Supporting Statement OMB 0579-0036
Animal Welfare

2015

Introduction:

The Animal and Plant Health Inspection Service (APHIS) is combining information collections 0579-0361, *Submission of Itineraries* and 0579-0392, *Animal Welfare: Retail Pet Stores and Licensing Exemptions* into this information collection – 0579-0036, *Animal Welfare*. Upon the reapproval of this information collection, APHIS will retire 0579-0361 and 0579-0392.

Terms of Clearance:

"In accordance with 5 CFR 1320, this information collection is approved for a period of three years. Before submitting this collection for reapproval, APHIS must demonstrate that the registration and licensing system is web-based and those portions of the collection can be completed electronically."

APHIS had an IT system titled Animal Care Information System (ACIS) which permitted licensees and registrants to complete much of the required information online; however, due to technical issues, this option for the regulated community had to be taken away. After such time, APHIS has dedicated itself to improving its modernization efforts over the Animal Welfare Act (AWA) licensing and registration process.

APHIS plans on making ACIS 3 available to its regulated community by February 2016 which will allow them to complete most licensing and registration documents, including annual reports online.

In addition, APHIS has identified this licensing and registration process as a process to be included in its master, cross-program new IT system titled eFile which is one system devoted to all of APHIS' certification, accreditation, registration, permits, and other licensing (CARPOL) activities and processes. This system is still in the design phase. APHIS has two contracting groups working on this system- one is aiding APHIS is the business documentation and planning and the other is building the system based on APHIS' requirements. Currently, eFile personnel are working their way through the CARPOL functions and are doing the "P" (permitting) first. The licensing and registration functions may come into production in the next 3+ years.

Other processes for computerization/moderation will be identified as an ongoing effort toward efficiency.

See question 3 below for more detailed information.

Justification:

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

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, hamsters, 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, APHIS, Animal Care (AC) has the responsibility to enforce the AWA (7 U.S.C. 2131-2156) and the provisions of 9 CFR, which implements the AWA.

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 6 of the AWA authorizes and requires individuals performing regulated dealer and exhibitor activities obtain a license from the Secretary.

Sections 10, 11, 12, and 13 of the AWA authorize and require certain recordkeeping requirements for

regulated facilities. Title 9 CFR Subchapter A, Part 2 stipulates certain conditions, including recordkeeping, for licensure or registration under the AWA, as well as certain conditions that must be documented in order for dealers, exhibitors, research facilities, etc., to hold, buy, sell and/or ship animals. Records of these conditions and their use must be kept for a period of at least 1 year. These records are necessary for APHIS to review and ensure that the licensees and registrants have met all licensing and registration documentation.

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 recordkeeping 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.

The records and reports herein provide APHIS with the data necessary for the review and evaluation of program compliance by regulated facilities, and provide a workable enforcement system to carry out the requirements of the AWA, and the intent of Congress, on a practical daily basis without resorting to more detailed and stringent regulations and standards which could be more burdensome to regulated facilities.

APHIS is asking OMB to approve its use of these information collection activities for an additional 3 years.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

APHIS uses the following information collection activities to help determine whether a reporting facility is following professionally acceptable standards governing care, treatment, and use of animals.

Section 1.1 – Definitions - Research Facility Exemption (Farms)

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.

Sections 2.1(a)(1); 2.2(a) - Application for License - Acknowledgment of Regulations and Standards (APHIS Form 7003A) (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms)(additional burden added from 0579-0392)

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 and 2.2 - Application for License – providing PII (draft APHIS 7030) (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms) (additional burden added from 0579-0392)

APHIS, to more accurately track and enforce the AWA, needs to collect PII/PIN from dealers and exhibitors during their application for license. This information has been collected in the past

as part of many of the existing forms and was removed from them so that it would only have to be collected once and would make handling and secure storage of the information easier and more effective. This form can be easily locked up while still allowing ready access to authorized APHIS personnel, as needed. In addition, APHIS has drafted a Systems of Records Notice (SORN) to cover/approve this information in regards to the Privacy Act, but that SORN is still in clearance.

