

February 19, 2020

**SUPPORTING STATEMENT
ANIMAL WELFARE
OMB NO. 0579-0036**

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 has an IT system titled Animal Care Information System (ACIS) which collects and stores the license, registration, and inspection data associated with the requirements of the Animal Welfare Act (AWA). APHIS continues to pursue making ACIS available to its regulated community to allow them to complete most licensing and registration documents, including annual reports, online.

APHIS has identified the on-line 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. Currently, eFile personnel are working their way through the CARPOL functions, starting with the “P” (permitting) function. Permitting for the import of live dogs was the first module completed. APHIS is now incorporating its other permitting functions into the permitting module. The licensing and registration functions may come into production in the next 3+ years.

Other processes for computerization/modernization including completing the research facility annual report of animal use 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 89-544) enacted August 24, 1966, and amended December 24, 1970 (Public Law 91-579); April 22, 1976 (Public Law 94-279); December 23, 1985 (Public Law 99-198); November 28, 1990 (Public Law 101-624); January 23, 2002 (Public Law 107-171); May 3, 2007 (Public Law 110-22); June 18, 2008 (Public Law 110-246); and January 10, 2013 (Public Law 112-261), requires the U.S. Department of Agriculture (USDA) to regulate the humane care and handling of most warm-blooded animals used for research or exhibition purposes, sold as pets, or transported in commerce. This legislation and its amendments were the result of extensive demand by organized animal welfare groups and private citizens requesting a Federal law to protect such animals. USDA, Animal and Plant Health Inspection Service (APHIS), Animal Care (AC) has the responsibility to enforce the AWA (7 U.S.C. 2131-2156) and the provisions of 9 CFR, Chapter 1, Subchapter A, which implements the AWA.

The stated purpose of the AWA, Section 2131, is as follows:

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

(2) to 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, for the 1985 amendment, 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."

Sections 2133 and 2134 of the AWA authorize and require individuals performing regulated

dealer and exhibitor activities to obtain and maintain a valid license from the Secretary of Agriculture.

Section 2135 requires dealers and exhibitors to certify that all dogs or cats were held 5 days before being sold or otherwise disposed of. No official form is required to comply with this requirement.

Section 2136 of the AWA authorizes and requires research facilities, handlers, carriers, and unlicensed exhibitors to obtain a registration from the Secretary of Agriculture.

Section 2140 of the AWA authorizes and requires certain recordkeeping by regulated facilities.

Section 2142 of the AWA authorizes the Secretary of Agriculture to promulgate humane standards, and recordkeeping requirements governing the purchase, handling, or sale of animals, in commerce, by dealers, research facilities, and exhibitors at auction sales and by the operators of such auction sales. Section 2142 of the AWA also authorizes the Secretary of Agriculture to require the licensing of operators of auction sales where any dogs or cats are sold, in commerce, under such conditions as he may prescribe.

Section 2143 of the AWA authorizes the Secretary of Agriculture to promulgate standards to govern the humane handling, care, treatment, and transportation of animals by dealers, research facilities, exhibitors, intermediate handlers, and carriers, including specific requirements with respect to animals in research facilities. These requirements include establishment of a Committee to assess the condition of animals and practices involving pain to animals and to ensure compliance with the requirements to minimize pain and distress to animals [implemented in 9 CFR, Subchapter A, Part 2, Section 2.31 Institutional Animal Care and Use Committee (IACUC)]. 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. Any deviations from the standards promulgated by the Secretary must be specified, explained, and approved by the IACUC (9 CFR, Subchapter A, Part 2, Section 2.36 Annual report).

Section 2148 of the AWA authorizes the Secretary of Agriculture to promulgate specific requirements with respect to live dogs imported into the United States (implemented in 9 CFR, Subchapter A, Part 2, Section 2.150 Importation of Live Dogs).

Section 2151 of the AWA authorizes the Secretary of Agriculture to promulgate such rules, regulations, and orders as he may deem necessary in order to effectuate the purposes of the AWA.

Section 2158 of the AWA adds certain recordkeeping requirements for dealers and research facilities and pounds and shelters if they sell or donate dogs or cats to dealers or research facilities. The section requires a State, county, or city owned and operated pound or shelter; a humane society or other organization under contract with a State, county, or city that operates a pound or shelter and that releases animals on a voluntary basis; each USDA licensed dealer; and each USDA registered research facility to certify that all dogs and cats were held five days to

give owners a chance to reclaim their animals. The certification must contain specific information regarding the animal, source, and transaction. The certification must also include that the last owner or dealer was notified that the animal may be sold for research. These records must be kept and maintained for at least one year. No official form is required to comply with this law.

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, carriers, and intermediate handlers to hold, buy, sell and/or ship animals. Records of these conditions must be kept for a period of one to three years. These records are necessary for APHIS to review and ensure that the licensees and registrants have met all licensing and registration documentation requirements. These records are also necessary to ensure that the animals are cared for in the manner that is required by the regulations.

Title 9 CFR, Subchapter A, Part 3 addresses the specifications for humane handling, care, treatment, and transportation of regulated animals, including areas such as facilities construction, veterinary care, personnel, feeding, water quality, sanitation, space requirements, transportation enclosures, and handling and care in transit. Subpart A addresses the specifications for dogs and cats, Subpart B for guinea pigs and hamsters, Subpart C for rabbits, Subpart D for nonhuman primates, Subpart E for marine mammals, and Subpart F for all other regulated animals.

The Federal Debt Collection Act of 1996 requires APHIS to obtain your Federal Taxpayer Identification Number; either the Federal Employer Identification Number (EIN) or your Social Security Number(s) (SSN). This number is for the purpose of collecting and reporting any delinquent amounts arising out of a relationship with the Federal Government.

The records and reports herein provide APHIS with the data necessary for the review and evaluation of program compliance by regulated facilities, and they 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 that 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.

APHIS has the regulatory authority to enforce the AWA. APHIS prepares responsive documents to Congress, industry organizations, animal advocacy groups, and the general public that pertain to animal welfare activities. Information for these documents depends on the proper recording and reporting of the information received in the above mentioned records. APHIS must be equipped with data on the animals at the regulated facilities in order to make a professional assessment of animal conditions. Failure to provide this data would be contrary to the intent of the Act and would prevent prosecution of violators.

Furthermore, the records and reports herein provide APHIS with the data necessary for the review and evaluation of program compliance by regulated facilities. This recorded information becomes a part of the enforcement system that carries out the requirements of the Act and the intent of Congress. This is accomplished on a practical daily basis without the use of more detailed and stringent regulations and standards that could be more burdensome to regulated facilities.

APHIS will collect the information from:

- Individuals or households: e.g. individuals bringing live dogs into the country; individuals submitting complaints about licensees and registrants; webinar/symposium audience members
- Businesses or other for-profit entities: e.g. entities with Inc., LLC, Ltd, corporation, partnership in the name; nurseries, garden centers
- Not-for-profit institutions: e.g. entities with foundation, haven, refuge, rehabilitation, rescue, sanctuary, SPCA, society, or organization in its name. This may include colleges, universities, medical facilities, zoological organizations, museums, and nature or conservation centers.
- Farms: e.g. entities with farm, ranch, orchard, dairy, range, patch in its name and the inventory is only farm animals.
- Foreign Federal governments: e.g. entities with a foreign country affiliation and their representatives. This may include the EU veterinarian, Peruvian Ministry of Agriculture, etc. and
- State, local, and Tribal governments: e.g. entities with “City of”, “County of”, “State of”, “Nation of” in its name. This may include Tribal organizations, state universities, public colleges or universities.

In the following paragraphs, “Section” refers to an appropriate part of the AWA or 9 CFR, Subchapter A.

Section 1.1 – Definitions - Research Facility Exemption (Business or Other For-Profit)

Section 2132 (e) of the AWA and Section 1.1 of the regulations define 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 or 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 and 2.2 - Online Prelicensing Tool to Guide Requests for Licensing/registration Packets (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

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. This question-based approach will be developed and implemented with the new APHIS IT system – eFile described below. Currently, this information is being exchanged on a case-by-case basis.

Sections 2.1, 2.2, 2.5, 2.25, 2.26, and 2.30 – Federal Debt Collection Form (APHIS Form 7030); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

The Federal Debt Collection Act of 1996 requires APHIS to obtain your Federal Taxpayer Identification Number (Federal Employer Identification Number (EIN) or Social Security Number(s) (SSN)) for the purpose of collecting and reporting any delinquent amounts arising out of a relationship with the Federal Government. The SSN or EIN is required to verify the identity of the applicant. A person may not possess more than one license. If a different ID number is used, a new license will be required.

Sections 2.1(a)(1) and 2.2(a) - Application for New License, Acknowledgment of Regulations and Standards (APHIS Form 7003A); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

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 Section 2.1(a)(3), must have a valid license. The applicant must submit a completed new license application, demonstrate compliance with the regulations and standards, and pay the required fees. A license is issued to a specific person for specific premises and do not transfer upon change in ownership, nor are they valid at a different location. The APHIS Form 7003A is used by applicants for a new license as a dealer or exhibitor. It requests the applicants name, valid mailing address, species and number of animals, and business activity and a valid premises address where animals, animal facilities, equipment, and records may be inspected for compliance. APHIS, to accurately track and enforce the AWA, needs to collect personal identifiable information/personal identification number (PII/PIN) from the dealers and exhibitors. This information is kept secure. These forms are stored in a secured building and room. Access is limited to

authorized APHIS personnel, as needed.

APHIS will supply a copy of the applicable regulations and standards to the applicant with each request for a new license application. The applicant will acknowledge receipt of the regulations and standards and agree to comply with them by signing the application form. APHIS personnel verify the accuracy of the information on the application during the physical inspection of the premises, animals, and records. Without the information on APHIS Form 7003A, the Animal Welfare Program would be unable to enforce the AWA.

Sections 2.1(d)(1) and 2.2(b) – Application for License Renewal and Annual Report, Acknowledgement of Regulations and Standards (APHIS Form 7003); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

Any person continuing to operate as a dealer, exhibitor, or operator of an auction sale, except persons who are exempted from the licensing requirements under Section 2.1(a)(3), must file an application for a license renewal and an annual report form (APHIS Form 7003) as required by Section 2.7, and pay the required fees, on or before the expiration date of the present license. Failure to comply will result in automatic termination of the license on its anniversary date. A license is issued to a specific person for specific premises and do not transfer upon change in ownership, nor are they valid at a different location. The APHIS Form 7003 is used by applicants for license renewal and reporting the annual business activity of the dealer or exhibitor. It requests the applicants name, valid mailing address, species and number of animals, and business activity and a valid premises address where animals, animal facilities, equipment, and records may be inspected for compliance. APHIS, to accurately track and enforce the AWA, needs to collect personal identifiable information/personal identification number (PII/PIN) from the dealers and exhibitors. This information is kept secure. These forms are stored in a secured building and room. Access is limited to authorized APHIS personnel, as needed.

The dealer or exhibitor agrees to comply with the regulations and standards by signing the license renewal and annual report form. APHIS personnel verify the accuracy of the information on the application during the physical inspection of the premises, animals, and records. APHIS will issue a license certificate (APHIS Form 7007). Without the information on APHIS Form 7003, the Animal Welfare Program would be unable to enforce the AWA.

