Animal and Plant Health Inspection Service

Veterinary Services

1400 Independence Ave, SW

Washington, DC 20250

VETERINARY SERVICES MEMORANDUM NO. 800.91

TO: Veterinary Services Leadership Team
Directors, Center for Veterinary Biologics
Biologics Licensees, Permittees, and Applicants

FROM: Jack A. Shere
Deputy Administrator

BRIAN MCCLUSKEY

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SUBJECT: Categories of Inspection for Licensed Veterinary Biologics Establishments

I. PURPOSE

The purpose of this memorandum is to provide a list of the categories used for in-depth inspections of licensed veterinary biologics establishments by inspectors of the Animal and Plant Health Inspection Service (APHIS) under the provisions of title 9, *Code of Federal Regulations* (9 CFR), part 115. Licensees may use this list of categories of inspection as an aid in understanding APHIS inspections and as a guide for self-inspections to determine their compliance with the Virus-Serum-Toxin Act (VSTA).

II. CANCELLATION

This memorandum cancels Veterinary Services (VS) Memorandum No. 800.91 dated May 13, 1999.

III. BACKGROUND

Regulations in 9 CFR, part 115 give authority for any USDA inspector to enter any establishment where any biological product is being prepared, at any hour during the day or night, and inspect without previous notification. APHIS does these unannounced inspections of licensed veterinary biologics establishments to determine whether products are being prepared in compliance with the VSTA and regulations. Internal guidelines have been developed for APHIS inspectors that list 14 categories of inspection for in-depth inspections, and what audits and observations may be made in each category. This list of categories is not necessarily all-inclusive, but may help the veterinary biologics industry to maintain compliance with the VSTA and regulations. APHIS inspectors will provide a summary of findings to the regulated entity after each on-site inspection.

Regulatory actions may be the result of observations and audits performed during an inspection. These actions may include holding the release of products from the marketplace and letters of advice and/or infractions.

A written response from the licensee/permittee regarding corrective and preventative actions taken for the documented noncompliance issues should be submitted to the Center for Veterinary Biologics-Inspection and Compliance (CVB-IC) in a timely fashion. This may require more than one response from the licensee/permittee.

IV. GUIDELINES

When inspecting licensed veterinary biologics establishments, APHIS inspectors should use the 14 categories of inspection described in this section to define inspection responsibilities. The checklist of audits and observations given for each inspection category should not be considered limiting or all-inclusive. Inspectors can inspect the entire premises of the establishment, including the following: all buildings, compartments, and other places; all biological products and organisms and vectors in the establishment; all materials and equipment, such as chemicals, instruments, apparatus, and the like; and, the methods used in the manufacture of, and any record pertaining to, the production, testing, storage, disposition, sale, or distribution of veterinary biological products produced or research conducted at each establishment.

Following is the list of inspection categories, with audits and observations for each, which APHIS inspectors may use for guidance when conducting inspections.

A. Licenses and Permits

1. *Audits*

a. Compare the firm's U.S. Veterinary Biologics Establishment License with information on file at the CVB. Review the ownership, parent company, and subsidiary and division relationships with the firm’s official in charge. Verify addresses, locations, and other information on the license. Confirm all stages of production are conducted within licensed premises.

b. Discuss the activity of each licensed product with the official in charge. Be sure that conditional licenses have not expired.

c. If a product is not being produced, determine the last date of production. The firm may wish to voluntarily return inactive product licenses to APHIS for termination for which they no longer have the equipment, facilities, and/or expertise to prepare.

d. For product licenses with restrictions, determine if the firm is following the restrictions.

e. Determine if the facility is approved for storing veterinary biological products imported under a U.S. Veterinary Biological Permit for Distribution and Sale. If so, determine compliance with the applicable regulations.

f. Review U.S. Veterinary Biological Product Permits for Research and Evaluation and any permits for the importation or transportation of organisms or vectors issued to the licensee and compare with information on file at the CVB. Ask for any additional permits the firm may have. Audit the firm's records for compliance with special requirements listed on the permits and with the regulations covering importation for research and evaluation. Determine if any of the permits have expired. Note: the firm must comply with the restrictions on the permit as long as they maintain the organism, regardless of the permit expiration date.

