March 2020

SUPPORTING STATEMENT
NATIONAL LIST OF REPORTABLE ANIMAL DISEASES
Docket APHIS-2017-0002
OMB Control No. 0579-XXXX

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 U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), Veterinary Services' (VS) ability to allow United States animal producers to compete in the world market of animal and animal product trade. The regulations in title 9, *Code of Federal Regulations* (9 CFR) Subchapter B (referred to below as the regulations) govern the cooperative control and eradication of livestock and poultry diseases. The regulations establish procedures through which Federal and State animal health authorities coordinate in their collective efforts to eradicate certain communicable animal diseases. Under the AHPA, the Secretary of Agriculture can respond to diseases through movement control, surveillance, and other activities including disease reporting. However, at present, the United States lacks thorough animal disease reporting requirements. The United States needs data on animal disease presence and absence to fulfill its international reporting obligations to the World Organization for Animal Health (OIE) and international trading partners.

APHIS is proposing to add a new part to the CFR that would provide for a National List of Reportable Animal Diseases (NLRAD), as well as disease reporting requirements for individuals identifying or suspecting a notifiable disease or condition. The proposed amendments would consolidate and clarify national disease reporting guidelines for veterinarians, and expand reporting requirements to include other animal health professionals who may encounter such diseases. Examples of animal health professionals include, but are not limited to, veterinary medical professionals, diagnostic laboratorians, biomedical researchers, public health officials, animal health officials, trained technicians, zoo personnel, and wildlife personnel with such training.

The National Animal Health Reporting System (NAHRS) collects monthly data from State veterinarians on the presence or absence of diseases reportable to the OIE within the United States.

All States voluntarily submit monthly reports on the presence or absence of OIE-notifiable diseases. VS collects and compiles this information for reports to APHIS, which prepares semiannual and annual reports for the OIE. The OIE requires these reports, which are also needed to facilitate trade with foreign countries.

The NLRAD structure, which will ultimately switch reporting platforms from NAHRS to a Data Integration Services (DIS)[1], will provide an ongoing national measure of the health status of the nation's livestock. VS' Strategy and Policy (S&P) unit will coordinate this voluntary monitoring to standardize disease information collection throughout the United States. S&P will provide a central point for collating State data into a single national report. The evolving international trade arena and increased competition have heightened the need to have accurate, timely information to maintain and increase U.S. animal agriculture's overseas market share. Introducing the required NLRAD component to improved electronic recording and monitoring, via DIS, provides information that helps meet this need.

APHIS is asking the Office of Management and Budget (OMB) to approve its use of the information collection activities described below in connection with its efforts to reduce the risk of introducing animal disease into 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.

Public Input on the List of Diseases; 9 CFR 57.2(c); Individual, Business, State
Changes to the NLRAD will be announced via the publication of a notice in the *Federal Register*. Updates and edits to the NLRAD will be considered when initiated by APHIS in response to Federal-level events or when changes or additions are requested by stakeholders. Stakeholders will be required to submit change requests in writing via postal mail or e-mail using the contact information provided in paragraph 9 CFR 57.2(a), and must include a justification for the proposed change. Examples of justifications can be found in the NLRAD System Standards Document available on the internet at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nlrad/ct_national_list_reportable_animal_diseases.

Notifiable Disease Reporting; 9 CFR 57.2(d) and 9 CFR 161.4(f); Business, State
Any animal health professional (such as veterinarians, laboratory personnel, biomedical researchers, public health officials, animal health officials, trained technicians, zoo personnel, and wildlife personnel) with knowledge of occurrence or suspected occurrence of an animal disease, disease agent, or condition listed as notifiable in the NLRAD will be required to immediately report such identification or suspicion to both APHIS and the State where the livestock is located. Reporting may be done through the NAHRS website at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/ct_usda_aphis_animal_health, or by contacting a local APHIS office.[2] Reporting to the State should be to the State animal health official

[1] The DIS will have enhanced capabilities for collecting animal disease-related data on a national scale. Once fully operational, this system will be available on the APHIS website.

[2] Contact information for APHIS offices can be found on the APHIS website at https://www.aphis.usda.gov/aphis/banner/contactus, or in the local phone directory (listed under

listed at https://www.usaha.org/upload/Federal%20and%20State%20Health/STATE_ANIMAL_HEALTH_OFFICIALS%20-%20Copy%204.pdf for the State in question.

The information collected may include either test-level or summary-level data. Test-level data provides results for individual samples as well as information about that sample and includes date of collection, date of testing, State of collection, animal species sampled, type of test performed, test result (i.e., quantitative measure), and test result interpretation (i.e., positive, not detected). Summary-level data provides results for multiple samples tested for the same disease and includes date or date range of collection, date or date range of testing, State of collection, animal species sampled, type of test performed and disease tested for, and total count of each test type (positive, not detected, inconclusive). Test-level data is the preferred level of data collection, preferably collected via electronic messaging directly from laboratory data systems, requiring no data entry. Reports may also be made by phone, email, fax, mail, or online interface.

