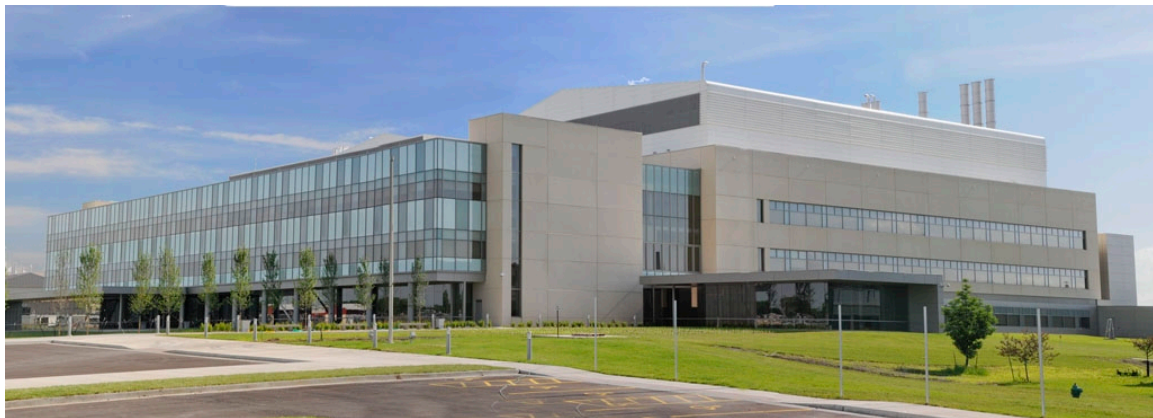


Chapter 4 – Diagnostics, Veterinary Biologics, and Disease Reporting

This chapter highlights the key 2010 accomplishments of APHIS' National Veterinary Services Laboratories (NVSL), Center for Veterinary Biologics (CVB), and the National Animal Health Laboratory Network (NAHLN). The chapter also describes some of APHIS' disease reporting functions, such as the National Animal Health Reporting System (NAHRS) and the online reporting of equine arboviral diseases.

The NVSL provides laboratory and diagnostic services for APHIS through its facilities in Ames, Iowa, and Plum Island, New York. The CVB, also headquartered in Ames with staff in Riverdale, Maryland, regulates veterinary biologics to ensure the safety and effectiveness of products used in animal disease prevention, diagnosis, and treatment.

Dedication of the National Centers for Animal Health in Ames, Iowa



On April 19, 2010, the National Centers for Animal Health held a dedication ceremony for the U.S. Department of Agriculture's (USDA) Consolidated Laboratory and Administrative Facilities. Ed Knipling, Agricultural Research Service Administrator, moderated the program, and Secretary of Agriculture Tom Vilsack gave the keynote address.

Ceremony participants included John Ferrell, USDA Deputy Under Secretary, Marketing and Regulatory Programs; Iowa Congressmen Tom Latham and Leonard Boswell; Iowa Senator Tom Harkin; Lieutenant Governor Patty Judge; Fred Schuster, a representative for Iowa Senator Chuck Grassley; and Molly Jahn, USDA Acting Under Secretary, Research, Education, and Economics. The ceremony was attended by industry representatives and other interested stakeholders.

2010 CVB Highlights

The CVB licensed a wide variety of novel products that are critical for treatment, control, and diagnosis of existing, new, and emerging animal diseases. These products enhance the safety of the Nation's food supply, expand the marketability of exports, improve companion animal health, and enhance economic opportunities for agriculture.

