

**SUPPORTING STATEMENT - OMB NO. 0579-0146
TUBERCULOSIS**

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 enhancing the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), Veterinary Services' (VS) ability to allow U.S. animal producers to compete in the world market of animal and animal product trade.

In connection with this mission, VS participates in the Cooperative State-Federal Bovine Tuberculosis Eradication Program, which is a national program to eliminate bovine TB from the United States. This program is conducted under the authorities of the various States supplemented by Federal authorities regulating interstate movement of affected animals.

The APHIS TB regulations in Part 77 of title 9, *Code of Federal Regulations*, provide for the assignment of State TB risk classifications, the creation of TB risk status zones within the same State, and for the conduct of tests before regulated animals are permitted to move interstate. This system enhances the ability of States to move healthy, TB-free cattle, bison, and captive cervids interstate as well as internationally. Additionally, this zoning/testing system enhances the effectiveness of APHIS' Tuberculosis Eradication Program by decreasing the likelihood that infected animals will be moved interstate or internationally.

These zoning, testing, and animal movement activities necessitate the use of many information collection activities

APHIS is asking OMB to renew its approval of these information collection activities for an additional 3 years.

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 activities to support a Tuberculosis Eradication Program.

Annual Report, VS 6-38

To qualify for renewal of status, State animal health authorities must submit an annual report to APHIS certifying that the State (or zone within the State) is complying with the provisions of the MOU-for Bovine Tuberculosis Eradication. Federal personnel may prepare this report in States lacking sufficient employees to do so. This report must be submitted to APHIS each year between October 1 and November 30. It enables APHIS to carefully monitor State activities with regard to TB surveillance, containment, and eradication.

Each report must include information on the population and status of cattle and bison herds (e.g., numbers of accredited herds and herds under quarantine) within the State or zone, the number of cattle and bison slaughtered, the slaughter surveillance plan, monitoring of slaughter surveillance and test response rates, and the identification of any cattle or bison herds or individual cattle and bison in which TB has been confirmed. Herds designated by State or Federal representatives as being at high risk for harboring TB based on testing history, possible exposure to TB, or other epidemiological linkage, as determined by the Administrator, must also be identified, and the report must indicate whether those herds have undergone required retesting. The report must document that the levels of TB testing, slaughter inspections, and necropsies were sufficient to meet requirements. The report must also include a narrative statement addressing how the State or zone has met certain requirements.

Request for Zone Status

State animal health officials may formally request that APHIS designate part of their State as having a different TB status than the rest of the State. In this request, State animal health authorities must clearly delineate the boundaries of the requested zone. They must also provide evidence that the State has an effective veterinary organization and infrastructure, as well as the legal and financial resources to implement and enforce a TB eradication program.

Memorandum of Understanding for Zone Recognition

As part of its application for and retention of zones, a State must enter into an MOU with APHIS in which the State agrees to any conditions for zone recognition or future advancement of status. These MOUs are reviewed and updated annually.

Epidemiological Review of Zone Testing

State animal health officials seeking APHIS approval to create a TB status zone must maintain, in each intended zone, clinical and epidemiological surveillance of animal species at risk for TB at a rate that allows detection in the overall livestock population at a 2 percent prevalence rate with 95 percent confidence. To support the formal request for zone status, APHIS requires that the designated TB epidemiologist (who may be either a

State employee or a Federal employee) review reports of all testing for each zone within the State within 30 days of the testing.

TB Management Plan

If TB is diagnosed in a species not covered in 9 CFR part 77, in any State or zone, and if an APHIS risk assessment determines that the outbreak poses a risk to livestock within the State or zone, then the State or zone must implement a TB Management Plan within 6 months of the diagnosis. This plan must include provisions for (1) an immediate investigation of TB in livestock, wildlife, and animals held for exhibition; (2) the prevention of disease spread to other animals; (3) increased surveillance; (4) eradication in individual herds; and (5) a timeline for achieving this eradication. If the State or zone does not implement this plan within 6 months of diagnosis, the State or zone's TB status will be downgraded.

Accredited Herd Plan

Producers of accredited bovine herds in States or zones with a known wildlife reservoir of bovine TB or in a State or zone with a TB status of modified accredited or lower must submit a written herd plan to be approved by the APHIS designated and State TB epidemiologists. Federal personnel may prepare this plan in States lacking sufficient employees to do so. This plan describes that adequate precautions have been taken and the herd has in place appropriate biosecurity measures, documented in the plan, that ensure the herd has not been exposed to TB during the accreditation process and will not be exposed to TB following accreditation.

