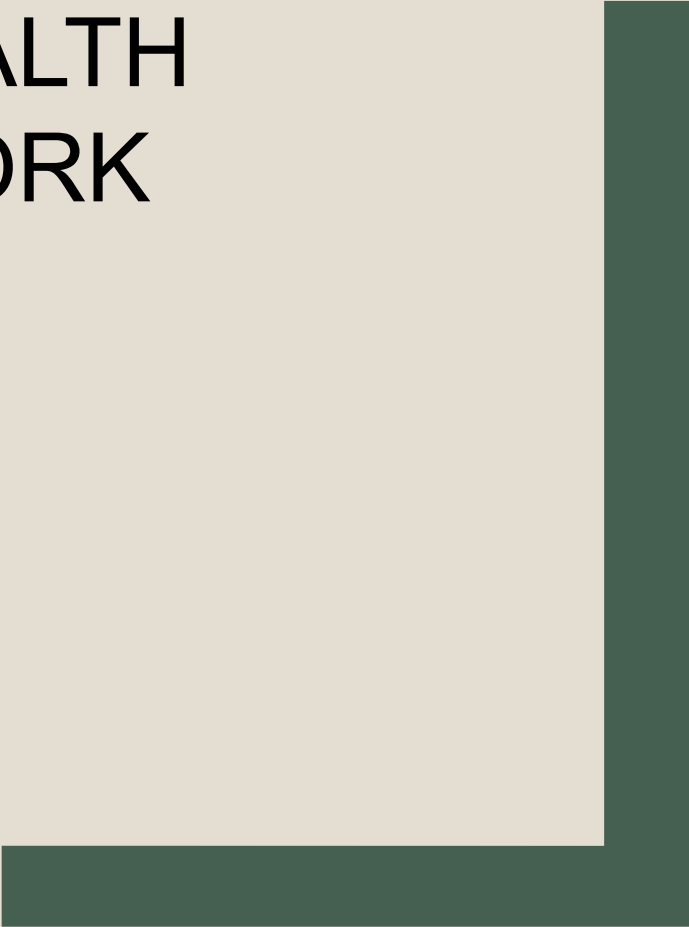




NATIONAL ANIMAL HEALTH LABORATORY NETWORK

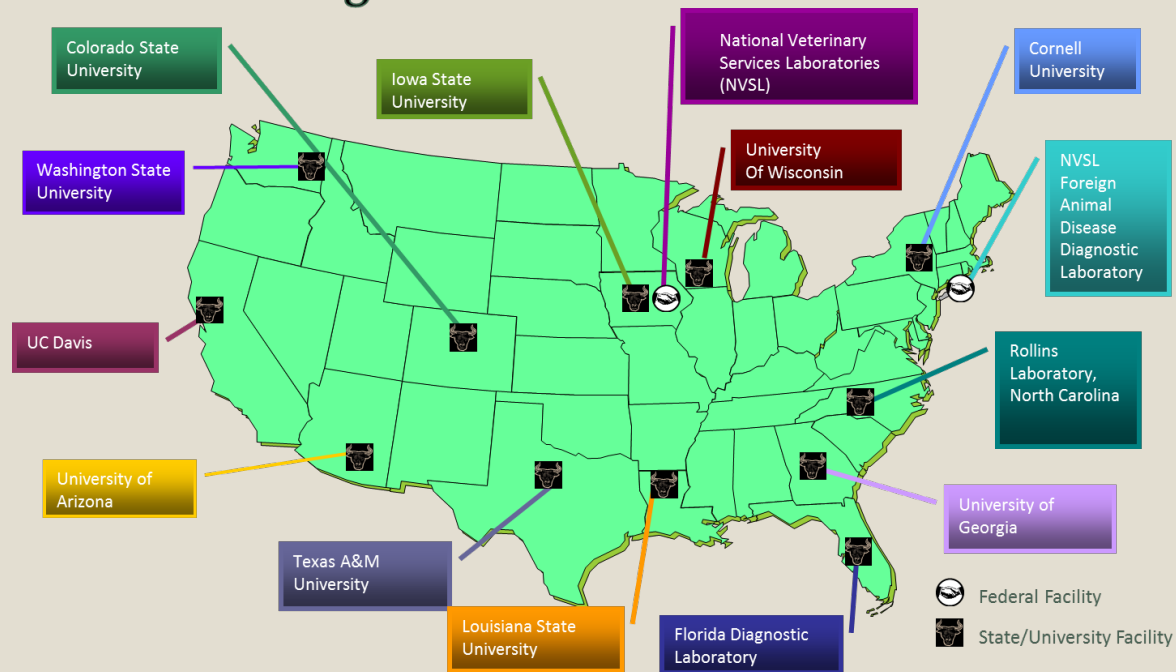
OVERVIEW

2018



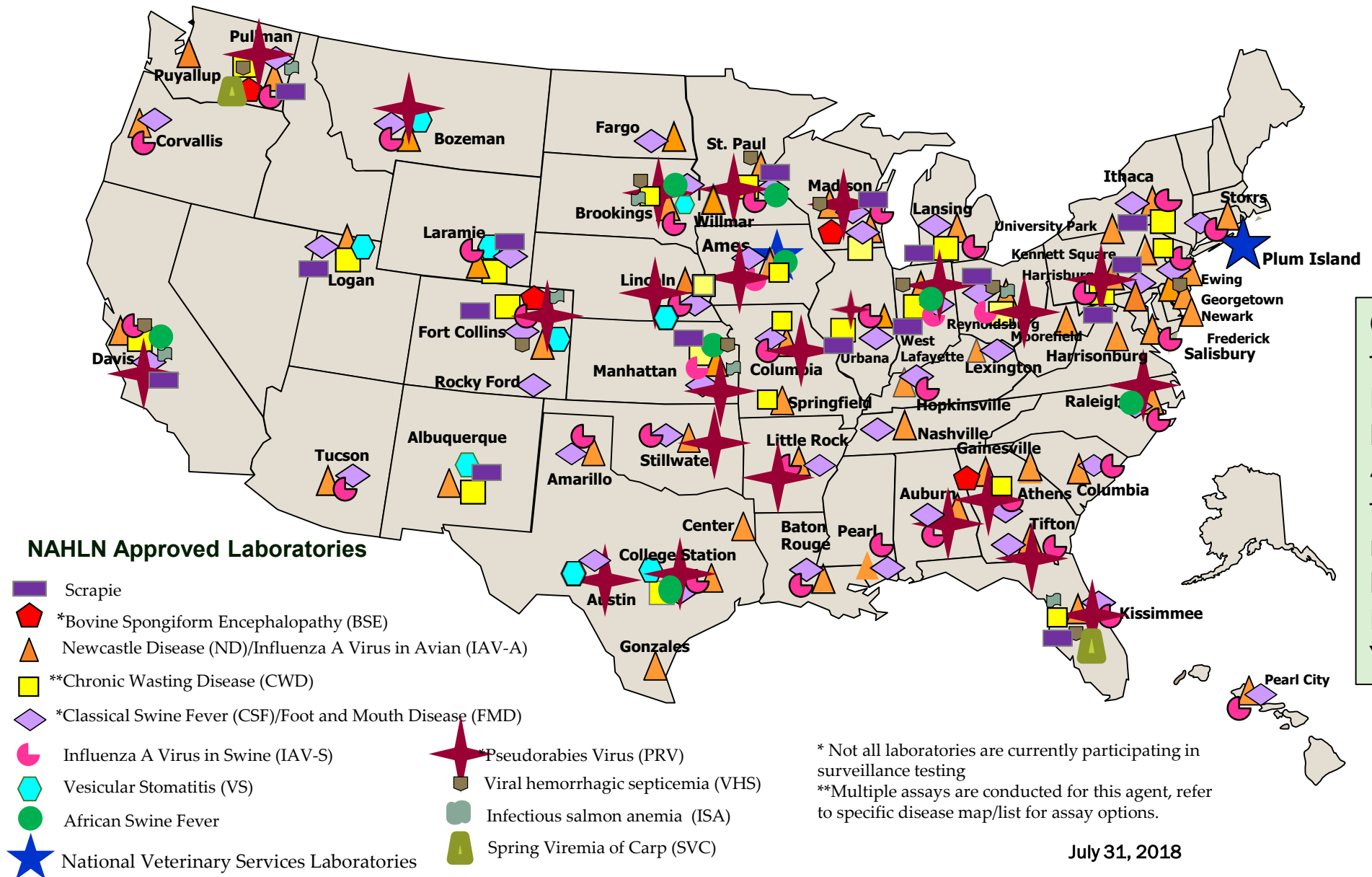
National Animal Health Laboratory Network (NAHLN)

The original 12 NAHLN laboratories



- Formed in 2002
- State, University, and Federal veterinary diagnostic labs that deal with diseases of animals including endemic, exotic, zoonotic, and emerging diseases
- **Partnership** between:
 - USDA (APHIS and NIFA)
 - AAVLD
 - NAHLN Laboratories

National Animal Health Laboratory Network (NAHLN)



Currently there are 59 NAHLN laboratories in 42 states plus the NVSL reference laboratories in Iowa and New York.