- **New Products** – The CVB licensed six new products including: Encephalomyelitis-Influenza-West Nile Virus Vaccine, Tetanus Toxoid, Canine Distemper-Adenovirus Type 2, Parvovirus Antibody Test Kit, Dot Blot, and Bovine Virus Diarrhea RNA Test Kit.
- **Transition of California-licensed Products** – In September 2010, California approved the transfer of its State Biologics Program to the CVB. CVB subsequently began the process of conditionally licensing all California products with restrictions. This approach to licensing products previously licensed by the California Department of Food and Agriculture is intended to ensure the continued availability of products throughout the transition process. Under these conditions, the CVB conditionally licensed nine California-only products before the deadline. This total includes licenses for new products such as anaplasmosis vaccine, avirulent live culture, and *Staphylococcus aureus* bacterin-toxoid. It's expected that nearly all of these products will meet the requirements for full licensure in 2 to 3 years.
- **Addressing the Concerns of Industry Stakeholders** – The CVB and other APHIS representatives met with the Animal Health Institute, Association of Veterinary Biologics Companies, and Congressional delegates to conduct strategic discussions around CVB program operations, activities, priorities, and directions. To enhance international market access, the CVB worked with its stakeholders to develop and implement a new policy for export product labeling. The CVB also initiated new processes for product development plans and in vitro reference qualification/requalification to streamline and increase predictability for product licensing.
- **Veterinary Biological Serials and Inspections** – In 2010, the CVB processed more than 14,400 veterinary biological serials (comprising more than 75 billion doses of vaccines and diagnostic kits) into the marketplace. In addition to product inspection activities, the CVB conducted more than 60 inspections of both domestic and international production facilities. These included in-depth inspections of licensed facilities for compliance with title 9 of the *Code of Federal Regulations* select agent inspections, observation of efficacy and duration-of-immunity studies, and special investigations. International

cooperative agreement inspections involved production sites in Belgium, Spain, and Canada.

- **Compliance** – CVB effected 82 regulatory actions, issued 28 warning notices, and conducted 37 investigations of possible regulation violations. Additionally, CVB received 471 adverse events reports for veterinary biological products.
- **Export Certificates** – The CVB processed more than 3,000 certificates of licensing and inspection for the export of veterinary biologics. The licensing and inspection certificates promote safe agricultural trade and the continued marketing of U.S.-produced vaccines throughout the world. These certificates were processed within 14 or fewer working days. The CVB also processed more than 1,000 export certificates. Many trading partners require these documents, before the importation of product into their countries, as certification that products were produced under the Virus-Serum-Toxin Act.
- **Testing Products for Program Diseases** – The CVB conducted approximately 1,350 tests on vaccines and diagnostic test kits used in APHIS' surveillance and eradication activities and programs.
- **International Standards** – The CVB continued its role as a partner in the development of international standards. The Center's continued involvement in the International Cooperation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) led to the development of several new technical guidelines relating to post-license monitoring of product performance. As a result, three VICH Guidance Documents for Pharmacovigilance of Veterinary Medicinal Products were finalized. The adoption and implementation of these international standards serve to promote trade with Japan, Canada, Australia, New Zealand, and the European Union.
- **International Organization for Standardization (ISO) Accreditation** – The CVB continued its commitment to consistency, standardization, and predictability in its business processes by conforming to existing International Organization for Standardization (ISO) 9001 Standards (ISO 9001:2000). CVB received this certification in 2010 for the fourth consecutive year. The certification provides external recognition that CVB business practices meet international standards for quality products, customer satisfaction, and process improvement.
- **Expertise and Training** – The CVB provided expertise and training at a joint CVB/Institute for International Cooperation in Animal Biologics program. The training was designed to educate industry representatives and foreign officials, many from emerging markets, on U.S. regulatory processes. This year, 139 delegates from 16 countries participated in the course. The CVB also provided instruction and expertise to a representative from the Turkish Ministry of Agriculture and Rural Affairs, and to approximately 100 regulatory, regional, and

industry officials at the China Institute of Veterinary Drug Control in Beijing, China. Additionally, the CVB participated in a joint Food and Drug Administration/USDA workshop on Approving Veterinary Drugs and Biologics at the Committee of the Americas for Veterinary Medicines Meeting in Columbia.

Disease Reporting

National Animal Health Reporting System (NAHRS)

The NAHRS gathers data from State animal health officials on the presence of confirmed World Organization for Animal Health (OIE)-reportable diseases in specific livestock, poultry, and aquaculture species in the United States. NAHRS is a joint effort of the United States Animal Health Association (USAHA), the American Association of Veterinary Laboratory Diagnosticians (AAVLD), and APHIS. The system functions as part of a comprehensive and integrated animal health surveillance system and is coordinated by APHIS' National Surveillance Unit.

The United States meets its OIE reporting obligations using a variety of sources, including the NAHRS, foreign animal disease (FAD) reports, and national program disease surveillance reports. Appendix 2 lists the U.S. status of the occurrence of OIE-reportable diseases in the United States.