Wildlife Risk Survey

When a wildlife component of disease exists in an area State and Federal animal health officials may work with herd owners to conduct reviews which identify possible risks of disease infection from wildlife sources.

Report of TB Eradication (Monthly Report), VS 6-2

Each State must prepare a report within 30 days of the end of each month for the entire State or for each zone within a State. The State's designated TB epidemiologist prepares and submits the report, which covers the tuberculin testing that took place during the month and the reasons for the testing. Federal personnel may prepare this report in States lacking sufficient employees to do so. The epidemiologist submits the report to APHIS through the Automated Web Based Data Submission (AWBDS), which APHIS staff accesses as needed.

Report of Suspicious TB Lesions or Thoracic Granulomas in Regular Kill Cattle, VS 6-35

This form is submitted by Food Safety and Inspection Service (FSIS) and State meat inspection personnel with suspicious lesions detected during slaughter examination to the National Veterinary Services Laboratory (NVSL), the FSIS laboratory in Athens, GA, or California's Department of Food and Agriculture laboratory for TB histopathology and bacteriology. All identification devices from the suspicious animal must be sent with the specimens to facilitate traceback of laboratory-positive cases to their herd of origin. The

form identifies the samples, indicates what testing is needed, and provides any available clinical history.

Necropsy Specimen Submission Form, VS 10-4

This form is used by States submitting specimens, for any reason other than routine slaughter inspection, for TB examination primarily at NVSL. VS Form 10-4 contains information identifying the individual animal from which the specimen was taken as well as the animal's herd or flock and the type of specimen submitted. It also sets forth the purpose for submitting the specimen. The form is then sent with the sample to the laboratory for analysis. Without the information contained on the form, NVSL personnel or personnel in other Federal laboratories could not identify or properly process the specimens sent to them for analysis.

Supplemental Necropsy Specimen Submission

States submit this information which accompanies samples from domestic livestock submitted specifically on behalf of the TB program, and supplements Form VS 10-4.

Wildlife Bovine TB Surveillance Specimen Submission Form

States submit this form which accompanies samples from wildlife submitted specifically on behalf of the TB program, and supplements Form VS 10-4.

Restricted Animal Movement Permits, VS 1-27 and Continuation Sheet, VS 1-27A

This form, or an equivalent State form, is required for all movements of TB-restricted animals. APHIS or State officials use information obtained from the animal owner at the time animals are loaded for transport 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 official identification, so that each animal in the shipment can be identified. This form accompanies the shipment and is submitted to APHIS after the animals reach their destination.

Caudal Fold Test Record, VS 6-22 and 6-22B

Accredited, State, or Federal veterinarians use this form and the other VS Forms 6-22 listed below to record vital data, including official identification, regarding tuberculin tests conducted on cattle and other animals. The forms are submitted to either the State animal health office or the VS Area Office for processing and entry into the Generic Data Database (GDB). Individual animals and herds are tested for routine purposes such as sale, show, and milk ordinance and other State regulations. They are also tested for disease investigation where possible TB association has been shown.

TB Test Record (Special), VS 6-22C

This form records data for the comparative cervical tuberculin test (CCT) applied by State or Federal veterinarians to animals classified as suspects after a previously applied caudal fold or single cervical test.

Comparative Cervical Tuberculin Test Results, VS 6-22D

This form graphs responses recorded on the VS 6-22C report by State or Federal veterinarians to aid in the final classification of an animal as negative, suspect, or reactor.

TB Test Record, Gamma

APHIS requires that any laboratory conducting this test report results to the designated State TB epidemiologist so the epidemiologist can classify the animals tested. Federal personnel may prepare this report in States lacking sufficient employees to do so.

Affected Herd Data

When a herd is identified as TB-affected, the Federal regional TB epidemiologist, in conjunction with the designated State TB epidemiologist, assembles the available epidemiological data regarding the affected herd, proposed testing protocols, and estimated risks and submits it to the National Surveillance Unit (NSU) of the Centers for Epidemiology and Animal Health. NSU works with VS TB staff to develop a recommendation for the APHIS Administrator on whether the herd should undergo a test-and-remove plan or a depopulation-and-repopulation plan.

