

**DEPARTMENT OF AGRICULTURE****Animal and Plant Health Inspection Service****9 CFR Parts 149, 160, and 161****[Docket No. APHIS–2006–0089]****RIN 0579–AB92****Trichinae Certification Program****AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Proposed rule.

**SUMMARY:** We are proposing to establish a voluntary Trichinae Certification Program for U.S. pork that has been produced under disease-prevention conditions. Under the proposed program, we would certify pork production sites that follow prescribed good production practices that reduce, eliminate, or avoid the risk of exposure of animals to the zoonotic parasite *Trichinella spiralis*, a disease of swine. Such a program should enhance the ability of producers to export pork and pork products to overseas markets. This proposed program, which would be funded by program fees, has been developed as a cooperative effort by the U.S. Department of Agriculture, the National Pork Board, and the pork processing industry. If adopted, this program would include those producers who choose to participate in the program, as well as slaughter facilities and other persons that handle or process swine from pork production sites that have been certified under the program.

**DATES:** We will consider all comments that we receive on or before July 16, 2007.

**ADDRESSES:** You may submit comments by either of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>, select “Animal and Plant Health Inspection Service” from the agency drop-down menu, then click “Submit.” In the Docket ID column, select APHIS–2006–0089 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site’s “User Tips” link.

- **Postal Mail/Commercial Delivery:** Please send four copies of your comment (an original and three copies) to Docket No. APHIS–2006–0089, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700

River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2006–0089.

**Reading Room:** You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

**Other Information:** Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Dave Pyburn, National Trichinae Coordinator, VS, APHIS, 210 Walnut Street Room 891, Des Moines, IA 50309; (515) 284–4122.

**SUPPLEMENTARY INFORMATION:****Background**

Under the Animal Health Protection Act (7 U.S.C. 8301–8317), the Administrator of the U.S. Department of Agriculture’s (USDA’s) Animal and Plant Health Inspection Service (APHIS) may carry out operations and measures to detect, control, or eradicate any pest or disease of livestock (including the drawing of blood and diagnostic testing of animals). Such operations can include animals at a slaughterhouse, stockyard, or other point of concentration. The Administrator may also cooperate with State authorities, Indian tribe authorities, or other persons in the administration of regulations for the improvement of livestock and livestock products. For example, APHIS administers regulations in subchapter G of chapter I, title 9, of the Code of Federal Regulations (CFR) that address poultry improvement through the National Poultry Improvement Plan (NPIP). The NPIP is a cooperative Federal-State-industry mechanism consisting of a variety of programs intended to prevent and control egg-transmitted, hatchery-disseminated poultry diseases. As a result, customers can buy poultry or poultry products from flocks that have been certified free of certain diseases or produced under disease-prevention conditions.

APHIS’ regulations in 9 CFR parts 160 through 162 govern the accreditation of veterinarians. Accredited veterinarians are approved by the APHIS Administrator to perform certain regulatory tasks to control and prevent the spread of animal diseases throughout the United States.

Under the Federal Meat Inspection Act (FMIA), as amended (21 U.S.C. 601 *et seq.*), and the Poultry Products Inspection Act (PPIA), as amended (21 U.S.C. 451 *et seq.*), the USDA’s Food Safety and Inspection Service (FSIS) inspects meat and poultry slaughtered or processed at official establishments. Such inspection is required to ensure the safety, wholesomeness, and proper labeling of meat and poultry. In addition to mandatory inspection, FSIS, under the authority of the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621–1627), provides a range of voluntary inspection, certification, and identification services to assist in the orderly marketing of various animal products and byproducts. FSIS regulations covering inspection and other related activities are found at 9 CFR chapter III.

Under the Agricultural Marketing Act of 1946, USDA’s Agricultural Marketing Service (AMS) provides analytical testing services that facilitate marketing and allow products to obtain grade designations or meet marketing or quality standards. Pursuant to this authority, AMS develops and maintains laboratory certification and approval programs as needed by the agricultural industry, to support domestic and international marketing of U.S. products.

**Trichinae In Swine**

*Trichinella spiralis* is a parasitic nematode (roundworm) that is found in many warm-blooded carnivores and omnivores, including swine. Trichinae is a generic term that refers to *Trichinella spiralis*. Trichinae has a direct life cycle, which means it completes all stages of development in one host. Transmission from one host to another host can only occur by ingestion of muscle tissue that is infected with the encysted larval stages of the parasite. When ingested, muscle larvae are freed from the cyst by digestion in the stomach and then enter tissues of the small intestine, where they undergo development to the adult stage. Male and female adult parasites mate, and the females produce newborn larvae that leave the intestine and migrate through the host circulatory system to striated muscle tissue. There, the larvae penetrate a muscle cell, modify it to become a unique cyst, and mature to become infective for another host. The total time required for this to occur is from 17 to 21 days. Adult males die after mating, but adult females continue to produce larvae in the host for several weeks before they die and are expelled. Once adult worms are expelled and larvae reach and encyst in musculature,

no further contamination can occur. Animals that are infected with trichinae are at least partially resistant to a subsequent infection due to a strong and persistent immunity.

Trichinae may be passed on to humans who consume undercooked meat infected with the encysted parasite. Humans who are infected with the parasite generally experience flu-like symptoms, such as fever.

Trichinae has a longstanding association with swine and pork products, not only in the United States but around the world. The concept that many people have about the need to cook pork thoroughly is based on the risk of becoming infected with this parasite. The historical problem of trichinae infection in swine is the basis for strict Federal regulations relating to the methods used to prepare ready-to-eat pork products.

Despite the historical problems of trichinae and its association with the pork industry, changes have occurred in the last 50 years that have caused a major decline in the prevalence of this parasite in swine raised in the United States.

Historically, trichinae infection in swine was associated with feeding them raw meat waste products. Major inroads with respect to the reduced incidence of trichinae infection occurred with the advent of meat waste cooking laws in response to vesicular exanthema (1953–1954) and the hog cholera eradication program (1962). Of equal importance has been the movement to high levels of biosecurity and hygiene under which most U.S. swine are now raised as producers increasingly use intensive management systems in raising swine.

Despite the fact that trichinae is rare in today's U.S. swine industry, pork still suffers from its historical association with the parasite. Today, the trichinae issue is a question of perception versus reality. Human cases of trichinellosis reported to the Centers for Disease Control and Prevention declined from about 500 per year in the 1940's to fewer than 50 per year over the last decade. Further, many of these cases resulted from non-pork sources such as bear and other game meats. However, the dramatic declines in the prevalence of trichinae in U.S. swine and the extremely low number of cases in humans in the United States remain largely unrecognized by consumers and our trading partners.

Today, exposure of domestic swine to trichinae is limited to just a few risk factors that include: Consumption by swine of uncooked meat waste products contaminated with trichinae, consumption of rodents or other

wildlife infected with trichinae, and cannibalism among swine within an infected herd. Generally, the way that swine become infected can be determined by a simple evaluation of farm management practices. Since it is illegal to feed raw meat waste products to swine, this particular source of infection should never be an issue. However, feeding of any raw or undercooked meat scraps, including table waste, does pose a risk. Of much greater significance is the exposure of swine to rodents and wildlife infected with trichinae. Rodents, and rats in particular, serve as a reservoir host for trichinae infection. Rodents can pick up infection from landfills, carrion, or even dead swine. When rat populations are in close proximity to swine, it is possible that either live or dead rats will be caught and eaten by the swine. If the rat happens to be infected, then trichinae infection will occur. The same type of risk holds true for other small mammals. Swine that have free range to browse outdoors occasionally encounter carcasses that they may consume. Small mammals that have been shown to have higher prevalence rates for trichinae include raccoons, skunks, and opossums. The risk of exposure of swine to trichinae at the production site can be greatly reduced, if not eliminated, by taking the following steps:

- Do not feed uncooked waste products, table scraps, or animal carcasses to swine. This is particularly important in the case of carcasses from hunted or trapped wildlife.
- Eliminate or minimize the exposure of swine to live wildlife. Create barriers that are effective in separating swine from skunks, raccoons, and other small mammals.
- Implement and maintain an effective rodent control program at the pork production site. Biosecurity, maintaining perimeters, baiting, and trapping are all part of rodent control.
- Maintain good hygiene at the pork production site. Remove dead swine as soon as they are found. Keep barns free from clutter and store feed securely.

#### *Trichinae Control*

Despite the relatively low prevalence of trichinae in swine in many developed countries, considerable energy goes into preventing human exposure to this parasite. There are a variety of ways in which trichinae control is approached. A number of countries require slaughter testing of each carcass. In fact, for pork exported to the European Union (EU), packers in the United States test carcasses using the same methods employed by European meat inspectors. While the need for such measures may

no longer seem as immediate, given that trichinae is almost nonexistent in U.S.-produced pork, it is apparent that some organized approach to demonstrating product safety is still needed for overseas markets. The following discussion summarizes the potential methods that are currently used for trichinae control.

#### *Slaughter Testing*

Many countries require slaughter testing of each carcass. Such testing is largely a continuation of measures implemented when trichinae was a serious problem. In many countries, slaughter inspection programs are required.

Approved slaughter testing methods for trichinae in swine include direct methods for visualization of parasites. Since it is not possible to see trichinae cysts within meat tissue by macroscopic examination, it is necessary to perform one of several laboratory tests. The oldest method, and one still frequently used, is called the compression method. Small pieces of pork collected from the pillars (crus muscle or hanging tenderloin) of the diaphragm are compressed between two thick glass slides (a compressorium) and examined microscopically for the presence of *Trichinella spiralis* larvae.

An improvement over the compression method, and a method that is now widely used in Europe, is the pooled sample digestion method. Samples of tissue collected from sites where parasites concentrate, such as the diaphragm, masseters, or tongue, are subjected to digestion in acidified pepsin. Larvae, which are freed from their muscle cell cysts by this process, are recovered by a series of settling steps, then visualized and counted under a microscope. Requirements for performing the digestion test are found in the Directives of the European Economic Community, in the FSIS regulations in 9 CFR 318.10(e), and in various other publications.

Another method of testing swine for trichinae infection is an indirect method that looks for antibodies to the parasites in swine sera, plasma, whole blood, tissue fluid, or meat juice. The enzyme-linked immunosorbent assay (ELISA) method has been used extensively for testing in both pre- and post-slaughter applications and is an extremely useful tool for determining or monitoring trichinae infection in herds.

Where fresh pork is not routinely tested for trichinae, as is the case in the United States, alternative measures are used to prevent exposure of humans to potentially contaminated product. These include processing methods such

as cooking, freezing, irradiation, and curing along with recommendations to the consumer concerning the need for thorough cooking.

In lieu of carcass testing or treatment to show that swine or pork product is not infected or contaminated, there are still other means to ensure the safety of the product. These include herd testing to prove that trichinae infection is not present in a particular geographical region (*i.e.*, certification by region) or raising swine under prescribed conditions that reduce, eliminate, or avoid the risk of exposure of swine to trichinae (*i.e.*, certification of individual pork production sites). In the former case, considerable testing on a regular basis is required to document the absence of infection. In the latter case, documentation of good production practices is necessary to show that swine have not had an opportunity to become exposed to or infected with trichinae.

#### Certification By Region

The basis for a regional approach to certification is found in the Office International des Epizooties (OIE) International Animal Health Code. (Recommendations relating to Trichinellosis (*Trichinella spiralis*) appear in Part 2, Article 2.2.9.3 of the International Animal Health Code, 2001.) The OIE Code provides that domestic swine in a country, or part of the territory of a country, may be considered free from trichinae based on the following factors: Trichinellosis in humans and animals must be reported; there is an effective disease reporting system in place that has proven to be capable of capturing the occurrence of cases; and it has been found that trichinae infection does not exist in the domestic swine population based on regular testing of a statistically significant sample of the population, or trichinellosis has not been reported in 5 years and a surveillance program shows that the disease is absent from wild animal populations.

As noted previously, the United States has an extremely low incidence of trichinae infection in swine. Although human trichinellosis is a reportable disease, the United States has no history of regular testing to determine trichinae infection in swine, nor do most States require the reporting of trichinae infection in swine when detected. Because a number of countries, such as those in the EU, require some form of testing for trichinae, implementing a trichinae control program in the United States would remove certain obstacles faced by exporters of U.S.-produced pork. One

way to accomplish this goal within a reasonable timeframe would be to certify that herds were produced under the requirements of the Trichinae Certification Program and based on the use of good production practices that reduce, eliminate, or avoid the risk of exposure of swine to trichinae infection.

Recent research efforts and pilot studies involving APHIS, FSIS, USDA's Agricultural Marketing Service (AMS), Agricultural Research Service (ARS), and Cooperative State Research, Education, and Extension Service (CSREES), the National Pork Board, and other private industry and packer groups have led to the development of a program for certification of swine from pork production sites. Certification of swine as produced under the requirements of the Trichinae Certification Program is contingent on pork production sites following certain good production practices that reduce, eliminate, or avoid risk factors for the transmission of trichinae to swine, as well as systematic monitoring and testing of the product at the slaughter facility. The concept of risk management for control of *Trichinella spiralis* in the domestic swine population is endorsed by the U.S. Animal Health Association, the National Institute for Animal Agriculture, and the American Association of Swine Veterinarians.

A program for the certification of pork production sites that follow good production practices incorporates many of the principles of a Hazard Analysis and Critical Control Points or "HACCP" system. The specific hazard is the risk of exposure of swine to *Trichinella spiralis*. The critical control points in addressing this hazard, which are based on a number of studies on the epidemiology of trichinellosis and its transmission to domestic swine, focus on addressing those practices that potentially allow swine to ingest raw or undercooked meat waste products or rodents or animal carcasses that contain trichinae. The certification process in this type of program encompasses the following basic steps:

- Accredited veterinarians trained in good production practices relative to exposure to trichinae work with producers to ensure that trichinae risk factors are reduced, eliminated, or avoided at pork production sites;
- The site audit performed by trained USDA-accredited veterinarians serves as a method to document that risks of infection are eliminated or satisfactorily controlled. Audits need to be done periodically to ensure that good production practices relative to trichinae control remain in place;

- On a regular basis, a statistically valid sample of the total number of swine from certified production sites is tested at the slaughter facility laboratory or some other onsite or offsite laboratory using licensed or accepted testing methods to verify the absence of trichinae infection; and

- QVMOs perform random "spot audits" of certified production sites to ensure the overall integrity and consistency of the program.

The regular site audit takes into account those management practices that affect the risk of exposure of swine to trichinae, such as feed integrity (*i.e.*, source and storage), building construction and condition as it pertains to biosecurity, integrity of rodent control programs, and general management and hygiene factors as they pertain to rodent control, swine cannibalism, and other issues. As a part of the process of raising swine under good production practices, the producer needs to maintain certain records that document its adherence to good production practices, with those records being verified in the site audit. The producer also is responsible for adhering to good production practices between site audits.

A pilot program for the certification of pork production sites as being produced under the requirements of the Trichinae Certification Program that involved the above-mentioned agencies of USDA, as well as private industry, was conducted in Iowa, Minnesota, and South Dakota in 1997 and 1998. The purpose of the pilot program was to evaluate a process-verification system for the production of pork. An on-farm audit, consisting of 55 questions, was developed to identify those risk factors that could expose swine to *Trichinella spiralis*. The audit was administered by USDA-trained accredited veterinary practitioners at 198 pork production sites in the 3-State area. All swine raised on sites where audits were conducted were slaughtered at a single packing plant and a sample from each carcass was tested by the pooled sample digestion and ELISA methods. Few production sites met all criteria established within the audit for good production practices similar to those proposed in this document. Most of the deficiencies related to the absence of a regular rodent control program around and in swine production facilities. However, it was determined that more than 85 percent of these sites could meet good production practice criteria with minor improvements in site management. From a total of 221,123 carcass samples tested from farms audited during a 6-month period, no trichinae-positive carcasses were

detected by digestion or ELISA methods. Based on the outcome of this pilot program, an improved, more succinct audit was developed with objective measures for those good production practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella spiralis*. This revised version of the site audit is currently being used in a second pilot program involving pork production sites located in Colorado, Illinois, Iowa, Minnesota, Missouri, Nebraska, Oklahoma, and South Dakota that are supplying swine to a slaughter facility in Iowa.

This second pilot program began in December of 2000. Pork product sites were selected based on their willingness to participate in the program. As of December 2004, there were approximately 125 sites participating in the program. Program sites have completed one or more official pilot audits conducted by qualified accredited veterinarians that indicate the site is following certain good production practices designed to reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella spiralis*. The slaughter facility in Iowa has conducted verification testing on swine carcasses from a statistically valid sample of the participating sites that have attained "certified" status. Close to 100 accredited veterinarians have also been trained as site auditors during this period.

The primary purpose of this second pilot program is to verify the adequacy of the selected good production practices in minimizing, reducing, or eliminating the risk of exposure of swine to *Trichinae spiralis*, as well as to confirm that the site audit and slaughter plant sample testing protocols provide a dependable means of verifying that good production practices are being followed. This second pilot program will continue until rulemaking establishes the Trichinae Certification Program.

#### *Collaboration with AMS and FSIS*

As previously stated, APHIS has collaborated with FSIS and AMS, among other entities, in developing a program for certification of swine from pork production sites. This collaboration included the research efforts of AMS as well as their continuing role in training laboratory technicians who work in slaughter facilities on how to conduct trichinae ELISA tests. FSIS has supported the trichinae program through its research efforts at the beginning of the pilot program and its direct participation in the program at federally inspected slaughter facilities. Moreover, in a

proposed rule published in the **Federal Register** on February 27, 2001 (66 FR 12590–12635), FSIS, in proposing to remove prescriptive trichinae treatment requirements in favor of performance standards, pointed to the program as one means by which establishments that produce pork products can ascertain whether their suppliers have taken measures to prevent trichinae infection of their herds. In that document, FSIS also discussed its role in verifying that processors properly check status of pigs, testing samples as required, and maintaining adequate animal identification and records under the program. Both AMS and FSIS have been important and willing partners in this pilot program, and we expect this collaboration to continue.

As a result of the cooperative research efforts and pilot programs just referenced, we are proposing to establish regulations for a voluntary Trichinae Certification Program to appear as a new part 149 in 9 CFR subchapter G of the regulations. The current title of Subchapter G, "Poultry Improvement", would be changed to "Livestock Improvement" to reflect that the subchapter's regulatory coverage would now encompass animals other than poultry. The proposed Trichinae Certification Program would provide for the certification of pork production sites that follow certain prescribed management practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella spiralis*. In addition to establishing a new part 149, we also would make certain changes to existing regulations in 9 CFR parts 160 and 161 covering the accreditation of veterinarians that are needed for this Trichinae Certification Program. The full text of the proposed regulations appears in the rule portion of this document. Our discussion of the proposed provisions follows.

#### *Purpose and Scope*

Proposed § 149.0 would provide that the Trichinae Certification Program described in part 149 is intended to enhance the ability of swine producers, as well as slaughter facilities and other persons that handle or process swine from pork production sites that have been certified under the program, to export fresh pork and pork products to overseas markets. We would include this statement in the regulations because, although we recognize that producers may wish to participate in the program for domestic marketing purposes, such uses would be outside the scope of APHIS' authority. Any domestic marketing uses of the program, such as the labeling of products, would

have to be conducted in accordance with the regulations of FSIS and AMS.

#### *Definitions*

Proposed § 149.1 would contain definitions for the terms used in part 149.