NAHRS is a voluntary, cooperative system for reporting animal diseases. In 2010, 47 States reported monthly disease information. States that do not participate in NAHRS are still required to report FADs and VS national program diseases to APHIS surveillance data systems. A NAHRS online reporting tool allows State animal health officials to complete monthly NAHRS reports using the Internet with the assurance of secure data transfer and information confidentiality. State animal health officials may also use the NAHRS online tool to view summary reports or past monthly reports.

Data reported to NAHRS are validated by the States, NVSL, and Veterinary Services' National Center for Animal Health Programs. Other sources of national animal health data also may be accessed for validation.

2010 NAHRS Highlights

- **Enhanced Aquaculture Reporting** – In 2010, the NAHRS online reporting tool application continued to include all OIE-listed aquaculture diseases of fish, mollusks, and crustaceans. VS and the NAHRS Aquaculture Working Group continue their efforts to enhance national aquaculture disease reporting by defining NAHRS reporting criteria and case development, as well as providing training to APHIS VS aquaculture liaisons on NAHRS and OIE reporting.
- **National List of Reportable Animal Diseases** – APHIS, in cooperation with USAHA, AAVLD, State animal health officials, and industry representatives, continues to work on developing a National List of Reportable Animal Diseases (NLRAD) and appropriate associated reporting criteria. An NLRAD would assist in supporting international trade, standardize reporting by States, assist in meeting obligations of OIE reporting, and improve zoonotic and endemic animal disease reporting.

Equine Arboviral Web Reporting

APHIS provides weekly updates on the number of disease cases associated with West Nile virus and eastern and western equine encephalitis during the transmission season (approximately June through November). This information is available on the APHIS Web site at www.aphis.usda.gov/vs/nahss/equine. In 2010, there were 125 equine cases of West Nile virus reported in 28 States. This compares to 2009 totals of 276 cases in 36 States. There were 247 equine cases of eastern equine encephalitis reported in 18 States in 2010, compared to 301 cases in 18 States reported in 2009.

Equine arbovirus reporting is accomplished through collaboration with the Centers for Disease Control and Prevention (CDC) and State veterinary and public health officials. CDC provides arbovirus case information to APHIS from its ArboNET reporting system, an electronic-based surveillance and reporting system used to track and report arboviral activity. APHIS sends the equine case information weekly to State veterinary officials for their confirmation, and posts the confirmed data on the National Animal Health Surveillance System (NAHSS) Web site.

The Web site was developed at the request of the USAHA Infectious Diseases of Horses Committee and the American Horse Council. The site is intended to provide timely and accurate equine arbovirus case information to individuals associated with the horse industry, including horse owners, animal health professionals, and regulatory officials, public health officials, and those in related academic and research fields.

2010 NVSL Highlights

***Salmonella* Enteritidis** – In response to the Food and Drug Administration (FDA) rule “Prevention of *Salmonella* Enteritidis (SE) in Shell Eggs during Production, Storage, and Transportation” the NVSL began offering an accelerated testing option for SE-suspect isolates in 2010. Submitters with a Group D *Salmonella* isolate associated with this FDA program can request that the isolate be treated as an “FDA SE Rule Out” on the VS 10-3 submission form. The results of this test will indicate that the isolate is either confirmed as SE or confirmed as not SE. No further serotyping of non-SE isolates will take place under this program unless the submitter resubmits as a normal serotyping request. Since it is easier to rule out a specific serotype compared to identifying an unknown, results will typically be reported in 1 to 3 business days after receipt of the isolate.

Also in 2010, the NVSL expanded its abilities to perform molecular characterization of *Salmonella* by multiple-locus variable number tandem repeat analysis (MLVA) as well as by antimicrobial resistance testing. Serotyping training was provided through the National Poultry Improvement Plan’s *Salmonella* workshops and a *Salmonella* Group D proficiency test for environmental samples was distributed. .

Collaboration with Federal Bureau of Investigations for Forensic Analysis – In September 2010, the NVSL Foreign Animal Disease Diagnostic Laboratory (FADDL) participated in several training exercises with the Federal Bureau of Investigation’s (FBI) Hazardous Evidence Analysis Team (HEAT). The exercises were planned and executed in collaboration with partner laboratories of several Federal agencies, including the FBI and the National Bioforensic Analysis Center (NBFAC) in Frederick, Maryland. These collaborative exercises are essential to ensure that all participating agencies have the knowledge, resources, and skills to rapidly and effectively conduct forensic analysis related to foreign animal diseases.

