SUPPORTING STATEMENT
ANIMAL WELFARE; AMENDMENTS TO LICENSING PROVISIONS AND TO REQUIREMENTS FOR DOGS
DOCKET: APHIS-2017-0062

March 2019

NOTE: Upon approval of this information collection and implementation of the final rule, this information collection will be merged into 0579-0036. In addition, these proposed burden activities will replace the current burden activities associated with APHIS Forms 7002 and 7003A and medical records for dogs in 0579-0036.

A. Justification

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

Under the Animal Welfare Act (AWA or the Act, 7 U.S.C. 2131 *et seq*.), the Secretary of Agriculture is authorized to promulgate standards and other requirements governing the humane handling, care, treatment, and transportation of certain animals by dealers, exhibitors, operators of auction sales, research facilities, carriers and intermediate handlers. The Secretary has delegated responsibility for administering the AWA to the Administrator of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), Animal Care (AC). Definitions, regulations, and standards established under the AWA are contained in the Code of Federal Regulations (CFR) in 9 CFR parts 1, 2, and 3 (referred to below as the regulations). Part 1 contains definitions for terms used in parts 2 and 3. Part 2 provides administrative requirements and sets forth institutional responsibilities for regulated parties, including licensing requirements for dealers, exhibitors, and operators of auction sales. Dealers, exhibitors, and operators of auction sales are required to comply in all respects with the regulations and standards (9 CFR 2.100(a)) and to allow APHIS officials access to their place of business, facilities, animals, and records to inspect for compliance (9 CFR 2.126). Part 3 provides standards for the humane handling, care, treatment, and transportation of covered animals. Part 3 consists of subparts A through E, which contain specific standards for dogs and cats, guinea pigs and hamsters, rabbits, nonhuman primates, and marine mammals, respectively, and subpart F, which sets forth general standards for warmblooded animals not otherwise specified in Part 3.

APHIS is proposing to amend the licensing requirements under the AWA regulations, and strengthen the veterinary care standards for regulated dogs. The amendments include, but are not limited to, the following new information collection requirements: the use of a new fixed-term license application for dealers and exhibitors that expires after 3 years, at which time they would be required to demonstrate compliance before obtaining another fixed-term license; requiring license applicants to disclose any animal cruelty convictions or others violations of Federal, State, or local laws or regulations pertaining to animals, to assess their fitness for licensure; and enhancing adequate veterinary care for dogs including the maintenance of medical records. The proposed license application would replace an existing initial license application and an annual

license renewal application. APHIS anticipates that the proposed license application would take the same amount of time to complete as the existing applications, but would only be required every 3 years, instead of an annual renewal. The proposed rule would also require licensees and registrants who hold dogs to maintain a written program of veterinary care, signed by the facility's attending veterinarian, that provides for preventative and emergent care needs, and to maintain medical records on the preventative care provided to dogs, and to track medical conditions and treatment for ill and injured dogs.

APHIS is requesting the Office of Management and Budget (OMB) to approve for 3 years the use of these information collection activities to help ensure that AWA licensees and registrants demonstrate compliance with the applicable standards in Part 3, providing for the humane handling, care, treatment, and transportation of animals under the AWA.

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

APHIS will use the following information activities to help ensure that AWA licensees and registrants demonstrate compliance with the applicable standards in Part 3, providing for the humane handling, care, treatment, and transportation of animals under the AWA.

Sections 2.1and 2.2 - Application for License and Acknowledgment of Regulations and Standards - APHIS Form 7003 (A) (or equivalent) (Business or Other For-Profit; Not-For-Profit Institution; 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 license application, demonstrate compliance with the regulations and standards, and pay the required fee. Under the proposed rule, a 3-year term license would be issued to a specific person for specific activities, animals, and approved sites and would not transfer upon change in ownership, location, activities, or animals. The APHIS Form 7003A is used by applicants for a license as a dealer or exhibitor. It requests the applicant's 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. In addition, the proposed rule would require applicants to provide information and records demonstrating adequate knowledge of and experience with exotic and wild animals (if used for AWA-regulated purposes) and disclose any other location where the person may exhibit animals, if applicable, as well as disclose any plea of *nolo contendere* (no contest) or finding of violation of Federal, State, or local laws or regulations pertaining to animal cruelty or the transportation, ownership, neglect, or welfare of animals. 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. Digital records, including completed electronic forms, can be uploaded into or directly entered into and stored in APHIS' system Animal Care Information System (ACIS) 3.0. 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.

APHIS will supply a copy of the APHIS Form 7003A and the applicable regulations and standards to an applicant upon request. Signing the application form is an acknowledgement that the applicant has reviewed the AWA and the regulations and standards and agrees to comply with them. APHIS personnel use the information on the application during the physical inspection of the premises, animals, and records. Without the information on APHIS Form 7003A, APHIS would be unable to effectively administer the AWA.