2. *Observations*

a. Note the location of buildings and equipment used to produce, test, and store products to be sure that all premises are properly identified on the establishment license. Note any change in ownership, location, or operation of the establishment.

b. Verify that every product observed in production or testing on the licensed premises has a license or permit. Ensure products prepared under the Food and Drug Export Reform and Enhancement Act do not adversely impact the preparation of licensed/permitted veterinary biological product.

c. Review permit restrictions and determine if the permittee is in compliance with these restrictions for imported products for distribution and sale.

d. Inspect facilities where research material imported under permit is handled, and the conditions for handling this material, to be sure they meet requirements. Check for any other imported biologics on the licensed premises. Biologics exported from the United States may only be returned under a permit for research and evaluation.

B. Personnel

1. *Audits*

a. Compare the firm's APHIS Form 2007 file with information on file at the CVB for changes in key personnel. Review for deletions, additions, or job changes. Confirm the names of the official liaison, alternates and site contacts. Determine if personnel designated as liaison and alternate are knowledgeable about the day-to-day activities at the firm and in a position to make agreements with APHIS.

b. Review the firm's process of determining who should have an APHIS Form 2007 on file with the CVB and the system used to maintain the listing. Identify the person responsible for making periodic reviews of the APHIS Form 2007 file.

c. Review training records for essential functions conducted regarding licensed/permitted products.

d. Request a current copy of the firm's organizational chart or obtain the information necessary to establish official lines of responsibility within the firm. Review the relationships between production, testing, marketing, and quality assurance.

e. Determine who supervises the care and welfare of animals, and which veterinarian or animal care personnel determines the health of admitted animals.

2. *Observations*

a. Observe if employees in key positions have APHIS Form 2007s on file at the CVB. Observe if employees follow lines of responsibility as shown on the organizational chart or as explained by management. See VS Memorandum No. 800.63.

b. Observe operations to determine if employees, in general, are adequately trained and supervised so as to be competent in good laboratory techniques and preparation of veterinary biological products. Be aware of personnel health conditions that might affect the product.

c. Notice if the number of employees is adequate, if they are observing in-house rules, and their general attitude toward their work.

C. Facilities

1. *Audits*

a. Inspect the premises and compare with the facility documents. See VS Memorandum No. 800.78.

b. When comparing facilities with the filed facility documents, look for evidence of unreported remodeling, new stationary equipment, relocated key items, and other discrepancies.

c. Confirm that legends showing special-use facilities such as a public diagnostic clinic, diagnostic facilities, separate and apart research areas, export-only

products, pharmaceutics production, and FDA Export Reform and Enhancement Act production are correct. Determine the location and adequacy of isolation facilities for incoming animals, if required.

2. *Observations*

a. Verify that the actual use of production and testing rooms is as reported in the blueprint legends. Evaluate this use for any possible adverse effect on the product.

b. Observe the material, construction, and finish of all areas related to the production of biological products or ingredients of biological products. Verify that these areas may be readily and thoroughly cleaned.

c. Verify that the lights, hot and cold water supplies, and drainage systems are adequate and functioning.

d. Verify the heating, ventilation, and air conditioning systems are sufficient to adequately address issues of biocontainment and mitigate cross-contamination for the protection of products and personnel.

e. Observe the arrangement and construction of the facilities. Determine if this arrangement and construction provide adequate and appropriate isolation for each product to prevent cross-contamination from other products.

f. Observe traffic patterns through the production area. Observe enforcement of movement restrictions. Restricted areas should be posted as such.

g. Verify that dressing rooms, toilet facilities, and lavatory accommodations are appropriately placed, sufficient in number, and separated from production. Soap, towels, and hot water should be available.

D. Equipment

1. *Audits*

a. Identify equipment and environmental rooms used in production, testing, and storage of product. Verify that the location of equipment matches the code designated in the blueprint legends. Confirm the unique identity of equipment through production records, maintenance logs, and operation as intended by the manufacturer of the equipment.

b. Review the records of operation of specialized equipment, and determine if the equipment is functioning properly and recordkeeping is in compliance.

c. Determine what system is used and what records are kept by the firm to ensure that automatically controlled equipment is operating properly. If the firm has an exemption from having automatic recorders on sterilizers, determine if the records kept meet the provisions of regulations.

2. *Observations*

a. Look for equipment or compartments not shown on the blueprint and/or the blueprint legend. Determine if they are being used in production, testing, or storage of product and if the equipment or compartment is being used and maintained in compliance with the regulations and manufacturer's recommendations.

b. Observe the operation of equipment and compartments, and determine if they are being operated properly.

c. Determine if each piece of equipment is uniquely identified so that the use of the equipment may be adequately documented and traced in the manufacturing records when used in production.

d. Assure that all equipment is being sterilized according applicable requirements. Exemptions to the regulations must be on file with the CVB. Confirm that equipment exempted from sterilization requirements listed in the regulations is being treated as allowed for in the exemption on file with the CVB. See VS Memorandum No. 800.78.

