



United States Department of Agriculture  
Animal and Plant Health Inspection Service

A Proposal to Standardize and Consolidate the APHIS Laboratory  
Approval Process

January 2014

## **Issue**

The Animal and Plant Health Inspection Service (APHIS) approves animal diagnostic laboratories to conduct disease-specific testing per authority established in Title 9 of the Code of Federal Regulations (9 CFR). Currently, APHIS' authority is based on a composite of multiple, disparate disease-specific regulations. APHIS proposes to consolidate the existing authorities into a single regulation and establish a set of standard procedures to conduct all current diagnostic laboratory approvals.

Consolidating authorities into a single regulation and establishing uniform approval procedures would simplify and clarify the approval process for the numerous laboratories approved by APHIS for multiple disease diagnostics, as well as simplify the monitoring of laboratory approvals. For both diagnostic laboratories and APHIS, consolidating and standardizing the process would create a clearer and more user-friendly approval process, improve efficiency in obtaining approval(s) to conduct testing for single or multiple diseases, reduce the administrative burden associated with both obtaining and tracking laboratory approvals, and simplify the steps required to renew an existing approval.

## **Disease-Specific Laboratory Approval Processes to be Consolidated**

Although disease-specific regulatory authorities for diagnostic laboratory approval evolved independently over time, they contain many similar elements that can readily be consolidated and standardized in a single regulation. Conversely, these disease-specific authorities also contain dissimilar elements that should be standardized to minimize confusion, decrease complexity, and increase efficiency in the overall approval process.

Currently, APHIS laboratory approval processes are established in the following regulations (9 CFR):

- 9 CFR 54 (Scrapie Genotyping)
- 9CFR 75 (Equine Infectious Anemia)
- 9CFR 77 (Tuberculosis)
- 9CFR 78 (Brucellosis)
- 9CFR 80 (Johnes Disease)
- 9CFR 85 (Pseudorabies)
- 9CFR 95 (Contagious Equine Metritis)

Also, guidance documents outline laboratory approval procedures for additional diseases. These include:

- VS Memo 552.5 Approval of Laboratories to Conduct Diagnostic Test for Bovine Tuberculosis
- VS Memo 555.16 Approval of Laboratories to Conduct Tests for Equine Infectious Anemia
- VS Memo 555.8 Approval of Laboratories to Conduct Tests for Bluetongue and Bovine Leukosis
- VS Memo 557.6 Approval of Laboratories to Conduct Official Genotype Tests for Sheep
- VS Memo 558.2 Approval of Laboratories to Conduct Diagnostic Procedures for Contagious Equine Metritis (CEM)
- VS Memo 561.33 Official Diagnostic Tests for Pseudorabies and Laboratories Approved to Conduct Official Serological Tests
- VS Memo 567.2 Approval of Laboratories Conducting Aquatic Animal Pathogen Detection Assays for Export Health Certification
- VS Guidance 15200 Approval of Laboratories to Conduct ELISA Testing for Equine Piroplasmiasis

Specific laboratory approvals covered in the regulations and guidance documents include testing for:

*Anaplasmosis*  
*Aquaculture*  
*Bluetongue*  
*Bovine Leukosis*  
*Brucellosis*  
*Contagious Equine Metritis*  
*Equine Infectious Anemia*  
*Equine Viral Arteritis*  
*Johnes Disease*  
*Pseudorabies (for export)*  
*Equine Piroplasmiasis*  
*Tuberculosis (gamma interferon)*  
*Tuberculosis (histopathology and culture)*  
*Genotyping (ovine)*

### **Structure for Consolidated APHIS Laboratory Approval Process**

APHIS requests comments for the elements needed to formulate a standardized laboratory approval process to be codified in a single regulation. The consolidated regulation could contain elements common to current regulations and guidance documents. Examples of possible elements to be covered include:

*Application Process*  
*Facilities and Inspection Requirements*  
*Reporting Requirements*  
*Accepted Testing Procedures*  
*Training and Proficiency of Personnel*  
*Requirements to Maintain Approval*  
*Terms of Approval*  
*Removal and Appeal Process*

APHIS would attempt to standardize as many of the approval steps as possible when designing the process. Any elements that could not be standardized could be evaluated using disease-specific check lists that also use a format standardized for all diseases. The new process would create a single reference for laboratories seeking APHIS laboratory approval for any applicable disease. The process would also aim to

include flexibility for laboratories to secure additional diagnostic approvals quickly if they are required to facilitate trade and/or ensure the quality of diagnostics for new or emerging diseases.

The National Animal Health Laboratory Network (NAHLN) and the National Poultry Improvement Plan (NPIP) each have their own approval processes for specific diseases. Changing the current approval process for these entities at this time may not be beneficial or efficient; however, comments regarding the inclusion or exclusion of diseases approved by these entities are welcome, as are any comments regarding the possible integration of laboratory approval processes utilized by other entities.

### **Summary**

APHIS proposes to standardize and consolidate the veterinary diagnostic laboratory approval process to simplify regulatory oversight and compliance. Veterinary diagnostics that are regulated by APHIS but are not part of the NAHLN or NPIP would be included in the consolidation. Comments are solicited to help define a standard laboratory approval process. The goal of this initiative is to create a uniform regulation covering topics commonly included in many 9 CFR animal disease-specific regulations and guidance documents. The proposed regulation would increase transparency of the overall approval process and maximize efficiency for both the approved laboratories and the APHIS personnel responsible for overseeing the approval process.