

EIA Laboratory Inspector Training

This training will prepare you to evaluate a laboratory for compliance with requirements set by Veterinary Services for performing EIA testing

SECTION: OVERVIEW

LESSON: SYLLABUS

Page 1

Training Syllabus

- Contacts: for questions about training content, laboratory inspections, or EIA testing, please contact the Diagnostic Virology Laboratory at the National Veterinary Services Laboratories (NVSL): 515-337-7551
- This training is intended for Animal Health Technicians and Veterinary Medical Officers charged with performing EIA laboratory inspections
- No prior experience with laboratory inspections is required or assumed
- Learning outcomes: Upon completion of this training, you will be able to evaluate a laboratory for compliance with requirements set by Veterinary Services for performing EIA testing
- Note: there is no audio for this training

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Course Navigation and Content

- At any time, you can click on Menu (at the bottom left of the screen) to see the course outline and navigate to any of the topics
- There is a five question knowledge review at the end of the course. The review is not graded but enables you to measure your comprehension of the course material.
- To view, save, or print a file with all the course screens, [click here](#)

LESSON: TOPICS

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Topics

1. Background information about the disease
2. Regulations: Why inspect the labs?
3. Definitions from VS Memorandum 555.16
4. Your role as an inspector
5. Process: Prepare for an inspection
6. Process: How to set up an inspection
7. Inspection Checklist: Parts I - VI
8. Reporting inspection results
9. Knowledge review

LESSON: BACKGROUND

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Background on Equine Infectious Anemia

- The US has the world's largest horse population, about 9.5 million
- EIA is a viral disease of all members of the horse family (horses, ponies, donkeys, asses, mules, zebras)

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Background on Equine Infectious Anemia

- EIA occurs throughout the world

- The EIA virus is transmitted mechanically by man or biting flies
- Once infected, a horse is always infected. EIA is a persistent, lifelong infection.
- There is no vaccine or treatment for the disease

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Background on Equine Infectious Anemia

- The US tests about 2 million samples per year, with fewer than 200 test positive horses found per year in the last 3 years
- The laboratories you will inspect can perform either one or both of the following tests:
 - AGID: agar gel immunodiffusion
 - ELISA: enzyme-linked immunosorbent assay

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Background on Equine Infectious Anemia

- Federal regulations control only the quarantine and movement of reactors (confirmed EIA positive animals) between states
- Each state has its own testing and quarantine regulations. Some states require euthanasia of reactors.

LESSON: REGULATIONS

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Regulations

9 CFR: Code of Federal Regulations, Title 9--Animals and Animal Products

- Part 75: Communicable Diseases In Horses, Asses, Ponies, Mules, and Zebras
- Section 75.4: Interstate movement of equine infectious anemia reactors and approval of laboratories, diagnostic facilities, and research facilities

- Link: http://www.access.gpo.gov/nara/cfr/waisidx_10/9cfr75_10.html

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Regulations

VS Memorandum No. 555.16

- Outlines the policy and procedures for approval of laboratories to perform tests for equine infectious anemia (EIA) and the requirements for those laboratories when performing EIA tests
- Attachment 1 is the Inspection Checklist
- Attachment 2 is the Laboratory Director Agreement
- Link (requires access to the APHIS WE network):
http://vssharepoint.we.aphis.gov/memos_notices/default.aspx

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Regulations

Equine Infectious Anemia: Uniform Methods and Rules (UM&R)

- Minimum standards for detecting, controlling, and preventing equine infectious anemia
- Link:
http://www.aphis.usda.gov/vs/nahss/equine/eia/eia_umr_jan_10_2007.pdf

LESSON: Definitions from VS Memo 555.16

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Definitions from VS Memo 555.16

Official Test

Any test for the laboratory diagnosis of equine infectious anemia that utilizes a diagnostic product that is:

- (1) Produced under license from the USDA; and
- (2) Conducted in a laboratory approved by APHIS.

