

**United States Department of Agriculture
Center for Veterinary Biologics**

Standard Operating Policy/Procedure

The Inspection Proper

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The Inspection Proper

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1. Purpose and Scope

This document describes the Inspection Proper. The Inspection Team must determine that the products have been produced and tested by competent people using acceptable facilities, equipment and methods; that products being marketed are not worthless, contaminated, dangerous, or harmful; and that reports and records of production and testing of products are accurate and complete.

2. Rules of Conduct

The ideal relationship is one of mutual understanding, confidence, and respect. Although this ideal cannot always be reached, the inspector should observe these rules of conduct and procedure which will approach the ideal as nearly as possible. There are certain specific rules to be followed by all inspectors.

- The inspector is in the position of an observer and should in no way assume a note of supervision or enter into operational management.
- The inspector should be reasonable in demands on the time of laboratory personnel by limiting questions and conversation to that directly related and necessary to the inspection.
- The inspector should not discuss possible exceptions with sub-supervisory laboratory personnel or engage in conversations concerning controversial subjects.
- The inspector shall be aware that all information obtained is privileged and shall not be conveyed in any manner or form except to those officially authorized by the Center for Veterinary Biologics Inspection and Compliance (CVB-IC) Director.
- The inspector should observe all organisms and vector control requirements of the laboratory.

3. Established Inspection Techniques

The following techniques are commonly used in inspection: 1) selective audit; 2) observation; 3) perambulation; 4) evaluation of internal control; 5) completion of worksheets; and 6) issuance of a formal report.

3.1 Audit

The inspector selects certain records for an in-depth review. Related records are reviewed to establish the validity of the entries on the master records selected. Exceptions are noted.

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3.2 Observation

The inspector personally substantiates that the information provided to the Animal and Plant Health Inspection Service (APHIS) and records kept by the firm are in agreement with what was found at the actual situation or site at the establishment.

3.3 Perambulation

This is a special class of observations. The inspector unobtrusively watches ongoing operations for a sufficient time to observe unusual or uncharacteristic occurrences, especially regarding techniques of manufacture.

3.4 Internal Control

Well-managed enterprises have checks and balances built into their methods of operation to minimize and/or expose errors. The inspector, using experience and judgment, explores the adequacy of these controls. These findings may determine further inspection actions to accomplish a comprehensive inspection.

3.5 Worksheets

The inspector personally makes a record of the findings in such a logical and systematic manner that this record may be later admissible as evidence of the audit and findings in a court of law.

3.6 Formal Reports

The inspector communicates the findings in a written form that can be used later for discussions with supervisors, licensee representatives, other team members, subsequent teams, and others properly authorized to use the information gathered.

4. Division of Responsibilities

Following the assignments made during the pre-inspection meetings, each team member proceeds to obtain information and evaluate the information obtained from the various sources. Findings are reviewed with the team to assure a coordinated effort. If necessary, the team leader reassigns individual activities to maximize the effectiveness of the inspection. The team leader evaluates, coordinates, and finalizes the actions that are taken.

5. Conducting the Inspection

The inspection proper has three phases: 1) an initial meeting with the licensee representative(s) for making introductions, contacts and schedules, and explaining the purposes of the inspection;

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2) the inspection activities themselves; and 3) a wrap-up meeting with the licensee to discuss the inspection findings.

5.1 Introductions

Upon arrival do the following so senior management officials will know what to expect:

5.1.1 The inspector should identify themselves to the licensee's receptionist. A printed card is useful.

5.1.2 Ask for the firm's official government liaison by name. If the liaison is not available, ask for the designated alternate. If none of the designated official representatives are available, ask to see the individual in charge.

5.1.3 The inspector should identify themselves again to the official representative showing his/her official government badge and identification card. This should be a deliberate act even if the inspector is well known to the representative. Section 157 of Title 5, U.S. Code, gives authority to make the inspection only when it is shown that the inspector is duly authorized. The official identification may be delayed until the initial meeting with the management staff, but must be done before any inspection activities.

- Do not trade the official government badge or identification card for a firm's identification badge.
- Do not allow the firm to copy the inspector's numbered badge. In some cases, the firm may photocopy the inspector's VS1-4 identification card.
- Do not provide the firm with any personal identification, such as a driver's license or Social Security card.
- Do not sign a confidentiality agreement connected in any way related to the duties as an inspector for the Center for Veterinary Biologics. The obligations under Veterinary Services Memorandum No. 800.2, *Confidential Information Concerning the Veterinary Biologics Program*, may be explained to the firm. If necessary, contact the IC Section Leader or the CVB-IC Director.