Assistance to South Korea for Control of a Foot-and-Mouth Disease Outbreak – During the recent foot-and mouth disease (FMD) outbreak in South Korea, the North American FMD Vaccine Bank (NAFMDVB) assisted the Republic of South Korea by providing FMD antigen concentrate for vaccine (NVSL FADDL is responsible for daily operations of the NAFMDVB). NVSL worked closely with the National Veterinary Stockpile and animal health authorities of Canada and Mexico to ship FMD antigen concentrate to the vaccine manufacturer for delivery of FMD vaccine to South Korea. The NAFMDVB was established in 1982 by an agreement between the United States, Canada, and Mexico to assure rapid availability of vaccines to control an outbreak of FMD.

Foreign Animal Disease Diagnostician Course – The foreign animal disease diagnostician course was held at NVSL's Plum Island facility in February and June 2010. The course is a 2-week classroom and laboratory session for training State, Federal, and military veterinarians in field identification and diagnosis of 11 diseases in poultry and livestock not found in the United States.

Participation in Foreign Animal and Zoonotic Disease Defense Workshop – NVSL participated in two workshops hosted by the Foreign Animal and Zoonotic Disease Defense (FAZD) on agricultural screening tools, with a focus on technical gaps in agricultural screening, surveillance samples, and diseases of interest. Detection of FMD virus (FMDV) in milk and FMDV serology were identified as important gaps during the workshops. The FAZD is a Department of Homeland Security Center of Excellence and is a collaboration of Federal, State and University partners.

Bovine Tuberculosis – In 2010, NVSL provided laboratory support for tuberculosis (TB) area testing and herd depopulation for nine beef herds in Kentucky, Michigan, Mississippi, Nebraska, and South Dakota, and two dairy herds in Colorado and Ohio. More than 9,300 cultures and 10,300 tests were performed. In addition, support was provided for TB wildlife surveys in five States.

Brucellosis – *Brucella abortus* was recovered in 2010 from a female bison residing in a herd in Montana and from a beef herd in Wyoming. Isolates from both cases underwent variable number tandem repeat typing to aid epidemiological investigations.

Johne's Disease – Proficiency panels for Johne's disease organism detection (culture and direct polymerase chain reaction) were mailed to participants in March 2010. A total of 61 laboratories (52 U.S. laboratories, 9 international, 3 Canadian, 3 European Union, and 1 from New Zealand) participated, with 117 individual panels and 60 pooling panels distributed.

The NVSL also provided diagnostic laboratory support for the 2009 National Animal Health Monitoring System Goat Study (Johne's Disease) from February through September 2010.

Piroplasmosis Surveillance – Starting in October 2009, an outbreak of equine piroplasmosis (EP) in Texas and New Mexico required testing of more than 10,000 horses at the NVSL. VS approved other laboratories to conduct movement testing using commercial competitive enzyme-linked immunosorbent assay (cELISA) in response to the increased demand for testing for inter- and intrastate movement of equids for EP caused by *Babesia caballi* and *Theileria equi*. The list of APHIS approved laboratories is available on the APHIS Web site at http://www.aphis.usda.gov/animal_health/lab_info_services/approved_labs.shtml.

The Diagnostic Virology Laboratory (DVL) provided pandemic H1N1 swine-origin influenza virus isolates to University collaborators to conduct research on swine influenza virus (SIV). Since December, the DVL has provided an additional 33 virus isolates and 62 extracted viruses to USDA researchers, and a total of 14 diagnostic specimens and 155 field isolates to the CDC as part of ongoing multiple investigations of proposed human infections with SIV. SIV surveillance is currently conducted in 37 SIV-approved NAHLN laboratories.

International Partnerships – NVSL continues to expand its international impact as part of two different OIE twinning projects. Projects with Chile and Panama were initiated in 2010 and join the ongoing twinning project with Brazil. In 2010, NVSL sent two subject matter experts to review the Lanagro-SP national reference laboratory in Campinas, Brazil.

In addition to the international twinning activities, on-site training at the Ames campus was provided to a group of laboratory scientists from Mexico City, Mexico, on isolation, identification, and characterization of Newcastle disease virus.