Section 2.2(b) – Application for License Renewal - Acknowledgement of Regulations and Standards (APHIS 7003) (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms) (additional burden added from 0579-0392)

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 2.5(a)(2) - License Request to Surrender License (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms(additional burden added from 0579-0392))

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. This request may be emailed.

Section 2.5(e) - Written Statement License is Lost (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms) (additional burden added from 0579-0392)

A licensee with an invalid license must surrender it to the APHIS, AC, Regional Director. If the licensee cannot 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 2.1, 2.2, and 2.5 - Application for License – providing PII (draft APHIS 7030) (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms)

APHIS to more accurately track and enforce the AWA needs to collect PII from dealers and exhibitors during their license renewal. This information is kept secure. See above for more information.

Section 2.3 – Request for Pre-licensing Inspection (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms) (additional burden added from 0579-0392)

This section provides for the request for additional pre-licensing inspections if the requestor did not pass on the first inspection. There is no set method for making such a request, although it may be made in writing.

Section 2.6(e) - Written Request for Correction of Dollar Amount of Business (Business) (additional burden added from 0579-0392)

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 2.8, 2.27(a), 2.30(c)(1) - Change of Address Notification (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms)(additional burden added from 0579-0392)

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 to Reinstate Suspended or Revoked License (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms) (additional burden added from 0579-0392)

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 for Denied License or Renewal (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms) (additional burden added from 0579-0392)

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 and 2.30(a)- Application for Registration (APHIS 7011) (Business and Not-for-Profit)

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 this 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 7023/7023a) to each reporting research facility as required under Section 13 (7)(A) and Section 25 of the AWA.

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 2.1, 2.2, and 2.5 - Application for Registration– providing PII (draft APHIS 7030) (Business and Not-for-Profit)

APHIS to more accurately track and enforce the AWA needs to collect PII from dealers and

exhibitors for registration application. This information is kept secure. See above for more information.

Section 2.27(b)(1) - Written Request to be Placed in Inactive Status (Business and Not-for-Profit)

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 (Business and Not-for-Profit)

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(c)(2) – Written Notification of Resumption of Registration (Business)

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.

Section 2.31 - Written Notification of Failure to Adhere to Correction Scheduled (Business and Not-For-Profit)

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), 2.31(d), (e) - Records of IACUC Activities (Business and Not-for-Profit)

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 APHIS 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.

Sections 2.33(a)(1) and 2.40(a)(1)(b) - Written Program of Veterinary Care (APHIS 7002 or equivalent)(Business and Not-For-Profit) (additional burden added from 0579-0392)

Section 13 of the AWA requires that animals intended for use in research, exhibition purposes, or for use as pets are provided adequate veterinary care. Sections 2.33 and 2.40 of the regulations require registrants and licensees have an attending veterinarian to provide veterinary care to its animals that complies with the regulations. All licensees and registrants that employ a part-time attending veterinarian are required to establish through formal arrangements a written program of veterinary care that provides adequate veterinary care to the animals and regularly scheduled visits to the premises of the licensee and registrant. The written program of veterinary

care is a document that is maintained at the facility. Although APHIS Form 7002 is not a mandatory form, it is widely used. The design of this form allows for its use by different types of facilities for various species of animals. The information contained in APHIS Form 7002 allows verification that the facility has an attending veterinarian and a written program of adequate veterinary care.

In the attending veterinarian's absence, an inspector may review APHIS Form 7002, maintained at the facility, to compare the observed health status of the animals to the written program of veterinary care. If necessary, an inspector may contact the attending veterinarian, identified in the written program, for supplemental information regarding the facility's program of veterinary care. Without the information contained in the written program of veterinary care it would be very difficult to assess and enforce the requirement of an adequate program of veterinary care as required under Section 13 of the AWA.

