9.4 kg on 5/9/05 which is a 27% weight loss in 35 days. The dog experienced elevated body temperatures ranging from 103 to 108 degrees F for 24 to 48 hour periods of time on 4 separate occasions after beginning the study. There were multiple notations in the dog's record that it did not eat during the febrile episodes. The combination of recurrent episodes of elevated body temperature with inappetance in Dog #1654 would be considered to be distressful to the animal. The progressive and steady weight loss documented in this dog is further evidence of distress. There was not a search for alternatives to the condition of the unrelieved distress experienced by the animal. This protocol had been categorized as USDA Pain Category "D"; however, this dog did not receive any specific measures to alleviate its distress and this animal should be considered to be a USDA Pain Category "E" animal. The PI must provide justification for withholding appropriate agents from the animal and the facility must include the explanation under Column "E" when submitting their Annual Report for FY2005 as required under 2.36 (b) (7). The PI must provide the required information to the IACUC for review. Correct by July 1, 2005.

Veterinary care violations included another incident where a primate lost the skin off both hands leading to finger amputation (same date):

2.33 (b) (3) - "Each research facility shall establish and maintain programs of adequate veterinary care that include.....(3) Daily observation of all animals to assess their health and well-being.....a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian."
And in the area of animal handling episodes led to the scalding death of a monkey in a
cage washer, a beagle asphyxiated, a rhesus monkey developed a hemothorax due to improper
handling, and another monkey was burned due to negligence (same date):

2.38 ( f x 1 )
MISCELLANEOUS.

"Handling of all animals shall 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 following animal handling incidents were noted to have occurred at the facility. Animals must be handled in a
manner that does not cause physical harm. This requirement was not met in these incidents. The facility needs to ensure
that animal handling practices are improved to prevent additional incidents. Correct from this day forward.

1. It was learned during the conduction of the inspection that a Squirrel NHP had died in November 2001 after going
through the cage washer in area 3. The facility no longer any written records available pertaining to this incident. On 6/1/04
Rhesus NHP #831 died after going through the cage washer after three different employees had checked the cage before it
was put through the cage washer in area 9. Five employees attended training sessions on 6/4/04 and 6/7/04. In addition it
was learned that a Rat died on 8/30/04 after going through the same cage washer in area 9.

2. Beagle Dog #1855 was found dead in its cage on 4/5/04. The front half of the dog's body had passed through the
vertical bars of the enclosure door and the animal was wedged between the bars. The cause of death was presumed to be
asphyxiation but no post mortem examination was performed. It was learned that the dogs in that room were individually
housed but Dog #1855 had been observed days earlier inside the enclosure of the dog next door but this was not reported.
Modifications to the caging were made within one day after the dog was found dead.

3. Rhesus NHP #588 was found dead in its enclosure on the morning of 10/30/04. The animal had been fitted with a
collar and micro chip on 10/28/04 and had been squeezed in its cage during the afternoon of 10/29/04 to scan the micro chip.
Personnel commented that the NHP was overly fractious and uncooperative at the time of handling. A post mortem
examination attributed the cause of death to be hemothorax related to self inflicted trauma or due to difficulties associated
with the handling of the animal.

4. Cyno NHP #497 sustained a thermal injury on both hands after undergoing a procedure on 9/2/04 that included
anesthesia. The thermal injury resulted when supplemental heat was provided to the animal using both an electrical heat
fan and a heat lamp. It was also learned during the course of the inspection that a NHP had received a thermal injury under
similar circumstances over 5 years ago.
Harvard University piled up 18 violations in the areas of veterinary care, housing, and IACUC. It is clear that the inspector sees major problems at Harvard University, such as incorrect anesthesia in rabbits (4/7/05):

2.31 (d) (1) (xi) - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements....(xi) Methods of euthanasia used must be in accordance with the definition of the term set forth in 9 CFR part 1, Sec. 1.1 of this subchapter, unless a deviation is justified for scientific reasons, in writing, by the investigator."