Section 2.3 – Request for 1st Pre-licensing Inspection; Signature Acknowledging Receipt of Inspection Report (APHIS Forms 7008, 7080, 7081, 7082, 7083, 7084, 7085, and 7086); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

An applicant's facility must meet all applicable regulations and standards to obtain a license. APHIS conducts a prelicense phone conversation with the applicant prior to the facility inspection to discuss the requirements of the regulations and standards and to determine if the facility is ready for the 1st prelicense inspection. APHIS personnel use the dealer/exhibitor pre-license discussion questions as a guide to facilitate the discussion (APHIS Forms 7080, 7082, 7084, and 7086). The prelicense inspection is scheduled at a time agreeable to the applicant and the inspector. APHIS personnel conduct the inspection along with the applicant following a

prelicense inspection checklist (APHIS Forms 7081, 7083, or 7085) and document their findings on an inspection report (APHIS Form 7008). The applicant signs the report acknowledging receipt of the report. APHIS

Section 2.3 – Request for 2nd and 3rd Pre-licensing Inspection; Signature Acknowledging Receipt of Inspection Report (APHIS Forms 7008, 7081, 7083, and 7085); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

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. APHIS personnel conduct the inspection along with the applicant following a prelicense inspection checklist (APHIS Forms 7081, 7083, or 7085) and document their findings on an inspection report (APHIS Form 7008). The applicant signs the report acknowledging receipt of the report.

Section 2.5(a)(2), (e) - Request for Voluntary License Termination and Written Statement License Certificate is Lost (APHIS Form 7032); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

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. A license certificate (APHIS Form 7007) which is invalid shall be surrendered to the AC Regional Director. If the license certificate cannot be found, the licensee shall provide a written statement so stating to the AC Regional Director. The Request for Voluntary License Termination/Registration Cancellation form (APHIS Form 7032) may be used for this purpose.

Section 2.6 – Annual License Fee Credit Card Authorization (APHIS Form 7031); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

Each applicant for a new license or license renewal must pay the required fees. Payment of fees may be made by credit or debit card, certified check, cashier's check, or money order.

The paper-based system of records contains the credit card information for persons who used a credit card to pay for a license application or license renewal using the credit card authorization form (APHIS Form 7031). The credit card information is retained for audit purposes only. In addition, the database and electronic payment component of the system collects and retains the last four digits of the credit card and the expiration date or the check number, the name of the person, and the amount collected for those who have applied for a license or renewal of a license requiring a payment. This information is kept secure. These forms are stored in a secured building and room. Access is limited to authorized APHIS personnel, as needed. The APHIS eFile system will support online payment of the application and license fees.

Without the financial information on APHIS Form 7031 (credit card authorization form) the Animal Welfare Program would be unable to collect the appropriate license fees paid by credit

card and enforce the AWA.

Section 2.6(e) - Written Request for Correction of Renewal Application including Dollar Amount of Business (APHIS Form 7003); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

A licensee must submit a complete and accurate application for a new license or license renewal. APHIS personnel verify the accuracy of the information on the application during application processing and/or during the physical inspection of the premises, animals, and records. A corrected application is to be submitted to the appropriate Animal Care office before a license is issued or renewed.

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. The information is submitted on the license renewal application.

Sections 2.8, 2.27(a), and 2.30(c)(1) – Notification of Change (APHIS Form 7033); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

A licensee or registrant is responsible for notifying the APHIS AC Regional Director of any change in the name, address, ownership of his business, or other change in operations 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. The Notification of Change form (APHIS Form 7033) may be used for this purpose.

Section 2.10(a) - Written Request to Reinstate Suspended or Revoked License; (Business or Other For-Profit, Not-For-Profit, and State, Local, and Tribal Governments)

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) – Denial of a New License Including Response to a Request for a Hearing; (Business or Other For-Profit, Not-For-Profit, and State, Local, and Tribal Governments)

An applicant whose new 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 2.12 –Termination of a License Renewal; (Business or Other For-Profit, Not-For-Profit, and State, Local, and Tribal Governments)

An applicant whose license has been terminated may request a hearing in accordance with the applicable rules of practice for the purpose of showing why the application for license renewal

should not be denied.

Sections 2.25, 2.26, and 2.30(a) - Application for New Registration, and Acknowledgment of Regulations and Standards (APHIS Form 7011A); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

Any person operating or desiring to operate as a research facility, carrier, intermediate handler, or exhibitor not required to be licensed must have a valid registration. The applicant must submit a completed new registration application. The APHIS Form 7011A is used by applicants for a new registration. It requests the applicants name, valid mailing address, species and number of animals, and business activity and a valid premises address where animals, animal facilities, equipment, and records may be inspected for compliance. APHIS, to accurately track and enforce the AWA, needs to collect personal identifiable information/personal identification number (PII/PIN) from the registrant. This information is kept secure. These forms are stored in a secured building and room. Access is limited to authorized APHIS personnel, as needed.

APHIS will supply a copy of the applicable regulations and standards to the applicant with each request for a new registration application. The applicant will acknowledge receipt of the regulations and standards and agree to comply with them by signing the application form. APHIS will issue a registration certificate (APHIS Form 7021). APHIS personnel verify the accuracy of the information on the application during the physical inspection of the premises, animals, and records. Without the information on APHIS Form 7011A, the Animal Welfare Program would be unable to enforce the AWA.

Sections 2.25, 2.26, and 2.30(a) - Application for Registration Update (APHIS Form 7011); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

Each registrant continuing to operate as a research facility, carrier, intermediate handler, or exhibitor not required to be licensed must update his/her registration by completing and filing the APHIS Form 7011 every three years with the appropriate Animal Care office.

The APHIS Form 7011 is used by applicants for registration renewal. It requests the applicants name, valid mailing address, species and number of animals, and business activity and a valid premises address where animals, animal facilities, equipment, and records may be inspected for compliance. APHIS, to accurately track and enforce the AWA, needs to collect personal identifiable information/personal identification number (PII/PIN) from the registrant. This information is kept secure. These forms are stored in a secured building and room. Access is limited to authorized APHIS personnel, as needed.

The registrant agrees to comply with the regulations and standards by signing the registration renewal form. APHIS personnel verify the accuracy of the information on the application during the physical inspection of the premises, animals, and records. Without the information on APHIS Form 7011, the Animal Welfare Program would be unable to enforce the AWA.

Sections 2.27(b)(1) and 2.30(c)(2) - Written Request to be Placed in Inactive Status (APHIS Form 7033); (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 used by facilities that wish to remain registered, even though they are not performing regulated activities. The Notification of Change form (APHIS Form 7033) may be used for this purpose.

Sections 2.27(b)(2) and 2.30(c)(3) - Request for Voluntary License Termination or Registration Cancellation) (APHIS Form 7032); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

A registrant which goes out of business or which ceases to function as a research facility, carrier, intermediate handler, or unlicensed 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 appropriate Animal Care office. APHIS Form 7032 may be used to submit the request. 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.

Sections 2.27(b)(1) and 2.30(c)(2) – Written Notification of Resumption of Registration (APHIS Form 7011A); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

A registrant that 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 (APHIS Form7023/7023A/7023B/7023C) of its status (active or inactive). The registrant will notify the appropriate Animal Care office in writing at least 10 days before using, handling, or transporting animals again after being in an inactive status. This is no longer applicable. Resumption of research activities after cancellation requires a new registration application, APHIS Form 7011A.

Section 2.31(c)(3) - Written Notification of Failure to Adhere to Correction Scheduled; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

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), (d), (e), 2.35(a), (f) - Records of IACUC Activities; (Business or Other For-Profit, Not-For-Profit, and State, Local, and Tribal Governments)

A research facility is required to review, at least once every six months, the research facility's program of humane care and use of animals; inspect, at least once every six months, all of the research facility's animal facilities; and prepare reports of these evaluations. The IACUC is to make recommendations to the Institutional Official regarding any aspect of the research facility's program, facilities, or personnel training. The inspection and program evaluation reports are maintained at the research facilities and reviewed by the APHIS inspector during inspections.

A research facility is required to review and, if warranted, investigate concerns involving the care and use resulting from public complaints received and from reports of noncompliance received from facility personnel.

A research facility will maintain the following IACUC records: (1) minutes of IACUC meetings, including records of attendance, activities of the IACUC, and IACUC 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 three 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 three 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.

The reporting and recordkeeping requirements are necessary to ensure that the research facility is complying with the AWA.

Sections 2.33(a)(1),(b)(3) and 2.40(a)(1),(b)(3) - Written Program of Veterinary Care for Research Facilities or Exhibitors/Dealers (APHIS Form 7002 or equivalent); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

Section 2143 of the AWA requires that animals intended for use in research, exhibition, or as pets be provided adequate veterinary care. Title 9, CFR, Sections 2.33 and 2.40 require registrants and licensees to have an attending veterinarian to provide veterinary care to their 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. Use of APHIS Form 7002 is optional and 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.

9 CFR Sections 2.33(b)(3) and 2.40(b)(3) require that licensees and registrants establish a mechanism of direct and frequent communication with the attending veterinarian so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian, including on weekends, holidays, and in emergency situations.

During inspections, an APHIS official may review APHIS Form 7002 maintained at the facility, to compare the observed health status of the animals to the documents. If necessary, an inspector may contact the attending veterinarian, identified in the written program of veterinary care, for supplemental information regarding an animal's health or 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 for adequate veterinary care in Section 2143 of the AWA.

Sections 2.35(b), (c), (d), (e), 2.38(g)(2), (8), 2.75, 2.76, 2.132, and 2.133 - Records Disclosing Live Dog and Cat Acquisitions and Disposition (APHIS Forms 7001 (optional), 7005, and 7006 and 7006A); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

Each licensee and registrant will make, keep, and maintain records or forms which fully and correctly disclose the required information concerning each dog or cat purchased 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. The records will include any offspring born of any animal while in his/her possession or under his/her control.

The records must include: The name and address of the person from whom a dog or cat was purchased or otherwise acquired; the name and address of the person to whom a dog or cat was sold or given; the official dog or cat identification; a description of each dog or cat; the method of transportation; and the date and method of disposition of a dog or cat, e.g., sale, death, euthanasia, or donation.

As required in Section 2.75(a)(2) APHIS Forms 7005, 7006, and 7006A are mandatory forms to be used by dealers and exhibitors. These forms record the required acquisition and disposition information. APHIS officials review these records during inspections to identify and trace animals that may have been illegally sold and/or transferred. A licensee may request a variance to use a computerized record keeping system that is approved by the Administrator.

Research facilities may use the USDA Interstate and International Certificate of Health Examination for Small Animals (APHIS Form 7001), Record of Acquisition and Dogs and Cats on Hand (APHIS Form 7005), and Record of Disposition of Dogs and Cats (APHIS Forms 7006 and 7006A – continuation sheet) to keep and maintain the information required by the AWA. Other methods of maintaining the records are allowed as long as the required information is retained and APHIS has access to the records.

Section 2.36 - Annual Report of Research Facility (APHIS Forms 7023, 7023A, 7023B, and 7023C); (Business or Other For-Profit, Not-For-Profit, and State, Local, and Tribal Governments)

Each research facility is required to submit a report to the appropriate Animal Care office that provides specific assurances, lists the IACUC-approved exceptions to the regulations and standards, the numbers of animals that are used for research activities, and the pain level the animals experienced during the research, teaching, testing, or experimentation. The optional forms, APHIS Form 7023, 7023A – continuation sheet, 7023B - Column E explanations, and 7023C - Site Specific Annual Report of Research Facility provide research facilities a standardized method to report the required information.

APHIS officials review the reports to ensure consistency with the observed activities at the facilities and in the facility records. APHIS Forms 7023, 7023A (continuation sheet), and 7023B (Column E explanations) may be used to submit this report. The new APHIS Form 7023C (Site Specific Annual Report of Research Facility) may be used to document the site specific data if the research facility has more than one location housing animals. It is to be retained at the facility and made available for review by APHIS personnel.

The electronically fillable APHIS 7023 forms are available via the APHIS website. This information is stored in a database format necessary to generate a summary report.

