



Laboratory Approval

Support CAHPS and NAHP&S with a flexible and comprehensive APHIS
laboratory approval process

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NVSL has been given the regulatory oversight over laboratory approval for testing of animal diseases as outlined in the 9 CFR 71.22.

§ 71.22 Approval of laboratories to conduct official testing.

- (a) **Approvals.** State, university, and private laboratories must obtain APHIS approval to conduct official testing for those diseases covered by subchapters B, C, and D of this chapter. Laboratories seeking approval must meet the requirements of this section.

▼ Title 9 Animals and Animal Products	Part / Section
▼ Chapter I Animal and Plant Health Inspection Service, Department of Agriculture	1 – 199
▶ Subchapter A Animal Welfare	1 – 12
▶ Subchapter B Cooperative Control and Eradication of Livestock or Poultry Diseases	49 – 56
▶ Subchapter C Interstate Transportation of Animals (Including Poultry) and Animal Products	70 – 89
▶ Subchapter D Exportation and Importation of Animals (Including Poultry) and Animal Products	91 – 99
▶ Subchapter E Viruses, Serums, Toxins, and Analogous Products; Organisms and Vectors	101 – 124

Introduction to APHIS lab approval

- Historically as APHIS oversight of laboratories became needed, each program would develop their own lab approval process with their own SMEs.
- This caused a patchwork of laboratory approvals with different rules.
- Harmonization was clearly needed.
- Proposed rule published in Federal Register in January 2020.
- The draft Program Standards document provides the framework to harmonize laboratory approval processes while allowing for specialization to meet specific program needs.

What does the framework look like?

- All laboratories apply for approval in the same manner.
 - APHIS lab portal (managed by the NAHLN)
 - Requires some enhancements.
- All laboratories are responsible for requesting renewal and must sign/resign each program specific lab approval agreement every 2 years.
 - APHIS Portal will have the ability to send out reminder emails.
 - Laboratories that do not have a current agreement will be removed from the disease specific approval list.
- Program specific agreements outline responsibilities and expectations.
 - Every expectation must be outlined in the agreement. If not in the agreement, we cannot hold the laboratories responsible.
- All laboratories face the same disciplinary process.
 - Probation, suspension, recission.

Oversight

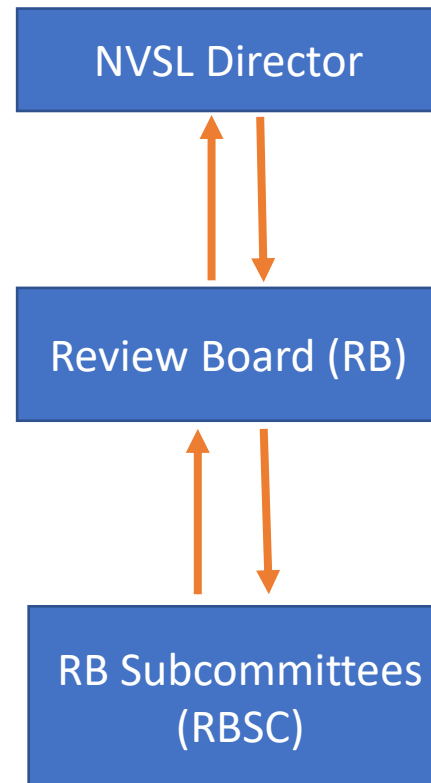
RBSC: (Aquatic Health Team)

Setting the standards

- Subject matter experts that determine and develop the requirements to evaluate lab performance.
- Proposes the disease and test methods to be evaluated
- Determines the ancillary requirements, ie accreditation, inspection
- Oversees NVSL execution of any PTs

Executing the program

- Gathers feedback, complaints and identifies areas of improvement.
- Works with SAHO, AVIC to identify disciplinary actions.
- Ensures laboratories maintain standards and the requirements meet the needs of industry



RB: (VS unit rep Directors)

Oversees all program specific RBSCs.

