

Implementation of the Revised NAHLN Laboratory Qualification Checklist for Membership of a Veterinary Diagnostic Laboratory

January 7, 2009



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Background

- 2001 – VS Memo 580.4 revised
 - Updated VS policy and procedure for FAD/ED investigations
- 2002 – NAHLN founded
- 2007 – NALHN Review
 - Identified a need to ensure quality of NAHLN Laboratories
- 2008 – Laboratory Issues Working Group (WG)
 - Revised NAHLN checklist and policy document
 - Developed VS Memo 580.4 guidance documents
- 2008 – VS Memo 580.4 revised
 - Included potential use of the NAHLN Laboratories



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NAHLN Laboratory Qualification Checklist

- Revisions were substantial and require completion by all NAHLN Laboratories
- NAHLN Checklist and Policy document were provided to the NAHLN Laboratory Directors in December 2008
 - Instructions were included
 - Checklist must be completed and returned by February 27, 2009
 - Signatures
 - Supportive Documentation



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Sections of the NAHLN Checklist

- Section A, will be completed by VS NAHLN
- Section B, include names and addresses of **all** laboratory facilities, if there are multiple
- Section C, read statements and agreements thoroughly and mark the agreement if you will comply
 - Section C, Item 5, list the city and state location(s) that will be testing for the agent/disease
- Section D, provide signature, title, and date of all requested authorities
 - Some title blocks have pull down boxes so the correct title can be selected
 - Submit completed and signed checklist to NAHLN office by February 27, 2009



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Section

FOR NVSL USE ONLY

A.

Date Received:

Date Reviewed:

Action:

Approved

Not Approved

Section Laboratory Name:

B. Laboratory Director:

Address:

City:

State:

Telephone: - -

Fax: - -

Include name and address of all facilities (branch or system laboratories and contact person that would be included in NAHLN activities:



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NAHLN Laboratory Qualification Checklist for

Section

C. Membership of a Veterinary Diagnostic Laboratory

MEMORANDUM to:

- o Laboratory Director and, in Select Agent registered laboratories, Responsible Official (RO) of laboratory requesting or renewing National Animal Health Laboratory Network (NAHLN) Testing Laboratory status.
- o State Animal Health Official
- o Area Veterinarian in Charge (AVIC)
- o State Department of Agriculture Director, Agriculture Commissioner or equivalent
- o Dean of College (if appropriate)

SUBJECT: NAHLN Laboratory Qualification Checklist for Renewal or Membership of a Veterinary Diagnostic Laboratory



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1. Laboratories are expected to have developed and/or reviewed their sample receiving and handling activities, guidelines and standard operating procedures (SOP) to ensure consistency with agent-specific issues of laboratory safety, sample and specimen handling, worker training, select agent materials and facility requirements associated with the agent-specific functional designations for which you are applying. General pertinent overview information on high consequence livestock pathogens and toxins and select agents can be obtained at www.aphis.usda.gov/vs/ncie/bta.html and www.cdc.gov/od/sap and is delineated in the DHHS/CDC publication, Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition <http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>
- Yes, I have developed and/or reviewed our laboratory's sample and specimen handling, laboratory safety, guidelines and SOPs to ensure consistency with agent-specific, worker training, select agent materials and facility requirements associated with the agent-specific functional designations to ensure consistency with the BMBL.**



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Item 1 Question

- Will NAHLN provide guidelines for agent specific risk assessment?
 - Example: BSL required for FMD or HPAI
 - **Answer:**
 - BMBL guidelines will be used as a reference.
 - Modeling will be used to make recommendations and develop policy if capacity at suggested BSL is not available.
 - Other countries have developed policies to use BSL-2 space rather than BSL-3.



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2. Due to the potential for foreign animal disease (FAD) investigations to contain highly contagious disease causing agents like foot-and-mouth disease, classical swine fever virus, highly pathogenic avian influenza, and velogenic Newcastle disease; NAHLN laboratory employees working with samples from FAD investigations shall observe a five (5) day quarantine avoiding contact with specific susceptible species and their premises. Areas where susceptible species are present include but are not limited to farms, zoos, wildlife parks, circuses, rodeos, carnivals and county fairs with livestock, feedlots, livestock sale barns, pet bird stores, and veterinary clinics which treat and house livestock.