E. Sanitation

1. *Audits*

a. Audit the firm's records to ensure that sanitizing is done at the appropriate time and place, and with the appropriate chemicals, as specified in the facility's blueprint legends.

b. Determine if the chemicals used for sanitation are appropriate for the microorganisms in each room.

2. *Observations*

a. Notice if the outside premises are properly drained, clean and orderly, and free from accumulated trash or construction debris.

b. Note whether an adequate effort is being made to control vermin, especially in animal quarters.

c. Determine if waste disposal methods are in accordance with the applicable regulations. See VS Memorandum No. 800.56.

d. Look for clutter inside the premises to determine if clutter has affected product quality. Check for accumulation of unnecessary materials, particularly in halls, production rooms, and coolers.

e. Notice whether all personnel, including maintenance people who enter production areas, are wearing appropriate clothing. Note if special clothing requirement areas are posted and requirements enforced.

f. Watch for unsanitary practices by employees.

F. Establishments and/or Products Pending Licensure (Prelicensing)

1. *Audits*

a. Examine records to confirm that the firm has obtained permission from CVB-Program, Evaluation, and Licensing (PEL) for any research that is conducted in production facilities with organisms, antigens, or fraction not already approved for a licensed product. Determine the impact to licensed/permitted product regarding the preparation of experimental product and review mitigating steps implemented by the firm or required by the CVB. Confirm that restrictions or conditions required by PEL were met. See VS Memorandum No. 800.64.

b. Verify that the Seed material is adequately identified and accounted for.

c. Review records for proper disposal of animals used in the preparation or testing of experimental products.

d. Differentiate between research being conducted using microorganisms related to currently licensed products and work with new microorganisms not related to licensed products. Complete records are required for both, but fewer restrictions may be required for microorganisms related to currently licensed products.

e. Review field trial records for compliance with special restrictions and requirements. Account for product prepared and distributed for field trials. Determine if the product was prepared in accordance with the Outline of Production on file. Determine if all responses were reported to PEL. Determine if the detailed records support the summaries sent to PEL.

g. Review the minutes of Institutional Biosafety Committee meetings. Determine if appropriate members have been appointed. Determine if all biotechnology

work,especially recombinant product work, is being addressed and if appropriate policy and procedures have been established.

g. Determine if prelicensing serials were prepared in production facilities and tested on licensed premises.

h. Determine if the expiration dating on newly licensed products has been confirmed, submitted to PEL for review, and documented in the Outline of Production.

2. *Observations*

a. Determine if the separation of personnel, supplies, and equipment between research and production is adequate.

b. Observe the in-house controls on movement of personnel, supplies, and equipment and the airflow control between research, production, and testing areas.

c. Check for production-related testing in research areas.

d. Check methods for disposing of research material.

e. Observe specific research or prelicensing activities as requested by PEL.

f. Observe if employees are following biosafety policies.

g. Determine if biosafety policies are adequate.

G. Seeds and Cells

1. *Audits*

a. Determine if the Master Seeds and Master Cell Stocks being used in production agree with those listed in the corresponding Outline of Production.

b. Determine if the Master Seed and Master Cell Stock were prepared and tested according to the regulations and Outlines of Production.

c. Review the records for each passage level of seed and cell stock used in the preparation of product for accountability and identification, tracing them from acquisition to production of serials. Records must be complete and reflect compliance with the regulations and corresponding Outline of Production.

d. Determine if the licensee's system of identification is adequate to ensure that the proper Master Seed or Master Cell Stock has been used at the proper passage level in production. Verify that the Master Seeds, Working Seeds, Production Seeds, and Master Cell Stocks used in producing the product serial each have the same identity and were prepared as those used in developing prelicense testing data. Also, verify that the passage levels of the Master Seeds, Working Seeds, Production Seeds, and Master Cell Stocks used in producing the product serial are all acceptable based on the corresponding passage levels used in developing the prelicense testing data and specified in the Outline of Production.

e. Determine where Master Seeds and Master Cell Stocks are maintained, handled, and produced. These materials have very specific requirements, which should be consistent with information in the blueprint legends.

f. Review records of Master Cell Stocks for batches of primary cells to determine their source, if the source animal was free of disease, and if acquisition was according to the regulations. Determine if batches of primary cells have been adequately tested.

g. Review Master Seed production and testing records. Review immunogenicity test records. Determine if the bench records for each serial of product are complete and clearly trace to the Master Seed.

h. Review testing records for ingredients of animal origin to determine compliance with the regulations.

