Animal and Plant Health Inspection Service

September 2016

U.S. National List of Reportable Animal Diseases (NLRAD) Framework

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Executive Summary

The development of the United States National List of Reportable Animal Diseases list and this Framework has been a joint effort on the part of Veterinary Services and numerous stakeholders. In July 2014, a concept paper was shared for review. Based on the interest and comments received on the concept paper, this Framework was developed to more specifically address NLRAD implementation. Prior to the implementation of the NLRAD, the Animal and Plant Health Inspection Service (APHIS) will follow the rule making process and, when complete, will publish in the Federal Register.

The NLRAD is divided into two categories: Notifiable Diseases and Conditions and Monitored Diseases (see Appendix A). Monitored diseases are reported through periodic summary reporting of occurrence. The Notifiable Diseases and Conditions section is subdivided into emergency incidents, emerging disease incidents, and regulated disease incidents. A disease or condition listed as notifiable must be brought to the attention of the Federal and State veterinary authorities within prompt, defined timeframes, in accordance with national and State regulations. NLRAD regulatory authorities will require Federal and State reporting from any individual, producer, veterinarian, laboratory personnel, wildlife or zoo personnel, researcher, public health official, or others with knowledge of occurrence or suspected occurrence of a notifiable disease.

The NLRAD list is intended to be a dynamic document that will be reviewed annually to determine if there are any diseases that need to be added to or removed from the list or change the category in which a disease has been placed. Standard operating procedures (SOP) have been developed for the process to update the list. A VS internal cross-unit team will be established to consider any updates and stakeholders will be given the opportunity to submit suggested revisions. The VS Deputy Administrator will provide the final approval of the list and all changes will be codified via a *Federal Register* notice.

Laboratories will play a key role in the implementation of the NLRAD Framework including: definitions, reporting criteria, and details involving information sharing and communication. The actions and responsibilities identified in the NLRAD Framework are applicable to both publically funded veterinary diagnostic laboratories and private diagnostic laboratories; all laboratories, both National Animal Health Laboratory Network (NAHLN) and non-NAHLN, performing diagnostic testing in the United States are required to recognize and abide by the NLRAD rule. This Framework includes laboratory case classifications and a Reporting Guidance for Laboratories table in Appendix B.

NLRAD reporting is required at many levels, from Federal and State officials to the general public, making both internal and external communication critical. The NLRAD rule will not change how national reporting is accomplished for monitored diseases, FADs, or regulatory program diseases. Regulations and requirements for these diseases will continue to follow established guidance. For non-FADs or non-regulatory program notifiable diseases (such as high priority or emerging diseases): anyone who identifies an occurrence or suspected occurrence is required to report it to the VS Deputy Administrator and State Animal Health Officials.

Data management will play a central role in NLRAD activities and processes including: data acquisition, processing, analysis, and reporting in alignment with defined reporting criteria for NLRAD-listed diseases and

incidents. There are existing IT systems currently used for monitored diseases, emergency incidents, and regulated disease incidents. A component in the data system to support Comprehensive and Integrated Surveillance (CIS) will be used for emerging disease incidents.

APHIS ensures confidentiality to the extent possible and treats sensitive producer information with the respect and security it deserves. This will not change with the implementation of NLRAD.

Section 1. Introduction

The United States National List of Reportable Animal Diseases (NLRAD) is a uniform, science- and policy-based, nationally supported standardized list of animal diseases. It provides the basis for consistent reporting with uniform case findings and reporting criteria. It facilitates domestic and international commerce; assists in meeting international reporting obligations to the World Organization for Animal Health (OIE) and trading partners; supports the generation of export certifications; contributes to the assessment and reporting of listed zoonotic and endemic animal diseases; and facilitates response to an emerging disease or issue in the United States.

Regulatory action will officially recognize the NLRAD and codify specific reporting requirements for laboratory personnel, veterinarians, producers, and others to State and Federal animal health authorities. The U.S. agriculture infrastructure is vulnerable to significant damage from listed as well as emerging diseases. Creating the NLRAD provides consistent reporting across the United States and helps animal health officials protect the U.S. agriculture infrastructure.

The NLRAD was developed in direct collaboration with numerous stakeholders including the United States Animal Health Association (USAHA), American Association of Veterinary Laboratory Diagnosticians (AAVLD), and National Assembly of State Animal Health Officials (NASAHO). The NLRAD list (Appendix A) is primarily based on the OIE list of reportable diseases. It is intended to complement and supplement State reportable disease lists and builds on the current National Animal Health Reporting System (NAHRS). The NLRAD focuses primarily on livestock, poultry and aquaculture species; however, it is recognized that wildlife, companion animals, and zoo animals have the potential to play a significant epidemiologic role in a disease affecting our Nation's agriculture industry.

1.1 Stakeholders

A partial list of likely stakeholders and responsible parties, along with their anticipated roles, is presented below:

Stakeholders	Interest
Representatives of industries: • Aquatic • Avian/poultry • Beef & bison • Cervid • Dairy	- Industry-specific scientific, policy, and trade issues

• Equine • Pork • Small ruminant	
State Animal Health Officials	- State diagnostics and regulatory disease control programs - Significant input and influence on the diseases on the list and the reporting process, including routine reporting of disease occurrences
Veterinary, wildlife, and public health diagnostic laboratories	- Animal disease diagnostics and communication of results
Tribal leaders	- Tribal-specific policy and disease control issues, reporting
Responsible Parties	**Responsibility**
Veterinary Services (VS) • Surveillance, Preparedness and Response Services (SPRS) • National Import and Export Services (NIES) • Science, Technology, and Analysis Services (STAS) • Program Support Services (PSS)	- Cooperative data sharing and reporting - Implementation and management of VS disease activities - Import, export and international health status management - Development of Federal emergency response plans for notifiable and emerging diseases - Development of VS documents and stakeholder communication
SPRS • National Veterinary Accreditation Program (NVAP) • Directors, Assistant Directors (ADs), Epidemiologists and Field Staff • One Health Coordination Center (OHCC)	- Oversee the regulation of, education and communication to accredited veterinarians - Passive and active surveillance support, field investigations, implementation of Federal response plans if necessary, disease reporting - Zoonotic related considerations related to an NLRAD-listed disease incident
STAS • Surveillance, Design, and Analysis (SDA) • Office of STAS Interagency Coordination (OSIC) • Risk Identification and Risk Analysis (RIRA) • National Veterinary Services Laboratories (NVSL) • National Animal Health Laboratory Network (NAHLN) Program Office	- Development of reporting criteria and case definitions for the NLRAD-listed diseases, data collection, NAHRS and OIE reporting - Risk-based analysis, spatial analysis, epidemiologic investigation support - Coordination with other governmental entities - Diagnostic laboratory support; expertise, reference laboratory services

	- Uphold NAHLN lab standards and quality; coordination of laboratory data reporting and payment to laboratories
PSS • Division of Information Technology (DIT) • Writing, Outreach, and Regulatory Division (WORD) • Writing, Editing, and Regulatory Coordination (WERC)	- IT systems for data management - Planning and coordinating stakeholder communications such as GovDelivery notices and outreach events - Preparation of regulatory workplans to implement and update the NLRAD - Issue and maintain guidance documents and program standards
APHIS Wildlife Services (WS) and State wildlife management agencies	- Passive and active surveillance support related to NLRAD-listed diseases that affect wildlife
Veterinary, wildlife, and public health diagnostic laboratories	- Sample testing and test reporting (notifiable and monitored) - Reporting animal or farm location if relationship found to a human case of an NLRAD-listed disease
Producers, veterinarians, laboratories, animal owners, or anyone with knowledge of a 'NLRAD Notifiable' disease in an animal	- Reporting of suspected/or known disease occurrences

1.2 Authority

The authority for the NLRAD comes primarily from the Animal Health Protection Act (AHPA) codified in 7 U.S.C. 8301-8322, which grants the USDA Secretary the authority over the control and eradication of animal diseases. Further, the Homeland Security Presidential Directive (HSPD-9) requires the establishment of a

> "…national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies. The [Secretary of Agriculture and other, relevant Department heads] shall develop robust, comprehensive, and fully coordinated surveillance and monitoring systems, including international information, for animal disease…that provides early detection and awareness of disease, pests, or poisonous agents; develop systems that as appropriate, track specific animals and plants, as well as specific commodities and food…"

Additionally, a December 2015 U.S. Government Accountability Office (GAO) report entitled: Emerging Animal Diseases- Actions Needed to Better Position USDA to Address Future Risks recommended that USDA better define roles and responsibilities related to how the agency will respond to emerging animal diseases. These actions would include the laboratories' role in the detection and identification of disease incidents as well as the communication and reporting of findings.

1.3 Existing Guidance

In 2014, VS Guidance 12001 Policy for the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents (FAD/EDI) was updated and provides VS policy for the investigation and communication of a potential Foreign Animal Disease/Emerging Disease Incident (FAD/EDI). Specific communication and operational procedures are provided in the Foreign Animal Disease Investigation Manual.

Veterinary Services has also developed a *Veterinary Services Proposed Framework for Response to Emerging Animal Diseases in the United States* and a subsequent *Emerging Animal Disease Preparedness and Response Plan.* The framework describes four goals for addressing emerging diseases that include:

1) Undertake global awareness, assessment, and preparedness for animal diseases or pathogens not currently in the United States that may be of animal or public health concern or have trade implications;
2) Detect, identify, and characterize disease incidents;
3) Communicate findings and inform stakeholders; and
4) Respond quickly to minimize the impact of disease incidents.

While the NLRAD Framework describes the reporting requirements for specified diseases as well as emerging diseases, the *Emerging Animal Disease Preparedness and Response Plan* describes the processes by which USDA will identify, evaluate and respond to emerging diseases in animal populations. It should be noted that with regard to emerging diseases VS will undertake adaptive response measures, rather than a predetermined control action.

