Revised April 29, 2014

Supporting Statement
Blood and Tissue Collection
At Slaughtering and Rendering Establishments
OMB No. 0579-0212

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 i**s** 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 the 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 United States' ability to compete in the world market of animal and animal product trade.

Veterinary Services (VS), a program within USDA's Animal and Plant Health Inspection Service (APHIS), administers regulations governing the interstate movement of animals to prevent the dissemination of animal disease within the United States. These regulations are contained in title 9, *Code of Federal Regulations* (9 CFR), subchapter C, Interstate Transportation of Animals (Including Poultry) and Animal Products, part 71. The regulations also address animal testing for disease surveillance. APHIS uses epidemiological data from tests to assess the prevalence of disease and to identify sources of disease.

Disease surveillance activities at slaughtering and rendering facilities are conducted under listing agreements signed by Federal personnel and slaughter and rendering establishment owners and operators. An establishment is listed after it undergoes inspection to ensure that it meets facility and access requirements.

APHIS may withdraw or deny the listing of an establishment if it determines that the establishment is no longer in compliance with APHIS regulations. APHIS must notify the establishment, in writing, of the denial or withdrawal. The establishment may appeal the denial or withdrawal but must do so in writing.

APHIS will also withdraw the listing if the owner or operator of the establishment notifies the Administrator, in writing, that the establishment no longer handles animals moved interstate under APHIS regulations or that the person who signed the listing agreement is no longer responsible for the day-to-day operations of the establishment.

APHIS is asking OMB to approve, for an additional 3 years, its use of these information collection activities in connection with its efforts to perform testing at slaughtering and rendering establishments to help prevent the spread of animal disease within 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.

APHIS uses the following information collection activities to perform testing at slaughtering and rendering establishments to help prevent the spread of animal disease within the United States.

Request for Appeal of Denial of Listing
If APHIS denies the listing of an establishment, the owner or operator of that establishment may appeal the denial 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 Administrator will grant or deny the appeal, in writing, as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. The owner or operator must send the request for appeal directly to APHIS.

Request for Appeal of Withdrawal of Listing
If APHIS withdraws approval from an establishment, the owner or operator of that establishment may appeal the 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 reasons for the proposed withdrawal are incorrect or do not support the withdrawal of the listing. The Administrator will grant or deny the appeal, in writing, as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. The owner or operator must send the request for appeal directly to APHIS.

Withdrawal of an Establishment
The Administrator will automatically withdraw the approval of an establishment to handle livestock for blood and tissue collection if the operator of the establishment notifies the Administrator, in writing, that the establishment no longer handles livestock moved interstate, or that the person who signed the listing agreement is no longer responsible for the day-to-day operations of the establishment.

Listing Agreement
APHIS surveillance programs characterize program diseases, track known disease problems, identify new and emerging disease problems for which Federal and State programs do not exist, and document disease freedom status for exotic diseases that do not exist in the United States. Meeting APHIS' wide animal disease surveillance goals requires the collection of blood or tissue samples at slaughter at different times, and under different circumstances. To accommodate these activities, APHIS requires these slaughtering or rendering facilities to enter into a listing agreement with APHIS.

The listing agreement requires the plant to allow APHIS to collect samples. It contains the name, address, and telephone number of the slaughtering facility and lists the type of animal carcasses handled at the facility. The listing agreement is especially helpful during disease outbreaks to avoid delay and disease spread. When a disease is suspected in a given area, sampling will be used to determine its presence or absence, and to estimate the incidence or prevalence if it is present. The amount of sampling may increase in selected areas when a disease outbreak is suspected, then reduced in that area when sufficient tests have been done to prove the suspicion was unfounded or, if found, after the disease is eradicated. Sampling is also needed to provide data for new or updated risk analyses in support of disease control programs, and, as required, opening international markets for animal products.

Facility Inspection Report (VS 10-5)
The Administrator will list a slaughtering or rendering establishment after determining that it meets facility and access requirements. Form VS 10-5 is used for this purpose. The form will be provided, completed, and signed by a VS official where the establishment is located, using information provided by establishment personnel. The VS Area Office retains the original inspection report.

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 Requests for Appeal to the denial or withdrawal of an approved establishment require an original signature from the facility owner and are therefore not candidates for electronic submission.

The Notice of Withdrawal also requires an original signature from the establishment owner, and is therefore not a candidate for electronic submission.