We would define an *accredited veterinarian* as a veterinarian approved by the APHIS Administrator in accordance with 9 CFR part 161 to perform functions specified in 9 CFR, chapter I, subchapters B, C, D, and G.

The term *Agricultural Marketing Service* or *AMS* would refer to the Agricultural Marketing Service of the United States Department of Agriculture, while the *AMS Administrator* would refer to the Administrator, Agricultural Marketing Service, or any person authorized to act for the AMS Administrator. An *AMS representative* would be defined as any individual employed by or acting as an agent on behalf of the Agricultural Marketing Service who is authorized by the AMS Administrator to perform the services required by proposed part 149.

The term *Animal and Plant Health Inspection Service* or *APHIS* would refer to the Animal and Plant Health Inspection Service of the United States Department of Agriculture.

An *animal disposal plan* would be defined as a written document that describes methods for the removal and disposal of dead swine or swine remains from a pork production site, while an *animal movement record* would be defined as a written record of the movement of swine into or from a pork production site.

The term *APHIS Administrator* refers to the Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the APHIS Administrator, while an *APHIS representative* would refer to any individual employed by or acting as an agent on behalf of the Animal and Plant Health Inspection Service who is authorized by the APHIS Administrator to perform the services required by proposed part 149.

We would define an *approved laboratory* as a non-Federal laboratory approved by the Agricultural Marketing Service and recognized by the APHIS Administrator or FSIS Administrator for performing validated tests to determine the presence of trichinae infection in reference to the Trichinae Certification Program.

The term *audit* would be defined as an inspection process, as provided in proposed part 149, that generates a written record documenting a pork production site's adherence to the required good production practices.

There would be two types of audits, a site audit and a spot audit, both of which are defined below. An *auditor* would be defined as a qualified accredited veterinarian (QAV) or a qualified veterinary medical officer (QVMO) who is trained and authorized by APHIS to perform auditing activities under the Trichinae Certification Program.

The term *certification* or *certified* would refer to the designation given by the APHIS Administrator to a pork production site that has been determined to be in compliance with the specific good production practices and other program requirements of the Trichinae Certification Program as provided in part 149.

The term *certified pork* would refer to pork or pork products originating from certified swine from a certified production site with identity of such animals or carcasses maintained throughout receiving, handling, and processing.<sup>1</sup>

A *certified production site* would be defined as a pork production site that has attained a program status of Stage II or higher based on adherence to good production practices and other program requirements as provided in proposed part 149.

The term *certified swine* would refer to swine produced under the Trichinae Certification Program on a certified production site.

The term *decertification* or *decertified* would be defined as the removal of the certified status of a production site by the APHIS Administrator when it has been determined that the criteria of the Trichinae Certification Program are not being met or maintained.

*Enzyme-linked immunosorbent assay* or *ELISA* would refer to a method of testing swine for the presence of trichinae infection by looking for antibodies to *Trichinella spiralis* in the sera, plasma, whole blood, tissue fluid, or meat juice of swine.

The term *EPA* would refer to the United States Environmental Protection Agency.

A *feed mill quality assurance affidavit* would be defined as a written statement signed by the feed mill representative and the producer that documents the quality and safety of feed or feed ingredients delivered from the feed mill to the pork production site.

*Food Safety and Inspection Service* or *FSIS* would refer to the Food Safety and Inspection Service of the United States

Department of Agriculture, while the *FSIS Administrator* would refer to the Administrator, Food Safety and Inspection Service, or any person authorized to act for the Administrator. An *FSIS program employee* would be defined as any individual employed by or acting as an agent on behalf of the Food Safety and Inspection Service who is authorized by the FSIS Administrator to perform the services required under proposed part 149.

The term *good manufacturing practices* would be defined as feed manufacturing practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella spiralis*, while the term *good production practices* would refer to pork production management practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella spiralis*.

The term *harborage* would be defined as any object, debris, clutter, or area that could serve as shelter or refuge for rodents or wildlife.

We would define a *laboratory approval audit* as an audit performed by AMS representatives to determine if a laboratory meets minimum requirements for approval, as established by AMS, for performing validated tests under proposed part 149.

We would define *National Trichinae Certified Herd* as all swine raised on certified production sites in the United States.

The term *person* would be defined as any individual, corporation, company, association, firm, partnership, society, joint stock company, or other legal entity.

A *pest control operator* refers to a person trained and State-licensed in the control of pests and vermin (particularly rodents).

*Pooled sample digestion method* or *digestion method* would refer to a method of testing swine for trichinae infection by identifying the presence of *Trichinella spiralis* from a sample of the animal's muscle tissue.

We would define a *pork production site* or *site* as a geographically definable area that includes pork production facilities and ancillary structures under common ownership or management systems and the surrounding space within a 100-foot perimeter of the swine housing and feeding areas.

The term *positive test result* would mean the outcome of a validated test indicating the presence of *Trichinella spiralis*.

The term *process-verification testing* would refer to the testing of a statistically valid sample of swine belonging to the National Trichinae Certified Herd at the time of slaughter

using a validated test to verify that the adherence to good manufacturing practices and good production practices is resulting in the absence of *Trichinella spiralis* infection in swine from that herd.

We would define a *producer* as an individual or entity that owns or controls the production or management of swine.

A *qualified accredited veterinarian* or *QAV* would refer to an accredited veterinarian who has been granted an accreditation specialization by the APHIS Administrator pursuant to 9 CFR 161.5 based on completion of an APHIS-approved orientation or training program in good production practices in swine management, and who is authorized by the APHIS Administrator to perform site audits and other specified program services required in proposed part 149. A *qualified veterinary medical officer* or *QVMO* would refer to a VMO of the State or Federal Government who is trained in good production practices and is authorized by the APHIS Administrator to perform site audits, spot audits, and other specified program services required in proposed part 149.

The term *rodent control logbook* would be defined as a written record that documents a rodent control program for a pork production site.

We would define a *site audit* as an audit, performed by a QAV or a QVMO, to determine the trichinae risk factor status of a pork production site based on the site's adherence to all of the required good production practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella spiralis*.

The term *slaughter facility* would be defined as a slaughtering establishment operating under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or a State meat inspection act that receives certified swine under the Trichinae Certification Program.

We would define the term *slaughter facility representative* as any individual employed by, or acting as an agent on behalf of, a slaughter facility who is authorized by the slaughter facility to perform specified program services required in proposed part 149.

A *spot audit* would refer to an audit of a certified pork production site performed by a QVMO to ensure program integrity and consistency.

Pork production sites that are in the Trichinae Certification Program would be assigned a particular program status as either a Stage I enrolled site, a Stage II certified site, or a Stage III certified site. The term *Stage I enrolled* would refer to the preliminary program status

<sup>1</sup> The labeling of all certified pork or pork products leaving a slaughter or processing facility must comply with 9 CFR 317.4 and all other applicable FSIS labeling regulations.

of a pork production site attained when the APHIS Administrator approves the outcome of an initial site audit. We would define the term *Stage II certified* as that program status attained upon APHIS approval of a site audit of a Stage I enrolled site, while the term *Stage III certified* would refer to program status attained upon APHIS approval of a site audit of a Stage II certified site and maintained upon APHIS approval of subsequent site audits for renewal of Stage III certified status.

The term *sterile zone* would be defined as an open area immediately adjacent to and surrounding those building(s) used to house and feed swine that serves as both a buffer and detection zone for rodent and wildlife activity.

The term *temporary withdrawal* would be defined as the voluntary withdrawal of a certified production site from the Trichinae Certification Program at the request of the producer for a period not to exceed 180 days.

*Trichinae* would be defined as a generic term that refers to *Trichinella spiralis*.

We would define *Trichinae Certification Program* or *program* as a voluntary pre-harvest pork safety program in which APHIS certifies pork production sites that follow all of the required good production practices that reduce, eliminate, or avoid the risk of exposure of swine from their sites to *Trichinella spiralis*.

The *Trichinae Identification Number* or *TIN* would be a number assigned to a pork production site by the APHIS Administrator.

We would define the term *Trichinella spiralis* as a parasitic nematode (roundworm) capable of infecting many warm-blooded carnivores and omnivores, including swine.

The abbreviation *USDA* would refer to the United States Department of Agriculture.

The term *validated test* would be defined as an analytical method licensed by APHIS or accepted by AMS for the diagnosis of *Trichinella spiralis* in swine.

A *veterinary medical officer* or *VMO* would be defined as a veterinarian employed by the State or Federal Government who is authorized to perform official animal health activities on their behalf.

We would define a *waste feeding logbook* as a written record that documents the presence of good production practices with respect to the feeding of meat-containing waste to swine and compliance with applicable State and Federal food waste feeding laws and regulations.

### *Program Participation*

Proposed § 149.2 would provide information on producer participation in the trichinae certification program. A producer's initial enrollment and continued participation in the program would require that the producer adhere to all of the required good production practices, as confirmed by periodic site audits, and comply with other recordkeeping and program requirements provided in proposed part 149. Pork production sites accepted into the program by APHIS would participate under one of the following three program stages: Stage I enrolled, Stage II certified, or Stage III certified.

#### Stage I Enrolled Status

Under proposed § 149.2(a), attaining Stage I enrolled status would signify that a pork production site has met all of the required good production practices and other recordkeeping and program requirements provided in part 149. Although enrolled in the program, Stage I enrolled sites would not be able to identify their swine as products from a certified production site. If a Stage I enrolled site is found not to be adhering to one or more good production practices as a result of a site audit or a spot audit, or fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment for consideration as a Stage II certified site, it would lose its status as a Stage I enrolled site. As provided in § 149.3(d), the site audit must be performed no sooner than 150 days from the date the site was awarded Stage I enrolled status, and must be completed, with the audit form and payment submitted to APHIS, no later than 210 days from the date the site was awarded Stage I enrolled status.

#### Stage II Certified Status

Under proposed § 149.2(b), attaining Stage II certified status would signify that a pork production site is adhering to all of the required good production practices and complies with other recordkeeping and program requirements provided in part 149. An APHIS-issued certificate or letter indicating the site's status as a Stage II certified site would have to be filed at the site and be readily available for inspection. Once a site attains Stage II certified status, it would then be able to identify its swine as certified product from a certified production site.

A Stage II certified site that is found not to be adhering to one or more good production practices as a result of a site audit or a spot audit, or that fails to follow the prescribed timetable for

completing a site audit and submitting the completed audit form and payment for consideration as a Stage III certified site, would be decertified by APHIS and would be ineligible to identify swine from that site as certified product from a certified production site. As provided in § 149.3(e), a Stage II certified site must complete a site audit for Stage III certified status. Under § 149.3(e), the site audit must be performed no sooner than 240 days from the date the site was awarded Stage II certified status, and must be completed, with the audit form and payment submitted to APHIS, no later than 300 days from the date the site was awarded Stage II certified status. As further provided in § 149.2(e), once a site is decertified, the producer would have to repeat the process of requesting a new site audit for Stage I enrolled status. If a decertified site is reenrolled after a successful Stage I site audit, then a new program anniversary date for that site would be established based on the date of enrollment and the site would be reinstated at Stage II status.

#### Stage III Certified Status

Proposed § 149.2(c) would cover sites attaining Stage III certified status. The primary distinction between Stage II and Stage III certified sites would be that once a site is awarded Stage III certified status, it would not be required to undergo another site audit for recertification for another 14 to 16 months. In contrast, a Stage II certified site would have to undergo another site audit 8 to 10 months after it receives its Stage II certification. We would allow a longer period to elapse between site audits for Stage III sites based on their record of already successfully completing site audits at the Stage I and Stage II program levels. All other aspects of Stage III certification would be the same as described above in the discussion of Stage II certification.

#### *Change in Ownership*

Proposed § 149.2(d) would provide the steps to be taken in the event there is a change of ownership in a site participating in the program. If there is a change in ownership in a Stage I enrolled site, and the new ownership wishes to remain in the program, then the Stage I enrolled site would continue on the same timetable as under the previous ownership for completing a site audit for Stage II certified status. No additional site audit would be required as a result of the change of ownership since another site audit would occur anyway within 6 months or less if the site intends to remain in the program.

If there is a change of ownership in a Stage II or Stage III certified site, however, we would require that a site audit be performed within 60 days of the ownership change in order for the site to maintain its certified status. If the site audit is satisfactory, then the Stage II or Stage III certified site would continue in the program only as a Stage II certified site. We would require a Stage III certified site to revert to Stage II certified status after a change in ownership so that the site would have another site audit within 1 year's time. This would provide us with greater assurances that the new ownership is adhering to the good production practices. A new program anniversary date for purposes of performing future audits would be established based on the date the site was audited to continue in the program as a Stage II certified site.

If the results of a site audit following a change in ownership are not satisfactory, then the site would be decertified by APHIS. Should the producer wish to participate in the program once again, he or she would have to request a new site audit for Stage I enrolled status once the particular deficiencies have been resolved. If a site is decertified by APHIS, but is reenrolled after a successful Stage I site audit, then a new program anniversary date for the site would be established based on the date of reenrollment.

#### *Site Decertification and Program Withdrawal*

Proposed § 149.2(e) would cover site decertification by APHIS, as well as voluntary site decertification and voluntary program withdrawal initiated by the producer.

#### *Decertification by APHIS*

In proposed § 149.2(e)(1), a Stage II or Stage III certified site that is found not to be adhering to one or more good production practices as a result of a site audit or a spot audit, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment to continue participation in the program, would be decertified by APHIS. Once a site is decertified, swine from that site could not be identified as certified product from a certified production site. In order to participate in the program once again, the producer would have to follow the procedures for requesting an initial site audit for Stage I enrolled status. If a decertified site is reenrolled after a successful Stage II site audit, then a new program anniversary

date for that site would be established based on the date of reenrollment.

#### *Temporary Withdrawal by Producer*

Proposed § 149.2(e)(2) would provide that a producer may request that one or more of their certified production sites be temporarily withdrawn from the program. A producer might choose this option because he or she foresees not having access to animals from certified sources on a temporary basis. A producer's request to have a site temporarily withdrawn would have to be made in writing and would be subject to the APHIS Administrator's approval. Each site could be temporarily withdrawn no more than once every 2 years for a period not to exceed 180 days.

While a site is temporarily withdrawn, the producer could not identify swine from that site as certified product from a certified production site. However, the producer would still have to adhere to all good production practices and other program requirements while the site is temporarily withdrawn, unless specifically waived by the Administrator. This would include providing documentation in the animal movement record of the arrival and departure of all swine from the site, as well as whether the swine arriving at the site are from certified or noncertified sources.

Before being reinstated as a certified production site, the temporarily withdrawn site would have to pass a site audit to indicate that it is adhering to all good production practices (including any practices previously waived by the Administrator). If swine 5 weeks of age or older originating from noncertified sources are received at the site during the time of withdrawal, then the site audit would have to be performed within 30 days of the date the last swine from noncertified sources was removed from the site, but no later than 180 days from the date the site was granted temporarily withdrawn status. If the site audit is satisfactory and it is determined that the site is adhering to good production practices and other program requirements, then the site would be reinstated as a Stage II certified site (regardless of the site's previous status as a Stage II or Stage III certified site). The timetable for performing future site audits for attaining and renewing Stage III certified status would be based on the date the site was reinstated as a Stage II certified site.

If the site audit for reinstatement as a certified production site is not satisfactory due to the producer's failure

to adhere to one or more good production practices, or if the period of temporary withdrawal has exceeded 180 days, then the site would be decertified by APHIS. Once the site is withdrawn by APHIS, the producer would have to request an initial site audit for Stage I enrolled status in order for the site to be reenrolled in the program. If a site is withdrawn by APHIS and then reenrolled after a successful Stage I site audit, then a new program anniversary date for that site would be established based on the date of reenrollment as a Stage I enrolled site.

#### *Program Withdrawal*

Under proposed § 149.2(e)(3), if a producer decides to withdraw one or more pork production sites from the program, then the producer would have to notify the APHIS Administrator in writing of this intent. Once this is done, the site would be removed from the program. If at a later date the producer requests that the site be reinstated in the program, then the producer would have to follow the procedures for requesting an initial audit for Stage I enrolled status. If the site is reenrolled after a successful Stage I site audit, then a new program anniversary date for that site would be established based on the date of reenrollment.

#### *Request for Review*

Under proposed § 149.2(f), if there is a conflict as to any material fact relating to the results of a site audit, spot audit, or other determination affecting a producer's program status or ability to participate in the program, the producer may submit a written request for review to the APHIS Administrator. The producer would have to include in the request the reasons, including any supporting documentation, why the audit result or other determination should be different than the result or determination made by the Administrator. The initial audit result or other determination would remain in force pending the completion of the Administrator's review. The decision by the Administrator upon reviewing the producer's written request would be final.

#### *Site Audit*

Proposed § 149.3 would contain more specific information on performing site audits. Proposed § 149.3 also would describe all of the required good production practices that would be the primary basis for determining whether a site can participate in the program.

General

Proposed § 149.3(a) would set forth the procedures for arranging and performing a site audit, as well as the process for providing notification of the audit results. This paragraph would apply to sites seeking status as a Stage I enrolled or a Stage II certified site, as well as sites seeking or renewing their status as a Stage III certified site.

The producer would be responsible for contacting a QAV to request a site audit. A list of available QAVs could be obtained by accessing the Trichinae Certification Program Web site on the Internet at <http://www.aphis.usda.gov/vs/trichinae>, or by contacting the APHIS area office. Telephone numbers for APHIS area offices can be found in local telephone books or on the Internet at [http://www.aphis.usda.gov/vs/area\\_offices.htm](http://www.aphis.usda.gov/vs/area_offices.htm). If a QAV is not available to perform a site audit, the producer could then contact the APHIS area office to request that a QVMO perform the site audit. The site audit would be arranged at a mutually agreed-upon time. We also would require that the producer or the producer's designated representative accompany the auditor during the site audit.

While performing the site audit, the producer would record whether the producer is adhering to good production practices at the site, as discussed below in proposed § 149.3(b), that reduce,

eliminate, or avoid the risk of exposure of swine to *Trichinella spiralis*. In performing the site audit, the auditor would use APHIS-approved audit forms. Once the auditor has completed all sections of the audit form, the producer or the producer's designated representative would have to sign the audit form attesting to the accuracy of the information obtained during the site audit. The producer's signature also would evidence his or her intent to continue adhering to the good production practices and other program requirements. The auditor also would sign the audit form at this time.

The producer would be responsible for the cost of each site audit performed at the pork production site. If a QAV performs the site audit, then the producer would pay the QAV directly at a mutually agreed-upon time and rate. If a QVMO performs the site audit, then the producer would pay the QVMO at the time the site audit is performed in accordance with the rate and other conditions set by the QVMO's governmental employer. In the case of a site audit performed by a QVMO employed by APHIS, the producer would pay APHIS by certified check or U.S. money order for this service at a rate determined in accordance with proposed § 149.8.

In addition to the cost of the site audit, the producer also would have to

pay a separate fee, as specified in proposed § 149.8, to cover APHIS' administrative costs in processing the audit and operating the program. We are proposing a program fee of \$51, payable to APHIS by certified check or U.S. money order, to be remitted to the auditor at the time each site audit is performed. To arrive at the program fee of \$51, APHIS examined costs associated with the pilot program and itemized those costs based on 127 applications processed during the pilot program.<sup>2</sup>

The basic steps in the calculation for each particular service are: (1) Calculate direct labor costs by determining the average amount of direct labor required to perform the service and multiply the average direct labor hours by the average salary and benefit costs for employees; (2) calculate the pro rata share of administrative support costs; (3) determine the premium costs (if any); (4) calculate the pro rata share of agency overhead and departmental charges, respectively, including the salary of the National Coordinator; (5) add all costs; and (6) round up to the next \$0.25 for all fees less than \$10 or round up or down to the nearest dollar for all fees greater than \$10. Table 1 below shows how APHIS arrived at this rate.

