Supporting Statement OMB-0579-0036
(Animal Welfare Reports and Records)

Introduction **June 2009**

Collections 0247 and 0254 have been merged into this collection for better efficiency. This merger was announced in the Federal Register Notice published in December 2008. Collections 0247 and 0254 will be discontinued after this renewal package for 0036 has been approved.

Justification:

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

The Laboratory Animal Welfare Act (AWA) (Public Law 890544) enacted August 24, 1966, and as amended, requires the U.S. Department of Agriculture, (USDA), to regulate the humane care and handling of dogs, cats, guinea pigs, hamster, rabbits, and non human primates. This legislation was the result of extensive demand by organized animal welfare groups and private citizens requesting a Federal law covering the transportation, care, and handling of laboratory animals.

USDA, Animal and Plant Health Inspection Service (APHIS), Regulatory Enforcement and Animal Care (AC) has the responsibility to enforce the Animal Welfare Act (7 U.S.C. 2131-2156) and the provisions of 9 CFR, Subchapter A, which implements the Animal Welfare Act.

The stated purpose of the AWA, Section 1(b), is as follows:

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

(2) to assure the humane treatment of animals during transportation in commerce; and

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

Additionally, the Congress further finds:

"...(1) the use of animals is instrumental in certain research and education for advancing knowledge of cures and treatment for diseases and injuries which afflict both humans and animals;

(2) methods of testing that do not use animals are being and continue to be developed which are faster, less expensive, and more accurate than traditional animal experimentation for some purposes and further opportunities exist for the development of these methods of testing;

(3) measures which eliminate or minimize the unnecessary duplication of experiments on animals can result in more productive use of Federal funds;

(4) measures which help meet the public concern for laboratory animal care and treatment are important in assuring that research will continue to progress."
Section 3 of the AWA authorizes and requires individuals performing regulated dealer and exhibitor activities obtain a license from the Secretary.

Section 6 of the AWA authorizes and requires each research facility, intermediate handler, carrier, and exhibitor not licensed under Section 3 register with the Secretary.

Sections 10, 11, 12, and 13 of the AWA authorize and require certain record keeping requirements for regulated facilities. Paragraph 2.75 of the regulations (9CFR, Subchapter A, Part 2) stipulates that dealers, exhibitors, etc., will keep and maintain records which fully and correctly disclose specific information concerning each animal purchased, acquired, transported, sold, or otherwise disposed of, and will maintain such records for at least 1 year.

Section 13 of the AWA also authorizes the Secretary to promulgate specific requirements with respect to animals in research facilities (9 CFR, Subchapter A, Part 2, Section 2.31 Institutional Animal Care and Use Committee (IACUC). These requirements include establishment of an Institutional Animal Committee to assess animal care, treatment, and practices in experimental research, facility and program inspections and provisions that minimize animal pain and distress in experimental procedures. Any deviations from these requirements must be documented, justified, and approved by the Institutional Animal Committee.

Each research facility will report at least annually to the Secretary that the provisions of the AWA are followed and that professionally accepted standards for the care, treatment, and use of animals are followed in research and experimentation.

Section 28 of the AWA adds certain record keeping requirements for dealers and research facilities and pounds and shelters if they sell or donate animals to dealers or research facilities.

These records must be kept and maintained for at least 1 year after disposing of the animals. Each pound must certify that the animals were held for a minimum of 5 days to include a Saturday, to give owners a chance to reclaim their animals. Certification that all animals were held 5 days by the pound or shelter and that the last owner or dealer was notified that the animal may be sold for research prior to acquisition of the animal is required. No official form is required to comply with this regulation.

2. Indicate how, by whom, and for what purpose the information is to be used.

The records and reports herein provide APHIS with required information which helps to determine whether a reporting facility is following professionally acceptable standards governing care, treatment, and use of animals.

Section 1.1 - Research Facility Exemption

Section 2, (e), of the AWA defines which types of research facilities are required to comply with the animal welfare regulations and standards. This section also gives the Secretary the authority to exempt by regulation any such research facility from registration under the AWA if they do not use live dogs or cats and substantial numbers of animals for biomedical research. Each research facility that does not use live dogs or cats or substantial numbers of other animals may request in writing an exemption from registration under the AWA. The written exemption is a one time only requirement, strictly voluntary, and handled on a case by case basis within the Department. Without this exemption the Secretary would not have the authority to exclude those facilities from registration that do not require oversight under the AWA. Without this exemption the Secretary would be obligated to regulate and inspect only research facilities due to budget limitations.

Section 2.1(a)(1)(b)2.2(a) - Application for License - Acknowledgment of Regulations and Standards (APHIS Form 7003A)

The APHIS Form 7003A is used for applicants of a new license. This form provides information that supports the dealer's and exhibitor's need to license. It contains the dealers/exhibitor's classification, name, address, species and number of animals, and business activity. The APHIS Form 7003A is also used to acknowledge receipt of regulations and standards and agreement to comply with them as indicated in Section 2.2(a). Any person operating or desiring to operate as a dealer, exhibitor, or operator of an auction sale, except persons who are exempted from the licensing requirements under paragraph (a)(3) of this section, must have a valid license. A
person must be 18 years of age or older to obtain a license. A person seeking a license will apply
on a form which will be furnished by the AC Regional Director in the State in which that person

operates or intends to operate. The applicant will provide the information requested on the application form, including a valid mailing address through which the licensee or applicant can be reached at all times, and a valid premises address where animals, animal facilities, equipment, and records may be inspected for compliance. The applicant will file the completed application form with the AC Regional Director. APHIS will supply a copy of the applicable regulations and standards to the applicant with each request for a license application. The applicant will acknowledge receipt of the regulations and standards and agree to comply with them by signing the application form before a license will be issued. Without the information on APHIS Form 7003A, the Animal Welfare Program would be unable to enforce the AWA.

Section 2.1(e)(f)2.5(b) - Application for License Renewal (APHIS Form 7003)

The premises and facility listed on APHIS Form 7003 must comply with the regulations and standards before a license is issued. The APHIS Form 7003 is used for license renewal and annual report of business activity. The information provided on the APHIS Form 7003 furnishes APHIS the dollar volume each licensee produces each year. These figures are used to determine the annual license fee. This form is also used to acknowledge receipt of regulations and standards, and to certify the facility is in compliance with them as required in Section 2.2 (b). The information is also needed for the inspector's review prior to inspection of the facility. He/she needs to compare the report with records on hand at the facility. The necessary information is concerned with the dealer's and exhibitor's classification, name, address, species and number of animals, and business activity. On or before the expiration date of the license, a licensee who wishes a renewal submits to the AC Regional Director a completed application fee of $10, plus the annual license fee indicated in 2.6 by certified check, cashier's check, personal check, or money order. A voluntary licensee who wishes a renewal also submits the $10 application fee plus an annual license fee. An applicant whose check is returned by the bank will be charged a fee of $15 for each returned check. One returned check will be deemed nonpayment of fees and will result in denial of license. Payment of fees must then be made by certified check, cashier's check, or money order. An applicant will not be licensed until his/her payment has cleared normal banking procedures. Any person who is licensed must file an application for a license renewal and an annual report form (APHIS Form 7003) as required by 2.7, and pay the required fees, on or before the expiration date of the present license. Failure to comply with the annual reporting requirements, or to pay the required license fees prior to the expiration date of the license, will result in automatic termination of such license on the anniversary date of the license. Without the information on APHIS Form 7003, the Animal Welfare Program would be unable to enforce the AWA.

