August 2021

SUPPORTING STATEMENT
COMMUNICABLE DISEASES IN HORSES
OMB NO. 0579-0127

TERMS OF CLEARANCE: "Before this ICR is renewed, USDA should convert VS 1-27 to a common form or explain why that has not been done." APHIS has many forms eligible for conversion to common. This has become a priority for the Agency in 2021 and it anticipates making material progress on the project.

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 our ability to compete in the world market of animal and animal product trade. Reliable and trustworthy testing is a cornerstone of disease prevention. The approval of laboratories to conduct testing for equine infectious anemia (EIA) is a key part of USDA's strategy to control the disease.

Veterinary Services (VS), a program within USDA's Animal and Plant Health Inspection Service (APHIS), is responsible for administering regulations intended to ensure that animals affected with EIA are identified through proficient and reliable testing and that appropriate reporting occurs. Further, regulations ensure animals testing positive are moved interstate in a way that does not endanger the health of the U.S. equine population. APHIS regulations at title 9, *Code of Federal Regulations* (9 CFR) 75.4 deal specifically with regulating the interstate movement of horses affected with equine infectious anemia (EIA). VS provides guidance on approval of laboratories, diagnostic facilities, and research facilities.

Ensuring the testing of equines, and the safe movement of equines testing positive for EIA, requires VS to engage in a number of information collection activities, such as:

1. Guiding State animal health officials and animal owners in obtaining and completing a Permit for the Movement of Restricted Animals using VS Form 1-27, Permit for the Movement of Restricted Animals.

2. Guiding State animal health officials and accredited veterinarians in documenting a submission for a laboratory test for EIA using VS Form 10-11, the Equine Infectious Anemia Laboratory Test Form.
3. Conducting and documenting an investigation of the farm of origin for any equine that returns a positive result for an EIA test, using VS Form 10-12, Equine Infectious Anemia Supplemental Investigation form.
4. The approval of EIA laboratories, which identifies a laboratory and director and requires a signed agreement acknowledging the regulatory obligations inherent in operating an approved EIA laboratory.
5. Diagnostic and research laboratories must also notify VS in writing when they no longer accept EIA reactors moved interstate. Finally, any stockyard, diagnostic facility, or other facility that loses VS approval may request a hearing regarding the decision but must do so in writing.

Laboratories conducting any EIA test must be approved by the APHIS Administrator in consultation with the appropriate State animal health officials. To approve a request, APHIS needs to collect information regarding the laboratory's capacity to conduct accurate and reliable testing, measured by whether the laboratory:

i. Has technical personnel assigned to conduct the official test who have received training prescribed by the National Veterinary Services Laboratories (NVSL);
ii. Uses USDA-licensed antigen;
iii. Follows NVSL-prescribed standard test protocol;
iv. Meets NVSL-prescribed check test proficiency requirements; and
v. Reports all official test results to the State animal health official and the Area Veterinarian in Charge.

Laboratories must also enter into an agreement with APHIS and undergo regular inspections to receive and maintain approval.

APHIS is asking OMB to approve, for an additional 3 years, its use of these information collection activities in connection with its program to prevent the spread of EIA within the U.S. equine population.

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 prevent the spread of EIA within the U.S. equine population:

Permit for the Movement of Restricted Animals (VS Form 1-27); (9 CFR 71.3(d)(7)); (Business)

This form is used to properly document the movement of the restricted animal or animals to prevent disease from entering the livestock population at large. At the time animals are loaded and ready for transport, Federal officials use information obtained from the animal owner to

complete the form. The information obtained from the owner and entered on the form includes the owner's name and address, the points of origin and destination of the animals, the number of animals being moved, the purpose of the movement, and various pieces of animal identification data, such as a microchip number or a physical description, so that each animal in the shipment can be identified. This form accompanies the shipment and is submitted to VS after the animals reach their destination.

Equine Infectious Anemia Laboratory Test, and Other VS-Approved Test Forms (VS Form 10-11); (9 CFR 75.4(b)(2)); (Business)

(Previously titled Equine Infectious Anemia Laboratory Test)

This form is used to properly identify and document the animal being tested, identify the veterinarian submitting the sample, indicate a reason for testing and test type requested, and provide the approved EIA lab a way to document the testing and result. VS will also accept this information presented using approved forms other than the 10-11. The equine owner requests the EIA test of a veterinarian and provides the information needed to complete the form. There may be several reasons to have the equine tested, such as State regulations, interstate or international animal movement, an event or other local requests for a negative test or change of ownership. The veterinarian obtains and submits a blood sample from the equine, along with the test form to a VS approved EIA laboratory. The VS Form 10-11 or approved form provides a physical description of the equine, the date the sample was taken, the owner's name and address, and the name of the veterinarian who submits the sample. The laboratory personnel need the information on VS Form 10-11 or approved form to link the blood sample to the equine from which the sample was drawn. Laboratory personnel complete the form, indicating test results and other details.

