

#### § 149.4

(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

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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.<sup>4</sup>

<sup>4</sup>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.

(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 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.<sup>6</sup> If the eligible

<sup>5</sup>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).

<sup>6</sup>More information regarding sampling sizes may be obtained by writing to USDA,

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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 sec-

tion 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.