Section 2.2(b) - Acknowledgement of Regulations and Standards

APHIS will supply a copy of the applicable regulations and standards to the applicant for license renewal with each request for a license renewal. Before a license will be renewed, the applicant for license renewal will acknowledge receipt of the regulations and standards and certify by

signing the application form that, to the best of the applicant's knowledge and belief, he/she is in compliance with the regulations and standards and agrees to continue to comply with the regulations and standards.

Section 2.5(a)(2) - License Request to Surrender License

A licensee may voluntarily terminate his/her license upon request, at any time, by writing to the APHIS, AC Regional Director. The licensee need only submit one written request to officially terminate his/her license under the AWA.

Section 2.5(f) - Written Statement Stating that License has Been Lost

A licensee with an invalid license must surrender it to the APHIS, AC, Regional Director. If the licensee can not find his/her license, he/she must submit a written statement to the APHIS, AC, Regional Director so stating as official verification of license submission.

Section 2.6(e) - Written Request for Correction of Dollar Amount of Business

A licensee may demonstrate in writing that the dollar amount of his/her business in the present year will change from that of the previous year. This written demonstration of change in dollar amount of business allows a licensee to address the expected change in the amount of the cost of the license renewal.

Section 2.7 - Annual Report by Licensees (burden cleared under section 2.1(e)(1)

Each year, within 30 days prior to the expiration date of his/her license, a licensee will file with the AC Regional Director an application for license renewal and annual report upon a form which the AC Regional Director will furnish to him/her upon request.

Section 2.8, 2.27(a), 2.30(c)(1) - Change of Address Notification

A licensee is responsible for notifying the APHIS AC Regional Director of any change in the name, address, management or substantial control or ownership of his business or operation, or of any additional sites, within 10 days of the change(s). This information is required to ensure that the responsible individuals are identified in the official facility records. The ability to identify the responsible individuals, a valid address, and any sites where animals are held and maintained is necessary to implement compliance and enforcement of the AWA, regulations, and standards. This information is also required to comply with Section 25 of the AWA which requires a comprehensive and detailed written report to the President of the Senate and the Speaker of the House of Representatives including the identification of exhibitors and other

persons and establishments licensed by the Secretary under Sections 3 and 12 of the AWA.

Section 2.10(a) - Written Request for Reinstatement of Suspended or Revoked License

Any person whose license has been suspended for any reason may apply to the APHIS AC Regional Director, in writing, for reinstatement of his/her license.

Section 2.11(b) - Request for Hearing of Denied Initial License

An applicant whose license application has been denied may request a hearing in accordance with the applicable rules of practice for the purpose of showing why the application for license should not be denied.

Section 2.25(a) - Application for Registration (see 2.30 for Research Facilities) (APHIS Form 7011 and APHIS 7011A)

The form is used for registration of carriers, intermediate handlers, research facilities, and exhibitors not required to be licensed under Section 3 of the AWA. Each registrant must update his/her registration by completing and filing the form every 3 years with the AC Regional Director. The data collected is necessary to effectively enforce provisions of the AWA. Information collected is basic to the needs of an orderly computer record system that is used to track facility compliance with the regulations and standards. If this information were not collected, full enforcement of the AWA would be limited or totally ineffective. APHIS relies on this form for the number and species of animals that facilities have in their animal inventory and the facility business classification. The inspectors need the information regarding the animals and business activity to prepare for the facility inspection and to verify the application data during the inspection. APHIS needs the APHIS Form 7011 information to establish and maintain an accurate and current accounting of research, registered exhibitors, carrier, and intermediate handler compliance activities. The APHIS Form 7011 provides the administrative structure for each registrant which enables APHIS to deal with the proper officials. APHIS uses the information from this form to mail the annual report (APHIS Form 7023 and APHIS Form 7023A) to each reporting research facility as required under Section 13 (7)(A) and Section 25 of the AWA.

Section 2.26 - Acknowledgment of Regulations and Standards

The registrant acknowledges receipt and agrees to comply with the regulations and standards by signing a form provided for this purpose by APHIS, and by filing it with the AC Regional Director.

Section 2.27(b)(1) - Written Request to be Placed in Inactive Status

A registrant who has not used, transported, or handled an animal for a period of at least 2 years may request, in writing, to be placed in inactive status. The written request asking to be placed in inactive status is a voluntary action that is expedient for both the registrant and APHIS, AC. The facility acknowledges that it is not presently performing regulated activities but does intend to do so in the foreseeable future. This one time written request eliminates the need for both re-registration processes by the facility and APHIS, AC, as well as facility inspections during the period of inactive status.

Section 2.27(b)(2) - Written Request for Cancellation of Registration and Registration after Requesting Cancellation (see 2.30(a)(1)

A registrant which goes out of business or which ceases to function as a carrier, intermediate handler, or exhibitor, or which changes its method of operation so that it no longer uses, handles, or transports animals, and which does not plan to use, handle, or transport animals again at any time in the future, may have its registration canceled by making a written request to the AC Regional Director. The former registrant is responsible for reregistering and demonstrating its compliance with the Act and regulations should it start using, handling, or transporting animals at any time after its registration is canceled.

Section 2.30(a)(1)(b) - Application for Registration (Research Facilities) (APHIS Form 7011)

The APHIS Form 7011 will be filed with the AC Regional Director for the State in which the research facility has its principal place of business, and will be updated every 3 years by the completion and filing of a new registration form which will be provided by the AC Regional Director. APHIS will supply a copy of the regulations and standards with each registration form. The research facility will acknowledge receipt of and agree to comply with the regulations and standards by signing a form provided for this purpose by APHIS, and by filing it with the AC Regional Director. APHIS needs the APHIS Form 7011 information to establish and maintain an accurate and current accounting of research, registered exhibitors, carrier, and intermediate handler compliance activities. The APHIS Form 7011 provides the administrative structure for each registrant which enables APHIS to deal with the proper officials. APHIS uses the information from this form to mail the annual report (APHIS Form 7023) to each reporting research facility as required under Section 13 (7)(A) and Section 25 of the AWA.

Section 2.30(c)(2) - Written request to be Placed in Inactive Status, Annual Report of Status (cleared under 2.36(a), and Written Notification of Resumption of Active Status

A research facility which has not used, handled, or transported animals for a period of at least 2 years may be placed in an inactive status by making a written request to the AC Regional Director. A research facility will file an annual report of its status (active or inactive). A research facility will notify the AC Regional Director in writing at least 10 days before using,

handling, or transporting animals again after being in an inactive status.

