National Veterinary Services Laboratories FM-NAHLN-0023.03 REQUEST TO DEVIATE FROM A NAHLN DOCUMENT

NAHLN Laboratories must submit a completed "Request to Deviate From a NAHLN Document" form prior to offprotocol use of NAHLN assays, work instructions or other NAHLN document. To submit a form, the NAHLN Laboratory must complete blocks A through E. This instruction guide will provide information on how to complete the form, how to submit the form, and how the decision on the request will be reported back to the submitting NAHLN Laboratory.

Completing the form

Block A:

- Laboratory name:

- Laboratory Director:

- Laboratory Director's Telephone number:

- Laboratory Director's e-mail address:

Block B:

- Enter date range or period of time for when deviation is requested. It is acceptable to list "indefinite until next SOP

version released".

- Enter the associated NAHLN SOP number and version number. Only include one SOP number per deviation request.

- Enter the associated NAHLN SOP name.

Block C:

- Enter description of the proposed planned deviation including specific information.

Block D:

- Enter a technical justification for the proposed planned deviation. Provide an explanation of the verification process used

To determine that the deviation will not affect test results.

Block E:

- Laboratory Director's Review requires both signature and date.

Submitting the form to the NAHLN Program Office

- Scan completed form and e-mail to: nahln@aphis.usda.gov.

- Use the following for the subject line of the e-mail submission:

Request immediate review: Submitting a "Request to Deviate from a NAHLN Document"

Reporting of approval or denial to the submitting NAHLN Laboratory (Block F)

- The submitted request will be reviewed and signed by the NVSL Reference Laboratory and the NAHLN Coordinator/designee.

- The submitted request will either be checked as "deviation approved" or "deviation denied". NVSL Officials must concur

in order for deviation to be accepted.

- The reviewed form will be signed and returned to the submitting laboratory by e-mail.

- If the deviation is denied, the reason for the denial will be included in the Justification box.

Form Template Approved by /s/ Christina M. Loiacono