The codified reference to the NLRAD is intended to indicate that the actual list will be in VS Guidance Document format. This rulemaking will be flexible and responsive to essential updates and changes to the list as needed.

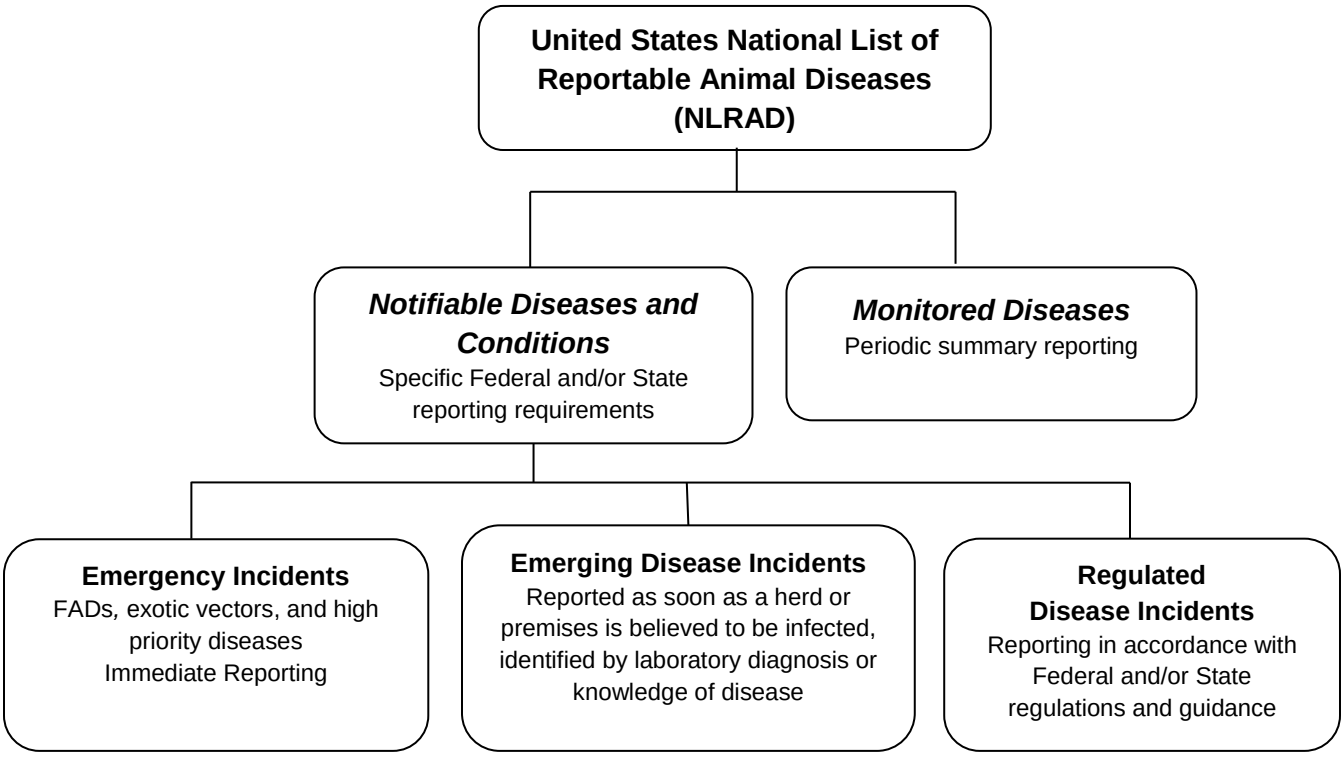
1.4 Regulatory Plan

Veterinary Services intends to proceed as quickly as possible with codification of the NLRAD in regulation. Once comments on this document are received and reviewed, APHIS will begin drafting the proposed rule.

Section 2. NLRAD Structure and Reporting

2.1 Format of the Reportable Animal Disease List

FIGURE 1. REPORTABLE DISEASES, CONDITIONS, AND INCIDENTS



2.2 United States National List of Reportable Diseases

The NLRAD is a list of diseases reportable to VS, the U.S. national veterinary authority. The NLRAD is divided into two categories: Monitored Diseases and Notifiable Diseases and Conditions. The Notifiable Diseases and Conditions section is subdivided into emergency incidents, emerging disease incidents, and regulated disease incidents. The category in which a disease is placed is not finite but can be moved from one category to another in accordance with NLRAD updates and editing procedures. VS and State animal health officials (SAHO) must closely communicate and cooperate on required reporting. Monitored diseases are reported through periodic summary reporting of occurrence.

2.2.1 Overview of Notifiable Diseases and Conditions

A disease or condition listed as notifiable by the national veterinary authority must be brought to the attention of the Federal and State veterinary authorities within prompt, defined timeframes, in accordance with national and State regulations. NLRAD regulatory authorities will require Federal and State reporting from any individual, producer, veterinarian, laboratory personnel, wildlife or zoo personnel, researcher, public health official, or others with knowledge of occurrence or suspected occurrence of a notifiable disease.

For reporting purposes:

A list of SAHOs can be found at: http://www.usaha.org/Members.aspx

A list of the contact information for VS Assistant Director (AD) offices in each state can be found at: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/contact-us

The vast majority of reporting of NLRAD notifiable diseases is expected to be through veterinarians and diagnostic laboratories; however, due to the serious nature of notifiable diseases and their possible deleterious impact on U.S. animal agriculture, reporting of these diseases is required by anyone who has knowledge or suspicion of these diseases.

2.2.1.1 Emergency Incidents (FADs, exotic vectors, and high priority diseases)

VS Guidance 12001 describes the investigation response to an FAD or EDI. It defines a FAD as a terrestrial animal disease or pest, or an aquatic animal disease or pest not known to exist in the United States or its territories, and reporting is required by accredited veterinarians (see 5.1.2). Regulations and requirements for these diseases remain in place. Authority under the NLRAD rule would require reporting by anyone identifying or suspecting a notifiable disease or condition; the implementation of the. NLRAD will not otherwise change how national reporting and investigation is accomplished for FADs or regulated diseases.

2.2.1.2 Emerging Animal Disease Incidents

An emerging animal disease (Appendix A) is defined as**:** A disease, infection, or infestation in domestic or wild animals that is a threat to terrestrial animals, aquatic animals, or humans, and meets one of the following criteria:

1. An unknown agent that is causing disease, infection, or infestation in a herd/flock/premises and has the potential to result in a significant animal or public health impact, and applied diagnostic tests have yielded negative or non- definitive results; OR
2. A newly identified agent that is causing disease, infection, or infestation in a herd/flock/premises and has the potential to cause significant animal or public health impact, or is occurring in multiple herds/flocks/premises; OR
3. A previously identified or known pathogenic agent that has a change in epidemiology, such as:
    a. Increased pathogenicity,
    b. Expanded host range,
    c. Change in geography of an agent with the potential to cause a significant animal or public health impact, or
    d. Unexpected morbidity/mortality

Suspected emerging animal diseases must be reported immediately to both State and Federal animal health authorities. A case must be reported as soon as the herd or animal is determined to be infected through observation of case-compatible signs (if developed) or other knowledge of infection. Specific details on continued disease reporting once an emerging disease has been identified will be determined on an incident basis.

2.2.1.3 Regulated Disease Incidents

The implementation of the NLRAD expands the reporting requirement to anyone with knowledge of occurrence, but does not otherwise change national reporting requirements for FADs or regulated diseases. Current regulations and requirements for these diseases remain in place.

2.2.2 Overview of Monitored Disease(s)

A monitored disease is a disease or condition where occurrence is routinely tracked and data are used to monitor changes in a given population and its environment, or to report on disease occurrence. SAHOs and VS ADs are the primary responsible parties for collecting, collating, and reporting data on monitored diseases. Laboratories will report positive testing and occurrence information to the SAHO in the State where the laboratory is located and the State where the animal is located (if different). SAHOs collect monitored disease occurrence data on diseases that meet case definitions; data are primarily from veterinary, wildlife, and public health diagnostic laboratories but can include data from any verifiable source.

Monthly summary data on all NLRAD reportable diseases, including both notifiable and monitored diseases will continue to be routinely reported by SAHOs to VS through a national reporting system such as the NAHRS, in accordance with program guidance. Monitored diseases usually have no Federal regulatory action associated with identification.

Section 3. NLRAD List Maintenance and Standard Operating Procedures

The NLRAD SOPs emphasize that the OIE-listed diseases are the basis of the NLRAD. These SOPs describe processes for approving, maintaining, and reporting of NLRAD-listed diseases or incidents. These procedures include the annual review, updating, editing, and approval of the NLRAD criteria for revising case definitions, and disease reporting.

3.1 Approval and Annual Review of the NLRAD

On an annual basis, VS, in collaboration with SAHOs, the USAHA and AAVLD, the industries, and other stakeholders will review the NLRAD and make recommendations for any changes to the NLRAD-listed diseases. The routine review process for the NLRAD list will be initiated no later than May of each year. May is the month when the OIE General Assembly meets and adopts changes to the OIE-listed diseases. The NLRAD review will evaluate diseases that are added to or removed from the OIE-listed diseases; diseases that are recommended for addition or removal by VS or by stakeholders; diseases recommended to be moved from one category to

another; and new pathogens that emerge. The VS Deputy Administrator will have the final authority for approval and maintenance of the NLRAD. All changes to the NLRAD will be communicated via a *Federal Register* notice.