5.1.4 The licensee representative should be informed that the inspector is on the premises to conduct an inspection. Arrange a meeting with the representative, the individual in charge, and with as many of the supervisory or management staff as may be necessary to have present at the initial meeting. If this meeting cannot be done in a timely fashion (within the first 15 to 20 minutes upon arrival), then the inspector may request to forgo the meeting until a later time that day and begin the tour of the facilities.

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5.2 Refusal of Entry

If, after proper identification (see **Section 5.1**), the firm denies the inspector access to the licensed premises, areas of the premises, or documents that are germane to the inspection, then the inspector should proceed as described in the current version of **ICSOP0028, *Refusal of Entry for Inspection, Assault, and Bribery Procedures***.

5.3 Initial Meeting

Go over the following points in the initial meeting, being brief, businesslike, and courteous:

5.3.1 State the purpose. Explain what an inspection means. Go over the inspection categories in a general manner.

5.3.2 Develop a preliminary schedule with the licensee. Allocate time for:

- An orientation tour of the facilities
- License/blueprints/legends review
- A product review (Review of production records can include all records from the acquisition of seed material to the last container of product leaving the plant including operating procedures and records.)
- An equipment records and equipment operation review
- Review of experimental, field trial, and consumer complaint records
- Review of labels and packaging procedures and records and
- Wrap-up discussion session.

5.3.3 Discuss the APHIS Biologics Program Inspection Policy which is as follows:

- Will go anywhere it is felt is necessary but will respect licensee policy as nearly as possible and will not interfere with operations if it can be possibly avoided.
- Will accept individual to observe and accompany the inspector at any and all times. The firm may designate whomever they wish.
- Will discuss policy matters only with individuals specifically designated by the firm to do this.
- Will not instruct or admonish any employee.
- Will discuss findings only with employees that management designates. The items discussed will be repeated to management later.

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5.3.4 Discuss what the inspectors need to help them in their inspection.

- How will inspectors move about the plant?
- Obtain the names of observers, if any, who will accompany inspectors. Establish the ground rules for observers.
- What are the working hours? Does the company work in shifts?
- Obtain a schedule of activities that will be occurring while inspectors are in the plant. This may include:
 - filling room schedules
 - test starting dates, animal challenge dates, observation times
 - inoculation or harvesting schedules
 - batching schedules
- Determine the locations where records are kept. This should include the following types of records:
 - labels and label files
 - animal acquisitions and disposals
 - production and testing records
 - sterilizer, lyophilizer and filling records
 - outlines of production
 - stock culture and master seed records--testing
 - distribution records
 - inventory records
- Where may inspectors work? Obtain working space in a location convenient to the records area and to production and testing facilities if possible.

5.4 Worksheets

The preliminary work sheets prepared during pre-inspection review are utilized during the inspection proper. Examples of typical worksheets that may be used in the inspection are as follows:

- Daily Inspection Notes
- Additional Daily Inspection Notes
- Inspection Product Check-Off Sheet
- Additional Product Inspection Notes
- Product Destruction Record (APHIS Form 2045)

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All worksheets, other notes, schedules, copies of documents, exhibits, and employee statements become part of the notes. These must be usable as supporting evidence for all exceptions noted.

- Make notes legible, clear, and indelible.
- Cross-index or number so sequences can be maintained and any omissions made apparent.
- Identify by date or by person preparing.

5.5 How to Evaluate Exceptions

There are three types of exceptions: Minor, less serious, and serious

5.5.1 Minor exceptions. Are not apt to affect quality of product but indicate laxity or error that could become more serious if not corrected. If numerous minor exceptions are noted during the inspection, it is indicative of poor management and should be considered as having cumulative effect.

5.5.2 Less serious exceptions. By repetition or very nature, may affect quality of a product. They may require evaluation at the CVB-IC office before final action is taken.

Holding release of serials or products may be required.

5.5.3 Serious exceptions. Violations of this degree will probably affect the quality of the product or products or may be willful. This type of violation will require more thorough documentation and referral to higher authority. Either stop sale or temporary suspension of license should be considered.