- Supports harmonization between the program requirements.
- Reviews, recommends to NVSL Director to approve/deny documents submitted to RBSC.
- Reviews disciplinary packets

APHIS Portal is the Key to managing the process with approved labs (update planned FY24)

Lab Customer

- Apply for approval
- Order PTs
- Modify orders until PTs are shipped.
- Manage list of technicians
- Renew approval agreements.
- Ability to request out of band PTs where appropriate.

RB

- Review and approve applications
- Approve PT orders and modifications.
- Removes, suspends labs.
- Emails laboratories with programmatic updates

PT Admin

- Set estimated annual PT schedule
- “Open PT event”
 - Sets exact ship dates.
 - Obtains final kit numbers and shipping list.
 - Closes the event.
- Ships out additional orders within event time frame.

RBSC

- Designs and sets up PT
- Receives results and grades PTs
- Develops Summaries emails those
- Manages SOPs and reference to guidance documents within portal.
- Approves out of band PT requests

Customizing the process for the program

1. Methods available for approval
2. Approval overview/type
3. Testing protocols
4. Training requirements
5. Proficiency test requirements
6. Reporting requirements
7. Facility Inspections
8. Other

The RBSC consisting of NVSL S&P and FiOps SME's will develop these requirements.



1. Methods Available for Approval

- a. Serology – CF, ELISA, etc... test
- b. Isolation/Culture Agent Identification
- c. PCR

2. Approval Overview

- a. Lab approval vs. technician approval
- b. Additional application requirements

3. Testing Protocols

- a. Minimum # of tests, if applicable
- b. Approved protocol(s) requirements, if applicable
- c. Protocol submission and review/approval requirements
- d. Requirement for submitting samples to NVSL for confirmation
- e. Sample retention requirements
- f. Sample requirements (type, age, pooling, etc)
- g. Test component requirements (kit, reagents, etc)



4. Training

- a. Specific training requirements
- b. Lab vs. technician training
- c. Training format (In-person, virtual, other)
- d. Personnel requirements (education, experience, training, other)

5. Proficiency Testing Requirements

- a. Including procedures re: failed PTs
- b. Grading

6. Reporting

- a. Timeframe and distribution of reporting nonnegative results
- b. Requirement for reporting and distribution of all results and numbers of tests
- c. Recordkeeping/retention requirements
- d. Results reporting format, test components, and terminology

7. Facility Inspections

- a. Inspection requirements (yes or no)
- b. Include any additional requirements (see general checklists in program standards)
- c. Frequency of inspections

8. Other

Approved laboratory interaction with APHIS

No National Consequence	Low Consequence	Moderate Consequence/ or Unknown	Highest Consequence
Approved laboratory conducts testing per agreement with minimal requirements	Approved laboratories release final report with terms such as Detected or Positive. Decisions are made based on the results of the approved laboratory even if NVSL is not able to replicate.	Laboratories will be limited to using reporting terms like as “non-negative”, inconclusive (as determined by the program) and will not use “detected or positive” until after NVSL confirmation.	Call APHIS/SAHO with results Do not release a report or inform submitter IMT is formed
No samples sent to NVSL	Sequences or samples are sent to NVSL for characterization only within 1-3 business days.	Samples sent to NVSL next business day as priority two for confirmation and characterization.	Samples sent to NVSL immediately as a priority one. SAHO/AVIC office communicates with producer.
No APHIS supported national sequence database. Good approach to assist with harmonization of test results and demonstration of competency	No VS Field response. Maintains a US National sequence database to help with source attribution and epidemiology.	A field response will be initiated.	Testing and surveillance are closely managed by the program.

Next steps?

- All things hinge on the laboratory agreement.
 - Identify acceptable methods for each disease.
 - Develop the lab agreement addressing topics 1-8.
 - Develop documents needed to guide sampling, collection, post detection response.
- For execution:
 1. Laboratories to sign the program/disease specific agreement.
 2. Conduct a lab inspection
 3. Remediate any deficiencies
 4. Execute the approval