Supporting Statement-OMB No. 0579-0090
Specimen Submission

This is a reinstatement of a previously approved information collection with changes.

A. 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 Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease. The AHPA is contained in Title X, Subtitle E, Sections 10401-18 of P.L. 107-171, May 13, 2002, the Farm Security and Rural Investment Act of 2002.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the United States' ability to globally compete in the trade of animals and animal products. Animal disease prevention cannot be accomplished without the existence of an effective disease surveillance program, an activity carried out by the United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS).

The animal disease surveillance program is based on information submitted on VS Forms 10-4 and 10-4A. The VS Forms 10-4 and 10-4A are critical to VS' mission. They are routinely used whenever specimens (such as blood, milk, tissue, or urine) from any animal (including cattle, swine, sheep, goats, horses, and poultry) are submitted to the National Veterinary Services Laboratories (NVSL) for disease testing. If the information was not collected (or collected less frequently), APHIS would not have the critical information necessary to effectively operate a disease surveillance program. No purpose would be served by submitting a specimen for laboratory analysis that was not accompanied by the appropriate documentation to identify the animals and herds from which the specimens were taken.

The Cattle Fever Tick Eradication Program and the National Tick Surveillance Program are based on information submitted on VS Form 5-38. This information identifies the individuals submitting the tick samples as well as the samples' animal sources.

APHIS is asking OMB to approve its use of this information collection activity for 3 years, associated with disease prevention in its efforts to maintain both a disease surveillance program and healthy animal population in the United States.

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 activities associated with disease prevention in its efforts to maintain both a disease surveillance program and healthy animal population and for enhancing the United States' ability to globally compete in the trade of animals and animal products.

VS Form10-4, Specimen Submission and VS Form I0-4A, Continuation Sheet for Specimen Submission (Business and State)

VS Forms 10-4 and 10-4A are completed by State veterinarians or other State representatives, accredited veterinarians, private laboratories, and research institutions. Authorized individuals complete the form using information obtained through discussions with the animal owners.

The animal disease surveillance program is based on the information submitted on VS Forms 10-4 and 10-4A. This information identifies the individual animal from which specimens were taken, the animal's herd or flock, the type of specimen submitted, and the purpose for submitting the specimen. The form is then sent with the sample to NVSL for analysis. Without the information contained on this form, NVSL staff would not be able to identify or process the specimens sent for analysis. Additionally, if the information was not collected (or collected less frequently), APHIS would not have the critical information necessary to effectively operate a disease surveillance program.

VS Form 5-38, Parasite Submission Form (Business and State)

State veterinarians or other State representatives, accredited veterinarians, private laboratories, research institutions, and owners or producers complete VS Form 5-38. The form records the submitter's name, business name and address, telephone number, email address, and NVSL ID number (this information identifies the individual submitting the tick samples); the host animal owner's name and address; and identification information for the sample such as an ID number, the date collected, the county, State, and country where the sample was collected; the host animal's origin location; the host animal species; where the tick was found on the host animal; identification information for the animal; and the number of animals in the lot where the host animal was found and the number of animals infested.

Both the Cattle Fever Tick Eradication Program and the National Tick Surveillance Program are based on the information submitted on VS Form 5-38.

The information on species of ticks determination is critical to personnel with the APHIS National Center for Import and Export (at U.S. border ports) and the APHIS Cattle Fever Tick Eradication Program, who are responsible for surveillance and eradication of cattle fever ticks (*Boophilus* spp.). If the information was not collected (or collected less frequently), APHIS would not have the critical tick species information necessary to effectively operate a surveillance and eradication program for cattle fever ticks.

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.

The NVSL Laboratory Information Management System (LIMS) requires submission of specimens with hard copies of VS Forms 10-4 and 10-4A to ensure proper identification of the samples; therefore, the forms currently cannot be transmitted electronically.

VS Form 5-38 must bear an original signature and is therefore not available electronically.

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.

The information that APHIS collects is not available from any other source. APHIS is the only Federal agency responsible for preventing, detecting, controlling, and eradicating animal diseases from the United States.

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

The information collected from small businesses (approximately 25 percent) is the absolute minimum needed to operate a national disease surveillance program.

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.

The animal disease surveillance program is based on the information submitted on VS Forms 10-4, 10-4A, and 5-38. If the information was not collected (or collected less frequently), APHIS would be unable to access the critical information necessary to effectively operate a disease surveillance program. No purpose would be served by submitting a specimen for laboratory analysis that is not accompanied by the appropriate documentation to identify the animals and herds from which the specimens were taken.

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, government 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 statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**

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

There are no special circumstances associated with this information collection. This information collection is conducted in a manner consistent with the guidelines established 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 record keeping, 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 engaged in productive consultations with the following individuals in connection with the information collection activities:

Joseph L. Corn, PhD
Southeastern Cooperative Wildlife Disease Study
589 D.W. Brooks Drive
College of Veterinary Medicine
University of Georgia
Athens, Georgia 30602
Phone: 706-542-1741

Rey Molina
Texas Animal Health Commission State-Federal Laboratory
8200 Cameron Road Suite A186
Austin, TX 78754
Phone: 512-832-6580

Dr. James Maxwell
Bureau of Diagnostic Laboratories
Bronson Animal Disease Diagnostic Laboratory
Tick Identification Program
P.O. Box 458006
Kissimmee, FL 34745-8006
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On Thursday, February 11, 2016, page 7284, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a **3-year renewal** of this collection of information. During that time, APHIS received two comments from interested members of the public. The first comment was received from a concerned citizen about her perception of the general maltreatment of animals; this comment has no relevance to the purpose of this collection. The second comment was from an anonymous citizen that supports the work that is being done via this information collection.

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.

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C. 552a.

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 he made of the information, the explanation to he given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no questions of a personal or sensitive nature.

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 83-1**.

See APHIS Form 71. Burden estimates were developed from discussions with accredited veterinarians, State veterinarians, and other personnel who are qualified to submit specimens for laboratory analysis; as well as herd owners who provide the information necessary for completing the VS Forms10-4, 10-4A, and 5-38.

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

Respondents are animal owners, State veterinarians or other State representatives, accredited veterinarians, private laboratories, and research institutions. APHIS estimated the total annualized cost to these respondents to be $318,620.40. APHIS arrived at this figure by multiplying the hours of estimated response time (8,715) by the estimated average hourly wage of the above respondents ($36.56). This hourly rate was derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2014 Report - Occupational Employment and Wages in the United States. See http://www.bls.gov/oes/current/oes_stru.htm

13. Provide estimates of the total annual cost burden to respondents or record keepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and14). 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.

No annual cost burden is associated with capital and startup costs, operation and maintenance expenditures, and purchase of services.

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 annualized cost to the Federal government is estimated at $218,936. (See APHIS Form 79.)

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

ICR Summary of Burden:

N

	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	27,659	0	27,659	0	0	0
Annual Time Burden (Hr)	8,715	0	8,715	0	0	0
Annual Cost Burden ($)	0	0	0	0	0	0

With this reinstatement there is a program change resulting +27,659 total annual responses, and +8,715 total burden hours.

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

APHIS has no plans to publish information collected in connection with this program.

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.

The VS Forms 10-4 and 10-4A are used in six information collections (0579-0090, 0579-0101, 0579-0146, 0579-0189, 0579-0212, and 0579-0324); therefore, APHIS is seeking approval to not display the OMB expiration date on these forms.

Not applicable for VS Form 5-38. APHIS will display the expiration date.

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

APHIS can certify compliance with all provisions.

B. Collections of Information Employing Statistical Methods

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