Equine Infectious Anemia Supplemental Investigation (VS Form 10-12); (9 CFR 75.4(b)(2)); (Business)

This form is used to guide animal health officials in conducting the investigation and to help make decisions or impose quarantines. If a blood sample is positive for EIA, then a disease outbreak investigation occurs. Animal health officials may use this form during the investigation. The VS Form 10-12 gathers such information as the population and layout of the premises, the vaccination history of all animals on the premises, and a site sketch of the farm.

Agreement for Approved Livestock Facility (Signature Only); (9 CFR 71.20; 9 CFR 71.22); (Business)

The owner or operator of a participating stockyard, laboratory, or diagnostic or research facility must promise to adhere to VS guidance and regulations when carrying out EIA-related activities. These requirements are spelled out in an agreement that the owner or operator must sign and return to VS.

Request for Hearing; (9 CFR 71.20(b); 9 CFR 71.22(j)); (Business)
If VS opts to deny or withdraw approval from a stockyard, laboratory, or diagnostic or research facility, the owner or operator of that facility may appeal the denial or withdrawal in writing within 10 days after receiving notification (30 days for laboratories). The appeal must include all of the facts and reasons on which the owner or operator relies to show that the establishment was wrongfully denied listing or approval. The owner or operator of the establishment may also request a hearing on the matter. During the hearing, the owner or operator may present arguments in support of continuing approval. The request for this hearing must be made in writing by the owner or operator and sent directly to VS.

Written Notification of Approval or Withdrawal; (9 CFR 71.22(i); CFR 75.4); (Business)
APHIS will automatically withdraw approval for a diagnostic or research facility to receive EIA reactors moved interstate when the facility's operator notifies APHIS, in writing, that the facility no longer receives reactors moved interstate.

Application to Conduct Laboratory Equine Infectious Anemia (EIA) Testing (VS Form 10-16); (9 CFR 71.22; 9 CFR 75.4; VSG 15201.1); (Business and State)
(Previously titled Proposal to Conduct Laboratory EIA Testing)

- Applicants for laboratory approval must provide the following information:
- Acknowledgment of familiarity with VS Guidance Document (VSG) 15201.1.
- Anticipated client base (veterinary practice, sales barn, regional, university, statewide, national)
- A description of the anticipated hours of operation and staffing plan.
- Anticipated number of samples to be tested annually.
- A description of any plans for mobile or satellite testing.
- A description of proposed operational start date and training plans for personnel.
- A description of the proposed laboratory space or plans for creating the proposed laboratory space. The applicant should attach documentation (e.g., photographs or plans) of the proposed laboratory space.
- Laboratory and laboratory director's contact information.
- Signature of the laboratory director.

The proposal and other available information will be reviewed by the animal health official for the State in which the laboratory is located, who will work with the local AVIC to reach a consensus on whether to accept or deny the proposal.

This was proposed during the last renewal and is now being collected using VS Form 10-16.

Review of Requirements and Interview; (9 CFR 75.4; VSG 15201.1); (Business and State)
A Federal animal health official, with a State animal health official, will review with the laboratory director the regulatory and technical requirements for conducting EIA tests. The inspection checklist, standards for accepting samples, reporting results, and reporting summary data will be reviewed. The laboratory director will demonstrate a thorough working knowledge of the requirements detailed in VSG 15201.1.

Agreement to Conduct Equine Infectious Anemia (EIA) Testing (VS Form 10-15); (9 CFR 75.4; VSG 15201.1); (Business)

(Previously titled Agreement to Conduct EIA Testing)

The laboratory director agrees to:

- Provide and maintain adequate and appropriate facilities as described in VSG 15201.1 and the associated inspection checklist.
- Provide technical personnel, suitable to perform official EIA testing, trained at NVSL that have successfully completed individual proficiency tests.
- Accept only samples submitted by a veterinarian authorized in the State where the sample was obtained and submitted with a properly completed and legible approved test form.
- Conduct all testing in accordance with official NVSL test protocols, as described in literature accompanying the diagnostic test kits or in VSG 15201.1.
- Use only APHIS-approved diagnostic test kits.
- Submit all non-negative samples to NVSL for confirmation (those testing positive, suspect, discrepant, or equivocal in any of the licensed EIA diagnostic tests, as defined in the diagnostic test kit in use or NVSL protocols).
- Seek, and satisfactorily meet, annual laboratory proficiency (check) test requirements, per NVSL protocols and deadlines.
- Perform at least 500 EIA tests per year, in order to maintain testing competency.
- Meet regulatory obligations regarding prompt reporting of results to State and Federal officials.
- Provide appropriate resources for adequate record keeping and to meet the summary data requirements described.
- Undergo an annual inspection to maintain approval.
- Maintain current contact information and respond to official requests and inquiries.