Sections 2.38(a) and 2.125 – Registrant Furnish All Requested Information; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

Each research facility, intermediate handler, carrier, dealer, operator of an auction sale, 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.

Sections 2.38(b) and 2.126(a) – Access and Inspection of Records and Property (APHIS Form 7008); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

Each licensee/registrant shall allow APHIS officials to inspect the animals, records, and property. APHIS personnel conduct the inspection along with the applicant following the guidelines in the Inspection Guide and document their findings on an inspection report (APHIS

Form 7008). The applicant signs the report acknowledging receipt of the inspection report. This is necessary to enforce the provisions of the Act, the regulations, and the standards.

Section 2.38(g)(1), (2), (11), 2.50(a), (b), (c), 2.55 – Official Identification of Dogs and Cats; Removed Tags Retained for 1 Year; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

All dealers, exhibitors, and research facilities are to identify all live dogs and cats on the premises, purchased, or otherwise acquired, sold or otherwise disposed of, delivered for transportation, transported, or removed from the premises with (i) An official USDA sequentially numbered tag; (ii) A record book 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; (iii) A duplicate tag to accompany the animal when it leaves the compound or premises, (iv) A distinctive and legible tattoo marking, or (v) A collar which individually identifies the dog or cat by number.

All official tag or tattoo numbers shall be correctly listed in the records of purchase, acquisition, disposal, or sale which shall be maintained in accordance with § 2.35. All official tags removed and retained by a dealer, exhibitor, or research facility will be 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.

Section 2.38(h)(1) and 2.78(a), (b), (c) - Health Certificate in Transport, Inspection by a licensed veterinarian (APHIS Form 7001, optional); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

Facilities licensed and registered under the AWA, any department, agency, or instrumentality of the United States, or of any State or local government transporting dogs, cats, and non-human primates in commerce are required to provide a health certificate executed and issued by a licensed veterinarian. The optional APHIS form 7001 “United States Interstate and International Certificate of Health Examination for Small Animals” satisfies the requirements and provides a standard, uniform health certificate for interstate and international movement of such animals. The health certificate provides documentation of the animal's health status prior to transportation in commerce as determined by a licensed veterinarian.

Section 2.38(h)(2), 2.78(b) - Exceptions to Health Certificates; (Business or Other 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(i)(1)(3), 2.102 – Written Agreement to comply with AWA for Persons Holding Animals for a Research Facility and IO Recognizes Official Site (APHIS Form 7009, retired)

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. The additional site is listed on the new and renewal registration forms. APHIS Form 7009 “Request for Approval of Holding

Facility” is no longer required and has been retired. A written agreement is no longer required. The additional site is officially added to the registration.

Section 2.50(e), 2.75(b), and 2.80 – Record of Acquisition, Disposition, or Transport of Animals (Other Than Dogs and Cats) (APHIS Forms 7019, 7020, and 7020A); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

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.

When any animal, other than a dog or cat, is confined in a primary enclosure, it will be identified by a label attached to the primary enclosure which bears a description of the animal(s) 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, or the primary enclosure may be marked with a painted or stenciled number which will be recorded in the records of the dealer or exhibitor together with (a) a description of the animals; (b) the species of the animals; and (c) any distinctive physical features of the animals, or a tag or tattoo may be applied to each animal in the primary enclosure by the dealer or exhibitor which individually identifies each animal by description or number. These forms provide an inventory record of animals other than dogs and cats that are on-hand, and they provide information on the disposition of regulated animals other than dogs and cats, as required in Section 2140 of the AWA and Section 2.75 of the regulations. The information is maintained by the sending and receiving facilities and must accompany the animals during transit. The records must be held for 1 year after an animal is euthanized or disposed of and for any period in excess of one year as necessary to comply with any applicable Federal, State, or local law or request by the APHIS Administrator. The records may be used in investigations or proceedings under the AWA. USDA inspectors examine the 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 origin and destination 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 data with data collected on other forms in this information collection package.

Section 2.75(a)(2)(i) – Written Request for Variance Using Other Than APHIS Form 7005, 7006, and 7006A; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

Dealers (other than operators of auction sales and brokers to whom animals are consigned) and exhibitors are required to use specific forms, APHIS Forms 7005 and 7006, to make, keep, and maintain the animal acquisition and disposition records required by §2.75(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 or Other For-Profit)

Dealers and exhibitors are required to use specific forms, APHIS Forms 7005 and 7006, to make, keep, and maintain the animal acquisition and disposition 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 2.76(a) – Auction Sales or Brokers Records; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

As required by section 2142 of the AWA, operators of auction sales must 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 used 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.

Every operator of an auction sale or broker shall make, keep, and maintain records or forms which fully and correctly disclose the following information concerning each animal consigned for auction or sold, whether or not a fee or commission is charged: The name and address of the person who owned or consigned the animal(s) for sale; The name and address of the buyer or consignee who received the animal; The USDA license or registration number of the person(s)

selling, consigning, buying, or receiving the animals if he or she is licensed or registered under the Act; The vehicle license number and State, and the driver's license number (or photographic identification card for non-drivers issued by a State) and State of the person, if he or she is not licensed or registered under the Act; The date of the consignment; The official USDA tag number or tattoo assigned to the animal under §§ 2.50 and 2.54; A description of the animal; The auction sales number or records number assigned to the animal.

One copy of the record containing the required transaction information shall be given to the consignor of each animal, one copy of the record shall be given to the purchaser of each animal: *Provided, however,* That information which indicates the source and date of consignment of any animal need not appear on the copy of the record given the purchaser of any animal. One copy of the record containing the information required by paragraph (a) of this section shall be retained by the operator of such auction sale, or broker, for each animal sold by the auction sale or broker.

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.

Sections 2.77 and 2.79(a), (b) – Carriers and Intermediate Handlers Records; Consignor Written Guarantee; Attempt to Notify Consignor; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

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 or local government, the accepting carrier or intermediate handler shall keep and maintain a copy of the health certification completed as required by § 2.78, tendered with each live dog, cat, or nonhuman primate.

No carrier or intermediate handler shall 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.

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 of the guarantee and a shipping

document 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 demonstrate 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 2.125 – Information Concerning Dealers, Exhibitors, Operators of Auction Sales, Intermediate Handlers, and Carriers Business-Beyond What is Currently Required; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

Each dealer, exhibitor, operator of an auction sale, intermediate handler, and carrier shall furnish to any APHIS official any information concerning the business of the dealer, exhibitor, operator of an auction sale, intermediate handler or carrier which the APHIS official may request in connection with the enforcement of the provisions of the Act, the regulations and the standards in this subchapter. The information shall be furnished within a reasonable time and as may be specified in the request for information.

Section 2.126(c) – Submission of Itinerary of Exhibition with Overnight Travel (APHIS Forms 7010 and 7010A); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments)

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 office. This itinerary must include the name, 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, 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 2.132(c) and 2.133 – Procurement of Dogs, Cats, and Other Animals by a Pound or Shelter; Certification for: Breeders, Dealers, Research, Non-Regulated Pounds and Shelters (Note: The FY2017 Appropriations bill and continuing resolution prohibits spending appropriations funds to license dealers that sell random source dogs.)

Accurate and complete records shall be separately maintained by the licensee or registrant who also operates a private or contract animal pound or shelter and by the pound or shelter. If the animals are lost or stray, the pound or shelter records shall provide: An accurate description of the animal; how, where, from whom, and when the dog or cat was obtained; how long the dog or cat was held by the pound or shelter before being transferred to the dealer; and the date the dog or cat was transferred to the dealer.

Dealers must provide a valid certification to anyone acquiring random source dogs and cats from them. This certification must include: The name, address, USDA license number, and signature of the dealer; the name, address, USDA license or registration number, if such number exists, and signature of the recipient of the dog or cat; a description of each dog or cat being sold, provided, or made available; the official USDA-approved identification number of the animal; the name and address of the person, pound, or shelter from which the dog or cat was acquired by the dealer.

The certification must also include an assurance that the person, pound, or shelter was notified that the cat or dog might be used for research or educational purposes; the date the dealer acquired the dog or cat from the person, pound, or shelter; and if the dealer acquired the dog or cat from a pound or shelter, a signed statement by the pound or shelter that it met the holding period requirements. 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.

Section 2.150, 2.151(a) (b), 2.152 – Application and Permit to Import Live Dogs for Resale, Import Permit and Certifications, Notification of Arrival (APHIS Forms 7040, 7040A, 7040B, 7041, and eFile); (Business or Other For-Profit, Not-For-Profit, Farms); (New)

No person shall import a live dog from any part of the world into the continental United States or Hawaii for purposes of resale, research or veterinary treatment unless the dog is accompanied by an import permit issued by APHIS and is imported into the continental United States or Hawaii within 30 days after the proposed date of arrival stated in the import permit.

An application for an import permit must be submitted to the Animal and Plant Health Inspection Service, Animal Care, 4700 River Road Unit 84, Riverdale, MD 20737-1234 or through Animal Care's Web site (http://www.aphis.usda.gov/animal_welfare). Application forms for import permits may be obtained from Animal Care at the address listed above. The import permit may also be electronically requested using eFile.

The completed application include the name and address of the person intending to export the dog(s) to the continental United States or Hawaii; The name and address of the person intending to import the dog(s) into the continental United States or Hawaii; The number of dogs to be imported and the breed, sex, age, color, markings, and other identifying information of each dog; The purpose of the importation; The port of embarkation and the mode of transportation; The port of entry in the United States; The proposed date of arrival in the continental United States or Hawaii; and The name and address of the person to whom the dog(s) will be delivered in the continental United States or Hawaii and, if the dog(s) is or are imported for research purposes, the USDA registration number of the research facility where the dog will be used for research, tests, or experiments.

Health certificate. Each imported dog must be accompanied by an original health certificate issued in English by a licensed veterinarian with a valid license to practice veterinary medicine in the country of export that: Specifies the name and address of the person intending to import the dog into the continental United States or Hawaii; Identifies the dog on the basis of breed, sex,

age, color, markings, and other identifying information; States that the dog is at least 6 months of age; States that the dog was vaccinated, not more than 12 months before the date of arrival at the U.S. port, for distemper, hepatitis, leptospirosis, parvovirus, and parainfluenza virus (DHLPP) at a frequency that provides continuous protection of the dog from those diseases and is in accordance with currently accepted practices as cited in veterinary medicine reference guides; States that the dog is in good health (i.e., free of any infectious disease or physical abnormality which would endanger the dog or other animals or endanger public health, including, but not limited to, parasitic infection, emaciation, lesions of the skin, nervous system disturbances, jaundice, or diarrhea); and Bears the signature and the license number of the veterinarian issuing the certificate. The importer may use APHIS Form 7041-Live Dog Import Health and Rabies Certificate. Any format is acceptable as long as the required information is included.

Rabies vaccination certificate. Each imported dog must be accompanied by a valid rabies vaccination certificate that was issued in English by a licensed veterinarian with a valid license to practice veterinary medicine in the country of export for the dog not less than 3 months of age at the time of vaccination that: Specifies the name and address of the person intending to import the dog into the continental United States or Hawaii; Identifies the dog on the basis of breed, sex, age, color markings and other identifying information; Specifies a date of rabies vaccination at least 30 days before the date of arrival of the dog at a U.S. port; Specifies a date of expiration of the vaccination which is after the date of arrival of the dog at a U.S. port. If no date of expiration is specified, then the date of vaccination shall be no more than 12 months before the date of arrival at a U.S. port; and bears the signature and the license number of the veterinarian issuing the certificate. The importer may use APHIS Form 7041-Live Dog Import Health and Rabies Certificate. Any format is acceptable as long as the required information is included.