NAHLN VISION

The National Animal Health Laboratory Network (NAHLN): a network of animal disease diagnostic laboratories that works effectively as a team, provides ongoing disease surveillance, responds quickly to disease events, communicates diagnostic outcomes to decision makers in a timely manner, and has the capability and capacity to meet diagnostic needs during animal disease outbreaks.

NAHLN MISSION

The NAHLN is a nationally coordinated network and partnership of Federal, State, and university-associated animal health laboratories. NAHLN laboratories provide animal health diagnostic testing, methods research and development, and expertise for education and extension to detect biological threats to the nation's animal agriculture, thus protecting animal health, public health, and the nation's food supply.

Purpose of the NAHLN has remained unchanged since 2002

- Early detection of high-consequence disease
 - *Targeted surveillance based on population density & risk*
- Rapid response following confirmation of disease
 - *Surge capacity to test outbreak samples*
- Appropriate recovery from an outbreak
 - *Large numbers of samples tested to show freedom*

Annual laboratory review and approval process

- ***The Agreement for Participation in the NAHLN is renewed annually***
 - *Annual approval for testing of NAHLN scope diseases of high consequence*
 - *Demonstrates continued adherence to established NAHLN policies and procedures*
- Annual review by VS Program Staff and NVSL reference laboratories
- Successful completion of annual proficiency testing
- Laboratories self-assess providing their capability and capacity
 - *Verification by NAHLN program staff*
 - *Information is used to designate Laboratory Levels*
 - Level 1, Level 2, Level 3, Affiliate, Specialty

Agreement for Participation in the NAHLN

Agent/Disease	Assay	Please list the location(s) requesting approval
African Swine Fever	<input type="checkbox"/> Real time PCR	
Avian influenza / Newcastle disease *	<input type="checkbox"/> Real time PCR	
Bovine spongiform encephalopathy	<input type="checkbox"/> ELISA	
Classical swine fever	<input type="checkbox"/> Real time PCR	
Chronic wasting disease	<input type="checkbox"/> ELISA	
	<input type="checkbox"/> Immunohistochemistry (IHC)	
Foot and mouth disease	<input type="checkbox"/> Real time PCR	
Infectious salmon anemia virus	<input type="checkbox"/> Real-time PCR	
	<input type="checkbox"/> Conventional PCR	
Pseudorabies virus	Primary screen (select one)	
	<input type="checkbox"/> PRV gB ELISA	
	<input type="checkbox"/> automated latex	
Scrapie	Secondary screen	
	<input type="checkbox"/> PRV g1 ELISA	
Scrapie	<input type="checkbox"/> Immunohistochemistry (IHC)	
Spring Viremia of Carp	<input type="checkbox"/> Real time PCR	
Swine influenza virus	<input type="checkbox"/> Real time PCR – Matrix	
	<input type="checkbox"/> Real time PCR – Subtyping	
	<input type="checkbox"/> Virus Isolation (VI)	
	<input type="checkbox"/> Sequencing	
Vesicular stomatitis**	<input type="checkbox"/> Complement fixation (CF)	
	<input type="checkbox"/> Real-time PCR	
Viral hemorrhagic septicemia virus	<input type="checkbox"/> Real-time PCR	
	<input type="checkbox"/> Virus isolation (VI)	

Note: Agents/diseases or assays may be added or removed from the above list based on program needs.