The director must sign and date this document and provide the laboratory's address and contact information.

This was proposed during the last renewal and is now being collected using VS Form 10-15.

Memorandum of Recommendation and Justification; (9 CFR 75.4; VSG 15201.1); (State)

This document will be signed by the State animal health official and the AVIC once they agree to approve the laboratory to conduct testing and the laboratory passes inspection. The document will be sent to NVSL with the above listed documents via approved electronic or other means.

Monthly Summary Reporting; (9 CFR 75.4; VSG 15201.1); (Business)

VS requires monthly summary reporting to gain national-level information on disease prevalence and testing. VS uses the data to inform decisions and policy for disease control. Timely and accurate reporting facilitates trade by providing transparency to markets and our international trading partners. Approved laboratories report summary EIA test results monthly to APHIS via a VS approved Excel spreadsheet, or other VS approved electronic means of data submission within 30 days of the close of the previous month. Laboratories report the number of positive and negative tests (via agar gel immunodiffusion (AGID) and enzyme-linked immunoabsorbent assay (ELISA) tests), and State of origin.

Denial or Withdrawal of Laboratory Approval; (9 CFR 75.4; VSG 15201.1); (Business and State)

(Previously titled Denial and Withdrawal of Approval of Laboratories)

Denial or withdrawal of approval may occur when any EIA laboratory or diagnostic facility fails to meet the criteria for approval discussed above. Further, approval for a laboratory or diagnostic facility to conduct the official EIA test is automatically withdrawn when the operator notifies the NVSL, in writing, that the laboratory or facility no longer conducts the official test. The AVIC and the State animal health official review and approve the request for withdrawal.

In the case of a denial, the operator of the laboratory or facility will be informed of the reasons for denial and may appeal the decision in writing to the Administrator within 10 days (30 days for laboratories) after receiving notification of the denial. The appeal must include all of the facts and reasons on which the person relies to show that the laboratory or facility was wrongfully denied approval to conduct the official test. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision.

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 Surveillance Collaborative Services will not be utilized. The program will utilize the Veterinary Services Process Streamlining (VSPS) to capture the information needed.

The Veterinary Services Process Streamlining (VSPS) provides a consistent and standard method of data capture at all levels and provides data dissemination to the appropriate existing databases. This provides a more comprehensive analysis tool for animal tracking and disease analysis which in turn, would allow VS to respond quickly to any threats to animal health in the United States.

VS Form 1-27 can be completed using VSPS but ultimately must physically accompany the shipment of animals.

VS Form 10-11 is available as an electronic form for submission through VSPS.

VS Form 10-12 is available as a paper form and fillable PDF. It is not available for purely electronic transmission.

VS Form 10-15 and VS Form 10-16 are available as fillable PDF and do not interface with VSPS. They are filed by federal officials in EMRS to maintain a single record and for easy access by Federal and State officials from multiple sections.

Agreements require original signatures by all signing parties to be valid and are therefore not candidates for electronic submission.

Requests for hearing and written notification of approval withdrawal may be made via a telephone call or email to APHIS. For legal purposes, however, electronic communication must be followed up in writing containing original signatures.

The monthly summary report can be submitted via email using the VS approved Excel spreadsheet and can be accessed via Data Integration Services (DIS) by animal health officials.

The items related to laboratory approval require original signature and are not candidates for electronic submission.

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 for the EIA program is exclusive to its mission of regulating the interstate movement of equines to prevent the spread of disease and is not available from any other source.

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

APHIS estimates 90 percent of the respondents are considered small businesses. The information APHIS collects is the minimum needed to ensure that EIA testing is reliable, reporting is accurate and timely, and equines moving interstate do not pose a health threat to the U.S. equine population.

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 were collected less frequently or not collected, APHIS would be unable to establish an effective defense against the spread of EIA. This could have serious health consequences for U.S. equines and trade and economic consequences for the U.S. equine industry.

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;**

Request for Hearing - If APHIS denies the listing of an establishment, the owner or operator of that facility may appeal the denial and request a hearing in writing within 10 days after receiving notification.

Written Notification of Approval Withdrawal - If APHIS withdraws approval from a facility, the owner or operator of that facility may appeal the withdrawal in writing within 10 days after receiving notification (30 days for laboratories).

The monthly summary report is due to APHIS from approved laboratories each month.

- **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.**

No other 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 conducted a yearlong EIA discussion group, composed of industry, commercial and private EIA laboratories, test kit manufacturers, veterinary practitioners, EIA researchers, and academics. That feedback greatly influenced the current and existing guidance and added information collection activities such as the monthly reports. APHIS held ongoing discussions while formulating and finalizing the current guidance with State animal health officials, industry members, and practitioners. Leading up to and following publication of the guidance (and associated information collection) APHIS reached out to Federal and State animal health

officials, National Animal Health Laboratory Network labs, all approved EIA labs and accredited veterinarians.