Research. The age restrictions, vaccination requirements, and good health requirements do not apply to any person who imports a live dog from any part of the world into the continental United States or Hawaii for use in research, tests, or experiments at a research facility, provided that: Such person submits satisfactory evidence to Animal Care at the time of his or her application for an import permit that the specific provision(s) would interfere with the dog's use in such research, tests, or experiments in accordance with a research proposal and the proposal has been approved by the research facility IACUC.

Veterinary care. The age restrictions, vaccination requirements, and good health requirements of this section do not apply to any person who imports a live dog from any part of the world into the continental United States or Hawaii for veterinary treatment by a licensed veterinarian, provided that: The original health certificate required in paragraph (a)(1) of this section states that the dog is in need of veterinary treatment that cannot be obtained in the country of export and states the name and address of the licensed veterinarian in the United States who intends to provide the dog such veterinary treatment; and The person who imports the dog completes a veterinary treatment agreement with Animal Care at the time of application for an import permit and confines the animal until the conditions specified in the agreement are met. Such conditions may include determinations by the licensed veterinarian in the United States that the dog is in good health, has been adequately vaccinated against DHLPP and rabies, and is at least six months of age. The person importing the dog shall bear the expense of veterinary treatment and confinement.

Upon the arrival of a dog at the port of first arrival in the continental United States or Hawaii, the person intending to import the dog, or his or her agent, must present the import permit and any applicable certifications and veterinary treatment agreement required by this subpart to the collector of customs for use at that port.

Sections 3.6(b)(1)(iii), 3.6(c)(1)(ii), and 3.6(d) – Approval for Less Than Minimum Housing Requirements for Dogs and Cats; (Business or Other For-Profit); (New)

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 at a research facility or, 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 or exhibitor, 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.

Innovative primary enclosures that do not precisely meet the floor requirements for space will be allowed in research facilities when approved by the IACUC, and in dealer premises when approved by the Administrator only if there is sufficient space and the opportunity to express species-typical behavior. Records of the approval must be maintained and are subject to APHIS' inspection.

Section 3.6(c)(4) – Approval to Tether Dogs; (Business or Other For-Profit); (New)

Permanent tethering of dogs is prohibited for use as primary enclosure. Temporary tethering of dogs is prohibited for use as primary enclosure unless approval is obtained from APHIS.

Section 3.8, 3.8(b)(1)(2), 3.8(c)(1), 3.8(c)(3)(iii), 3.8(d)(1)(2)(3) - Exercise Plan for Dogs; Record Keeping (APHIS Form 7013); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

Research facilities, dealers, and exhibitors are required to maintain written standard procedures for the exercise of dogs. The frequency, method, and duration of the opportunity for exercise shall be determined by the attending veterinarian and, at research facilities, in consultation with and approval by the Committee. The attending veterinarian is authorized to exempt certain animals from the exercise requirements based on the animal's needs. At research facilities, the IACUC must approve research exemptions during its review process. Any such exceptions must be recorded and reviewed periodically by the attending veterinarian or the IACUC.

The written standard procedures will be maintained by the facility 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(b),(c),(e), 3.14(h), 3.16(a), (b), 3.19(a), 3.35(b), (c), 3.36(h), 3.37(g), 3.60(b), (c), 3.61(g), 3.62(g), 3.66(a)(3), 3.86(b), (c), (e), 3.87(g), 3.89(a)(b), 3.92(a), 3.112(b),(c), 3.113(g), 3.118 (a)(2)(3), 3.136(b),(c), 3.137(e),(f), and 3.139(d),(e): Consignments to Carriers and Intermediate Handlers; Shipping Documents and Written Instructions for Food, Water, Medication, and Special Care Attached to Enclosure; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

Certain information, instructions, and certifications are required for the humane transportation of animals in commerce. The consignor must provide information such as the name, address, and telephone number of the consignee, the consignor's name and address, and 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.

The optional certifications, such as acclimation to lower temperatures and certification that the transport cage complies with standards, while not mandatory, 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 a destination in a speedy and humane manner. APHIS' inspectors at airports and shipping points also use these documents to reference instances of violations for possible legal action, locate facilities or persons who are evading regulation under the law, or other actions necessary for the enforcement of the Act.

Sections 3.13(f), 3.35(d), 3.60(d), 3.86(f), 3.112(d), and 3.136(d) - Attempt to Notify Consignor; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

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.

Sections 3.14(a)(6), 3.19(b)(2), 3.36(g), 3.61(f), 3.87(f), 3.92(b)(2), 3.113(f), 3.137(e) - Marking Requirements for Transport Enclosure (“Live Animals”); (Business or Other For-Profit, Not-For-Profit, Farms, Foreign Federal government, and State, Local, and Tribal Governments); (New)

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 regulated animals are being shipped. These markings are required to ensure the proper handling and the safety of animals being shipped.

Sections 3.28(c)(3), 3.53(c)(3), 3.80(b)(2)(iii), and 3.80(c) – Innovative Primary Enclosures; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

Innovative primary enclosures not precisely meeting the floor area and height requirements for species to which these sections apply (hamster, guinea pigs, rabbits, and nonhuman primates) may be used at a research facility when approved by the IACUC, or by dealers and exhibitors when approved by the Administrator. For nonhuman primates, such enclosures are to provide environment enrichment to promote socialization may in part to satisfy the requirement to provide a physical environment adequate to promote the psychological well-being of primates. Documentation is necessary in order to properly enforce the law and to keep from putting unnecessary burdens on regulated facilities that may utilize innovative enclosures to satisfy other requirements of this subchapter. These documents will be subject to APHIS' inspection.

Sections 3.77(f), 3.78(d), 3.103(c), and 3.127(d) –Perimeter Fencing Variance from Requirements; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

For several species, 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 out unwanted humans and animals. Potentially dangerous species require an 8-foot perimeter fence; other animals require a 6-foot fence. Alternate safety protocols may be used with the approval of the Administrator of APHIS. Requests for approval of alternative security measure are required for all animals other than cats, dogs, guinea pigs, hamsters, and rabbits. 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.

Sections 3.81, 3.81(d), and 3.81(e)(1)(2)(3) - Environmental Enhancement Program for Nonhuman Primates for Research Facilities or Exhibitors/Dealers (APHIS Form 7050); (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

Each facility housing nonhuman primates must develop, document, and follow a plan that must address social grouping, environment enhancement, and primates or groups of primates that have special needs. The facility may use APHIS Form 7050: Environment Enhancement Plan or an equivalent format to document the environment enhancement program. The attending veterinarian or the IACUC is authorized to exempt certain animals from the plan based on the animals' needs or research requirements. Any such exceptions must be recorded and reviewed periodically by the attending veterinarian or the IACUC. The plan must be in accordance with professionally accepted standards as directed by the attending veterinarian. Restraint devices

must be used only in necessary instances for health reasons or research protocol. When continuous restraint is to be for more than 12 hours, it must be approved as part of a research proposal by the IACUC committee. The plan will be maintained by the facility and reviewed by APHIS' inspectors during inspection to ensure that the intent of the Act is followed. APHIS inspectors use APHIS 7051: the Environment Enhancement Plan Evaluation Tool as a job aide to conduct a comprehensive review of a facility's environment enhancement program. This information is required to ensure compliance with the regulations and standards.

Section 3.83 –Watering Requirements; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

Any exemptions from the specifications for watering requirements must be required in the judgment of the attending veterinarian or required by a research proposal and approved by the IACUC. This will help to ensure that the intent of the Act has been met.

Section 3.100(g) - Variance for Marine Mammal Facilities; (Business or Other For-Profit, Not-For-Profit, Farms); (New)

All persons subject to the Animal Welfare Act who maintain or otherwise handle marine mammals in captivity must comply with the provisions of this subpart, except that they may apply for and be granted a variance, by the Deputy Administrator, from one or more specified provisions of § 3.104. An application for a variance must be made to the Deputy Administrator in writing. The request must include: The species and number of animals involved, A statement from the attending veterinarian concerning the age and health status of the animals involved, and concerning whether the granting of a variance would be detrimental to the marine mammals involved, Each provision of the regulations that is not met, The time period requested for a variance, The specific reasons why a variance is requested, and The estimated cost of coming into compliance, if construction is involved.

A research facility may be granted a variance for specified requirements of this subpart if necessary for research purposes and explained fully in the experimental design.

Section 3.101(a)(3) - Facilities, General; (Business or Other For-Profit, Not-For-Profit); (New)

A written protocol for the cleaning of primary enclosure surfaces so that they do not constitute a health hazard to the animal(s) must be developed and maintained at the regulated facility. This plan will include cleaning, and where appropriate, disinfecting schedules and methods. These protocols are kept on site at the facility and are to be made available for APHIS inspection. These protocols need only be developed once or as needed based on any changes.

Section 3.101(b) - Contingency Plans; (Business or Other For-Profit, Not-For-Profit); (New)

Written contingency plans are required to outline protocols in the event of a power failure (water and power) and in the event of an emergency, such as a natural disaster, that would require

evacuation of the animals, including release into the wild and how to regain their custody. These plans must be available for APHIS inspectors to review. In general, they would only need to be changed if there was a change in back-up power systems or changes in animals/enclosures affected.

Section 3.104(a) - General Space Requirements; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

All animals must be maintained in enclosures which meet or exceed space requirements as set forth in Section 3.104. However, temporary holding of animals in smaller enclosures for the purposes of nonmedical training, breeding, holding or transfer is allowable if such confinement is justified in writing by the attending veterinarian on a weekly basis. These recordkeeping requirements are consistent with those of Section 3.110(b) for medical treatment and holding of marine mammals for medical training. These records are to be kept in the animal's individual medical record. This information is also used in documenting instances of violations for possible legal action.

Section 3.105(c) - Feeding; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

Feeding records for all marine mammals, noting individual daily food consumption, must be maintained at the facility for one year and be made available for APHIS inspection. Additionally, the attending veterinarian must be notified immediately if any animal shows decrease or lack of appetite for more than 24 hours. This information requires documentation of appropriate feeding for all marine mammals. A facility is recording and maintaining this information to comply with the APHIS standards. APHIS does not require a particular format for these records. This information is also used in documenting instances of violations for possible legal action.

Section 3.106(b)(3) - Weekly and Daily Water Testing for Marine Mammals; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

Bacterial water quality testing must be done every week, and those results must be recorded and made available to the APHIS inspector. Chemical additives and pH must be tested daily. This information is used to document instances of violations for possible legal action.

Section 3.108(b) - Employees or Attendants; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

Each marine mammal facility must document the participation and successful completion of a facility training course for each employee. Such a course is necessary, among other things, to comply with the requirement to provide adequately trained personnel. This information is also used in documenting instances of violations for possible legal action.

Section 3.109 - Separation; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

Marine mammals known to be social in the wild are required to be housed with at least one compatible animal of the same or related species. However, if this cannot be done, any singly housed marine mammal must have a written plan, approved by the attending veterinarian, developed in conjunction with the husbandry and training staff(s), which justifies these arrangements, as well as addresses the length of time the animal is expected to be housed alone, the type and frequency of enrichment and interaction provided, and periodic review by the attending veterinarian. This plan will be reviewed by APHIS inspectors to ensure that all singly housed marine mammals are receiving appropriate care and not being subjected to unwarranted isolation. This information is also used in documenting instances of violations for possible legal action.

Section 3.110(b) - Veterinary Care: Written Justification for Holding in Smaller Enclosure for More Than 2 Weeks; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

Animals cannot be held for the purpose of medical treatment and/or medical training for periods of time in excess of 2 weeks in medical or other enclosures which do not meet the space requirements of Section 3.104 without written justification by the attending veterinarian in the animal's medical record. These records will be inspected by APHIS to ensure that no animals are being kept for medical reasons in primary enclosures which do not meet AWA requirements unless deemed medically necessary by the attending veterinarian. This information is also used in documenting instances of violations for possible legal action.