In the event of positive or suspect positive laboratory findings on samples from FAD investigations, the following personnel decontamination procedures must be followed; disrobe upon exiting the laboratory suite, remove mucus material which may contain trapped inhaled particles by expectoration and blowing nose, clean underneath finger nails, scrub hands and arms, and shower for at least three (3) minutes.

- Yes, I agree to comply with the personnel quarantine policy stating that persons who are working in or visiting the NAHLN laboratory suite facility where high risk animal pathogens from an FAD investigation may have been present are restricted from contact with susceptible animals for a period of five (5) days, and to follow the decontamination procedures upon positive laboratory findings. This policy will be presented to and reviewed with staff and visitors, and acknowledged by signature.**



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Item 2 Questions

- How do laboratories without BSL-3 capacity respond to this item?
 - **Answer:**
 - Laboratories should indicate in a cover letter that they do not have BSL-3 space and provide the SOP detailing their processes to handle FAD/ED investigations and/or outbreak samples.
 - If a laboratory does not believe they have the appropriate BSL space to process samples, they should indicate in a cover letter that they will not accept FAD/ED investigation or outbreak samples.
 - Such a statement would not preclude laboratories from participating in surveillance activities.



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Item 2 Questions continued

- Personnel decontamination procedures
 - Is a shower required in the laboratory?
 - **Answer: No**
 - BMBL guidelines will be used as a reference.
 - Ideal situation is to have a shower egress in laboratory.
 - If shower egress not available, state that in a cover letter and provide SOP detailing the procedures that will be used.
 - Example: Wash hands and arms and change clothes prior to exiting laboratory and proceed to shower in the facility.



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Item 2 Questions continued

- Will NAHLN membership be restricted to laboratories with BSL-3 capacity?
 - **Answer:** No
 - BSL availability will be considered when FAD/ED agents are being investigated.
 - If laboratories do not believe they have the facilities to safely handle samples from FAD/ED investigation or outbreaks, they should indicate that in a cover letter.
 - Such a statement would not preclude the laboratory from participating in surveillance activities.



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Item 2 Questions continued

- Does the 5 day quarantine apply to only employees working directly with the specimens or all employees in the building?
 - **Answer:** The quarantine applies to all employees working in the laboratory suite or in direct contact with the specimens.



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Item 2 Questions continued

- Will NAHLN provide significant infrastructure funds to build BSL-3 capacity as was done for original core member laboratories?

– **Answer:**

- The modeling efforts will be used to identify gaps in BSL-3 capacity and prioritize funding of additional space.
- Building/remodeling space is contingent on receiving additional funding.
- Modeling will be used to develop contingency plans/policy if adequate levels of BSL-3 space are not available.



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3. NAHLN laboratories may be involved with the use, transfer, and possession of high consequence livestock pathogens and toxins and select agent materials. Whether or not the NAHLN laboratory is registered to possess Select Agents, they will be required to follow notification and transfer processes and be compliant with current regulations of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and USA Patriot Act of 2001 (<http://www.selectagents.gov/>).
- Yes, I understand my responsibilities and agree to follow the current notification and transfer process associated with Select Agents.**



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4. NAHLN laboratories will be expected to ship samples during an outbreak. There are specific requirements for shipment of dangerous goods (International Air Transport Association) and shipment of organisms (Title 9 Code of Federal Regulations, Part 122).
- Yes, I have reviewed and understand the International Air Transportation Association and USDA requirements for shipment of dangerous goods and agents and will have personnel trained and qualified and the permits necessary to appropriately ship samples.**



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5. Given the above, and initial review of the current NAHLN testing efforts, list the agent-specific testing capacities you are applying for. These initial self-classifications signify that your laboratory is currently capable of performing tests of this type, possesses the necessary equipment and personnel trained in its use, and would be willing to perform the tests in matrices such as animal, food, and environmental samples.

Yes, my laboratory is currently capable of performing the agent-specific test types being applied for, possesses the necessary equipment and personnel trained in its use, and would be willing to perform the tests on the specified sample matrices.