Section 2.35(a),(f); 2.38(g)(2),(8) - Recordkeeping (Business and Not-For-Profit)

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; 2.132 Records Disclosing Live Dogs and Cats Purchased (APHIS 7001 (optional) APHIS 7005 and APHIS 7006) (Business and Not-For-Profit)

These sections provide for the recordkeeping requirements for obtaining dogs, cats, and other animals by dealers or research institutions. Among the records required are the name and address of the person supplying the animals; the identification of the animals, including a description, gender, age, identification number or tattoo, date of transaction, and, where required, health certificate. In addition, the licensee must also obtain a certifying statement from any unlicensed source indicating the validity of and reason for the exemption from licensure under which they are operating. The USDA Interstate and International Certificate of Health Examination for Small Animals (APHIS 7001), Record of Acquisition and Dogs and Cats on Hand (APHIS Form 7005), and Record of

Disposition of Dogs and Cats (APHIS 7006) are forms which may be used by research facilities to keep and maintain the information required by the AWA. Other methods of maintaining the records are allowed as long as the above information is retained and APHIS has access to the records.

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) - Research Facility Transportation Records (Business and Not-For-Profit)

Every research facility transporting, selling, or disposing of any live dog or cat to another person, maintains records or forms which fully and correctly disclose the following information: (1) name and address of the person to whom a live dog or cat is transported, sold, or otherwise disposed of; (2) the date of transportation, sale, euthanasia, or other disposition of the animal; (3) method of transportation, including the name of the initial carrier or intermediate handler, or if a privately owned vehicle is used to transport the dog or cat, the name of the owner of the privately owned vehicle. One copy of the record containing the information above accompanies each shipment of any live dog or cat sold or otherwise disposed of by a research facility.

Section 2.36(a),(b) - Annual Report – Research (APHIS 7023 and 7023A) (Business and Not-For-Profit)

This report (APHIS Form 7023 and 7023a – continuation sheet) 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 was available in an electronic format that could 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; however, due to current technical difficulties this capability is no longer available. See the introductory Terms of Clearance section and question 3 below for the future of this report submission.

Section 2.38(a); 2.125 – Research Facility Furnish All Requested Information(Business and Not-For-Profit)

Each research facility, intermediate handler, carrier, and exhibitor furnishes to an APHIS official any information concerning the business of the 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) - Removed Tags Retained for 1 Year(Business and Not-For-Profit) (additional burden added from 0579-0392)

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 in Transport (APHIS 7001 (optional)) (Business and Not-For-Profit)

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 Certificates(Business and Not-For-Profit)

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 AWA for persons holding animals for a research facility (APHIS 7009) (Business and Not-For-Profit)

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) - Institutional Official Recognizes Official Site(Business and Not-For-Profit)

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

Section 2.40 – Written Program of Veterinary Care (APHIS 7002 (optional) or none) (State, Local, or Tribal Governments; Business; Not-For-Profit; and Farms)

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 2.50(c) – Official tag, records and record book maintained, records of animals other than dogs and cats delivered for transport(State, Local, or Tribal Governments; Business; Not-For-Profit; and Farms)

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.

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/Enclosure(State, Local, or Tribal Governments; Business; Not-For-Profit; and Farms)

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 Enclosure/Container(State, Local, or Tribal Governments; Business; Not-For-Profit; and Farms)

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 2.55(b) - Official Tags Kept for 1 Year (APHIS 7001a)(State, Local, or Tribal Governments; Business; Not-For-Profit; and Farms)

United States Interstate and International Certificate of Health Examination for Small Animals, records tag numbers of small animals. All official tags removed and retained by a dealer or exhibitor will be held until called for by an APHIS official or for a period of 1 year.

