

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(v) Before being reinstated as a certified production site, the temporarily withdrawn site must pass a site audit to indicate that it is now adhering to all good production practices (including any practices waived by the Administrator at the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the site is now adhering to good production practices and other program requirements provided in this part, then the withdrawn site will be reinstated as a Stage II certified site.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 respon-

sibility 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

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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 off-site 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

³The 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>.

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.

(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).

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§ 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