

**SUPPORTING STATEMENT
NATIONAL VETERINARY SERVICES LABORATORIES REQUEST FORMS
OMB NO. 0579-0430**

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 (7 U.S.C. 8301-8317) provides the Secretary of Agriculture broad authority to prohibit or restrict, through orders and regulations, the importation or entry of any animal, article, or means of conveyance if USDA determines that the prohibition or restriction is necessary to prevent the introduction or spread of any pest or disease of livestock within the United States. Disease prevention is the most effective method for maintaining a healthy animal population.

As an element of the Animal and Plant Health Inspection Service (APHIS) disease prevention mission, the National Veterinary Services Laboratories (NVSL) safeguard U.S. animal health by ensuring timely and accurate laboratory support is provided through a nationwide animal health diagnostic system. The NVSL's work necessitates the use of several information collection activities including completion of the VS Form 4-9 (Request for Reagents or Supplies); VS Form 4-10 (NVSL Contact Information Update); VS Form 4-11 (NVSL Application for Laboratory Training); and VS Form 4-12 (NVSL Laboratories Kit and Instrument Order Form).

APHIS is asking the Office of Management and Budget (OMB) to approve its use of these information collection activities for an additional 3 years in connection with APHIS' efforts to safeguard the U.S. animal population from pests and diseases.

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 effectively safeguard the U.S. animal population from pests and diseases:

Request for Reagents or Supplies (VS Form 4-9); (9 CFR 130.14); (Foreign Government; State, Local, or Tribal Government; Business)

Diagnostic laboratories (Federal, State, university, or private) or researchers (academia, private, or government), both domestic and foreign, must complete a VS Form 4-9 to request reagents or supplies from the NVSL. This form is used to ensure that all of the proper information needed to process their requests efficiently and accurately is collected. The form is used every time a customer requests reagents or supplies (typically four times per year for an average customer).

NVSL Customer Contact Update (VS Form 4-10); (9 CFR 130.14); (Foreign Government; State, Local, or Tribal Government; Business; Non-Profit; Individual)

Established diagnostic submitters, diagnostic laboratories (Federal, State, university, or for-profit businesses) or researchers (academia, private, government, nonprofit business), both domestic and foreign, can provide updated contact information. This form is not required, but is offered as a courtesy to customers who wish to proactively inform the NVSL of changes in contact information. The form helps ensure that the NVSL obtains all necessary information to update records efficiently and accurately.

Request for Training at NVSL (VS Form 4-11); (9 CFR 130.14); (Foreign Government; State, Local, or Tribal Government; Business)

Laboratory personnel (Federal, State, university, private, foreign, or domestic) who wish to take an NVSL class must contact the NVSL training department directly via this form. This form helps ensure that the NVSL gets the information it needs to process training requests efficiently and accurately. The NVSL needs the information to know which courses the public wishes to take and to document that they have approval from the Area Veterinarian in Charge (when required).

NVSL Laboratories Kit and Instrument Order Form (VS Form 4-12); (9 CFR 130.14); (Business; State)

Laboratory personnel use this form to order test kits and testing/sampling equipment from NVSL. The sender provides his or her name (as the contact), the name of the requesting organization, the requesting organization's address and telephone number, and the date of the request. Requesting contacts can fax or email the form to the NVSL Shipping Department.

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 VS 4-9, VS 4-10, VS 4-11, and VS 4-12 may be downloaded from the APHIS Electronic Forms Library, and be submitted email, fax, or U.S. mail. Information from the VS 4-10 and VS 4-11 may also be transmitted via telephone. Web-based interfaces to submit these forms have been considered and may be implemented as resources and security considerations allow.

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. These forms pertain to interactions specifically with the NVSL (reagent orders, NVSL-sponsored training). Contact information is configured according to customer preferences to receive communications and shipments specifically from the NVSL.

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

Approximately 70 percent of respondents are universities and other small businesses. The optional nature of the forms minimizes the burden.

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 the information is collected less frequently or not collected, APHIS will be unable to process reagent orders and provide requested training. The reagents, test kits, and testing supplies the NVSL distributes are critical for veterinary diagnostic testing and cannot be bought elsewhere. The training the NVSL provides is necessary to ensure that APHIS-approved laboratories are conducting diagnostic testing in the proper manner with proficient personnel, and in some circumstances cannot be conducted in alternative locations. Both of these service activities are critical to the NVSL mission as the USDA's national reference laboratory.