Approved Herd Plan

The owner of a TB-affected herd must develop, with the help of a State or Federal veterinarian, a written disease management plan. The plan helps the owner eradicate TB from the herd efficiently and effectively. Owners of infected herds who purchase replacement cattle must have an approved herd plan in place to qualify for APHIS indemnity if the cattle become reactors on subsequent tests. The plan is submitted to APHIS through the VS area office.

The plan may be either a test-and-remove plan or a depopulation-and-repopulation plan. A test-and-remove plan must include appropriate herd test frequencies, tests to be used, and any additional disease or herd management practices deemed necessary to eradicate TB from the herd and to efficiently and effectively prevent further spread of infection.

Herd plans may require a change in herd management, construction of barriers, pest control, and, in some cases, additional surveillance for TB on the owner's property. Compliance with an individual herd plan usually is evident during a site visit and the owner would not have to provide additional information or documentation.

Affected Herd Testing Results

The regional TB epidemiologist, in conjunction with the State-designated TB epidemiologist, will assemble the data from each herd test required under a test-and-remove herd plan. The data will be submitted to NSU to evaluate further herd management.

Depopulation and Repopulation Agreement

A depopulation-and-repopulation plan must be approved by APHIS, State agricultural officials, and State natural resources officials (if applicable). It must be in place before the premises may be restocked. The depopulation and repopulation plan ensures that

infection is not brought into the new herd. It may contain measures to mitigate the introduction of disease from non-livestock sources and to monitor the herd to ensure that disease has not returned.

TB Infected Herd Field Report, VS 6-22A

The State-designated TB epidemiologist uses this form to record all identifying devices, descriptions, and origin information regarding TB reactors to determine sources of infection. Federal personnel may prepare this report in States lacking sufficient employees to do so. The form is sent to the VS Area Office, with copies kept at the VS Regional Office.

Report on Herd Revealing Reactors to Tuberculin Tests, VS 6-4

This form, filled out by State or Federal veterinarians, provides a summarized history of the TB testing activities in an affected herd. The first page lists all TB tests completed on the herd, the number of responders, and the ultimate findings at slaughter. This page also indicates the number of reactors by their origin, as well as the number of exposed cattle sold from the affected herd. Such information on sources of reactors and sales of exposed cattle is the focus of APHIS-State epidemiological investigations of affected herds.

Investigation for Evidence of TB (Reactor), VS 6-4A

This form, which is also filled out by the State-designated TB epidemiologist, provides for complete coverage of the investigation made on every purchased animal into a TB affected herd. Federal personnel may prepare this form in States lacking sufficient employees to do so. Each form is intended to account for a single animal. Therefore, a separate form should be completed for each purchased animal in a TB-affected herd. A single form may represent multiple animals if it is highly likely that they came from the same location.

Investigation for Evidence of TB (Exposed), VS 6-4B

This form, which is also filled out by the State-designated TB epidemiologist, provides for complete coverage of the investigation made on every animal that left a TB affected herd. Federal personnel may prepare this form in States lacking sufficient employees to do so. Each form is intended to account for a single animal. Therefore, a separate form should be completed for each animal that left the infected herd. A single form may represent multiple animals if it is highly likely that their destination was the same location.

Appraisal and Indemnity Report, VS 1-23

Forms are required for indemnity payment for animals depopulated for TB. APHIS and State animal health personnel complete this form and provide the herd owners with the official appraised value of the animals that will be indemnified. Herd owners must sign this form when an agreed-upon price per animal is obtained. The form is faxed to the regional office for approval and is kept on file in the office of the Area Veterinarian in Charge.

Request for 15-Day Extension

The Area Veterinarian in Charge may extend the time limit for destruction of animals for TB purposes to 30 days when he or she receives a request from the herd owner for such an extension prior to the expiration date of the original 15-day period allowed and circumstances beyond the control of the owner warrant such an extension. APHIS has no specific form or format for the request.

Proceeds from Animals Sold to Slaughter, VS 1-24

This form is used by the producer to record gross income from the slaughter sale of individual animals and all expenses related to the transportation, marketing, and slaughtering processes. The producer then sends the form to APHIS. The information allows APHIS personnel to arrive at a net salvage value to be used for determining net indemnity amounts allowable per individual animal.