1. The medical records for Rabbits #1 through #10 that were used under Protocol #93-15 during January and February 2005 were reviewed. The protocol stated that the animals would undergo anesthesia followed by euthanasia and tissue collection. The anesthesia was listed as an intramuscular injection of xylazine 5 mg/kg and ketamine 35 mg/kg, and the euthanasia agent was listed as an intravenous injection of pentobarbital 200 mg/kg (also known as Nembutal). A review of the medical records revealed that the approved regimen was not followed; a detailed discussion is found elsewhere in this report. Because of the discrepancies in the dosages of drugs administered to the animals, it is not clear whether the method of euthanasia used was in accordance with the definitions set forth in 9 CFR. The IACUC needs to re-visit this protocol to determine whether the method of euthanasia used in these Rabbits was appropriate. Correct by May 16, 2005.

and:

2.33 (b) (5) - "Each research facility shall establish and maintain programs of adequate veterinary care that include....(5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures."

1. The medical record of the Wallaby used under Protocol #25-04 in March and April 2005 was reviewed at the time of the inspection. The protocol states that the analgesic Flunixin meglumine will be administered every 12 hours for 24 hours after the completion of a minor surgical procedure. The animal underwent a minor surgical procedure on 3/23/05 that ended at 2:15PM and it received an injection of Flunixin meglumine at 2:15PM; the next injection of Flunixin meglumine was given at an unspecified time in the PM on 3/24/05. The Wallaby underwent another minor surgical procedure on 4/4/05 that ended at 2:45PM and it received an injection of Flunixin meglumine at 2:50PM; no Flunixin meglumine was administered to the Wallaby on 4/5/05, but an injection of Flunixin meglumine was administered at an unspecified time in the PM on 4/6/05 according to the medical record. A conversation with the Clinical Veterinarians at the time of the inspection confirmed that the schedule of administration of Flunixin meglumine in the Wallaby following the 2 different minor surgical procedures was not in accordance with the approved analgesic regimen stated in the protocol. The post-procedure administration of analgesics

and:

2.32 (a)
PERSONNEL QUALIFICATIONS.
"It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel."

1. Due to the non-compliant items identified on this report under Sections 2.31 (c), 2.31 (d), and 2.33 (b), it can only be concluded that the investigators from Protocols #93-15 and #25-04, as well as other facility personnel who were involved in the incident on 2/21/05 involving Rabbit #6 from Protocol #95-15 were not appropriately trained and familiar with their duties and responsibilities. The research facility needs to assure and document that these personnel undergo additional training. Correct from this day forward.
While the Harvard Medical School lines up lower in the list of violators, it seems to be most sensible to discuss the two sections of the school together. The Medical School had 14 violations in the areas of veterinary care, housing, environmental enhancement, and IACUC. These infractions included procedures that deprive primates of water and improperly anesthetize cats (6/20/05):

2.31 (d) (1) (ii) - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements.....(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources.....used to determine that alternatives were not available."

3. Protocols #02440 and #01146 describe the use of water control in NHP's. The animals receive water and fluid rewards when performing learned behavioral tasks. According to the protocols, if the animals receive a certain volume of water and fluid during the time when they are working, then they may not receive any additional fluid until the following day. The water control described in these protocols could be expected to result in more than momentary distress in the NHP's due to unrelieved thirst during the time without access to fluids and a search for alternatives would be required, but the water control described in these protocols has been listed as USDA Pain Category "C" (no more than momentary pain or distress). The IACUC needs to address this issue in these protocols. Correct by September 1, 2005.

2.31 (d) (1) (iv) (C) - "The IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements.....(iv) Procedures that may cause more than momentary or slight pain or distress to the animals will.....(C) Not include the use of paralytics without anesthesia."

1. Protocol #02440 involves the use of a neuromuscular blocking agent and isoflurane anesthesia in cats. The anesthesia records for animals used in the study were reviewed. The records do not state that the animals were under a surgical plane of anesthesia before the paralytic was added, there was no explanation given for the increases in heart rate that were recorded after the paralytic was added, the average maintenance concentration of isoflurane after the paralytic was added ranged from 0.25% to 0.75% which is a very low level when used as the sole anesthetic agent, there were no noxious stimuli applied as part of the assessment of the depth of anesthesia under paralytic, and there were comments made about the status of some of the animals during the procedure that could be associated with insufficient anesthetic depth. The IACUC and AV need to determine that the study animals are adequately anesthetized during the administration of the paralytic agent in this protocol. Correct by August 1, 2005.

And a primate death by strangulation occurred (same inspection date):

2.38 (f) (1) - "Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm."