Section 3.110(d), 3.110(e), 3.110(g), 3.111(f)(2), 3.111(f)(3-4), 3.111(g)(3), 3.111(g)(4), 3.111(g)(6)- Veterinary care: Health Care Recordkeeping and Necropsy Requirements and Record Keeping; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

Licensees and registrants are required to establish a mechanism of direct and frequent communication with the attending veterinarian so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian, including on weekends, holidays, and in emergency situations.

Health records are needed to convey timely information on animal health, behavior, and well-being to the attending veterinarian and all other personnel involved in an animal's care. They may include information on an animal's health, medications, surgical or other operative procedures, pre-, post-, and intra-operative care, and behavior made by care givers, behaviorists, veterinarians, and anyone else involved in animal care. Every facility should have a system of health records that is organized, comprehensive, accurate, current, and complete to demonstrate the delivery of adequate veterinary care. This information should be available to APHIS inspectors upon request.

Individual animal records must be maintained at the facility for all marine mammals and be made available for APHIS inspection. These records must at least contain animal identification information, examination results, diagnostic tests and results, and documentation of all treatments. As part of the individual animal veterinary care, a complete physical exam will be performed every 6 months. As part of the health records, an animal profile, which will include the marine mammal identification, weight, length, axillary girth, appetite, and behavior, is recorded. All other information generated through the physical exam is also be recorded. APHIS inspectors will use this information to evaluate compliance with the veterinary care requirements under the AWA, as well as monitoring acute and long-term effects of the interactive program on the health and well-being of the animal.

The attending veterinarian will record the nutritional status and reproductive status of the animal. These records will be used to monitor the health and well-being of the program animals, used in evaluation of adequate veterinary care and feeding requirements under the AWA.

Copies of the animal's medical record must accompany the animal when transferred to another facility. This requirement will facilitate the continuation of adequate veterinary care of the marine mammal by making sure the receiving party has a complete medical history.

A complete necropsy on any marine mammal which dies in captivity must be conducted by or under the direct supervision of the attending veterinarian, and a preliminary and final report must be written. The report must include a listing of all results of the gross necropsy (preliminary report) and histopathological and special testing (final report). This report must be maintained on site for a period of 3 years, and made available to APHIS inspectors upon request. Reporting of necropsy results and maintenance of these records for inspection is necessary to allow APHIS to evaluate veterinary care under the AWA. Retention of records for three years allows evaluation of disease, handling, or husbandry trends in marine mammal deaths at the facility. This information is necessary for APHIS enforcement of the requirements for providing adequate veterinary care for regulated animals. This information is also used in documenting instances of violations for possible legal action.

SWTD program individual animal veterinary records must be maintained at the facility for 3 years, and made available to APHIS on request. Veterinary records are a necessary to evaluate if adequate veterinary care is provided to the animals. Retaining records for 3 years for the SWTD programs is necessary to monitor the potential effects of the interactive program on the long term health and well-being of the animals. This information is also used in documenting instances of violations for possible legal action.

Individual animal feeding and behavioral records must be maintained on site for a period of at least 3 years. Due to the specialized nature of the SWTDs, evaluation of feeding and behavioral records by APHIS inspectors is necessary to ensure proper handling and care under the AWA. This information is also used in documenting instances of violations for possible legal action.

SWTD records are not currently required due to suspended enforcement in 1999.

Section 3.110(f) - Veterinary Care: Exemption from Annual Examinations; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

All cetaceans and sirenians must be examined by the attending veterinarian annually unless APHIS grants an exception from this requirement based on considerations related to the health and safety of the cetacean or sirenian. The facility would need to request such an exemption and submit it to APHIS. This documentation would ensure the health and well-being of the animals.

Section 3.111(e) (4), 3.111(e) (7) - Handling at Interactive Programs: Written Rules and Instructions; (Business or Other For-Profit); (New)

Written rules and instructions must be supplied to members of the public participating in SWTD programs. The participants must agree, in writing, to abide by the rules and instructions of the attendants. The interactive nature of the SWTD programs provides a risk of injury to the animals and the public. Rules to safeguard the dolphins must be followed to prevent undue risk to the health and well-being of the dolphins. Providing written instructions and obtaining written agreement from the human participants is necessary to maintain and enforce these safeguards.

Written criteria for the conditions and procedures for termination of a SWTD session where unsatisfactory human/dolphin interactive behaviors are exhibited must be submitted to APHIS. Such written criteria are needed to provide consistent and adequate safeguards when a facility is faced with interactions deemed unsatisfactory and/or dangerous to the health and well-being of the marine mammal or member of the public. This information is also used in documenting instances of violations for possible legal action.

This not currently required due to suspended enforcement in 1999.

Section 3.111(f) (1) – Recordkeeping: Description of Swim with the Dolphin Program; (Business or Other For-Profit); (New)

A description of the SWTD program, including identification of all animals in the program, description of the educational content of the program, the agenda for the interactive session, method and content of pre-encounter orientation and rules, facility description, animal training procedures used prior to participation in the program, a resume of all staff involved with the marine mammals, assessment of current animal behavior patterns by the attending veterinarian, a written program of veterinary care (APHIS Form 7002) if the attending veterinarian is part-time or a consultant, and a description of the animal behavior monitoring program which will be used to assess behavioral changes in program animals, must be submitted to APHIS.

The use of APHIS form 7002 has been addressed in previous OMB review of Parts 1 and 2 of the AWA regulations. The use of written rules and orientation materials is addressed under Section 3.111(e) (4). Facilities descriptions are necessary to evaluate compliance with the space requirements listed in Section 3.111(a). Submission of a resume for employees is necessary to evaluate compliance with the regulations covering employees and attendants in Section 3.111(c). Animal identification information is necessary to evaluate compliance with program animal

requirements in Section 3.111(d). Training procedures and animal behavior monitoring are necessary to evaluate compliance with handling requirements in 3.111(e) (2).

The nature of SWTDs, the unique risks associated with interactive programs, and the unavailability of any long term evaluation of the effects of SWTD programs on marine mammals, necessitates the documentation of SWTD procedures, protocols, and safety measures. This documentation is submitted once from each facility. This information is also used in documenting instances of violations for possible legal action.

This is not currently required due to suspended enforcement in 1999. However, some facilities may voluntarily provide the information.

Section 3.111 (f) (5) – Recordkeeping: Statistical Summaries of Swim with the Dolphin Programs; (Business or Other For-Profit); (New)

Statistical summaries of dolphin and human participation in the SWTD program must be maintained at the facility for 3 years and provided to APHIS semiannually. These summaries will be used to evaluate the interactive programs and aid in monitoring of safety of such interactive activities. The facility must also report to APHIS any changes in the SWTD program semi-annually. This information allows maintenance of accurate records on the facility and program by APHIS to be used to evaluate compliance with Section 3.111(e). This information is also used in documenting instances of violations for possible legal action.

This is not currently required due to suspended enforcement in 1999. However, some facilities may voluntarily provide the information.

Section 3.111(f) (7) – Recordkeeping: Incident Reports; (Business or Other For-Profit); (New)

All incidents resulting in injury to either marine mammal or human must be reported to APHIS within 24 hours of the incident, and a written report of the incident must be submitted to APHIS within 7 days. Included in the written report must be a plan to prevent further occurrences of similar incidences. Interactive programs carry a risk of injury to the participants. Reporting of such incidences in a timely manner will help monitor the safety of such programs and allow appropriate intervention when indicated to prevent injury to the dolphins or people.

This is not currently required due to suspended enforcement in 1999. However, some facilities may voluntarily provide the information.

Section 3.111(g) (5) - Veterinary care: Attending Veterinarian Examine Water Quality Records; (Business or Other For-Profit); (New)

The attending veterinarian shall examine water quality records and provide a written assessment, to remain at the SWTD site for at least 3 years, of the overall water quality during the preceding month. Such records shall be made available to an APHIS official upon request during inspection. Maintaining adequate water quality in the enclosures for SWTD programs is crucial

to ensuring the health and well-being of the marine mammals and human participants in the interactive sessions. Water quality records are addressed in Section 3.106(b) (3). This information is also used in documenting instances of violations for possible legal action.

This is not currently required due to suspended enforcement in 1999. However, some facilities may voluntarily provide the information.

Sections 3.112(a) and 3.116(b) - Consignments to Carriers and Intermediate Handlers, Care in Transit Plan for Travel more than 2 Hours; Health Certificates; (Business or Other For-Profit, Not-For-Profit, Farms, and State, Local, and Tribal Governments); (New)

All marine mammals being transported must be accompanied by a health certificate signed by the attending veterinarian. Any format is acceptable as long as the required information is included. The attending veterinarian must note on the accompanying health certificate the existence of certain health and medical conditions. This provision allows for documentation that all animals being transported are in good health, or, if consistent with the conditions set forth in Section 3.116 (marine mammals), are acceptable candidates for transport. This information will be used in documenting instances of violations for possible legal action.

Any transport of a marine mammal which will exceed 2 hours in duration requires that a transportation plan approved by the attending veterinarian be developed. This plan should specify the need to have a veterinarian in attendance or not. Such planning is necessary to ensure that the animal is handled in the most humane and expeditious manner as required in Section 2.131. This information is also used in documenting instances of violations for possible legal action.

USDA-APHIS-Animal Care Online Complaint Form and Animal Welfare Compliant Form (APHIS Form 7087); (Individuals or Household, Business or Other For-Profit); (merged from 0579-0377)

USDA APHIS provided a way for members of the general public to electronically submit via the Internet concerns about animals regulated under the Animal Welfare Act (AWA) and Horse Protection Act (HPA). Complaint information is sent to a general email box for the field office that manages complaints for the State where the incident occurred (acwest@aphis.usda.gov and aceast@aphis.usda.gov). APHIS acknowledges that the online complaint has been received by immediately sending the submitter an electronic response that shows what they submitted and that APHIS will look into their concerns. Their contact information is not stored in any database. The contact information, if provided, is used to contact the submitter if additional information is needed. The Animal Welfare Complaint form (APHIS Form 7087) is used internally to capture information from a complainant submitted through other methods. The complaint details are stored for 3 years with the files of the facility on which the complaint was filed. The relevant PII would be redacted based on the appropriate exemption if APHIS receives a Freedom of Information Act Request (FOIA) request for the complaint information.

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.

APHIS uses the Animal Care Information System 3.0 (ACIS 3.0) to provide a standard approach to collect, record, analyze, maintain, and report information to cooperating and regulatory entities. ACIS 3.0 electronically collects and manages customer data for license, registration, and research facility annual report data, which are part of the Animal Care collection. The system is designed to comply with the Government Paperwork Elimination Act (GPEA) and e-Authentication. It will be used by the Animal Care Program office in conducting inspections to determine compliance with the Animal Welfare Act (AWA) and the Horse Protection Act (HPA) throughout the United States, and as a central point for information sharing whereby ACIS 3.0 business processes, standard operational procedures, and data can be shared internally.

APHIS makes several electronically fillable and printable forms available through the Web site to reduce the burden on the regulated entities to fulfill the requirements of the applicable regulations.

- A request for an APHIS license or registration kit may be submitted online at https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/SA_Regulated_Businesses/SA_Request_License_Registration_Application_Kit.

The following required forms are to be completed with a physical signature of the sender, and submitted to APHIS:

- APHIS Form 7003A Application for a New License
- APHIS Form 7003 Application for License Renewal and Annual Report
- APHIS Form 7031 Credit Card Authorization Sheet
- APHIS Form 7011 Application for Registration Update
- APHIS Form 7011A Application for a New Registration
- APHIS Form 7030 Federal Debt Collection Act Form
- APHIS Form 7031 Credit Card Payment Authorization

The APHIS Form 7008: USDA, APHIS, Animal Care Inspection Report and Narrative is electronically completed by the APHIS employee. The regulated entity physically signs the paper version of the report acknowledging receipt of the report.