Certificate for Movement, Variable by State

A movement certificate must accompany certain cattle, bison, or captive cervids moved interstate from States or zones with a TB status below accredited free. An accredited veterinarian or a State or Federal official issues the certificate in accordance with 9 CFR 77.10, 9 CFR 77.12, and 9 CFR 77.14. State health certificates are used in all States for the movement of regulated animals. (Most State-required health certificates require more information than that indicated in 9 CFR part 77, and are used regardless of Federal regulations.)

Steers or spayed heifers (or officially identified, sexually intact heifers moved to an approved feedlot) that originate from a modified accredited State or zone must be accompanied by a certificate stating that they have tested negative to an official TB test conducted within a specified number of days prior to the date of movement. The certificate must also accompany captive cervids that (1) are being moved interstate from States or zones not recognized as accredited-free; (2) are being used as breeding animals, and (3) are not from accredited herds. This certification ensures that TB-infected animals are not moved interstate. Additional uses for movement certificates are listed in the attached spreadsheet.

Retention of Movement Certificates

To retain APHIS recognition of a TB status zone, a State must continue to comply with the requirements in part 77 as well as APHIS requirements for maintaining the TB risk classification of each zone within the State. This requires monitoring the movement of regulated animals into and out of zones, as described above. APHIS requires State animal health authorities to retain, for at least 2 years, all certificates used for the movement of regulated animals.

Commuter Herd Agreement

A commuter herd agreement must be in place between the owner and State and Federal officials before any commuter herd movement and must be reviewed and renewed annually to remain in effect. The commuter agreement allows the herd owner to move animals from pastures on opposite sides of a State or zone boundary without having to comply with interstate movement requirements. The cattle must move in the course of

normal ranching operations, without change of ownership, directly to or from another premises owned, leased, or rented by the same individual.

Recordkeeping for Approved Feedlots

Approved feedlot owners must keep, for 5 years, records of all livestock identification, inventory, changes in inventory, and the origin and destination of all livestock moved into and out of approved facilities.

Template for Owner Participation in Projects to Evaluate New TB Tests

Livestock owners read and sign a document that indicates their voluntary participation in the evaluation of TB tests for approval as official TB eradication program tests.

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 6-38 used for the Annual Report to Qualify for Renewal of State or Zone Status is not a candidate for electronic submission because it requires original signatures.

A Request for State or Zone Status is unique to each situation; therefore, the information developed does not readily fit a preformatted form. Moreover, although the requests may be prepared electronically, original signatures are required, so they are not candidates for electronic submission.

The MOUs for recognition of split-State status may be prepared electronically, but because original signatures are required they are not candidates for electronic submission.

Epidemiological reviews of zone testing are part of an ongoing process performed monthly. Each State may review the results through different methods and the information developed may not readily fit a preformatted form.

The TB Management Plan is unique to each situation and may be prepared electronically, but because original signatures are required, it is not a candidate for electronic submission.

An accredited herd plan is unique to each herd and may be prepared electronically, but because original signatures are required, it is not a candidate for electronic submission.

The Wildlife Risk Survey is unique to each situation and may be prepared electronically, but because original signatures are required, it is not a candidate for electronic submission.

The data for the monthly report form, VS 6-2, is entered into a database and processed in Fort Collins. After processing, the designated TB epidemiologist validates the data.

The Report of Suspicious TB Lesions or Thoracic Granulomas in Regular Kill Cattle, VS 6-35, is not a candidate for electronic submission as it requires original signatures. Hard copies must accompany samples when submitted to accredited laboratories because data can only be entered by NVSL personnel.

The Necropsy Specimen Submission Form, VS 10-4, is completed at necropsy and must accompany the specimen submission; it also requires an original signature. Therefore, it is not a candidate for electronic submission.

The supplemental Necropsy Specimen Submission, is completed at necropsy and must accompany the specimen submission. Therefore, it is not a candidate for electronic submission.

The Wildlife Bovine Tuberculosis Surveillance Specimen Submission Form must accompany the specimen submission and therefore is not a candidate for electronic submission.

The Restricted Animal Movement Permit (VS 1-27) and Continuation Sheet (VS 1-27A) is a multipart form requiring original signatures. Therefore, it is not a candidate for electronic submission.

The TB Test (Caudal Fold Test) Record, VS 6-22 and 6-22B, may be prepared electronically but requires original signatures. The record therefore is not a candidate for electronic submission.

The TB Test Record (Special), VS 6-22C, and Comparative Cervical Tuberculin Test Results, VS 6-22D, may be prepared electronically but require original signatures. They are therefore not candidates for electronic submission.