3.2 Updates and Edits to the NLRAD

Updates and edits to the NLRAD will be considered when:

- Changes are made to the OIE List of Reportable Diseases
- An emerging disease or issue is identified with significant animal or public health impact
- Changes are made in VS regulations, memoranda, or guidance documents
- Changes are made on the National Veterinary Stockpile (NVS) list; Health and Human Services (HHS)/USDA Select Agent List; or Centers for Disease Control and Prevention (CDC) Category A, B, C bioterrorism agent/disease list
- Changes or additions are requested by stakeholders

3.3 Standard Procedures and Structure of the NLRAD Review and Approval Process

3.3.1 Routine Updates of the NLRAD

1. Each year in May, the OIE World Assembly of Delegates General Assembly meets to review and adopt or reject recommended changes to the international standards for animal health (terrestrial and aquaculture) including the OIE-listed diseases for the following year.
2. VS will establish an internal cross-unit team to conduct an internal review of the NLRAD list and process. Consideration will be given to updates and edits to the NLRAD described under 3.2. Recommendations from the cross-unit team will be recorded.
    a. Additions to the OIE-listed diseases will be incorporated into the recommended NLRAD list for the following calendar year.
    b. Deletions of diseases from the OIE-listed diseases will be reviewed and considered for deletion versus continued listing on the NLRAD.
    c. Written proposals addressed to the VS Deputy Administrator requesting the addition or deletion of a non OIE-listed disease to the NLRAD will be reviewed.
        i. The VS SPRS Commodity Health Center with the main responsibility for the submitted, proposed disease changes will present the proposal to the entire NLRAD review group with a recommendation to accept or reject the proposal to change the NLRAD.
        ii. The VS cross-unit team will develop a recommendation to accept or reject the proposed changes to the NLRAD.
    d. All other updates and edits to the NLRAD will be reviewed.
    e. On a quorum majority of the internal VS cross-unit team, recommendations will be provided to the VS Executive Team (VSET) regarding the composition of the NLRAD for the following calendar year. All dissenting opinions from the majority also will be made available for the VSET to review.

f. Case definitions for all recommended diseases will be reviewed by VS. Definitions will be updated or created as necessary.

3. The USAHA/AAVLD NAHRS Steering Committee, a subcommittee of the USAHA/AAVLD Committee on Animal Health Surveillance and Information Systems, will review the recommended NLRAD and provide recommendations, if any, to the VS cross-unit team. The NAHRS Steering Committee includes broad membership representation from APHIS, laboratories, SAHOs, and industry commodity groups. The NAHRS Steering Committee has been closely involved in the development of a NLRAD and the NAHRS. The VS cross-unit team will consider the NAHRS Steering Committee recommendations and evaluate if any changes should be made to the NLRAD prior to VS leadership review. These recommendations will also be available to the VSET for review.
4. The VSET will review and provide initial approval or disapproval of the recommended NLRAD. If not approved, the recommended NLRAD list will go back to the VS cross-unit team to address concerns expressed by the VSET.
5. The NASAHO reviews recommended changes to the proposed NLRAD.
6. Additional stakeholder input is requested (e.g., USDA Stakeholder Announcement)
7. The internal VS cross-unit team will evaluate feedback, and with VSET input, decide if changes or edits are required to the recommended NLRAD.
8. VS Deputy Administrator will provide the final approval for the NLRAD, which will go into effect the following calendar year. (Completed November timeframe, this will allow time for NLRAD preparation for upcoming year)
9. All changes to the NLRAD will be codified via a *Federal Register* notice.

3.3.2 Addition of an Emergency Issue or Emerging Disease to the NLRAD

In situations where additions to the NLRAD-listed diseases require expedited action, such as in the case of an emergency issue or newly identified emerging disease or incident, the updates and edits to the NLRAD will follow this emergency approval procedure:

a. The VS cross-unit team recommends the expedient addition of a disease(s) to the NLRAD and the recommended reporting requirements.
b. A case definition for the disease proposed for addition to the NLRAD will be developed.
c. VSET decides on initial approval or disapproval of an expedient addition/edit to NLRAD.
d. NASAHO reviews the request and provides input.
e. The VS Deputy Administrator accepts or rejects the final approval for the emergency addition of the disease to the NLRAD.
f. Implementation of reporting requirements with notification of stakeholders will take effect as soon as feasible.

3.3.3 Addition of a Non OIE-Listed Disease or Condition to the NLRAD

In conjunction and collaboration with VS, stakeholders may recommend adding a disease or condition to the NLRAD. The disease or condition could include:

1. The disease has a history of causing significant production losses in susceptible species and morbidity or mortality are related to the agent and not solely management or environmental factors. There is a direct economic impact from the disease linked to its associated morbidity, mortality, or effects on product quality; OR
    a. The disease has been shown to have, or scientific evidence indicates that it is likely to have, a significant negative effect on wildlife; OR
    b. The agent that causes the disease is of high public health concern (zoonotic); natural transmission to humans has been proven and human infection is associated with severe consequences.
2. The infectious etiology of the disease is proven, or if the etiology is not yet known, an infectious agent is strongly associated with the disease; AND
    a. A repeatable and robust means of detection/diagnosis exists; AND
    b. A robust case definition is available to clearly identify cases and how cases are to be distinguished from other pathologies.
3. The disease has met the definition of an Emerging Disease (Appendix A).

A written proposal addressed to the VS Deputy Administrator should be submitted stating the reasoning for the suggested addition. The written proposal will include evidence of the significance of production losses or morbidity/mortality related to the agent of the disease or condition; or on the significant impact to animals or public health. If the disease is determined to be reportable, the information collected on the disease should assist VS and stakeholders with controlling, eradicating, managing, or developing baseline information related to the disease. The approval of the proposal to add a non OIE-listed disease will go through the standard procedures outlined in 3.3.1, Routine Updates of the NLRAD.

Section 4. Laboratory Role in NLRAD

Laboratories will play a key role in the implementation of NLRAD including: definitions, reporting criteria, and details involving information sharing and communication. The actions and responsibilities identified in the NLRAD Framework are applicable to both publically funded veterinary diagnostic laboratories and private diagnostic laboratories; all laboratories, both NAHLN and non-NAHLN, performing diagnostic testing in the United States are required to recognize and abide by the NLRAD.

The NLRAD Framework focuses on the diseases in the two NLRAD categories—notifiable and monitored disease lists, which include emerging diseases. The laboratories further classify the agents into known and unknown agents until they can be identified via a diagnostic test.

4.1 Disease Definitions

4.1.1 Known Agents

Notifiable diseases and conditions and monitored diseases are those defined by the most current version of the NLRAD list. Most diseases on the notifiable diseases and conditions and monitored diseases lists already have a defined case definition based on known diagnostics and epidemiology of the agent. VS maintains a library of case definitions for known agents.

4.1.2 Emerging Animal Disease

A complete case definition for an emerging animal disease can be found in Appendix A. In summary, an emerging disease is a disease, infection, or infestation in domestic or wild animals that is a threat to terrestrial animals, aquatic animals, or humans.

4.2 Case Definitions

Standardized national case definitions and reporting criteria are essential to the usefulness of reported animal disease data. The development of national standardized case definitions requires collaboration and coordination between many internal and external partners. VS STAS Center for Epidemiology and Animal Health (CEAH) coordinates the development of case definitions for all diseases on the NLRAD and is responsible for ensuring that the necessary expertise is collated into the document (e.g., epidemiology, disease specialists, laboratory, and emergency response). Case definitions will include input from State and Federal animal health officials. For FADs and regulatory program diseases, final approval is at the VS Deputy Administrator level. For endemic diseases, initial approval is at the VS SPRS Commodity Health Centers level.

4.3 Case Classification

The case classification or state of the disease is used to define the trigger for communication/reporting. The state of the disease can be classified into three categories (suspect, presumptive, and confirmed):

4.3.1 Monitoring and Notifiable Diseases

In general, known agents from the monitoring and notifiable lists can be classified as the following:

- **Suspect case:** Epidemiological information indicative of exposure, or clinical signs consistent with the disease of concern.
- **Presumptive case**: A suspect case that has epidemiological information indicative of exposure and positive screening test. In some instances, a presumptive case classification can be considered as a final or confirmed case with no further diagnostics planned. This will be stated in the specific disease case definitions.
- **Confirmed case:** A laboratory confirmation has been made using the accepted diagnostic test(s) for the disease of concern that unequivocally determines the presence of the agent of concern.

4.3.2 Emerging Animal Diseases

The case classification for emerging diseases is:

- **Suspect**: Presence of clinical signs and meets the case definition for emerging disease, laboratory has received submissions from multiple sources/farms; applied diagnostic tests yielded negative or non-definitive results.
- **Presumptive**: Laboratory receives preliminary diagnostic results identifying a new or known agent meeting the case definition for emerging animal disease.
- **Confirmed:** Confirmed presence of a newly identified or known agent via sequencing, virus isolation, or other technologies.

Section 5. NLRAD Communication

Communication will play an integral role in NLRAD implementation. NLRAD reporting is required at multiple layers of society from Federal and State officials to the general public, making both internal and external communication critical. An outline of who must report what information, when, and to whom is presented below.

5.1 Reporting an NLRAD Disease

NLRAD will not change how national reporting is accomplished for monitored diseases, FADs, or regulatory program diseases. Regulations and requirements for these diseases will continue to follow established guidance as provided by the U.S. Code of Federal Regulations (CFR) or VS guidance documents. For non-FADs or non-regulatory program notifiable diseases (such as high priority or emerging diseases), anyone who identifies an occurrence or suspected occurrence of a notifiable disease is required to report it to the VS AD and SAHO.

> For reporting purposes:
>
> A list of SAHOs can be found at: http://www.usaha.org/Members.aspx
>
> A list of the contact information for VS AD offices in each State can be found at: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/contact-us

SAHOs and VS ADs must closely communicate and cooperate on required reporting to ensure all responsible parties are in the notification (reporting) process and duplication of reporting does not become an issue. A standardized reporting process related to non-FADs or non-regulatory program notifiable diseases will be cooperatively developed and information and data sharing on NLRAD will be expanded to provide appropriate feedback to stakeholders and responsible parties. Inclusion of Tribal Nations as cooperators will occur through SAHOs and the APHIS Native American Program Coordinator.