Each exception must be related to the Virus-Serum-Toxin Act (VSTA) or to the regulations issued pursuant to the Act. An inspector must not go beyond this authority and should develop the habit of carefully determining what regulation might be violated when a possible exception is noted. This will insure that the inspector has not exceeded the delegated authority and that the inspector will be continually increasing the effectiveness of work.

6. Inspection Notes

Inspection notes are the true inspection report. The typed report is just a summary. Everything in the summary report must be taken directly from notes or attachments. Nothing can appear in the summary that is not documented in notes or attachments. Remember, notes are confidential business information and must be kept secure or in the inspector's possession at all times.

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6.1 Some of the uses of notes are:

- Writing the summary (formal) report
- Reference for the next inspection
- Reference to support action relating to special requests, complaints and testing
- Reference to support regulatory action
- Legal evidence for court proceedings (Notes will always accompany personnel to court.)
- Documenting what was done for supervisory or program review

6.2. Following are a few reminders to assist in preparing notes:

- Use preprinted forms (Daily Inspection Notes and Daily Inspection Notes Continued). If the form is not available, be sure to include the same basic information as called for on the preprinted form--initials, date, page X of Y, etc.
- Write legibly. Prepare notes with care. Notes may be the most important writing ever done in this job.
- Complete notes include **who, what, where, when, why** and **how**.
- Use indelible ink and only one color.
- Where possible, tie statements to a specific product and serial number.
- Document the source of information:
- Describe observations – in addition to **what** was seen, include **when, where,** and **who** was involved.
- Person – always identify **who** told the information – then confirm everything told from records or observations. The weakest way to confirm information is from another person.
- Immediately mark all exhibits or other documents received with the name of the person they were received from, the date and inspector's initials on the back of each page. Attach them to the notes and make reference to them in the notes.

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- Document the times at the firm. Show clock hours including time left for lunch or other breaks.
- Document that the inspector identified themselves (identification card) and stated that the purpose is to inspect. (This validates the inspection per VSTA and the Code of Federal Regulations, Title 9 (9 CFR) Part 115.1.)
- Document the time, building number, floor, and who guided any tours that were taken.
- Document agreements or anything else the firm volunteers to do and the name of the firm official making the agreement.
- The notes should be in complete sentences, phrases or bullet statements. Remember that two years from now, the inspector must be able to look at what was written and know exactly what it means.
- Notes should be concurrent – completed within 24 hours. Stop frequently during the day to complete notes. Put down the date the notes were completed to show compliance with above.
- Notes must be facts only – what is seen, read, heard, smelled, or touched. Opinions or judgments may not be included in notes. Notes should be clear enough for the reader to make their own judgment or opinion concerning an issue. (Informed scientific opinions or judgments may be used in the summary report or memos recommending action, only if supported by details in the notes.)
- When violations are seen, do not put down just the 9 CFR number – document in detail exactly what is observed. Always list findings; never what should be done to correct the problem.
- Anything that appears to be a noncompliance or violation should be documented in much more detail than general observations. Write down every detail. Go back if something is found missing.
- Error correction should be done by making a single line through the error and initialing.
- Number or otherwise separate paragraphs in notes so particular items can easily be found later.

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7. Inspection Routines

Use of a planned routine to gather information on the compliance status of specific items or procedures is the best assurance that necessary information will be discovered. There is no way that all of the routines that are needed can be described. The following, however, are several routines of major importance covering the areas of records, products, production procedures, and controlled equipment. During the course of use of these planned routines, it is almost certain that items will be discovered that need further comprehensive investigation. The information that will subsequently develop as these "leads" are pursued will be almost wholly dependent upon ingenuity and resourcefulness as an inspector.

8. Serial Record Audit

For a complete serial record review, start with the bulk/batch assembly record.

8.1 Complete Serial Audit

- Review selected serial assembly records against the appropriate outline. These should include complete identification of all added ingredients and account for each step in final processing through completion of the bulk serial.
- Observe for losses or gains in volume, actual or estimated measurements, authentication of critical steps, and identification of the operator.
- Identify each bulk lot, raw ingredient, major equipment, procedure, or test.
- Certify the procedures against the outline at this point.
- Determine if major equipment is identified and has been properly sterilized.
- Hold other identified items for checking later.