TABLE 1.—COSTS CONSIDERED IN ARRIVING AT THE \$51 PROGRAM FEE  
[Based on 127 applications processed]

	Number of hours	Hourly salary (FY 05)	Benefits @24.26%	Direct labor costs
<b>Direct Labor:</b>				
Area Epidemiology Officer <sup>2</sup> .....	13.23	\$42.55	\$10.32	\$699.58
Clerk <sup>3</sup> .....	71.44	16.29	3.95	1,445.77
Inspector <sup>4</sup> .....	25.40	29.63	7.19	935.18
Total direct labor costs .....				3,080.53
Support costs at 62.31% .....				1,919.47
Subtotal .....				5,000.00
Agency overhead at 16.15% .....				807.50
Subtotal .....				5,807.50
Departmental charges at 4.57% .....				265.40
Subtotal .....				6,072.90
Reserve component .....				303.64
Total full cost for processing 127 applications .....				6,376.54
Full cost per application .....				50.21
Full cost per application, rounded up to the nearest whole dollar .....				\$51.00

<sup>2</sup>Includes time to review the application, compare to standards, identify any nonconformities, call the auditor (if necessary), approve/deny application, and sign.

<sup>3</sup>GS 5/step 5 clerk (includes time to process and file paperwork, identify auditing veterinarian, and perform data entry).

<sup>4</sup>GS 11/step 5 inspector (includes time for spot audits).

<sup>2</sup>FSIS and AMS would not charge any additional program fees for the site audit, however, FSIS does charge \$15 for export certificates.



The auditor will submit the completed audit form, program fee, and payment for services (if the auditor was an APHIS-employed QVMO) to the nearest APHIS area office. If a QAV performs the site audit rather than a QVMO, the QAV will submit the completed audit form and program fee to APHIS in a timely manner.

Upon receipt of the completed audit form and payment, APHIS would evaluate the site audit and provide the producer with written notification of the audit results. A pork production site found to meet all good production practices and other program requirements would be issued program status at the appropriate program stage. If the audit shows that the site does not meet all good production practices or other program requirements, APHIS would provide the producer with written notification that would include documentation of the deficiencies that prevented the site from being conferred program status. It would be the producer's responsibility to work with a veterinarian or other consultants to correct those deficiencies should the producer seek to enroll in the program at a later time.

#### Good Production Practices

Proposed § 149.3(b) would set forth all of the required good production practices that producers would have to adhere to in order to participate in the program. As discussed previously, these good production practices are designed to reduce, eliminate, or avoid those risk factors involving the exposure of swine to *Trichinella spiralis*. The good production practices would be as follows:

- The movement of all non-breeding swine 5 weeks of age or older into or from the pork production site would have to be documented in an animal movement record, as provided in proposed § 149.7, that ensures that all such swine moved into or from the site can be subsequently traced back to that site, or to any previous site (if applicable). Additional information relating to the animal movement record is provided below under the heading "Recordkeeping at Site."

- All non-breeding swine entering a site would have to have originated from another certified production site, except that non-breeding swine less than 5 weeks of age may have originated from a certified or noncertified production site. We would provide this exception because swine less than 5 weeks of age do not as yet eat solid food, and therefore do not present a risk of ingesting the *Trichinella spiralis* parasite through infected food sources.

The animal movement record would have to include the TIN of the certified production site from which the swine originated. If the swine are less than 5 weeks of age and come from a noncertified site, then the animal movement record would have to provide the name and full address of the noncertified site where the swine originated.

- Feed or feed ingredients from offsite sources that are used at the site would have to meet all good manufacturing practices or other quality assurance standards recognized by the feed industry. The adherence to good manufacturing practices or other quality assurance standards would have to be documented in a feed mill quality assurance affidavit. Additional information relating to the feed mill quality assurance affidavit is provided below under the heading "Recordkeeping at Site."

- Swine housing and feeding areas, feed preparation and storage areas, and office areas and connecting hallways at the site would have to be inspected regularly and found free of fresh signs of rodent and wildlife activity. Any movable rodent harborage (exterior or interior) on the site that is not necessary to the day-to-day operation of the site would have to be removed. Harborage that cannot be removed or is movable but necessary to the day-to-day operation of the site (e.g., bales of hay, etc.) would have to be checked for signs of rodent or wildlife activity. In addition, domesticated animals, including pets such as dogs and cats, would have to be excluded from the swine housing and feeding areas and feed preparation and storage areas at the site. Evidence of rodent activity or rodent infestation would consist of fresh rodent droppings, fresh gnawing marks, new structural damage, rodent urine, rodent blood, rodent smear marks (body oil), rodent tracks, or recent burrowing or burrow use. Evidence of wildlife activity would consist of wildlife feces, footprints, fur, or hair observed in or near the stored feed or feed ingredients, dead or live wildlife observed in or near the stored feed or feed ingredients, or wildlife burrows or nests observed in or near the stored feed or feed ingredients. Exterior rodent bait stations and/or traps would have to be placed around the perimeter of those building(s) housing the swine, as well as around the perimeter of outdoor swine feeding areas. Exterior rodent bait stations and/or traps also would have to be placed around areas of potential rodent entry into building(s) used to house and feed swine (i.e., doorways, vent openings, loading chutes, cool cells, etc.). Interior

rodent bait stations and/or traps would have to be placed near high-risk rodent zones such as entryways, hallways, office areas, swine load out areas, vents, cool cells, storage areas, utility rooms, cabinets, locker rooms, bathrooms, and break rooms. Interior rodent bait stations and/or traps would have to be placed so that swine would not come in contact with the bait or trap. Rodent bait stations and/or traps also would need to be placed near exterior or interior harborage on the site that cannot be removed or that is movable but necessary to the day-to-day operation of the site. In all instances, rodent bait stations would have to be intact, systematically maintained, and contain fresh bait that consists of an EPA-registered rodenticide formulation that is applied according to its label. In addition, a sterile zone would have to be maintained around the perimeter of those building(s) used to house and feed swine. The sterile zone would have to be devoid of harborage or feed or water sources that could attract rodents or wildlife, but would have to contain rodent bait stations and/or rodent traps. The sterile zone also would have to be devoid of any vegetation unless it is decorative vegetation that is well maintained (i.e., residential height grass, flowers, shrubs, or trees). A sterile zone with decorative vegetation would require increased rodent control measures. The producer would need to provide documentation of rodent control practices, as described above, by maintaining at the site an up-to-date rodent control logbook with a site diagram and other recordkeeping evidencing implementation of rodent control measures, which could include documents provided by a pest control operator, as provided in proposed § 149.7. Additional information relating to the rodent control logbook is provided below under the heading "Recordkeeping at Site."

- Feed or feed ingredients stored at the site would have to be prepared, maintained, and handled in a manner that protects the feed or feed ingredients from possible exposure to or contamination by rodents or wildlife. Any movable harborage in the immediate vicinity of feed production and feed storage areas that is not necessary to the day-to-day operation of the site would have to be removed. Harborage that cannot be removed or harborage that is movable but necessary to the day-to-day operation of the site (e.g., bales of hay, etc.) would have to be checked for signs of rodent or wildlife activity. Rodent bait stations and/or traps would need to be placed

around (and in, if applicable) all feed preparation and storage areas, as well near any harborage in the vicinity that cannot be removed or that is movable but necessary to the day-to-day operation of the site. Rodent bait stations would have to be intact, systematically maintained, and contain fresh bait that consists of an EPA-registered rodenticide formulation that is applied according to its label. In addition, feed or feed ingredients that are stored in paper bags would have to be elevated off the floor and be a sufficient distance away from the walls to allow for inspection, baiting, and/or trapping. The rodent control logbook, as provided in § 149.7, would have to document that adequate rodent control procedures have been implemented in the feed production and feed storage areas.

- Swine could not have access to wildlife harborage or dead or live wildlife at the site. Wildlife harborage would include wood or wooded lots and other natural areas where wildlife would have access. Dead or live wildlife could not be intentionally fed to swine.

- If meat-containing waste is fed to swine at the site, then the producer would have to hold a license or permit that authorizes the feeding of such waste. Cooking times and temperatures of meat-containing waste to be fed to swine would have to be consistent with applicable State and Federal laws and regulations. In addition, up-to-date records of waste feeding and cooking practices, in the form of a waste feeding logbook provided for in proposed § 149.7, would have to be maintained at the site. Cooked food waste products that are stored prior to feeding could not be mixed or contaminated with uncooked or undercooked meat waste material. Household food waste, regardless of whether it contains meat or is cooked or undercooked, also could not be fed to swine. We include this last requirement as another measure to prevent the attraction of rodents or wildlife to the site. Additional information relating to the waste feeding logbook is provided below under the heading "Recordkeeping at Site."

(The Swine Health Protection Act [SHPA, 7 U.S.C. 3801–3813] was enacted in 1980 to prevent the introduction of foreign animal diseases to U.S. domestic swine populations as a result of being fed raw or improperly treated food waste of animal origin. APHIS' regulations promulgated under the SHPA in 9 CFR part 166 require the following: Persons must have a license to feed waste materials, food waste products must undergo proper heat treatment prior to being fed to swine,

facilities and animals are subject to periodic inspection, and records must be maintained with respect to the removal of all treated and untreated garbage from the licensee's premises. The Federal laws and regulations establish a minimum set of standards to be followed. States are free to set more stringent standards [which a number of States have done], including the prohibition of feeding of food waste materials to swine altogether.)

- The site would need to have in place procedures that are carried out with regard to the prompt removal and proper disposal of dead swine and swine remains found in pens. We would require this practice to eliminate the opportunity for cannibalism among swine, as well as to prevent the attraction of rodents or wildlife. Such procedures would have to be documented in the animal disposal plan, as provided in proposed § 149.7. Additional information relating to the animal disposal plan is provided below under the heading "Recordkeeping at Site."

- General hygiene and sanitation of the pork production site would have to be maintained at all times to prevent the attraction of rodents and wildlife. We would require that solid non-fecal waste (facility refuse) be placed in covered receptacles and be regularly removed from the site. We also would require that spilled feed be regularly removed and properly disposed of.

- All records required under proposed § 149.7 would have to be kept up-to-date and readily available for inspection at the site. Additional information relating to producer recordkeeping requirements is provided below under the heading "Recordkeeping at Site."

#### *Initial Site Audit for Stage I Enrolled Status*

Proposed § 149.3(c) would cover the steps for producers seeking to enroll their pork production site in the program. Interested producers should first request and review a pre-audit information packet prepared by APHIS that discusses the program, as well as the steps in preparing for and requesting an initial site audit. The pre-audit information packet could be obtained from a QAV, State or Federal animal health offices, or the National Pork Board, or by writing to: USDA, APHIS, Veterinary Services, Trichinae Certification Program, 210 Walnut St., Room 891, Des Moines, IA 50309.

When the producer and the producer's herd health personnel believe that the site meets program standards, the producer then should

arrange for an initial site audit, as discussed above under proposed § 149.3(a). Upon completion of the initial site audit and submission of the completed audit form and payment, APHIS would make a determination as to program enrollment within 30 days of receipt of the audit form. A pork production site that is found to meet all good production practices and other program requirements would be awarded Stage I enrolled status.

#### *Site Audit for Stage II Certified Status*

Proposed § 149.3(d) would cover the steps for a Stage I enrolled site to advance in the program as a Stage II certified site. The site audit would have to be performed no sooner than 150 days (i.e., approximately 5 months) from the date the site was awarded Stage I enrolled status, and would have to be completed, with the audit form and payment submitted to APHIS, no later than 210 days (i.e., approximately 7 months) from the date the site was awarded Stage I enrolled status. APHIS would make a determination on whether to certify the site within 7 days of receiving the completed audit form and payment. We would provide this expedited review for sites seeking status as Stage II certified sites so that producers could start identifying their animals as certified swine, assuming that the Stage I enrolled site is found to meet all good production practices and other program requirements and is awarded Stage II certified status.

A Stage I enrolled site that is found during a site audit not to be adhering to one or more good production practices, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment, would not be awarded Stage II certified status and would lose its program status as a Stage I enrolled site.

#### *Site Audit for Stage III Certified Status*

Proposed § 149.3(e) would cover the steps for a Stage II certified site to advance to Stage III certified site status. The site audit would have to be performed no sooner than 240 days (i.e., approximately 8 months) from the date the site was awarded Stage II certified status, and would have to be completed, with the audit form and payment submitted to APHIS, no later than 300 days (i.e., approximately 10 months) from the date the site was awarded Stage II certified status. APHIS would review the completed audit form and make a determination as to Stage III certified status within 30 days of receipt of the audit form and payment.

A Stage II certified site that is found to meet all good production practices and other program requirements would be awarded Stage III certified status. If a Stage II certified site is found during a site audit not to be adhering to one or more good production practices, or fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment, then the site would be subject to decertification by APHIS as provided in proposed § 149.2(e).

#### *Site Audit for Renewal of Stage III Certified Status*

Proposed § 149.3(f) would cover the steps for Stage III certified sites seeking to renew their program status as a Stage III site. The site audit would have to be performed no sooner than 14 months from the date the site was awarded Stage III certified status or the date that status was last renewed, and would have to be completed, with the audit form and payment submitted to APHIS, no later than 16 months from either the date the site was awarded Stage III certified status or the date that status was last renewed. APHIS would review the completed audit form and make a determination as to the site's continued status as a Stage III certified site within 30 days of receipt of the audit form and payment.

A Stage III certified site that is found to meet all good production practices and other program requirements would have its status as a Stage III certified site renewed. If a Stage III certified site is found during a site audit not to be adhering to one or more good production practices, or fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment, then the site would be subject to decertification by APHIS as provided in proposed § 149.2(e).

#### *Spot Audit*

In addition to regularly scheduled site audits, certified production sites also would be subject to spot audits. Spot audits, including random spot audit and spot audits for cause, would be covered in proposed § 149.4.

The APHIS Administrator would select certified production sites at random for a spot audit in order to:

- Ensure the integrity of the auditing process;
- Verify that the audit process is performed in a consistent manner across the program; and
- Verify that all required good production practices are being maintained between regularly scheduled site audits.

A certified production site also could be subject to a spot audit for cause to trace back and investigate any positive test results based on testing of certified swine from that site at the slaughter facility.

All spot audits would be performed by a QVMO at no cost to the producer. APHIS would provide the producer with written notification of the results of the spot audit, including documentation of any deficiencies noted during the audit. If the site is found not to be adhering to one or more good production practices, then the site would be subject to decertification by APHIS as provided in proposed § 149.2(e).

#### *Offsite Identification and Segregation of Certified Swine*

Under proposed § 149.5, certified swine moved from the certified production site to another location, whether to another certified production site, buying station, collection point, or slaughter facility, would have to remain segregated from noncertified swine at all times, and otherwise maintain their identity as certified swine in such a way that they could be readily traced back to the certified production site from which they came. Information relating to the identification of the certified swine would have to be documented in the animal movement record maintained by the producer. Failure to properly segregate or maintain the identity of certified swine from noncertified swine after leaving the certified production site would result in the loss of certified status for that shipment of swine. We would leave it up to producers or other handlers to determine how they wish to segregate the certified swine and otherwise maintain their identity as certified swine throughout the marketing process.

#### *Slaughter Facilities*

Proposed § 149.6 would cover the program responsibilities of participating slaughter facilities in regard to the verification, segregation, testing, and recordkeeping of swine from certified production sites. Participating slaughter facilities that fail to comply with any of the applicable requirements of § 149.6 would not be allowed to continue participating in the program and no pork or pork products will be issued a certificate of export that identifies the product as being from the Trichinae Certification Program unless all requirements of this section are followed. This would not preclude, however, FSIS from issuing an export certificate for those products if they were to be instead sent to a country that

did not require certifications with respect to trichinae or if the products were subsequently frozen in order to meet an importing country's requirements in that way. FSIS would provide general oversight to verify that these functions are being carried out properly, while AMS would specifically oversee the laboratory approval and ongoing performance of laboratories that perform process-verification testing under this program. FSIS would issue instructions to slaughter facilities relating to program requirements at the time any final rule implementing the program described in this proposed rule is published. Further information with regard to laboratory approval requirements would be available from AMS as discussed under "Process-Verification Testing of Certified Swine."

#### *Verification of Certification*

Proposed § 149.6(a) would require that a slaughter facility receiving certified swine verify the current certification status of the pork production site from which the animals came. The slaughter facility could verify the current certification status of individual sites by maintaining dated certification documentation on file. The current certification status of individual sites also would be available on the Trichinae Certification Program Web site on the Internet at <http://www.aphis.usda.gov/vs/trichinae>. If the slaughter facility is unable to verify a site's certification status through documentation on file or through the program Web site, the slaughter facility then should contact the APHIS area office in the State where the site is located.

#### *Maintaining Identity and Segregation of Certified Swine and Pork Products*

Proposed § 149.6(b) would require that in order for a slaughter facility to identify product as certified pork, the certified swine and edible pork products derived from certified swine would have to remain segregated from swine and edible pork products from noncertified sites throughout receiving, handling, and processing at the facility, as well as while awaiting shipment from the facility. The slaughter facility also would have to maintain the identity of the certified swine or pork in a manner that would allow the swine or pork to be traced back to the certified production site from which it came. A slaughter facility's failure to properly segregate or maintain the identity of certified swine and edible pork products derived from the certified swine would result in the loss of certified status for that shipment of swine, as well as the

edible pork products derived from those animals. It would be up to the slaughter facility to determine how it wishes to segregate and properly maintain the identity of certified swine and edible pork products derived from certified swine in its control. It is recommended that certified swine be processed in groups either at the beginning or at the end of the day or on separate days from noncertified animals.

#### Process-Verification Testing of Certified Swine

Proposed § 149.6(c) would require slaughter facilities handling and processing certified swine from certified production sites to carry out process-verification testing at their expense in order to determine the *Trichinella spiralis* infection status of those animals. Under proposed § 149.6(c)(1), process-verification testing would have to be performed by using a validated test. This would include any test licensed by APHIS, such as those using the ELISA method, or otherwise accepted by AMS, such as the pooled sample digestion method. A copy of the testing methods and checklist for conducting validated tests would be available by contacting the Trichinae Program Manager, USDA, AMS, Science and Technology, Technical Services Branch, 1400 Independence Avenue SW., Mail Stop 0272, Washington, DC 20250-0272; or by telephone at (202) 690-0621.

In proposed § 149.6(c)(2) we would require that such testing be performed in an approved laboratory that has been approved for trichinae testing by AMS. In addition to providing services relating to initial laboratory approval, AMS would monitor the ongoing performance and proficiency of laboratories that perform process-verification testing under the program.

The approved laboratory could be maintained and operated by the slaughter facility or by another business entity either on the premises of the slaughter facility or at another location. We would require that the laboratory staff performing the process-verification testing be approved by AMS. Once approved, laboratory staff performing this particular testing function would be subject to periodic proficiency test panels from AMS that would have to be analyzed correctly in order to maintain their approved status. This periodic proficiency testing would be done for purposes of quality assurance. Further information on approved laboratory requirements, including any annual certification fee information, could be obtained by contacting the AMS Trichinae Program Manager.