5.1.1 Who Should Report and To Whom

5.1.1.1 Notifiable Diseases

NLRAD regulatory authorities will require reporting to the VS AD and the SAHO by anyone with knowledge of occurrence/or suspected occurrence of all diseases or conditions listed as NLRAD notifiable. This includes any individual, producer, veterinarian, laboratory personnel, wildlife or zoo personnel, researcher, public health official, or others with knowledge of occurrence or suspected occurrence of a notifiable disease. As an example, accredited veterinarians are currently required by regulation to immediately report to the VS AD and the SAHO all diagnosed or suspected cases of a communicable disease for which VS has a control or eradication program, or animal diseases not known to exist in the United States. The vast majority of reporting of NLRAD notifiable diseases is expected to be through veterinarians and diagnostic laboratories; however, due to the serious nature of notifiable diseases and their possible deleterious impact on U.S. animal agriculture, reporting of these diseases is required by anyone who has knowledge or suspicion of these diseases.

5.1.1.2 Monitored Diseases

SAHOs are the primary responsible parties for collecting, collating, and reporting data on monitored diseases to the VS AD or through an established State reporting process. Laboratories are required to report positive testing and occurrence information to the SAHO in the State where the laboratory is located and the State where animal is located (if different). SAHOs collect monitored disease occurrence data on diseases that meet case definitions; data are primarily from veterinary, wildlife, and public health diagnostic laboratories but can include data from any verifiable source.

5.1.2 Data Reporting Responsibilities

- ***Diagnostic Laboratories-*** Laboratories, including publically funded, private, NAHLN, or non-NAHLN, are responsible for reporting the diagnostic information related to an NLRAD-listed monitored disease to the SAHO, both where the laboratory is located and where the sample was collected; back to the submitter of the sample; and to other parties as needed. For NLRAD-listed notifiable diseases and conditions, the VS AD must also be notified. [See Appendix B for detailed timeframes for laboratory reporting based on NLRAD category of disease and case classification.]
- ***Accredited Veterinarians***- Accredited veterinarians are required to report disease occurrence for NLRAD-listed notifiable diseases and conditions, as well as each State's supplemental reporting disease list. 9 CFR 161.4 (f) states that "an accredited veterinarian shall immediately report to the Veterinarian-in-Charge [note: now referred to as the VS AD] and the SAHO all diagnosed or suspected cases of a communicable animal disease for which APHIS has a control or eradication program in 9 CFR chapter I, and all diagnosed or suspected cases of any animal disease not known to exist in the United States as provided by §71.3(b) of this chapter." For NLRAD-listed monitored disease and conditions, reporting is required only to the SAHO.

- ***Non-accredited Veterinarians***- Although not required by the current CFR to report, anyone with knowledge of occurrence/or suspected occurrence of all NLRAD-listed diseases or conditions is required by NLRAD to report (for monitored diseases and conditions only to the SAHO, for notifiable disease and conditions to the VS AD and SAHO).
- ***Others*** – NLRAD requires reporting by anyone with knowledge of occurrence/or suspected occurrence of all NLRAD-listed diseases or conditions (for monitored diseases and conditions only to the SAHO, for notifiable disease and conditions to the VS AD and SAHO). This includes any individual, producer, wildlife or zoo personnel, public health official, or others with knowledge of occurrence or suspected occurrence of an NLRAD-listed disease.
- ***State Officials***- the SAHO is one of the initial and primary points of contact on all NLRAD-listed disease categories; direct communication with the SAHO is important. Generally, as much data and information as available and requested will be provided to the SAHO(s) both where the laboratory is located and where the sample was collected. SAHOs must closely communicate and cooperate on required reporting with VS ADs, especially on NLRAD-listed notifiable diseases and conditions. For NLRAD-listed monitored diseases and conditions, SAHOs are the primary responsible parties for collecting, collating, and reporting data, within established time frames, directly to the VS AD or through an established State reporting process.
- ***Federal Officials***- VS Guidance 12001 provides detailed guidance on notification to Federal officials for FAD investigations, confirmations, and emerging disease investigations. The key Federal officials include the VS AD and NVSL officials. For other notifiable diseases and conditions and emerging diseases, the same Federal officials need to be included in the communication. For monitored diseases, select VS analysts receive the information from SAHOs to include in U.S. OIE reports.
- ***Industry associations***- Summary information will be shared as determined appropriate by the laboratory and SAHO based on industry expectations and relationships in each State. In cases of FADs and emerging diseases, the content and timing of this communication should be agreed upon and well-coordinated among State and Federal officials.

5.1.3 When Disease Reporting Should Occur

The vast majority of reporting of NLRAD-listed diseases and conditions is expected to be through veterinarians and diagnostic laboratories; however, due to the serious nature of notifiable diseases and their possible deleterious impact on U.S. animal agriculture, immediate reporting of these diseases is required by anyone who has knowledge or suspicion of these diseases.

While the NLRAD Framework provides standardized guidance at a national level for reporting the known and unknown agents/diseases for each of the NLRAD disease categories, it is vital that each State and Federal animal health authority and diagnostic laboratory(ies) within that State have specific discussions about the expectations for the trigger and timeline for reporting diseases and agents of significance in that State.

As the vast majority of NLRAD-listed diseases will be reported through laboratories, more specific guidelines have been established.

Appendix B consist of tables that outline the laboratory reporting specifics for monitored, notifiable, and emerging diseases, respectively, for each case classification including the trigger at the laboratory for reporting results, timeframe, and reporting mechanism.

5.1.3.1 Laboratory Requirements for Monitored Disease List Reporting

Monitored diseases are those that are generally endemic in the United States and are required to be reported to the OIE; associated data are used to monitor changes in disease occurrence over time.

- Case classification: These diseases are usually reported once confirmed by diagnostic results. These are not reported at the suspect level.
- Timeframe: The minimum reporting timeframe for agents on the monitored disease list is monthly. The monitored diseases reporting timeframe may vary by State, based on the disease conditions in that State and expectations of the State and Federal animal health officials.

5.1.3.2 Laboratory Requirements for Notifiable Diseases and Conditions Reporting

These are divided into FADs, non-FADs, and emerging diseases.

5.1.3.2.1 Foreign Animal Disease (FAD) Laboratory Reporting Requirements

The diseases on the notifiable list are of highest reporting priority.

- Case classification: These diseases are reported at least at the suspect level upon receipt of preliminary diagnostic results.
- Timeframe: Due to the high priority and concern, a FAD must be brought to the attention of the State and Federal veterinary authorities immediately –no later than the same day presumptive diagnostic results are available. In most instances, State and Federal authorities are aware of suspect cases based on clinical signs and epidemiology that trigger FAD investigations.

5.1.3.2.2 Non-Foreign Animal Disease (non-FAD) Laboratory Reporting Requirements

These include regulatory and high-priority endemic diseases.

- Case classification: Non-FADs on the Notifiable Diseases and Conditions List can be reported as presumptive (triggered by preliminary positive diagnostic results and epidemiological information) or as a confirmed case, depending on the disease. The distinction is made based on the level of concern within each State, specific VS program disease guidance, CFR requirements for reporting, and/or OIE standards.
- Timeframe: In general, these diseases will be reported to the State and Federal veterinary authorities immediately, no later than the next day following generation of either preliminary or confirmatory diagnostic results for that disease; the case classification for reporting will be in either preliminary or

confirmatory state, which will be agreed upon for each non-FAD disease on the Notifiable Disease List prior to reporting.

5.1.3.2.3 Emerging Diseases Laboratory Reporting Requirements

- Case classification: A suspect case triggers initial reporting by the laboratory when specific or known assays have been conducted yielding a negative or non-definitive result and it meets one or more criterion of the emerging disease definition (Appendix A). The presentation/submission of similar cases from multiple sources or farms will also trigger reporting. The reporting will rely upon the professional judgment and expertise of the veterinarian and laboratorian.
    - Follow-up reporting upon presumptive and confirmatory laboratory results is required.
- Timeframe: The case should be reported immediately, once the definition of emerging disease is met and classified as suspect. The exact timeframe will depend upon the evolution and behavior of the specific disease/agent. The expectation is that initial reporting will occur as soon as possible from initial case presentation; however, highly infectious agents of concern should be reported immediately.
    - Follow-up reporting should occur immediately, no later than the same day that diagnostic results are available.

5.1.4 What Information Should Be Reported

Successful implementation of the NLRAD and emerging disease reporting requires a thorough understanding of what specifically will be reported, who will receive the information and how they will receive it, and clear expectations from all involved about how that information will be used.

Information required will vary based on the time of reporting and the type of NLRAD category of disease. For example, suspect cases may not have diagnostic methodology or results reported. The minimum data that should be reported in each NLRAD disease category are described in this section.

5.1.4.1 Monitored Diseases

Required data reporting for a monitored disease can range from simple occurrence information reporting (yes/no) to expanded case and testing information requested for certain diseases. State, Federal, and industry representatives will collaborate to identify significant diseases in which expanded case and testing information may be collected. The collection, analysis, and reporting of this additional case and epidemiological information will help State, Federal, and industry officials document and monitor national and State disease trends; help meet travel and movement requirements; and evaluate and implement management, control, response, and prevention activities. Expanded information on NLRAD-listed monitored diseases will only occur when there is a cooperative effort between Federal, SAHO, and industry requesting that additional information be collected.