1. An NHP died on 7/12/04 after it was left unattended while restrained in a primate chair when the investigator went to lunch. The NHP managed to gain access to the silastic tubing that supplied juice and subsequently strangled. According to the standard operating procedure for the laboratory, NHP's were never to be left unattended when restrained. Animals must be handled in a manner that does not cause physical harm. The facility and the investigator have implemented modifications in procedures and restraint equipment to ensure that another incident does not occur.
The second Covance (VA) facility totaled 16 violations in nine months. These violations were in the areas of veterinary care, environmental enhancement, housing/facilities, IACUC and misc. They included episodes where pathological conditions went untreated including broken bones and gastrointestinal tract pain (7/14/05):

2.31 (d) (1)
In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing.

***In the following studies, the Protocol Animal Care and Use Forms show the pain/distress classification as "No painful procedures anticipated." This classification includes the statement, "However, if pain is observed, appropriate veterinary services will be provided..."

- In Study D and F, the animals experienced numerous compound related effects and received no veterinary treatment.

- In Study G, animal I-57739 suffered a broken leg and received no treatment or pain relief due to study considerations.

- In Study H, the Protocol Animal Care and Use form indicates that "veterinary assistance will be obtained" for animals showing signs of toxicity, by providing "supportive care or euthanasia, as appropriate to the condition of the animal, or dosing will be stopped, as indicated by responses." However, animals I-57639 and I-57654 did not receive treatment for chronic gastrointestinal problems and pain respectively.

Since veterinary treatment was not provided to the animals experiencing pain and/or distress, these studies should have had a written scientific justification for withholding treatment that it is approved by the IACUC. This information is necessary in order for the IACUC to perform its functions effectively. Correct all active and subsequent studies in which veterinary treatment is withheld.

A draining lesion, anorexia, a severe skin condition, swollen eyes, and an unspecified injury went untreated (same date):

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

2.33(a)(2)
Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section. Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

***In the following studies, the attending veterinarians lack of authority was a cause for withholding treatment a recommended treatment, or a delay in treating or euthanizing animals.

- Study J, animal I-57607 had an infected, draining lesion on his abdomen. The study director and clinical veterinarian agreed that early euthanasia was appropriate, but the client wanted the opinions of a few IACUC members before a decision was made. Although the veterinarian was allowed to treat the animal with antibiotics and pain medication, the client and the IACUC over-ruled the veterinarian's decision to provide euthanasia and the animal remained on study for five more days until the previously scheduled day of euthanasia arrived.

- Study animal I-57739, injured himself in his cage. The veterinarian determined that the right leg had been broken and prognosis was poor, even with surgical intervention. Veterinarian recommended euthanasia. The animal remained in his cage without treatment from 4-14-05 to 4-18-05 when it was euthanized after data collection. This study had been approved by the IACUC as a study that anticipated no pain, but would allow appropriate veterinary service to be provided if pain was observed. However, the veterinarian was not allowed to use his/her professional judgment to provide adequate veterinary care.

- Animal I-56620, under Study K, was seen by a veterinarian for a laceration of a digit. The veterinarian recommended a 5 day treatment of antibiotic. The treatment was not administered.
Environmental enhancement was also an issue at Covance leading to animals with clear psychopathology:

3.81(c)
Research facilities must develop, document, and follow an appropriate plan for environment enhancement adequate to promote the psychological well-being of nonhuman primates. The plan...must address...nonhuman primates requiring special attention (such as)...infants and young juveniles... (and) those that show signs of being in psychological distress through behavior or appearance.

Special Considerations

***The plan for environment enhancement of nonhuman primates is outlined in Department Operating Procedure NA-TOPS-201: General Animal Care and Environmental/Psychological Enrichment - Felines, Canines, Primates, and Swine. This document contains no provisions for primates requiring special attention i.e. young juveniles and those showing signs of psychological distress.

***There does not appear to be an effective mechanism for identifying, documenting, and addressing animals displaying stereotypical behavior or other signs of psychological distress. Stereotypies are supposed to be entered on a Request for Veterinary Services, however, only one such request was found when the forms from Jan 2004 to the present were examined.

- In Study P, animal Z208 was noted on pre-study physical to have “alopecia from self trauma”. No evidence could be found indicating that this entry triggered a plan for consideration of special needs since over grooming can be a sign of psychological distress.
- In room 220, Study Q, 2 animals (#s I-58335 and I-58344) were observed on 3 separate occasions exhibiting stereotypical behavior, i.e. “wiping” the cage floor and “grooming” the bars at the top of the cage. No mention of this problem could be found on any documents related to this study or to these animals.
The University of Connecticut, Farmington accumulated 15 violations in nine months. These violations were primarily in the areas of housing/facilities and IACUC. They included improper anesthesia (2/7/05):

2.31 (c) (7) - "The IACUC, as an agent of the research facility, shall.....(7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities."

