response. Each sample tested will be reported as positive or negative, and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value. A completed worksheet for diagnostic test evaluation is required to be submitted with the compiled output data and may be obtained by contacting the NPIP Senior Coordinator. Data and the completed worksheet for diagnostic test evaluation must be submitted to the NPIP Senior Coordinator 4 months prior to the next scheduled General Conference Committee meeting, which is when approval will be sought.

(5) The findings of the cooperating laboratories will be evaluated by the NPIP Technical Committee, and the Technical Committee will make a majority recommendation whether to approve the test kit to the General Conference Committee at the next scheduled General Conference Committee meeting. If the Technical Committee recommends approval, the final approval will be granted in accordance with the procedures described in §§ 147.46, 147.47, and 147.48.

(6) Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) and that have been approved for use in the NPIP in accordance with this section are listed in the NPIP Program Standards.

(b) *Approved tests modification and removal.* (1) The specific data required for modifications of previously approved tests will be taken on a case-by-case basis by the technical committee.

(2) If the Technical Committee determines that only additional field data is needed at the time of submission for a modification of a previously approved test, allow for a conditional approval for 60 days for data collection side-by-side with a current test. The submitting party must provide complete protocol and study design, including criteria for pass/fail to the Technical Committee. The Technical Committee must review the data prior to final approval. This would only apply to the specific situation where a modified test needs additional field data with poultry to be approved.

(3) Approved diagnostic tests may be removed from the Plan by submission of a proposed change from a participant, Official State Agency, the Department, or other interested person or industry organization. The data in support of removing an approved test will be compiled and evaluated by the NPIP Technical Committee, and the Technical Committee will make a majority recommendation whether to remove the test kit to the General Conference Committee at the next scheduled General Conference Committee meeting. If the Technical Committee recommends removal, the final decision to remove the test will be granted in accordance with the procedures described in §§ 147.46, 147.47, and 147.48.

[81 FR 53251, Aug. 12, 2016, as amended at 83 FR 28356, June 19, 2018]

PART 149—VOLUNTARY TRICHINAE CERTIFICATION PROGRAM

Sec.

AUTHORITY: 7 U.S.C. 1622 and 8301–8317; 21 U.S.C. 136a; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 73 FR 60479, Oct. 10, 2008, unless otherwise noted.

§ 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 foreign 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 Program 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.[1]

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.

Confinement unit. A structure on a pork production site in which swine are housed and fed that is totally roofed and that is constructed in such a manner as to prevent swine from being exposed to free-flying birds and other wildlife, and from coming into contact with the carrion of free-flying birds or other wildlife.

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* spp. 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 Inspection

[1] 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.

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* spp.

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

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* spp. 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 confinement unit.

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

Premises Identification Number (PIN). A number assigned to a pork production site by the APHIS Administrator.

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* spp. 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 a program certification by the APHIS Administrator pursuant to §161.5 of this chapter based on completion of an APHIS-approved 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.[2]

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* spp.

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.

[2] Accredited veterinarians interested in obtaining program certification related to the Trichinae Certification Program should contact APHIS' National Trichinae Coordinator at (515) 284–4122 or write to: USDA, APHIS, Veterinary Services, Trichinae Certification Program, 210 Walnut St., Room 891, Des Moines, IA 50309.

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 the confinement unit 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* spp.

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* spp.

Trichinella spp. Parasitic nematodes (roundworms) 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* spp. 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.

[73 FR 60479, Oct. 10, 2008, as amended at 74 FR 65010, Dec. 9, 2009]

§ 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 be subject to a review by APHIS to consider the nature of the infraction(s), and may 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 products 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 subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in paragraph (e)(1) of this section. During the time a site is decertified, swine from that site cannot be identified as certified products 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) In order to maintain Stage III certified status, sites must arrange for site audits to renew such status according to the timetable set forth in §149.3(f). Under §149.3(f), 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 status was last renewed.

(5) 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 subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in paragraph (e)(1) of this section. During the time a site is decertified, swine from that site cannot be identified as certified products 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.* When a change of ownership occurs at a Stage II or Stage III certified site, the previous owner of the site must notify APHIS of this change as soon as the transaction is finalized. Within 60 days of this notification, 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 this notification, otherwise the site may be subject to decertification, in accordance with paragraph (e)(1) of this section. If the site audit is satisfactory, then the Stage II or Stage III certified site will continue in the program, initially as a Stage II certified site. However, 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, and the producer of the site must arrange for a site audit to gain (or regain) Stage III certified status based on that new anniversary date and according to the timetable prescribed in §149.3(e). If the results of the site audit do not meet program requirements, the Stage II or Stage III site will be subject to a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in paragraph (e)(1) of this section. 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 of the good production practices as a result of a site 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 subject to a review by APHIS to consider the nature of the infraction(s) and to determine whether the site should be decertified. Decertification will result from infraction(s) that APHIS determines to be substantive, prolonged, and/or repeated as a result of this review.

