January 2020

SUPPORTING STATEMENT
Approval of Laboratories to
Conduct Official Testing; Consolidation of Regulations
APHIS-2016-054
OMB No. 0579-0472

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

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 enhancing the ability of U.S. producers to compete in the global market of animal and animal product trade.

The regulations of the Animal and Plant Health Inspection Service (APHIS) require APHIS approval or certification for laboratories conducting tests for disease management as well as live animal interstate movement, import and export. APHIS published a final rule consolidating these regulations and establishing a set of standard procedures by which APHIS conducts all future diagnostic laboratory approvals. The consolidated regulations provide consistent inspection protocols, proficiency testing methods, quality system guidelines, and definitions. This also facilitates the approval of additional laboratories in emergency situations. The consolidated regulations serve to simplify regulatory oversight and compliance.

APHIS is asking OMB to approve use of the associated information collection activities for 3 years.

2. Indicate how, by whom, 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 to approve laboratories to conduct official animal disease testing.

Notification for Intent to Request Approval (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(a)

The laboratory must inform APHIS via telephone or email of its intent to request approval. This initial contact notifies the APHIS Veterinary Services (VS) that the laboratory is initiating the process. This is necessary because there are two components to acquiring APHIS approval — VS' evaluation of the technical information/proficiency testing results and the laboratory site inspection (see below).

Application for APHIS Approval (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(a), (g)

Laboratories requesting approval to conduct official testing must also submit an application package to VS. The application must contain:

- The laboratory's name, physical location, and mailing address.
- The names of the legally responsible official and the laboratory director.
- A description of the laboratory facilities and equipment used in performing tests.
- A list of specific diagnostic assays for which the laboratory has requested approval.
- Test protocols.
- A list of individuals performing the tests, including their names, professions, and technical qualifications.
- A statement confirming that the laboratory has met proper storage conditions.
- The testing agreement (see below for agreement description)

Any previously approved laboratories that wish to maintain their approved status are required to reapply for APHIS approval at least 1 month before their approval term expires, or at least every 2 years, whichever comes first.

Laboratories also have to submit applicable portions of the application materials if APHIS suspends approval to conduct testing. Reasons for suspension include changes that affect the laboratory's ability to provide quality testing services, such as no longer employing an individual approved to conduct official testing, a move to different facilities, or a natural disaster that impacts power or water systems.

Inspection (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(b)

APHIS will approve laboratories to conduct official testing only after the physical facilities have passed an inspection conducted by an APHIS representative and after VS has consulted with the State animal health official in the State in which the laboratory or diagnostic facility is located and has determined that the laboratory applicant:

- Has technical personnel assigned to conduct official testing who have successfully completed VS' National Veterinary Services Laboratories (NVSL) training. (APHIS employees conduct this training).
- Uses U.S. Department of Agriculture licensed test materials as appropriate.
- Follows standard NVSL test protocols.
- Meets NVSL check test proficiency requirements.
- Refers samples to NVSL for confirmation as appropriate.

- The laboratory provides the State animal health official and the AVIC with timely reports of any positive test results.
- Maintains an annual test minimum as appropriate.
- Accepts samples only from a USDA Category II accredited veterinarian and with approval to conduct accredited activities in the State in which the sample was drawn.
- Accepts submissions only with approved, properly and completely filled, test forms.
- Accepts submissions only on animals properly identified (microchips, drawings, photographs, breed registration number, etc.).

APHIS will inspect the laboratory premises, equipment, and functions. The laboratory director (or his or her representative present at the time of inspection) must provide his or her contact information as well as that of the laboratory in general; the names of employees trained and authorized by APHIS to conduct tests and the dates of their authorization.

Checklist and Agreement – (Private Sector) (State, Local, and Tribal Government) - 9 CFR 71.22(b)-(f)

APHIS evaluates laboratories during the inspection and while evaluating the application materials. Checklist and agreement documents will be used for the following purposes:

1) In the agreement, laboratory applicants must provide the laboratory name and address as well as contact information for all facilities (branch or system laboratories) to be involved with testing. Applicants must also specify the proposed participating surveillance programs and the associated testing. The agreement also asks the laboratory to list the assays it can perform for recognized program and foreign animal diseases; and to aver: That it can document implementation of a quality system (see further below); that it will abide by APHIS testing and reporting procedures, or will seek permission for a deviation if necessary; that its personnel will not use test material for research, distribute any materials outside of the laboratory, and comply with select agent regulations; that it will accept and test samples in support of disease investigations and outbreak situations, if it has the approval, capability, and capacity to assist in testing samples; and that it can and will track and report disease adequately.

2) Applicants must sign and date the checklist, and obtain signatures from applicable State authorities, if needed, and the Area Veterinarian in Charge.

