Approval of Laboratories to Conduct Testing for EIA - VSG 15201.1

GUIDANCE IS EFFECTIVE UPON RELEASE 11 OCT 2019

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. Reduce confusion, facilitate trade, compliance and trace-back.	The VS Form 10-11 is the official Federal form and serves as the reference standard for all other approved forms. Revisions and 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.	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. • **Approved EIA laboratories** must only accept accurately and fully completed, official forms with sample submissions. • **States and all other providers** of EIA test forms must submit prospective forms to VS for approval, or switch to VS 10-11 or VSPS e10-11. • **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 official EIA test form.	EIA test forms existing at the time of publication of this document and State EIA test forms, both paper and	4.C.2	• **Approved EIA laboratories** can accept existing forms until 01MAY2020 • **States and all other providers** of EIA test forms are provided time to seek approval for existing forms, modify non-compliant forms, or switch to VS

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Allow for business continuity	electronic, will be accepted as valid for submissions until 01MAY2020**.**		10-11 or VSPS e10-11. Prospective forms must be submitted to VS for approval.
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.
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. • **SAHO's** may anticipate increased demand for State authorization. • **AVIC** may anticipate increased demand for Veterinary Accreditation/authorizations.
Accept only accurate and fully completed EIA test forms and identification of animals. Uniquely identify the animal to facilitate trace-back and reduce fraud.	Require narrative description of the equine; include: name, age, breed, color, gender, distinctive markings and, when present: brands, tattoos, scars, cowlicks, blemishes, regardless of other ID methods utilized.	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 forms. • **SAHO and AVIC** officials will assist in compliance.
Require confirmation of non-negative results at NVSL. Provide consistent test procedures nationally. Gain accurate and timely data.	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.

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Provide test kit information to NVSL.			• **NVSL** - expect more referral samples and facilitate rapid turnaround.
Require monthly summary data submission to Equine Health Team and State Animal Health Officials. Provide accurate & timely national EIA data directly to those who produce it, for use by decision makers.	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 and ELISA and origin state) using the format specified.	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.
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.
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.

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			• 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. Clarify standards for maintaining approval	Checklist is improved and more specific. There is increased emphasis on documentation of requirements, reporting and data submission requirements.	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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