8.2 Production Lot Audit (antigen production)

- Review the selected production lot or batch records of raw biologics and compare each step against the outline.
- Determine record keeping compliance.
- Trace back to appropriate seed or culture and forward to the serial assembly.
- Identify all ingredients, cell cultures and tests for later checking.

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- Review selected ingredient records against the outline, special outline or standard laboratory procedure.
- Note record keeping compliance.
- Identify tests run and raw materials used. Be sure to note special requirements for certain ingredients (e.g., E.I.A. test for horse serum).
- Review selected cell culture production records against outline and regulations.
- Identify raw materials and tests run on cell cultures.
- Review selected diluent production records for compliance – the same as listed for serial audit (see **Section 8.1**).
- Review each selected test procedure and compare each step against the outline or 9 CFR.
- Identify ingredients of test materials or animals used (for further audit at a later time). This includes all ingredients of animal origin.
- Determine if identification is adequate.
- Check to see that special testing equipment is operating properly.
- Review each selected animal record and compare with outline, special outlines or 9 CFR testing requirements.
- Check to see that identification of the animals is adequate.
- Determine compliance with appropriate Animal Welfare regulations and 9 CFR Part 117 regulations.
- Review animal health program with responsible official including routine medications given.
- Consult with the veterinarian-of-record to see how often care or advice is required.

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8.3 Compliance Criteria for Records

Records are defined in 9 CFR 116.1 as "detailed records of information necessary to give a complete accounting of the activities within each establishment." The records will contain sufficient detail so that any person familiar with the production of the product can clearly understand each step in production.

8.3.1 Check on chronology. There should be no evidence that entries are being recorded at any other time than at the time essential steps of production, testing and destruction are actually being done. The steps should follow the same sequence that has been approved in an outline of production.

8.3.2 Check identity of items. Records should sufficiently identify ingredients, cell passages, seed cultures, etc., so entries reflect precisely what is processed.

8.3.3 Check on dates. Records show the time and date(s) applicable to each step required. Be sure records are dated. Be sure time is recorded when essential to accurately assess the process as filed in the outline of production.

8.3.4 Check on quantity. Identity and quantity of ingredients, material, or product added or removed at each important step must be shown. Unusual gain or loss from start to finish must be accounted for.

8.3.5 Check on identity of personnel. Designated individuals shall initial or sign the records as they make measurements or judgments. These initials must be later identifiable.

8.3.6 Check on location of items. Locations of products in storage or in distribution shall be recorded so the items can be traced and located.

8.3.7 Check on legibility and indelibility of records. All records must be legible and indelible and kept for at least 2 years after the expiration date of the product. Records common to two or more lots of product should be traceable. All records must be available upon request.

8.3.8 Check for deviations from approved methods. Any deviations must be explained in enough detail to allow APHIS inspectors to judge whether purity, safety, efficacy, or potency of the product was affected. If products were judged to be adversely affected, a record from APHIS permitting the deviation must also be on file.

Two things must be stressed in record audit:

- Accountability
- Identity

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8.4 Use of Outlines of Production

The inspectors complete their review of the products that were tentatively selected and of worksheets prepared during the pre-inspection review.

- Request the officially stamped copy of the product outline or special outline for the product, procedure, or equipment selected for examination.
- Check the page dates against the pre-inspection notes.
- Request completed detailed licensee records for the serial or other procedure selected.
- Review the records and compare with requirements in the outline.
- Observe procedures and compare with requirements in the outline.
- Make notes on the product check-off sheets. Record all exceptions.
- Check supporting records to substantiate the validity of the primary records.

8.5 Routines in the Observation of Production Procedures

The inspector will schedule their observations of production procedures from the production schedule provided by the firm and from pre-inspection notes.

- Consult pre-inspection notes to assist in selecting critical procedures to observe and make actual selection.
- Consign observation to one or more team members taking into consideration their field of specialization.
- Check with the firm for production schedules, schedule changes and request to observe procedures.
- Determine and follow specific restrictions necessary to enter limited access areas.
- Take the assigned product and physically follow the route of movement from room to room within the facility. Compare with the blueprint check-off sheet; note if each activity is where pre-inspection notes indicate.
- Spend enough time at each phase being observed to thoroughly understand exactly what movements are being made in what sequence. Mentally be able

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to do the complete sequence of movements. Return to the outline and recheck correct procedure. Record any deviations.