APHIS held national industry and veterinary meetings, webinars, and teleconferences; sent email and newsletters; and held individual conversations and phone calls. No significant concerns were raised regarding how frequently or how much data is collected; the convenience and clarity of reporting formats and other collection instruments; and the clarity of, and necessity for, any recordkeeping requirements. Specific individuals contacted and consulted include:

Dee Ellis
Texas Animal Health Commission
P.O. Box 12966
Austin, TX
tel. 800-550-8242

Courtney McCracken
New York State Department of Agriculture and Markets
Division of Animal Husbandry
10 B Airline Drive
Albany, NY
tel. 518-457-3502

Bill Brown
Kansas Department of Agriculture
1320 Research Park Drive
Manhattan, KS
tel. 785-564-6601

On Friday, February 12, 2021, APHIS published in the Federal Register Vol 86 No 28 Pages 9317-9318, a 60-day notice seeking public comments on its plans to request a 3-year approval of this collection of information. APHIS received no comments from the public.

9. Explain any decision to provide any payment or gift to respondents, other than re-enumeration 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 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 accredited veterinarians, and with staff at approved laboratories.

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

Respondents are producers, veterinarians, State animal health officials, and laboratory directors. APHIS estimates the total annualized cost to these respondents to be $5,585,066. APHIS arrived at this figure by multiplying the hours of estimated response time (92,610 hours) by the estimated average hourly wage of the above respondents ($41.62) and then multiplying the result by 1.449 to capture benefit costs.

The average hourly rates used to calculate the estimate are for owners and shippers ($36.93, SOCC 11-9013 (farmers, ranchers, and other agricultural managers)); veterinarians ($52.09, SOCC 29-1131); and laboratory, diagnostic, and research facility personnel ($35.84, SOCC 19-1011 (animal scientists)). The rates were found at the U.S. Bureau of Labor Statistics website https://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 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 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.

See APHIS Form 79. The annualized cost to the Federal Government is estimated at $8,871,752.

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

	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	1,156,728	0	(457)	(258,890)	0	1,416,075
Annual Time Burden (Hr)	92,610	0	(455)	(24,940)	0	118,005

This request for renewal is for 1,156,728 estimated responses and 92,610 estimated burden hours, reflecting decreases of 259,347 estimated responses and 25,395 hours of estimated burden from the previous renewal request.

Adjustments to Agency estimates resulted in a decrease of 258,890 estimated responses and 24,940 estimated burden hours, mainly attributed to a decrease in the number of laboratory tests (VS 10-11) conducted during the last reporting period as well as a decrease in the number of approved laboratories conducting EIA testing (monthly summary reporting).

Discretionary program changes resulted in a decrease of 457 estimated responses and 455 estimated hours of burden. The EIA Supplemental Investigation estimated time per response was increased from 25 minutes to 30 minutes to more accurately reflect processing time; the change added 2 hours of burden. The estimated response time for Agreement for Approved Livestock Facility was slightly increased but the change did not alter the overall burden hour estimate.
The activity “Inspection” was determined to be performed by Agency employees internally and was removed from this information collection request, resulting in decreases of 457 estimated responses and 457 estimated burden hours.

The following activities have been renamed in this renewal request Supporting Statement. In some cases, the titles may have been abbreviated on the APHIS Forms 71.

- Equine Infectious Anemia Laboratory Test, and Other VS-Approved Test Forms was previously titled Equine Infectious Anemia Laboratory Test;
- Application to Conduct Laboratory Equine Infectious Anemia (EIA) Testing was previously titled Proposal to Conduct Laboratory EIA Testing;
- Agreement to Conduct Equine Infectious Anemia (EIA) Testing was previously titled Agreement to Conduct EIA Testing;
- Denial or Withdrawal of Laboratory Approval was previously titled Denial and Withdrawal of Approval of Laboratories.

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

APHIS plans to post this information regularly (at least quarterly and annually) on its page: http://www.aphis.usda.gov/animal-health/equine-health-eia.

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.

VS Form 1-27 is used in multiple information collections, each with its own OMB approval expiration date; it is not practical to include the date. APHIS is seeking approval to not display the OMB approval expiration date on this form. The Agency has made it a priority to develop procedures and to convert the multi-ICR forms into common forms.

VS Forms 10-11 and 10-12 are serially numbered to track the movement of the shipment for regulatory purposes. APHIS is seeking approval to not display the OMB approval expiration date on these two forms as destroying unused stocks of the forms with each renewal would be cost prohibitive.

VS will post the expiration date on the VS Forms 10-15 and 10-16.

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

APHIS can certify 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.