Sections 2.30(c)(3) (APHIS Form 7011 and APHIS 7011A) - Written Request to Cancel Registration and Reapplication after Cancellation of Registration

A registrant (research facility 2.30(c)(3) and carrier/exhibitor 2.27(b)(1)) that has canceled its registration in writing is responsible for reregistering and demonstrating compliance with the AWA, regulations, and standards before it starts using, handling or transporting animals following registration cancellation. This documentation is required to identify those facilities that should be registered under the AWA. APHIS needs the APHIS Form 7011 information to establish and maintain an accurate and current accounting of research, registered exhibitors, carrier, and intermediate handler compliance activities. The APHIS Form 7011 provides the administrative structure for each registrant which enables APHIS to deal with the proper officials. APHIS uses the information from this form to mail the annual report (APHIS Form 7023) to each reporting research facility as required under Section 13 (7)(A) and Section 25 of the AWA.

Section 2.31(c)(3) - Reports of Facility Inspection and Program Review and Written Notification of Failure to Adhere to Correction Schedule

An agent of a research facility prepares reports of its evaluations conducted and submits the reports to the Institutional Official of the research facility. The reports are reviewed, signed, and must include any minority views. The reports are updated at least once every six months upon completion of the required semi-annual evaluations and will be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected will be reported in writing within 15 business days to APHIS and any Federal agency funding that activity.

Sections 2.31(c)(4)(5)(6)(7)(8), 2.31(d)(2)(4)(5)(6)(7)(8), (e) - Records of IACUC Activities

The requirements for assurances by research facilities are necessary for APHIS inspectors to verify that the requirements in Section 13 of the AWA are being met. APHIS inspectors review these assurances during routine inspections to confirm that each research facility has established the procedures necessary to comply with the AWA. These assurances are statements that a facility provides to APHIS, verifying they are complying with specific requirements of Section 13 of the AWA. Specific assurances include: that the principal investigator considered alternatives to painful procedures; that the facility is adhering to the standards of Section 13; and there is no unnecessary duplication of research using laboratory animals. Without the documented assurances, additional regulations and standards, and an increased number of

inspections would be required to confirm compliance by research facilities. The reporting and recordkeeping requirements are necessary to ensure that the research facility is complying with the AWA. The inspection and program evaluation reports are maintained at the research facilities and reviewed by the APHIS inspector during inspections. They are reviewed to ensure that the research facilities are carrying out their responsibilities under the AWA. Problems identified on these reports are reviewed by the APHIS inspector and discussed with the Committee members to determine if the problems are ongoing or are promptly corrected. APHIS inspectors review the records to evaluate the effectiveness of the Committee to provide oversight of the facility's animal care and use program. The information contained in these records provides an overview of the facility's ability to comprehend and comply with the regulations and standards with minimal input from the APHIS inspector. The inspectors use the information in these records to verify the assurance statements submitted by research facilities to APHIS in Form 7023. This information is also used by the inspector to determine which facilities require additional assistance and/or monitoring to facilitate compliance with the regulations and standards. Without this information it would be difficult to corroborate whether the IACUC is providing oversight of each research facility's animal care and use program. Evaluation of the animal care and use program and enforcement of the AWA would be difficult without these mandatory records and recordkeeping requirements.

Section 2.33(a)(1) and 2.40(a)(1)(b) - Written Program of Veterinary Care (APHIS Form 7002 – Optional)

Each dealer or exhibitor will have an attending veterinarian who will provide adequate veterinary care to its animals in compliance with this section. Each dealer and exhibitor will employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements will include a written program of veterinary care and regularly scheduled visits to the premises of the dealer or exhibitor; and(2) each dealer and exhibitor will ensure 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. Each dealer or exhibitor will establish and maintain programs of adequate veterinary care that include: (1) the availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter; (2) the use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care; (3) daily observation of all animals to assess their health and well-being; (4) adequate guidance to personnel involved in the care and use of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia; and (5) adequate pre-procedural and post-procedural care in accordance with established veterinary medical and nursing procedures.

Section 2.35(a)(1)(2)(3)(f) and 2.38(g)(2)(8) - Recordkeeping

The research facility will maintain the following IACUC records: (1) minutes of IACUC

meetings, including records of attendance, activities of the Committee, and Committee deliberations; (2) records of proposed activities involving animals and proposed significant changes in activities involving animals, and whether IACUC approval was given or withheld; and (3) records of semiannual IACUC reports and recommendations (including minority views). All records and reports will be maintained for at least 3 years. Records that relate directly to proposed activities and proposed significant changes in ongoing activities reviewed and approved by the IACUC will be maintained for the duration of the activity and for an additional 3 years after completion of the activity. All records will be available for inspection and copying by authorized APHIS or funding Federal agency representatives at reasonable times. APHIS inspectors will maintain the confidentiality of the information and will not remove the materials from the research facilities' premises unless they are needed to investigate a possible violation, or for other enforcement purposes. Whenever the Administrator notifies a research facility in writing that specified records will be retained pending completion of an investigation or proceeding under the Act, the research facility will hold those records until their disposition is authorized in writing by the Administrator. All official tag or tattoo numbers will be correctly listed in the records of purchase, acquisition, disposal, or sale.

Section 2.35(b)(d)(1) Records Disclosing Live Dogs and Cats Purchased - (APHIS Forms 7001 and 7005)

Every research facility will make, keep, and maintain records or forms which fully and correctly disclose the following information concerning each live dog or cat purchased or otherwise acquired, owned, held, or otherwise in their possession or under their control, transported, euthanized, sold, or otherwise disposed of by the research facility. The records should include any offspring born of any animal while in the research facility's possession or under its control. The USDA Interstate and International Certificate of Health Examination for Small Animals (APHIS Form 7001) and Record of Acquisition and Dogs and Cats on Hand (APHIS Form 7005) are forms which may be used by research facilities to keep and maintain the information required.

Section 2.35 (c)(d)(2)(e) APHIS 7001 and APHIS 7001A (Continuation Sheet), United States Interstate and International Certificate of Health Examination for Small Animals.

Individual States and foreign countries presently require health certificates for animals entering the State or country. Airlines and intermediate handlers routinely require health certificates for animals delivered for transportation in order to protect themselves from claims of causing illness or injury during transport. Each State issues its own health certificate for animals. There is, however, no uniformity among such certificates and a great variation in content and format. There is no international certificate for such animals, and States do not have the authority to issue international certificates. Carriers and intermediate handlers are faced with a variety of certificates from different States, and some foreign countries will only accept a Federal (USDA) international health certificate. Additionally, facilities licensed and registered under the AWA,

Section 2.35 (c) (2)(3), must provide health certificates when transporting dogs, cats, and nonhuman primates in commerce. This certificate satisfies the requirements under the AWA and provides a standard, uniform health certificate for interstate and international movement of such animals. These certificates provide AC with a traceable trail of animal movements in case of violation or fraud of the provisions under the AWA.

