Approval of Laboratories to Conduct Testing for EIA - VSG 15201.1

The Guidance was effective as of the 15 OCT 2019 release date. Clarifications as of December 2019 are noted in RED. This document seeks to explain the changes in the new guidance, reference where they can be found and highlight who is affected and how. Please consult the actual guidance document as the definitive source.

Requirement and Rationale	**New Guidance**	**Location of Guidance**	**Who is affected?** What actions are required?
Read, Sign & Return new Director's Agreement Acknowledge new requirements and regulatory obligations.	NVSL must receive a new, signed EIA Director's Agreement that acknowledges receipt and an understanding of the requirements before it will make the annual proficiency test available to that laboratory.	6.L	• **Approved EIA laboratories** must read, sign and return a new Director's Agreement. • **SAHO** may assist in explaining new guidance, outreach and compliance efforts. • **AVIC** may assist in explaining new guidance, outreach and compliance efforts.
Require the use of an official test form & standardize the information contained therein.	The VS Form 10-11 is the official Federal form and serves as the reference standard for all other USDA approved forms. Revisions and	4.C.2	• **Owners** may see a change in the form their veterinarian uses. • **Category II submitting veterinarians** must obtain, accurately and fully complete the official form. VS 10-11, Box 5: location of animal at blood draw – please indicate the animal's usual residence - stable/farm/ranch - and not a temporary or testing location. • **Approved EIA laboratories** must only accept accurately and fully completed, official USDA approved forms with sample submissions. • **States and all other providers** of EIA test forms must submit prospective forms to USDA VS for approval, or switch to VS 10-11 or VSPS e10-11.

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Reduce confusion, facilitate trade, compliance and trace-back.	changes to the official VS 10-11 will reflect the most current information and data points required. Other VS approved EIA test forms which contain identical information/data points as the VS 10-11 are official.		• **AVIC** may need to ensure adequate stock of paper VS 10-11, familiarize with VSPS e10-11, anticipate greater use of VSPS. • **Trading Partners** should be made aware of the change occurring.
Allow 6 month waivers on use of existing EIA test forms. Allow for business continuity	EIA test forms existing at the time of publication of this document and State EIA test forms, both paper and electronic, will be accepted as valid for submissions until April 15 2020.	4.C.2	• **Approved EIA laboratories** current forms are waivered until April 15 2020. • **States and all other providers** of EIA test forms are provided time to seek USDA VS approval for existing forms, modify non-compliant forms, or switch to VS 10-11 or VSPS e10-11. Prospective forms must be submitted to VS for approval. • The note at the bottom of the FEB2018 VS 10-11 (current form) regarding acceptance of old forms is an error and will be removed on the next printing.
Clarify the application process for initial laboratory approval. Provide clarity and transparency.	New laboratory approval is based on laboratory's ability to provide accurate and reliable testing and meet regulatory and reporting requirements, with appropriate facilities.	6.A	• **New applicants for an approved EIA laboratory** must demonstrate adequate resources, facilities & staffing. Must have knowledge of, and commitment to meeting the regulatory and reporting requirements. • Approval requires consensus between **AVIC** and **SAHO**. • **SAHO** makes decisions based on the priorities of the State.

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Accept sample submissions only from Category II accredited veterinarians. The submitting veterinarian is knowledgeable on regulatory requirements and is accountable.	Approved EIA labs may accept only those samples submitted by a veterinarian who is federally accredited (Category II) and authorized to perform accredited duties in the State where the sample originated; or a State or Federal animal health official.	6.F.1	• **Category II submitting veterinarians** must obtain and maintain Category II veterinary accreditation status. • **Category II submitting veterinarians** must ensure they are authorized to perform those duties in the state the sample was obtained. • **Approved EIA laboratories** may only accept samples from Category II accredited veterinarians authorized to perform those duties in the state the sample was obtained. Check the accreditation status of your customers as they enter your system, at least annually and whenever you have any doubts about the accreditation status. The AVIC and the Equine Health Team will assist you as needed. • **SAHO's** may anticipate increased demand for State authorization. • **AVIC** may anticipate increased demand for Veterinary Accreditation/authorizations. Three ways lab personnel can determine accreditation status and states where an accredited veterinarian is authorized 1. Look up tool: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap/ct_areavet Go to check my accreditation status, Enter NAN and last name of veterinarian. 2. Call NVAP coordinator or your AVIC Go to NVAP website for PDF list of coordinators for each area: https://www.aphis.usda.gov/animal_health/vet_accreditation/downloads/nvap_coordinator.pdf 3. Use Veterinary Services Process Streamlining https://vsapps.aphis.usda.gov/vsps/ Contact a Network Associate for information on how you can sign up for VSPS: https://www.aphis.usda.gov/animal_health/prof_development/downloads/vsps_training_network_end_user.pdf
Accept only accurate and fully completed EIA test forms and identification of animals. Uniquely identify the animal to	Require narrative description of the equine; include: name, age, breed, color, gender, distinctive markings and, when present: brands, tattoos, scars, cowlicks, blemishes,	C.2 6.F.3	• **Category II submitting veterinarians** must accurately and fully complete the form according to instructions, and uniquely identify the animal. Blank fields are not acceptable. • **Approved EIA laboratories** will only accept accurately and fully completed USDA approved forms. • **SAHO and AVIC** officials will assist in compliance. **Clarification I:** Before the laboratory distributes the final results the submitting veterinarian may request changes to the VS Form 10-11 - including address corrections or spelling mistakes acceptable to the laboratory. Alternatively, if a laboratory receives an incomplete form, it may, at its discretion, contact the submitting veterinarian to confirm they wish the laboratory to correct the omission, while the lab continues to process the sample. However,