Wild Bird Surveillance – NVSL continued to participate in surveillance activities in migratory wild birds for H5 and H7 avian influenza (AI). Approximately 244 presumptive positive H5 or H7 specimens were received during 2010, with the confirmation of 213 out of 244 presumptive positive specimens by the H5 or H7 reverse real-time polymerase chain reaction (rRT-PCR) assay. A total of 66 low pathogenicity AI (LPAI) viruses were isolated from wild birds and 10 presumptive positive specimens were positive for both H5 and N1 when tested by the H5 and N1 rRT-PCR assays.

Virulent Newcastle disease virus has also been isolated from wild cormorants from Michigan and from five different submissions from Florida during 2010.

Contagious Equine Metritis – NVSL responded rapidly and efficiently with diagnostic support during an outbreak of contagious equine metritis that began in FY 2009 and continued into FY 2010. The CEM outbreak required the testing of nearly 1,000 horses with multiple samples at multiple collection times. In addition to providing diagnostic support, NVSL shipped more than 20,000 sampling kits, developed a molecular forensic method to identify individual strains of the causative agent, developed a laboratory approval policy, and developed and conducted a training module to increase diagnostic capacity.

ISO Accreditation – NVSL became the first veterinary diagnostic laboratory to become accredited under the American Association of Laboratory Accreditation's Veterinary Diagnostic Laboratory program, setting the standard for the industry in 2009. In 2010, NVSL added 26 new tests to the accreditation list to advance on the long term goal of

attaining ISO 17025 accreditation for greater than 80 percent of our test methods, or greater than 95 percent of reported results by the end of 2013.

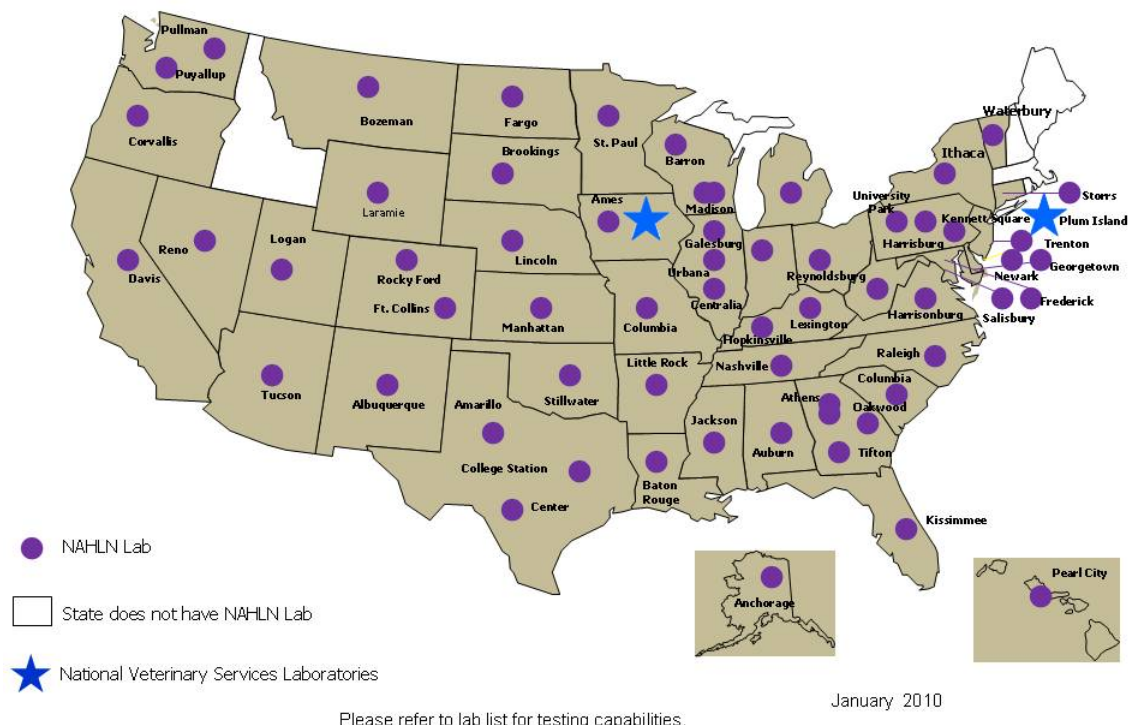
Outreach – In 2010, NVSL co-sponsored a new Ag-Discovery program along with CVB, Iowa State University, the Agricultural Research Service and other agencies. This program targets the recruitment of high school students from under-represented populations to increase their interest in life sciences and possible federal careers that exist in those areas.