Areas of the Agreement

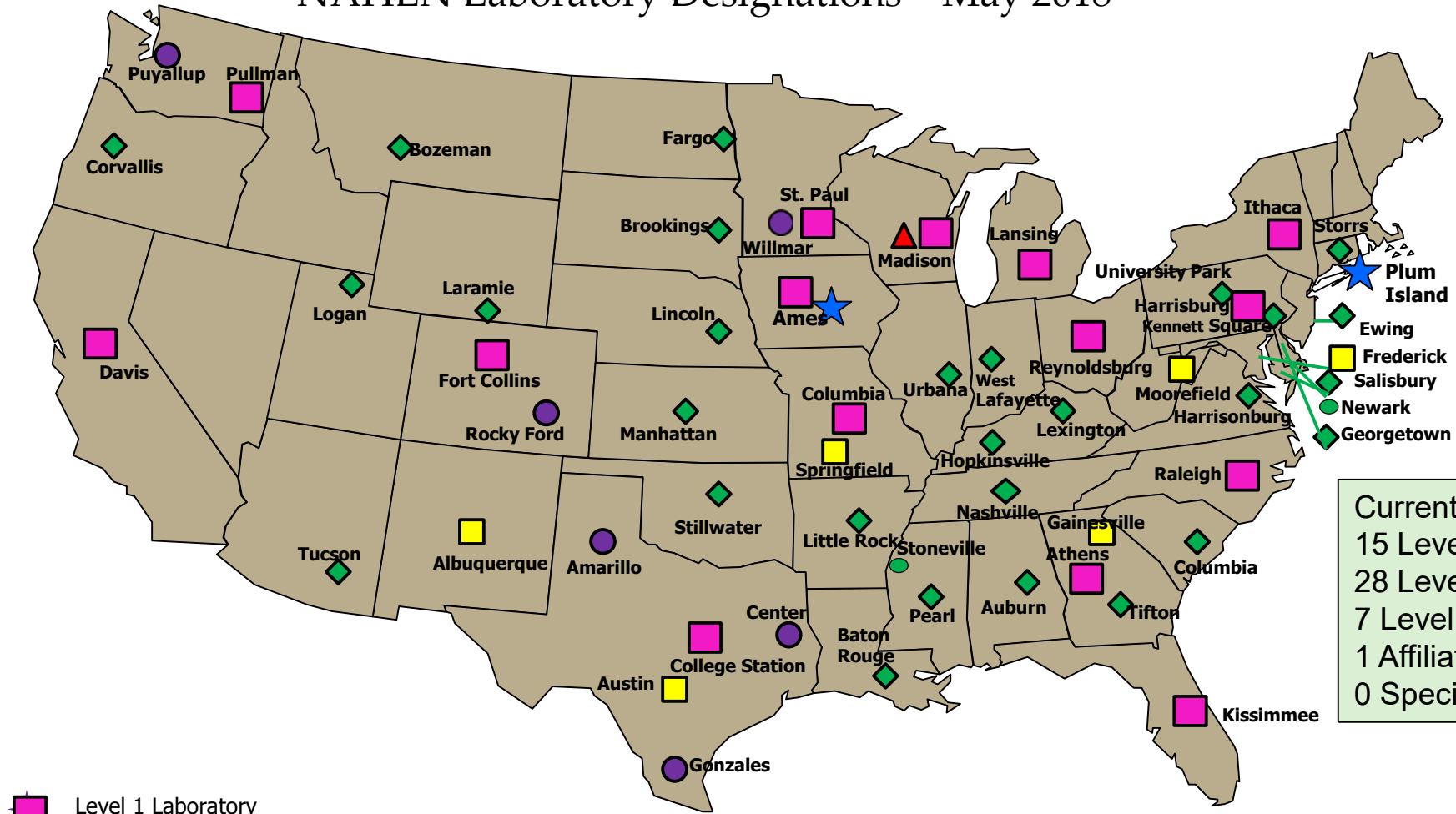
1. Maintain a Quality Management System
2. Provide testing for Foreign Animal Disease (FAD) and Emerging Disease (ED) Investigations, Provide outbreak and recovery testing
3. Provide appropriate sample handling
4. Provide required communications and reporting
5. Support the NAHLN mission

Approval to test for diseases under NAHLN scope must be requested annually.

NAHLN Laboratory Designations

- Level 1: Perform at highest standards of the NAHLN
 - Must have 3rd party accreditation (AAVLD or ISO 17025)
 - Must provide test results electronically (e.g. “messaging”)
 - Must have commissioned biosafety level 3 (BSL-3) space
- Level 2: Participate in surveillance/surge testing, and support NAHLN as resources allow
 - Must either be accredited or have provisional accreditation through 3rd party
 - Must be actively messaging test results, or working towards messaging
- Level 3: Participate primarily in surveillance testing activities.
 - Must have functional quality management system and agree to periodic audits by the NAHLN Program Office if not accredited through a 3rd party
 - Must have a functional electronic laboratory information management system
- Affiliate: Labs whose mission falls outside the scope of animal agriculture
 - Examples: US Geological Surveillance National Wildlife Health Center, US Department of Defense Veterinary Food Analysis and Diagnostic Laboratory
- Specialty: Private labs that have a specific capability needed by the NAHLN
 - Example: aquaculture testing