All EIA tests are official tests and must be conducted at approved facilities by approved personnel certified in accordance with the procedures outlined in the memorandum

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Definitions from VS Memo 555.16

Official Test Form

- The VS10-11 is the official Federal test form for EIA
- Approved electronic forms containing equivalent information to the VS10-11 may be used

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Definitions from VS Memo 555.16

Official Test Form (continued)

- In some states, a state-approved form is acceptable within the originating state
- The VS10-11, approved electronic versions, and state approved EIA test forms are all considered official EIA test forms

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Definitions from VS Memo 555.16

Approved Laboratory

1. State, Federal, or University laboratory

- Under direct supervision of:
 - State animal health official (SAHO)

- US military laboratory director
- APHIS-VS animal health official
- University laboratory director
- Must meet all the requirements of the memo
- **At least one laboratory employee** must complete the EIA training course at NVSL and be currently and actively involved with the EIA testing

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Definitions from VS Memo 555.16

Approved Laboratory (continued)

2. Private laboratory

- No official supervisory affiliation with at State, Federal, or University laboratory
- Must meet all the requirements of the memorandum
- **All employees conducting EIA tests** must complete the EIA training course at NVSL
- Types of private laboratories:
 - a. Permanent (stationary) laboratory
 - b. Mobile laboratory
 - c. Satellite laboratory

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Definitions from VS Memo 555.16

Private laboratory types (continued)

- a. Permanent (stationary) laboratory
- b. Mobile laboratory:
 - maintains the same physical and proficiency requirements as a stationary laboratory

- may only be used in the state for which it was approved
- unless permission is obtained from SAHO and AVIC in another state

c. Satellite laboratory:

- an alternate location for an existing, approved stationary EIA laboratory used at equine sales facilities or auction markets to meet transfer of ownership or interstate movement requirements for EIA testing
- facility must have an appropriate controlled environment for testing
- laboratories must have the ability to distinguish test records for EIA tests completed at the satellite laboratory

LESSON: Your Role As an Inspector

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Your Role As an Inspector

- As an inspector, your role is to inspect the laboratory to ensure they are capable of performing testing according to the rules and regulations and assist in providing information about EIA regulations
- Only approved laboratories may conduct official EIA tests
- You serve as the “eyes and ears” of Veterinary Services in the field

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Your Role As an Inspector

VS Memo 555.16 requires that the Federal inspecting official verify the following:

- Compliance with the memo
- Determine whether tests are being conducted according to official protocols
- Determine whether personnel conducting the tests are certified by VS to perform EIA tests
- Review completion of official test charts and verification of reported annual EIA tests performed
 - Note: Attachment 1 does not have a line for number of tests; please provide the information under "Additional Remarks"

LESSON: Process: Prepare for an Inspection

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Process: Prepare for an Inspection (1 of 5)

- **Area Office notifies inspector**
- **Obtain pertinent information and prepare for inspection:**
- Link to VS Memo 555.16 and its Attachments (requires access to the APHIS WE network):
http://vssharepoint.we.aphis.gov/memos_notices/default.aspx
- Location: can be stationary, mobile, or satellite
- Determine if it is an existing or new lab
- Familiarize yourself with personnel training requirements
 - You will verify that all persons conducting EIA tests are trained in compliance with Memo requirements

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Process: Prepare for an Inspection (2 of 5)

Existing lab:

- Continued approval requires:
 - An official inspection conducted by Federal personnel at least every 2 years
 - Additional inspections may be conducted at the discretion of the Area Veterinarian in Charge if there are performance or compliance concerns
 - Passing a proficiency test from NVSL every year
- If the physical location of the lab changes, an official inspection and completion of a proficiency test in the new facility must be conducted within the first 30 days of operation
- The lab must have a valid Director's Agreement (Attachment 2)
- You will verify the annual number of EIA tests performed by the lab

- Approved labs are subject to inspection by a Federal or State animal health official at any time during the lab's normal business hours

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Process: Prepare for an Inspection (3 of 5)

New laboratory – after application is accepted:

- A Federal or State veterinary medical officer will review the regulatory and technical responsibilities and criteria inherent in conducting and reporting EIA tests with a laboratory official
 - A copy of the inspection check list and standards will be provided to the laboratory director
- A Federal animal health official will inspect the physical facilities of the laboratory and record the results on the laboratory inspection checklist (Attachment 1 of VS Memo 555.16).
 - The laboratory must be inspected and found in compliance before employees are eligible for EIA training
 - At the time of the inspection, the laboratory will not have reagents in place
- The laboratory director must sign the Agreement (Attachment 2 of VS Memo 555.16) to acknowledge that he or she understands the regulatory and technical responsibilities of the laboratory.