Proposed § 149.6(c)(3) would cover the requirements for process-verification testing relating to sample size and testing frequency. We would require that process-verification testing be performed in accordance with the following minimum standards relating to sample size and frequency:

- Slaughter facility officials would need to determine the yearly processing capacity of the slaughter facility over the next 12 months. Officials could use the processing capacity during the past 12 months if the past 12 months were representative of a typical year.

- Slaughter facility officials would have to estimate the percentage of swine processed that would likely come from certified production sites considering all swine expected to be processed during the selected 12-month period. Swine that come from certified production sites would be considered the eligible population to be sampled.

- Slaughter facility officials would then need to use the Trichinae Certification Slaughter Facility Sample Size Determination Table to determine the number of samples to collect from the population of swine from certified production sites. If the eligible population is not shown in the table, the next largest number would be used to determine the number of samples to collect. Slaughter facility officials would select from the table the number of samples to collect from the column that reflects a 99 percent confidence level of detecting a positive carcass in the population. The number selected would represent the total number of samples that slaughter facility officials would have to collect and test per year and per month during the selected 12-month period.

- We would require that for each sample collected, slaughter facility officials would have to maintain the identity of the sample using the TIN of the certified production site that was the source of the swine from which the sample was taken.

- FSIS program employees at the slaughter facility would review and verify that an adequate number of samples have been collected and proper frequency of collection is maintained. FSIS would report this information to APHIS.

- AMS representatives would verify through a laboratory approval audit that the laboratory performing process-verification testing is correctly following written procedures relating to the receipt, handling, identification, and testing of samples. These written procedures would have to be maintained by the laboratory in a quality assurance manual, as explained

below under proposed § 149.6(c)(6). In addition, a laboratory that performs process-verification testing at a location other than the slaughter facility would have to include a declaration of methodology used to test samples when providing test results.

- The APHIS Administrator may also, at APHIS' expense, periodically request the testing of swine brought to the slaughter facility from specific certified production sites. Requests to test swine from specific certified production sites would count towards the slaughter facility's total monthly testing requirement.

Proposed § 149.6(c)(4) would cover the requirements with regard to the handling of test results. We would require that the results of process-verification testing of certified swine handled at the slaughter facility be retained in a separate file or notebook as written records at the slaughter facility and be readily available for inspection by FSIS program employees. FSIS also would report to APHIS the results of all process-verification testing.

In the event of a positive test result, the slaughter facility representative would have to immediately notify the FSIS program employee designated by the FSIS Administrator, who in turn would report the TIN of the certified production site that was the source of the swine from which the sample was taken and the test results of the affected sample to the respective APHIS area office. The following sequence of events would take place following a positive test result:

- If a test sample is found positive based on the digestion method, then the certified production site that was the source of the swine from which the sample was taken would be decertified.

- If a test sample is found positive based on an ELISA test method, and is confirmed positive by further testing using the digestion method, then the certified production site that was the source of the swine from which the sample was taken would be decertified.

- If a test sample is found positive based on an ELISA test method, but is not confirmed positive by further testing using the digestion method, then the certified production site that was the source of the swine from which the sample was taken would be investigated by APHIS personnel. The investigation may include a spot audit of the affected site. Additional testing also may be performed. This investigation would determine if the production facility has sufficient safeguards and is following good production practices. While a certified production site is under investigation, the site's program status

as a certified production site would be suspended. While a site is under suspension, the producer would have to continue to adhere to all good production practices and other recordkeeping and program requirements; however, swine from the suspended site could not be identified as product from a certified production site. The APHIS Administrator would determine the program status of the site within 30 days of the initiation of the suspension. A finding that risk factors are inadequately addressed in the site investigation or the finding of additional positive test results based on samples from animals or carcasses from the affected site would be grounds for APHIS decertification of the site.

Proposed § 149.6(c)(5) would cover slaughter facility recordkeeping requirements relating to the handling of animals from certified production sites. We would require that all slaughter facilities that receive certified swine would have to maintain records with regard to the number of certified swine processed, the source of the certified swine, including the TIN of the certified production site from which the swine came, and all test results relating to process-verification testing. These records would have to be retained at the slaughter facility for a period of at least 3 years following the processing of such animals.

Slaughter facilities handling certified swine also would need to have documented procedures on how certified swine under its control, and the edible pork products derived from certified swine, would remain segregated from swine and edible pork products from noncertified sites throughout receiving, handling, and processing at the facility, as well as while awaiting shipment from the facility. The slaughter facility also would have to have documented procedures for maintaining the identity of the certified swine or pork with respect to the certified production site from which it came.

We also would require that all records and other documentation required to be maintained by the slaughter facility under proposed part 149 would have to be readily available for inspection by FSIS program employees.

Proposed § 149.6(c)(6) would cover recordkeeping requirements for approved laboratories that perform process-verification testing under this program. Approved laboratories would be required to have written procedures that specify standards for sample size, sample handling, sample identification, and sample test methods used in process-verification testing. All such

written procedures would have to be maintained in a laboratory quality assurance manual specifically for this program, or as a separate section of an existing laboratory quality assurance manual, and would have to be retained at the approved laboratory throughout the time the approved laboratory is performing process-verification testing under this program. All such written procedures relating to process-verification testing also would have to be readily available for inspection by FSIS program employees or AMS representatives.

Proposed § 149.6(c)(7) would cover the slaughter facility overall responsibility for process-verification testing. In the event the testing is contracted to an outside approved laboratory, the slaughter facility would still retain overall responsibility that the testing is carried out as required. The slaughter facility would be responsible for obtaining testable samples and for ensuring that the correct number of testable samples are sent to the outside testing lab. Once the slaughtering facility receives those test results back from the outside testing lab, the slaughter facility would be responsible for maintaining those results in its trichinae testing records.

#### *Recordkeeping at Site*

Proposed § 149.7 would cover recordkeeping requirements for producers participating in the program. Under proposed § 149.7(a), Stage I enrolled sites, Stage II or Stage III certified sites, and any site that has been suspended or voluntarily decertified would have to maintain the following records: Animal disposal plan, animal movement record, feed mill quality assurance affidavit (if applicable), rodent control logbook, and waste feeding logbook (if applicable). All such records would have to be readily available for inspection at the pork production site at the time of an audit by a QAV or QVMO, or by other APHIS representatives during normal business hours.

#### *Animal Disposal Plan*

The animal disposal plan would have to meet certain minimum requirements. Specifically, the animal disposal plan would have to:

- Provide for the removal of all dead swine or swine remains from swine pens immediately upon detection. Inspections for purposes of detecting dead animals would have to occur at least once every 24 hours.
- Specify how often and at what intervals the swine pens are observed each day.

- Provide for the proper storage of dead swine or swine remains in accordance with local, State, and Federal laws and regulations. If the carcass storage facility or composting facility is located on the site, then the animal disposal plan would have to provide for a storage or composting facility that precludes rodent or wildlife contact with dead swine or swine remains being stored or composted.

- Provide for the disposal of swine and other mammals by rendering, incineration, composting, burial, or other means, as allowed by and in accordance with local, State, and Federal laws and regulations. For sites that use rendering services, the animal disposal plan also would have to include the name, address, and phone number of the renderer.

- Be updated as animal disposal practices are changed at the site.
- Be signed and dated by the producer as well as the caretaker of the site (if the caretaker is a different person than the producer).
- Be valid for a period no longer than 2 years after the date of signature by the producer and (if applicable) the site caretaker.

#### *Animal Movement Record*

The animal movement record would have to meet certain minimum requirements. Specifically, the animal movement record would have to:

- Be filled out completely and properly, accounting for the movement of all non-breeding swine into and from the pork production site.
- In the case of non-breeding swine coming into the site, include the date and number of arriving animals, as well as the TIN of the certified production site where the animals originated, or alternatively, if the swine are less than 5 weeks of age and originated from a noncertified site, the name and full address of the noncertified site where the animals originated. The animal movement record would have to clearly document that all non-breeding swine 5 weeks of age or older that arrive at the site originated from another certified production site.
- In the case of non-breeding swine leaving the site, include the date and number of departing animals, and their destination.

- Document the number of dead non-breeding swine that are removed from the site, as well as the number of dead non-breeding swine that are buried or composted at the site, if swine burial or composting is permitted in that State or locality.

All entries to the animal movement record would have to be signed or

initialed, as well as dated, by the producer or other site caretaker making the entry. We would take into account that pork production sites seeking Stage I enrolled status may have limited documentation regarding these activities. However, we would still require that such sites have initiated documentation that addresses these matters. The 180-day enrollment period would provide Stage I sites further opportunity to develop their recordkeeping.

#### *Rodent Control Logbook*

The rodent control logbook, which may include records from a pest control operator, would have to meet certain minimum requirements. Specifically, the rodent control logbook would have to:

- Include a rodent control diagram for the site indicating the location of all rodent bait stations and rodent traps at the site. The diagram would have to be updated whenever bait stations are added, moved, or removed.
- Document the number of rodent traps set (if applicable), the number of new rodent bait stations set, and how often bait is refreshed.
- Document the disposal method for all unused bait that is replaced.
- Document the brand name and active ingredient of bait, which would have to be EPA registered and applied according to its label, as well as the quantity of bait used (number of pounds).
- If possible, document the number of rodents caught or killed and indicate whether they are mice or rats.
- If possible, document the number of rats sighted monthly.

All entries to the rodent control logbook would have to be signed or initialed, as well as dated, by the producer or other site caretaker making the entry. It would have to be updated at least monthly.

#### *Feed Mill Quality Assurance Affidavit*

The feed mill quality assurance affidavit, to be used in conjunction with feed or feed ingredients delivered to the pork production site, would have to meet certain minimum requirements. Specifically, the feed mill quality assurance affidavit would have to:

- Include the name of the producer and the identity of the site, including the TIN if it has been issued, and the site address, as well as the name and address of the feed mill and the name and title of the feed mill representative.
- Provide that the feed mill is following good manufacturing practices, and further specify, as evidence of these

good manufacturing practices, the following:

That the feed mill has a rodent control system that is maintained by the feed mill itself or by a pest control firm (include name and address of pest control firm);

The frequency with which such rodent control system is maintained (*i.e.*, on a weekly basis, etc.); and

That the feed mill maintains records of pest management practices or has records generated by a pest control operator, which would have to be made available to the producer upon request.

- Be signed by the feed mill representative and by the producer or the producer's designated representative, and would remain in effect for a period of 2 years.

#### *Waste Feeding Logbook*

If the producer feeds meat-containing food waste to swine at the site, the producer would have to maintain a waste feeding logbook that meets certain minimum requirements. Specifically, the waste feeding logbook would have to:

- Include the name of the producer and the identity of the site, including the TIN if it has been issued, the site address, and the number of the license or permit authorizing the feeding of such waste to swine.
- Be kept up-to-date with documentation evidencing adherence to applicable State and Federal food waste feeding laws and regulations.
- Provide information as to the method used in cooking the meat-containing food waste.
- For each batch of meat-containing food waste cooked, record the batch number (if applicable to the operation), the temperature at which such food waste is cooked and the length of time it is held at that temperature, and the method for verifying the temperature and length of time cooked.
- For each batch of meat-containing food waste cooked, document the sources of meat.
- Evaluate and document on at least a monthly basis the level of sanitation of the site, taking into account the following factors:

Whether garbage containers are clean and covered with lids;

Sanitation of cooking area and equipment;

Sanitation of feeding areas and waste disposal;

Sanitation of storage areas;

Rodent control system around equipment, storage, and feeding areas;

Sanitation of waste hauling trucks or containers;

Access of other animal species to food waste (wild animals, dogs, cats, etc.); and

The potential for cross-contamination between cooked product and raw meat-containing food waste.

All entries to the waste feeding logbook would have to be signed or initialed, as well as dated, by the producer or other site caretaker making the entry.

Under proposed § 149.7(b), we would require that all required records and other documentation to be maintained by producers in the program would have to be kept at the pork production site for a period of 2 years. In addition, under proposed § 149.7(c), we would require that these records be readily available for inspection at the pork production site at the time of an audit by a QAV or QVMO, or by other APHIS representatives during normal business hours.

#### *Program Fees and Charges*

Proposed § 149.8 would address the subject of program fees and charges. The producer would be responsible for the cost of each site audit performed at the pork production site. If a QAV performs the site audit, then the producer would have to pay the QAV directly at a mutually agreed-upon time and rate. If a QVMO performs the site audit, then the producer would pay the QVMO at the time the site audit is performed in accordance with the rate and other conditions set by the QVMO's governmental employer. Further, if the QVMO who performs the site audit is employed by APHIS, then the producer would have to pay APHIS for this service at a prescribed hourly rate as set forth in proposed § 149.8. We are proposing that the rates for the services of an APHIS-employed QVMO would be \$84 per hour and \$21 per quarter hour, with a minimum charge of \$25 per service. If an APHIS-employed QVMO performs the site audit outside his or her normal tour of duty, then the rates would increase to \$100 per hour and \$25 per quarter hour for Monday through Saturday and holidays and \$112 per hour and \$28 per quarter hour for Sundays. These proposed rates are comparable to current rates charged for other veterinary services conducted by APHIS employees, and are designed to recover the cost incurred by APHIS in providing these services. Payment to APHIS for the services of an APHIS-employed QVMO would have to be in the form of a certified check or U.S. money order and would have to be remitted to the QVMO at the time the service is provided.

In addition to the cost of the site audit, proposed § 149.8 would provide that the producer also would have to pay APHIS a program fee at the time of each site audit in the amount of \$51 to cover APHIS' administrative costs in processing the audit and operating the program. This program fee, payable to APHIS by certified check or U.S. money order, would be due at the time of submitting the completed site audit form for APHIS evaluation. This program fee would not be subject to refund, regardless of the results of the site audit or other determination as to the producer's program status.

Finally, proposed § 149.8 provides that a producer would not be charged for the cost of having a spot audit performed at the pork production site.

#### *Pilot Program Sites*

In proposed § 149.9, pork production sites that are participating in an APHIS-approved trichinae pilot program at the time the final rule for establishing the Trichinae Certification Program becomes effective would maintain their same program status as either a Stage I enrolled, Stage II certified, or Stage III certified site, as well as their same program anniversary date for purposes of completing future site audits and submitting completed audit forms and payment. We are proposing this provision to recognize those producers that volunteered to participate in our pilot program and invested their time and effort, as well as the expenditure of money to upgrade their sites, in order to be in compliance with good production practices and other pilot program requirements.

#### *Changes to 9 CFR Part 160*

Section 160.1 of the regulations in 9 CFR part 160 contains definitions for terms appearing in parts 160 through 162 on accreditation of veterinarians. We are proposing to add a new definition to § 160.1 for the term *qualified accredited veterinarian* or *QAV*, which we would define as an accredited veterinarian who has been granted an accreditation specialization by the APHIS Administrator pursuant to § 161.5 of our regulations based on completion of an APHIS-approved orientation or training program. We would make this change in conjunction with another proposed change to part 161, as discussed below.

#### *Changes to 9 CFR Part 161*

The regulations in 9 CFR part 161 contain the requirements and standards for accredited veterinarians and suspension or revocation of such accreditation. We are proposing to add

a new § 161.5 on specializations for accredited veterinarians. Under proposed § 161.5, an accreditation specialization recognized by the APHIS Administrator may be granted to an accredited veterinarian upon completion of an orientation or training program approved by APHIS. An accredited veterinarian who is granted such a specialization would be referred to as a qualified accredited veterinarian or QAV. For certain accredited specializations, the cost of orientation or training would be borne by the accredited veterinarian.

QAVs would be authorized to perform those activities and functions specifically provided for elsewhere in chapter I of 9 CFR. Additional information on accreditation specializations, including training requirements and fees, could be obtained by contacting the National Veterinary Accreditation Program, VS, APHIS, 4700 River Road Unit 46, Riverdale MD 20737, (301) 734-6188.

Under proposed § 161.5, the Administrator of APHIS would grant the status of qualified accredited veterinarian or QAV to those accredited veterinarians who complete an APHIS-approved orientation or training program covering that particular specialization. Therefore, an accredited veterinarian who completes the APHIS-approved training in good production practices in swine management could become a QAV, and then be authorized to perform site audits and other specified program services under the Trichinae Certification Program in part 149.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

For this proposed rule, we have prepared an economic analysis. The economic analysis, which is set out below, provides a cost-benefit analysis as required by Executive Order 12866 and an analysis of the potential economic effects of this proposed rule on small entities as required by the Regulatory Flexibility Act.

We currently do not have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, in accordance with 5 U.S.C. 603, we have prepared an initial regulatory flexibility analysis. We are inviting comments about potential effects of this proposed

rule on small entities. In particular, we are interested in determining the number and kinds of small entities that may incur benefits or costs from the implementation of this proposed rule, and the economic effects of those benefits or costs.

In accordance with the Animal Health Protection Act (7 U.S.C. 8301-8317), the Secretary of Agriculture has the authority to promulgate regulations and conduct programs to detect, control, or eradicate any pest or disease of livestock (including the drawing of blood and diagnostic testing of animals). Such programs can include animals at a slaughterhouse, stockyard, or other point of concentration. The Secretary may also cooperate with State authorities, Indian tribe authorities, or other persons in the administration of regulations for the improvement of livestock and livestock products.

In accordance with 21 U.S.C. 601 *et seq.*, the Secretary of Agriculture is authorized to inspect meat and meat products at any slaughtering, packing, meat-canning, rendering, or similar establishment, while under 21 U.S.C. 451 *et seq.*, the Secretary of Agriculture is authorized to inspect poultry and poultry products at official establishments. Finally, in accordance with 7 U.S.C. 1621 through 1627, the Secretary of Agriculture is authorized to provide a range of voluntary inspection, certification, and identification services to assist in the orderly marketing of various animal products and byproducts.

Based upon available data and expected effects, we believe that some producers and facilities may come to the conclusion that the benefits of the proposed program, in terms of increased exports and lower costs to meet the requirements of importing countries, would justify the costs of their participation.

#### *Costs for Participating Producers*

According to USDA's National Agricultural Statistics Service (NASS), there were an estimated 75,350 hog and pig producers in the United States in 2002 [see NASS Agricultural Statistics, 2003 (Table 7-26)]. This was down from 80,880 producers in 2001. Since 2002, the number of producers has declined even further with 67,330 operations reported in 2005. Although the structure of the industry has changed over time, the number of hogs as well as consumption of pork has remained relatively constant over the same period. The number of producers who would participate in the certification program is not known. Participation by producers would depend primarily on

economic and other market competitiveness considerations. Participation will be based on how much of the producers' pork would enter into export markets that have trichinae requirements.

We believe that most producers, especially the larger ones, are likely to participate in the program. This is because they have already implemented and routinely follow many of the proposed good production practices required for certification. Industry experts have estimated that 90 to 95 percent of commercial pork production sites in the United States could meet the proposed program requirements for site certification with, at most, only minimal facility changes (i.e., those costing approximately \$500 over a 5-year period, equivalent to a present value of about \$440 when discounted at 7 percent). However, recent experience with the pilot program has shown that while 90 to 95 percent of these sites could meet the requirements with only minimal changes, it is likely that only

40 to 50 percent would actually choose to participate. In general, larger producers have more mitigations in place so they are more readily able to participate. Small producers could participate in the program as well as long as they are able to meet program risk mitigations. At worst, only moderate facility changes (i.e., those that cost \$2,500 over 5 years) would likely be required. The estimated cost of \$2,500 for moderate facility changes consists of \$1,500 in first year startup costs and maintenance costs of \$250 per year for the next 4 years. (For further information, see Cummings, David and Koprak, Christine, "Cost Analysis of Trichinae-Free Program Alternatives," USDA, APHIS, Centers for Epidemiology and Animal Health, December 1998, referred to below as the CEAH analysis. Copies of the CEAH analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**).