5.1.4.2 Notifiable Diseases and Conditions

VS Guidance 12001 includes the critical data and information that needs to be collected during an investigation. An example of the ideal data set for these diseases would include information found on most laboratory's accession forms:

- Sample identification-- sample ID, animal ID, species, accession number, +/- FAD number, sample type
- Location information-- Owner information, State where sample was collected, and premises identification number (or other approved identification, in coordination with the SAHO)
- Testing information-- Diagnostic methodology, results, and interpretation
- Dates--Date collected, date tested
- Epidemiological information-- clinical signs, case/herd history and type, reason for submission, (+/-) vaccination history

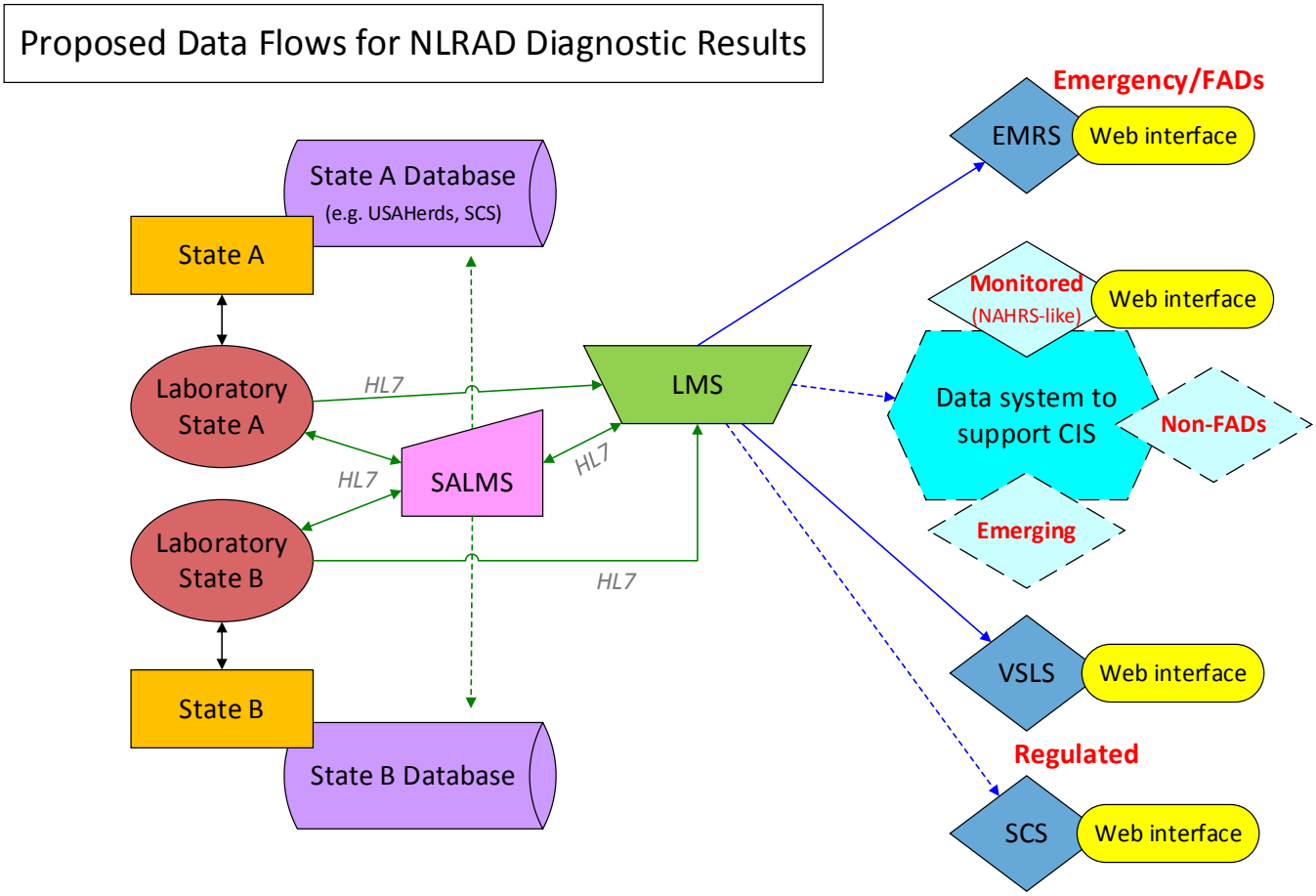
5.2 Communication within APHIS

NLRAD will not change how APHIS internal communication occurs for NLRAD-listed diseases or incidents. Procedures will continue to follow established guidance as provided in existing VS documents.

Section 6. Data Management

Data management will play a critical role in NLRAD activities and processes including data acquisition, processing, analysis, and reporting in alignment with defined reporting criteria for NLRAD-listed diseases and incidents. There are existing IT systems currently used for monitored diseases, emergency incidents, and regulated disease incidents. To fill the remaining gaps, a data system that supports Comprehensive and Integrated Surveillance (CIS) is under design which will leverage existing assets in conjunction with new acquisition and reporting components. This data system will have multiple components to support the remaining NLRAD data needs, such as those for emerging disease incidents and other regulated disease incidents, as well as serve as a point of data integration for users and analysts.

FIGURE 2. PROPOSED DATA FLOWS FOR NLRAD DIAGNOSTIC RESULTS.



Solid: established connection or system
Dashed: proposed connection or system
Colors and shapes denote separate entities (e.g. a laboratory, a database, etc.)

SCS = Surveillance Collaboration Services
LMS = Laboratory Messaging Services
NAHRS = National Animal Health Reporting System
SALMS = State Animal Laboratory Messaging System
USAHerds = United States Animal Health Emergency Reporting Diagnostic System
EMRS = Emergency Management Response System
FAD = Foreign Animal Disease
CIS = Comprehensive and Integrated Surveillance
VSLS = Veterinary Services Laboratory Submissions

6.1 Reporting Needs

Reporting needs vary depending on the NLRAD disease category.

6.1.1 Monitored Diseases

Data collection for monitored diseases is currently based on presence/absence information submitted monthly by SAHOs through the NAHRS. However, in its present state this system is not sufficient for the data collection and reporting needs of the NLRAD Framework. The required functionality will include the ability to collect, link, and store epidemiological data for specific diseases on an as needed basis in addition to capturing disease presence/absence information. Further, the system must be able to capture laboratory result data messaged using Health Level Seven International (HL7) standards and data standards from the diagnostic laboratories and connect with existing State databases (e.g., U.S. Animal Health Emergency Reporting Diagnostic System (USAHerds), Surveillance Collaboration Services (SCS)).

6.1.2 Notifiable Diseases

Regulations and requirements for data collection and reporting of emergency incidents and regulated disease incidents are well established. For such incidents, diagnostic testing results and epidemiological information for infected animals or herds should be collected and recorded with the least amount of data entry possible. The system supports HL7 messaging and USDA or industry accepted data standards. Most of the current systems used are designed to collect and manage only one type of data, and are set up for the collection of data from specific sources, i.e., laboratories versus field personnel. Integration of the various data streams is crucial for effective and timely surveillance. Depending on the disease, reports on its status may be created on a weekly, monthly, or quarterly basis, or other timeframe. These reports provide critical information for decision-makers responding to a disease incident.

Emerging disease incidents have slightly different data and reporting requirements than those of the other two notifiable disease categories. Diagnostic testing results and epidemiological information will be used not only to detect and initially evaluate the status of a potentially emerging disease threat, but also to help implement case definitions and disease reporting criteria for an agent once it has been confirmed as an emerging animal disease. At the time of initial reporting, the specific agent causing a potentially emerging disease may be unknown, or the agent may be a newly identified strain that has not been fully characterized.

6.2 Mechanism for Reporting: How Will Data be Reported?

There are many existing systems involved in the collection, processing, analysis, and reporting of information for monitored diseases, emergency incidents, and regulated disease incidents. The capability to capture emerging disease incidents and more information on monitored diseases is being developed as part of the data system to support CIS.

6.2.1 Reporting Monitored Diseases

The NAHRS program was designed to provide summary-level data on the presence of OIE-reportable diseases and other diseases of importance in the United States. NAHRS is currently a voluntary, collaborative effort between participating States, the AAVLD, USAHA, and APHIS and except for one equine disease, only collects presence/absence data. A "yes" response from a State indicates that at least one new case of that particular disease met the level of certainty for reporting during the specific month; a "no" response indicates that as far as a SAHO is aware, no new cases of disease met the level of certainty required to report the disease in the State that month. Information about animal disease status is reported monthly by SAHOs through the NAHRS Web Reporting Tool, an online application that sends data to an Oracle reporting schema managed by VS. As mentioned above, in its present state NAHRS is not sufficient for the data collection and reporting needs of the NLRAD framework.

The required functionality described in section 6.1.1 to meet the NLRAD framework needs for monitored diseases will be achieved through the development of a new component as part of the data system to support CIS. Information from the component will be one source used by VS analysts to complete reports on monitored diseases that meet international reporting requirements for OIE, trading partners, and other stakeholders.

6.2.2 Reporting Emerging Disease Incidents

VS recommends using a data system that supports CIS to collect and report information for emerging diseases. This component of the data system will be able to collect diagnostic test results for known, newly identified, and unknown agents (e.g., test results are inconclusive or negative, but other supporting evidence suggests a potentially emerging disease) as well as epidemiological information to characterize diseases that do not have agent-specific case definitions or disease reporting criteria. The system will be able to communicate with both internal and external systems and support electronic messaging using recognized data standards such as HL7 or Extensible Markup Language (XML).

6.2.3 Reporting Emergency Disease Incidents and Regulated Disease Incidents

Systems are already in place to handle the data flow and reporting for emergency disease incidents (Emergency Management Response System (EMRS), Laboratory Messaging Services (LMS)) and regulated disease incidents (SCS, Veterinary Services Laboratory Submissions (VSLS)). The data flow is supported by tools used by States (SCS, USAHerds, State Animal Laboratory Messaging System (SALMS)).