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facilitate trace-back and reduce fraud.	regardless of other ID methods utilized.		the laboratory will not release results until the form is properly completed. In all cases the laboratory must document and retain the request and changes with the laboratory copy of the VS Form 10-11. **Clarification II:** RE: (F 11) "After distribution of the final results the information recorded on the original VS Form 10-11 cannot be changed. In that case, take a new sample and submit a new form." The approved lab can accept a new, corrected, and serialized 10-11, created by the submitting veterinarian, if all the following are true: • It is at the request of the submitting veterinarian • The distributed copies can be collected and destroyed (paper or electronic record of serial number recorded as invalid) • It can be accomplished and completed within 30 days of sample date. • It is NOT for change in ownership! • The changes do not substantially affect identification of animal. • Approved examples: ○ Transposition of digits in a field ○ Errors in recording microchip digits (NOT a new #!) ○ Misspelling of name, use of barn name vs registered name ○ Age error • The lab must be comfortable with the corrections requested. If the lab is unwilling or uncomfortable they should request a new submission - it may be the easier solution. • The corrections and the collection of distributed copies, must be recorded and made available for yearly inspection and audit. Use the original date of results reported on the corrected form, in Laboratory Remarks Section note "Corrected Form—Original Serial #XXXXXX." Keep a copy of both forms. **Clarification III:** RE: (G1) "Negative Test Results: Laboratories should return official negative test results to the submitting veterinarian as soon as possible after completing the test. Laboratories can mail, email, fax, or otherwise electronically return results to the submitting veterinarian. However, if the veterinarian submitted the samples with OMB-approved, official paper VS 10-11 forms, then the laboratory must mail paper copies of PART 1 - VETERINARIAN/SUBMITTER and PART 3 – OWNER to the submitter within 30 days. Some venues or importing countries may require these paper forms. Some practitioners may feel these forms are more secure and prefer their use."

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			The lab can create and distribute electronic copies to State and Federal officials, and to the customer, the submitting veterinarian. If, however, the lab's customer submits a paper form and specifically asks for a paper form in return (either on every submission or on a single sample request) they must do so. As it suits their needs, labs may encourage customers to use an electronic submission format, commercial or otherwise. The VSPS system is free for practitioners and labs. •
Require confirmation of non-negative results at NVSL. Provide consistent test procedures nationally. Gain accurate and timely data. Provide test kit information to NVSL.	All samples testing positive, suspect, discrepant, or equivocal (as defined in the diagnostic test kit or NVSL protocols) in any of the licensed EIA diagnostic tests must be confirmed at NVSL	6.F.8	• **Owners** should plan on the possibility of a delay in receiving results. • **Category II submitting veterinarians** - inform clients of the possibility of delay in obtaining final results. • **Approved EIA laboratories** - have a plan in place for forwarding non-negative samples and for rapid turnaround of final results to owners. • **SAHOs** - consider ramifications to their particular procedures. • **AVICs** – anticipate increased reporting of non-negative results. • **NVSL** - expect more referral samples and facilitate rapid turnaround. Labs approved to run AGID are expected to continue to perform AGID on non-negative ELISA samples. Usually (and by prior agreement) the AGID lab will split the sample and send 2ml to NVSL, as they run their AGID. However, the ELISA lab still needs to report the non-neg. result to State and Federal officials. States that operate a 3 tier system can continue in that regard. State officials are free to act, quarantine or direct disposition of the reactor animal based on the local AGID result, or they may choose to wait until NVSL's result is received. While AGID results are expected to be in concurrence, the NVSL result is the final result.
Require monthly summary data submission to Equine Health Team and State Animal Health Officials. Provide accurate & timely national EIA data	Laboratories must provide the Equine Health Team and the relevant State animal health official with timely reports of monthly totals of negative and positive EIA tests grouped by test type (e.g. AGID	6.H	• **Approved EIA laboratories** must record accurate data and transmit it monthly to SAHO & Equine Health Team using approved format. • **SAHO** will no longer serve as intermediary between laboratories and the Federal officials charged with generating national level data and reporting that data. This will increase accuracy and timeliness of national data. Accurate and prompt national data provides transparency for trade partners and facilitates trade. • **Federal** officials have a plan in place to receive and manage data directly from the laboratories.