- Maintain an awareness of potential contamination; be aware of people's personal habits, environment factors affecting sterility, air movement, proximity to other organisms in use, etc.
- Watch if routines for strict sterility are being broken, particularly harvest, bulk mixing, and fill.
- Watch for deviations in proper lab procedure – placement of a sterile item on a non-sterile surface, then reusing.
- Observe if all surfaces of sterile rooms are being cleaned, walls and ceilings, as well as floors and lab tops.
- Notice if the line supervisor is aware of the conditions or restrictions of the outline. Often outlines are written and filed by management without line supervisor involvement.
- Watch measurement of ingredients – compare with allowed amounts in the outline.
- Watch the recording of each step as it is done, verifying it is concurrent with operations.
- Watch for evidence of reprocessing – watch steps taken post-incubation – compare with that allowed in the outline. Keep sufficient notes on the observation to enable proof as to whether or not a procedure is according to the outline.
- Call other inspectors to witness alleged exceptions. If procedure is dangerous to product or production people, call a team conference and request immediate review by firm personnel. TAKE ACTION.
- Go into coolers; check if unlabeled serials can be mixed up. Check if unreleased serials can be mistakenly sold or distributed.
- Recognize anything that is unlabeled or unidentified and require it be immediately identified and properly labeled, otherwise quarantine it and destroy under APHIS supervision.

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- Be on the lookout for organisms in abnormal amounts or in abnormal places as signs of possible research or extra testing in production areas--maintain an awareness of what organisms are authorized where.
- Watch for activity in rooms where not so indicated in blueprints or legends.
- Watch if proper lab clothing and if safety equipment is in use or only present on a token basis.
- Watch for movement of people through a restricted area who are on official business but are not observing the restrictions (maintenance men, firm executives).
- Watch for nuisance things – food in coolers, lunching in laboratory rooms, desks and files in sterile rooms, lounging of idle employees in sterile rooms (often these are hidden and make good places to avoid the supervisor).
- Make notes on product check-off sheet. Record all exceptions and failures to follow good manufacturing practices.

8.6 Inspection of Controlled Equipment

The inspector checks the operating condition and regulation compliance of all automatically controlled equipment.

- Review team assignments for observing firm's equipment.
- Review the pre-inspection list of firm's equipment. Add any new equipment found at the firm.
- Observe working schedules and determine periods of high and low equipment use. Areas with constant temperature control should be checked during both the high and low activity periods and on several different days.
- Schedule observation time with appropriate firm supervisory personnel. Determine and follow special procedures for entering limited access areas.
- Check CO₂ incubators and determine if appropriate CO₂ percent atmosphere is being provided. Determine how the CO₂ levels are monitored and how often they are double checked by the licensee.
- Observe controlled freezing of completed product and note the time elapsing from harvest to reaching the final storage temperature. Compare freezing rate and time elapsed to outline requirements.

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- Observe sterilizers for loading that provides for circulation of heat or steam.
- Observe pasteurizers for temperature of both serum and water bath. The firm should be checking their pasteurizing recording equipment against accurate thermometers once a week or once every run if operated less often.
- Observe lyophilizer and determine if each vial in the serial or subserial is being held and lyophilized under essentially identical conditions. Watch for shelf temperature variations, non-uniform stoppering, mixed container sizes in a unit, a subserial in more than one drying chamber, etc. If breakdowns have occurred, how are the vials handled? What do the records show? What precautions are taken?
- Observe fermentors and bioreactors and determine if the environment provided the product is in accord with that specified in the outline. Review records and note breakdown, manual operation, sterilization, automatic additions, and maintenance of sterility.
- Determine if the automatic controlling equipment is providing the environment within limits required by the outline or regulations. Note time, temperature and recovery time after doors are opened, hot or cold material added, etc.
- Determine how often the firm checks their equipment manually or with standardized measures.
- Review the record keeping system. Be sure manual or standardizing checks are recorded.
- Make notes on all equipment checked and record all exceptions to outline or regulation requirements.

9. Daily Team Review

The team leader may assemble all members of the team daily.

- Meet at a location where privacy is assured. This permits free discussion and prevents disclosures of privileged information.
- Review the activities of each member of the team.
- Discuss each exception found.