****Protocol #2003-025 was approved on 8/14/03 and underwent annual review on 7/29/04. The protocol involves the use of general anesthesia in cats, describes the monitoring methods during the anesthesia, and states that a maximum number of 10 procedures will be performed on the cats during a study session. Cats #78, #79, and #80 were used on 9/1/04 under this protocol. A review of the three animals' medical records from the 9/1/04 procedure revealed that a different method of anesthesia than was stated in the IACUC approved protocol was used, the monitoring of the cats under anesthesia was not as described in the IACUC approved protocol, and the number of procedures performed on each cat was not recorded to ensure the maximum number allowed under the protocol was not exceeded. It was learned from reading documents in the official protocol file and from talking with personnel about the events of 9/1/04 that some concerns were raised as a result. The IACUC needs to address the issues raised concerning the unapproved deviations of this protocol. Correct by May 1, 2005.

And:

**PRIMARY ENCLOSURES.**

"Primary enclosures (for dogs and cats) must be constructed and maintained so that they.....(ii) Protect the dogs and cats from injury."

****Cats are group housed in B2010 and allowed unrestricted access to a large portion of the room. There is a drainage trough that runs along the length of the far wall that has a floor drain in the trough that has been capped to prevent access by the cats. At the time of the inspection, people from maintenance were working on the drainage system and were forcing air through the pipes. This resulted in some noise that attracted the cats to the drain area to investigate. The inspector observed that some water was spraying up into the room from the pipes beneath the trough through holes that would be used to secure a drain cover (if the drain were not capped off) and also from around the drain itself where it was installed in the floor due to an incomplete seal. This situation could be hazardous for the cats from direct contact with any debris or any chemicals that might be in the pipes and then contained in the water spraying into the room. Correct by February 19, 2005."
Vanderbilt University piled up 13 violations of the AWA in nine months. These infractions included non-compliances in areas of veterinary care, environmental enhancement, IACUC, food/water, etc. Examples of the Vanderbilt violations include an incident where a primate was killed through negligence (5/3/05):

2.33(b) Each research facility shall establish and maintain programs of adequate veterinary care that include: (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases...

A squirrel monkey identified as Lil Wayne was found dehydrated and in a state of collapse on March 21, 2005 following water shut off during facility renovations. Available records for the squirrel monkey indicate that veterinary care was initiated at the time the monkey was found in a collapsed state and was continued for several days. The records indicate that the monkey's condition failed to significantly improve and later worsened leading to a recommendation for euthanasia. Further, available records failed to provide evidence of veterinary treatment for the period of 22 hours immediately prior to the start of the terminal procedure/euthanasia which may have resulted in discomfort, pain and/or distress for the monkey. Adequate veterinary care must be provided as long as necessary to avoid or minimize discomfort, pain and/or distress.

3.83 Potable water must be provided in sufficient quantity to every nonhuman primate housed at the facility. If potable water is not continually available to the nonhuman primates, it must be offered to them as often as necessary to ensure their health and well-being...

Conversations with APHIS officials and available records provided information regarding the shut off of the water supply to room UU housing the squirrel monkeys during facility renovations in March 2005. The water shut off directly contributed to the dehydration and collapse of a squirrel monkey named Lil Wayne on March 21 resulting in the subsequent euthanasia of the monkey. In the future, the disruption of water supplies must be coordinated with the animal care staff to ensure that water is provided to ensure the animals health and well-being.
Emory University accumulated 13 AWA violations in nine months. While the majority of Emory’s infractions were in the housing/facilities area one episode when rhesus monkeys were duct taped to restraint chairs for simple blood withdrawal illustrates the callous disregard for animals which is evident at Emory (6/14/05):

PERSONNEL QUALIFICATIONS.

c) Training and instruction of personnel must include guidance in at least the following areas:

(1) Humane methods of animal maintenance and experimentation, including:

(ii) Proper handling and care for the various species of animals used by the facility