Producers seeking to participate in the program would be required to pay the

veterinarians' audit fees to perform both the initial and subsequent site audits. These fees are estimated at about \$150 per audit. After the first three audits are completed over a 15-month period at a cost of \$450, certified production sites would be subject to audits only once every 15 months.

In addition to the cost of the site audit, the producer would be responsible for paying a separate program fee to APHIS at the time of each site audit. This program fee would cover APHIS' administrative costs in processing the audit and operating the program. As proposed, the program fee would be \$51. Also, producers may have to pay for the postmortem blood, tissue, or meat juice sample tests if the cost of these tests is passed on to them by the slaughter facilities.

Based on the information presented in the preceding paragraphs, we have prepared the following table summarizing the estimated costs of participating in the program over 5 years:

TABLE 2.—ESTIMATED COSTS FOR PARTICIPATING PRODUCERS

	Year				
	1	2	3	4	5
Estimated site audit fees .....	\$300	\$150	\$150	\$150	\$150
Program fees .....	102	51	51	51	51
Subtotal .....	<sup>1</sup> 402	<sup>2</sup> 201	<sup>3</sup> 201	<sup>3</sup> 201	<sup>3</sup> 201
Facility improvement costs: <sup>4</sup>					
Minimal .....	100	100	100	100	100
Moderate .....	1,500	250	250	250	250
Yearly total .....	\$502 to \$1,902 year 1; \$301 to \$451 each year, years 2 to 5.				
5-year total .....	\$1,706 to \$3,706 over 5 years.				

<sup>1</sup> Assumes site audit and program fees for attaining both Stage I Enrolled and Stage II Certified status during year 1.

<sup>2</sup> Site audit and program fees for moving from Stage II to Stage III Certified status.

<sup>3</sup> Site audit and program fees for renewal of Stage III Certified status.

<sup>4</sup> Experience with the pilot program has shown that 90 to 95 percent of sites could meet program requirements with only minimal facility improvements, so only 5 to 10 percent of sites might have to incur the moderate facility improvement costs.

For producers that decide to participate in the program, a potential downside is the possibility that swine from their sites could test positive for trichinae at slaughter, resulting in a loss of program status as a certified site. Once a site is decertified, swine from that site could not be identified as product from a certified production site. In order to participate in the program once again, the producer would have to follow the procedures for requesting an initial audit for Stage I enrolled status.

It is reasonable to assume that most producers who decide not to participate in this program would be small in size, although there are some small producers that would also need to make only

minimal changes to satisfy program requirements.

*Costs for Participating Slaughter Facilities*

The number of slaughter facilities that may wish to process certified swine and export their meat as produced under the Trichinae Certification Program is uncertain. As with producers, participation would depend on economic competitiveness considerations. Certain countries that import pork require testing for trichinae. Therefore, any facility that wants to export pork must meet these testing requirements. Slaughter facilities would have to determine whether it would be

better to continue to follow their traditional trichinae testing protocols, or whether sourcing animals from certified producers while observing the program requirements for slaughter facilities would provide them an economic incentive.

Slaughter facilities that purchase swine from certified production sites would be required to carry out certain functions relating to verification, segregation, testing, and recordkeeping of certified swine under its control. Testing at the slaughter facility would entail taking tissue, blood, or meat juice specimens from a sample of the certified swine population processed at the facility in order to determine the



*Trichinella spiralis* infection status of the tested animals and to verify that the trichinae management practices at the production level are adequate. The number of required test samples would vary among individual facilities, depending on the total number of animals from certified production sites that are slaughtered. The testing requirements are designed to produce a 99 percent confidence level of detecting a positive carcass in the population based on a prevalence of 0.013 percent. For example, a plant that slaughters 1 million certified swine per year would be required to run 34,802 tests annually, but a plant that slaughters 5,000 certified swine per year would need to run 4,996 tests each year.

Slaughter facilities could conduct sample testing using either an ELISA or a pooled diaphragm test and would have the option of processing the test samples themselves at the slaughter facility or sending it to an offsite commercial laboratory. On-site processing of test samples should result in lower costs per test once the necessary testing equipment is in place. In this regard, it is anticipated that many slaughter facilities, especially the large and medium ones, would acquire ELISA test readers, regardless of whether they participate in the certification program, due to FSIS' HACCP inspection procedures and because of the public's demand for food safety and quality. ELISA test readers cost about \$5,000 each, while pooled diaphragm digestion test readers cost \$2,900.

An ELISA test costs approximately \$0.83 per swine using the services of a commercial laboratory, and up to \$0.66 per swine if processed by the slaughter facility itself. By comparison, a digestion test costs approximately \$1.72 per swine if processed by a commercial laboratory, and \$0.92 per swine if processed by the slaughter facility.<sup>3</sup>

An ELISA test, therefore, is less costly than a digestion test. However, if an ELISA test is used and the results are positive, then those findings would have to be confirmed by using a digestion test. For a large slaughter facility required to run 34,802 tests each year, the ELISA test would cost \$28,886 annually if processed by a commercial laboratory and \$22,969 if processed by the slaughter facility itself, and the digestion test would cost \$59,859

annually if processed by a commercial laboratory and \$32,018 if processed by the slaughter facility itself. For a small plant required to run 4,996 tests each year, the ELISA test would cost \$4,147 annually off site and \$3,297 annually on site, and the digestion test would cost \$8,593 annually off site and \$4,596 annually on site.

As discussed above, the number of slaughter facilities that would participate in the program by purchasing swine from certified production sites is uncertain. If slaughter facilities do wish to accept certified swine and identify pork as produced under the Trichinae Certification Program, it is not known whether they would absorb all the testing costs or pass on some of those costs to producers or consumers.

Slaughter facilities may experience negative effects from this proposed rule in the event of a trichinae positive test. Given the rarity of trichinae in swine currently, the likelihood of a positive test from an animal that comes from a certified production site would be small. However, if there was a positive test result, presumably there would be some cost to the slaughter facility since it could lose a source of certified animals if the site is decertified. The total cost to the slaughter facility in the event of a positive test is uncertain at this time.

#### *Costs for Participating Accredited Veterinarians*

The proposed rule would provide accredited veterinarians who are qualified to conduct site audits under the program with another source of revenue. To become qualified, accredited veterinarians would need to complete an APHIS-approved orientation or training program in good production practices in swine management. At least initially, APHIS would provide this special training to accredited veterinarians itself, charging them an amount sufficient to recover the Agency's costs, estimated at \$50 per trainee. QAVs would need requalification training, but this would not occur more than once every 2 years, and the accredited veterinarians would be charged the same \$50 fee. Currently, veterinarians do not have to pay a fee or receive periodic training to maintain accreditation status. However, for certain accredited specializations, such as conducting site audits under the trichinae certification program, we are proposing that the accredited veterinarian would be responsible for the cost of orientation and periodic training to perform this activity.

The special training would not be mandatory for accredited veterinarians, so any training costs would be voluntarily assumed. For those accredited veterinarians who do opt for the training in order to perform site audits for producers, the cost of the training would be offset by income in the form of fees received from producers for site audits.

#### *Impact on Federal Agencies*

Unlike traditional disease eradication programs, herd certification programs are indefinite, and exist for as long as the producer wishes to maintain certification status. Due to the changes in the meat inspection process that have occurred at the slaughter and processing level, increasingly, packers will require various forms of food security certifications as criteria for producers that wish to sell their product to them.

In fiscal year (FY) 2007, trichinae certification activities would shift from being in the pilot phase to the early national program roll out phase, assuming this proposed rule is implemented. In late FY 2007 or early FY 2008, the trichinae certification program would become a national program, available in increasing numbers of States and involving potentially thousands of herds. Initial national program emphasis would be placed on 5 of the 17 major swine producing States that account for approximately 94 percent of the Nation's total swine production, but the program would be made available to all who volunteer to participate.

Successful implementation of the trichinae certification program would require integration of APHIS on-farm activities with AMS and FSIS plant and processing actions to ensure the safety and quality of animal derived food products. The impacts on AMS and FSIS are expected to be minimal. AMS representatives would certify laboratories with respect to trichinae testing, and FSIS program employees would check records in plants to ensure compliance with testing and recordkeeping requirements, as well as provide general oversight that plants are carrying out other program responsibilities properly. The personnel and time requirements for AMS and FSIS to meet their obligations are not expected to be significant.

#### *Export Benefits Associated with the Program*

The proposed program is designed to increase sales and marketability of fresh pork products destined for foreign markets, which would benefit

<sup>3</sup> These figures are from the CEAH analysis. It is important that because the CEAH study was published in 1998, the findings are somewhat dated. Throughout this analysis, the data used in the CEAH analysis have been updated where possible in order to obtain a more current estimate of the cost.

participating swine producers and slaughter facilities.

The United States is a net exporter of pork and has been the second largest exporter of pork, trailing the European Union (EU), in recent years. Other major exporters include Canada and Brazil. Japan, Mexico, and Canada are the primary markets for U.S. pork exports. The United States also exports pork to Russia and the EU, but these averaged less than 5 percent of total exports over the 2000 to 2005 period. Additionally, the United States is a net importer of pork in trade with the EU, with exports to the EU declining from 2001 to 2005. Although not certain, a voluntary trichinae certification program could increase opportunities for participating producers and slaughter facilities to export to countries that monitor for *Trichinella spiralis* in pork.

How much this program would increase U.S. pork exports is not known. U.S. pork exports have been increasing for the past decade and are expected to continue to increase. Approximately 9 percent of U.S. pork production is exported. Given the steady per capita domestic consumption over the past decade, if U.S. pork production is to continue to grow, the growth likely will be driven by export demand. A voluntary trichinae certification program is one step in keeping U.S. producers competitive in the world market.

According to Canadian animal health personnel, maintaining trichinae free status for most of Canada has been instrumental in facilitating the country's \$1 billion annual export market for pork (\$410 million in fresh cuts), as well as in maintaining its annual per capita consumption of pork totaling 28 kg (H. Ray Gamble, Trichinae Fact Sheet, <http://www.aphis.usda.gov/vs/trichinae/>). However, it should be noted that the majority of Canadian exports of pork go to the United States and Mexico, neither of which have trichinae-specific entry requirements for imported pork. So while it may be helpful, it is not certain that the proposed voluntary trichinae certification program would automatically lead directly to increased exports of pork and pork products.

The EU and Russia have traditionally been markets where the United States has not had a large presence. It is the industry's hope that the certification program would open these markets to more pork from the United States. The United States recently signed an agreement with the Russian Federation that would allow pork into Russia either after being tested for trichinae or frozen. Before now, Russia required both in

order to be permitted into the country. Additionally, Brazil has historically been Russia's largest supplier of pork. However, outbreaks of foot-and-mouth disease in the latter part of 2005 hampered Brazil's ability to supply that market. Thus, other exporters, including the United States, are looking to capitalize on this opportunity to gain market share in the Russian pork market.

The voluntary certification program could potentially lead to increased exports to countries that require trichinae testing, such as the European Union. The U.S. Meat Export Federation (USMEF) believes U.S. exports to the EU would increase with the certification of new EU-approved plants and reduction in costs associated with trichinae testing. The weak dollar will also help the cause of U.S. exports. Increases in exports may not be immediate since there are currently only three EU-approved plants that are not able to fill the U.S. quota. Furthermore, the USMEF sees a potential for growth in the processed pork products market, i.e., fully cooked bacon, rather than the fresh, chilled, and frozen sector.

Currently, domestic exporters face a duty free quota of 45,000 metric tons of pork to the EU. In 2005, the United States sent approximately 6,600 metric tons of pork to the EU, which accounted for 0.7 percent of total U.S. exports. If exports to the EU were to increase by 16,000 metric tons over those reported in 2005 as expected by the National Pork Producers Council (NPPC), the EU share of U.S. exports would increase to approximately 2.5 percent. Additionally, the NPPC estimates that an increase of this magnitude would increase the value of exports by \$60 million. This represents a threefold increase in the 2005 value of exports to the EU, or a 3.4 percent share of the total \$2.3 billion pork export market. However, based on historical unit values for U.S. exports of pork to the EU and the world and the estimated increase in exports to the EU, the value increase predicted by the NPPC appears to be overly optimistic. Additionally, based on the expert opinion of pork analysts at USDA's Economic Research Service, it is unlikely that the voluntary certification program would change the European Union's mix of pork imports.

Testing costs under the voluntary certification program outweigh the costs of testing and freezing under the current regime. This is a result of the fact that the United States does not export large amounts of pork to countries having mandatory testing and freezing requirements. In fact, the average costs of testing and freezing per pig

slaughtered are \$0.02,<sup>4</sup> compared to \$0.15 in the lowest cost scenario under the voluntary certification program. This cost comparison assumes the same slaughter numbers in both cases, and a 50 percent participation rate in the trichinae certification program. However, there may be certain producers that would benefit since APHIS is not able to look at each producer individually and must average results across all producers. APHIS welcomes any comments the public may have on the potential cost savings related to testing and freezing.

#### *Cost-Benefit Summary*

As discussed, producers, slaughter facilities, and accredited veterinarians would be subject to certain costs if they chose to participate in the trichinae certification program. Producers would likely incur added expenses to ensure that their sites meet good production practices. Similarly, slaughter facilities that choose to receive certified swine for processing also would likely incur additional costs in following program requirements, including the testing of certified swine processed at the facility in order to verify that the good production practices at the production level are adequate. Accredited veterinarians who wish to perform site audits would have to pay the cost of the training that would be necessary before performing this service for producers. The program itself would not impose additional costs on U.S. consumers, although some slaughter facilities may pass on a portion of their costs to consumers.

As indicated in the CEAH analysis, a voluntary certification program involving periodic testing at slaughter would be less expensive than a program that would involve mandatory national testing. Also, because the program is voluntary, producers who judge the costs to exceed the benefits for their individual operation could opt not to participate in the program.

We expect that costs incurred by producers, slaughter facilities, and accredited veterinarians in choosing to participate in the voluntary program would be justified in the long term by the program's export and food safety benefits. Producers and slaughter facilities should benefit from increased export opportunities that develop as a result of the increased availability of certified pork products, while accredited veterinarians participating in

<sup>4</sup> Testing costs are derived from the 1998 CEAH study and have been adjusted for inflation. Freezing costs were obtained from Dave Pyburn, the APHIS National Trichinae Coordinator.

the program would have a potential source of additional income.

*Alternatives to the Proposed Rule*

In considering alternatives to the proposed rule, we looked to the findings of the CEAH analysis of Trichinae Certification Program alternatives. The CEAH analysis compared the costs of two alternative methods for achieving Trichinae Certification Program status in U.S. swine: An evolving on-farm certification program (*i.e.*, voluntary program) that involves periodic testing at the slaughter facility versus a national carcass testing program by the pooled sample digestion method (*i.e.*, mandatory program). Part I of the CEAH analysis describes inputs, assumptions, and projected costs for an evolving on-farm certification alternative. Part II describes inputs, assumptions, and projected costs for a national carcass testing program using the digestion method.

Bottom-line results of this analysis are expressed as average annual cost per pig over 5 years. It is important to note that where possible, the data in the CEAH study have been updated through 2002 in order to obtain better estimates of the cost of a voluntary certification program versus a mandatory program. Where recent data were not available, data from the 1998 study was used and adjusted for inflation in years 2 through 5. Although startup and maintenance costs for on-farm certification were averaged over 5 years, actual spending by producers may be higher in the first year and lower in years 2 through 5 of each 5-year period.

In the CEAH analysis, one component of proposed on-farm certification is periodic ELISA testing at slaughter. Projected costs for on-farm certification were calculated in Part I under options in which (1) large and medium slaughter facilities do required ELISA testing monthly and (2) large and medium slaughter facilities do ELISA

testing quarterly. It was assumed that small slaughter facilities could only accomplish the required ELISA testing quarterly.

*Voluntary Certification Program*

In projecting costs for on-farm certification using ELISA testing, the most influential variables were the percentage of U.S. producers that would incur zero, minimal, or moderate costs to establish and maintain good production practices (GPP) sufficient for on-farm certification, and how much these costs would be. Regarding the percentages of sites that would incur costs, it was necessary to consider a range of scenarios because data, experiences, and perceptions varied significantly. The three GPP scenarios appear in table 3 below. Regarding the dollar amounts of those costs, minimal startup and maintenance costs were estimated to be \$500 over 5 years, and moderate costs to be \$2,500 over 5 years.

TABLE 3.—AVERAGE ANNUAL COST PER PIG UNDER ON-FARM CERTIFICATION

Percentage of sites that would incur no additional costs, minimal GPP costs, or moderate GPP costs	Average annual cost per pig over 5 years
(a) Based on monthly ELISA testing at large/medium facilities:	
Scenario 1: 90, 5, 5 .....	\$0.148
Scenario 2: 36, 32, 32 .....	0.225
Scenario 3: 4, 48, 48 .....	0.271
(b) Based on quarterly ELISA testing at large/medium facilities:	
Scenario 1: 90, 5, 5 .....	0.142
Scenario 2: 36, 32, 32 .....	0.219
Scenario 3: 4, 48, 48 .....	0.265

**Mandatory Certification Program**

The alternative program, national carcass testing by the digestion method as described in Part II of the CEAH analysis, would entail testing every carcass at slaughter. Under this option, USDA would require swine producers to participate in a trichinae certification program. The CEAH analysis assumes that 95 percent of all sites would be certified under a mandatory program. Sites that are not certified would have to have their swine undergo testing by the digestion method at slaughter. The producers of these non-certified animals would assume the cost of testing.

It is assumed that larger facilities would use their own laboratories for testing, and smaller facilities would send their samples to independent laboratories for testing. All laboratories would be monitored by AMS. Average annual cost per pig under national carcass testing by the digestion method was calculated to be \$0.854, which significantly exceeded the highest cost

scenario for an on-farm certification program.

Would the additional benefits of a mandatory program outweigh the costs? The CEAH analysis shows that a voluntary certification program involving periodic testing at slaughter is less expensive than under a national carcass testing program using the digestion method. While there are no cost estimates for producers who choose not to participate in a voluntary program, it is reasonable to assume that they choose not to participate based on some benefit-cost calculation, either formal or informal (*i.e.*, costs of participating outweigh the benefits). The CEAH analysis assumes that most of the sites that would not participate in a voluntary program would involve producers with fewer than 100 head of swine. These producers would qualify as small businesses under the Small Business Administration (SBA) criteria, under which producers with not more than \$750,000 in annual receipts are

considered small businesses. Imposing a mandatory certification program could place an undue burden on swine producers considered to be small businesses.

*Maintain Status Quo*

Under this option, USDA would not establish a voluntary trichinae certification program. Producers and consumers would forgo benefits associated with the program and any potential benefits from increased exports and improved food safety would not be realized. Producers exporting to countries that monitor for *Trichinella spiralis* in pork would have to continue to test individual animals. The savings that could be realized from a voluntary certification program that would require testing only a sample of animals would not be captured.