National Animal Health Laboratory Network (NAHLN)

APHIS partners with veterinary diagnostic laboratories throughout the United States to ensure there is adequate diagnostic capacity and capability for early detection of, rapid response to, and recovery from, animal health emergencies. This includes emerging diseases and FAD agents that threaten the Nation's food supply and public health. NAHLN has grown from 12 laboratories in 2002 to 63 laboratories in 45 States (figure 1). The NAHLN is comprised of 59 State and university laboratories; the Department of the Interior laboratory in Madison, Wisconsin; the Food Safety and Inspection Service laboratory in Athens, Georgia; and the NVSL campuses in Ames, Iowa, and Plum Island, New York.

Figure 1.

Geographic Locations of NAHLN Laboratories



NVSL conducts proficiency tests and trains the NAHLN member laboratories annually or semi-annually. These tests focus on standardized screening methods for the currently targeted diseases in the NAHLN: AI, exotic Newcastle disease, scrapie, chronic wasting disease (CWD), bovine spongiform encephalopathy (BSE), vesicular stomatitis virus, classical swine fever (CSF), FMD, SIV, and pseudorabies virus (PRV). The NAHLN laboratories perform screening assays and forward any suspect or positive samples to the appropriate section of the NVSL for confirmatory testing.

2010 NAHLN Highlights

NAHLN Laboratory Review Process – NAHLN collaborated with AAVLD to establish a review process for NAHLN laboratories to ensure the development and implementation of a quality system consistent with AAVLD, OIE, and ISO standards. Standardized reports detailing nonconformances and requirements to maintain NAHLN status are provided to each audited laboratory. A summary report was prepared which details the site visits conducted in 2009, the issues found, and the program goals for 2010.

NAHLN Information Technology (IT) System—In 2010, 36 NAHLN laboratories were approved for CSF testing and 54 NAHLN laboratories were approved for AI surveillance testing; (36 of the AI-approved laboratories participated in Wildlife Services Wild Bird AI Surveillance). The NAHLN IT team also provided enhancements for messaging and subsequent reporting that allow additional NAHLN laboratories to message into the production system. Eleven laboratories were using electronic messaging into the production system, and final testing of updates to include ELISA results in the CSF result messages was completed.

Surveillance Activities – NVSL continued to support multiple national surveillance programs in 2010 (e.g., AI, SIV, and CSF) through partnership with the NAHLN. Personnel at five new laboratories were trained on high throughput molecular diagnostics for FMD and CSF, resulting in a total of 36 trained laboratories. The Train-the-Trainer Program provided 12 trainers from 12 laboratories and added African swine fever and rinderpest PCRs to help increase our laboratory response preparedness and capacity.

PRV Surveillance – In November 2009, V S' NCAHP swine staff began implementing a new PRV surveillance plan. This plan outlined numerous surveillance streams, with the objectives of rapid disease detection, demonstration of disease freedom, and to monitor international and domestic sources of PRV. Eleven NAHLN laboratories participated in the PRV pilot. PRV Surveillance continued in 2010 in support of serological testing of swine cases submitted to diagnostic laboratories, herds classified as high risk, feral swine, herds exposed to feral swine, and traceback testing from the Regions.

Fourteen NAHLN laboratories were selected to participate in the 2010 surveillance. Selection was based on the laboratories' testing capacities and capabilities, previous sample submission numbers, and input from the National Surveillance Unit. A webinar was conducted to review the cooperative agreement process and the PRV surveillance plan, including sampling, testing, proficiency testing, data collection, reporting, and the communication plan.

FMD Exercises – The NAHLN, in collaboration with the National Agriculture Biosecurity Center at Kansas State University and the CNA Corporation, coordinated a series of FMD tabletop exercises based on recommendations from the AI table top exercise in 2010. Representatives from multiple VS program units participated in a policy-level workshop with the objectives to: identify existing policies related to laboratories, NAHLN activation and sample shipping during an FMD outbreak; determine roles and responsibilities of individual units related to laboratory decisions before, during, and following an FMD outbreak; and clearly define gaps and processes for VS to address before and during the subsequent exercises.