Section 2.36(a)(b) - Facility Submits Annual Report (APHIS Form 7023 and 7023A)

This report (APHIS Form 7023) is necessary to determine whether a reporting facility is following professionally acceptable standards governing care, treatment, and appropriate use of animals. The report helps ensure APHIS that the registered facilities are complying with the intent of the law and that the animals are receiving proper veterinary care and treatment. The report also requires each facility to document the numbers of animals that are used for research activities and classify them according to the painful procedures performed. The report also contains all scientifically justified and approved deviations from the standards and regulations. APHIS inspectors use this information to prioritize facility inspections which improves program delivery. This information also allows the inspectors to concentrate their attention on those animal use activities that include procedures which produce more than momentary pain in animals used for research or experimentation. Without the information reported on this form it would be difficult to address the primary concern of the 1985 Amendments to the AWA, which is to, minimize painful and distressful procedures in laboratory animals. APHIS uses the information reported on this form to compile data for the Annual Report to Congress which addresses and summarizes animal welfare activities during each fiscal year. Throughout each fiscal year frequent inquiries are made to the Animal Care Staff in regard to the information collected in the report.

This form is also available in an electronic format that can be completed online using a facility specific password. This information is collected directly in the database format necessary to generate the Annual Report to Congress.

Research facilities which qualify will submit a request to the Secretary for exemption from registration. The research facility's request will be analyzed by the Secretary to determine if the facility meets the criteria for exemption. Without the provision for this exemption, all research facilities would have to be registered resulting in unnecessary recordkeeping and monitoring of research activities by the Secretary. The request by the research facility is a one-time submission.
Animals are counted each year they are on an animal use protocol. If an animal is used in more than one research activity in a reporting year, they are counted in the category that contains the most painful procedure(s).

Section 2.38(a) - Research Facilities Will Furnish any Official Information

Each research facility furnishes to an APHIS official any information concerning the business of the research facility which the APHIS official may request in connection with enforcement of the
provisions of the AWA, regulations, and standards. The requested documents are required to ensure compliance with the AWA and supplement enforcement as part of an investigation when such actions are indicated.

Section 2.38(g)(11) - Tags Removed are Retained for One Year

All official tags removed and retained by a research facility are held until called for by an APHIS official or for a period of 1 year. The retention of the removed tags is required to trace dogs and cats that are purchased or provided to a research facility to prevent the use of stolen pets for research activities.

Section 2.38(h)(1) - Health Certificate Must Accompany Animal in Transportation (see Section 2.35(b) (APHIS Form 7001 and 7001A)

Individual States and foreign countries presently require health certificates for animals entering the State or country. Airlines and intermediate handlers routinely require health certificates for animals delivered for transportation in order to protect themselves from claims of causing illness or injury during transport. Each States issues its own health certificate for animals. There is, however, no uniformity among such certificates and a great variation in content and format. There is no international certificate for such animals, and States do not have the authority to issue international certificates. Carriers and intermediate handlers are faced with a variety of certificates from different States, and some foreign countries will only accept a Federal (USDA) international health certificate. Additionally, facilities licensed and registered under the AWA must provide health certificates when transporting dogs, cats, and nonhuman primates in commerce. This certificate satisfies the requirements under the AWA and provides a standard, uniform health certificate for interstate and international movement of such animals. These certificates provide AC with a traceable trail of animal movements in case of violation or fraud of the provisions under the AWA. If the AWA were not enforced, the provisions listed in paragraphs (1) and (2), and (3) could not be ensured.

No research facility, including a Federal research facility, will deliver to any intermediate handler or carrier for transportation, in commerce, or will transport in commerce any dog, cat, or nonhuman primate unless the dog, cat, or nonhuman primate is accompanied by a health certificate executed and issued by a licensed veterinarian.

Section 2.38(h)(2)(3) - Exceptions to Health Certificate Regulations

Exceptions to the health certification requirement may be acquired for animals shipped to a research facility for purposes of research, testing, or experimentation when the research facility

requires animals not eligible for certification. The exceptions may be acquired from the Secretary via a written request. This documentation is required on an individual animal basis to allow shipment of animals that are required for research purposes but do not qualify for certification. Without this exception research facilities would not be able to acquire animals that are specifically needed for specific research activities.

Section 2.38(h)(3)(i)(1) - Written Agreement to Comply with Regulations by Person Holding Animals for Research Facility (see Section 2.102(a)(1) (APHIS Form 7009)

If any research facility obtains prior approval from the AC Regional Director, it may arrange to have another person hold animals provided the other person agrees, in writing, to comply with the regulations and to allow inspection of the premises by an APHIS official during business hours. The Institutional Official agrees, in writing, that the other person or premises is a recognized animal site under its research facility registration. APHIS Form 7009 is used for approval.

Section 2.38(h)(3)(i)(3) - Institutional Official Agrees in Writing that Site is Recognized (APHIS Form 7009)

The Institutional Official agrees, in writing, that the other person or premises is a recognized animal site under its research facility registration.

Section 2.50(b)(2) - Records of Tag Numbers Maintained

If any live dog or cat is already identified by an official tag or tattoo which has been applied by another dealer or exhibitor, the dealer or exhibitor who purchases or otherwise acquires the animal may continue identifying the dog or cat by the previous identification number, or may replace the previous tag with his/her own official tag or approved tattoo. In either case, the class B dealer or class C exhibitor will correctly list all old and new official tag numbers or tattoos in his/her records of purchase which is maintained in accordance with 2.75 and 2.77. Any new official tag or tattoo number will be used on all records of any subsequent sales by the dealer or exhibitor, of any dog or cat.

Section 2.50(c)(2)(ii) - Recordbook Maintained

A recordbook containing each animal's tag number, a written description of each animal, the data required by 2.75(a), and a clear photograph of each animal will be maintained. A second duplicate tag is required to accompany the animal when it leaves the compound or premises. In order to enforce the AWA requirement for accountability of the animals on hand, these procedures are necessary. Compliance with the regulatory requirements of identification and recordkeeping is mandatory.

Section 2.50(e)(1)(3)(d)(3) - Records of Animals Except Dogs and Cats Delivered for Transport (burden cleared under sections 2.75 and 2.77)

All animals, except dogs and cats, delivered for transportation, transported, purchased, sold, or otherwise acquired or disposed of by any dealer or exhibitor are identified by the dealer or exhibitor at the time of delivery for transportation, purchase, sale, acquisition or disposal, as provided for in this paragraph and in records maintained as required in 2.75 and 2.77. When any animal, other than a dog or cat, is not confined in a primary enclosure, it will be identified on a record, as required by 2.75, which will accompany the animal at the time it is delivered for transportation, transported, purchased, or sold, and will be kept and maintained by the dealer or exhibitor as part of his/her records.

Section 2.50(e)(2)(i) - Label Attached to Container

A label will be attached to the primary enclosure which bears a description of the animals in the primary enclosure, including (a) the number of animals; (b) the species of the animals; (c) any distinctive physical features of the animals; and (d) any identifying marks, tattoos, or tags attached to the animals.