3) VS staff record the date they receive each completed checklist. Staff reviews and verifies the information from each completed checklist:

    - The State and name of the laboratory, and the name of the Laboratory Director.
    - The date the packet was received.
    - Completeness of the checklists and the required signatures.
    - Listed branch or system laboratories.

- The surveillance programs for which the laboratory, including branch or system laboratories, seeks approval.
- The surveillance programs that the laboratory no longer wishes to participate in.

4) Checklists will be approved if they:

   - Have been completed appropriately.
   - Contain the required signatures.
   - Contain any necessary supplemental documentation and show sufficient evidence of an implemented quality system.

5) Laboratories must agree to regular site visits and successfully show use of a quality system.

Documentation of Accreditation Status – (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(d)

Accredited laboratories must provide proof of accreditation status, such as a certificate from the American Association of Veterinary Laboratory Diagnosticians or from a body authorized to grant accreditation acceptable to the World Organization for Animal Health (OIE) under ISO 17025. Accreditation can be granted for 1 to 5 years. The applicant need only submit proof of accreditation once during the accreditation period. APHIS animal health program staff record the source of accreditation and the certificate expiration date.

Documentation of Implemented Quality System – (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(c)

Applicants must document implementation of a quality management system. Quality systems may be comprised of elements such as documentation of procedures, recordkeeping, training, reporting, and corrective actions taken if standards and procedures are not reached or maintained. Required documentation includes the laboratory's Quality Manual and System Standard Operating Procedures (SOPs). A new applicant must provide all available documents, while a laboratory applying to continue participation need only submit any document modified since the previous submission. APHIS staff reviews the documents to assess a laboratory's quality system.

Quality Document Verification Form – (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(c)

A summary of the requested quality documentation within the applicant laboratory's quality system must be verified by the laboratory director before submission to APHIS. The laboratory director identifies current and revised documents and provides updated versions.

Quality Assurance/Control Plans - (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(c)
Laboratories produce and maintain appropriate quality assurance and quality control plans. To obtain APHIS approval for certification, laboratories must give APHIS a copy of these plans.

Recordkeeping of Quality Assurance/Control Plans - (Private Sector) (State, Local, and Tribal Government) -9 CFR 71.22(c)
Laboratories must maintain copies of their quality control and assurance plans for 5 years. Recordkeeping is critical to ensure swift and accurate animal health investigations.

Notification of Proposed Changes to Assay Protocols - (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(h)
Laboratories must conduct testing using APHIS-approved assay methods and submit to APHIS, in advance and in writing, any proposed changes to assay protocols..
Laboratories that generate results based on modified protocols that have not received written approval risk losing approval status. Consequently, APHIS must approve any proposed changes before the laboratory incorporates those changes. Without APHIS' prior approval, APHIS would be unable to determine if the Agency can endorse the test results.

Recordkeeping: Supporting Assay Documentation (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(h)
To verify a laboratory's compliance with APHIS-approved protocols, which are in accordance with OIE recommendations, APHIS may request supporting pathogen detection and identification assay documentation for test results that support specific export health certification endorsed through the appropriate VS Field Operations Office. The laboratory should keep this documentation for 5 years.

Reporting – (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(f)
Approved laboratories must report test results to APHIS and State animal health officials using an individualized timeline established by APHIS at the time of laboratory approval. Laboratories would have to submit test results in periods ranging from 24 hours to 30 days depending on the type test and the disease in question Approved laboratories must also report any changes that affect their approved status, such as no longer employing an individual approved to conduct official testing, a move to different facilities, or a natural disaster that impacts power or water systems.

Test Exemption - (Private Sector) (State, Local, and Tribal Government) - 9 CFR 71.22(g)
Laboratories not conducting the minimum number of tests as required in 9 CFR 71.22(g) (3) during a single reporting period would be assigned probationary status. A reporting period would be less than or equal to the time for which the laboratory has been approved to conduct testing by APHIS. Laboratories under probation could continue to conduct official testing. If the minimum number of tests are not performed during two

consecutive reporting periods, the laboratory would not be eligible for renewal of APHIS approval. Exceptions to this requirement may be granted by APHIS on request.

Submission of Sample Copies of Diagnostic Reports - (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(f)
Laboratories produce diagnostic reports. To obtain APHIS approval for certification, laboratories must give APHIS a copy of these reports.

Recordkeeping of Sample Copies of Diagnostic Reports - (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(f)
Laboratories must maintain records of the sample copies of diagnostic reports for 2 years. APHIS uses these records to compare the actual reports with the templates the laboratory has submitted for use.