*Initial Regulatory Flexibility Analysis*

The Regulatory Flexibility Act requires agencies to evaluate the potential effects of their proposed and

final rules on small business, small organizations and small governmental jurisdictions. Section 603 of the Act requires agencies to prepare and make available for public comment an initial regulatory flexibility analysis (IRFA) that describes expected impacts of a proposed rule on small entities. Section 603(b) of the Act specifies that an IRFA shall contain:

- A description of the reasons why action by the agency is being considered;
- A succinct statement of the objectives of, and legal basis for, the proposed rule;
- A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- A description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;
- An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule;
- A description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities.

#### *Reasons for the Action*

APHIS is proposing a voluntary trichinae certification program. Currently, any pork going into the European Union and Russia, along with a few other countries, must be tested and found free of *Trichinella spiralis*. Additionally, the meat must be frozen before shipment. Under the proposed voluntary program, producers could choose to certify a production site rather than undergo testing of each carcass at the slaughter facility that is destined for certain markets.

Due to favorable changes in Europe regarding the certification of slaughter facilities in the United States, industry participants feel a certification program like the one proposed here could help domestic producers obtain a larger share of the EU market, as well as open that market to the exportation of fresh chilled, rather than frozen, products. Additional market forces, combined with the effects of this voluntary program, may also open the Russian market to additional imports of U.S. pork.

#### *Objectives and Legal Basis*

The objective of the rule is to give producers the ability to certify a production site rather than testing each individual carcass destined for markets that require trichinae testing, specifically the EU and Russia. The certification program presented here would be strictly voluntary, thus APHIS would not require producers to undergo certification. The program is based on APHIS' authority under the Animal Health Protection Act.

#### *Small Entities That May Be Affected*

The proposed rule, if implemented, would have potential implications for swine producers and slaughter facilities both in terms of the costs they might incur to satisfy program requirements and in terms of the benefits associated with any increase in fresh pork sales as a result of the program's establishment. For both producers and slaughter facilities, the majority of establishments that we expect to take part in the program are small entities (not more than \$750,000 in annual receipts for producers and 500 employees for slaughter facilities). Over 80 percent of U.S. swine producers and 95 percent of slaughter facilities are small businesses according to these SBA guidelines.

Participation of producers in the trichinae certification program would be voluntary. Small operations could decide not to participate in the program if they believe the costs of maintaining certified status outweigh the benefits of producing certified swine. Slaughter facilities would also face this decision. Because participation is voluntary, the proposed rule is not expected to have an adverse impact on small businesses.

#### *Reporting, Recordkeeping, and Other Compliance Requirements*

Producers would have to pay for a site audit by the accredited veterinarian, program fees for certification from APHIS, and possibly testing. Slaughter facilities that purchase swine from certified production sites would be required to carry out certain functions relating to verification, segregation, testing, and recordkeeping of certified swine under its control. Thus, the slaughter facility would have to keep records of the number of animals slaughtered from certified sites. They would also have to make sure that certified and non-certified animals were kept separate throughout the whole process. These facilities would also be responsible for keeping records related to testing. In the end, however, it is a voluntary program, so participants only

take on this burden if they feel the program would benefit them.

#### *Duplicating, Overlapping, or Conflicting Federal Rules*

APHIS has not identified any duplication, overlap, or conflict of the proposed rule with other Federal rules.

#### *Economic Impact on Small Entities*

The Agency does not expect the proposed rule to result in significant economic impacts on small entities, and has therefore not set forth alternatives to minimize such impacts. Participation of producers in the Trichinae Certification Program would be voluntary. Small operations could opt to not join or withdraw from the program if they found the costs of maintaining certified status outweigh the benefits of producing certified swine. Because it is voluntary, the proposed rule is not expected to have an adverse impact on small businesses.

#### *Summary of Initial Regulatory Flexibility Analysis*

The proposed rule would establish a voluntary trichinae certification program. Producers who wish to participate would have to pay for an audit by an accredited veterinarian of their site. Additionally, they may incur the costs of carcass testing if the slaughter facility conducting the testing passes that cost to the producer. However, since this is a purely voluntary program, producers may opt not to incur any of these expenses.

Individuals in the pork industry are hopeful this certification program would help domestic producers gain market share in countries that require trichinae testing, particularly the EU and Russia. The EU is reducing the certification requirements for slaughter facilities, and industry participants feel the voluntary certification program would substitute for the mandatory testing of all carcasses destined for that market. The benefits of the rule lie in its potential to open markets requiring mandatory trichinae testing to additional domestic product. However, the extent to which these markets would open is unknown. Costs under the certification program appear to be higher than current testing costs due to the fact that a small amount of product is currently sent to the EU and Russia. However, certain producers may find it to their advantage to participate given their particular situation. Since the program is voluntary and does not impose any costs on producers not wishing to participate, small entities would not be negatively impacted by this proposed rule. In the end,

producers will participate in the program if they feel the benefits garnered from the certification program will outweigh the costs they incur.

#### Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

#### Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

#### National Environmental Policy Act

An environmental assessment has been prepared for this proposed rule. The assessment provides a basis for the conclusion that the implementation of the Trichinae Certification Program, as provided for in the proposed rule, would preclude any potential adverse effects on endangered and threatened species and their habitats, and would not have a significant impact on the quality of the human environment.

The environmental assessment has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

The environmental assessment may be viewed on the Regulations.gov Web site or in our reading room. (Instructions for accessing Regulations.gov and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this proposed rule.) In addition, copies may be obtained by calling or writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**. Comments on the environmental assessment may be submitted using the methods described under **ADDRESSES**.

#### Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information

collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS–2006–0089. Please send a copy of your comments to: (1) Docket No. APHIS–2006–0089, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238, and (2) Clearance Officer, OCIO, USDA, room 404–W, 14th Street and Independence Avenue, SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

The proposed Trichinae Certification Program is a voluntary program to certify pork as produced under good production practices that reduce, eliminate, or avoid the animal's risk of exposure to *Trichinella spiralis* infection risk factors. *Trichinella spiralis* or trichinae is a parasitic disease of warm-blooded carnivores and omnivores, including swine. Uniform program standards have been developed by organizations representing the pork industry, State animal health agencies, and USDA. These standards provide the guidelines for implementing the requirements for this voluntary program.

In this program, pork production sites would be audited by USDA trained and accredited veterinarians. During the site audit, the veterinarian would observe and collect information about the site, including swine sources, feed sources, rodent and wildlife control, and facility hygiene. This information would be collected on USDA-approved official program audit forms. APHIS would review the information obtained from the site audit to ensure that the required program standards relating to good production practices are in place and being maintained at the site in order to reduce, eliminate, or avoid the risk of exposure of swine to trichinae. APHIS would maintain a database containing records for each pork production site participating in the program. Listings of certified production sites by TIN and program status would be posted on the Trichinae Certification Program Web site at <http://www.aphis.usda.gov/vs/trichinae> and would be accessible to APHIS personnel, as well as slaughter facility representatives whose facilities handle certified swine.

In most instances, the information relating to a pork production site's

adherence to required good production practices would be collected during the audit. Completed forms would be submitted to the local APHIS area office. Site suitability for program enrollment or certification would be determined by the local APHIS area office. Program data would be entered locally. National summary data would be available to APHIS personnel involved in administering the program.

Producers choosing to participate in the program would be subject to certain recordkeeping requirements that evidence their adherence to all of the required good production practices. Producers would have to maintain the following records: Animal disposal plan, animal movement record, feed mill quality assurance affidavit (if applicable), rodent control logbook, and waste feeding logbook (if applicable).

Slaughter facilities handling certified swine also would be subject to certain recordkeeping requirements as to the number of certified swine processed, the source of the certified swine, and test results relating to process-verification testing. Such slaughter facilities also would be required to have documented procedures on how certified swine under its control, and the edible pork products derived from these animals, would remain segregated from swine and pork from noncertified sources.

Approved laboratories that perform process-verification testing under the Trichinae Certification Program would be required to maintain written procedures that pertain to the performance of process-verification testing.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 0.3842102 hours per response.

*Respondents:* Auditors, herd owners, slaughter facilities, and approved laboratories.

*Estimated annual number of respondents:* 54,500.

*Estimated annual number of responses per respondent:* 2.992532.

*Estimated annual number of responses:* 163,093.

*Estimated total annual burden on respondents:* 62,662 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

### E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

### List of Subjects

#### 9 CFR Part 149

Animal diseases, Hogs, Laboratories, Meat and meat products, Meat inspection, Reporting and recordkeeping requirements.

#### 9 CFR Part 160

Veterinarians.

#### 9 CFR Part 161

Reporting and recordkeeping requirements, Veterinarians.

Accordingly, we propose to amend title 9 CFR chapter I as follows:

### SUBCHAPTER G—LIVESTOCK IMPROVEMENT

1. In subchapter G, the subchapter heading would be revised to read as set forth above.

2. In subchapter G, a new part 149 would be added to read as follows:

### PART 149—VOLUNTARY TRICHINAE CERTIFICATION PROGRAM

Sec.

149.0 Purpose and scope.

149.1 Definitions.

- 149.2 Program participation.
- 149.3 Site audit.
- 149.4 Spot audit.
- 149.5 Offsite identification and segregation of certified swine.
- 149.6 Slaughter facilities.
- 149.7 Recordkeeping at site.
- 149.8 Program fees and charges.
- 149.9 Pilot program sites.

**Authority:** 7 U.S.C. 8301-8317; 7 U.S.C. 1622; 7 CFR 2.22, 2.80, and 371.4.

#### § 149.0 Purpose and Scope.

The Trichinae Certification Program described in this part is intended to enhance the ability of swine producers, as well as slaughter facilities and other persons that handle or process swine from pork production sites that have been certified under the program, to export fresh pork and pork products to overseas markets.

#### § 149.1 Definitions.

*Accredited veterinarian.* A veterinarian approved by the APHIS Administrator in accordance with part 161 of this chapter to perform functions specified in subchapters B, C, D, and G of this chapter.

*Agricultural Marketing Service (AMS).* The Agricultural Marketing Service of the United States Department of Agriculture.

*AMS Administrator.* The Administrator, Agricultural Marketing Service, or any person authorized to act for the AMS Administrator.

*AMS representative.* Any individual employed by or acting as an agent on behalf of the Agricultural Marketing Service who is authorized by the AMS Administrator to perform services required by this part.

*Animal and Plant Health Inspection Service (APHIS).* The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

*Animal disposal plan.* A written document that describes methods for the removal and disposal of dead swine or swine remains from a pork production site.

*Animal movement record.* A written record of the movement of swine into or from a pork production site.

*APHIS Administrator.* The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the APHIS Administrator.

*APHIS representative.* Any individual employed by or acting as an agent on behalf of the Animal and Plant Health Inspection Service who is authorized by the APHIS Administrator to perform the services required by this part.

*Approved laboratory.* A non-Federal laboratory approved by the Agricultural Marketing Service and recognized by

the APHIS Administrator or FSIS Administrator for performing validated tests to determine the presence of trichinae infection in reference to the Trichinae Certification Program.

*Audit.* An inspection process, as provided in this part, that generates a written record documenting a pork production site's adherence to the required good production practices.

*Auditor.* A qualified accredited veterinarian (QAV) or a qualified veterinary medical officer (QVMO) who is trained and authorized by APHIS to perform auditing activities under the Trichinae Certification Program.

*Certification (certified).* A designation given by the APHIS Administrator to a pork production site for compliance with good production practices and other program requirements of the Trichinae Certification as provided in this part.

*Certified pork.* Pork products originating from certified swine from a certified production site with identity of such animals or carcasses maintained throughout receiving, handling, and processing.<sup>1</sup>

*Certified production site.* A pork production site that has attained a program status of Stage II or higher, based on adherence to good production practices and other program requirements as provided in this part.

*Certified swine.* Swine produced under the Trichinae Certification Program on a certified production site.

*Decertification (decertified).* Removal of the certified status of a production site by the APHIS Administrator when it has been determined that the criteria of the Trichinae Certification Program are not being met or maintained.

*Enzyme-linked immunosorbent assay (ELISA).* A method of testing swine for the presence of trichinae infection by looking for antibodies to *Trichinella spiralis* in the sera, plasma, whole blood, tissue fluid, or meat juice of swine.

*EPA.* The United States Environmental Protection Agency.

*Feed mill quality assurance affidavit.* A written statement signed by the feed mill representative and the producer that documents the quality and safety of feed or feed ingredients delivered from the feed mill to the pork production site.

*Food Safety and Inspection Service (FSIS).* The Food Safety and Inspection Service of the United States Department of Agriculture.

*FSIS Administrator.* The Administrator, Food Safety and

<sup>1</sup> The labeling of all certified pork or pork products leaving a slaughter or processing facility must comply with 9 CFR 317.4 and all other applicable FSIS labeling regulations.

Inspection Service, or any person authorized to act for the Administrator.

**FSIS program employee.** Any individual employed by or acting as an agent on behalf of the Food Safety and Inspection Service who is authorized by the FSIS Administrator to perform the services required by this part.

**Good manufacturing practices.** Feed manufacturing practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella spiralis*.

**Good production practices.** Pork production management practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella spiralis*.

**Harborage.** Any object, debris, clutter, or area that could serve as shelter or refuge for rodents or wildlife.

**Laboratory approval audit.** An audit performed by AMS representatives to determine if a laboratory meets minimum requirements for approval, as established by AMS, for performing validated tests under this part.

**National Trichinae Certified Herd.** All swine raised on certified production sites in the United States.

**Person.** Any individual, corporation, company, association, firm, partnership, society, joint stock company, or other legal entity.

**Pest control operator.** A person trained and State-licensed in the control of pests and vermin (particularly rodents).

**Pooled sample digestion method (digestion method).** A method of testing swine for trichinae infection by identifying the presence of *Trichinella spiralis* from a sample of the animal's muscle tissue.

**Pork production site (site).** A geographically definable area that includes pork production facilities and ancillary structures under common ownership or management systems and the surrounding space within a 100-foot perimeter of the swine housing and feeding areas.

**Positive test result.** Outcome of a validated test indicating the presence of *Trichinella spiralis*.

**Process-verification testing.** Testing of a statistically valid sample of swine belonging to the National Trichinae Certified Herd at the time of slaughter using a validated test to verify that the adherence to good manufacturing practices and good production practices is resulting in the absence of *Trichinella spiralis* infection in swine from that herd.

**Producer.** An individual or entity that owns or controls the production or management of swine.

**Qualified accredited veterinarian (QAV).** An accredited veterinarian who

has been granted an accreditation specialization by the APHIS Administrator pursuant to § 161.5 of this chapter based on completion of an APHIS-approved orientation or training program in good production practices in swine management, and who is authorized by the APHIS Administrator to perform site audits and other specified program services required by this part.

**Qualified veterinary medical officer (QVMO).** A VMO of the State or Federal Government who is trained in good production practices and is authorized by the APHIS Administrator to perform site audits, spot audits, and other specified program services required by this part.

**Rodent control logbook.** A written record that documents a rodent control program for a pork production site.

**Site audit.** An audit, performed by a QAV or a QVMO, to determine the trichinae risk factor status of a pork production site based on the site's adherence to all of the required good production practices that reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella spiralis*.

**Slaughter facility.** A slaughtering establishment operating under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*) or a State meat inspection act that receives certified swine under the Trichinae Certification Program.

**Slaughter facility representative.** Any individual employed by, or acting as an agent on behalf of, a slaughter facility who is authorized by the slaughter facility to perform the specified program services required by this part.

**Spot audit.** An audit of a certified pork production site performed by a QVMO to ensure program integrity and consistency.

**Stage I enrolled.** Preliminary program status of a pork production site attained when the APHIS Administrator approves the outcome of an initial site audit.

**Stage II certified.** Program status attained upon APHIS approval of a site audit of a Stage I enrolled site.

**Stage III certified.** Program status attained upon APHIS approval of a site audit of a Stage II certified site and maintained upon APHIS approval of subsequent site audits for renewal of Stage III certified status.

**Sterile zone.** An open area immediately adjacent to and surrounding those building(s) used to house and feed swine that serves as both a buffer and detection zone for rodent and wildlife activity.

**Temporary withdrawal.** The voluntary withdrawal of a certified production site from the Trichinae Certification

Program at the request of the producer for a period not to exceed 180 days.

**Trichinae.** A generic term that refers to *Trichinella spiralis*.

**Trichinae Certification Program (program).** A voluntary pre-harvest pork safety program in which APHIS certifies pork production sites that follow all of the required good production practices that reduce, eliminate, or avoid the risk of exposure of swine from their sites to *Trichinella spiralis*.

**Trichinae Identification Number (TIN).** A number assigned to a pork production site by the APHIS Administrator.

**Trichinella spiralis.** A parasitic nematode (roundworm) capable of infecting many warm-blooded carnivores and omnivores, including swine.

**USDA.** The United States Department of Agriculture.

**Validated test.** An analytical method licensed by APHIS or accepted by AMS for the diagnosis of *Trichinella spiralis* in swine.

**Veterinary medical officer (VMO).** A veterinarian employed by the State or Federal Government who is authorized to perform official animal health activities on their behalf.

**Waste feeding logbook.** A written record that documents the presence of good production practices with respect to the feeding of meat-containing waste to swine and compliance with applicable State and Federal food waste feeding laws and regulations.

#### § 149.2 Program participation.

A producer's initial enrollment and continued participation in the trichinae certification program requires that the producer adhere to all of the good production practices, as confirmed by periodic site audits, and comply with other recordkeeping and program requirements provided in this part. Pork production sites accepted into the program by APHIS will participate under one of the following three program stages:

(a) **Stage I enrolled status.** (1) Stage I enrolled status signifies that the site has met good production practices and other recordkeeping and program requirements provided in this part.

(2) Swine from a Stage I enrolled site cannot be identified as products from a certified production site.

(3) A Stage I enrolled site must complete a site audit for Stage II certified status in accordance with § 149.3(d). Under § 149.3(d), the site audit must be performed no sooner than 150 days from the date the site was awarded Stage I enrolled status, and must be completed, with the audit form

and payment submitted to APHIS, no later than 210 days from the date the site was awarded Stage I enrolled status.

(4) A Stage I enrolled site that is found not to be adhering to one or more good production practices as a result of a site audit or spot audit, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment for consideration as a Stage II certified site, will lose its status as a Stage I enrolled site.

(b) *Stage II certified status.* (1) Stage II certified status signifies that the site is adhering to all of the required good production practices and other recordkeeping and program requirements provided in this part.

(2) An APHIS-issued certificate or letter indicating the site's status as a Stage II certified site must be filed at the site and be readily available for inspection.

(3) Swine from a Stage II certified site may be identified as certified product from a certified production site.

(4) A Stage II certified site must complete a site audit for Stage III certified status in accordance with § 149.3(e). Under § 149.3(e), the site audit must be performed no sooner than 240 days from the date the site was awarded Stage II certified status, and must be completed, with the audit form and payment submitted to APHIS, no later than 300 days from the date the site was awarded Stage II certified status.

(5) A Stage II certified site that is found not to be adhering to one or more good production practices as a result of a site audit or spot audit, or that fails to meet the Stage III site audit requirements of § 149.3(e) within the prescribed timetable, will be decertified by APHIS as provided in paragraph (e) of this section. During the time a site is decertified, swine from that site cannot be identified as product from a certified production site.

(c) *Stage III certified status.* (1) Stage III certified status signifies that the site is adhering to all of the required good production practices and other recordkeeping and program requirements provided in this part.

(2) An APHIS-issued certificate or letter indicating the site's status as a Stage III certified site must be filed at the site and be readily available for inspection.