Section 2.50(e)(2)(ii) - Record Number Stenciled on Container

The primary enclosure will be marked with a painted or stenciled number which will be recorded in the records of the dealer or exhibitor together with (a) the number of animals; (b) the species of the animals; and (c) any distinctive physical features of the animals.

Section 2.75(a)(1) - Dealers/Exhibitors Make and Keep Records on Dogs and Cats (APHIS Forms 7005, 7006 and 7006A)

As required in Section 2.75(a)(2) APHIS Forms 7005, 7006, and 7006A are mandatory forms that are used by dealers and exhibitors. Research facility use of these forms is optional, but they must make and maintain records containing the same information. These forms are necessary for adequate accounting of dogs and cats under the AWA. APHIS Form 7005 accounts for acquisition and dogs and cats onhand. The information required on this form includes the name, address, vehicle license number, driver's license number, or USDA license number, if the individual is licensed, for all acquired dogs and cats. APHIS Forms 7006 and 7006A are used to account for the disposition of dogs and cats. The information on these forms is used to determine to whom the animals are sold, official animal identification, method of transportation, and date of disposition of the dogs and cats. APHIS inspectors review these records during inspections and report violations which are found. These records are used by APHIS employees

to identify and trace animals that have been illegally sold and/or transferred. These forms must be used by licensees to ensure that all of the required information is recorded and maintained. No other paper recordkeeping system complies with Section 2.75(a)(2) of the regulations. A licensee may submit a variance for a computerized record keeping system that is approved by the Administrator. Without this recorded information it would be difficult to determine the sources and disposition of dogs and cats used for regulated activities. It also would be difficult to determine compliance with the AWA or to successfully prosecute many of the violators.

Each dealer, other than operators of auction sales and brokers to whom animals are consigned, and each exhibitor will make, keep, and maintain records or forms which fully and correctly disclose the following information concerning each dog or cat purchase or otherwise acquired, owned, held, or otherwise in his/her possession or under his/her control, or which is transported, euthanized, sold, or otherwise disposed of by that dealer or exhibitor. The records will include any offspring born of any animal while in his/her possession or under his/her control.

Section 2.75(a)(2)(i) - Written Request for Variance

Dealers and exhibitors are required to use specific forms, APHIS Forms 7005 and 7006, to make, keep, and maintain the animal identification records required by 2.7(a)(1) of the regulations. Dealers and exhibitors may request a variance to the mandatory use of the forms if they have a computerized recordkeeping system that is determined by the Administrator to meet the requirements of the regulations. The request for a variance must consist of a written statement describing why the use of the mandatory APHIS Forms 7005 and 7006, are unsuitable for the dealer/exhibitor to make, keep, and maintain. Without the ability to apply for a variance to the mandatory use of the APHIS Forms 7005 and 7006, some dealers and exhibitors with computerized recordkeeping systems that meet the regulations would be required to switch to a more expensive and less expedient form of paper recordkeeping system.

Section 2.75(a)(2)(ii) - Request for Hearing

Dealers and exhibitors are required to use specific forms, APHIS Forms 7005 and 7006, to make, keep, and maintain the animal identification records. Dealers and exhibitors may request a variance to the mandatory use of the forms if they have a computerized recordkeeping system that is determined by the Administrator to meet the requirements of the regulations. If the Administrator determines that the computerized recordkeeping system does not meet the regulations, a licensed dealer may request a hearing for the purpose of showing why the request for the variance should not be denied. Without the ability to request a hearing, a dealer or exhibitor would not have access to due process under the law.

Section 2.75(b)(1) - Dealer/Exhibitor Maintains Record on other than Dogs and Cats (APHIS Forms 7019 and 7020)

APHIS Form 7019 provides an inventory record of animals, other than dogs and cats onhand, while APHIS Form 7020 provides for the disposition of regulated animals, other than dogs and cats, as required in Section 10 of the AWA and Section 2.75 of the regulations. The information provided is maintained by the sending and receiving facility and must accompany the animal during transportation. USDA inspectors examine records during inspections of facilities and identify certain animals moved illegally and animals exposed to disease. In addition, the records assist with the detection of animal origins and destinations and ensure the humane care and handling of such animals by identifying the responsible person(s) in cases of violation or noncompliance. The inspectors also compare the information submitted on APHIS Form 7003, License renewal, and APHIS Form 7019 to verify licensing fees and ownership and location of animals. It would be very difficult to enforce the AWA without the information contained in these records because of the extensive number of animal sales and transfers that occur. Every dealer other than operators of auction sales and brokers to whom animals are consigned, and exhibitor will make, keep, and maintain records or forms which fully and correctly disclose the following information concerning animals other than dogs and cats, purchased or otherwise acquired, owned, held, leased, or otherwise in his/her possession or under his/her control, or which is transported, sold, euthanized, or otherwise disposed of by that dealer or exhibitor. The records will include any offspring born of any animal while in his/her possession or under his/her control.

Section 2.76(a) - Operators of Auction Sales or Brokers Make and Keep Records

Operators of auction sales will keep pertinent records of sellers and buyers of all regulated animals bought and sold. Auction activity, on a national basis, has been minimal. However, auction sales are utilized by dealers, exhibitors, and persons exempt under the AWA for the sale of regulated animals. Therefore, records that verify the buying and selling at auctions are important to AWA enforcement. Records are reviewed by inspectors during auction inspections

for possible violation of the AWA. Information contained in auction records is extremely important for identifying unlicensed exotic animal dealers and exhibitors. A lack of data from auction sales would leave a serious weakness in enforcement capabilities. There is no form provided for this recordkeeping requirement.

Section 2.77(a) - Guarantee in Writing of Consignor

The consignor provides a written guarantee that the shipment fee for any animal shipped C.O.D. will be paid to the shipper if the animal is not claimed by the consignee. This payment also includes the return payment, and out-of-pocket costs such as feeding, care, and boarding. This written guarantee is necessary to ensure that the animals will receive the necessary care if not claimed by the consignee and the shipper will be paid for services rendered. For all animals shipped C.O.D., the shipper will make and keep documentation containing the time and date and method of each attempted notification and final notification to consignee and the name of the

person notifying the consignee. This documentation is required to ensure the time, date, and

method used by the shipper to contact the consignee and verifies that the animal was not forgotten at the destination. This documentation also provides evidence that the consignee was not available and permits the shipper to return the animal to the consignor.

Section 2.77(b) - Documentation on Attempt to Notify Consignor

In connection with all live dogs, cats, or nonhuman primates delivered for transportation, in commerce, to any carrier or intermediate handler, by any dealer, research facility, exhibitor, operator of an auction sale, broker, or department, agency or instrumentality of the United States or of any State of local government, the accepting carrier or intermediate handler will keep and maintain a copy of the health certification completed as required by 2.79, tendered with each live dog, cat, or nonhuman primate.

