

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.

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§ 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