(3) Swine from a Stage III certified site may be identified as certified products from a certified production site.

(4) A Stage III certified site that is found not to be adhering to one or more good production practices as a result of a site audit or spot audit, or that fails to

follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment to determine its continued participation as a Stage III certified site, will be decertified by APHIS as provided in paragraph (e) of this section. During the time a site is decertified, swine from that site cannot be identified as product from a certified production site.

(d) *Change of ownership.* (1) *Stage I enrolled site.* If there is a change in ownership in a Stage I enrolled site, and the new ownership wishes to remain in the program, then the Stage I enrolled site will remain on the same timetable as under the previous ownership for purposes of completing a site audit for Stage II certified status. No additional site audit is necessary as a result of the change of ownership of the site.

(2) *Stage II or Stage III certified sites.* Within 60 days of a change in ownership of a Stage II or Stage III certified site, a site audit must be performed in order for the site to maintain its certified status. It is the new ownership's responsibility that a site audit be performed within 60 days of the change in ownership, otherwise the site will be decertified. If the site audit is satisfactory, then the Stage II or Stage III certified site will continue in the program only as a Stage II certified site. A new program anniversary date for that site will be established based on the date the site was audited to continue in the program as a Stage II certified site. If the results of the site audit do not meet program requirements, as determined by APHIS, the Stage II or Stage III site will be decertified. Once a site is decertified by APHIS, either because the new ownership fails to arrange for a site audit to be performed within the allotted 60-day time period, or because the site is found not to meet program requirements, a producer wishing to participate in the program again must follow the procedures for requesting an initial audit for Stage I enrolled status. If a decertified site is reenrolled after a successful Stage I site audit, a new program anniversary date for that site will be established based on the date of reenrollment.

(e) *Site decertification and program withdrawal.* (1) *Decertification by APHIS.*

(i) A Stage II or Stage III certified site that is found not to be adhering to one or more good production practices as a result of a site audit or spot audit, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment to continue participation in the program, will be decertified by APHIS.

(ii) During the time a site is decertified, swine from such sites cannot be identified as certified product from a certified production site.

(iii) Once a site is decertified by APHIS, a producer wishing to participate in the program again must follow the procedures for requesting a site audit for Stage I enrolled status. If a decertified site is reenrolled after a successful Stage I site audit, a new program anniversary date for that site will be established based on the date of recertification. If a decertified site is recertified after a successful Stage II site audit, a new program anniversary date for that site will be established based on the date of recertification.

(2) *Temporary withdrawal by producer.* (i) A producer may request that one or more certified production sites be temporarily withdrawn. A producer's request must be made in writing and is subject to the APHIS Administrator's approval.

(ii) Each certified production site can be temporarily withdrawn no more than once every 2 years for a period not to exceed 180 days.

(iii) During the time a site is temporarily withdrawn:

(A) Swine from such sites cannot be identified as certified product from a certified production site; and

(B) The producer must continue to adhere to all good production practices and other recordkeeping and program requirements provided in this part, unless specifically waived by the Administrator, including documentation in the animal movement record of the arrival and departure of all swine from the site, as well as whether the swine arriving at the site are from certified or noncertified sources.

(iv) Before being reinstated as a certified production site, the temporarily withdrawn site must pass a site audit to indicate that it is adhering to all good production practices (including any practices previously waived by the Administrator) as follows:

(A) The site audit must be performed while the site is still under temporary withdrawal status. If swine 5 weeks of age or older originating from noncertified sources are received at the site during the time of withdrawal, then the site audit for reinstatement must be performed within 30 days of the date the last swine from noncertified sources was removed from the site, but no later than 180 days from the date the site was granted temporary withdrawal status.

(B) If the results of the site audit are satisfactory and it is determined that the site is adhering to good production practices and other program



requirements provided in this part, then the withdrawn site will be reinstated as a Stage II certified site. The timetable for performing future site audits for attaining and renewing Stage III certified status will be based on the date the site was reinstated as a Stage II certified site.

(C) If the results of the site audit are not satisfactory due to the producer's failure to adhere to one or more good production practices, or, if the period of temporary withdrawal has exceeded 180 days, then the site will be decertified by APHIS. Once the site is decertified by APHIS, the producer must follow the procedures for requesting an initial site audit for Stage I enrolled status in order for the site to be reenrolled in the program. If a site is decertified by APHIS and then reenrolled after a successful Stage I site audit, a new program anniversary date for that site will be established based on the date of enrollment.

(3) *Program withdrawal.* (i) If a producer decides to withdraw one or more of pork production sites from the program, then it is the producer's responsibility to notify the APHIS Administrator in writing of this intent. When this is done, the site will be removed from the program.

(ii) If at a later date the producer requests that a site be reinstated in the program, then the producer must follow the procedures for requesting an initial audit for Stage I enrolled status. If a withdrawn site is reenrolled after a successful Stage I site audit, then a new program anniversary date for that site will be established based on the date of reenrollment.

(f) *Request for review.* If there is a conflict as to any material fact relating to the results of a site audit, spot audit, or other determination affecting a producer's program status or ability to participate in the program, the producer may submit a written request for review to the Administrator. The producer must include in the request the reasons, including any supporting documentation, why the audit result or other determination should be different than the result or determination made by the Administrator. The initial audit result or other determination will remain in force pending the completion of the Administrator's review. The decision by the Administrator upon reviewing the producer's written request will be final.

#### **§ 149.3 Site audit.**

(a) *General.* (1) The producer must contact a QAV to request a site audit. A list of available QAVs may be obtained by accessing the Trichinae Certification

Program Web site on the Internet at <http://www.aphis.usda.gov/vs/trichinae>, or by contacting the APHIS area office.<sup>2</sup> If a QAV is not available to perform a site audit, the producer may then contact the APHIS area office to request that a QVMO perform the site audit. The site audit is to be arranged at a mutually agreed-upon time.

(2) The producer or the producer's designated representative will accompany the auditor during the site audit.

(3) During the site audit, the auditor will record whether the producer is adhering to all of the required good production practices at the site, as provided in paragraph (b) of this section, in order to reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella spiralis*.

(4) The auditor will use APHIS-approved audit forms in performing the site audit. After the auditor has completed all sections of the audit form, the producer or the producer's designated representative must sign the audit form attesting to the accuracy of the information obtained during the site audit and to evidence his or her intent to continue adhering to the good production practices and other program requirements, as provided in this part. The auditor also must sign the audit form at this time.

(5) The producer is responsible for the cost of each site audit performed at the pork production site. If a QAV performs the site audit, then the producer will pay the QAV directly at a mutually agreed-upon time and rate. If a QVMO performs the site audit, then the producer will pay the QVMO at the time the site audit is performed in accordance with the rate and other conditions set by the QVMO's governmental employer. If an APHIS-employed QVMO performs the site audit, then the producer will pay APHIS by certified check or U.S. money order for this service at a rate determined in accordance with § 149.8.

(6) In addition to the cost of the site audit, the producer is also responsible for paying a separate program fee in an amount specified in § 149.8 to cover APHIS' administrative costs in processing the audit and operating the program. This program fee, payable to APHIS by certified check or U.S. money order, must be remitted to the auditor at the time each site audit is performed.

(7) The auditor will submit the completed audit form, program fee, and payment for the services of an APHIS-

employed QVMO, if applicable, to the nearest APHIS area office. If a QAV performs the site audit, the producer will be responsible for ensuring that the QAV submits the completed audit form and program fee to APHIS in a timely manner.

(8) Upon receipt of the completed audit form and payment, APHIS will determine the initial enrollment or certification status for the site based on an evaluation of the site audit. APHIS will provide the producer with written notification of the audit results. Pork production sites that meet all good production practices as provided in paragraph (b) of this section, as well as other program requirements provided in this part, will be issued program status at the appropriate program stage.

(9) If the site audit shows that the site does not meet all good production practices or other program requirements, APHIS will provide the producer with written notification that includes documentation of the deficiencies that prevented the site from being conferred program status.

(b) *Good production practices.* In a site audit, the auditor will determine whether all of the required good production practices are being carried out at the site to reduce, eliminate, or avoid the risk of exposure of swine to *Trichinella spiralis* as follows:

(1) The movement of all non-breeding swine 5 weeks of age or older into or from the pork production site must be documented in an animal movement record, as provided in § 149.7, that ensures that all such swine moved into or from the site can be subsequently traced back to that site, or to any previous site (if applicable).

(2) All non-breeding swine entering a site must have originated from another certified production site, except that non-breeding swine less than 5 weeks of age may have originated from either a certified or noncertified production site. The animal movement record must include the TIN of the certified production site from which the swine originated. If the swine are less than 5 weeks of age and come from a noncertified site, then the animal movement record must provide the name and full address of the noncertified site where the swine originated.

(3) Feed or feed ingredients from offsite sources that are used at the site must meet good manufacturing practices or other quality assurance standards recognized by the feed industry. The adherence to good manufacturing practices or other quality assurance standards must be documented in a feed

<sup>2</sup> Telephone numbers for APHIS area offices can be found in local telephone books or on the Internet at [http://www.aphis.usda.gov/vs/area\\_offices.htm](http://www.aphis.usda.gov/vs/area_offices.htm).

mill quality assurance affidavit, as provided in § 149.7.

(4) Swine housing and feeding areas, feed preparation and storage areas, and office areas and connecting hallways at the site must be inspected regularly and found free of fresh signs rodent and wildlife activity. Any movable harborage (exterior or interior) on the site that is not necessary to the day-to-day operation of the site must be removed. Harborage that cannot be removed or is movable but necessary to the day-to-day operation of the site (e.g., bales of hay, etc.) must be checked for signs of rodent or wildlife activity (e.g. fresh droppings, tracks, signs of gnawing or burrowing). In addition, domesticated animals, including pets such as dogs and cats, must be excluded from the swine housing and feeding areas and feed preparation and storage areas at the site (evidence of rodent activity or rodent infestation consists of fresh rodent droppings, fresh gnawing marks, new structural damage, rodent urine, rodent blood, rodent smear marks (body oil), rodent tracks, or recent burrowing or burrow use. Evidence of wildlife activity consists of wildlife feces, footprints, fur, or hair observed in or near the stored feed or feed ingredients, dead or live wildlife observed in or near the stored feed or feed ingredients, or wildlife burrows or nests observed in or near the stored feed or feed ingredients). Exterior rodent bait stations and/or traps must be placed around the perimeter of those building(s) housing the swine, as well as around the perimeter of outdoor swine feeding areas. Exterior rodent bait stations and/or traps also must be placed around areas of potential rodent entry into building(s) used to house and feed swine (i.e., doorways, vent openings, loading chutes, cool cells, etc.). Interior rodent bait stations and/or traps must be placed near high-risk rodent zones such as entryways, hallways, office areas, swine load out areas, vents, cool cells, storage areas, utility rooms, cabinets, locker rooms, bathrooms, and break rooms, and systematically maintained. Interior rodent bait stations and/or traps must be placed so that swine will not come in contact with the bait or trap. Rodent bait stations and/or traps also must be placed near exterior or interior harborage on the site that cannot be removed or that is movable but necessary to the day-to-day operation of the site. In all instances, rodent bait stations must be intact, systematically maintained, and contain fresh bait that consists of an EPA-registered rodenticide formulation that is applied

according to its label. In addition, a sterile zone must be maintained around the perimeter of those building(s) used to house and feed swine. The sterile zone must be devoid of any harborage or feed or water sources that could attract rodents or wildlife, but must contain rodent bait stations and/or rodent traps. The sterile zone also must be devoid of any vegetation unless it is decorative vegetation that is well maintained (i.e., residential height grass, flowers, shrubs, or trees). A sterile zone with decorative vegetation will require increased rodent control measures. The producer must provide documentation of rodent control practices by maintaining at the site an up-to-date rodent control logbook with a site diagram and other recordkeeping evidencing implementation of rodent control measures, which can include documents provided by a pest control operator, as provided in § 149.7.

(5) Feed or feed ingredients stored at the site must be prepared, maintained, and handled in a manner that protects the feed or feed ingredients from possible exposure to or contamination by rodents or wildlife. Any movable harborage in the immediate vicinity of feed production and feed storage areas that is not necessary to the day-to-day operation of the site must be removed. Harborage that cannot be removed or harborage that is movable but necessary to the day-to-day operation of the site (e.g., bales of hay, etc.) must be checked for signs of rodent or wildlife activity. Rodent bait stations and/or traps must be placed around (and in, if applicable) all feed preparation and storage areas, as well near any harborage in the vicinity that cannot be removed or that is movable but necessary to the day-to-day operation of the site. Rodent bait stations must be intact, systematically maintained, and contain fresh bait that consists of an EPA-registered rodenticide formulation that is applied according to its label. In addition, feed or feed ingredients that are stored in paper bags must be elevated off the floor and be a sufficient distance away from the walls to allow for inspection, baiting, and/or trapping. The rodent control logbook, as provided in § 149.7, must document that adequate rodent control procedures have been implemented in the feed production and feed storage areas.

(6) Swine must not have access to wildlife harborage or dead or live wildlife at the site. This harborage limitation includes wood or wooded lots and other natural wildlife access areas. Dead or live wildlife must not be intentionally fed to swine.

(7) If meat-containing waste is fed to swine at the site, then the producer must hold a license or permit that authorizes the feeding of such waste to swine. Cooking times and temperatures of meat-containing waste must be consistent with applicable State and Federal laws and regulations. In addition, up-to-date records of waste feeding and cooking practices, in the form of a waste feeding logbook must be maintained at the site, as provided in § 149.7. Cooked food waste products that are stored prior to feeding must not be mixed or contaminated with uncooked or undercooked meat waste material. Household food waste, regardless of whether it contains meat or is cooked or undercooked, also must not be fed to swine.

(8) Procedures must be in place and carried out for the prompt removal and proper disposal of dead swine or swine remains found in pens in order to eliminate the opportunity for cannibalism, as well as to prevent the attraction of rodents or wildlife. Such procedures must be documented in the animal disposal plan, as provided in § 149.7.

(9) General hygiene and sanitation of the site must be maintained at all times to prevent the attraction of rodents and wildlife. Solid non-fecal waste (facility refuse) must be placed in covered receptacles and be regularly removed from the site. Spilled feed also must be regularly removed and properly disposed of.

(10) All records required under § 149.7 must be kept up-to-date and readily available for inspection at the site.

(c) *Initial site audit for Stage I enrolled status.* (1) Producers interested in participating in the program should request and review a pre-audit information packet prepared by APHIS that discusses the program, as well as the steps in preparing for and requesting an initial site audit.<sup>3</sup> When the producer and the producer's herd health personnel believe that a site meets program standards, the producer may arrange for an initial site audit, as provided in paragraph (a) of this section.

(2) Upon completion of the initial site audit and submission of the completed audit form and payment, APHIS will

<sup>3</sup> The pre-audit information packet may be obtained from a qualified accredited veterinarian (QAV), State or Federal animal health offices, or the National Pork Board, or by writing to: USDA, APHIS, Veterinary Services, Trichinae Certification Program, 210 Walnut St., Room 891, Des Moines, IA 50309. A pre-audit packet also may be requested electronically through the program Web site on the Internet at <http://www.aphis.usda.gov/vs/trichinae>.

review the completed audit form and make a determination within 30 days as to enrollment of the site in the program. A pork production site that is found to meet all good production practices and other program requirements in this part will be awarded Stage I enrolled status.

(d) *Site audit for Stage II certified status.* (1) A producer of a Stage I enrolled site must arrange for another site audit for Stage II certified status. The site audit must be performed no sooner than 150 days (*i.e.*, approximately 5 months) from the date the site was awarded Stage I enrolled status, and must be completed, with the audit form and payment submitted to APHIS, no later than 210 days (*i.e.*, approximately 7 months) from the date the site was awarded Stage I enrolled status.

(2) APHIS will review the completed audit form and make a determination as to Stage II certified status within 7 days of receipt of the audit form and payment. (i) A Stage I enrolled site that is found to meet all good production practices and other program requirements in this part will be awarded Stage II certified status.

(ii) A Stage I enrolled site that is found, during a site audit, not to be adhering to one or more good production practices, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment, will not be awarded Stage II certified status and will lose its program status as a Stage I enrolled site.

(e) *Site audit for Stage III certified status.* (1) A producer of a Stage II enrolled site must arrange for another site audit for Stage III certified status. The site audit must be performed no sooner than 240 days (*i.e.*, approximately 8 months) from the date the site was awarded Stage II certified status, and must be completed, with the audit form and payment submitted to APHIS, no later than 300 days (*i.e.*, approximately 10 months) from the date the site was awarded Stage II certified status.

(2) APHIS will review the completed audit form and make a determination as to Stage III certified status within 30 days of receipt of the audit form and payment. (i) A Stage II certified site that is found to meet all good production practices and other program requirements in this part will be awarded Stage III certified status.

(ii) A Stage II certified site that is found, during a site audit, not to be adhering to one or more good production practices, or that fails to follow the prescribed timetable for completing a site audit and submitting

the completed audit form and payment, will be subject to decertification by APHIS as provided in § 149.2(e).

(f) *Site audit for renewal of Stage III certified status.* (1) A producer seeking to renew a site's Stage III certified status must arrange for another site audit. The site audit must be performed no sooner than 14 months from the date the site was awarded Stage III certified status or the date that status was last renewed, and must be completed, with the audit form and payment submitted to APHIS, no later than 16 months from either the date the site was awarded Stage III certified status or the date that the status was last renewed.

(2) APHIS will review the completed audit form and make a determination as to renewing the site's Stage III certified status within 30 days of receipt of the audit form and payment. (i) A Stage III certified site that is found to meet all good production practices and other program requirements in this part will have its status Stage III certified site renewed.

(ii) A Stage III certified site that is found, during a site audit, not to be adhering to one or more good production practices, or that fails to follow the prescribed timetable for completing a site audit and submitting the completed audit form and payment, will be subject to decertification by APHIS as provided in § 149.2(e).

#### § 149.4 Spot audit.

(a) In addition to regularly scheduled site audits, certified production sites will be subject to spot audits. (1) *Random spot audit.* Certified production sites will be selected by the APHIS Administrator at random for a spot audit in order to:

- (i) Ensure the integrity of the audit process;
- (ii) Verify that the audit process is performed in a consistent manner across the program; and
- (iii) Verify that all required good production practices are being maintained between regularly scheduled site audits.

(2) *Spot audit for cause.* A certified production site may be subject to a spot audit to trace back and investigate any positive test results as a result of testing of certified swine from that site at the slaughter facility.

(b) All spot audits will be performed by a QVMO. The producer of the certified production site subject to spot audit will not be charged for the spot audit. APHIS will provide the producer with written notification of the results of the spot audit, including documentation of any deficiencies noted during the audit. If the site is

found not to be adhering to one or more of the required good production practices, then the site will be subject to decertification by APHIS as provided in § 149.2(e).

#### § 149.5 Offsite identification and segregation of certified swine.

Certified swine moved from a certified production site to another location, whether to another certified production site, buying station, collection point, or slaughter facility, must remain segregated from noncertified swine at all times and otherwise maintain their identity as certified swine in such a way that they could be readily traced back to the certified production site from which they came. Information relating to the identification of the certified swine must be documented in the animal movement record maintained by the producer. Failure to properly segregate or maintain the identity of certified swine from noncertified swine after leaving the certified production site will result in the loss of certified status for that shipment of swine.