Data collected for notifiable diseases includes animal species and age; epidemiological information such as clinical signs, case/herd history and type, and vaccination history; location information; and testing information.

Data collected for emerging disease investigations and outbreaks may require more information depending on the situation. APHIS will use diagnostic testing results, number of detections, and epidemiological information to detect and evaluate the status of a potential emerging disease threat. Once APHIS confirms there is an emerging animal disease, it will use this information to create specific case definitions and disease reporting criteria. At the time of first reporting, the specific agent causing a potential emerging disease may be unknown, or the agent may be a newly identified but incompletely characterized strain.

Individual animal disease control or eradication programs may have data systems to collect additional information for disease investigation and response. APHIS, or the State animal health official, will notify reporters if they need to use one of these data systems. The APHIS data systems used for notifiable diseases include Surveillance Collaborations Services (SCS), Veterinary Services Laboratory Submissions (VSLS), Emergency Management and Response System (EMRS) 2.0, Laboratory Messaging Services (LMS), and any subsequent applications that replace or augment these. States may use additional data systems not listed here.

Monthly Laboratory Reporting to States; 9 CFR 57.2(d)(2); Business, State

State and private laboratories will be required to report occurrence information of confirmed cases of an animal disease or condition listed as monitored in the NLRAD on a monthly basis to the State where the animal is located by contacting the State animal health official listed at https://www.usaha.org/upload/Federal%20and%20State%20Health/STATE_ANIMAL_HEALTH_OFFICIALS%20-%20Copy%204.pdf.

NAHRS Monthly State Report Form (VS 12-10); 9 CFR 57.2(d)(2); State

The process for States to report diseases listed as monitored in the NLRAD (comprised of endemic (present) diseases in the United States) would stay as it is (and as such, NAHRS is covered in 0579-0299). States will voluntarily track and report information on monitored and notifiable diseases to

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Animal and Plant Health Inspection Service (APHIS), Veterinary Services).

APHIS via the NAHRS (soon to be DIS). The NAHRS collects monthly data from State veterinarians on the presence or absence of diseases reportable to the OIE within the United States. APHIS' current proposal would make such reporting from States mandatory. Also, laboratories encountering cases of monitored diseases would be required to report occurrence information to the State where the animal is located. Laboratories will also have to send monthly summary reports to the State animal health official regarding detection of monitored diseases. Reporting requirements for monitored diseases apply only to laboratories and State animal health officials.

Basic reporting fields for monitored diseases include date or date range applicable to knowledge of State, disease, and status (present, absent, unknown); basically, a yes or no answer as to the disease's presence/occurrence. APHIS may request voluntary submission of additional case and testing information for some monitored diseases, such as number of diagnostic tests conducted, number of confirmed cases, vaccination status, number of susceptible animals, or other epidemiological information. This additional information request will occur when Federal, State, and industry representatives together identify significant diseases where additional information will help monitor disease trends; meet travel and movement requirements; and carry out control, response, and prevention activities. Information will be collected whenever possible via electronic messaging directly from laboratory data systems, requiring no data entry. Reporting may also be made by phone, email, fax, mail, or online interface.

The NAHRS Monthly State Report Form (VS 12-10) is used by State veterinarians to report data submitted from private practitioners, State and Federal veterinarians, and State laboratories to the VS Science, Technology, and Analysis Services (STAS) Office. Most data submitted is based on test results as well as observational data. The form is divided into 11 sections: Multispecies, Bovine, Farmed Cervids, Caprine and Ovine, Equine, Porcine, Poultry, Lagomorph, Other Diseases, Bee, and Aquaculture. The top of the form has a space to indicate the State of origin and the current month and year. Each section lists rows of OIE notifiable diseases that correspond to each of the species, with a column for the respondent to indicate the presence or absence of each disease as well as a space for comments. There is also an optional section where States may report the presence of unlisted diseases.

Submitters may collect additional data for non-negative results reported for specific diseases or incidents.

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 NAHRS Monthly State Report Form (VS 12-10) can be downloaded from the APHIS NAHRS website htttps://www.aphis.usda.gov/animal_health/nahrs/downloads/nahrsstatereportform.pdf.

The APHIS data systems used for notifiable diseases include Surveillance Collaborations Services (SCS), Veterinary Services Laboratory Submissions (VSLS), Emergency Management and Response System (EMRS) 2.0, Laboratory Messaging Services (LMS), and any subsequent applications that replace or augment these. States have the option of completing and submitting their NAHRS form

electronically through the internet using these systems. They can also email, fax, or mail the form to Fort Collins, Colorado.