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Process: Prepare for an Inspection (4 of 5)

Key personnel

- You will identify the laboratory director and employees conducting EIA testing, and verify they meet requirements
- Laboratory director: person who signs the Director's Agreement; function can be served by clinic owner or laboratory department head
- Laboratory officials familiar with EIA work in the lab can participate in the inspections
- EIA technician: performs testing and signs or initials results
 - Note: If a person is not certified to act as an EIA technician, they should not be involved with performing the laboratory portion of the testing

The type of lab determines personnel training requirements

- Federal, State, and University labs: at least one EIA technician actively involved with EIA testing must complete training at NVSL
- Private labs: all EIA technicians must complete training at NVSL

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Process: Prepare for an Inspection (5 of 5)

- **Obtain VS Memo 555.16, including:**
 - Attachment 1: Laboratory Inspection for Equine Infectious Anemia (EIA) Testing
 - You will use this checklist during your inspection
 - Attachment 2: Agreement to Conduct Equine Infectious Anemia (EIA) Testing
 - You will verify that this Agreement is valid during your inspection
- For existing labs, you will verify the annual number of EIA tests performed by the lab
 - Note: Attachment 1 does not have a line for number of tests; please provide the information including time frame for the number of tests under "Additional Remarks"
- If you have questions about laboratory practices while performing an inspection, you can call the Diagnostic Virology Laboratory at the National Veterinary Services Laboratories (NVSL) for assistance: 515-337-7551

LESSON: Process: How to Set Up an Inspection

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Process: How To Set Up an Inspection (1 of 2)

- **Contact the laboratory**
- **Discuss user fees**
 - Laboratories are responsible for payment before, or at the time of inspection
 - User fees for time and travel dedicated to laboratory inspections are charged under USDA APHIS service code 2005 "Hourly Fee (EIA) (BT) (BL)"
 - APHIS Form 81, Statement of Service, can be used to show user fee charges

- To view an example of the form, [click here](#)
- **Identify key personnel** involved with EIA testing and inform them you will verify training records during the inspection

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Process: How To Set Up an Inspection (2 of 2)

- **For new labs**, you will:
 - Verify the director's agreement (VS Memo 555.16, Attachment 2)
 - Complete the Laboratory Inspection Checklist (VS Memo 555.16, Attachment 1)
 - Only Sections I, II, and VI apply to new labs
- **For existing labs**, you will:
 - Verify the director's agreement (VS Memo 555.16, Attachment 2)
 - Complete all sections of the Laboratory Inspection Checklist (VS Memo 555.16, Attachment 1)
 - Review completed test charts and verify that the annual EIA tests performed corresponds with what the lab reported. Labs must keep a tally of test results for each calendar year. The State Veterinarian may impose additional requirements.
- Set up your appointment for inspection

SECTION: Inspection Checklist

LESSON: Inspection Checklist: I. Laboratory

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NVSL: Call 515-337-7551 for Assistance

- If you have questions about laboratory practices while performing an inspection, you can call the Diagnostic Virology Laboratory at the National Veterinary Services Laboratories (NVSL) for assistance: 515-337-7551

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Inspection Checklist: I. Laboratory

- Separate room or portion of room is used for testing
- Adequate open bench space (at least 3-5 feet) and lighting is available to perform test
- Sink is available in same area with hot and cold running water

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Inspection Checklist: I. Laboratory

- Laboratory temperature is maintained at all times between 68 and 77 °F (20 and 25 °C), or an incubator is available to maintain these temperatures for these tests where required

Media:incubators

Media: incubatorsOpen

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Inspection Checklist: I. Laboratory

- Laboratory, and laboratory equipment is clean and properly stored
- Appropriate disposal facilities are available in accordance with local rules and regulations
 - Consult the State Veterinarian or Department of Health if you have questions

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Inspection Checklist: I. Laboratory

- Only laboratory equipment and supplies are within the laboratory. No eating, drinking, applying cosmetics, handling contact lenses, or storage of food allowed in the lab.