6.2.3.1 Surveillance Collaboration Services (SCS)

VS purchased a commercial off-the-shelf software module named CoreOne from Trace First Ltd, configured it to meet business needs, and re-branded it as SCS. SCS supports routine animal health surveillance and program management under the purview of VS SPRS. Instances for all 50 States plus Puerto Rico, Navajo Nation, and Virgin Islands and two national programs are in place for managing animal health information. However, some States use their own private CoreOne application rather than VS' version, SCS, or they use an entirely different State database (see 6.2.3.5). The main functions of SCS include recording data on persons, domains (premises

and herds/flocks/tanks), individual animals, movements, laboratory submissions, and laboratory results. Individuals granted permissions for a certain instance can access the data and summary reports.

6.2.3.2 Veterinary Services Laboratory Submissions (VSLS)

VSLS is an application designed to merge collection site information with the corresponding laboratory test results for the collected samples. Site information is entered manually into the system from approved VS paper forms or through the use of Mobile Information Management (MIM) devices such as personal digital assistants (PDA) and tablet PCs. Laboratory testing results are entered manually or messaged by the labs to VSLS where they are joined to the collection site information. The application allows the animal disease information to be staged and managed until the information from the collection site, the sample information, and the testing information are deemed complete. Once this dataset, known as a submission, is complete, the information is moved by Rhapsody (a VS Message Routing system) to the appropriate production repository, such as SCS. Reports are available in VSLS to help users track ongoing work submissions and support routine surveillance efforts. Several regulated diseases on the NLRAD are currently managed using VSLS.

6.2.3.3 Laboratory Messaging Services (LMS)

LMS was an outgrowth of the NAHLN Information Technology System that was initiated circa 2005. To meet the request of the AAVLD, VS implemented LMS to facilitate the expediency and accuracy of information shared by NAHLN labs. Laboratories electronically message specimen data and test results from the NAHLN's own laboratory information systems directly to LMS using HL7, a set of international standards for transfer of clinical and administrative data between software applications. The messaged data is stored in VS repositories, currently Oracle and SQL Server, although the former is deprecated. The data can be accessed directly through a reporting schema. NAHLN laboratories will message test results for diseases on the NLRAD according to the instructions and standards outlined in the Laboratory Implementation Plan. For emergency incidents and regulated disease incidents, the premises identification number or other unique identifier can be used to join the test result for a sample with its epidemiological information provided through another system such as EMRS 2.0.

6.2.3.4 Emergency Management Response System (EMRS) 2.0

The EMRS 2.0 is a Web-based application used for the reporting of investigations of foreign animal diseases, surveillance and control programs, State specific disease outbreaks, and national animal health emergency responses. It is a Microsoft Dynamics Customer Relationship Management (CRM) application which SAHOs and Federal officials use to manage FAD investigations and incident response. Besides handling collection site and epidemiological information, EMRS 2.0 provides tracing and logistics support which are integral to the management of a disease response. Testing results may be entered directly into EMRS 2.0 but are also pulled directly from LMS where they are joined to collection sites and investigations using matching algorithms based primarily on premises ID and specimen barcodes. In the event that test results cannot be matched, they are retained in EMRS and searchable.

6.2.3.5 State Databases

Each State has a designated system to manage its animal health information. However, the extent of use, how data are input, and which data are captured vary greatly by State. The choice of system primarily depends on the business needs of the State. The two systems currently in place in the States are primarily USAHerds and SCS. USAHerds is an enterprise repository for animal health data and is available to State departments of agriculture.

6.2.3.6 State Animal Laboratory Messaging System (SALMS)

SALMS was developed by Cornell University's Animal Health Diagnostic Center (AHDC) to address a gap in the expedient and efficient transfer of electronic information among the veterinary diagnostic laboratory community in the United States, i.e. between individual laboratories, from laboratories to State databases, and/or from laboratories to VS' LMS. SALMS, which is hosted inside Cornell University's secure firewall, provides a routing and messaging service for any and all Federal and State veterinary diagnostic laboratories. Messaging utilizes industry standards (XML and/or HL7) and no specific software or mechanism is mandated for a lab to participate. Since the primary function of SALMS is to move data from one place to another, it does not read or store data longer than necessary to facilitate secure transfer, thus eliminating confidentiality or data ownership issues. Integration with LMS and SALMS currently exists but is not widely used by labs.

6.3 Next Steps

The first priority is to develop the components of the data system to support CIS as described above to support NLRAD. VS will work jointly with stakeholders in the development of detailed requirements, documentation, and plans for core data management functions identified and defined by the Data Management Association (DAMA) Data Management Body of Knowledge Functional Framework. These functions include:

- *Data Governance* for the planning, supervision, and control over data management and use;
- *Data Architecture Management* as an integral part of the enterprise architecture;
- *Data Development* such as analysis, design, building, testing, deployment, and maintenance;
- *Database Operations Management* to provide support for structure physical data sets;
- *Data Security Management* to ensure privacy, confidentiality, and appropriate access;
- *Reference and Master Data Management* to manage production repositories and replicas;
- *Data Warehousing and Business Intelligence Management* to enable access to decision support data for reporting and analysis;
- *Document and Content Management* for storing, protecting, indexing, and enabling access to data found in unstructured sources;
- *Meta Data Management* for integrating, controlling, and delivering meta data; and
- *Data Quality Management* for defining, monitoring, and improving data quality.

Section 7. Information Release

The NLRAD consists of two general categories of reportable diseases: monitored diseases and notifiable diseases and conditions. VS does not maintain producer information associated with monitored diseases. The only information associated with monitored diseases publicly reported by VS is the presence or absence of disease in a given State. Notifiable diseases and conditions are categorized into three types of incidents: emergency (foreign animal disease, exotic vectors, etc.), emerging disease, and regulated disease. Currently, VS has systems and procedures in place regarding the management of producer information during emergency and regulated disease incidents.

The NLRAD dual-reporting mandate subjects information to both State and Federal Freedom of Information Act (FOIA) or similar types of laws. The APHIS FOIA staff is the first point of contact for all Federal information requests. When a FOIA request is received, the APHIS FOIA staff has to weigh a number of factors and evaluate both the request and the collection of information to ensure that APHIS complies not just with FOIA, but with all other legal requirements as well. Each FOIA request is handled on a case-by-case basis. APHIS treats all sensitive producer information with the respect and security it deserves and would not treat the emerging disease information any differently.

Official information releases include press conferences, news releases, and stakeholder announcements. Any release of information that would be made will be coordinated with SAHOs and appropriate stakeholders including information flow during an emerging disease investigation.

Most diagnostic laboratories already have in place their own policies to protect client information and it is expected that they would be the same and applicable to all of the diseases and agents listed in NLRAD, including emerging diseases.

Additionally , there are a number of options available for the protection of intellectual property around the sharing of agents, diagnostic methodology and assays, and data that can be utilized. These options should all be used where appropriate and as much work as possible be done *a priori* to expedite and address concerns before a situation arises. For example, Material Transfer Agreements (MTA) can be written and signed between institutions. This is common practice and has been successfully used in the past for sharing isolates, data, diagnostic methods, etc. These agreements can define the use of the material for purposes of analysis, confirmatory and/or supplemental diagnostics, further diagnostic or vaccine development, etc. The MTA also defines expectations regarding each party's transfer of the material, communication of findings, and expectations for sharing information.

Specifically for cases in which NVSL becomes involved it is important to understand and communicate NVSL's role. NVSL has responsibilities to support laboratories in their diagnosis and provide consultation given their subject matter expertise. NVSL also has responsibility as the U.S. reference laboratory for animal health to protect U.S. animal agriculture and public health.

Section 8. Summary

The development and implementation of a NLRAD is a significant undertaking that will benefit the U.S. agricultural industry by enhancing U.S. animal disease surveillance and standardization of animal disease reporting. The development, implementation, and acceptance of a NLRAD will occur with extensive stakeholder input.

Section 9. Acronyms

AAVLD	American Association of Veterinary Laboratory Diagnosticians
AD	Assistant Director (formerly the Area Veterinarian in Charge or AVIC)
AHDC	Animal Health Diagnostic Center
AHPA	Animal Health Protection Act
AI	Avian Influenza
APHIS	Animal and Plant Health Inspection Service
ARS	USDA Agricultural Research Service
CDC	Centers for Disease Control and Prevention
CEAH	STAS Center for Epidemiology and Animal Health
CFR	U.S. Code of Federal Regulations
CIO	Chief Information Officer
CIS	Comprehensive and Integrated Surveillance
CRM	Customer Relationship Management
CVB	STAS Center for Veterinary Biologics
DAMA	Data Management Association
DHS	U.S. Department of Homeland Security
DIT	Division of Information Technology
EDF	Emerging Disease Framework
EDI	Emerging Disease Incident
EMRS	Emergency Management Response System
FAD	Foreign Animal Disease
FDA	U.S. Food and Drug Administration
FOIA	Freedom of Information Act
FS	USDA Forest Service

FSIS	USDA Food Safety and Inspection Service
FWS	U.S. Fish and Wildlife Service
GAO	Government Accountability Office
HHS	Department of Health and Human Services
HL7	Health Level Seven International
LMS	VS Laboratory Messaging Services
MIM	Mobile Information Management
NAHLN	National Animal Health Laboratory Network
NAHRS	National Animal Health Reporting System
NASAHO	National Assembly of State Animal Health Officials
NLRAD	U.S. National List of Reportable Animal Diseases
NOAA	U.S. Department of Commerce National Oceanic and Atmospheric Administration
NVAP	SPRS National Veterinary Accreditation Program
NVSL	STAS National Veterinary Services Laboratories
NVS	SPRS National Veterinary Stockpile
OHCC	One Health Coordination Center
OIE	World Organisation for Animal Health (formerly Office International des Epizooties)
OSIC	STAS Office of Interagency Coordination
PDA	Personal Digital Assistant
PIN	Premises Identification Number
PSS	Program Support Services
RIRA	STAS Risk Identification Risk Analysis
SAHO	State Animal Health Official
SALMS	State Animal Laboratory Messaging Service
SCS	Surveillance Collaboration Services