Agent/Disease	Assay	Please list the location(s) requesting approval (City, State)
Avian influenza	Real time PCR	
Bovine spongiform encephalopathy	ELISA	
Classical swine fever	Real time PCR	
Chronic wasting disease	Immunohistochemistry	
Foot and mouth disease	Real time PCR	
Newcastle disease	Real time PCR	
Scrapie	Immunohistochemistry	
Vesicular stomatitis	Complement fixation	



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Item 5 Question

- How do laboratories request participation for testing additional agents/diseases?

– **Answer:**

- Indicate additional agents/diseases on the checklist
- Requests can be emailed to the NAHLN office at NAHLN@aphis.usda.gov
- The decision to add laboratories for agents/diseases will be determined by surveillance and anticipated outbreak capacity needs.



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6. A plan for operational flow of animal samples, food samples, and low-risk environmental samples to and between state and federal veterinary diagnostic laboratories is essential. Standard operating procedures to ensure appropriate flow of samples and assay results during a foreign animal disease investigation are available in the current version of VS Memo 580.4. Standard operating procedures to ensure appropriate flow of samples and assay results for surveillance programs are outlined in testing protocols and agreements. These protocols also include details for confidential alert and notification of appropriate state and federal officials only. (State Animal Health Official, AVIC, etc).

Yes, I have reviewed and agree to abide by the standard operating procedures for sample accession, NAHLN testing and reporting, and notification with the State Animal Health Official, the AVIC, and other appropriate officials; information will not be released to any other parties.



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7. During routine surveillance, samples may need to be sent from the state of origin to another state for testing. If NAHLN laboratories are participating in those surveillance efforts, they may be expected to accept samples from another state. NAHLN laboratories will be expected to document communication of the receipt of these samples and the test results to their State Animal Health Official. The State Animal Health Official will be responsible for contacting the AVIC.

Yes, I agree to accept and test samples from another state during routine surveillance. I also understand the receipt of samples and the test results will have documented communication with the State Animal Health Official. The State Animal Health Official has been consulted and is in agreement concerning receipt and testing of samples and will be responsible for contacting the AVIC.



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Item 7 Questions

- Is acceptance of samples from another state contingent on funding?

– **Answer:** Yes

- We are working with National Center for Animal Health Emergency Management (NCAHEM) to determine how to expedite funding for both FAD/ED investigations and outbreaks.

- May the NAHLN laboratory modify the agreement to insert contingent on payment?

– **Answer:** No

- The agreements on the checklist can not be modified.
- Laboratories may attach a cover letter stating their concerns.



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Item 7 Questions continued

- Who is responsible for paying for tests diverted from other states?
 - **Answer:**
 - USDA will pay for the testing of NAHLN agents/diseases associated with FAD/ED investigations and outbreaks.
 - USDA is working on processes to ensure efficient payment.
 - Blanket Purchase Agreements will facilitate the process.



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8. In a disease outbreak, samples may need to be sent from the state of origin to another state for testing. NAHLN laboratories will be expected to accept and test samples from another state as well as to document communication of the receipt of these samples to their State Animal Health Official. The State Animal Health Official will be responsible for contacting the AVIC.
- Yes, I agree to accept and test samples from another state during a disease outbreak if my laboratory has the capacity to assist in testing samples and the State Animal Health Official in my state consents to the importation and testing of the samples. I also understand the receipt of samples will have documented communication with the State Animal Health Official. The State Animal Health Official will be responsible for contacting the AVIC.**



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9. In a disease outbreak, NAHLN laboratories providing testing for impacted states may need assistance from NAHLN laboratory personnel located in non-impacted states. Your laboratory may be expected to provide trained and proficiency tested personnel to help in the testing efforts. Associated travel and wages would not be paid for by your laboratory. Personnel would be rotated on a mutually agreed upon schedule. This possible movement of personnel would be coordinated through the NAHLN office.
- Yes, if my state is not impacted by the outbreak, I agree to make all reasonable attempts to provide personnel from my laboratory to assist a NAHLN laboratory providing testing to state(s) impacted by the outbreak.**



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Item 9 Question

- If a laboratory cannot commit to sending personnel to another laboratory during an outbreak, will it prohibit the laboratory from being designated as a NAHLN laboratory?
 - **Answer: No**
 - NAHLN is requesting laboratories to agree to make a reasonable attempt to provide personnel if they are needed during an outbreak.
 - We recognize that all laboratories have daily operations that must be maintained and may not have available personnel.