APHIS has identified the licensing and registration process and the research facility annual report for animal use submissions (APHIS Forms 7003, 7003A, 7030, 7011, and 7011A, 7023, 7023A, and 7023B) 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 activities and processes. The person or facility will be able to input the necessary information directly into an IT system. APHIS anticipates that this will save time and cost both for the regulated community and for AC. A physical signature will no longer be required. The ID authentication and/or electronic signature will be utilized.

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

The regulated entity is required to submit or maintain information to comply with the AWA. The information may be maintained using one of the optional forms created by APHIS or an equivalent format.

The following optional documents or equivalent format may be submitted via regular mail, courier services (such as FedEx, UPS, etc.) to APHIS at the respondents' preference. The documents require a physical signature of the sender. The use of electronic submissions (fax and e-mail) afford a decrease in notification time, record of submission, and reduction of paperwork, costs, and mailing activities:

- APHIS Form 7023 Annual Report of Research Facility
- APHIS Form 7023A Continuation Sheet for Annual Report of Research Facility
- APHIS Form 7023B Annual Report of Research Facility Column E Explanation
- APHIS Form 7032 Request for Voluntary License Termination/Registration Cancellation
- APHIS Form 7040 Application and Permit to Import Live Dogs for Resale
- APHIS Form 7040A Continuation of Application and Permit to Import Live Dogs for Resale
- APHIS Form 7040B Additional Information for Application and Permit to Import Live Dogs for Resale
- APHIS Form 7041 Live Dog Import Health and Rabies Certificate

The following optional documents or equivalent format may be submitted via email, fax, regular mail, courier services (such as FedEx, UPS, etc.) to APHIS at the respondents' preference. The use of electronic submissions (fax and e-mail) afford a decrease in notification time, record of submission, and reduction of paperwork, costs, and mailing activities:

- APHIS Form 7010 Submission of Itinerary of Exhibition with Overnight Travel
- APHIS Form 7010A Submission of Itinerary of Exhibition with Overnight Travel Continuation Sheet
- APHIS Form 7033 Notification of Change,
- Request for Pre-Licensing Inspection,
- Written Request for Correction of Dollar Amount,
- Exceptions to Health Certificates,
- Request for Variance, and
- Perimeter Fencing Variance from Requirements

The regulated entity may use the following optional forms or equivalent formats to fulfill the requirements of the applicable regulations and are maintained at the facility to be available for review by APHIS personnel.

- APHIS Form 7001 United States Interstate and International Certificate of Health Examination for Small Animals
- APHIS Form 7002 Program Of Veterinary Care (PVC)
- APHIS Form 7019 Record of Animals On-Hand (Other than Dogs and Cats)
- APHIS Form 7020 Record of Acquisition, Disposition or Transport of Animals (Other than Dogs and Cats)
- APHIS Form 7020A Continuation Sheet for Record of Acquisition, Disposition or Transport of Animals (Other than Dogs and Cats)
- APHIS Form 7023C Site Specific Annual Report of Research Facility Animal Use
- APHIS Form 7013 Exercise Plan For Dogs
- APHIS Form 7050 Environmental Enhancement Program for Nonhuman Primates for Research Facilities or Exhibitors/Dealers
- Marine Mammal Feeding Records

The following mandatory forms are available from the website to fulfill the requirements of the applicable regulations and are maintained at the facility and made available for APHIS review.

- APHIS Form 7005 Record of Acquisition & Dogs and Cats on Hand
- APHIS Form 7006 Record of Disposition and Acquisition of Dogs and Cats
- APHIS Form 7006A Continuation Sheet for Record of Disposition of Dogs and Cats

Section 2.75(a)(2) requires licensees to use APHIS Forms 7005 and 7006 to keep acquisition/disposition records on dogs and cats. APHIS 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 use of an approved computerized recordkeeping system will reduce the burden for the licensee.

APHIS fillable and printable PDF forms are available online at https://www.aphis.usda.gov/aphis/resources/forms/ct_aphis_forms.

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 of the information required to fulfill the requirements of the applicable regulations.

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

The information collected is the minimum required to ensure the humane handling and care of animals under the AWA. APHIS estimates 95 percent of the businesses completing this information collection are considered small entities.

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 not be possible for APHIS to confirm or enforce facility compliance with the regulations for animal health, adequate veterinary care, and animal identification without the required records.

The collection of the information set forth in these sections of the regulations includes the numbers of animals on hand, categories of experimentation, identification of animals, location of premises, and the assurance by responsible officials that standards are in compliance and are vital to meeting the intent of the Act. Records must be available for AC inspectors. Without these records, investigations and proceedings against violators would be impossible. If none or only partial knowledge could be obtained from records, animal health certification would be a risk, and animals exposed to disease could not be properly accounted for or traced. The health and veterinary care and housing enforcement would be negated due to inadequate recordkeeping. APHIS must be equipped with data on research facilities in order to make a professional assessment of animal conditions. Not providing this data would be contrary to the intent of the Act and prevent prosecution of violators. The marketing of dogs, cats, and/or primates from dealers and exhibitors without supportive documentation could contribute to the violation of the standards of the Act. This data is necessary to ensure that animals used for regulated purposes are provided humane care and treatment and to prevent the sale or use of stolen animals.

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; NO**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

All incidents resulting in injury to either marine mammal or human must be reported to APHIS within 24 hours of the incident, and a written report of the incident must be submitted to APHIS within 7 days. This is not currently required due to suspended enforcement in 1999. However, some facilities may voluntarily provide the information.

- **requiring respondents to submit more than an original and two copies of any document; NO**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years; NO**
- **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; NO**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB; NO**
- **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 NO**
- **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**

There are no other special circumstances. The collection of information is conducted in a manner consistent with the 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.

APHIS held consultations with the following non-government organizations or individuals in connection with the AWA information collection activity associated with this program:

Gail C. Golab, PhD, DVM, MANZCVS, DACAW
 Chief Veterinary Officer
 American Veterinary Medical Association
 1931 North Meacham Road, Suite 100
 Schaumburg, IL 60173-4360
 o: 847.285.6618 | c: 630.336.0062
 GGolab@avma.org

Mr. James Gesualdi, Attorney at Law
 58 Wingam Drive
 Islip, Long Island, New York 11751-4112
 631-224-4801

goosepf@aol.com

Mathew Bailey
National Association of Biomedical Research
1100 Vermont Avenue, NW, Suite 1100
Washington, DC 20005
202.857.0540
mbailey@nabr.org

On July 12, 2018, pages 32260-32261, APHIS published in the *Federal Register* (Vol. 83, No. 134), 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. They were from an animal welfare organization, an organization representing veterinarians, and the general public. APHIS reviewed each of the comments carefully. APHIS responses to those comments that address the information collection are below. The organization representing veterinarians and the animal welfare organization generally support extending the information collection.

Two organizations requested clarification on the revisions requested in the Notice. One commenter questioned if the revision is “limited to the optional use of automated, electronic, mechanical, and other collection technologies (e.g., permitting electronic submission of responses)....” One commenter requests APHIS “describe the revisions it intends to make to its current information collection activities and explain in further detail which information gathering activities it is requesting extension of, including a description of which forms it intends to renew and the content of any new forms.”

The revisions include combining burden previously approved/filed with comment under 0579-0093, Animal Welfare; 0579-0379, Animal Welfare Import Permit; and 0579-0377, USDA-APHIS-Animal Care Online Complaint form into this information collection; 0579-0036, *Animal Welfare*. Upon the re-approval of this information collection, the Animal Care Online Complaint form will be removed from 0579-0377. The updated information collection also includes optional use of automated, electronic, mechanical, and other collection technologies, electronically fillable optional forms, additional optional documents, and clarification of optional methods for submitting the information to APHIS. The information collection package was updated due to recalculation of the burden estimates, and adjustments to burden estimation due to recalculation of the number of respondents using updated data sources; recalculation of the number of responses per respondent; recalculation of the number of hours per response using updated data sources. APHIS also updated the correlation of the number of record holders with the number of respondents due to the assumption that the respondent will maintain a record of the information provided to the government. APHIS recalculated the annual hours per record keeper to create and file the record. The information collection package renewal includes the addition of new forms, the addition of forms currently in use, but not previously approved, and the review and revision of current forms including the license applications to ensure congruence with the information required for the administration and enforcement of the AWA, regulations, and standards.

One commenter stated, “While APHIS is concerned with minimizing the burden of the collection of information on regulated entities, the minimal burden placed on regulated entities as a result of this information gathering is vastly outweighed by the necessity of collecting this information for the proper administration and enforcement of the AWA.” In accordance with the Paperwork Reduction Act of 1995, APHIS announced its intention to request to revise and extend approval of the information collection associated with the AWA regulations. The Paperwork Reduction Act is designed to reduce the total amount of paperwork burden the federal government imposes on private businesses and citizens. It measures the burden of activity against the need for information with the purpose of maximizing practical utility of information collected by the Federal Government and minimizing paperwork burden on the public and Agency cost. It also strives to eliminate redundancies and improve collection of information.

One commenter stated “Although the Notice is unclear, it appears that APHIS requests to continue gathering information through inspection reports and related records (including photographs, documentation, and inventories). This information is particularly important to the continued enforcement of the AWA, as well as to the public, and such records (including the substance of inspection records and information sufficient to identify a particular facility, such as its name and address) should be made entirely available to the public without redactions. (See generally Complaint, Humane Soc'y of the U. S. v. U.S. Dep't of Agric., No. 1:18-cv-00646TNM (D.D.C. March 21, 2018))” APHIS records, including inspection report, photographs, documentation, and inventories are released when authorized and in a manner consistent with the Freedom Of Information Act (FOIA) and Privacy Act.

One commenter stated “distinguishing between personal and business addresses for information gathering purposes is irrelevant and unnecessary”. APHIS has determined that distinguishing between the business address and a personal address where the owners reside at the facility is necessary for the review and evaluation of program compliance with the Privacy Act of 1974.

One commenter does not support the continued use of APHIS Form 7003: Application for License Renewal. The commenter stated they “believe APHIS’ relicensing scheme is unlawful and does not comply with the AWA. Briefly, Form 7003 allows licensees to “self-certify” that they are compliant with the AWA when applying for a renewal of their license.” The AWA is silent regarding the requirements for renewing licenses (as opposed to granting initial ones), and, under *Chevron*, USDA’s license-renewal process is a permissible construction of the statute. District courts and the Fourth and Eleventh Circuits have affirmed this reasoning. Congress authorized the Secretary of Agriculture to “make such investigations or inspections as he deems necessary to determine whether” AWA violations are occurring (7 U.S.C. § 2146(a)); and if such an inspection identifies violations, Congress provides a licensee with due process before its license is revoked (*id.* at § 2149(a)). Thus, because USDA has the power to inspect and initiate enforcement proceedings at any time, the court found it reasonable under *Chevron* for USDA to make its license renewal process purely ministerial.

One commenter suggests APHIS consider gathering additional information from license applicants such as: (1) requiring all applicants to disclose any animal cruelty convictions or other violations of Federal, State, or local laws or regulations pertaining to animals. On August 24, 2017, APHIS published in the Federal Register an advanced notice of proposed rulemaking

(ANPR) and request for comments on animal welfare procedures for applying for licenses and renewals. APHIS solicited public comment on potential revisions to the licensing requirements under the AWA regulations to promote compliance with the Act, reduce licensing fees, and strengthen existing safeguards that prevent any individual whose license has been suspended or revoked, or who has a history of noncompliance, from obtaining a license or working with regulated animals. The ANPR specifically requested public comments on requiring license applicants to disclose any animal cruelty convictions or other violations of Federal, State, or local laws or regulations pertaining to animals. APHIS solicited public comment on these topics to help us consider ways to reduce regulatory burden and more efficiently ensure the sustained compliance of licensees with the Act. On October 23, 2017, APHIS extended the comment period to close on November 2, 2017. APHIS received 42,172 comments. All comments are being reviewed.

