

§ 147.53

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NPIP office of the Service as an authorized laboratory qualified to perform the assays provided for in this part.

(a) *Check-test proficiency.* The NPIP will serve as the lead agency for the coordination of available check tests from the National Veterinary Services Laboratories. The authorized laboratory must use a regularly scheduled check test for each assay that it performs.

(b) *Trained technicians.* The testing procedures at the laboratory must be run or overseen by a laboratory technician who has attended and satisfactorily completed Service-approved laboratory workshops for Plan-specific diseases within the past 4 years.

(c) *Laboratory protocol.* Official Plan assays must be performed and reported as described in the NPIP Program Standards or in accordance with other procedures approved by the Administrator in accordance with §147.53(d)(1). Assays must be performed using control reagents approved by the Plan or the reagent manufacturer.

(d) *State site visit.* The Official State Agency will conduct a site visit and recordkeeping audit annually. This will include, but may not be limited to, review of technician training records, check test proficiency, and test results. The information from the site visit and recordkeeping audit will be made available to the NPIP upon request.

(e) *Service review.* Authorized laboratories will be reviewed by the Service (NPIP staff) every 3 years. The Service's review may include, but will not necessarily be limited to, checking records, laboratory protocol, check-test proficiency, technician training, and peer review.

(f) *Reporting.* (1) A memorandum of understanding or other means shall be used to establish testing and reporting criteria to the Official State Agency, including criteria that provide for reporting H5 and H7 low pathogenic avian influenza directly to the Service.

(2) *Salmonella pullorum* and *Mycoplasma* Plan disease reactors must be reported to the Official State Agency within 48 hours.

(g) *Verification.* Random samples may also be required to be submitted for

verification as specified by the Official State Agency.

§ 147.53 Approved tests and sanitation procedures.

(a)(1) All tests that are used to qualify flocks for NPIP classifications must be approved by the Administrator as effective and accurate at determining whether a disease is present in a poultry flock or in the environment.

(2) All sanitation procedures performed as part of qualifying for an NPIP classification must be approved by the Administrator as effective at reducing the risk of incidence of disease in a poultry flock or hatchery.

(b) Tests and sanitation procedures that have been approved by the Administrator may be found in the NPIP Program Standards. In addition, all tests that use veterinary biologics (e.g., antiserum and other products of biological origin) that are licensed or produced by the Service and used as described in the NPIP Program Standards are approved for use in the NPIP.

(c) New tests and sanitation procedures, or changes to existing tests and sanitation procedures, that have been approved by the NPIP in accordance with the process described in subpart E of this part are subject to approval by the Administrator. NPIP participants may submit new tests and sanitation procedures, or changes to current tests and sanitation procedures, through that process.

(d)(1) Persons who wish to have a test approved by the Administrator as effective and accurate at determining whether a disease is present in a flock or in the environment may apply for approval by submitting the test, along with any supporting information and data, to the National Poultry Improvement Plan, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094. Upon receipt of such an application, the NPIP Technical Committee will review the test and any supporting information and data supplied with the application. If the NPIP Technical Committee determines the test to be of potential general use, the test will be submitted for consideration by the General Conference Committee of the NPIP in accordance with subpart E of this part, and the Administrator will

respond with approval or denial of the test.

(2) Persons who wish to have a sanitation procedure approved by the Administrator as effective at reducing the risk of incidence of disease in a poultry flock or hatchery may apply for approval by submitting the sanitation procedure, along with any supporting information and data, to the National Poultry Improvement Plan, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094. Upon receipt of such an application, the NPIP Technical Committee will review the sanitation procedure and any supporting information and data supplied with the application. If the NPIP Technical Committee determines the sanitation procedure to be of potential general use, the sanitation procedure will be submitted for consideration by the General Conference Committee of the NPIP in accordance with subpart E of this part, and the Administrator will respond with approval or denial of the test.

(e)(1) When the Administrator approves a new test or sanitation procedure or a change to an existing test or sanitation procedure, APHIS will publish a notice in the FEDERAL REGISTER making available the test or sanitation procedure. The notice will also provide for a public comment period.

(2)(i) After the close of the public comment period, APHIS will publish a notice in the FEDERAL REGISTER indicating that the test or sanitation procedure will be added to the NPIP Program Standards, or that the NPIP Program Standards will be updated to reflect changes to an existing test or sanitation procedure, if:

(A) No comments were received on the notice;

(B) The comments on the notice supported the action described in the notice; or

(C) The comments on the notice were evaluated but did not change the Administrator's determination that approval of the test or sanitation procedure is appropriate based on the standards in paragraph (a) of this section.

(ii) If comments indicate that changes should be made to the test or sanitation procedure as it was made available in the initial notice, APHIS

will publish a notice in the FEDERAL REGISTER indicating that changes were made to the initial test or sanitation procedure.

(iii) Whenever APHIS adds or makes changes to tests or sanitation procedures, APHIS will make available a new version of the NPIP Program Standards that reflects the additions or changes.

(iv) If comments present information that causes the Administrator to determine that approval of the test or sanitation procedure would not be appropriate, APHIS will publish a notice informing the public of this determination after the close of the comment period.

§ 147.54 Approval of diagnostic test kits not licensed by the Service.

Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) may be approved through the following procedure:

(a) The sensitivity of the kit will be estimated in at least three authorized laboratories selected by the Service by testing known positive samples, as determined by the official NPIP procedures found in the NPIP Program Standards or through other procedures approved by the Administrator. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(b) The specificity of the kit will be estimated in at least three authorized laboratories selected by the Service by testing known negative samples, as determined by tests conducted in accordance with the NPIP Program Standards or other procedures approved by the Administrator in accordance with § 147.53(d)(1). If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(c) The kit will be provided to the cooperating laboratories in its final form and include the instructions for use. The cooperating laboratories must perform the assay exactly as stated in the supplied instructions. Each laboratory