SDA	Surveillance, Design, and Analysis
SOP	Standard Operating Procedures
STAS	VS Science, Technology, and Analysis Services
SPRS	VS Surveillance, Preparedness, and Response Services
NIES	VS National Import and Export Services
UM&R	VS program Uniform Methods and Rules
USAHA	United States Animal Health Association
USAHerds	United States Animal Health Emergency Reporting Diagnostic System
USDA	United States Department of Agriculture
VS	Veterinary Services
VSET	VS Executive Team (VS Leadership)
VSLS	Veterinary Services Laboratory Submissions
WS	APHIS Wildlife Services
XML	Extensible Markup Language

Section 10. References

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Section 11. Appendices

11.1 Appendix A. U.S. National List of Reportable Animal Diseases

Notifiable disease – a disease listed by the national veterinary authority that must be brought to the attention of both the Federal and State veterinary authorities within defined timeframes according to national and State regulations and guidance. In addition to the listed notifiable diseases, these animal disease conditions are notifiable and must be immediately reported:

1. Suspicion or detection of any animal disease or infection not known to exist in the United States
2. Exotic vectors (flies, myiasis, acariases (mites) and ticks), if identified, should be reported to State and Federal animal health officials for further investigation.
3. **Emerging disease:** A disease, infection, or infestation in domestic or wild animals that is a threat to terrestrial animals, aquatic animals, or humans, and meets one of the following criteria:
    a. An unknown agent that is causing disease, infection, or infestation in a herd/flock/premise and has the potential to result in a significant animal or public health impact, and applied diagnostic tests have yielded negative or non- definitive results; OR
    b. A newly identified agent that is causing disease, infection, or infestation in a herd/flock/premise and has the potential to cause significant animal or public health impact, or is occurring in multiple herds/flocks/premises; OR
    c. A previously identified or known pathogenic agent that has a change in epidemiology, such as:
        i. Increased pathogenicity
        ii. Expanded host range
        iii. Change in geography of an agent with the potential to cause a significant animal or public health impact
        iv. Unexpected morbidity/mortality

Monitored disease – a disease in which occurrence is routinely tracked and data used to detect disease occurrence changes in a given population and its environment, or to report on disease occurrence. State animal health officials routinely report the data to the veterinary authority according to NLRAD NAHRS guidance.

Multiple-Species Diseases—disease notification will occur in any species the disease occurs in, especially related to NLRAD Notifiable Diseases. The primary species of occurrence is indicated by the following notations: (Bovine (B); Caprine and Ovine (C/0); Cervid, Equine (E); Lagomorphs (L), Porcine (P); Poultry (PO); Aquaculture (AQ).

Notifiable Multiple-Species Diseases	Monitored Multiple-Species Diseases
• Akabane B, C/O	• Bluetongue (endemic types 2,10,11,13,17) B, C/O
• Anthrax B, C/O, E, P	• Echinococcosis/hydatidosis *(E. granulosis, E. multiocularis, E. oligarthrus, or E. vogeli)* B, C/O, P
• Aujeszky's disease (Pseudorabies, PRV) B, C/O, P	• Paratuberculosis (Johne's disease) B, C/O
• Bluetongue (non-endemic) B, C/O	• Q fever B, C/O
• Brucellosis (*Brucella abortus*) B	• Tularemia L, C/O, E, P
• Brucellosis (*Brucella melitensis*) B, C/O	

- Brucellosis (*Brucella suis*) B, P
- Chronic wasting disease Cervid
- Crimean Congo hemorrhagic fever B, C/O
- Epizootic hemorrhagic disease (EHD) B, Cervid
- Equine encephalomyelitis (Eastern) E
- Equine encephalomyelitis (Venezuelan) E
- Foot-and-mouth disease B, C/O, P
- Glanders *(Burkholderia mallei)* E
- Heartwater B, C/O
- Japanese encephalitis E, P
- Melioidosis (*Burkholderia pseudomallei*) B, C/O, P
- New and Old World screwworms B, C/O, E, P
- Rabies B, C/O, E, P
- Rift Valley fever B, C/O
- Rinderpest B, C/O, P
- Surra (*Trypanosoma evansi*) B, E
- Trichinellosis E, P
- Tuberculosis *(M. bovis, M. tuberculosis)* B
- Vesicular stomatitis B, C/O, E, P
- West Nile fever/virus C/O, E

Notifiable Cattle Diseases	**Monitored Cattle Diseases**
• Bovine babesiosis	• Anaplasmosis *(A. marginale, A. centrale)*
• Bovine spongiform encephalopathy	• Bovine genital campylobacteriosis (*Campylobacter fetus venerealis*)
• Contagious bovine pleuropneumonia	• Bovine viral diarrhea (BVD, mucosal disease)
• Hemorrhagic septicemia	• Enzootic bovine leucosis (BLV)
• Lumpy skin disease	• Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV)
• Theileriosis (East Coast fever)	• Malignant catarrhal fever
• Trichomoniasis	
• Trypanosomosis (tsetse transmitted)	

Notifiable Swine Diseases	**Monitored Swine Diseases**
• African swine fever	• Porcine cysticercosis
• Classical swine fever	• Porcine reproductive and respiratory syndrome (PRRS)
• Nipah virus	• Swine erysipelas
• Swine vesicular disease	• Transmissible gastroenteritis (TGE)
• Vesicular exanthema	
• Porcine epidemic diarrhea virus (PEDv)	
• Porcine deltacorona virus disease	

Notifiable Sheep & Goat Diseases	**Monitored Sheep & Goat Diseases**
• Contagious caprine pleuropneumonia	• Contagious agalactia
• Nairobi sheep disease	• Caprine arthritis/encephalitis (CAE)

- Peste des petits ruminants
- Scabies
- Scrapie
- Sheep pox and goat pox
- Enzootic abortion of ewes (ovine chlamydiosis, *Chlamydophila abortus)*
- Maedi-visna
- Ovine epididymitis *(Brucella ovis* infection)
- Salmonellosis *(Salmonella* Abortusovis*)*

Notifiable Equine Diseases	**Monitored Equine Diseases**
• African horse sickness • Contagious equine metritis • Dourine • Equine encephalomyelitis (Western) • Equine infectious anemia (EIA) • Equine piroplasmosis • Equine rhinopneumonitis/equine herpesvirus-1 myeloencephalopathy (EHV1-EHM) • Hendra	• Equine influenza (Virus Type A) • Equine rhinopneumonitis EHV-1 (non-EHM) • Equine viral arteritis

Notifiable Avian Diseases	**Monitored Avian Diseases**
• Duck viral hepatitis • Exotic (virulent) Newcastle disease per OIE definition • Fowl typhoid (*Salmonella enterica*- Gallinarum) • Highly pathogenic avian influenza (AI) and low pathogenic AI in poultry as defined in Chapter 10.4, • Pullorum disease (*Salmonella enterica*- Pullorum) • Turkey rhinotracheitis	• Avian chlamydiosis • Avian infectious bronchitis • Avian infectious laryngotracheitis • Avian mycoplasmosis *(M. gallisepticum)* • Avian mycoplasmosis (*M. synoviae*) • Infectious bursal disease (Gumboro disease)

Notifiable Fish Diseases	**Monitored Fish Diseases**
• Epizootic hematopoietic necrosis • Epizootic ulcerative syndrome (EUS) • Gyrodactylosis (*Gyrodactylus salaris*) • Infectious haematopoietic necrosis (IHN) • Infectious salmon anemia (ISA) • Oncorhynchus masou virus disease (herpesvirosis of salmonids)* • Red sea bream iridoviral disease • Spring viremia of carp (SVC) • Viral encephalopathy and retinopathy* • Viral hemorrhagic septicemia (VHS) • Infection with salmonid alphavirus	• Bacterial kidney disease (*Renibacterium salmoninarium*)* • Infectious pancreatic necrosis* • Koi herpesvirus diseases • Piscirickettsiosis (*Piscirickettsia salmonis*)* • Whirling disease (*Myxobolus cerebralis*)* • White sturgeon iridoviral disease*

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Notifiable Amphibian Diseases	**Monitored Amphibian Diseases**
• None at this time	• Infection with *Batrachochytrium* • Infection with ranavirus

Notifiable Mollusc Diseases	Monitored Mollusc Diseases
• Infection with abalone herpes-like virus • Infection with *Bonamia exitiosa*/*roughleyi* • Infection with *Bonamia ostreae* • Infection with *Marteilia chungmuensis** • Infection with *Marteilia refringens* • Infection with *Marteilia sydneyi** • Infection with Ostreid herpesvirus-1 microvar (OsHV-1 microvar) • Infection with *Perkinsus olseni/atlanticus* • Infection with *Vibrio tapetis** • Infection with *Xenohaliotis californiensis*	• Infection with *Haplosporidium costale* (seaside organism)* • Infection with *Haplosporidium nelson*i (MSX)* • Infection with *Mikrocytos mackini** • Infection with *Perkinsus marinus* • Infection with Quahog parasite unknown *under APHIS review

Notifiable Crustacean Diseases	Monitored Crustacean Diseases
• Crayfish plague (*Aphanomyces astaci*) • Infectious hypodermal and haematopoietic necrosis • Infectious myonecrosis • Necrotizing hepatopancreatitis • Spherical baculovirosis (*Penaeus monodon*-type) • Taura syndrome • Tetrahedral baculovirosis (*B. penaei*)* • White spot disease • White tail disease • Yellowhead disease • Acute hepatopancreatic necrosis disease	• None at this time