Section 2.78(a)(c) - Health Certificate Must Accompany Dog, Cat, or Nonhuman Primate (APHIS Form 7001)

Individual States and foreign countries presently require health certificates for animals entering the State or country. Airlines and intermediate handlers routinely require health certificates for animals delivered for transportation in order to protect themselves from claims of causing illness or injury during transport. Each State issues its own health certificate for animals. There is, however, no uniformity among such certificates and a great variation in content and format. There is no international certificate for such animals, and States do not have the authority to issue international certificates. Carriers and intermediate handlers are faced with a variety of certificates from different States, and some foreign countries will only accept a Federal (USDA) international health certificates. Additionally, facilities licensed and registered under the AWA must provide health certificates when transporting dogs, cats, and nonhuman primates in commerce. This certificate satisfies the requirements under the AWA and provides a standard, uniform health certificate for interstate and international movement of such animals. These certificates provide AC with a traceable trail of animal movements in case of violation or fraud of the provisions under the AWA. If the AWA were not enforced, the provisions listed in paragraphs (1) and (2), and (3) could not be insured. No dealer, exhibitor, operator of an auction sale, broker, or department, agency, or instrumentality of the United States or of any State or local government will deliver to any intermediate handler or carrier for transportation, in commerce, or will transport in commerce any dog, cat, or nonhuman primate unless the dog, cat, or nonhuman primate is accompanied by a health certificate executed and issued by a licensed veterinarian or an exemption issued by the Secretary.

Section 2.78(a)(b) - Licensed Veterinarian Must Inspect Dog, Cat, or Nonhuman Primate

No dealer, exhibitor, operator of an auction sale, broker, or department, agency, or instrumentality of the United States or any State or local government will deliver to any intermediate handler or carrier for transportation, in commerce, or transport in commerce any dog, cat, or nonhuman primate unless the dog, cat, or nonhuman primate is accompanied by a health certificate executed and issued by a licensed veterinarian. The health certificate states that: (1) the licensed veterinarian inspected the dog, cat, or nonhuman primate on a specified date which will not be more than 10 days prior to the delivery of the dog, cat, or nonhuman primate for transportation; and (2) when so inspected, the dog, cat, or nonhuman primate appeared to the licensed veterinarian to be free of any infectious disease or physical abnormality which would endanger the animal(s) or other animals or endanger public health. The Secretary may provide exceptions to the health certification requirement on an individual basis for animals shipped to a research facility for purposes of research, testing, or experimentation when the research facility requires animals not eligible for certification. Requests should be addressed to the Animal and Plant Health Inspection Service, Animal Care, 4700 River Road, Unit 84, Riverdale, Maryland 20737-1234.

Section 2.78(a)(2) - Licensed Veterinary Health Certificate (APHIS Form 7003)

The premises and facility listed on APHIS Form 7003 must comply with the regulations and standards before a license is issued. The APHIS Form 7003 is used for license renewal and annual report of business activity. The information contained in APHIS Form 7003 furnishes APHIS the dollar volume each licensee produces each year. These figures are used to determine the annual license fee. This form is also used to acknowledge receipt of regulations and standards, and to certify the facility is in compliance with them as required in Section 2.2 (b). The information is also needed for the inspector's review prior to inspection of the facility. He/she needs to compare the report with records onhand at the facility. The necessary information is concerned with the dealer's and exhibitor's classification, name, address, species and number of animals, and business activity. All dogs, cats, and nonhuman primates must be accompanied by a health certificate issued by a licensed veterinarian within 10 days of transit verifying that the animal appears to be free of any infectious disease or physical abnormality which would endanger the animal or other animals or endanger public health. This documentation is required to ensure that only healthy animals are transported to protect the animals and people. Without this health certification requirement there would be no method to ensure that only healthy animals are transported which is a prerequisite for safe travel conditions for both humans and animals.

Section 2.78(b) - Request for Exemption to Health Certificate (burden cleared under Section 2.38(h))

The Secretary may provide exceptions to the health certification requirement on an individual basis for animals shipped to a research facility for purposes of research, testing, or experimentation when the research facility requires animals not eligible for certification.

Requests should be addressed to the Animal and Plant Health Inspection Service, Animal Care, 4700 River Road, Unit 84, Riverdale, Maryland 20737-1234.

Section 2.79(a) - Consignor Guarantees in Writing

No carrier or intermediate handler will accept any animal for transportation, in commerce, upon any C.O.D. or other basis where any money is to be paid and collected upon delivery of the animal to the consignee, unless the consignor guarantees, in writing, the payment of all transportation, including any return transportation, if the shipment is unclaimed or the consignee cannot be notified in accordance with paragraphs (b) and (c) of this section, including reimbursing the carrier or intermediate handler for all out-of-pocket expenses incurred for the care, feeding, and storage or housing of the animal.

Section 2.79(b)(1) - Record of Attempt to Notify Consignee (burden cleared under Section 2.77(a))

Any carrier or intermediate handler receiving an animal at a destination on a C.O.D. or other basis will attempt to notify the consignee at least once every 6 hours for a period of 24 hours after arrival of the animal at the animal holding area of the terminal cargo facility. The carrier or intermediate handler will record the time, date, and method of each attempted notification, the final notification to the consignee, the name of the person notifying the consignee on the shipping document and on the copy of the consignee, on the shipping document accompanying the C.O.D. shipment. If the consignee cannot be notified of the C.O.D. shipment within 24 hours after its arrival, the carrier or intermediate handler will return the animal to the consignor, or to whomever the consignor has designated, on the next practical available transportation, in accordance with the written agreement required in this section. Any carrier or intermediate handler which has notified a consignee of the arrival of a C.O.D. or other shipment of an animal, where any money is to be paid and collected upon delivery of the animal to the consignee, which is not claimed by the consignee within 48 hours from the time of notification, will return the animal to the consignor, or to whomever the consignor has designated, on the next practical available transportation, in accordance with the written agreement required in this section and will notify the consignor.

Section 2.80(a)(b) - Records Must be Maintained (cleared under Sections 2.35, 2.75, and 2.76)

No dealer, exhibitor, broker, operator of an auction sale, carrier, or intermediate handler will, for a period of 1 year, destroy or dispose of, without the consent in writing of the Administrator, any books, records, documents, or other papers required to be kept and maintained under this part. Unless otherwise specified, the records required to be kept and maintained under this part will be held for 1 year after an animal is euthanized or disposed of and for any period in excess of 1 year as necessary to comply with any applicable Federal, State, or local law. Whenever the

Administrator notifies a dealer, exhibitor, broker, operator of an auction sale, carrier, or intermediate handler in writing that specified records will be retained pending completion of an

investigation or proceeding under the Act, the dealer, exhibitor, broker, operator of an auction sale, carrier, or intermediate handler will hold those records until their disposition is authorized by the Administrator.

Section 2.102(a)(1) - Approval to Hold Animals (APHIS Form 7009)

Section 2.102 for dealers, exhibitors, and intermediate handlers, and Section 2.38 for research facilities require completion of APHIS Form 7009 for approval of a holding facility. The form provides information which allows APHIS to be aware of animals being maintained at sites other than that of the licensee or registrant, which is important to the AWA's enforcement. The ability to retrieve data on an approved holding facility ensures the well-being of the animals, the known location of animals, and maintains adequate enforcement by APHIS. An approved holding facility is used by licensees and registrants to enable unlicensed or unregistered facilities to hold animals for them at locations away from the licensed or registered premise. Both the licensee or registrant and the holding facility must agree to abide by the regulations and standards and to allow inspection by APHIS inspectors.