The TB Test Record, Gamma, may be prepared electronically but requires an original signature. It is therefore not a candidate for electronic submission.

Affected herd data and affected herd test results are not submitted through formal electronic means because the information is unique to each herd and may not fit a preformatted response.

An Approved Herd Plan, whether a depopulation and repopulation plan or a test-and-remove plan, is unique to each herd. It may be prepared electronically but because original signatures are required, it is not a candidate for electronic submission.

VS 6-22A, the field report for TB-infected herds, may be prepared electronically, but because it requires an original signature, it is not a candidate for electronic submission.

The Report on Herd Revealing Reactors to Tuberculin (VS 6-4) may be prepared electronically, but because it requires an original signature, it is not a candidate for electronic submission.

VS 6-4A (for investigation for evidence of TB on reactor animals) may be prepared electronically, but because it requires an original signature, it is not a candidate for electronic submission.

VS 6-4B (for investigation for evidence of TB on exposed animals) may be prepared electronically, but because it requires an original signature, it is not a candidate for electronic submission.

The Appraisal and Indemnity form (VS 1-23) is a multipart form. It requires an original signature and is therefore not a candidate for electronic submission.

The request for a 15-day extension, which is usually written, requires an original signature and is therefore not a candidate for electronic submission.

The form for Proceeds from Animals Sold to Slaughter (VS 1-24) requires an original signature and is therefore not a candidate for electronic submission.

The Certificate for Movement must accompany the interstate movement of animals and therefore is not a candidate for electronic submission.

The Commuter Herd Agreement requires an original signature and is therefore not a candidate for electronic submission.

APHIS will review the records of approved feedlots electronically if that can be done, but it does not require facilities to keep the records electronically.

The Template for Owner Participation in Projects to Evaluate New TB Tests requires an original signature and is therefore not a candidate 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 in connection with this information collection is not available from any other source, because APHIS is the only Federal agency responsible for preventing, detecting, controlling, and eradicating bovine TB from the United States.

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

APHIS estimates that 19 percent of the respondents for this information collection are small businesses (accredited veterinarians). The information collected is the absolute minimum needed to initiate and maintain an effective bovine TB surveillance, containment, and eradication program in the United States.

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, APHIS would be unable to operate an effective bovine TB surveillance, containment, and eradication program. Consequently, bovine TB would likely spread to areas of the United States that are currently not affected by this disease.

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;**

Epidemiological Review of Zone Testing

To support a State's formal request for zone status, APHIS requires that the State's designated APHIS TB epidemiologist review reports of all testing for each zone within the State within 30 days of the testing. VS requires review of the reports within 30 days because TB spreads quickly in some cases. Rapid review of test results allows APHIS and States to respond promptly and appropriately to the TB situation in the State and/or proposed zone.

Monthly TB Report

APHIS requires that each State prepare a report within 30 days of the end of each month for the entire State or for each zone within a State covering the tuberculin testing that took place during the month and the reasons for the testing. The report is required monthly because TB spreads quickly in some cases. Frequent testing and rapid review of results allows APHIS and States to respond promptly and appropriately to the TB situation in the State and/or proposed zone.

- **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;**

Recordkeeping for Approved Feedlots

Approved feedlot owners must keep, for 5 years, records of all livestock identification, inventory, changes in inventory, and the origin and destination of all livestock moved into and out of approved facilities. State or Federal animal health authorities must be granted access to those records on request during normal business hours. VS requires retention of these records for 5 years to ensure traceability of any animal that is in or has gone through the approved feedlot back to the animal's herd of birth or origin.

- **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 individuals 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:

William L. Hartmann DVM, MS
 Executive Director and State Veterinarian
 Minnesota Board of Animal Health

625 North Robert Street
Saint Paul, MN 55155
Phone: 651-201-6825
Cell: 612-756-0847
Fax: 651-296-7417
Bill.hartmann@bah.state.mn.us

John Tilden
Tuberculosis Eradication Program
525 West Allegan Street
Lansing, MI 48909
Phone: 517-241-2934
tildenj@michigan.gov

Mike VanderKlok
Bovine Tuberculosis Eradication Coordinator
525 West Allegan Street
Lansing, MI 48909
Phone: 517-241-2460
vanderklok@michigan.gov

On Thursday, August 23, 2012, pages 50980 and 50981, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. During that time, APHIS received 1 comment from an interested member of the public that didn't pertain to paperwork.