(2) The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress

***Personnel conducting studies in NS lab 2248 were observed utilizing inappropriate restraint methods. Two Rhesus macaques were chained for a series of blood collections. The forearms/hands and lower legs/feet of each animal were secured to the frame of the chair with duct tape. There was no padding/protective layer under the tape and the fingers and toes could not be visualized. This results in animal discomfort, inability to monitor distal limbs for vascular compromise, and limited ability to quickly and safely release the animal. Questioning of the involved individuals indicates poor understanding of humane methods of animal experimentation. Personnel using animals to conduct studies must be aware of methods to minimize distress and utilize them unless scientifically justified and approved by IACUC. Correct by: 01 Jul 05.
Executive Summary

The examples of negligence, abuse, and callousness exhibited by research facility staff as recounted in the inspection report quotations contained in this document are enough to make the layman cringe in disbelief. A monkey strangled on plastic tubing at Harvard because the researcher who was in charge of the primate went to lunch. At the Boehringer Ingelheim pharmaceutical company in Ridgefield (CT) a beagle asphyxiated after becoming trapped between the bars of a cage. At this same facility a squirrel monkey died after being run through a cage washer (a repeat incident), other primates lost all the skin off their hands or sustained thermal injuries. At Vanderbilt a squirrel monkey named Lil’ Wayne was found in a state of collapse due to the shutoff of water during renovations; he was euthanized. At Emory University two rhesus monkeys were duct taped to restraint chairs for blood withdrawal. Dogs at the Southern Research Institute were starved during a two week period to the point that one dog lost more than 38% of his/her body weight. Dogs at Covance laboratories are also deprived of food. Veterinary care at many facilities is inadequate or non-existent, expired drugs are used, animals are denied proper anesthesia, primates are deprived of water, the list of abuses is both interminable and unbelievable.

The vast majority of these violations are taking place under the jurisdiction of the Eastern Regional Office of the USDA/APHIS/AC. A report published by the Office of the Inspector General of the USDA stated that this entity has drastically reduced the number of enforcement actions taken against all entities, including labs. Apparently the research institutions in his sector are using this announcement as license to ignore federal law on a wholesale level. They know that there are effectively no penalties they have taken advantage of the situation.

From a scientific point of view the information presented in this report is catastrophic. Research protocols are routinely not followed, procedures are changed or ignored, and effects of drugs are ignored. This total lack of consistency results in data is compromised, or more likely useless. Drugs are not dosed appropriately. Anesthetics are under dosed, or not used at all. The use of expired drugs is commonplace. The sloppiness and disregard for any semblance of scientific method is shocking. Companies that test therapies, drugs and procedures are so careless that animals are killed in the process of cleaning cages. Prestigious universities maim and kill dogs and primates out of sheer negligence. The American public should be appalled at the reality of life and death within our nation’s laboratories. It is no wonder that our drugs are unsafe. It is clear that animal research in the U.S. is anything but scientific.

It appears that the Animal Welfare Act doesn’t exist in laboratories within the eastern US. In the recent past the University of Wisconsin was fined for killing primates in a cage washer. However, the Boehringer Ingelheim Company, who has apparently done the same thing repeatedly, has not been prosecuted. It may be that the relevant variable is not how the law is violated, but who finds out about it. The UW prosecution followed media attention resulting from intervention by a local animal protection organization. If the Eastern Regional Office of the USDA/APHIS/AC is to retain any vestige of credibility then enforcement actions must be immediately initiated against several research facilities.
Actions and Recommendations

SAEN will take several actions as a result of the information in this report:

1. The USDA will be contacted and immediate enforcement actions will be requested against Harvard (both labs), Boehringer Ingelheim, Covance (both labs), the University of Wisconsin, Vanderbilt, Emory, the Southern Research Institute, and other labs.

2. The Office of the Inspector General will be contacted to request a follow-up investigation of the Eastern Regional Office of the USDA and the non-enforcement of the AWA by this entity.

3. The FDA will be contacted regarding potentially compromised drug tests at Charles River, Boehringer Ingelheim and both Covance facilities.

Recommendations for the alleviation of the current situation within US labs:

1. Replace the supervisory staff of the Eastern Regional Office of the USDA. Apparently these officials lack interest in law enforcement.

2. Development of automatic penalties for infractions that take the life of an animal or seriously compromise the welfare of an animal’s (i.e. actions that deprive animals of food, water, etc.)

3. The authority of the USDA to fine labs must be increased. OIG audits have stated that research facilities consider the level of fines routinely levied by the USDA part of the cost of doing business. These fines should be made substantial enough to be true incentives to follow regulations. Tripling the current level of penalties should be sufficient.