VS is studying the possible modification of its current NAHRS reporting system to accept data from additional stakeholders and reduce the amount of data entry required. The modified reporting system will increase automated checking, acceptance, and summary of data.

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 collected in connection with this program is not available from any other source. APHIS is the only Agency responsible for preventing the introduction of exotic animal diseases into the United States, and monitoring and reporting the status of OIE-notifiable diseases within the United States. The type, quantity, and frequency of data collected by the NAHRS (soon to be DIS) is unique in 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 is the absolute minimum needed to evaluate the risk of introducing animal disease into the United States. APHIS anticipates most information collected will come from States and State and commercial laboratories. APHIS estimates that more than 75 percent of the commercial laboratories are small entities.

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 was collected less frequently or not collected at all, it would significantly cripple APHIS' ability to evaluate the risk of introducing disease into the United States. This would make a disease incursion event much more likely, with potentially serious effects on the U.S. livestock industry and international trade. Moreover, the United States needs to monitor and report on the health status of U.S. commodities to meet its obligations to the OIE.

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;**

APHIS will require laboratories and State animal health officials to report monthly on monitored diseases to expedite monitoring for disease presence and control.

- **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.**

Apart from the monthly reporting requirement, 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 engaged in productive consultations with the following individuals concerning the information collection activities associated with this initiative:

Anthony Frazier, Alabama State Veterinarian
1445 Federal Drive
Montgomery, AL 36107
Phone: 334-240-7255 ext. 1
Fax: 334-240-7198

Email: stvet@agi.alabama.gov

Jim Logan, Wyoming State Veterinarian
1934 Wyott Drive
Cheyenne, WY 82002
Phone: (307) 777-7515
Fax: (307) 777-6561

Francois Elvinger, Executive Director
Animal Health Diagnostic Center and New York State Veterinary Diagnostic Laboratory
Department of Population Medicine and Diagnostic Sciences
Cornell University College of Veterinary Medicine
240 Farrier Road
Ithaca, NY 14853
Phone: (607) 253-3900
Fax: (607) 253-3943
Email: diagcenter@cornell.edu

APHIS contacted these respondents by email and phone to discuss the information APHIS collects to administer its disease testing and surveillance practices. 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 via email or phone that they had no concerns with any of these items and had no further recommendations.

APHIS' published in the Federal Register on April 2, 2020 (85 FR 18471) a proposed rule notice that describes the information gathering requirements and provides 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 decision 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.

APHIS ensures confidentiality to the extent possible and treats sensitive producer information with the respect and security it deserves. While APHIS makes every effort to keep responses confidential certain non-sensitive details could be released as required by a Freedom of Information Act (FOIA) request. APHIS stores all confidential information from its surveys in secure electronic databases. In short, no additional assurance of confidentiality is provided with this information collection, and 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 83-1.**

  See APHIS Form 71. Burden estimates were developed from discussions with wildlife and zoo personnel, veterinary medical professionals, laboratory personnel, and animal or public health officials.

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

  APHIS estimates the total annualized cost to these respondents to be $1,675,437. APHIS arrived at this figure by multiplying the total burden hours (27,381) by the estimated average hourly wage of the respondents ($42.82) and then multiplying the result by 1.429 to capture benefit costs.

  Salaries were based on the figures in the May 2018 Bureau of Labor Statistics Occupational Employment Statistics survey (see https://www.bls.gov/oes/current/oes_stru.htm) -- Veterinarians: $50.59, Wildlife officials: $32.58 (zoologists and wildlife biologists), Laboratory personnel: $32.54 (Animal Scientists), and Public health officials: $55.57 (Managers).

  According to DOL BLS news release USDL-20-0451, dated March 19, 2020 (see https://www.bls.gov/news.release/pdf/ecec.pdf), 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 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 $660,581.

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

This is a new collection.

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

Information from these studies will be tallied automatically as data are submitted to provide descriptive information regarding the presence of notifiable diseases as a report on the status of U.S. animal health. Results will appear in monthly and semi-annual OIE reports that indicate the presence of these diseases within the United States.

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 requests a waiver from displaying the OMB approval expiration date on the form within this information collection request. It will be listing two ICR control numbers with different expiration dates until the ICR's are merged. Expiration dates make unused paper stocks obsolete every three years, and their destruction would be wasteful. Users unfamiliar with the forms or programs often confuse the ICR expiration date for the form version date. Forms generated by information systems cannot be revised in a timely manner as such projects are not cost effective every three years. All of these problems compound when the agency attempts to manage three formats (print, PDF-F, and IS) of a form at the same time, making form file management very difficult as each form has several production files. The problem compounds when updating a series of forms in a single ICR or across multiple ones.

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 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.