The second component of the exercise series involved a simulated FMD outbreak in Kansas and Iowa to examine early, mid-, and late-response laboratory activities regarding the decision-making process for NAHLN activation and deactivation; testing capacity at each of the State's NAHLN laboratories; surveillance sample collection protocols; testing algorithms; integration of surveillance and testing results; and communication and coordination processes.

The third component of the exercises consisted of 15 followup exercises in NAHLN laboratories across the country, each involving single or multiple States. These exercises were designed to practice the policy implementation, decision-making, and communication identified in the first two components of the series.

FMD Negative Cohort – NAHLN coordinated negative cohort studies for FMD, African swine fever (ASF), and rinderpest as an important component to the validation of the rt-PCR assays for these diseases. NAHLN worked closely with the Proficiency and Validation Services and Diagnostic Services Sections at FADDL on the training, development, and review of proficiency tests for 12 participating NAHLN laboratories. Focus was also on coordinated communication with VS' National Center for Animal Health Emergency Management (NCAHEM), VS' Regional staff, the participating NAHLN laboratories, and State Animal Health Officials on the purpose of the negative cohort, expectations of false positive results, and processes for sharing the negative cohort testing results.

NAHLN Methods Technical Working Group – Established in July 2006, the technical working group is composed of personnel from NAHLN laboratories, NVSL, the Department of the Interior, USDA's Food Safety and Inspection Service, and the National Center for Foreign Animal Disease in Winnipeg, Manitoba. The working group provides input on various aspects of methods validation and approval of methods. In 2010, a Dossier Review Team, consisting of members of the NAHLN Methods Technical Working Group, met to evaluate data on a number of potential influenza assays to detect novel 2009 H1N1.

The team reviewed the data generated by the Diagnostic Virology Laboratory and recommended the testing algorithm currently used by the NAHLN laboratories. The methods comparison processes developed by the group have been used to evaluate several studies. The processes and training materials were discussed at an International Atomic Energy Agency/OIE sponsored meeting on test validation in October 2010 and were used by OIE as a model for training.

Training on the Quality Management Systems – The NAHLN Program Office along with members of the AAVLD Accreditation Committee and NVSL personnel developed and delivered a Quality Management System (QMS) Training Program in August 2010. Held at the NCAH facility in Ames, Iowa, participants were provided interactive class training on quality system requirements, the accreditation process, document control, internal auditing, and root cause analysis

Movement to Member Laboratory Designation – The NAHLN is comprised of four laboratory designations: Adjunct, Contract Member, Member, and Core Member Laboratory. In 2009, the list of requirements was updated to further define each laboratory designation's roles and responsibilities within the network. In 2010, cooperative agreements were established with 12 AAVLD-accredited laboratories to move them from Contract Member Laboratories to Member Laboratory status. Funding has been provided to support their quality management system and their capability to electronically transmit the standardized test result data to the NAHLN information technology system. The participating laboratories have reported improvements in their quality management systems and progress toward successful and consistent Health Level 7 messaging of test result data.

NAHLN Portal – FoodShield was used to develop a NAHLN portal used for the following modules:

- A secure mechanism to electronically comment on and release SOPs.
- A laboratory directory that includes information on physical space, personnel and equipment.
- A mechanism to monitor assay performance and report proficiency test results.
- A mechanism to train others in the validation process.
- Work Group space to post documents and schedule meetings and calls.

A kick off meeting was held in December 2010.

NAHLN Newsletter–The first issue of *The NAHLN Quarterly*, an electronic newsletter with the purpose of increasing communication with stakeholders, was provided to NAHLN laboratory directors in February 2009. Since then, eight issues have been released and subscriptions have increased to more than 1,300. Subscribers include NAHLN laboratory directors, State Animal Health Officials, APHIS program staff, animal industry representatives, and other State, Federal, and international representatives. A readers review was conducted that indicated strong satisfaction with the newsletters' content.

Capacity Estimation Software–The FAZD Center at Texas A & M University worked with NAHLN program staff and NAHLN laboratories to develop a diagnostic testing

capacity calculator. The calculator includes multiple technologies and can be personalized for individual laboratories. The calculator also helps to identify the rate of limiting processes and helps to maximize efficiency. NAHLN laboratories participated in the requirements and user acceptance testing. A prototype will be available to the laboratories in 2011.