Section 2.75(a)(1) - Dogs and Cats held by Exhibitors - (APHIS Forms 7005, 7006 and 7006A) (State, Local, or Tribal Governments; Business; Not-For-Profit; and Farms) (additional burden added from 0579-0392)

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(State, Local, or Tribal Governments; Business; Not-For-Profit; and Farms) (additional burden added from 0579-0392)

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(Business)(additional burden added from 0579-0392)

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 (see above). 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 and 2.80 – Records on Animals Other than Dogs and Cats – (APHIS 7019, 7020, or equivalent) (State, Local, or Tribal Governments; Business; Not-For-Profit; and Farms)

The information provides an inventory record of animals, other than dogs and cats onhand and provides for the disposition of regulated animals, other than dogs an cats, as required in Section 10 of the AWA and Section 2.75 of the regulations, The information is maintained by the sending and receiving facility and must accompany the animals during transit. USDA inspectors examine the records during inspection of facilities and identify certain animals moved illegally and animals exposed to disease. In addition, the records assist with the detection of animal origin and destination 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 data with data collected on other forms in this information collection package.

Section 2.76(a) – Auction Sales or Brokers Records(Business)(additional burden added from 0579-0392)

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) – Consignor Written Guarantee; attempt to notify consignor(Business)

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 2.78(a)(c) - Health Certificate – Transport Dogs, Cats, or Nonhuman Primates(APHIS 7001) (State, Local, or Tribal Governments; Business; Not-For-Profit; and Farms)(additional burden added from 0579-0392)

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) - Dogs, Cats, or Nonhuman Primates Inspected by Licensed Veterinarian(State, Local, or Tribal Governments; Business; Not-For-Profit; and Farms) (additional burden added from 0579-0392)

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 2.102(a)(1) - Approval to Hold Animals /Have Someone Else Hold Animals(APHIS 7009) (State, Local, or Tribal Governments; Business; Not-For-Profit; and Farms) (additional burden added from 0579-0392)

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.

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 – Information Concerning Business – Beyond What is Currently Identified (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms) (additional burden added from 0579-0392)

This is where APHIS solicits information from other law enforcements, such as description of missing animals to descriptions of facilities at a particular time.

Section 2.133 - Certification for: Breeders, Dealers, Research, Non-Regulated Pounds and

Shelters (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms)

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 2.1 and 2,2 - Online Prelicensing Tool to Guide Requests for Licensing/registration Packets (State, Local, and Tribal Governments; Business; Not-for-Profit; and Farms) (additional burden added from 0579-0392)

This tool (aid) helps members of the public determine what, if any, license or registration is required under the AWA for the activity they want to undertake with the animals identified. This tool is voluntary and, if used appropriately, will minimize unnecessary paperwork and streamline the application process by focusing the applicant in the correct direction. No data is maintained from this activity by APHIS, and the person is free to apply for a license/registration regardless of the results.
Note: This question approach is being used in the creation of the new APHIS IT system – eFile, described below.

Section 2.126(c) – Submission of itineraries(new from 0579-0361)

Whenever an animal or animals are to be exhibited at any location other than the designated primary facility for a time period to include at least one overnight stay away from the facility, the licensee or registrant must submit a written itinerary to the appropriate Animal Care Regional office. This itinerary must include the name and/or other animal identification, species name, sex, and age of each animal, the name of the person exhibiting the animal, the owner of the animal(s) if not the licensee or registrant, the business name of the exhibitor and owner, any names being used to promote the tour, and the current USDA licensee or registration number(s), the dates the animal(s) will be away from the facility, all anticipated dates for all stops, and all site names and complete addresses of all stops and layovers. Submissions of itineraries to APHIS can be made via mail, e-mail, commercial delivery service or fax. APHIS maintains records for 3 years in the facility file.