2. *Observations*

a. Observe any production or testing procedures in progress for compliance with the Outline of Production or regulations. Note if the Seeds are monitored regularly for virulence, how they are maintained, how frequently they are passed, how they are stored, how much current inventory, etc.

b. Determine where Master Seed, Working Seed, and Production Seed are prepared. Only Master Seed may be prepared in separate and apart research facilities; Working Seed and Production Seed must be prepared on licensed premises in acceptable facilities.

c. Determine if the methods of maintenance, storage, and inventory of Master Seeds and Master Cell Stocks are in compliance with the regulations and corresponding Outline of Production.

d. Check to see if there are separate storage facilities for virulent or dangerous microorganisms and if there is a possible impact on licensed product quality.

H. Production (through batching)

1. *Audits*

a. Review records of production procedures for accountability and identification by tracing serials and production lots from raw ingredients to filling. Verify that records are complete and that each critical step is listed in the Outline of Production. If recordkeeping deficiencies are found, determine if they apply only to that serial or lot, or if they are consistent deficiencies for that product, group of products, or all products.

b. Determine if the serial or production lot has been prepared according to the version of the Outline of Production in effect when the lot was presented to the CVB for market release (this includes sample submission); compare the date of production with the date on the outline used for reference. Check to see that each step listed in the outline is documented in the records. Review the records to determine if all critical steps are described in the Outline of Production. If deviations from the Outline are noted, determine if they apply only to that serial or lot, that product, a group of products, or all products.

c. Determine if the manufacturer's recordkeeping system provides for the unique identification, tracking, and recording of each ingredient and if safeguards are in place to prevent errors in the preparation of the product.

d. Determine how serial numbers are assigned and what system is used.

e. Determine how annual outline reviews are done and by whom. Determine if the reviews are adequate to ensure compliance in the preparation of products.

2. *Observations*

a. Evaluate any production procedure in progress for compliance with the most recent Outline of Production and facility documents.

b. Determine if the identity of in-process material is maintained. Ensure suitable tags or labels are used to adequately identify all ingredients used in the preparation of biological products. Note the manner of identification used and the consistency of its use, e.g., color coding, lot numbers, product name.

c. Observe whether proper laboratory techniques and sterile practices are followed by laboratory personnel where required.

d. Observe the preparation of equipment and media and other ancillary procedures in the service area for compliance with the regulations and applicable special outlines.

e. Note any production procedures that differ from the Outline of Production, and evaluate the effect on the product. Even though the procedures may be within limits of acceptable laboratory practice or are intended to improve the product, variations are not allowed unless the Outline is changed to reflect the variations. Determine if approved outlines are available to, and used by, line supervisors.

f. Look for any procedures that may adversely affect the product.

I. Final Production (filling through packaging)

1. *Audits*

a. Review filling records for recorded losses or gains, fill checks, and filling problems. Determine compliance with the fill ranges as filed in the Outline of Production. Determine how over-filled or under-filled vials are handled and if the firm has a written policy covering this.

b. Determine the lyophilization requirements for each product. Review lyophilization records of selected serials for compliance and recordkeeping practices. Determine if temperature probe readings are identified on the recording charts.

c. Determine if all reprocessing was authorized, i.e., if further procedures were conducted on serials of liquid product after bulking and identification (other than filling and labeling) only when provided in the Outline of Production or when authorized by the CVB.

d. Review records of controlled freezing to determine if procedures follow the Outline of Production for products where this is critical, such as Marek's Disease Vaccine.

e. Determine if losses incurred through breakage, loss of vacuum, etc., are recorded in the serial records.

f. Determine if the firm can substantiate that the container label, the carton label, and the enclosure used were appropriate for the final use product.

g. Determine if subserials are being appropriately identified when further processed at different times or under different conditions, such as lyophilization in different dryers or at different times.

h. Review the records to determine if all critical steps are described in the Outline of Production.