One commenter suggested APHIS require exhibitor license applicants to disclose if they (1) possess five or fewer state or locally prohibited species but exempt from USDA licensing; (2) have liability insurance and coverage; and (3) have a website advertising exhibition. The Secretary of Agriculture is authorized to collect information necessary for the administration and enforcement of the AWA. APHIS does not believe the collection of the suggested information is necessary to review an exhibitor license application.

One commenter suggested APHIS require exhibitor license applicants to disclose if they intend to exhibit animals while traveling. APHIS is currently informed if exhibitors intend to exhibit animals while traveling. Title 9, Code of Federal Regulations, Section 2.126 requires an exhibitor who intends to exhibit any animal at any location other than their approved site (including, but not limited to, circuses, traveling educational exhibits, animal acts, and petting zoos), except for travel that does not extend overnight, to submit a written itinerary to the appropriate AC office.

One commenter suggests APHIS add to the current license application forms clear warning language informing applicants of the consequences of providing false information. Title 9, Code of Federal Regulations, section 2.11 (denial of initial license application) states that a license will not be issued to any applicant who... (6) Has made any false or fraudulent statements or provided any false or fraudulent records to the Department or other government agencies... Each applicant is provided a copy of the Animal Welfare Act and Title 9, Code of Federal Regulations, Chapter 1, Subchapter A, Animal Welfare. The requirements for compliance with the AWA and regulations are discussed with each applicant during the pre-license process.

APHIS received two general comments that were outside the scope of the notice. One commenter expressed concerns about APHIS activities to provide Federal leadership and expertise to resolve wildlife conflicts to allow people and wildlife to coexist. One commenter expressed concerns regarding USDA slaughter methods for cattle.

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

This information collection activity involves no payments or gifts to respondents.

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

Section 2143(a)(6)(B) of the AWA – Confidentiality

No rule, regulation, order, or part of this chapter shall be construed to require a research facility to disclose publicly or to the Institutional Animal Committee during its inspection, trade secrets or commercial or financial information which is privileged or confidential.

Section 2157(a), (b) of the AWA - Release of trade secrets-confidential information prohibited

It shall be unlawful for any member of an Institutional Animal and Use Committee to release any confidential information of the research facility including any information that concerns or relates to – the trade secrets, processes, operations, style of work, or apparatus; or the identity, confidential statistical data, amount or source of any income, profits, losses, or expenditures, of the research facility. It shall be unlawful for any member of such IACUC – to use or attempt to use to his advantages; or to reveal to any other person, any information which is entitled to protection as confidential information under subsection (a) of this section.

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 Sections 2143(a)(6)(B) and 2157(a), (b) of the AWA and Section 2.35(f) of the regulations. No additional assurance of confidentiality is provided with this information collection.

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.

This information collection activity asks no questions of a personal or sensitive nature. However, APHIS, to more accurately enforce the AWA, can collect PII/PIN from licensees and registrants during their application for license or registration. This information includes the name, mailing address, site address, and financial data of the applicant. The tax identification number of each applicant is requested to validate that it is the same person during the

license/registration renewal process. The paper-based system of records contains the credit card information for persons who used a credit card to pay for a license application or license renewal using APHIS Form 7031. This information is retained for audit purposes only.

In addition, the database and electronic payment component of the system collects and retains the last four digits of credit card and expiration date or check numbers of persons, name of person, and amount for those who have applied for a license or renewal of a license requiring a payment. This form is stored in a secured building, room, and cabinets. Access is limited to authorized APHIS personnel, as needed.

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.

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.

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**
- **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 there are 13,183 respondents in this information collection. They include individuals; State, local, and tribal governments; foreign governments; and businesses, farms, and not-for-profit entities.

See APHIS Form 71 for hour burden estimates. The estimates were developed from historical FY data from the Animal Care Information System, from estimates of infrequent responses, from discussions with APHIS personnel, and estimated time required to provide the information.

APHIS estimated the annualized cost to the respondents by multiplying their mean hourly wage by the total number of burden hours needed to complete the work: $\$23.86 \times 366,030 \text{ hours} = \$8,733,476$. \$23.86 is the mean hourly rate for all occupations derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2016 Report - Occupational Employment and Wages in the United States (see <http://www.bls.gov/news.release/pdf/ocwage.pdf>).

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.) 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 capital/start-up costs. APHIS collects approximately \$1,225,945 in license and application fees each year.

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 \$14,530,440. See APHIS Form 79 for more details. The estimates were developed from historical FY data from the Animal Care Information System, from estimates for the items with infrequent responses, from interviews and discussions with APHIS personnel and subject-matter-experts, and using the estimated time required to collect, process, analyze, tabulate, and/or publish the information.

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	1,164,585	0	972,860	- 24,446		216,171
Annual Time Burden (Hr)	366,030	0	271,347	- 41,681		136,364
Annual Cost Burden (\$)	0	0	0	0	0	0

Overall, the total responses increased by 948,414 and the total burden hours increased by 229,666 due to program changes, adjustments, and potential violations (which have been entered into ROCIS as program changes).

There is a program change of +763,402.00 responses and +138,418.50 hours due to the merging of an activity from 0579-0377 and the addition of new activities from previously discontinued or non-finalized information collections. These figures also include activities and burden hours not previously reported.

The following item was added from 0579-0377:

Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015) Comments
057-0377	USDA-APHIS Animal Care Online Complaint Form	NA	705.00	352.50	0.00	0.00	235.00	116.50

The following activities are new:

Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
2.150, 2.151 and 2.152	Application and Permit to Import Live Dogs for Resale, Import Permit and Certifications, Notification of Arrival	APHIS Form 7040	32.00	8.00	0.00	0.00	-9,066.00	-2,268.00
2.150, 2.151 and 2.152	Continuation of Application and Permit to Import Live Dogs for Resale	APHIS Form 7040A	32.00	8.00	0.00	0.00	-9,066.00	-2,268.00
2.150, 2.151 and 2.152	Additional Information for Application and Permit to Import Live Dogs for Resale	APHIS Form 7040B	32.00	8.00	0.00	0.00	-9,066.00	-2,268.00
2.150, 2.151 and 2.152	Live Dog Import Health and Rabies Certificate	APHIS Form 7041	32.00	8.00	0.00	0.00	-9,066.00	-2,268.00

Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
------------------------	-------------	------	-------------------	--------------------	------------------------	----------------------------	---------------------------------------	-----------------------------------

2.150, 2.151 and 2.152	Application and Permit to Import Live Dogs for Resale, Import Permit and Certifications, Notification of Arrival	APHIS eFile	32.00	8.00	0.00	0.00	-9,066.00	-2,268.00
3.6	Approval for Less Than Minimum Housing Requirements for Dogs and Cats	None	2.00	0.50	0.00	0.00	-58.00	-59.50
3.13, 3.14, 3.16, 3.19, 3.35, 3.36, 3.38, 3.60, 3.61, 3.62, 3.66, 3.86, 3.87, 3.89, 3.92, 3.112, 3.113, 3.118, 3.136, 3.137, and 3.139	Consignments to Carriers and Intermediate Handlers; Shipping Documents and Written Instructions for Food, Water, Medication, and Special Care Attached to Enclosure	None	1,128.00	564.00	0.00	0.00	-23,072.00	-1,286.00
3.13, 3.35, 3.60, 3.86, 3.112, and 3.136	Attempt to Notify Consignor	None	1,128.00	282.00	752.00	752.00	1,680.00	984.00
3.14, 3.19, 3.36, 3.61, 3.87, 3.92, 3.113, and 3.137	Marking Requirements for Transport Enclosure ("Live Animals")	None	6,865.00	549.20	0.00	0.00	-9,135.00	-250.80
3.28, 3.53, and 3.80	Innovative Primary Enclosures	None	11.00	5.50	0.00	0.00	-28.00	-33.50
3.77, 3.78, 3.103, and 3.127	Perimeter Fencing Variance from Requirements	None	30.00	15.00	0.00	0.00	-270.00	-285.00
Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
3.81	Environmental Enhancement Program for	APHIS Form 7050	743.00	1,486.00	743.00	371.50	-736.00	-364.50

	Nonhuman Primates for Research Facilities or Exhibitors/Dealers							
3.83	Watering Requirements	None	11.00	5.50	0.00	0.00	-79.00	-84.50
3.100	Variance for Marine Mammal Facilities	None	5.00	2.50	0.00	0.00	2.00	-0.50
3.101	Facilities, General	None	2.00	2.00	0.00	0.00	-258.00	-75.00
3.101	Contingency Plans	None	5.00	1.25	0.00	0.00	-255.00	-95.75
3.104	General Space Requirements	None	116.00	29.00	0.00	0.00	56.00	-4.00
3.105	Feeding	None	762,120.00	114,318.00	116.00	4,234.00	758,206.00	117,382.00
3.106	Weekly and Daily Water Testing for Marine Mammals	None	169,360.00	42,340.00	116.00	4,234.00	162,586.00	44,546.00
3.108	Employees or Attendants	None	116.00	29.00	0.00	0.00	-404.00	-434.00
3.109	Separation	None	116.00	58.00	116.00	29.00	152.00	37.00
3.110	Veterinary Care: Written Justification for Holding in Medical Enclosures Longer than 2 Weeks	None	116.00	29.00	116.00	29.00	192.00	36.00
3.110 and 3.111	Veterinary Care: Health Care Recordkeeping and Necropsy Requirements and Recordkeeping	None	1,392.00	696.00	116.00	29.00	-832.00	-412.50
3.110	Veterinary Care: Exemption from Annual Examinations	None	81.00	20.25	81.00	20.25	97.00	16.50
Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
3.111	Handling at Interactive	None	1.00	0.50	1.00	0.25	-58.00	-32.25

	Programs: Written Rules and Instructions							
3.111	Recordkeeping: Description of the Swim with the Dolphin Program	None	1.00	0.50	1.00	0.25	-58.00	-32.25
3.111	Recordkeeping: Statistical Summaries of Swim with the Dolphin Programs	None	2.00	2.00	1.00	0.50	-10,977.00	-3,747.50
3.111	Recordkeeping: Incident Reports	None	1.00	1.00	1.00	0.25	1.00	0.25
3.111	Veterinary Care: Attending Veterinarian Examine Water Quality Reports	None	1.00	0.50	1.00	0.25	-65,728.00	-5,675.25
3.112 and 3.116	Consignment to Carriers and Intermediate Handlers; Care in Transit Plan for Travel more than 2 Hours; Health Certificate	None	23.00	23.00	0.00	0.00	-2,527.00	-487.00

The following 8,108.50 responses and 72.13 hours of burden were not previously reported:

Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
2.1, 2.2, 2.5, 2.25, 2.26, 2.30	Federal Debt Collection Form	APHIS 7030	6865	1716.25	0.00	0	6,865.00	1,716.25
Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
2.3	Request for 1st Pre-Licensing Inspection; Signature Acknowledging Receipt of the	APHIS 7008	831.00	3,324.00	0.00	0.00	-3,669.00	2,963.00

	Inspection Report							
2.3	Request for 2nd and/or 3rd Pre-Licensing Inspection; Signature Acknowledging Receipt of Inspection Report	APHIS 7008	379.50	94.88	0.00	0.00	379.50	94.88
2.5	Request for Voluntary License Termination and Written Statement License Certificate if Lost	APHIS 7032	209.00	52.25	0.00	0.00	-354.00	-91.75
2.6	Annual License Fee	APHIS 7031 (Credit Card)	5,153.00	1,288.25	0.00	0.00	5,153.00	1,288.25
2.126	Submission of Itinerary of Exhibition with Overnight Travel	APHIS Form 7010	5,255.00	2,627.50	0.00	0.00	1,155.00	1,602.50
2.126	Submission of Itinerary of Exhibition with Overnight Travel Continuation	APHIS Form 7010A	5,255.00	2,627.50	0.00	0.00	1,155.00	1,602.50
3.8	Exercise Plan for Dogs, Record Keeping	APHIS 7013	2,462.00	1,231.00	2,462.00	615.50	-2,576.00	-9,103.50

APHIS has adjustments of -24,446 responses and -41,680.70 hours in the burden estimation due to recalculation of the number of respondents using updated data sources; recalculation of the number of responses per respondent; recalculation of the number of hours per response using updated data sources; and recalculations of the annual hours per record keeper to create and file the record.

Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
1.1	Definitions - Research Facility Exemption	None	1.00	0.50	0.00	0.00	-9.00	-4.50
2.1 and 2.2	Online Prelicensing Tool	None	2,768.00	1,384.00	0.00	0.00	-332.00	-1,716.00

Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
	to Guide Requests for Licensing/Registration Packets							
2.1, 2.2, 2.5, 2.25, 2.26, 2.30	Federal Debt Collection Form	APHIS 7030	6865	1716.25	0.00	0	6,865.00	1,716.25
2.1 and 2.2	Application for License and Acknowledgement of Regulations and Standards	APHIS 7003A	834	208.5	0.00	0.00	-8,966.00	-2,247.50
2.1 and 2.2	Application for License Renewal and Annual Report and Acknowledgement of Regulations and Standards	APHIS 7003	5,153.00	1,288.25	0.00	0.00	-11,087.00	-2,773.75
2.3	Request for 1st Pre-Licensing Inspection; Signature Acknowledging Receipt of the Inspection Report	APHIS 7008	831.00	3,324.00	0.00	0.00	-3,669.00	2,963.00
2.3	Request for 2nd and/or 3rd Pre-Licensing Inspection; Signature Acknowledging Receipt of Inspection Report	APHIS 7008	379.50	94.88	0.00	0.00	379.50	94.88
2.5	Request for Voluntary License Termination and Written Statement License Certificate if Lost	APHIS 7032	209.00	52.25	0.00	0.00	-354.00	-91.75
2.6	Annual License Fee	APHIS 7031 (Credit Card)	5,153.00	1,288.25	0.00	0.00	5,153.00	1,288.25
2.6	Written Request	APHIS	233.00	58.25	0.00	0.00	214.00	53.25

Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
	for Correction of Renewal Application including Dollar Amount of Business	7003						
2.8, 2.27, and 2.30	Notification of Change	APHIS 7033	688.00	688.00	0.00	0.00	643.00	675.00
2.10	Written Request to Reinstate Suspended or Revoked License	None	5.00	2.50	0.00	0.00	-42.00	-11.50
2.11	Denial of a New License Including Response to a Request for a Hearing	None	7.00	3.50	0.00	0.00	-12.00	-3.50
2.12	Termination of a License Renewal	None	5.00	2.50	0.00	0.00	-14.00	-4.50
2.25, 2.26, and 2.30	Application for New Registration, Providing Personal Identifiable Information, and Acknowledgement of Regulations and Standards	APHIS 7011A	199.00	49.75	0.00	0.00	29.00	6.75
2.25, 2.26, and 2.30	Application for Registration Update and Providing Personal Identifiable Information	APHIS 7011	700.00	175.00	0.00	0.00	530.00	132.00
2.27 and 2.30	Written Request to be Placed in Inactive Status	APHIS Form 7033 (notification of change)	1.00	0.25	0.00	0.00	-15.00	-4.75
2.27 and 2.30	Written Request for Cancellation of Registration	APHIS Form 7032	64.00	16.00	0.00	0.00	-13.00	-4.00
2.27 and	Written	APHIS	0.00	0.00	0.00	0.00	-10.00	-3.00

Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
2.30	Notification of Resumption of Registration	7011A						
2.31	Written Notification of Failure to Adhere to Correction Scheduled	None	134.00	33.50	134.00	21.44	263.00	52.94
2.31 and 2.35	Records of IACUC Activities	None	9,440.00	37,760.00	944.00	3,776.00	8,190.00	6,157.00
2.33	Written Program of Veterinary Care for Research Facilities	APHIS 7002 or equivalent	5,945.00	5,945.00	10,047.00	5,023.00	6,792.00	6,230.00
2.40	Written Program of Veterinary Care for Exhibitors or Dealers	APHIS 7002 or equivalent	5,047.00	5,047.00	10,047.00	5,023.50	1,534.00	3,087.50
2.35, 2.38, 2.75, 2.76, 2.132, and 2.133	Records Disclosing Live Dog and Cat Acquisitions and Dispositions	APHIS 7001 (optional)	8,364.00	4,182.00	2,788.00	2,788.00	3,630.00	-13,222.00
2.35, 2.38, 2.75, 2.76, 2.132, and 2.133	Records Disclosing Live Dog and Cat Acquisitions and Dispositions	APHIS 7005	8,364.00	4,182.00	2,788.00	2,788.00	3,630.00	-13,222.00
2.35, 2.38, 2.75, 2.76, 2.132, and 2.133	Records Disclosing Live Dog and Cat Acquisitions and Dispositions	APHIS 7006	8,364.00	4,182.00	2,788.00	2,788.00	3,630.00	-13,222.00
2.35, 2.38, 2.75, 2.76, 2.132, and 2.133	Records Disclosing Live Dog and Cat Acquisitions and Dispositions	APHIS 7006A	8,364.00	4,182.00	2,788.00	2,788.00	10,652.00	3,970.00
2.36	Annual Report of Research Facility	APHIS 7023	948.00	1,896.00	948.00	948.00	799.00	650.00
2.36	Continuation Sheet for Annual Report of Research Facility	APHIS 7023A	948.00	1,896.00	948.00	948.00	799.00	650.00

Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
2.36	Annual Report of Research Facility Column E Explanation	APHIS 7023B	948.00	1,896.00	948.00	948.00	799.00	650.00
2.36	Site Specific Annual Report of Research Facility	APHIS 7023C	948.00	1,896.00	948.00	948.00	1,896.00	2,844.00
2.38 and 2.125	Registrant Furnish All Requested Information	None	11,467.50	11,467.50	7,645.00	7,645.00	19,089.50	19,089.50
2.38 and 2.126	Access and Inspection of Records and Property; Signature Acknowledging Receipt of the Inspection Report	APHIS 7008	11,467.50	11,467.50	0.00	0.00	11,467.50	11,467.50
2.38, 2.50, and 2.55	Official Identification of Dogs and Cats; Removed Tags Retained for 1 Year	None	13,940.00	3,485.00	2,788.00	697.00	-3,257.00	-9,631.00
2.38 and 2.78	Health Certificate in Transport, Inspection by a licensed veterinarian	APHIS 7001 (optional)	3,530.00	1,765.00	0.00	0.00	-61,480.00	-7,014.00
2.38 and 2.78	Exceptions to Health Certificates	None	1.00	0.25	0.00	0.00	-5.00	-1.75
2.38 and 2.102	Written Agreement to comply with AWA for persons holding animals for a research facility and IO recognizes official Site	APHIS 7009 (retired)	0.00	0.00	0.00	0.00	-28.00	-14.00
2.50, 2.75 and 2.80	Record Animals on Hand (Other than Dogs and Cats)	APHIS Form 7019	3,630.00	3,630.00	3,630.00	3,630.00	-11,298.00	-14,366.00

Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
2.50, 2.75 and 2.80	Record of Acquisition, Disposition, or Transport of Animals (Other Than Dogs and Cats)	APHIS Form 7020	3,630.00	6,171.00	3,630.00	3,630.00	-11,298.00	-11,825.00
2.50, 2.75 and 2.80	Continuation Sheet for Record of Acquisition, Disposition, or Transport of Animals (Other Than Dogs and Cats)	APHIS 7020A	3,630.00	6,171.00	3,630.00	3,630.00	-11,298.00	-11,825.00
2.75	Written Request for Variance Using Other Than APHIS Form 7005, 7006, and 7006A	None	30.00	15.00	0.00	0.00	-20.00	-11.00
2.75	Request for Hearing	None	2.00	1.00	0.00	0.00	-4.00	-1.00
2.76	Auction Sales or Broker Records	None	1,123.50	2,247.00	749.00	749.00	1,802.50	2,989.00
2.77 and 2.79	Carriers and Intermediate Handlers Records; Consignor Written Guarantee; Attempt to Notify Consignor	None	1,128.00	1,128.00	752.00	752.00	1,380.00	880.00
2.125	Information Concerning Dealers, Exhibitors, Operators of Auction Sales, Intermediate Handlers, and Carriers Business-Beyond What is Currently Required	None	6,697.00	6,697.00	6,697.00	1,674.25	9,373.00	4,350.25
2.126	Submission of Itinerary of	APHIS Form	5,255.00	2,627.50	0.00	0.00	1,155.00	1,602.50

Section of Regulations	Description	Form	Total # responses	Total Annual Hours	Total # record-keepers	Total Record Keeping hours	Change in Total Responses (2017-2015)	Change in Total Hours (2017-2015)
	Exhibition with Overnight Travel	7010						
2.126	Submission of Itinerary of Exhibition with Overnight Travel Continuation	APHIS Form 7010A	5,255.00	2,627.50	0.00	0.00	1,155.00	1,602.50
2.132 and 2.133	Procurement of Dogs, Cats, and Other Animals by a Pound or Shelter; Certification for: Breeders, Dealers, Research, Non-Regulated Pounds and Shelters	None	0.00	0.00	0.00	0.00	-450.00	-4,500.00
3.6	Approval to Tether Dogs	None	1.00	0.25	0.00	0.00	-59.00	-59.75
3.8	Exercise Plan for Dogs, Record Keeping	APHIS 7013	2,462.00	1,231.00	2,462.00	615.50	-2,576.00	-9,103.50

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

APHIS uses the data regarding animals used in teaching, testing, and experimentation reported on APHIS Form 7023 to compile a summary of animal use in research during each fiscal year. 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 summary report is tabulated by State, facility type, and species of animals. Throughout each fiscal year, frequent inquiries are made to the Animal Care in regard to the information collected from the research facility annual reports. Inspection reports are available to the general public through the website link to the Public Search Tool.

The collected information also is tabulated to create a list of all registered exhibitors, carriers, intermediate handlers, and research facilities and all licensed dealers and exhibitors. The

tabulated data is shown by type, name, city, and state.

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 Form 7001 is also used in 0579-0020 which has a different expiration date. Therefore, APHIS is requesting not to display the expiration date.

APHIS requests the ICR expiration date not be displayed on the other forms in this information collection request. Expiration dates make unused paper stocks obsolete every three years, and their destruction would be wasteful. Users unfamiliar with the forms or programs often confuse the ICR expiration date for the form version date. Forms generated by information systems cannot be revised in a timely manner as such projects are not cost effective every three years. All of these problems compound when the agency attempts to manage three formats (print, PDF-F, and IS) of a form at the same time. Finally, posting ICR expiration dates makes form file management very difficult, as the number of production files double from 2 to 4 to possibly 8 when accounting for previous and new files with updated ICR banners; the problem compounds when updating a series of forms in a single information collection request, or in other information collection requests.

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

APHIS certifies compliance with all provisions of the Act.

B. Collections of Information Employing Statistical Methods.

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