4. Automatic suspension of federal funding to any laboratory with more than 9 AWA violations within a year should become an added penalty for non-compliance.
Audit Report
APHIS Animal Care Program
Inspection and Enforcement Activities

Report No. 33002-3-SF
September 2005
Executive Summary

Results In Brief

Animal care and use in the United States is a controversial topic with varying points of view from the public, animal rights groups, breeders, research laboratories, and others. In 1966, the Secretary of Agriculture was given the statutory authority to enforce the Animal Welfare Act (AWA), which set minimum standards of care and treatment for certain warm-blooded animals\(^1\) bred for commercial sale, used in research, transported commercially, or exhibited to the public.

This report presents the results of our audit of the Animal and Plant Health Inspection Service’s (APHIS) Animal Care (AC) unit, which has the responsibility of inspecting all facilities covered under the AWA and following up on complaints of abuse and noncompliance. We also reviewed AC’s coordination with the Investigative and Enforcement Services (IES) staff, which provides support to AC in cases where serious violations have been found. In addition, we evaluated the effectiveness of the Institutional Animal Care and Use Committees (IACUCs)—the self-monitoring committees at the research facilities responsible for ensuring compliance with the AWA.

We found that most AC employees are highly committed to enforcing the AWA through their inspections and are making significant efforts to educate research facilities and others on the humane handling of regulated animals. However, we identified several ways in which AC should improve its inspection and enforcement practices to ensure that animals receive humane care and treatment and that public safety is not compromised.

- *Due to a lack of clear National guidance, AC’s Eastern Region is not aggressively pursuing enforcement actions against violators of the AWA.*\(^2\) We found that regional management significantly reduced its referrals of suspected violators to IES from an average of 209 cases in fiscal years (FYs) 2002-2003 to 82 cases in FY 2004. During this same period, regional management declined to take action against 126 of 475 violators that had been referred to IES.\(^3\) In contrast, the Western Region declined action against 18 of 439 violators.

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\(^1\) Regulated animals are any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal. It excludes birds, rats of the genus *Rattus*, mice of the genus *Mus*, bred for use in research; horses not used for research; and other farm animals such as livestock and poultry under certain circumstances.

\(^2\) The data in this section, which we compiled from IES records, may include some Horse Protection Act cases, for which AC is also responsible.

\(^3\) IES estimates that these cases cost APHIS at least $291,000 to investigate.
We found cases where the Eastern Region declined to take enforcement action against violators who compromised public safety or animal health. For example, one AC inspector requested an investigation of a licensee whose primate had severely bitten a 4-year-old boy on the head and face. The wounds required over 100 stitches. Although this licensee had a history of past violations, IES has no record of a referral from AC. In another case, the Eastern Region did not take enforcement action when an unlicensed exhibitor’s monkey bit two pre-school children on separate occasions. The exhibitor failed to provide a sufficient public barrier and failed to handle the animal to ensure minimal risk to the public.

As a result, the two regions are inconsistent in their treatment of violators; the percentage of repeat violators (those with 3 or more consecutive years with violations) is twice as high in the Eastern Region than in the Western Region. Eastern Region inspectors believe the lack of enforcement action undermines their credibility and authority to enforce the AWA.

- **Discounted stipulated fines assessed against violators of the AWA are usually minimal.** Under current APHIS policy, AC offers a 75-percent discount on stipulated fines\(^4\) as an incentive for violators to settle out of court to avoid attorney and court costs. In addition to giving the discount, we found that APHIS offered other concessions to violators, lowering the actual amount paid to a fraction of the original assessment. An IES official told us that as a result, violators consider the monetary stipulation as a normal cost of conducting business rather than a deterrent for violating the law.\(^5\)

- **Some VMOs did not verify the number of animals used in medical research or adequately review the facilities’ protocols and other records.**\(^6\) We found that 13 of 16 research facilities we visited misreported the number of animals used in research. In reviewing the protocols, some Veterinary Medical Officers (VMOs) did not ensure that the facilities provided them with a complete universe of protocols from which to select their sample. These VMOs told us that the selection process was based on “good faith” and that they relied on the facilities to provide them with accurate records. In addition, a VMO did not review readily available disposition records that disclosed unexpected animal deaths at a research facility.

- **Some IACUCs are not effectively monitoring animal care activities or reviewing protocols.** During FYs 2002 through 2004, the number of research facilities cited for violations of the AWA has steadily increased.

