

# General Process for NAHLN Approval

## Initial steps to be completed by the applying laboratory to be considered for approval to the network:

- Complete and submit a Letter of Intent – this document provides preliminary information regarding a laboratory’s participation interest and network readiness.
- NAHLN Program Office, in consultation with representatives from the VS Commodity Health Centers and the NVSL Reference Laboratories, will review individual requests for disease agent approval and determine the status of a laboratory’s request based on surveillance program and national need (approval/denial).
  - *DECISION POINT – Laboratory is notified of request status, based on participation interests and disease program needs*
    - Approved - Proceed to next step
    - Not approved – STOP: Laboratory will not be accepted to network at this time
- Complete and submit the application form (Agreement for Participation in the National Animal Health Laboratory Network (NAHLN)) to the NAHLN Program Office indicating interest to participate in the network, request for specific testing approvals, and agreement to the standards outlined for NAHLN laboratories.
  - Completion of a NAHLN Agreement for Participation is required annually for all network laboratories.
- Provide documentation to the NAHLN Program Office confirming the implementation of a quality management system.
  - Accreditation certificate from accrediting body according to or consistent with ISO 17025 standards, including scope of accredited testing.
  - Completion of the Quality Document Verification Form with copies of the documents listed (this form will be provided by the NAHLN Program Office)
- *DECISION POINT – Documentation is reviewed for sufficient support of a quality management system*
  - Approved – Documentation provides evidence of quality system; proceed to next step
  - Not approved – Gaps in quality documentation are communicated to laboratory; time may be allowed for correction and re-submission
- Work with the NAHLN Program Office to schedule an on-site quality audit
  - *DECISION POINT – Final approval is based on outcome of quality audit*
    - Accepted – Evidence shows that quality system is implemented and effective
    - Not accepted – Gaps and/or concerns identified; time may be allowed for correction and review
- Successful completion of each of the above requirements will qualify a laboratory as eligible for network approval.

# General Process for NAHLN Approval

## Once network approval is granted:

- The NAHLN Program Office will provide the final determination of requested disease approvals back to the laboratory, along with appropriate Standard Operating Procedures (SOPs) and applicable permits.
- Laboratory staff participates in APHIS-sponsored proficiency training and testing for the specific diseases for which your laboratory is approved to test.
- Work with NAHLN Program Office to establish appropriate payment mechanisms, if applicable, for approved disease testing and infrastructure funding.
- Complete the laboratory capability and capacity assessment (current capabilities, resources, commitment by State, and other relevant factors) that will be provided by the NAHLN Program Office. This assessment will be used to determine the appropriate laboratory level:
  - All network laboratories complete this assessment annually during the 3<sup>rd</sup> / 4<sup>th</sup> quarter of each calendar year;
  - APHIS and NIFA will review and verify the information provided in the laboratory Self-Assessments, and other pertinent information;
  - Information from this assessment will be used to establish your laboratory's network level designation for the next fiscal year (Level 1, Level 2, Level 3, Affiliate, or Specialty);
  - Level 1, 2 and 3 laboratories will be eligible for infrastructure support based on the laboratory level designation assigned.