NAHLN Laboratory Designations – May 2018



Currently there are:
 15 Level 1 labs (6 branch labs)
 28 Level 2 labs (2 branch labs)
 7 Level 3 labs
 1 Affiliate lab
 0 Specialty labs

- Level 1 Laboratory
- Level 1 Branch Laboratory
- ◆ Level 2 Laboratory
- Level 2 Branch Laboratory
- Level 3 Laboratory
- ▲ Affiliate Laboratory
- ★ National Veterinary Services Laboratories

Please refer to lab list for testing capabilities.

May 21, 2018

NAHLN Coordinating Council

- The governing body of NAHLN providing recommendations to the NAHLN executive committee for decision
- Comprised of Federal, State and University stakeholders
- Provides a forum for members to discuss current and future needs of the NAHLN
- Specific activities of the Council include, but are not limited to:
 - Review and comment on the goals, strategic plan, and operational objectives of the NAHLN
 - Review and comment on the specific criteria that define NAHLN Laboratory levels and network structure
 - Discussion of those policies that relate to the NAHLN that do not infringe on the statutory authority of the Federal or State governments
 - Review and comment as necessary on any other programmatic or operational issues of relevance to the NAHLN in an effort to enhance the effectiveness of the Network.

Founding Principles and Features of NAHLN

- **Quality Standards**
 - *Operate within a quality management system to provide confidence in every aspect of how test is performed*
 - *AAVLD, ISO 17025, NAHLN approval*
- **Competency of Lab Personnel**
 - *Trained and tested laboratory personnel*
- **Standardized Protocols and Equipment**
 - *Use standardized protocols, reference materials, and equipment to ensure consistency among all labs*
- **Secure Electronic Communications and Reporting**
 - *Provide communications and especially test results in a secure and confidential manner*
- **Adequate Biosafety and Biosecurity**
 - *Use facilities with biosafety/biosecurity levels requisite for testing performed*
- **Assessment of Preparedness through Scenario Testing**
 - *Evaluate preparedness, identify and prioritize gaps, prepare for outbreak response and recovery*

All NAHLN laboratories must agree to support these founding principles in order to ensure the integrity of the network and the credibility of test results coming from any one of the labs in the network.

Quality Management System Training

Based on AAVLD, ISO17025 standards

- 17 trainings have been conducted since 2010 for 671 participants
 - Annual training in Ames, Iowa for all NAHLN lab members
 - International diagnosticians included in trainings upon request
 - Regional training for NAHLN lab member at a NAHLN lab
 - Regional training for Aquatic pathogen diagnosticians
 - Individual NAHLN lab training offered upon request

Interactive learning environment

- Document control, records, internal auditing, management review, corrective actions, root cause analysis, equipment
- Workshops: Root cause analysis, SOP and associated document development, QMS Jeopardy game
- Mock audit: Application of skills- auditing, reporting, responding

Web-based QMS training available

- Developed through a collaboration between NAHLN and the Washington Animal Disease Diagnostic Lab (NAHLN lab)



Trained Personnel

- Training provided at the National Veterinary Services Laboratories
- Train the Trainer
 - Initial training provided to NAHLN lab members who then train others in their labs or other NAHLN labs
 - Increase personnel trained and proficiency tested for Foot and Mouth Disease, Avian influenza and Newcastle Disease
 - Cross training for PCR accepted across diseases
- Quality Management System Training
 - Annual training for all NAHLN lab members
 - Web Based modules
- High Throughput System Training provided to NAHLN lab members

Proficiency Testing provided by the National Veterinary Services Laboratories

- ❖ African Swine Fever
- ❖ Bovine Spongiform Encephalopathy
- ❖ Classical Swine Fever
- ❖ Chronic Wasting Disease
- ❖ Foot and Mouth Disease
- ❖ Influenza A Virus-Avian
- ❖ Influenza A Virus-Swine
- ❖ Infectious Salmon Anemia
- ❖ Newcastle Disease
- ❖ Pseudorabies
- ❖ Scrapie
- ❖ Spring Viremia of Carp
- ❖ Viral Hemorrhagic Septicemia
- ❖ Vesicular Stomatitis Virus

