December 2021

Supporting Statement
Specimen Submission
OMB Control No. 0579-0090

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 [7 U.S.C. 8301 *et. seq.*]

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, as well as equivalent informal sources. 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 and identify the animals and herds from which the specimens were taken, allowing effective disease prevention and eradication.

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 so it can prevent animal disease, run an effective disease surveillance program, and ensure a 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.

Specimen Submission (VS Form 10-4) and Continuation Sheet (VS Form 10-4A); (9 CFR 54.8, 55.8, 71.21, 77.17, 77.33, Part 78, 79.4, 80.3, Part 85, Part 145, Part 146, Part 156); (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. These 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.

Parasite Submission Form (VS Form 5-38); (9 CFR Part 72, Part 156); (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 Border Ports staff (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.

Nonconforming Submissions (9 CFR 54.8, 55.8, 71.21, 77.17, 77.33, Part 78, 79.4, 80.3, Part 85, Part 145, Part 146, Part 156); (Business and State)

Occasionally the time pressures exerted by or field conditions existing during a disease outbreak leave submitters no time to find or fill out the 10-4; thus, they have to use whatever scrap of paper is

handy. NVSL accepts these nonconforming submissions in emergency situations as long as they contain the information required on the 10-4.

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 (or a nonconforming submission) to ensure proper identification of the samples. Customers also have the option to submit these forms electronically to the National Centers for Animal Health Portal as long as NVSL can unambiguously identify the sample and connect it to the owner and premises of origin.

VS Form 5-38 is available electronically at https://www.aphis.usda.gov/library/forms/pdf/VS_Form5_38.pdf; however, the form must bear an original signature and cannot be submitted 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.

APHIS estimates that approximately 25 percent of the business respondents are considered small entities. The information collected 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 and 10-4A, nonconforming submissions, and VS Form 5-38. 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 and identify the animals and herds from which the specimens were taken, allowing effective disease prevention and eradication.

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 3 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 respondents listed below. They were contacted by email and phone to discuss the information APHIS collects to administer its sample collection and testing activities. We discussed with them how we and they obtain the necessary data and how frequently; how much data is available; the convenience and clarity of reporting formats and other collection instruments; and the clarity of, and necessity for, any recordkeeping requirements. The respondents stated that they had no concerns with any of these items and had no further recommendations.

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On Wednesday, July 28, 2021, APHIS published in the Federal Register (86 FR 40445-40446), a 60-day notice seeking public comments on its plans to request a renewal of this collection of information. No comments from the public were received.

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 necessary information.

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

  APHIS estimated the total annualized cost to be $594,526. APHIS arrived at this figure by multiplying the hours of estimated response time (10,390 hours) by the estimated average hourly wage ($39.49) and benefits of the above respondents, and then multiplying the result by 1.449 to capture benefit costs.

  Respondents are animal owners ($36.93, SOCC 11-9013 (farmers, ranchers, and other agricultural managers)), State veterinarians or other State representatives ($33.08, agricultural inspectors), accredited veterinarians ($52.09, SOCC 29-1131), private laboratories, and research institutions ($35.84, SOCC 19-1011 (animal scientists)). This hourly rate was derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2020 Report - Occupational Employment and Wages in the United States. See http://www.bls.gov/oes/current/oes_stru.htm.

  According to DOL BLS news release USDL-21-0437 released March 18, 2021, employee benefits account for 31 percent of employee costs, and wages account for the remaining 69 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.449.

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.

There are fees associated with the submission of the VS Form 10-4/10-4A. These fees are collected via user fee account, check, money order or credit card payment.

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 $419,358.

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

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	32,546	0	0	5,353	0	27,193
Annual Time Burden (Hr)	10,390	0	0	1,785	0	8,605

This request for renewal is for 32,546 estimated responses and 10,390 estimated burden hours, reflecting increases of 5,353 responses and 1,785 hours of burden from the previous renewal request. The total number of respondents is 1,871.

The estimate adjustments are attributed to natural fluctuations over time. There are variations with program diseases, samplers being more assiduous in submitting, and the program having more accurate source of numbers or computing.

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 multiple information collections (0579-0040, 0579-0090, 0579-0146, and 0579-0189); therefore, APHIS is seeking approval to not display the OMB approval expiration date on these forms. The Agency is working towards developing procedures for converting the multi-ICR forms into common forms.

APHIS will display the expiration date on the VS Form 5-38.

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.