2. *Observations*

a. Observe and evaluate actual filling procedures, including aseptic technique, fill checks, proper mixing during fill, appropriate temperature control and maintenance of concurrent records. Determine if employees adhere to the specifications listed in the Outline of Production and how to handle unacceptably filled vials.

b. Confirm lyophilization procedures. Determine if placement of probes is adequate. Note stoppering devices.

c. Note in-house procedures for vial and label inspection, sampling, identification of unlabeled vials, and how product is controlled until released. Ensure suitable tags or labels are used to adequately identify all ingredients used in the preparation of biological products.

d. Review handling of diluent, how and where it is stored, and how it is accounted for. See VS Memorandum No. 800.74.

e. Examine freezing procedures. Determine if the time interval from filling to start of freezing and the rate at which product temperature is lowered is in accordance with the Outline of Production.

f. Observe several selected serials for product uniformity, color, volume, texture, opacity, labeling, packaging, serial number readability, and expiration date. Check labels to ensure they have not rubbed off and are legible.

g. Determine if products other than biologics are filled, packaged, or labeled on the licensed premises. Determine if adequate separation of licensed serials of product and nonlicensed product is maintained during filling, packaging, and labeling.

h. Observe how long serials are out of the cooler during finishing procedures. Determine if the firm has established the maximum time the product can be out of the cooler and can substantiate effects to quality of the product. Determine if this time may be detrimental to the product, including the lifetime of the product. Establish how they record/monitor out of cooler time.

i. Review records for any minor temperature deviations, including detailed summary of deviation, root cause analysis, investigation report, corrective and preventative actions, and the review process to determine effectiveness. See VS Memorandum No. 800.210.

J. Labels

1. *Audits*

a. Review the files of the firm's label inventories for inactive, expired, superseded, or obsolete labels.

b. Check labels for which there are special requirements as required by the regulations. Determine if these labels are in compliance.

c. Review the process regarding expiration date determinations. Ensure the process accounts for compliance with the regulations and the applicable Outline of Production. Include the process used for relabeling, e.g., when an extension of dating is approved by CVB.

d. Review the label control process for new and revised labels. Determine if the process is in control and can ensure compliance with the regulations.

e. Compare the label stock against the CVB filed label for accuracy.

f. Ensure that the firm maintains accountability for all labels printed for use on licensed products. Review inventory records, and compare with actual inventories. Determine accountability of damaged and destroyed labels.

2. *Observations*

a. Review the process used to ensure that all labels and labeling material printed is accounted for and that the inventory is accurate.

b. Determine serial numbers and expiration dates printed on labeling material is legible.

c. Observe the process in which serial numbers and expiration dates are inspected and verified for accuracy.

K. Testing

1. *Audits*

a. Records of testing performed, as required by the Outline of Production or regulations, to determine if all critical steps were documented, observations of results are clear, and records are authenticated by the individual performing the test. Evaluate records for evidence of falsification. Review records of selected tests for ingredients, bulk lots, serials, Seeds, Cell Stocks, and diluents for compliance with the regulations and the applicable Outline of Production or regulations.

b. Note if tests contain the proper controls and if critical components, reagents, and equipment are monitored for quality before and/or during the tests.

c. Make sure that all tests summarized on APHIS Form 2008 reports are supported by review of the testing bench records. See VS Memorandum No. 800.53.

d. Review any tests conducted by the firm that are not reported on the APHIS Form 2008. Determine whether or not the results of such tests may indicate an issue with the purity, safety, or potency of the product and require special attention. Note: the firm may test product in accordance with requirements from an importing country. Test results that raise questions regarding the purity, safety, potency, or efficacy of a serial should be reported to the CVB in accordance with VS Memorandum No. 800.57.

e. Evaluate whether retests are conducted according to regulations and/or the Outline of Production.

f. Check to see that the blueprint legend lists those microorganisms that are not named in the Outline of Production but that are necessary for testing purposes, such as organisms used for growth promotion testing or controls.

g. If the firm is authorized to use unlicensed facilities for potency testing in the Outline of Production, review testing records from the contract testing facility. Also, review licensee's audit plan of the contract testing facility to ensure on-going quality control. See VS Memorandum No. 800.115.

h. If the firm has been given an animal safety exemption, review product file for nonconformance to the Outline of Production and for impact to product. See VS Memorandum No. 800.116.

2. *Observations*

a. Observe testing procedures to determine if they are being performed in compliance with the Outline of Production and the regulations.

b. Observe testing procedures to determine if the firm is using proper laboratory technique along with proper recordkeeping.

c. Observe if proper testing controls are used and recorded.