Section 3.66 and 3.6 – Approval for less than minimum housing requirements for dogs and cats(Business)(new from 0579-0392)

There are additional space requirements for dogs and/or cats with litters of young. If the additional space provided for each offspring is less than 5 percent of minimum required for the dam, the lesser space must be approved by the attending veterinarian and, if the animals are being used in an active protocol, the Institutional Animal Care and Use Committee (IACUC) of a research facility. In the case of a dealer, the lesser space must be approved by the Administrator. These requirements are to ensure that the dogs and cats are afforded the required space to ensure

that the animals are comfortable in accordance with good husbandry practices. The applicable sections are 3.6(b)(1)(iii) for cats, and 3.6(c)((1)(ii) for dogs.

Section 3.8 – Written standard procedures (plan) for exercise and recording thereof And Documentation for exercise exemption and recordkeeping(Business)(new from 0579-0392)

Exercise and socialization for dogs. The 1985 amendments to the Act require the Secretary to promulgate standards for "...exercise of dogs as determined by an attending veterinarian in accordance with general standards promulgated by the Secretary...".

The written standard procedures will be maintained by the business and reviewed by APHIS' inspectors during inspections to ensure the intent of the Act is followed. The plan must be in accordance with professionally accepted standards as directed by the attending veterinarian.

Sections 3.13 and 3.86 – Consignment to carriers and intermediate handlers(Business)(new from 0579-0392)

Sections 3.13, 3.14, 3.16, 3.36, 3.61, and 3.86 – Shipping documents and written instructions for food, water, mediation, and special care attached to enclosure. Numbers accounted for under 3.113(Business)(new from 0579-0392)

Sections 3.137, 3.139, 3.13, 3.19, 3.35, 3.37, 3.60, 3.62, 3.14, 3.19, 3.36, 3.61, 3.87, 3.113, 3.137, 3.92 – Certification by Consignor and attending veterinarians that animal is acclimated to temperature outside requirements(Business)(new from 0579-0392)

Consignments to carriers and intermediate handlers. Certain information, instructions, and certifications are required for the humane transportation of animals 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) for some animals, and some are optional (enclosure requirements and acclimation to temperature). Shipping documents must be affixed to the transport enclosure or be carried by the attendant.

Sections 3.137, 3.139, 3.13, 3.19, 3.35, 3.37, 3.60, 3.62, 3.14, 3.19, 3.36, 3.61, 3.87, 3.113, 3.137, 3.92 – Marking requirements for transport enclosure ("live animals") (Business) (new from 0579-0392)(Reporting and Third Party Disclosure)

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.

Sections 3.77, 3.78, 3.103, 3.127 – Perimeter fencing variance from requirements(Business) (new from 0579-0392)

The outdoor areas of a sheltered housing facility or outdoor housing facility must be enclosed by a fence that is of sufficient height to keep unwanted species out. Fences less than 6 feet high must be approved by the Administrator of APHIS. Potentially dangerous species require an 8 foot perimeter fence. Alternate safety protocols may be used with the approval of the Administrator. Requests for approval of alternative security measure that meet or exceed the safety provided to the animals and the public in the regulations concerning perimeter fences for marine mammals and animals other than cats, dogs, guinea pigs, hamsters, rabbits, nonhuman primates, and marine mammals, must be submitted to APHIS for approval. These written requests are used to evaluate the extent to which the proposed deviation from the requirements protects the animals and the public and meets the intent of the regulations. If the plan meets or exceeds the current requirements, approval is granted. This process allows for flexibility in enforcing the regulations without compromising the health and safety of the animals and the safety of the public.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Section 2.75(a)(2) recordkeeping requirements for dealers and exhibitors with dogs and/or cats (not a standardized form; see question 2 above for more information) allows 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.

The APHIS form 7001is fillable printable and it is available at http://www.aphis.usda.gov/library/forms/pdf/APHIS7001.pdf.