Notifiable Bee Diseases	Monitored Bee Diseases (under review)
• None at this time	• Acarapisosis of honey bees • American foulbrood of honey bees • European foulbrood of honey bees • Small hive beetle infestation (*Aethina tumida*) • Tropilaelaps infestation of honey bees • Varroosis of honey bees

Notifiable Lagomorph Diseases	Monitored Lagomorph Diseases
• Myxomatosis • Rabbit hemorrhagic disease	• None at this time

Notifiable 'Other' Diseases	Monitored 'Other' Diseases
• Camel pox • Leishmaniasis	• None at this time

11.2 Appendix B: Laboratory Case Classification and Reporting Requirements

11.2.1 Monitored Disease List Reporting Guidance for Laboratories

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
Monitored Disease: Suspect	Clinical signs and meets case definition for monitored disease or submissions request for testing for monitored disease	N/A	N/A	N/A	N/A	Lab→ Continue testing

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
Monitored Disease: Presumptive	Receive preliminary diagnostic results; meets case definition for monitored disease at presumptive level	Lab	Submitter	Phone call followed up by email or email only; Recognize and utilize established processes.	Per lab's reporting policy to submitter (routine);	Lab → +/-Confirmatory Testing depending on protocol for that disease Veterinarian→ Treatment
			State Officials: +/- SAHO state where lab located	Recognize and utilize established State processes. Potentially Enhanced NAHRS	Reporting monitored diseases at presumptive level dependent on State requirements if more stringent than NLRAD (not a NLRAD requirement)	None expected

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
			SAHO of state where animal located	Recognize and utilize established State processes. Potentially Enhanced NAHRS	Reporting monitored diseases at presumptive level dependent on State requirements if more stringent than NLRAD (not a NLRAD requirement)	State Official → evaluates: (professional judgment) if presumptive lab diagnosis and other information meets case definition; reports to NAHRS on occurrence of disease;
			+/- Industry Associations			Industry → Awareness, planning

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
Monitored Disease: Confirmed	Confirmed presence of monitored disease; Meets case definition for monitored disease at confirmed level	Lab	Submitter	Lab report and/or phone call followed up by written lab report	Per lab's reporting policy to submitter (routine) NAHRS reporting requirement is MONTHLY	Veterinarian → Treatment- same or alternative specific treatment

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
					As appropriate for State/industry	
			State Officials – SAHO where animal is located	Enhanced NAHRS recognize and utilize established State processes.		+/- State response (may be in association with Federal response depending on disease and severity) -Mandatory NAHRS Reporting on occurrence
			State Officials – where lab is located	Enhanced NAHRS; recognize and utilize established processes.		+/- response in conjunction with SAHO of State where animal located State official reports to NAHRS on occurrence of disease

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
			+/- Industry Associations	As appropriate for State/industry		Industry → Awareness, planning

11.2.2 Notifiable Disease List Reporting Guidance for Laboratories

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
Notifiable Disease: **Suspect - FAD**	Clinical signs and history raise suspicion of FAD; Meets case definition for suspect FAD	Veterinarian FADD Lab	State and Federal Animal Health Officials	Laboratory submission with history; encourage a phone call with laboratory Phone call followed up by email or email; Recognize existing communication and reporting protocols in many States.	Immediately; as soon as a FAD is suspected	Lab→ Initiates diagnostic testing at NVSL and/or NAHLN lab **FAD/ED investigation per VS Guidance 12001**
Notifiable Disease: **Suspect - Regulatory diseases and high priority endemic diseases**	Testing requested for regulatory disease based on combination of clinical signs and history that raises suspicion of regulatory disease or as part of regulatory program	Lab (including NVSL)	State and Federal Officials	Phone call followed up by email or email; Recognize existing communication and reporting protocols in many States.	Follow regulatory program guidance & State regulations	State and Federal Officials → Awareness Action will follow State and Federal Guidance Action as a general rule is usually not at the Suspect level; however, for some diseases preliminary actions may occur.

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
					Per lab's reporting policy	
			Submitter	Lab report and/or phone call followed up by written lab report;		Submitter → Awareness of next step by State or Federal Officials
			+/- Industry associations	As appropriate for State/industry	As appropriate for State/industry	Industry → Awareness
CASE CLASSIFICATION	**TRIGGER at LAB/RESULTS**	**WHO REPORTS**	**REPORT TO WHOM**	**MECHANISMS FOR REPORTING**	**TIMELINE FOR REPORTING**	**ACTION**
Notifiable Disease: Presumptive - FAD **Notifiable Disease: Presumptive - Regulatory**	Receive preliminary diagnostic results Receive preliminary diagnostic results	Lab (including NVSL) Lab (including NVSL)	State and Federal Animal Health Officials	Phone call; recognize existing communication channels	Immediately	**Lab→ Completes diagnostic testing at NAHLN or NVSL** **State/Federal officials → Conduct FAD/ED investigation and follow up per VS Guidance 12001. Report to State Animal Health Officials if not already done so**

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
diseases and high priority endemic diseases					Per Lab's reporting policy For regulatory diseases: Federal reporting expectations are expedient reporting (24-72 hr.); reporting may be defined in disease case definition or federal regulations; For high priority endemic diseases: Reporting expectations at presumptive level based on State guidance	
			Submitter	Lab report and/or phone call followed		Awareness of next step by State or Federal Officials

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
				up by written lab report;		
			State and Federal Officials	Phone call followed up by email or email; Recognize existing communication and reporting protocols in many States.		For regulatory diseases: State and Federal Regulatory Program Guidance For high priority endemic diseases: Primarily State response. SAHO will evaluate all information in determining if presumptive diagnosis requires action. There may be preliminary actions but full response may wait until disease confirmation.
CASE CLASSIFICATION	**TRIGGER at LAB/RESULTS**	**WHO REPORTS**	**REPORT TO WHOM**	**MECHANISMS FOR REPORTING**	**TIMELINE FOR REPORTING**	**ACTION**
Notifiable Disease: Confirmed - FAD	Confirmation based on case definition	Lab (including NVSL)	State and Federal Officials	Phone call	Immediately	Actions per VS Guidance 12001 and FAD response plans

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
Notifiable Disease: **Confirmed - Regulatory diseases and high priority endemic diseases**	Confirmed presence of disease based on case definitions		Submitter/ Veterinarian	Lab report and/or phone call followed by written lab report;	Per Lab's reporting policy	State and program guidance
			State and Federal Officials	Phone call followed up by email or email; Recognize existing communication and reporting protocols in many States. Enhanced NAHRS data system	For regulatory diseases: State guidance; Federal reporting expectations are expedient reporting (24-72 hr.); reporting may be defined in disease case definition; For high priority endemic diseases: State guidance	For regulatory diseases: State and Federal Regulatory Program Guidance For high priority endemic diseases: Primarily State response; and +/- federal assistance State officials report into NAHRS data system
			Industry	As appropriate for State/industry	As appropriate for State/industry	Industry→ Awareness

11.2.3 Emerging Disease Reporting Guidance for Laboratories

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
Emerging Disease: Suspect	Clinical signs and meets case definition for emerging disease, +/- submissions from multiple sources/farms; → applied diagnostic tests yielded negative or non-definitive results	Veterinarian	Lab +/- State/Federal Officials if FAD/ED suspect	Laboratory submission with history; +/- phone call with laboratory	As soon as an emerging disease is suspected based on case definition criteria; this timeline will be dependent upon the evolution of the disease, but will be reliant upon the professional judgment and expertise of the veterinarian and laboratorian. Per lab's reporting policy	Lab→ Continue testing FAD/ED investigation per VS Guidance 12001
		Lab	State and Federal Officials	Phone call followed up by email with confirmation of receipt; Recognize existing communication and reporting protocols in many States.		State and Federal Officials → Awareness

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
			Submitter	Lab report and/or phone call followed up by written report for notification of next steps with State/Federal officials		Awareness of next step by State or Federal Officials
			+/- Industry associations	As appropriate for State/industry	As appropriate for State/industry	Industry → Awareness
Emerging Disease: Presumptive	Receive preliminary diagnostic results identifying a new or known agent meeting the case definition for emerging animal disease	Lab	State Officials	Phone call followed up by email with confirmation of receipt; Recognize existing communication and reporting protocols in many States	Immediately, no later than same day.	Lab → Confirmatory Testing
			Federal Officials	Official system for Federal reporting of TBD		State/Fed → Awareness, planning, FAD/ED investigation
			NVSL	Phone call followed up with email with confirmation of receipt;		NVSL → +/-Confirmatory Testing, consultation, and support

CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
			Submitter	Lab report and/or phone call followed up by written report;		Veterinarian→ Treatment
			+/- Industry associations	As appropriate for State/industry		Industry → Awareness, planning
CASE CLASSIFICATION	TRIGGER at LAB/RESULTS	WHO REPORTS	REPORT TO WHOM	MECHANISMS FOR REPORTING	TIMELINE FOR REPORTING	ACTION
Emerging Disease: Confirmed	**Confirmed presence of a newly identified or known agent via sequencing, VI or other technologies**	**Lab or NVSL**	**State Officials**	Phone call followed up by email with confirmation of receipt; recognize existing communication and reporting protocols in many States.	**Immediately, no later than same day.**	State, Federal Officials and Industry associations→ See response options (to be developed by another group)
			Federal Officials	Official conference call with lab, State and Federal	**Immediately, no later than same day.**	Fed → +/- OIE reporting

			Submitter	Lab report and/or phone call followed up by written report		Veterinarian → Treatment- same or alternative specific treatment
			Industry associations	As appropriate for State/industry	**As appropriate for State/industry**	Industry → See response options