
RESOLUTION NUMBER: 8

APPROVED

SUBJECT MATTER: Inclusion of Biosafety Level 3 Necropsy Space in the Process for National Animal Health Laboratory Network Laboratory Participation

BACKGROUND INFORMATION:

The National Animal Health Laboratory Network (NAHLN) supports United States animal agriculture by developing and increasing the capabilities and capacities of a national veterinary diagnostic laboratory network for early detection, rapid response, and appropriate recovery from high-consequence animal diseases.

Beginning in 2016, all laboratories in the NAHLN were transitioned to a new structure with the designations of Levels 1, 2, 3, Affiliate, or Specialty laboratories, as described in the “NAHLN Concept Paper”

See

(https://www.aphis.usda.gov/animal_health/nahln/downloads/NAHLN_structure_concept_paper.pdf)

The NAHLN Concept Paper describes critical needs and capacities for the various laboratory levels. For example, some Level 1 laboratory responsibilities are:

- Maintain capacity to provide surge testing for disease agents of interest;
- Be fully accredited by the American Association of Veterinary Laboratory Diagnosticians, International Organization for Standardization (ISO) 17025, or by another accrediting body with equivalent standards;
- Have staff members trained in testing procedures and proficiency tested in diseases of interest;
- Have the capability to electronically send diagnostic test results to United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) databases;
- As requested by the USDA, help other laboratories develop and implement Information Technology (IT) capabilities to permit them to communicate testing results with NAHLN;
- Provide and maintain biosafety level 3 laboratory (BSL3) space adequate for work performed;
- Accept samples that originate from other States affected by disease outbreaks, especially those from Level 2 laboratories;
- Have an acceptable periodic review conducted under the oversight of USDA.

The ongoing approval for state laboratories to participate in the NAHLN is described in the NAHLN document “General Process for NAHLN Approval” (Document # WI-NAHLN-0034.01). Processes include:

-continued-

- Completion of a laboratory capability and capacity assessment (current capabilities, resources, commitment by State, and other relevant factors), in a standardized format, The “NAHLN Laboratory Matrix”, which is largely based upon the NAHLN needs described in the NAHLN Concept Paper.
- USDA, APHIS and USDA, National Institute of Food and Agriculture review and verify the information provided in the laboratory Self-Assessments, and other pertinent information.
 - The information from this assessment is used to establish NAHLN laboratory network level designation for the next fiscal year (Level 1, Level 2, Level 3, Affiliate, or Specialty).
 - Level 1, 2 and 3 laboratory categorizations are used to decide NAHLN funding levels for infrastructure support based on the laboratory level designation assigned.

In 2020, NAHLN proposes adding BSL3 necropsy capacity and capability to the NAHLN Laboratory Matrix as a new criterion for annual evaluation of NAHLN laboratory level designation. This new addition does not enhance the mission of the NAHLN for the following reasons:

1. The primary mission of the NAHLN for early detection, rapid response, and appropriate recovery are not enhanced by BSL3 necropsy space in NAHLN laboratories.
 - a. Early detection of foreign animal disease (FAD) from field samples of diagnostic unknowns does not require BSL3 necropsy capacity and capability because diagnostic unknowns sent to the laboratory as a potential index case carcass do not yet have laboratory confirmed FAD, therefore, do not require BSL3 necropsy capacity and capability.
 - b. Effective and efficient rapid response to FAD does not require BSL3 necropsy capacity and capability, but rather is better accomplished by submitting samples collected in the field then shipped to NAHLN laboratories as samples, not carcasses. This optimizes biosecurity/biosafety of FAD response activities (samples safer to ship or transport to lab than carcasses) and reduces costs of FAD response activities (samples cheaper to ship to lab than carcasses). The practice of shipping samples to NAHLN labs during FAD response has been the normal procedure of the NAHLN since NAHLN inception.
 - c. Appropriate recovery from FAD does not require BSL3 necropsy capacity and capability for the reasons state in “b” above and, more practically, because proof of negative testing does not generate carcasses from FAD mortalities.
2. The addition of BSL3 necropsy laboratory capacity and capability to the NAHLN evaluation laboratory matrix may disadvantage Level 2 laboratories from reaching Level 1 status, and may reduce the number of Level 1 laboratories needed for effective implementation of the NAHLN mission.

RESOLUTION:

The American Association of Veterinary Laboratory Diagnosticians and United States Animal Health Association urge the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services and National Animal Health Laboratory Network (NAHLN) to remove Biosafety Level 3 necropsy capacity and capability from the annual NAHLN laboratory evaluation matrix used in the annual process for NAHLN laboratory approval and laboratory level designation.