NAHLN Methods Technical Working Group

- Working group is made up:
 - NAHLN lab members- Directors and Diagnosticians
 - NAHLN program staff
 - NVSL reference lab representatives
 - Center for Veterinary Biologics statistician

- Specific activities of the working group include, but are not limited to:
 - Provide input on methods validation and approval
 - Review available methods and associated gaps
 - Identify potential new technologies
 - Determine equivalency of modified methods or platforms
 - Review Dossiers and assay approval processes
 - Review continual performance assessment of assays
 - Develop performance characteristic summary documents

Current standardized methods provided by the National Veterinary Services Laboratories

- African Swine Fever
- Bovine Spongiform Encephalopathy
- Classical Swine Fever
- Chronic Wasting Disease
- Foot and Mouth Disease
- Influenza A Virus-Avian
- Influenza A Virus-Swine
- Infectious Salmon Anemia
- Newcastle Disease
- Pseudorabies
- Scrapie
- Spring Viremia of Carp
- Viral Hemorrhagic Septicemia
- Vesicular Stomatitis Virus

APHIS Laboratory Portal

- Secure mechanism to electronically manage laboratory directories, proficiency tests, SOPs, assay performance, and webinars/trainings
- Laboratories keep their information current
 - *Personnel*
 - *Facilities*
 - *Equipment*
- NAHLN program staff manages information on the following topics for each NAHLN lab through the Portal
 - *Proficiency Tests*
 - *SOPs*
 - *Mechanism to monitor assay performance*
 - *Working Groups information*
 - *Collaboration space to post documents*
 - *Mechanism to schedule meetings and training*



- The NAHLN Portal working group
 - Working group is made up of NAHLN lab members and NAHLN program staff
 - The group provides recommendations for enhancements to the Portal
 - The group beta tests the enhancements

Electronic Messaging of Test Results

- All NAHLN labs including NVSL are encouraged to send test results through secure electronic messages to USDA databases
 - Currently 73% of NAHLN labs including NVSL have the capability to message
 - Electronic messages for nine of the 14 NAHLN scope disease can be received into the USDA databases
 - Electronic messages provide results to decision makers in real-time
- Priorities for electronic messaging in NAHLN include:
 - Improve data quality coming into USDA databases
 - Standardizing the data moving out of USDA databases
 - Continue to expand number of labs with capability to message
 - Support efforts of the NAHLN labs to maintain messaging capabilities
 - Expand the ability to accept messages for all NAHLN scope diseases

Biosafety and Biosecurity Requirements

- All NAHLN labs must meet the standards for Biosafety and Biosecurity required for ISO 17025 and AAVLD accreditation
- All NAHLN labs are required to have Biosafety Level 2 testing facilities
- Level 1 NAHLN labs are required to have Biosafety Level 3 testing facilities

NAHLN Exercises and Drills Working Group

- Working group is made up of:
 - NAHLN lab members
 - NAHLN program staff
 - NVSL reference lab representatives
- There is active engagement with the NAHLN labs
 - Informational webinars
 - Drills
 - Monthly calls
- Internal exercises
 - Accessioning exercise
 - Barcoding exercise
 - Electronic messaging exercise
 - Foot and Mouth tabletop exercise
- External exercises
 - This group managed NAHLN participation in regional and National exercises

NAHLN Supports VS Initiatives

- Activities in support of the President's National Action Plan and USDA's Antimicrobial Resistance (AMR) Action Plan
- Implement laboratory piece of the National List of Reportable Animal Diseases (NLRAD) and emerging diseases
- Disease outbreaks of significance
 - *High Path Avian Influenza 2015*
 - *Newcastle Disease 2018*
- Surveillance in wildlife
 - *Avian influenza in wildbirds*
 - *Chronic wasting disease in wild cervids*
- Support testing of endemic diseases when necessary
 - *Porcine epidemic diarrhea and delta coronavirus*
 - *Seneca valley A virus*

Success of the NAHLN

- Strategically combines the infrastructure and expertise in the state veterinary diagnostic laboratories and the National Veterinary Services Laboratories.
- Established the animal health laboratory backbone of the United States emergency response and recovery program.
- Implemented national, standardized surveillance for high priority diseases.



United States Department of Agriculture

Dr. Christina M. Loiacono

Coordinator, National Animal Health Laboratory Network

U.S. Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

National Veterinary Services Laboratories

Christina.M.Loiacono@aphis.usda.gov