Media: badLab_foodOnDeck

Media: noFoodOrDrinkSign

LESSON: Inspection Checklist: II. Laboratory Supplies and Equipment

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Inspection Checklist: II. Laboratory Supplies and Equipment (AGID)

- High intensity light— that can be focused for reading AGID plates
- Blinds on windows or separate room, so light can be reduced to read AGID plates

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Inspection Checklist: II. Laboratory Supplies and Equipment (AGID)

- Medium 7-well immunodiffusion template cutter - a center well surrounded by 6 evenly spaced wells. Wells are 5.3 to 5.7 mm in diameter and 2.4 mm apart
- Balance— designed to read with accuracy to plus or minus 0.1 gram

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Inspection Checklist: II. Laboratory Supplies and Equipment (AGID)

- Method to remove agar plug - vacuum pump is suggested
 - Manual removal of the agar is allowed
- Equipment to make agar: Graduate measures, flasks, and additional appropriate glassware

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Inspection Checklist: II. Laboratory Supplies and Equipment (AGID)

- Source of heat for agar preparation (microwave, hot plate, autoclave)
- Refrigerator labeled for lab use, no food or drink

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Inspection Checklist: II. Laboratory Supplies and Equipment (AGID)

- Containers for incubating AGID plates on test (incubators suffice)
 - AGID plates should be incubated on a level surface

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Inspection Checklist: II. Laboratory Supplies and Equipment (AGID)

- Pipettes or pipette tips for delivery of reagents to wells

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Inspection Checklist: II. Laboratory Supplies and Equipment (AGID)

- Distilled water and chemicals for buffer (sodium bicarbonate, boric acid, distilled water)
- Noble agar

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Inspection Checklist: II. Laboratory Supplies and Equipment (AGID)

- Disposable 60 or 100 mm Petri dishes
- Materials or equipment to accurately measure pH within 0.2 pH unit

Media: AGIDpetriDishes

Media: AGIDpHmeter

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EIA AGID setup

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Inspection Checklist: II. Laboratory Supplies and Equipment (ELISA)

- Incubator (if 37 °C incubation is required for the ELISA test used)
 - Check the kit insert for the product to determine if the incubator is required.
- Refrigerator labeled for lab use, no food or drink

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Inspection Checklist: II. Laboratory Supplies and Equipment (ELISA)

- Wash bottles, pipetting devices, and plate holders

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Inspection Checklist: II. Laboratory Supplies and Equipment (ELISA)

- ELISA washer and reader (both are optional)

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Inspection Checklist: II. Laboratory Supplies and Equipment (ELISA)

- Centaur FP-ELISA II: Positive samples will produce color greater than the negative control
- VMRD ELISA: Positive samples will produce color equal to or greater than the positive control

Inspection Checklist: II. Laboratory Supplies and Equipment (ELISA)

- IDEXX HerdChek EIA cELISA (competitive ELISA): Positive samples will produce color equal or LESS than the positive control
 - there will be little or no color development in the POSITIVE samples
- Synbiotics ViraCHEK / EIA: Positive samples will produce color equal to or greater than the positive control

LESSON: Inspection Checklist: III. Control of Specimens and Reporting

Inspection Checklist: III. Control of Specimens and Reporting

- Laboratory should not be accessible to the general public during testing
- Laboratory assigns a unique accession number to each sample. The accession number is recorded on the official EIA reporting form.

Inspection Checklist: III. Control of Specimens and Reporting

- Specimens that are not appropriately identified should not be tested
- Specimens are received with proper submission form*—with name of owner, name and address of submitting veterinarian, location of animal at the time the test sample was obtained, complete animal identification, sample collection date, and signed by the submitting veterinarian.

*Some States have specific forms that they allow. Otherwise Form 10-11 is to be used

Inspection Checklist: III. Control of Specimens and Reporting

- The specimen identity is maintained on the worksheets and on the Petri dish and ELISA plates/strips
- Only those technicians certified to perform EIA testing should perform the tests. If a lab employee is not certified, they should not be involved with the laboratory portion of the testing.

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Inspection Checklist: III. Control of Specimens and Reporting

- The test results for each sample are recorded on a worksheet which should be made available for review
 - Worksheet forms may differ from the ones pictured here, but must allow for tracking of samples and reagents

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Inspection Checklist: III. Control of Specimens and Reporting

- The results are recorded on the reporting form*—with a copy kept in the laboratory. Results are reported only as negative, positive, or no test.
- The official test form must include the handwritten signature (or secure electronic signature) of the EIA technician. Technician initials are acceptable provided they unequivocally identify the person who performed the test.
 - Stamped signatures are NOT permitted

*Some States have specific forms that they allow. Otherwise Form 10-11 is to be used.

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Inspection Checklist: III. Control of Specimens and Reporting

- All tests are reported regardless of results. No unofficial EIA tests are performed to determine the status of the animals before the "official" test is performed. All EIA tests are official tests.