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directly to those who produce it, for use by decision makers.	and ELISA and origin state) using the format specified.		
Require 500 test annual minimum. Maintain testing proficiency.	Laboratories that perform fewer than 500 EIA tests annually should justify their approval/renewal and may be subject to additional inspections or proficiency panels initiated by NVSL or at the request of the State animal health official.	6.A.1.h 6.I.1.d 6.I.2.d 6.J.5.b.7 6.M.10 Attach #1	• **Approved EIA laboratories** should document performing 500 tests annually to maintain proficiency. **New applicants for an approved EIA laboratory** should expect to meet the 500 test minimum. • **Approved EIA laboratories** (or **new applicants for an approved EIA laboratory** that lack the expectation of meeting) the annual test minimum should be able to demonstrate proficiency, prepare for additional inspections and proficiency tests and the associated costs.
Require annual proficiency test (PT) Demonstrate testing proficiency.	Approved labs must pass a laboratory annual PT (1 test/ lab/yr.) regardless of how many approved EIA technicians there are. Labs that fail the annual PT are subject to withdrawal of approval. Failing an annual PT twice in 1 year is grounds for immediate removal.	6.A.1.g 6.I.1.c 6.I.2.c 6.J.2 6.J.3 6.J.5.b.7 6.M.10	• **Approved EIA laboratories** must be able to demonstrate testing proficiency. It is incumbent on the laboratory to maintain current contact information with NVSL, respond to NVSL communications, and to request the annual proficiency test.

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Withdraw laboratory approval for failure to meet regulatory requirements. Ensure reliable and accurate EIA testing and timely EIA information.	Laboratories must meet their requirements and regulatory obligations. Failure to meet these requirements will be grounds for withdrawal of laboratory approval.	6.M	**Approved EIA Laboratories** must: • Provide and maintain adequate and appropriate facilities. • Provide NVSL trained personnel, who completed individual PT. • Accept only samples submitted by a Category II accredited veterinarian authorized in the State where the sample was obtained. • Accept only submissions with an accurate and fully completed official test form. • Conduct all testing according to protocol. • Use only diagnostic test kits approved by the USDA. • Submit all non-negative samples to NVSL for confirmation. • Conduct all testing as official EIA testing; no screening or retesting. • Meet annual laboratory proficiency (check) test (PT) requirements. • Expect to perform at least 500 EIA tests per year. • Promptly report test results to State and Federal officials. • Submit monthly summary data & provide adequate record keeping. • Pass an annual inspection - required to maintain approval. • Maintain current contact information and respond to official inquiries. • Signed Director's Agreement (VS 10-15).
Require annual inspection. Maintain laboratory standards	Continued approval of laboratories will require an official inspection conducted by Federal personnel or a cooperative team of Federal and State personnel annually.	6.A.1.j 6.J.5 6.M.12 Attach#1.	• **Approved EIA laboratories** should schedule the annual inspections with their AVIC. • **AVICs** should be familiar with the requirement, have appropriate plans for scheduling inspections and be familiar with the EMRS2 tool.
Provide new inspection checklist.	Checklist is improved and more specific. There is increased emphasis	Attach.#1	• **Approved EIA Laboratories** can anticipate, prepare for, and schedule annual inspections. • **State and Federal regulators** have transparent and clear inspection guidelines.

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Clarify standards for maintaining approval	on documentation of requirements, reporting and data submission requirements.		**Clarification I:** *"Refrigerator … with a thermometer capable of high/low temperature memory/recording, and … weekly high/low temperature record/log is kept."* To comply use a thermometer that is: digital, with a resolution of at least 1°C, accuracy to ±2°C, Hi/Lo memory function. It should be maintained and calibrated according to the manufacturer's instructions. The weekly log could be a paper notebook kept with the refrigerator. NVSL is offering **best practice** recommendations to EIA Approved Labs about thermometers and associated calibration certificates. There is a spectrum of acceptable possibilities and we trust our inspectors to use professional judgment in deciding what will meet the requirement. Our Calibration Department also added that, given nothing was previously required of EIA Approved Labs concerning thermometers and associated calibration certificates. Option C is a great start with the goal of phasing into Option A as the new guidance document and requirements become more familiar. NVSL Calibration Department offered the following suggestions for thermometer calibration certificates: Option A: Most Preferred- Calibration from a fully **Accredited ISO17025** Vendor, that provides an official (legal) Calibration Report. Option B: Nice- Calibration provided by an **ISO 9001** Vendor, with a Calibration Report and/or a sticker on the unit Option C: Bare-bones- A calibration of some-sorts with a Calibration Report and/or a sticker on the unit **Clarification II:** "Pipettes must be properly calibrated a minimum of every 12 months, preferably every 6 months … Maintain pipette calibration records. " To comply use a commercial servicer who completes multi-point calibration and provides an individually-numbered ISO/IEC 17025 Certificate of Calibration on each pipette serviced.

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