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\(^4\) These fines are not mandatory but agreed to by the violator.
\(^5\) This was also discussed in OIG Audit No. 33600-1-Ch issued in January 1995.
\(^6\) Protocols are the researchers’ proposals for the use of animals in research.
from 463 to 600 facilities. Most VMOs believe there are still problems with the search for alternative research, veterinary care, review of painful procedures, and the researchers’ use of animals.

- **AC’s Licensing and Registration Information System (LARIS) does not effectively track violations and prioritize inspection activities.** The LARIS database records AC inspections and archives violation histories for all breeders, exhibitors, research facilities, and others. We determined that the system generates unreliable and inaccurate information, limiting its usefulness to AC inspectors and supervisors.

- **FMD and IES did not follow the law and internal control procedures in their processing and collection of penalties.** APHIS’ Financial Management Division (FMD) did not transfer 81 of 121 delinquent AC receivables totaling $398,354 to the U.S. Department of Treasury for collection as required by the Debt Collection Improvement Act of 1996 (see exhibit A). In addition, IES did not comply with APHIS’ internal cash controls to secure the collection of fines.

**Recommendations In Brief**

To ensure consistent treatment of violators, we recommend that AC incorporate specific guidance in AC’s operating manual that addresses referrals and enforcement actions. We also recommend that AC review all cases where the regions decline to take enforcement actions against violators.

To increase the effectiveness of stipulated fines, we recommend that APHIS eliminate the automatic 75-percent discount for repeat violators or direct violations, calculate fines based on the number of animals affected per violation, and seek legislative change to increase fines up to $10,000 for research facilities.

AC needs to emphasize the need for more detailed reviews of protocols, including those where animals are not present at the facility during the inspection. AC also needs to require research facilities to identify annually the number of protocols in their annual reports, and require the VMOs to verify the number of animals used in research.

To reduce the number of violations, AC needs to modify regulations to require IACUCs to conduct more frequent reviews of facilities identified as repeat violators (3 or more consecutive years with violations). We also recommend that AC require IACUCs to implement policies to fully train committee members on protocol review, facility inspections, and the AWA.

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7 Direct violations have a high potential to adversely affect the health and well-being of the animal.
For LARIS, AC needs to implement temporary measures to address system deficiencies until the new system is operational. Finally, IES and FMD need to follow APHIS policies for internal controls over cash collection, and FMD must timely process receivables for collection.

**Agency Response**

In its September 28, 2005, written response to the draft report, the APHIS National Office concurred with the report findings and recommendations, except for Recommendation 13. APHIS’ response is included in exhibit E of this report.

**OIG Position**

We accept APHIS’ management decision for Recommendations 2, 3, 6, 7, 9, 12, 14 through 18, and 20. The actions needed to reach management decision on Recommendations 1, 4, 5, 8, 10, 11, 13, and 19 are identified in the Findings and Recommendations section of the report. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer.
### Appendix B

#### Animal Welfare Act Violations by Laboratories

<table>
<thead>
<tr>
<th>AWA Code Section</th>
<th>2002 Violations</th>
<th>2004 Violations</th>
<th>2005 Violations</th>
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<tbody>
<tr>
<td>Violated</td>
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<tr>
<td>2.30 Facility Registration</td>
<td>21</td>
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<td>10</td>
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<tr>
<td>2.31 Institutional Animal Care &amp; Use Committee</td>
<td>635</td>
<td>890</td>
<td>1,116</td>
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<td>2.32 Personnel Qualifications</td>
<td>63</td>
<td>37</td>
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<td>2.33 Veterinary Care</td>
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<td>2.35 Recordkeeping</td>
<td>33</td>
<td>60</td>
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<td>2.36 Annual Report</td>
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<td>2.38 Miscellaneous</td>
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<tr>
<td>Total</td>
<td>1,106</td>
<td>1,491</td>
<td>1,780</td>
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</table>

An Increase of 53.7% for the period 2002 - 2005
## The Top 20 Violators of The Animal Welfare Act For 2005

<table>
<thead>
<tr>
<th>Facility</th>
<th>Vet Care</th>
<th>Personnel</th>
<th>Handling</th>
<th>Env Enh</th>
<th>Food/H2O</th>
<th>House/Fac</th>
<th>IACUC</th>
<th>Misc</th>
<th>Repeat</th>
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<tr>
<td>Covance (PA)</td>
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<td></td>
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<td></td>
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