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.**

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 contacted the following respondents by email and phone to discuss the information APHIS collects to distribute reagents and supplies and track training. APHIS discussed how data was collected 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 they had no concerns with any of these activities and had no further recommendations.

Elizabeth Lachapelle
Administrative Associate Senior III
IDEXX Laboratories Inc.
3 Centennial Drive
North Grafton, MA 01536
Tel: (508) 887-7934
Email Beth-lachappelle@idexx.com

Rebecca J. Franklin-Guild
Bacteriology/Mycology Technical Supervisor
Cornell University Animal Health Diagnostic Center
240 Farrier Road Room A2111
Ithaca, NY 14853
Tel. (607) 253-3915
Email rjf4@cornell.edu

Kaitlin R. Sprouse
Microbiologist Supervisor
Harrisonburg Regional Animal Health Laboratory
Virginia Department of Agriculture and Consumer Services
261 Mt. Clinton Pike
Harrisonburg, VA 22802
Tel. (540) 209-9133
Email kaitlin.sprouse@vdacs.virginia.gov

On September 21, 2020, APHIS published in the Federal Register (85 FR 59279) a 60-day notice seeking public comment on its plans to request a 3-year renewal of this collection of information. No comments 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. However, the confidentiality of information is protected under 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 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 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-I.**

See APHIS Form 71. Burden estimates were developed from discussions with State officials, academia contacts, and small businesses currently requesting these forms from NVSL.

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

Respondents are diagnostic laboratories (Federal, State, university, or private) or researchers (academia, private, and government), both domestic and foreign, as well as private veterinary practitioners. APHIS estimates the total annualized cost to these respondents to be \$62,881. APHIS arrived at this figure by multiplying the hours of estimated response time (1,223 hours) by the estimated average hourly wage of the above respondents (\$35.98) and then multiplying the result by 1.429 to capture benefit costs.

The average hourly wages were obtained from U.S. Department of Labor Bureau of Labor Statistics website at https://www.bls.gov/oes/current/oes_stru.htm. Occupations used were animal scientists (SOCC 19-1011, \$32.96); life, physical, and social science technicians (all others) (SOCC 19-4099, \$24.60); and veterinarians (SOCC 29-1131, \$50.39).

According to DOL BLS news release USDL-20-0451, dated March 19, 2020, benefits account for 30 percent of employee costs, and wages account for the remaining 70 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.429.

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.

No annual cost burden is associated with capital and start-up costs, operation and maintenance expenditures, or 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.

See APHIS 79. The estimated annualized cost to the Federal government is \$341,727.

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

	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	5,101	0	264	2,035	0	2,802
Annual Time Burden (Hr)	1,223	0	9	522	0	692

Since the last submission, there is an increase of 2,299 responses and 531 burden hours attributed to estimate adjustments and the addition of a new activity, “NVSL Laboratories Kit and Instrument Order Form.

The estimated time per response for “NVSL Customer Contact Update (VS Form 4-10)” was increased from 0.1 hours to 1.0 hours. However, the program has received few responses in the

last 3 years and the estimates have been reduced to placeholder values of 1 respondent, 1 response, 1 hour for each respondent type. This change resulted in a decrease of 55 responses and 4 hours of burden.

Estimate increases in the other underlying activities for this information collection request are due to increased disease-related activity in the United States. “Requests for Reagents or Supplies (VS Form 4-9)” has an increase of 463 respondents, 1,852 responses, and 463 hours of burden. “Request for Training at NVSL (VS Form 4-11)” has an increase of 239 respondents, 239 responses, and 61 hours of burden.

This request has one discretionary change with the addition of a new activity, “NVSL Laboratories Kit and Instrument Order Form (VS Form 4-12)” which has been inadvertently omitted from previous submissions. It adds 264 responses and 9 hours of burden to the information collection request.

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 it collects 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.

APHIS will display the OMB approval 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 under the Act.

B. Collections of Information Employing Statistical Methods

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