APHIS forms 7005, 7006, 7006A, 7019, and 7020 are available online at https://www.aphis.usda.gov/wps/portal/aphis/resources/forms/!ut/p/a1/04_Sj9CPykssy0xPLMnMz0vMAfGjzOJNPC2MjIwNjDwtggPNDDzdAvxMnY2MDA2MzIEKIoEKnN0dPUzMfQwMDEwsjAw8XZw8XMwtfQ0MPM2I02-AAzgaENIfrh-FqsTd0NEFqC_Yxy_Qw83AwNsQqgCfE8EK8LihIDc0wiDTUxEA4Mesbg!!/?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_resources%2Fsa_forms%2Fct_aphis_forms

The following burden items (not standardized forms; see question 2 above for more information) may be emailed, faxed, or mailed to APHIS at the respondents' preference:
Request to Surrender License,

Request for Pre-Licensing Inspection,
Written Request for Correction of Dollar Amount,
Change of Address Notification,
Written Request to Reinstate Suspended or Revoked License,
Written Request for Cancellation of Registration,
Exceptions to Health Certificates,
IO Recognizes Official Site,
Request for Variance, and
Perimeter Fencing Variance from Requirements.

Itineraries (not a standardized form; see question 2 above for more information) can be submitted to APHIS via regular mail, courier services (such as FedEx, UPS, etc.), faxed to the regional office, or emailed to the regional office. The use of electronic submissions (fax and e-mail) afford a decrease in notification time, record of submission, and reduction of paperwork and mailing activities if the party elects these modes of submission. Itineraries must be received by APHIS at least 2 days prior to proposed travel.

Currently, APHIS is pre-populating data fields on the following forms: APHIS forms 7003, 7011a, 7023, and 7023a. The pre-populated data is derived from previous submissions and populated by APHIS personnel before sending to the regulated community for updates to decrease the burden.

AC also plans to computerize the registration and licensing process including annual reports (APHIS forms 7003A, 7030, 7003, 7011, 7023, and 7023A). The person or facility will be able to input the necessary information directly into an IT system – ACIS. APHIS anticipates that this also will save time and cost both for the regulated community and for AC. AC anticipates having this available by end of 2015.

In addition, APHIS has identified this licensing and registration process (APHIS forms 7001, 7003A, 7030, 7003, 7011, 7023, and 7023A) as a process to be included in its master, cross-program new IT system titled eFile which is one system devoted to all of APHIS' certification, accreditation, registration, permits, and other licensing (CARPOL) activities and processes. This system is still being designed. APHIS has two contracting groups working on this system- one is aiding APHIS is the business documentation and planning and the other is building the system based on APHIS' requirements.

Other processes for computerization/moderation will be identified 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 these regulated animals.

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

The information APHIS collects is the minimum needed to ensure the humane handling and care of animals under the AWA. The majority (80%) of licensees are small business dealers.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

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.

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

Section 2.7 - Annual Report by Licensees

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.

- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**

Recordkeeping – Generally, facilities are to maintain these records for 3 years; however, whenever the Administrator notifies a research facility, in writing, that specified records will be retained pending completion of an investigation or proceeding under the AWA, the research facility will hold those records until their disposition is authorized, in writing, by the Administrator.

- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

No other special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

The following non-government organizations consulted with Animal Care Staff regarding the AWA:
Association of Zoos and Aquariums
8403 Colesville Road, Suite 710
Silver Spring, MD 20910

The Humane Society of the United States
(multiple contacts, multiple departments)
2100 L St., NW
Washington, D.C. 20037
Phone: 202-452-1100

Elephant Managers Association
1513 Cambridge Street
Houston TX 77030

On Tuesday, January 6, 2015, pages 485-486, 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. During that 60-day comment period, APHIS received four comments from the

public.

One comment was from a citizen that fully supports the AWA and this information collection.

Another comment was from a concerned citizen that thinks APHIS should do more and commented on topics not related to this information collection.

APHIS received a letter received from a concerned citizen who supports the AWA and this information collection, but thinks APHIS and Congress should do more to strictly enforce the humane handling and care of animals.