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.

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 individuals 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 animal health officials, producers and owners, and accredited veterinarians.

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

Respondents are State animal health officials, producers and owners (including feedlot owners), and accredited veterinarians. APHIS estimates the total annualized cost to these respondents to be \$685,972. APHIS arrived at this figure by multiplying the hours of estimated response time (24,499) by the estimated average hourly wage (\$28) of the above respondents. This hourly rate was derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2011 Report - Occupational Employment and Wages in the United States. See <http://www.bls.gov/news.release/pdf/ocwage.pdf>

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 startup cost component annualized over its expected useful life; and (b) a total operation, 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 \$2,502,811. (See APHIS Form 79.)

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 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	59,766	0	52,634	-153	0	7,285
Annual Time Burden (Hr)	24,499	0	20,697	-1,005	0	4,807
Annual Cost Burden (\$)	0	0	0	0	0	0

Overall, the total burden hours increased 19,692 due to program changes (+20,697 hours) and adjustments (-1,005 hours).

There were adjustments in respondents resulting in decrease of -1220 hours. The following burden items decreased in burden since the last submission (adjustments):

- Annual Report for retention status, entire state or each zone within a state (-75 hours)
- Request for zone status, application (-300 hours)
- Certificate for Movement (-20 hours)
- TB Management Plan (-600 hours)
- Epidemiological Review of Zone Testing (-225 hours)

The following burden items increased since the last submission (adjustments):

The certificate of TB Test (VS 6-22C and D) was separated into two separate burden items and their combined burden increased (+135 hours). (adjustment)

Retention of Movement Certificates (+80 hours). (adjustment)

Certificate for Movement (no change).

MOU for zones, initial and yearly renegotiation (previously named MOU) increased 500 hours because of States providing more detailed information than before thus increasing the response time. In addition to the States providing more information, what used to start out as a few day conference is now months of conference calls in an effort to save on travel costs. Some of the added information includes more detailed zoning to account for States, such as Michigan which have achieved split-State status and increased descriptions of funding as both Federal and State governments are required to be more accountable/transparent. In addition, APHIS removed the recordkeeping burden (-80 hours) (program change).

The following items are currently in violation of the Paperwork Reduction Act, many of them were previously approved under 0579-0084, that was retired a few years ago and the burden items were not moved into other information collections at the time of the retirement (program change):

VS 6-35 (+67 hours)
VS 1-27 (+2611 hours)
VS 6-22 and 6-22B CFT (+8470 hours)

The following items are new to the Tuberculosis program altogether (program change):

Wildlife Risk Survey (+1000 hours) This grew out of the Michigan split-State status situation.

Wildlife Bovine TB Surveillance Sample Submission Form (+80 hours) This came from discussions within APHIS (VS and Wildlife Services (WS)) to come up with a “worksheet” that addressed additional information in connection with the VS 10-4.

Commuter Herd Agreement (+ 80 hours) This came from lessons from the Brucellosis program.

Recordkeeping for Approved Feedlots (+600 hours) This came from discussions and added requirements for being approved feedlots for Tuberculosis purposes.

Template for Owner Participation (+5 hours) This came from the need to test the field testing capabilities of new Tuberculosis testing technologies.

The following items are new to this information collection package; however, they have been used in violation (program change):

VS 6-2 (+30 hours)
VS 10-4 (+58 hours)
Necropsy Specimen (+58 hours)
Request for 15-day extension (+375 hours)
Accredited Herd Written Plan (+72 hours)
TB Test, Gamma (+200 hours)
Affected Herd Data (+160 hours)
Approved Herd Plan (individual herd plan) Test and Remove Plan (+240 hours)
Affected Herd Testing Results (+64 hours)
Depop and Repop Agreement (+240 hours)
VS 6-22A (+4 hours)
VS 6-4 (+300 hours)
VS 6-4A (+75 hours)
VS 6-4B (+3750 hours)
VS 1-23 (+1338 hours)

VS 1-24 (+400 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 the 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 has no plans to seek approval for not displaying the OMB expiration date on the forms associated with this information collection with the exception of forms covered in multiple information collection packages (VS- 1-24, 1-23, 10-4, and 1-27).

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

APHIS can certify compliance with all the provisions in the Act.

B. Collections of Information Employing Statistical Methods

Statistical methods will not be used in this information collection.