Section 2.102(b)(1) - Approval to have Another Person Hold Animals

If any intermediate handler obtains prior approval of the AC Regional Director, it may arrange to have another person hold animals provided that the other person agrees in writing to comply with the regulations in part 2 and the standards in part 3 of this subchapter and to allow inspection of the premises by an APHIS official during business hours.

Section 2.125 - Dealer, Exhibitor, Intermediate Handler, and Carrier Furnish Information Concerning Business

Each dealer, exhibitor, intermediate handler, operator of an auction, and carrier will furnish to any APHIS official any information concerning the business which the APHIS official may request in connection with enforcement of the provisions of the AWA, regulations, and standards. The requested documents are required to ensure compliance with the AWA and supplement enforcement as part of an investigation when such actions are indicated.

Section 2.128(a)(1) - Written Description of Missing Animals

Each dealer, exhibitor, intermediate handler, and carrier will allow, upon request and during business hours, police or officers of other law enforcement agencies with general law enforcement authority (not those agencies whose duties are limited to enforcement of local animal regulations) to enter his/her place of business to inspect animals and records for the

purpose of seeking animals that are missing. The police or other law officer will furnish to the dealer, exhibitor, intermediate handler or carrier a written description of the missing animal and the name and address of its owner before making a search.

Section 2.132(e)(2) - Records Maintained by Licensee or Registrant (burden cleared under Sections 2.35, 2.75, and 2.76)

Accurate and complete records will be separately maintained by the licensee or registrant and by the pound or shelter. The records will be in accordance with 2.75 and 2.76, unless the animals are lost or stray. If the animals are lost or stray, the pound or shelter records will provide: (1) an accurate description of the animal; (2) how, where, from whom, and when the dog or cat was obtained; (3) how long the dog or cat was held by the pound or shelter before being transferred to the dealer; and (4) the date the dog or cat was transferred to the dealer. ____

Section 2.133 - Certification for Research Facilities – Dealers, Pounds, or Shelters

Dealers must provide a valid certification to anyone acquiring random source dogs and cats from them. This certification must include the source of the animal, the identification number, the dealer's name and license number etc. This documentation must be kept by dealers for 1 year and research facilities for 3 years. This certification documentation is required to prevent the use of stolen pets for research by providing a method to trace animals to the source.

Sections 3.13(b) and 3.86(b): Carriers and intermediate handlers must not accept a nonhuman primate, dog or cat for transport in commerce unless they are provided with the name, address and telephone number of the consignee and, in the case of nonhuman primates, a telex number, if applicable.

Sections 3.13(c) (1) (2)(3)(4), and 3.16(a): Certain information, instructions, and certifications are required for the humane transportation of dogs and cats in commerce. The consignor must provide current name and address; official identification of animals being shipped to carriers and intermediate handlers; food and water certification and instructions for each shipment. Some certifications are mandatory (food and water) and some are optional (enclosure requirements and acclimation to temperature).

Sections 3.13(c), 3.14(h), 3.16(b), and 3.86(c): Certain information, instructions, and certifications are required for the humane transportation of nonhuman primates, dogs, and cats in commerce. The consignor must provide current name and address; official identification of animals being shipped to carriers and intermediate handlers; food and water certification and instructions for each shipment. Some certifications are mandatory (food and water) and some are optional (enclosure requirements and acclimation to temperature).

3.13(e) and 3.19(a)(3): The optional certifications, such as acclimation to lower temperatures

and certification that the transport cage complies with standards are not mandatory; however, this certification may make it possible for the handlers to accept shipments that they would otherwise refuse. For example, airlines will not normally accept animals for transport in very cold weather. However, if the consignor's veterinarian certifies that the animals are acclimated to cold temperatures, then the airline may accept the shipment, which they would otherwise refuse. This provides a system for certain animals to be shipped if there is no threat of harm to them rather than applying a blanket prohibition on such movements.

This information and certification are necessary for carriers and intermediate handlers to properly care for and deliver the animals to designation in a speedy and humane manner. APHIS' inspectors at airports and shipping points also use this information to ensure compliance with the Act. When documenting instances of violations for possible legal action, or locating facilities or persons who are evading regulation under the law, this information is also required.

3.86(f): Carriers are required to attempt to notify consignee of arrival of a shipment of animals within 6 hours of arrival and at least each following 6 hours until the animals are claimed by the consignee or returned to the consignor. This requirement is designed to ensure that the animals are delivered in a timely fashion. Records must be kept to ensure APHIS' inspectors that the consignee was either contacted or the attempts were made to notify the party.

Section 3.14(a)(6) and 3.19(b): Markings identifying shipping crates to be holding live animals and directional arrows identifying the upright direction for the kennel are required on the crates when being shipped. These markings are required to identify kennels readily, therefore ensuring the proper handling and the safety of animals being shipped.

Section 3.86(e): A certificate of acclimation is required if a nonhuman primate is exposed to temperatures lower than the USDA regulatory standards.

Section 3.86(c) (1)(2)(3)(4) and 3.89(a): The following information must accompany each shipment of nonhuman primates or be attached to the primary enclosure used to transport a nonhuman primate: name, address, and telephone number of the consignee; written instructions for in-transit food and water requirements; certification that food and water were offered as described.

This information and certification is necessary for carriers and intermediate handlers to properly care for and deliver the animals to destination in a speedy and humane manner. APHIS' inspectors at airports and shipping points will use this information to ensure compliance with the Act and the humane transportation of the animals. This information is also used in documenting instances of violations for possible legal action and for location facilities or persons who are evading regulations under the law.

This information and certification is necessary for carriers and intermediate handlers to properly

care for and deliver the animals to destination in a speedy and humane manner. APHIS' inspectors at airports and shipping points will use this information to ensure compliance with the Act and the humane transportation of the animals.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other forms of information technology.

Section 2.75(a)(2) recordkeeping requirements for dealers and exhibitors with dogs and/or cats allow a facility to submit a written request for a variance to use an approved computerized record keeping system. The availability of this variance is to decrease the burden and expense of maintaining vast amounts of mandatory paper records by dealers and exhibitors with dogs and cats. APHIS acknowledged that it was necessary to allow dealer and exhibitor facilities to use approved computerized recordkeeping systems to facilitate compliance with the AWA.
At present, due to the extreme differences in the operation of the various licensees and registrants, a uniform technical reporting system is not possible. For example, standards for the dealer operations and the standards for the research community differ widely. Also, there is a vast difference in the physical plants and the economic and administrative structures of licensees and registrants. At this time, there is not a system that would improve APHIS' methods of attaining necessary information.