L. Animals

1. *Audits*

a. Determine if the firm is a registered research facility or a licensed animal dealer under the Animal Welfare Act. Record the registration or license numbers for reference. Review the last APHIS Animal Care inspection report to see if there were any deficiencies. Determine if they have been corrected.

b. For animals used in production and testing, review procurement and test records for completeness, for accuracy, and for compliance with requirements in the Outline of Production and Animal Welfare regulations. Where required, ensure that proper health certificates have been issued and filed, e.g., equine infectious anemia testing records for horses used in production or testing.

c. Determine the completeness of records for animals used in production or testing, and examine these records when inspecting according to the production and testing categories listed in this memorandum.

d. Determine if the firm keeps accurate records to identify animals and trace their final disposition. Certain animals must be quarantined before being removed from the premises and when moved must be accompanied by the appropriate forms.

2. *Observations*

a. Check for compliance with requirements of the Animal Welfare Act. Animals not subject to the Act should also be cared for in the spirit of the Act. Report items needing immediate attention to the Animal Care Sector Supervisor at once.

b. Note whether animals are adequately identified.

c. Determine if the firm has necropsy facilities for animals used for production and test purposes.

d. Determine if the admitting veterinarian examines the animals before admittance or in a separate quarantine area on the premises. Note if another employee examines the animals for the veterinarian.

e. Determine whether there is any preconditioning or treatment of animals that might adversely affect testing or production.

M. Distribution

1. *Audits*

a. Evaluate the method used by the licensee/permittee to reconcile estimated and actual inventories prior to marketing release.

b. Determine whether distribution records are adequate for inventory control.

c. Determine if the firm's records are such that the firm could carry out a total stop sale or recall down to user level should it become necessary.

d. Review documentation of any recent product recall or stop sale. Determine if the actions taken were appropriate and in accord with the regulations. See VS Memorandum No. 800.57.

e. Review the firm’s recall/stop sale policy to be sure that it is in accordance with APHIS requirements.

2. *Observations*

a. Evaluate the physical system of control and identification on pre- and post-release serials used to prevent inadvertent distribution of unreleased serials.

b. Review the release system with the firm to ensure adequate documentation and control. Verify who is designated to receive marketing release authorizations from Inspection and Compliance.

c. Compare the marketable inventory as reported on APHIS Form 2008 with the actual inventory. Determine if the firm uses a standard inventory variance and if this variance is reasonable. Any changes in inventory beyond the firm’s variance standard or in the absence of a firm standard should be reviewed further.

d. Determine if cooler space is adequate for licensed products at the normal level of production. Confirm the storage temperature of licensed product is in

accordance with the storage requirements stipulated in the regulations or Outline of Production.

e. Observe for expired product, product deemed unacceptable for marketing, or returned goods on premises. Determine how these goods are handled and disposed of. Review recordkeeping for returned goods. Determine if the firm re-distributes products and if the methods are acceptable. See VS Memorandum No. 800.60.

N. Miscellaneous

1. *Audits*

a. Discuss the firm's pharmacoviligance program with the responsible official. Review the adverse event report.

b. Ensure that only authorized samplers sign the APHIS Form 2020. Arrange to train new and current samplers as necessary. Verify the list of authorized samplers. See VS Memorandum No. 800.59.

c. Verify that products found unsatisfactory by the firm were destroyed and reported destroyed on an APHIS Form 2008. Ensure the reason for destruction listed on the APHIS Form 2008 matches the production/testing records reviewed. Determine if the licensee/permittee investigated as to why the product was found unsatisfactory for marketing.

d. Check the blueprint legends for notation of storage location of APHIS reserve samples.

2. *Observations*

a. Inspect storage areas to verify that products reported destroyed by the firm are not still being retained by the firm.

b. Inspect the quarantine area for separation and security.

c. Observe that only authorized samplers are selecting samples for APHIS testing.

d. Review sampling techniques. Be sure samples collected are representative of the entire serial. Review the methods of authentication and verify compliance with the regulations. Check the method of packing samples for shipment.

e. Review APHIS Form 2020 preparation with the sampler.

f. Observe reserve samples for proper authentication, made tamper evident, and document the chain of custody. See VS Memorandum No. 800.59.

g. Determine that products "to be destroyed under APHIS supervision" have been properly quarantined. Observe the destruction of these products and report it on APHIS Form 2045. Review the inventory and accounting of any samples retained from unsatisfactory serials.

V. IMPLEMENTATION/APPLICABILITY

This guidance is effective upon publication.