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- Tentatively rate each exception as minor, less serious or serious. Look for guidelines in special circumstances. Contact IC Management if unable to mitigate.
- Check the documentation of each exception to be sure it can be substantiated. Have it ready for the wrap-up session.
- Discuss the next day's activities and modify assignments if indicated.
- Prepare a summary of findings and assemble a rough form of the inspection report as the inspection is winding up. Present findings logically. Usually use the general inspection category outline in presenting exceptions. Cite 9 CFR references, note these may change upon policy review by the Inspection Section Leader. Note where dates must be set for corrections or where supervisors must be told of significant items. Have the rough form ready for verbal presentation at the plant wrap-up session.

10. The Wrap-up Session

Identification of an exception is only a beginning. Compliance with regulations is the desired end result. Many exceptions can be satisfactorily handled through meeting with representatives of management at the conclusion of the inspection.

- Record the names of the individuals attending the wrap-up session.
- Use the summary of exceptions prepared at the last team review session as the format for the verbal presentation.
- Allow each team member who worked on the category in which the exception was found to present the findings and exception(s) found. The team leader maintains responsibility for developing all actions to be taken as a result of the discussion on each category.
- Encourage an exchange of opinions with the representatives of the firm. Be sure any misconceptions or misunderstandings are resolved.
- Record the important points that are brought out in the discussion. If some differences cannot be reconciled, tell the firm representatives that final actions will be determined after consultations with the appropriate APHIS personnel.
- Ask the firm representatives to suggest a date by which each exception will be corrected. If a date is not reasonable, try to set one by negotiation. If these approaches fail, assign a date by which corrections must be made.

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- Attempt to have written confirmation of all agreements made at the meeting returned to the licensee within 15 days of the conclusion of the inspection.
- Keep three questions in mind during all negotiations, discussions and actions:
 - Is the action consistent with regulations?
 - Is the action consistent with APHIS policy?
 - Is the action reasonable?
- Discourage tape recording the sessions. Taping tends to inhibit open and candid discussion. If a firm's secretary transcribes all or portions of the proceedings, insist that a copy be sent to the team leader.
- Make favorable, as well as unfavorable, comments.

11. Guidelines for Actions in Special Circumstances

Inspectors will discover things which seem to indicate serious violations or willful noncompliance.

Document suspected or proven major violations using photocopies of records, employee statements and such other information as will stand legal scrutiny. See **ICSOP0016**, *Investigation and Processing of Alleged Violations of the Virus-Serum-Toxin Act*, for more information. Consult with the CVB-IC Director to confirm action.

Impose a stop sale or hold release on products involved in a major violation(s). Do this only after exploring all aspects of the situation and after contacting CVB-IC Management. Do not use this option too quickly.

Do not rescind a stop sale or hold release until the alleged violation is disproved or the need for it is clearly removed by subsequent events or instructions.

Maintain security on evidence of willful violations so the results of the investigation will not be compromised. Discuss evidence only with those who need to know.

11.1 Verbal Abuse of Veterinary Biologics Inspectors

A question has arisen as to what recourse there is when an inspector is subjected to verbal abuse by the owner or manager of a licensed or permitted facility. Based on a case involving Animal Welfare inspectors, the Office of the General Counsel has determined that if the harassment is of a nature which compromises the inspector's ability to properly inspect the facility, the inspection should be terminated and alleged violation initiated for failure to comply with the provisions of the VSTA. Consult the CVB- IC Director for advice.

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11.2 APHIS Employees' Safety Responsibilities While Conducting Inspections

In 1991, after a tragic loss of life to fire at a food processing plant in North Carolina, the Administrator issued a memorandum on employee responsibilities when safety violations are observed. Even though there is no regulatory authority for the safety of non-Federal employees at commercial facilities, there is a moral obligation to identify and report obvious unsafe conditions. If, during an inspection, conditions are observed that pose potentially disastrous consequences if not corrected, report safety hazards such as blocked fire exits or other workplace hazards to the owners or operators of the establishment.

12. Summary of Revisions

Version .03

- **5.1:** Additions regarding parameters concerning identification of inspector at a firm (information received from Select Agent Program for Inspectors)

Version .02

- The Contact information has been updated.
- **3.1/3.4:** These sections have been updated to use more common language.
- **5.3:** Batching schedules have been added.
- **8:** Batch has been added for clarification.
- **8.1:** The word “bulk” has been removed.
- **8.2:** Antigen production has been added for clarification.
- **9.** Noted that 9 CFR citations may be changed upon review.