Lastly, APHIS received a letter from the Human Society of The United States. In general, they support the AWA, but, in addition to the activities listed in this information collection, they suggest requiring research facilities to submit annual reports which identify number and species of animals used, if pain-relief was provided or if the animals experienced unrelieved pain and/or distress (more detailed annual reports than what are currently required). APHIS is working with its stakeholders to determine if this is necessary or recommended. Also, APHIS published, in the Federal Register, *A Petition to Define Alternatives to Procedures that may Cause Pain or Distress and to Establish Standards Regarding Consideration of these Alternatives* on Monday, March 30, 2015.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration of contractors or grantees.

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, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

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

However, APHIS, to more accurately enforce the AWA, can collect PII/PIN from dealers and exhibitors during their application for license. This information has been collected in the past as part of many of the existing forms and was removed from them so that it would only have to be collected once and would make handling and secure storage of the information easier and more effective. This printed/paper form can be easily locked up while still allowing ready access to authorized APHIS personnel, as needed. Plus, digital records, including completed electronic forms, can be uploaded into or directly entered into and stored in APHIS' system ACIS3. Information housed in that system is stored on one of APHIS' secure servers in which only authorized users have access. APHIS has an IT security program (which includes, but is not limited to, privileged access management) which complies with Federal IT security standards including, but not limited to, FISMA controls in order to ensure the protection of electronic data within its IT infrastructure. In addition, APHIS has drafted a Systems of Records Notice (SORN) to cover/approve this information in regards to the Privacy Act, but that SORN is still in clearance.

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.

See APHIS Form 71 for the burden estimate. The estimates were developed from historical data, calculated average number of licensees and registrants, and from discussions with field personnel.

•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.

APHIS estimates the total annualized cost to these respondents to be $2,850,008. APHIS arrived at this figure by multiplying the total burden hours (136,364) by the estimated hourly wage of the respondents ($20.90).

This average hourly rate for the above respondents is derived from the U.S. Department of Labor; Bureau of Labor Statistics May 2014 Report – National Occupational Employment and Wage Estimates United States. See http://www.bls.gov/oes/#tables.]

13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14.) The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

There are no additional costs associated with this information collection; however, APHIS does charge application and license fees (APHIS 7003 explanation in question 2 above).

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

The estimated cost for the Federal Government is $1,076,498 (See APHIS Form 79).

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	216,171	0	+120,234	0	0	95,937
Annual Time Burden (Hr)	136,364	0	+41,204	0	0	95,160
Annual Cost Burden ($)	0	0	0	0	0	0

There is a program change of +41,204 hours and +120,234 responses due to the merging of 0579-0361 and 0579-0392 into this information collection.

Submission of Itineraries is new to this information collection and was added from 0579-0361.

The following items are new to this information collection and were added from 0579-0392:

- Approval for less than minimum housing requirements for dogs and cats
- Written standard procedures (plan) for exercise and recording thereof
  And
  Documentation for exercise exemption and recordkeeping
- Consignment to carriers and intermediate handlers

- Shipping documents and written instructions for food, water, mediation, and special care attached to enclosure
- Certification by Consignor and attending veterinarians that animal is acclimated to temperature outside requirements
- Marking requirements for transport enclosure ("live animals")
- Perimeter fencing variance from requirements

In addition to the new items identified above, 0579-0392 adds additional burden to many of the existing burden items because, of the "new" additional/different regulated groups/respondents to the AWA.

Burden item(s) coming from these two information collections and/or adding burden to existing burden items are identified in question 2 above.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

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.

APHIS personnel take information from collected forms (such as APHIS form 7023) and aggregate the data to represent the total number of facilities and more of the aforementioned data. These totals are used to compile the annual AWA report to Congress.

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 reasons that display would be inappropriate.

APHIS is seeking approval to not display the OMB expiration date on APHIS 7002, 7020, and 7020a. These forms are used in multiple information collections; therefore, it is not practical to include an OMB expiration date because of the various expiration dates for each information collection.

APHIS will display the expiration date on all other forms.

18. Explain each exception to the certification statement identified under "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.

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