(ii) During the time a site is decertified, swine from such sites cannot be identified as certified products 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 products 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, including documentation in the animal movement record of the arrival and departure of all swine from this site, as well as whether the swine arriving at the site are from certified or noncertified sources, unless a program requirement is specifically waived by the Administrator.

(iv) If granted a waiver by the Administrator, a producer may receive swine 5 weeks of age or older originating from a noncertified source during the period of withdrawal.

(v) Before being reinstated as a certified production site, the temporarily withdrawn site must pass a site audit to indicate that it is now adhering to all good production practices (including any practices waived by the Administrator at the beginning of the period of withdrawal) 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 a noncertified source have been 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 a noncertified source 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 now 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, or, if the period of temporary withdrawal has exceeded 180 days, then the site will be subject to a review by APHIS to consider the nature of the infraction(s) and to determine whether to decertify the site, as provided in paragraph (e)(1) of this section. 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 or QVMO 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.* If a QAV is not available to perform a site audit, the producer must 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* spp.

(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) 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 possible 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 substantively 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* spp. 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 PIN 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 mill quality assurance affidavit, as provided in §149.7.

(4) Swine at the site must be housed and fed in a confinement unit. The confinement unit, feed preparation and storage areas, and office areas and connecting hallways at the site must be inspected regularly and found free of signs of rodent and wildlife activity (evidence of rodent activity 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). 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., equipment) must be checked for signs of rodent or wildlife activity. In addition, domesticated animals, including pets such as dogs and cats, must be excluded from the confinement unit and feed preparation and storage areas at the site. Exterior rodent bait stations and/or traps must be placed around the perimeter of the confinement unit. Exterior rodent bait stations and/or traps also must be placed around areas of potential rodent entry into the confinement unit (*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 the confinement unit. 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., equipment, 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 as 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 dead or live wildlife at the site. Dead or live wildlife must not be intentionally fed to swine.

(7) Swine at the site must not be fed waste that contains meat.

(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.[3] When the producer and the producer's herd health personnel believe that a site meets program standards, the producer must 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 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 be subject to a review by APHIS to consider the nature of the infraction(s), and may lose its status as a Stage I 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 a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in § 149.2(e)(1).

(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 the that 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.

[3] 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.*

(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 as a 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 a review by APHIS to consider the nature of the infraction(s) and determine whether to decertify the site, as provided in §149.2(e)(1).

(Approved by the Office of Management and Budget under control number 0579–0323)

§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 a review by APHIS to consider the nature of the infraction and to determine whether to decertify the site, as provided in §149.2(e)(1). Unless a spot audit results in decertification, it does not otherwise affect the timetables for the completion of site audits set forth in paragraphs (e) and (f) of §149.3.

§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 to determine the *Trichinella* spp. infection status of certified swine under its control as follows:

(1) *Validated tests.* Process-verification testing must be performed by using a validated test. When testing involves meat, the sample used for such testing must be at least 20 grams.[4]

(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).[5] 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 on the Internet at *http://www.aphis.usda.gov/vs/trichinae* to find the number of samples to collect from the population of swine from certified production sites.[6] If the eligible

[4] A copy of the testing methods and checklist for conducting validated tests may be obtained by contacting the AMS Trichinae Analyst and Laboratory Certification Program Manager, USDA, AMS, Science and Technology Programs, Technical Services Branch, 1400 Independence Ave., SW., Mail Stop 0272, Washington, DC 20250–0272. The manager may be contacted by phone at (202) 690–0621.

[5] A copy of the AMS Trichinae Accredited Laboratory Program Requirements may be obtained by contacting the AMS Trichinae Analyst and Laboratory Certification Program Manager (see footnote 4).

[6] More information regarding sampling sizes may be obtained by writing to USDA,

Continued

population is not listed in that table, 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 on that table that reflects a 99 percent confidence level of detecting a positive carcass in a population with a prevalence rate of 0.013 percent. The number selected from the table 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.

(iv) For each sample collected, slaughter facility representatives must maintain the identity of the sample using the PIN 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.

(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 PIN 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

APHIS, Veterinary Services, Trichinae Certification Program, 210 Walnut St., Room 891, Des Moines, IA 50309.

this part. During this suspension, swine at the site may be sent to slaughter; 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 PIN 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), and rodent control logbook. 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 PIN 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 PIN 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 information 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.

(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.

(Approved by the Office of Management and Budget under control number 0579–0323)

§ 149.8 Program fees and charges.

(a) *Site audit.* 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 1 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 2 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 1—RATES FOR SERVICES OF QVMO

Hourly rate:	
Per hour	$84.00
Per quarter hour	21.00
Per service minimum fee	25.00

TABLE 2—OVERTIME RATES FOR SERVICES OF QVMO (OUTSIDE THE EMPLOYEE'S NORMAL TOUR OF DUTY)

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 November 10, 2008 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.