

Agency that the participating slaughter plant is in compliance with the provisions of this part. The yearly audit will consist of an evaluation of 2 weeks' worth of records, selected at random, of the following data:

(1) The actual flock slaughter date for each flock. This information must come from a verifiable source. Verifiable sources include electronic record systems that have oversight from the Department's Grain Inspectors, Packers and Stockyards Administration or Food Safety and Inspection Service (FSIS) documents such as FSIS Form 9061-2.

(2) Laboratory test results for each flock slaughtered with the sample collection date and test result. The test must be NPIP-approved and performed in an authorized laboratory of the NPIP.

(b) A flock will be considered to be not conforming to protocol if there are no test results available, if the flock was not tested within 21 days before slaughter, or if the test results for the flocks were not returned before slaughter.

(c) Two or more flocks that are found to be not conforming to protocol in the yearly audit for a slaughter plant shall be cause for a deficiency rating for that plant. However, if the root cause for the deficiency was identified, corrected, and documented, the plant will be eligible for an immediate reevaluation of 2 additional weeks' worth of records, again selected at random. If no more than one missed flock is identified in this reevaluation, the plant will be considered in compliance and no further action will be required. Plants found to be deficient must provide a written corrective action plan to the auditor within 2 weeks of receipt of the deficiency rating. A followup audit on the information in paragraphs (a)(1) and (a)(2) of this section will occur within 90 days from the receipt of the corrective action plan. Slaughter plants will retain their classification and may continue to use the Plan emblem in §146.9(a) during this process. A failure on the followup audit may result in disbarment from participation according to the procedures in §146.12.

(d) On-site inspections of any participating flocks and premises will be con-

ducted if a State Inspector determines that a breach of testing has occurred for the Plan programs for which the flocks are certified.

(e) The official H5/H7 LPAI testing records of all participating flocks and slaughter plants shall be examined annually by a State Inspector. Official H5/H7 LPAI testing records shall be maintained for 3 years.

(Approved by the Office of Management and Budget under control number 0579-0007)

[71 FR 56328, Sept. 26, 2006, as amended at 74 FR 14716, Apr. 1, 2009; 75 FR 10658, Mar. 9, 2010]

§ 146.12 Debarment from participation.

Participants in the Plan who, after investigation by the Official State Agency or its representative, are notified in writing of their apparent non-compliance with the Plan provisions or regulations of the Official State Agency shall be afforded a reasonable time, as specified by the Official State Agency, within which to demonstrate or achieve compliance. If compliance is not demonstrated or achieved within the specified time, the Official State Agency may debar the participant from further participation in the Plan for such period, or indefinitely, as the Official State Agency may deem appropriate. The debarred participant shall be afforded notice of the bases for the debarment and opportunity to present his or her views with respect to the debarment in accordance with procedures adopted by the Official State Agency. The Official State Agency shall thereupon decide whether the debarment order shall continue in effect. Such decision shall be final unless the debarred participant, within 30 days after the issuance of the debarment order, requests the Administrator to determine the eligibility of the debarred participant for participation in the Plan. In such an event, the Administrator shall determine the matter de novo in accordance with the rules of practice in 7 CFR part 50, which are hereby made applicable to proceedings before the Administrator under this section. The definitions in 7 CFR 50.10 and the following definitions shall apply with respect to terms used in such rules of practice:

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(a) *Administrator* means the Administrator, Animal and Plant Health Inspection Service of the U.S. Department of Agriculture, or any officer or employee to whom authority has heretofore been delegated or to who authority may hereafter be delegated to act in his or her stead.

(b) [Reserved]

§ 146.13 Testing.

(a) *Samples*. Either egg or blood samples may be used for testing. Samples must be collected in accordance with the following requirements:

(1) *Egg samples*. Egg samples must be collected and prepared in accordance with part 147 of this subchapter.

(2) *Blood samples*. Blood samples obtained in the slaughter plant should be collected after the kill cut with birds remaining on the kill line. Hold an open 1.5 mL snap cap micro-centrifuge tube under the neck of the bird directly after the kill cut and collect drips of blood until the tube is half full. Keep the blood tubes at room temperature for the clot to form, which should require a minimum of 4 hours and a maximum of 12 hours. Refrigerate the tube after the clot has formed. Put tubes in a container and label it with plant name, date, shift (A.M. or Day, P.M. or Night), and flock number. After the clot is formed, the clot should be removed by the Authorized Agent in order to ensure good-quality sera. Prepare a laboratory submission form and ship samples with submission forms to the laboratory in a polystyrene foam cooler with frozen ice packs. Submission forms and the manner of submission must be approved by the Official State Agency and the authorized laboratory to ensure that there is sufficient information to identify the samples and that the samples are received in an acceptable condition for further tests to be reliably performed. Blood samples should be shipped routinely to the laboratory. Special arrangements should be developed for samples held over the weekend to ensure that the samples can be reliably tested. Blood samples for official tests shall be drawn by an Authorized Agent or State Inspector.

(b) *Avian influenza*. The official tests for avian influenza are described in

paragraphs (b)(1) and (b)(2) of this section:

(1) *Antibody detection tests*—(i) *Enzyme-linked immunosorbent assay (ELISA)*. ELISA must be conducted using test kits approved by the Department and the Official State Agency and must be conducted in accordance with the recommendations of the producer or manufacturer.

(ii) *The agar gel immunodiffusion (AGID) test*. (A) The AGID test must be conducted on all ELISA-positive samples.

(B) The AGID test must be conducted using reagents approved by the Department and the Official State Agency.

(C) The AGID test for avian influenza must be conducted in accordance with part 147 of this subchapter. The test can be conducted on egg yolk or blood samples. The AGID test is not recommended for use in waterfowl.

(D) Positive tests for the AGID must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

(2) *Agent detection tests*. Agent detection tests may be used to detect influenza A matrix gene or protein but not to determine hemagglutinin or neuraminidase subtypes. Samples for this testing should be collected from naturally occurring flock mortality or clinically ill birds.

(i) *The real time reverse transcriptase/polymerase chain reaction (RRT-PCR) assay*. (A) The RRT-PCR tests must be conducted using reagents approved by the Department and the Official State Agency. The RRT-PCR must be conducted using the National Veterinary Services Laboratories (NVSL) official protocol for RRT-PCR and must be conducted by personnel who have passed an NVSL proficiency test.

(B) Positive results from the RRT-PCR must be further tested by Federal Reference Laboratories using appropriate tests for confirmation. Final judgment may be based upon further sampling and appropriate tests for confirmation.

(ii) *USDA-licensed type A influenza antigen capture immunoassay (ACIA)*. (A) The USDA-licensed type A influenza ACIA must be conducted using test