However, AC has a system that allows research facilities to voluntarily input the requirements of the APHIS Forms 7023 and 7023A (Annual Report) directly into a computerized database using a facility specific password. The website address for Form 7023 is https://web01.aphis.usda.gov/AC/APHISACWeb2.nsf. APHIS thinks that this saves time and cost for the research facility.

AC also plans to computerize the registration and licensing process. The person or facility will be able to input the necessary information directly on a computer screen. APHIS anticipates that this also will save time and cost both for the regulated community and for AC. No timeframe has been set yet.

Other processes for computer input will be identified in the future as an ongoing effort toward efficiency.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

APHIS is the only Agency charged with enforcement of the AWA; therefore, there is no duplication. There is no duplication of APHIS Form 7001 - no other interstate or international health certificate exists for regulated animals.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

There is no similar data available elsewhere. APHIS is the only Agency with the mandate to request this data. The burden of mandatory use of APHIS Forms 7005 and 7006 for record-keeping requirements for dealers and exhibitors with dog and cats has been reduced by allowing a variance for computerized record systems. The majority of licensees are small business dog and cat dealers.

6. Describe the consequences to Federal programs or policy activities if the collection is not conducted or is conducted less frequently.

If APHIS did not collect this information or collected it less frequently, the effectiveness of APHIS' enforcement of the AWA would be severely compromised, and it would be impossible for APHIS to confirm or enforce facility compliance with the regulations for animal health, adequate veterinary care, and animal identification without the required records.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR, Section 1320.6.

The information collection is conducted in a manner consistent with the guidelines in 5 CFR 1320.5.

8. Consultations outside the Agency with persons to obtain their views on the requirements for information collection under the AWA.

The following individuals communicated personally with Animal Care Staff personnel regarding information collection under the AWA during 2009.

Dr. John Miller, Executive Director
Association for Assessment and Accreditation of
Laboratory Animal Care International
11300 Rockville Pike, Suite 1211
Rockville, MD 20852
(301) 231-5353

Ms. Kris Vehrs
American Zoo and Aquarium Association
8403 Colesville Road, Suite 710
Silver Spring, MD 20910
(301) 562-0777

Mr. Wilbur Amand, Executive Director
American Association of Zoo Veterinarians
6 North Pennell Road
Media, PA 19063
(301) 892-4812

On December 19, 2008, pages 77591-77592, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. One comment was received from a concerned citizen about her perception of the maltreatment of dogs and cats but it had no bearing on the paperwork collection.

9. Explain any decision to provide any payment or gift to respondents.

There are no payments or gifts provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

There is no confidentiality assured except for those documents which research facilities are required to keep on file describing their animal care and use procedures. APHIS inspectors will have access to these documents to ensure compliance with the AWA; however, they must maintain the confidentiality of such information and may not remove such information from the research facility unless it is required to support the investigation of a possible violation. The provision for such confidentiality is found in Section 13(a)(7)(A) of the AWA and Section 2.35(f) of the regulations.

11. Provide additional justification for any questions of a sensitive nature.

There are no questions of a sensitive nature asked of the respondents.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.

See APHIS Form 71 for hour burden estimates.

. Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

The cost to the public was determined by multiplying the total number of burden hours (87,252) times the wage per hour rate. APHIS, AC estimates that the average hourly wage is $26.01 x 87,252 hours = $ 2,269,424.50.

$26.01 is the hourly rate derived from the United States Department of Labor Bureau of Labor Statistics May 2008 Report – Occupational Employment and Wages in the United States, See http://www.bls.gov/news.release/ocwage.t03.htm

13. Provide estimates of the total annual cost burden to respondents or record keepers resulting from the collection of information (do not include the cost of any hour burden shown in Items 12 and 14.

There is zero annual cost burden associated with this program.

14. Estimates of annualized cost to the Federal government are as follows:

The estimated cost for the Federal Government is $617,603.87. (See APHIS Form 79.)

15. The reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1 are as follows:

There is an adjustment decrease of -11,831 burden hours because of recalculations of the

response times for completing the forms in addition to using the most recent data on numbers of licensees and registrants, resulting in updated estimates based on experience and historical data in addition to the merging of collections 0247 and 0254 into this collection.

16. The outline plans for tabulation and publication for collections of information are as follows:

Data regarding animals used in teaching, testing and experimentation is tabulated to provide an annual report to Congress mandated by the AWA. The report contains a listing of the number and species of animals used and categorizes whether they experience pain associated with the research procedures. The report to Congress is tabulated by State, facility type, and species of animal in the Appendix. The report also contains information on enforcement actions and numbers and types of inspections.

The collected information also is tabulated to develop individual booklets listing all registered exhibitors, carriers, intermediate handlers, and research facilities; and licensed dealers and exhibitors. The tabulated data is shown by State, license number, and name and address of exhibitors, dealers, research facility, etc. These booklets are forwarded with the Annual Report to Congress.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reason that display would be inappropriate.

APHIS Form 7009 – Request for Approval of Holding Facility - This form is composed of multiple parts using carbon to provide for duplicate copies. It is not practical to store this form for long periods of time because the carbon breaks down in storage. Therefore, APHIS is seeking approval to not display the OMB expiration date on this form.

The three forms listed below are used in a number of collections; therefore, it is not practical to include an OMB expiration date because of the various expiration dates for each collection. APHIS is seeking approval to not display the OMB expiration date on the forms listed below:

APHIS Form 7002 – Animal Care (Program of Veterinary Care for Research Facilities or Exhibitors/Dealers *(4 page form)(Multi- Collection Form)* 0579-0036 and 0579-0093

APHIS Form 7020 – Record of Acquisition, Disposition or Transport of Animals (Other than Dogs and Cats) *(Multi- Collection Form)* 0579-0036 and 0579-0092

APHIS Form 7020A – Continuation Sheet for Record of Acquisition, Disposition or Transport of Animals (Other than Dogs and Cats) *(Multi- Collection Form)* 0579-0036 and 0579-0092

APHIS will display the OMB expiration date on the forms listed below:

APHIS Form 7001 – United States Interstate and International Certificate of Health Examination for Small Animals

APHIS Form 7001A – United States Interstate and International Certificate of Health Examination for Small Animals (Continuation Sheet)

APHIS Form 7003 –Application for License (Renewal License)

APHIS Form 7003A – Application for License (New License)

APHIS Form 7005 – Record of Acquisition of Dogs and Cats on Hand

APHIS Form 7006 – Record of Disposition of Dogs and Cats

APHIS Form 7006A – Continuation Sheet for Record of Disposition of Dogs and Cats

APHIS Form 7011 – Application for Registration - New Registration

APHIS Form 7011A – Application for Registration – Registration Update

APHIS Form 7019 – Record of Animals on Hand (Other than Dogs and Cats)

APHIS Form 7023 – Annual Report of Research Facility

APHIS Form 7023A – Annual Report of Research Facility (Continuation Sheet)

18. Explain each exception to the certification statement identified in Certification for Paperwork Reduction Act.

APHIS is able to certify compliance with all the provisions under the Act.

B. Collections of Information Employing Statistical Methods.

There are no statistical methods associated with the information collection activities used in this program.