#### § 149.6 Slaughter facilities.

Only slaughter facilities that are under continuous inspection by the Food Safety and Inspection Service or under State inspection that the Food Safety and Inspection Service has recognized as equivalent to Federal inspection may participate in the program. To participate in the program, slaughter facilities must follow the relevant provisions of this section relating to verification, segregation, testing, and recordkeeping. Participating slaughter facilities that fail to comply with any of the applicable requirements of this section will not be allowed to continue to participate in the Trichinae Certification Program and the pork or pork products prepared by the facility will not be eligible for a certificate of export that identifies the product as meeting the standards of the Trichinae Certification Program.

(a) *Verification of certification.* A slaughter facility receiving certified swine must verify the current certification status of the pork production site from which the animals came. The current certification status may be verified by maintaining dated certification documentation on file or by accessing the Trichinae Certification Program Web site on the Internet at <http://www.aphis.usda.gov/vs/trichinae>. If the slaughter facility is unable to verify a site's certification status through documentation on file or through the program Web site, the

slaughter facility then should contact the APHIS area office in the State where the site is located.

(b) *Maintaining identity and segregation of certified swine and pork products.* For certified swine to be identified as certified pork, certified swine and edible pork products derived from certified swine must remain segregated from swine and edible pork products from noncertified sites throughout receiving, handling, and processing at the slaughter facility, as well as while awaiting shipment from the facility. The slaughter facility must maintain the identity of the certified swine or pork in a manner that allows the certified swine or pork to be traced back to the certified production site from which it came. A slaughter facility's failure to properly segregate or maintain the identity of certified swine and edible pork products derived from the certified swine will result in the loss of certified status for that shipment of swine, as well as the edible pork products derived from those animals.

(c) *Process-verification testing.* A slaughter facility processing certified swine is responsible for performing process-verification testing at its expense to determine the *Trichinella*

*spiralis* infection status of certified swine under its control as follows:

(1) *Validated tests.* Process-verification testing must be performed by using a validated test.<sup>4</sup>

(2) *Laboratory approval.* Process-verification testing must be performed in an approved laboratory that has been approved for trichinae testing by the Agricultural Marketing Service (AMS).<sup>5</sup> The approved laboratory may be maintained and operated by the slaughter facility or by another business entity either on the premises of the slaughter facility or at another location. Laboratory staff performing process-verification testing must be accredited by AMS to perform this program function. For purposes of quality assurance, all laboratory staff approved to perform process-verification testing will receive periodic proficiency test panels from AMS that must be analyzed correctly in order to maintain their approval status.

(3) *Testing sample size and frequency.* Process-verification testing must meet the following minimum requirements relating to sample size and frequency:

(i) Slaughter facility representatives shall determine the yearly processing capacity of the slaughter facility for the

next 12 months. Officials may use the processing capacity over the previous 12 months if this period is representative of a typical processing year.

(ii) Slaughter facility representatives shall estimate the percentage of swine processed that are likely to come from certified production sites considering all swine expected to be processed at the slaughter facility during the selected 12-month period. Swine that come from certified production sites are considered the eligible population to be sampled.

(iii) Slaughter facility representatives shall use the Trichinae Certification Slaughter Facility Sample Size Determination Table (see table 1) to find the number of samples to collect from the population of swine from certified production sites. If the eligible population is not listed in table 1, the next largest number will be used to determine the number of samples to collect. Select the number of samples to collect from the column that reflects a 99 percent confidence level of detecting a positive carcass in the population. The number selected from table 1 will be the total number of samples that slaughter facility representatives must collect and test per year and per month during the selected 12-month period.

TABLE 1.—TRICHINAE CERTIFICATION SLAUGHTER FACILITY SAMPLE SIZE DETERMINATION

Certified swine from certified production sites processed per slaughter facility per year	Samples to collect from the population per year at a 99 percent confidence level	Samples to collect from the population per month at a 99 percent confidence level
1,000 .....	1,000	84
5,000 .....	4,996	417
25,000 .....	18,938	1,578
100,000 .....	29,828	2,486
200,000 .....	32,462	2,705
400,000 .....	33,899	2,825
1,000,000 .....	34,802	2,900
2,000,000 .....	35,110	2,926
4,000,000 .....	35,266	2,939
5,000,000 .....	35,297	2,942

(iv) For each sample collected, slaughter facility representatives must maintain the identity of the sample using the TIN of the certified production site that was the source of the swine from which the sample was taken.

(v) FSIS program employees at the slaughter facility will review and verify that an adequate number of samples have been collected and that proper frequency of collection is maintained. FSIS will report this information to APHIS.

(vi) AMS representatives will verify through a laboratory approval audit that the laboratory performing process-verification testing is correctly following written procedures relating to the receipt, handling, identification, and testing of samples. These written procedures must be maintained by the laboratory in a quality assurance manual, as provided in paragraph (c)(6) of this section. In addition, a laboratory that performs process-verification

testing at a location other than the slaughter facility must include a declaration of methodology used to test samples when providing test results.

(vii) The APHIS Administrator may, at APHIS' expense, periodically request that testing be performed on swine brought to the slaughter facility from specific certified production sites. Requests to test swine from specific certified production sites will count towards the slaughter facility's total monthly testing requirement.

<sup>4</sup> A copy of the testing methods and checklist for conducting validated tests may be obtained by contacting the Trichinae Program Manager, USDA, AMS, Science and Technology, Technical Services

Branch, 1400 Independence Avenue, SW., Mail Stop 0272, Washington, DC 20250-0272; or by telephone at (202) 690-0621.

<sup>5</sup> A copy of the AMS Trichinae Accredited Laboratory Program Requirements may be obtained by contacting the Trichinae Program Manager (see footnote 3).

(4) *Results of testing.* (i) The results of all process-verification testing relating to certified swine handled at the slaughter facility must be retained in a separate file or notebook as written records at the slaughter facility and must be readily available for inspection by FSIS program employees.

(ii) FSIS will report to APHIS the results of all process-verification testing.

(iii) In the event of a positive test result, the slaughter facility representative must notify the FSIS program employee designated by the FSIS Administrator immediately, who in turn will report the TIN of the certified production site that was the source of the swine from which the sample was taken and the test results of the affected sample to the respective APHIS area office. The following sequence of events must take place following a positive test result:

(A) If a test sample yields a positive test result based on the digestion method, the certified production site that was the source of the swine from which the sample was taken will be decertified.

(B) If a test sample yields a positive test result based on an ELISA method and is confirmed positive by further testing using the digestion method, the certified production site that was the source of the swine from which the sample was taken will be decertified.

(C) If a test sample yields a positive test result based on an ELISA method, but is not confirmed positive by further testing using the digestion method, then the certified production site that was the source of the swine from which the sample was taken will be investigated by APHIS.

(1) The investigation may include a spot audit of the affected site. Further testing of animals or carcasses from the affected site also may be performed as part of the investigation. This investigation would determine if the production facility has sufficient safeguards and is following good production practices.

(2) While the affected site is under investigation, its program status as a certified production site will be suspended. While the site is under suspension, the producer must continue to adhere to all of the required good production practices and other recordkeeping and program requirements provided in this part; however, swine from the suspended site cannot be identified as product from a certified production site. The Administrator will determine the program status of the affected site within 30 days of the initiation of the suspension.

(3) A finding that risk factors are inadequately addressed in the site investigation or the finding of additional positive test results based on samples from animals or carcasses from the affected site will be grounds for APHIS decertification of the site.

(5) *Slaughter facility recordkeeping.* (i) All slaughter facilities that receive certified swine must maintain records relating to such animals, including the number of certified swine processed, the source of the certified swine, including the TIN of the certified production site from which the swine came from, and all test results relating to process-verification testing. Records relating to certified swine must be retained at the slaughter facility for a period of at least 3 years following the processing of such animals.

(ii) All slaughter facilities must have documented procedures on how certified swine under its control, and edible pork products derived from certified swine, will remain segregated from swine and edible pork products from noncertified sites throughout receiving, handling, and processing at the facility, as well as while awaiting shipment from the facility. The slaughter facility must also have documented procedures for maintaining the identity of the certified swine or pork with respect to the certified production site from which it came.

(iii) All such records and other documentation required to be maintained by slaughter facilities under this part must be readily available for inspection by FSIS program employees.

(6) *Approved laboratory recordkeeping.* Approved laboratories must have written procedures that specify standards for sample size, sample handling, sample identification, and sample test methods used in process-verification testing. All such written procedures must be maintained in a laboratory quality assurance manual specifically for this program, or as a separate section of an existing laboratory quality assurance manual, and must be retained at the approved laboratory throughout the time the approved laboratory is performing process-verification testing under this program. All such written procedures relating to process-verification testing must be readily available for inspection by FSIS program employees or AMS representatives.

(7) *Slaughter facility overall responsibility for process-verification testing.* The slaughter facility is responsible for obtaining testable samples and for ensuring that the correct number of testable samples are sent to the testing laboratory. Once the

slaughtering facility receives the test results, it is responsible for reporting those results in its facility trichinae testing record. Moreover, the slaughter facility is responsible for ensuring that process-verification testing is carried out in accordance with this part, including the reporting of test results, regardless of whether it is performed at the slaughter facility or another location, and regardless of whether the testing is performed by slaughter facility personnel or other persons.

#### **§ 149.7 Recordkeeping at site.**

(a) Stage I enrolled sites, Stage II or Stage III certified sites, and any site that has been suspended or voluntarily decertified must maintain the following program records: Animal disposal plan, animal movement record, feed mill quality assurance affidavit (if applicable), rodent control logbook, and waste feeding logbook (if applicable). All such records must be readily available for inspection at the pork production site at the time of an audit by a QAV or QVMO, or by other APHIS representatives during normal business hours.

(1) *Animal disposal plan.* The animal disposal plan must meet the following minimum requirements:

(i) It must provide for the removal of all dead swine or swine remains from swine pens immediately upon detection. Inspections for purposes of detecting dead animals must occur at least once every 24 hours.

(ii) It must specify how often and at what intervals the swine pens are observed each day.

(iii) It must provide for the proper storage of dead swine or swine remains in accordance with local, State, and Federal laws and regulations. If the carcass storage facility or composting facility is located on the site, then the animal disposal plan must provide for a storage or composting facility that precludes rodent or wildlife contact with dead swine or swine remains being stored or composted.

(iv) It must provide for the disposal of swine and other mammals by rendering, incineration, composting, burial, or other means, as allowed by and in accordance with local, State, and Federal laws and regulations. For sites that use rendering services, the animal disposal plan also must include the name, address, and phone number of the renderer.

(v) It must be updated as animal disposal practices are changed at the site.

(vi) It must be signed and dated by the producer, as well as the caretaker of the

site (if the caretaker is a different person than the producer).

(vii) It may be valid for a period no longer than 2 years after the date of signature by the producer and (if applicable) the site caretaker.

(2) *Animal movement record.* The animal movement record must meet the following minimum requirements:

(i) It must be filled out completely and properly, accounting for the movement of all non-breeding swine into and from the pork production site.

(ii) In the case of non-breeding swine coming into the site, it must include the date and number of arriving animals, as well as the TIN of the certified production site where the animals originated, or alternatively, if the swine are less than 5 weeks of age and originated from a noncertified site, the name and full address of the noncertified site where the animals originated. The animal movement record must clearly document that all non-breeding swine 5 weeks of age or older arriving at the site originated from another certified production site.

(iii) In the case of non-breeding swine leaving the site, it must include the date and number of departing animals, and their destination.

(iv) It must document the number of dead non-breeding swine that are removed from the site, as well as the number of dead non-breeding swine that are buried or composted at the site, if swine burial or composting is permitted in that State or locality.

(v) All entries to the animal movement record must be signed or initialed and dated by the producer or other site caretaker making the entry.

(3) *Rodent control logbook.* The rodent control logbook, which may include records from a pest control operator, must meet the following minimum requirements:

(i) It must include a rodent control diagram for the site indicating the location of all rodent bait stations and rodent traps at the site. The diagram must be updated whenever bait stations are added, moved, or removed.

(ii) It must document the number of rodent traps set (if applicable), the number of new rodent bait stations set, and how often bait is refreshed.

(iii) It must document the disposal method for all unused bait that is replaced.

(iv) It must document the brand name and active ingredient of bait, which must be EPA registered and applied according to its label, as well as the quantity of bait used (number of pounds).

(v) If possible, it should document the number of rodents caught or killed and indicate how many were rats.

(vi) If possible, it should document the number of rats sighted monthly.

(vii) All entries to the rodent control logbook must be signed or initialed, as well as dated by the producer or other site caretaker making the entry. It must be updated at least monthly.

(4) *Feed mill quality assurance affidavit.* The feed mill quality assurance affidavit, to be used in conjunction with feed or feed ingredients delivered to the pork production site, must meet the following minimum requirements:

(i) It must include the name of the producer and the identity of the site, including the TIN if it has been issued, and the site address, as well as the name and address of the feed mill and the name and title of the feed mill representative.

(ii) It must provide that the feed mill is following good manufacturing practices, and further specify, as evidence of these good manufacturing practices, the following:

(A) That the feed mill has a rodent control system that is maintained by the feed mill itself or by a pest control firm (include name and address of pest control firm).

(B) The frequency with which such rodent control system is maintained (*i.e.*, on a weekly basis, etc.); and

(C) That the feed mill maintains records of pest management practices or has records generated by a pest control operator, which must be made available to the producer upon request.

(iii) It must be signed by the feed mill representative and by the producer or the producer's designated representative, to remain in effect for a period of 2 years.

(5) *Waste feeding logbook.* If the producer feeds meat-containing food waste to swine at the site, the producer must maintain a waste feeding logbook that meets the following minimum requirements:

(i) It must include the name of the producer and the identity of the site, including the TIN if it has been issued, the site address, and the number of the license or permit authorizing the feeding of such waste to swine.

(ii) It must be kept up-to-date with documentation evidencing adherence to applicable State and Federal food waste feeding laws and regulations.

(iii) It must provide information as to the method used in cooking the meat-containing food waste.

(iv) For each batch of meat-containing food waste cooked, it must record the batch number (if applicable to the

operation), the temperature at which such food waste is cooked and the length of time it is held at that temperature, and the method for verifying the temperature and length of time cooked.

(v) For each batch of meat-containing food waste cooked, it must document the sources of meat.

(vi) It must evaluate and document on at least a monthly basis the level of sanitation of the site, taking into account the following factors:

(A) Whether garbage containers are clean and covered with lids;

(B) Sanitation of cooking area and equipment;

(C) Sanitation of feeding areas and waste disposal;

(D) Sanitation of storage areas;

(E) Rodent control system around equipment, storage, and feeding areas;

(F) Sanitation of waste hauling trucks or containers;

(G) Access of other animal species to food waste (wild animals, dogs, cats, etc.); and

(H) The potential for cross-contamination between cooked product and raw meat-containing food waste.

(vii) All entries to the waste feeding logbook must be signed or initialed, as well as dated, by the producer or other site caretaker making the entry.

(b) All such records and other documentation required under this section must be retained at the pork production site for a period of 2 years.

(c) All such records and other documentation required under this section must be readily available for inspection at the pork production site at the time of an audit by a QAV or QVMO, or by other APHIS representatives during normal business hours.

#### § 149.8 Program fees and charges.

(a) *Site audit.* The producer is responsible for the cost of each site audit performed at the pork production site.

(1) If a QAV performs the site audit, then the producer will pay the QAV directly at a mutually agreed-upon time and rate.

(2) If a QVMO performs the site audit, then the producer will pay the QVMO at the time the site audit is performed in accordance with the rate and other conditions set by the QVMO's governmental employer. Further, if the QVMO who performs the site audit is employed by APHIS, then the producer will pay APHIS for this service at the hourly rate listed in table 2 for each employee required to perform the service. If the APHIS-employed QVMO performs the site audit on a Sunday, on

a holiday, or at any time outside the normal tour of duty of that employee, then the producer will pay APHIS for this service at the hourly rate listed in table 3 for each employee required to perform the service. Payment to APHIS for the services of an APHIS-employed QVMO, by certified check or U.S. money order, must be remitted to the QVMO at the time the site audit is performed.

TABLE 2.—RATES FOR SERVICES OF QVMO

	Beginning Oct. 1, 2003
Hourly rate:	
Per hour .....	\$84.00
Per quarter hour .....	21.00
Per service minimum fee	25.00

TABLE 3.—OVERTIME RATES FOR SERVICES OF QVMO (OUTSIDE THE EMPLOYEE'S NORMAL TOUR OF DUTY)

	Beginning Oct. 1, 2003
Premium hourly rate Monday through Saturday and holidays:	
Per hour .....	\$100.00
Per quarter hour .....	25.00
Premium hourly rate for Sundays:	
Per hour .....	112.00
Per quarter hour .....	28.00

(b) *Program fee.* The producer must pay APHIS a program fee at the time of each site audit in the amount of \$51 to cover APHIS' administrative costs in processing the audit and operating the

program. This program fee, payable to APHIS by certified check or U.S. money order, is due at the time of submitting the completed site audit form for APHIS evaluation.

(c) A producer will not be charged for the cost of having a spot audit performed at the pork production site.

**§ 149.9 Pilot program sites.**

Pork production sites participating in an APHIS-approved trichinae pilot program at the time of implementation of the Trichinae Certification Program on [effective date of final rule] will maintain their same program status as either a Stage I enrolled, Stage II certified, or Stage III certified site, as well as their same program anniversary date for purposes of completing a site audit and submitting the completed audit form and payment.

**PART 160—DEFINITION OF TERMS**

3. The authority citation for part 160 would continue to read as follows:

**Authority:** 7 U.S.C. 8301–8317; 15 U.S.C. 1828; 7 CFR 2.22, 2.80, and 371.4.

4. In § 160.1, a new definition would be added, in alphabetical order, for *qualified accredited veterinarian (QAV)* to read as follows:

**§ 160.1 Definitions.**

\* \* \* \* \*

*Qualified accredited veterinarian (QAV).* An accredited veterinarian who has been granted an accreditation specialization by the Administrator pursuant to § 161.5 of this subchapter based on completion of an APHIS-approved orientation or training program.

\* \* \* \* \*

**PART 161—REQUIREMENTS AND STANDARDS FOR ACCREDITED VETERINARIANS AND SUSPENSION OR REVOCATION OF SUCH ACCREDITATION**

5. The authority citation for part 161 would continue to read as follows:

**Authority:** 7 U.S.C. 8301–8317; 15 U.S.C. 1828; 7 CFR 2.22, 2.80, and 371.4.

6. Section 161.5 would be added to read as follows:

**§ 161.5 Specialization.**

An accreditation specialization recognized by the Administrator may be granted to an accredited veterinarian upon completion of an orientation or training program approved by APHIS. For certain accredited specializations, the cost of orientation or training may be borne by the accredited veterinarian. An accredited veterinarian granted an accreditation specialization will be referred to as a qualified accredited veterinarian or QAV. A QAV will be authorized to perform those activities and functions specifically provided for elsewhere in this chapter, for example, in part 149.<sup>1</sup>

Done in Washington, DC, this 7th day of May 2007.

**Bruce Knight,**

*Under Secretary for Marketing and Regulatory Programs.*

[FR Doc. E7–9236 Filed 5–15–07; 8:45 am]

**BILLING CODE 3410–34–P**

<sup>1</sup> For further information on accreditation specializations, including training requirements and fees, contact the National Veterinary Accreditation Program, VS, APHIS, 4700 River Road Unit 46, Riverdale, MD 20737, phone (301) 734–6188.