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10. NAHLN laboratories may be asked to conduct screening tests on samples collected during foreign animal disease investigations in accordance with Veterinary Services (VS) Memorandum 580.4.
- Yes, I agree to accept and test samples from a foreign animal disease investigation, in accordance with VS Memorandum 580.4, if my laboratory has the capacity to assist in testing samples and the State Animal Health Official in my state consents to the testing of the samples. I also understand the receipt of samples will have documented communication with the State Animal Health Official. The State Animal Health Official will be responsible for contacting the AVIC.**



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Item 10 Questions

- Will the NAHLN laboratory receive compensation for samples received and tested as a result of a FAD?
 - **Answer:** Yes
 - The NAHLN laboratory will be reimbursed for all FAD/ED samples tested for NAHLN agents/diseases.
- If so, from whom and in what time frame?
 - **Answer:**
 - Blanket purchase agreement will facilitate payment.
 - Payment will be made by USDA within 30 days of receipt of the testing invoice.



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11. Established NAHLN standard testing procedures (within the agent-specific protocol) as well as use of NAHLN standardized reagents and controls must be used when testing and reporting testing results on the designated high consequence livestock pathogens and other biothreat agents. *Failure to comply with all regulations and policies by any party may result in immediate loss of the laboratory's approval to conduct NAHLN testing for high consequence livestock pathogens and bioterrorism (BT) agents.*
- Yes, I agree to adhere to the NAHLN testing protocol and standards for use of NAHLN reagents and controls.**



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12. Laboratory testing of specimens and samples related to a BT event may involve the need for secure storage and chain-of-custody procedures, as well as procedures for evidence collection and preservation to support potential evidentiary requirements of the FBI. NAHLN laboratories are expected to have established communication with the Weapons of Mass Destruction (WMD) Coordinator at your appropriate/local FBI Field Office. If FBI assistance is needed and you do not have a local FBI contact, contact the FBI at (202) 324-3000 or <http://www.fbi.gov/contact/fo/fo.htm>

- Yes, I have established communications with the appropriate FBI/WMD Coordinator to determine how and when the FBI wants to be notified. I understand that NAHLN laboratories are expected to establish communication with the FBI as appropriate.**



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13. The following is the NAHLN Notification Plan for Potential Animal, Food, and/or Environmental-Related Foreign Animal Disease and/or Bioterrorism Events (i.e. scenario in which an animal sample becomes suspect during the course of testing in the microbiology laboratory). Additional details on communication are outlined in standard operating procedures, communication, and response plans.

General NAHLN Notification Plan for Potential Animal, Food, and/or Environmental-Related Foreign Animal Disease and/or Bioterrorism Events

When a Veterinary Diagnostic Laboratory approved for a specific agent obtains a presumptive-level identification of a possible foreign animal disease (FAD) using the defined testing procedure contained in the current agent-specific protocols (provided by the NAHLN), the 1) State Animal Health Official and their respective state notification line, and 2) United States Department of Agriculture, APHIS, VS, NVSL and the AVIC will be immediately notified. Given the potential sensitivity of this information, procedures for confidential and secure communications shall be defined in advance and address issues of consistent and timely exchange of information in the event of an emergency response situation. It is important that this communication relationship be properly maintained in order to foster network integrity and future exchange of time-sensitive information. It should be kept in mind that some notification thresholds might vary according to challenges unique to a specific biological threat agent.