The Listing Agreement requires the original signatures of plant personnel, and therefore is not a candidate for electronic submission.

The Facility Inspection Report (VS 10-5) requires the original signatures of the establishment owner or operator, and therefore is 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 for the test-at-slaughter surveillance program is exclusive to its mission of regulating the interstate movement of animals to prevent the spread of disease, and is not available from any other source.

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

The information APHIS collects is the minimum needed to conduct its test-at-slaughter surveillance program. Each slaughtering and rendering establishment employs fewer than 500 employees; therefore, 100 percent are considered to be 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, APHIS would be unable to effectively operate a test-at-slaughter surveillance program. This would hamper APHIS' ability to detect disease in the U.S. animal population, to prevent disease spread within the United States, and to eliminate certain animal diseases from the United States.

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.

APHIS will conduct this information collection in a manner consistent with the guidelines established 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;**

  If APHIS denies the listing of an establishment, the owner or operator of that establishment may appeal the denial, in writing, within 10 days after receiving notification.

  If APHIS withdraws approval from an establishment, the owner or operator of that establishment may appeal the 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, governmental contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statue 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.**

There are no other special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

In 2013-2014, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

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Scientific and Technical Services
American Meat Institution
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Ken Mastracchio
North American Meat Association
1910 Association Drive, Reston, VA 20191
510-763-1533

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National Renderers Association
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Alexandria, VA 22314
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On Monday, February 10, 2014, pages 7634-7635, 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. APHIS received one comment from a concerned citizen about her perception of the general maltreatment of animals. It had no relevance to the purpose of this collection.

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. 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 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-I.

See APHIS Form 71. Burden estimates were developed from discussions with accredited veterinarians as well as slaughtering and rendering establishment personnel and their representatives.

•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 $37,219.95. APHIS arrived at this figure by multiplying the total burden hours (1,605 hours) by the estimated average hourly wage of the above respondents ($23.19).

Agricultural inspectors -$20.14
Butchers and other meat cutters - $14.21
Miscellaneous production workers - $13.59
Veterinarians - $44.83

The average hourly rate is derived from the U.S Department of Labor; Bureau of Labor Statistics Report, National Compensation Survey: Occupational Employment and Wages. http://www.bls.gov/oes/#tables

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.

The annualized cost to the Federal Government is estimated at $88,878.78. (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	9,628	0	-10,704	9,585	0	10,747
Annual Time Burden (Hr)	1,605	0	-2,676	1,590	0	2,691

There is a program change of -23 respondents, -10,704 annual responses, and -2,676 burden hours resulting from VS reviewing and closely monitoring procedures for this program, and determining that the VS 10-4 (Specimen Submission Form) and VS 10-4A (Continuation Sheet for the Specimen Submission Form) were no longer being used for collecting BSE specimens. Therefore, these forms are being removed from this collection. VS currently collects BSE information on three electronic forms approved under OMB No. 0579-0409, National Veterinary Services Laboratories; Bovine Spongiform Encephalopathy Surveillance Program: (1) Form 17-146 (BSE Surveillance Submission Form); (2) VS 17-146A (BSE Surveillance Submission Continuation Sheet); and (3) VS 17-131 (BSE Surveillance Data Collection Form).

However, the total number of respondents has risen from 63 to 1,925, which is an adjustment of +1,862 respondents. The annual responses have increased by 9,585 and the total burden hours have increased by 1,590. VS is continuing to collect Listing Agreements and also Facility and Inspection Reports (VS 10-5), but now is able to collect Listing Agreements and VS 10-5s from nearly all U.S. slaughtering and rendering establishments, which has caused the large increase in respondents. The removal of the VS 10-4 and 10-4A offset the increase of respondents to the decrease in annual responses and total burden hours.

Form	2010			2014			Changes		
	Respondents	Responses	Burden Hours	Respondents	Responses	Burden Hours	Respondents	Responses	Burden Hours
Listing Agreement	20	20	10	1925	1925	963	+1905	+1905	+953
VS 10-4 & 10-4A	23	10704	2676	0	0	0	-23	-10704	-2676
VS 10-5	20	20	2	1925	7700	639	-20 *	+7680	+637

* These respondents are the same as for the Listing Agreement and were counted twice in the previous collection.

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

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

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

APHIS will display the expiration date on VS Form 10-5. No other USDA forms are currently used in this collection.

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

APHIS can certify compliance with all provisions in the Act.

B. Collections of Information Employing Statistical Methods

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