Section 3.13 – Written Program of Veterinary Care for Dogs (Optional APHIS Form 7002 or equivalent) (Reporting and Recordkeeping) (Business or Other For-Profit; Not-for-Profit; Farms; and State, Local and Tribal Government)
Section 3.13 – Veterinary Medical Records for Dogs (preventive care and ill or injured) (Reporting and Recordkeeping) (Business or Other For-Profit; Not-for-Profit; Farms; and State, Local and Tribal Government)
The proposed rule would require a written program of veterinary care and maintenance of medical records for dogs. The written program of veterinary care would need to be signed by the attending veterinarian and include an annual hands-on veterinary examination for adult dogs and addresses husbandry issues for hair coat, toenails, teeth, skin, and ears. APHIS Form 7002 is an optional form that may be used for the written program of veterinary care. The written program of veterinary care and medical records for dogs should be maintained for 3 years. APHIS personnel use the information on the written program of veterinary care to assess the facility's compliance during the physical inspection of the premises, animals, and records. Without the information, APHIS would be unable to ensure the humane treatment of dogs, which would undermine the primary purpose of the Act.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, 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 licensing, registration, compliance inspections and research facility annual report data and information, 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 is used by APHIS in conducting inspections to determine compliance with the Animal Welfare Act (AWA), and as a central point for information sharing whereby ACIS 3.0 business processes, standard operational procedures, and data and information can be shared internally.

APHIS makes several electronically fillable and printable forms available through the website 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.

APHIS has identified the licensing process as a business 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. In the future, an applicant for a license 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 the government.

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 administration and 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, care, treatment, and transportation of animals under the AWA. APHIS estimates 95 percent of the businesses completing this information collection are considered small entities.

6. Describe the consequences 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.

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 1320.5.

- **requiring respondents to report information to the agency more often than quarterly;**

- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

- **requiring respondents to submit more than an original and two copies of any document;**

- **requiring respondents to retain records, other than health, medical, governmental contract, grant-in-aid, or tax records for more than three years;**

- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**

- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**

- **that includes a pledge of confidentiality that is not supported by authority established in statue or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**

- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

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

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

APHIS published an advanced notice of proposed rulemaking (Docket No. APHIS-2017-17967) soliciting public comment on these potential revisions to the licensing regulations. APHIS received more than 47,000 comments by that date, of which approximately 8,500 were unique (not duplicate or form letter) comments. They were from private citizens, breeders, exhibitors, animal interest groups, and professional organizations. APHIS reviewed and considered all of the comments and any information submitted with the comments in the development of the proposed rule (Docket No. APHIS-2017-0062).

APHIS also engaged in productive consultations with the following individuals concerning the burden activities contained in this proposed rule. APHIS received a range of views concerning the burden associated with this rule during its consultations and the comment period for the advanced notice of proposed rulemaking. These views ranged from generally supportive to concerned about the impact of the licensing changes on dealers and exhibitors.

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APHIS' proposed rule was published in the Federal Register on March 22, 2019 with a 60-day comment period. During this time, interested members of the public will have the opportunity to provide APHIS with their input concerning the usefulness, legitimacy, and merit of the information collection activities APHIS is proposing.

9. Explain any decisions to provide any payment or gift to respondents, other than remuneration 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 and attitudes, religious beliefs, and others that are 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 administer and enforce the AWA, can collect PII/PIN from applicants for licensure or registration under the AWA. This information includes the name, mailing address, site address, telephone number, 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 using APHIS Form 7031 (OMB approved under 0579-0036). 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 ACIS 3.0. 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.

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

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 hourly wage by the total number of burden hours needed to complete the work:

Licensing: $15.87 x 499 hours = $ 7,919 x 1.4706 for benefits = $11,645.68
Written Program of Veterinary Care for Dogs and Veterinary Medical Records for Dogs: $18.06 x 29,221 hours = $527,731.26 x 1.4706 for benefits = $776,081.21
Total: $787,726.89

$15.87 and $18.06 are the hourly rates derived from the U.S. Department of Labor, Bureau of Labor Statistics Report – Occupational Employment and Wages in the United States. See http://www.bls.gov/news.release/ocwage.pdf

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

There is no annual cost burden associated with capital and start-up costs, maintenance costs, and purchase of services in connection with this program. However, APHIS would charge a flat licensing fee of $120 every 3 years.

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.

See APHIS Form 79. The annualized cost to the Federal Government is estimated at $13,840,605.00.

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

- ICR Summary of Burden:

	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	382,148	0	382,148	0	0	0
Annual Time Burden (Hr)	29,720	0	29,720	0	0	0
Annual Cost Burden ($)	0	0	0	0	0	0

This is a new information collection resulting in 29,720 total burden hours.

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

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

Not applicable. APHIS will display the expiration date on the forms upon merging this information collection package into 0579-0036.

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

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

B. Collections of Information Employing Statistical Methods

Statistical methods are not used in this information collection.