- Yes, I agree to comply with the General NAHLN Notification Plan for Potential Foreign Animal Disease and/or Bioterrorism Events.**



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14. Materials (protocols, assays, reagents, controls, select agents, etc.) distributed by the NAHLN are for purposes related to animal health practice, multi-center validation studies, test validation and the need to participate in the network proficiency testing program. NAHLN materials are not intended for research use. There will be no distribution of high consequence livestock pathogens and toxins or select agents or of any NAHLN materials outside of the receiving facility to which the NAHLN originally transferred the materials unless approved in advance by National Veterinary Services Laboratories (NVSL), NAHLN. *Failure to comply with all regulations and policies by any party may result in immediate loss of the laboratory's approval to conduct NAHLN testing for high consequence livestock pathogens and BT agents.*
- Yes, I agree to participate in the NAHLN proficiency testing program, assure that our laboratory personnel will not distribute any NAHLN materials outside of the laboratory, and be compliant with current high consequence livestock pathogens and toxins and select agent regulations. I also understand that, if necessary, transfer of materials must be approved in advance of the transfer by NVSL, NAHLN personnel.**



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15. Once included in the NAHLN Network, the laboratory must have or develop the capacity to electronically transmit the standardized test result data to the NAHLN repository and must restrict access to samples and results only to those personnel previously approved for access to the secure NAHLN Website.
- Yes, I agree to have or develop the capacity to electronically transmit test result data to the NAHLN repository. I also understand that, if necessary, transfer of samples or results must be approved in advance of the transfer by NVSL, NAHLN personnel.**



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16. NAHLN laboratories may be involved in surveillance for early detection of foreign animal disease, surge testing during an outbreak, and testing samples during the outbreak recovery phase. As such, there must be a high degree of confidence in the quality of the laboratories and associated test results. All NAHLN laboratories must be fully accredited by AAVLD or by an accrediting body according to the OIE/ISO 17025 standard. If a NAHLN laboratory is not accredited, it must have implemented a Quality System consistent with OIE/ISO 17025 standards, be willing to participate in regular site visits, and must be approved by USDA, APHIS, VS, NVSL. Each NAHLN laboratory, regardless of type of accreditation or accreditation status, must agree to provide documentation concerning accreditation and implementation of an OIE/ISO 17025 Quality System, and must agree to NAHLN compliance audits and/or site visits upon request.
- Yes, I will provide documentation of accreditation and implementation of a Quality System consistent with OIE/ISO 17025 standards, and I will agree to site visits and/or NAHLN compliance audits upon request.**



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Section A Signature is Required from the Following Individuals:

- D.**
- Laboratory Director
 - Responsible Official (RO) or Biosafety Officer
 - Dean of College or Designated Authority
 - State Animal Health Official
 - AVIC
 - State Dept. of Agriculture Director, Agriculture Commissioner, or Equivalent

As well as Name, Title, Phone and Email for Laboratory Official Point of Contact and Alternate Point of Contact for High Consequence Livestock Pathogens and Toxins and Select Agents

Failure to comply with all regulations and policies by any party may result in immediate loss of the laboratory's approval to conduct NAHLN testing for high consequence livestock pathogens and BT agents.



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Required Documentation from Accredited Laboratory

- Documentation of accreditation
 - AAVLD
 - ISO 17025
 - Scope should include NAHLN activities



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Required Documentation from Non-accredited Laboratory

- Submit copy of Quality Manual
 - Documents
 - Organizational chart
 - SOPs
 - Document control
 - Corrective and preventative actions
 - Records management
 - Internal audits
 - Training of personnel and proficiency testing
 - Chain-of-custody procedures
 - Equipment maintenance/calibration
 - Sample receipt, handling, and traceability
 - Reporting test results



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Next Steps

- January 14, 2009
 - Laboratory Directors
 - Send additional questions to VS NAHLN office
- January 21, 2009
 - VS NAHLN office
 - Provide written responses to questions
- January – February 2009
 - Laboratory Directors
 - Coordinate completion of checklist
 - Provide completed checklist and documentation to VS NAHLN office by **February 27, 2009**



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Review of Completed Application Packets

- Review NAHLN Checklist for completion and signatures
- Review Quality System documentation
 - AAVLD or ISO 17025 Accredited
 - Review completed checklist
 - Not currently accredited
 - Review completed checklist
 - Review submitted documents for completion
 - Schedule laboratory visit
 - 1 year to implement quality system



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Notification of Acceptance

- Email will be sent to Laboratory Director
 - Email will include a letter of acceptance
 - CC AVIC and SAHO
- Letter of acceptance will also be mailed to Laboratory Director



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THANK YOU



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