- Official test results are reported to the State (s) and/or Federal animal health officials within the time specified by these officials
 - Results are reported to the state where the animal is located and the state in which the testing was performed

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Inspection Checklist: III. Control of Specimens and Reporting

- Specimens are held refrigerated or frozen for at least 2 weeks after results are reported and preferably for at least 30 days
 - Whole blood should not be frozen; if samples will be frozen, separate and freeze the serum

LESSON: Inspection Checklist: IV. EIA Reagents

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Inspection Checklist: IV. EIA Reagents

- Only reagents licensed by the USDA or supplied by NVSL are to be used
 - check kits for expiration dates

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Inspection Checklist: IV. EIA Reagents

- Unused portions must be refrigerated
- Unused or outdated reagents and the inoculated EIA AGID or ELISA plates must be appropriately discarded according to local rules and regulations

Media: AGIDkitOpen

Media: refrigerator

Inspection Checklist: IV. EIA Reagents

Licensed kits (as of December 2011):

Name	Type	Trade Name	Distributor
Synbiotics	ELISA	ViraCHEK/EIA	
Synbiotics	AGID	ViraCHEK/EIA	
IDEXX	ELISA	HerdChek EIA cELISA	
IDEXX	AGID		
VMRD	ELISA		
VMRD	AGID		
Safepath Laboratories	ELISA	FP ELISA II	Centaur

LESSON: Inspection Checklist: V. Test Procedure

Inspection Checklist: V. Test Procedure

- The procedure that is outlined in the appropriate test protocol must be followed
- Inspectors should confirm that the lab is following kit instructions

LESSON: Inspection Checklist: VI. Building and Cleanliness

Inspection Checklist: VI. Building and Cleanliness

- Inspection Checklist: VI. Building and Cleanliness
- The building is in good repair and provides a professional appearance inside and outside
- Adequate doors, windows, and screens are provided and are in good repair

- The laboratory is separated from the office, storeroom, and unused areas by partitions with doors

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Inspection Checklist: VI. Building and Cleanliness

- Adequate lighting is available
- Restrooms are available—clean and in good repair
- Laboratories are free of rodents, insects, and other pests

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Inspection Checklist: VI. Building and Cleanliness

- All refuse is placed in proper containers and removed frequently
- Clean laboratory clothes (coats) are being worn

SECTION: Reporting Inspection Results

LESSON: Reporting Inspection Results

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Reporting

- Copy of completed laboratory inspection given to laboratory
- Copy of original inspection to be maintained at area office

SECTION: Knowledge Review and Conclusion

LESSON: Knowledge Review

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Question 1

All EIA tests are considered official tests.

- A. TRUE
- B. FALSE

Correct answer: True

- There are no unofficial EIA tests.

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Question 2

At a **private** laboratory with three employees performing EIA testing, only one employee needs to have completed training at NVSL.

- A. TRUE
- B. FALSE

Correct answer: False

- For **private** laboratories, **all employees conducting EIA tests** must complete the EIA training course at NVSL

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Question 3

At a **state** laboratory with three employees performing EIA testing, only one employee needs to have completed training at NVSL.

- A. TRUE
- B. FALSE

Correct answer: True

- For **state** laboratories, **at least one laboratory employee** must complete the EIA training course at NVSL and be currently and actively involved with the EIA testing.

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Question 4

According to VS Memo 555.16, an EIA laboratory that is passing annual proficiency panels from NVSL and has not changed location is subject to official inspection:

- A. At least every year
- B. At least every 2 years
- C. At least every 4 years
- D. As needed

Correct answer: At least every 2 years

- For an existing EIA laboratory, continued approval requires an official inspection conducted by Federal personnel at least every 2 years.

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Question 5

Do user fees apply to EIA laboratory inspections?

- A. Yes, for all laboratories
- B. Not for state laboratories
- C. Not for satellite laboratories
- D. Not for any laboratory

Correct answer: Yes, for all laboratories

- Laboratories are responsible for payment before, or at the time of inspection. User fees for time and travel dedicated to laboratory inspections are charged under USDA APHIS service code 2005 "Hourly Fee (EIA) (BT) (BL)".

LESSON: Conclusion

Course Completion

To Receive Course Credit:

- You can click on the following link to evaluate the course. The link will take you to another website for the optional anonymous survey: [EIA Laboratory Inspector Training course feedback](#)
- When you close this window, you will return to your AgLearn "Home" page, and receive credit for completing the course.

To view, save, or print a file with all the course screens, [click here](#).