Request for Removal of Approved Status - (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22 (i)(3)
Laboratories voluntarily requesting removal of approved status do so in writing to VS. This will make APHIS aware of a laboratory's status for actual capacity or willingness to conduct the activities APHIS has approved.

Appeal of Approval Denial, Suspension, or Removal – (Private Sector) (State, Local, and Tribal Government) – 9 CFR 71.22(j)
If APHIS opts to deny or withdraw approval from a laboratory, the owner or operator of that facility may appeal the denial or withdrawal in writing within 10 days after receiving notification. 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. The owner or operator of that 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 the APHIS Administrator or the Administrator's official designee within 30 days of the laboratory's receipt of the NVSL Director's decision. Responses to these appeals would be provided within 60 days of receipt by APHIS.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, 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 Notification for Intent to Request Approval can be made via telephone or email to APHIS.

The following activities can be submitted via email or hard copy:

- Documentation of Accreditation Status.

- Documentation of Implemented Quality System.
- Quality Assurance/Control Plans.
- Notification of Proposed Changes to Assay Protocols.
- Reporting.
- Test Exemption.
- Submission of Sample Copies of Diagnostic Reports.
- Request for Removal of Approved Status.
- Appeal of Approval Denial, Suspension, or Removal

All recordkeeping activities may be maintained 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 APHIS collects 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. APHIS uses the information to ensure that the laboratories approved to help assess the nation's animal health status through targeted surveillance are capable of producing quality test results. The appropriate review and approval of these laboratories will enhance early detection of foreign animal disease agents and newly emerging diseases and allow us to better respond to animal health emergencies (including bioterrorist events) that threaten the nation's food supply and public health.

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

APHIS estimates that all of the private sector respondents could be considered small entities. However, the information APHIS collects in connection with this program is the absolute minimum needed to ensure that laboratories comply with APHIS-approved testing procedures.

6. Describe the consequences 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 APHIS did not collect this information, it could not:

- Ensure a national ability to coordinate actions to prevent foreign animal disease outbreaks in the United States.
- Maintain a state-of-the-art infrastructure for a Federal-State diagnostic laboratory system to receive confirmed and accurate test results and support response actions for all animal health events, from routine surveillance monitoring to large-scale outbreaks.

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;**

  Laboratories would have to submit test results in periods ranging from 24 hours to 30 days depending on the type test and the disease in question.

  If APHIS opts to deny or withdraw approval from a laboratory, the owner or operator of that facility may appeal the denial or withdrawal in writing within 10 days after receiving notification.

- **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;**

  APHIS requires that laboratories keep record for 5 years to ensure that animals can be traced in the event of a disease outbreak.

- **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, frequency of collection, the clarity of instructions and

recordkeeping, disclosure, or reporting from, 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 conduct its laboratory approval process. APHIS discussed with them how APHIS 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.

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APHIS' proposed rule (Docket Number APHIS-2016-0054) was published in the Federal Register on Thursday, May 30, 2019 with a 60-day comment period. Six comments were received but none resulted in any changes to this information collection request. APHIS' responses to the six comments can be found in the final rule Federal Register notice.

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 and attitudes, religious beliefs, and others that are considered private. This justification should include the reasons why the agency considers the questions necessary.

This information collection activity asks 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 State, university, and private laboratory personnel.

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 respondents to be $3,061,797.01. APHIS arrived at this figure by multiplying the hours of estimated response time (37,697 hours) by the estimated average hourly wage of the above respondents ($55.23), and then multiplying the result ($2,082,005.31) by 1.4706 to capture benefit costs.

The average hourly rates of $48.81 for veterinarians (used for State animal health officials) and $61.65 for natural science managers (used for laboratory directors) is derived from the U.S Department of Labor; Bureau of Labor Statistics report USDL-19-0493, Occupational Employment and Wages, May 2018.

According to DOL BLS news release USDL-18-1499, dated September 18, 2018 (see https://www.bls.gov/news.release/pdf/ecec.pdf), benefits account for 32 percent of employee costs, and wages account for the remaining 68 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.4706.

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 estimated should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

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

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

The annualized cost to the Federal Government is estimated at $295,806. (See APHIS Form 79.)

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

	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	5,306	0	0	0	0	0
Annual Time Burden (Hr)	37,697	0	0	0	0	0
Annual Cost Burden ($)	0	0	0	0	0	0

This is a new information collection resulting in 37,697 total burden hours.

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

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

17. If seeking approval to not display the expiration date of OMB approval of the information collection, explain the reasons that display would be inappropriate.

Not applicable. APHIS will display the expiration date on any forms associated with this action.

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 in the Act.

B. Collections of Information Employing Statistical Methods.

Statistical methods are not used in this information collection.