

SECTION VIII

PESTICIDE PRODUCT INSPECTIONS

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CHAPTER 1

INDUSTRY PRACTICES

1.1 INDUSTRY PRACTICES OVERVIEW

To fully understand the pesticide industry, an inspector must have a thorough understanding of the critical components of the industry including the:

- Definition of the term pesticide;
- Pesticide markets; and
- Pesticide distribution channels.

Definition of a Pesticide

In the United States, a pesticide is defined as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant. A pest is defined as an insect, rodent, nematode, fungus, or weed.

Thus, the term *pesticide* covers more than the common perception of insecticides and herbicides. Other substances covered in the definition of pesticides are antimicrobials, which include disinfectants, sanitizers, and anti-fouling agents. A list of representative classes of pesticides is shown in Table 1.

Pesticide Markets

There are three primary markets for pesticides: agricultural, institutional/industrial, and household. However, there are no clear-cut, distinct divisions between markets based on chemicals. A single active ingredient may serve several different markets.

The physical production of pesticides in the United States is divided into two major processes - manufacturing and formulation. The manufacturing phase is the synthesis of the active pesticidal ingredient. These active ingredients are then often transformed into pesticide products in the formulation process, which generally involves adding active ingredient to solvents, water, or petroleum distillates or mixing them with inert ingredients to produce liquids, dusts, powders, granules, or aerosols.

Table 1. Types of pesticides

Pesticide Class	Function
Insecticide	Controls or kills insects

Herbicide	Controls or kills weeds
Fungicide	Kills fungi
Nematocide	Kills nematodes
Rodenticide	Kills rodents
Bactericide	Kills bacteria
Acaricide	Kills spiders
Algicide	Kills algae
Miticide	Kills mites
Molluscicide	Kills snails, slugs
Avicide	Repels or controls birds
Slimicide	Controls slime
Piscicide	Kills or controls fish
Disinfectant	Destroys or inactivates microorganisms
Growth regulator	Stimulates/retards plant growth
Defoliant	Removes leaves
Desiccant	Speeds drying of plants
Repellant	Repels pests
Attractant	Attracts pests
Chemosterilant	Sterilizes pests

1.2 UNDERSTANDING THE REGULATED COMMUNITY

The inspector should be familiar with the functions and basic responsibilities under the prevailing regulations for each person (defined as any individual, partnership, association, corporation, or any organized group of persons, whether incorporated or not) involved in pesticide distribution channels. Below is a summary of these entities and their basic functions:

Producers

Producers produce or imports any pesticide or device or active ingredient used in producing a pesticide. *Produce* means to manufacture, prepare, propagate, compound, or process any pesticide, any active ingredient or device, or to package, repack, label, relabel, or otherwise change the container of any pesticide or device.

In general, manufacturing establishments produce the pesticide active ingredient from basic chemical feedstocks, including petrochemicals, acids, organics and inorganics, and gases. The result is a pesticide active ingredient, but not one that is in a form ready for use. Many establishments are able to produce several active ingredients. After synthesizing the raw material into an active ingredient, the next step is refinement, which is usually accomplished through further separation to recover solvents or excess reactants and purify intermediates and active ingredients. After this stage of processing, the active ingredient is ready for packaging and shipping.

Importers

It is common practice for a producer, formulator, or dealer to import a product produced outside of the country for sale and use within the country. This can be a finished ready-to-use product, a product requiring repackaging or relabeling, or a product requiring further processing. Several producers are multinational and have registered establishments in other countries.

Formulators

Formulation Ingredients

Adjuvant - used in a formulation to aid in the pesticide application or to improve the effectiveness; can include wetting agents, spreaders, emulsifiers, dispersing and foaming agents, foam suppressants, and penetrants.

Active ingredient - the ingredient that provides the pesticidal action in a formulation.

Diluent - an ingredient intentionally added to reduce the concentration of an active material.

Formulation - any substance or mixture of one or more active ingredients and inerts.

Inert - an ingredient (also known as an excipient) intentionally added to a formulation other than the active ingredient such as solvents, emulsifiers, wetting agents, carriers, and conditioning agents.

Surfactant - a substance that allows two otherwise immiscible ingredients to mix with each other.

Technical grade of active ingredient - a material containing an active ingredient: (1) that contains no inert ingredient other than one used for purification of the active ingredient, and (2) that is produced on a commercial or pilot-plant production sale.

The pesticide formulating industry formulates active ingredients produced by pesticide producers into pesticide products that are distributed in ready-to-use forms to contract packagers, custom blenders, distributors, warehousemen, dealers, or retailers.

Pesticide formulation is a physical process that converts the highly-concentrated pesticide active ingredient into concentrations appropriate for the end user--the applicator.

The formulating process consists of blending operations where active ingredients (the ingredient that provides the pesticidal action in a formulation) are mixed with inert ingredients (see box on previous page). The following sections identify and discuss the various forms of pesticides and how types of pesticides are formulated.

Liquids - Liquid pesticides are formulated by dissolving an active ingredient in appropriate liquids (i.e., water or solvents). This results in a pesticide product that is ready-made for application by spray or dip. Examples of such products and their formulation include trifluralin (4 pounds per gallon of mineral spirits) and pyrethrin (a 20/80 percent mixture in deodorized kerosene).

Dusts and Wettable Powders - Dusts and wettable powders are formulated by mixing an active ingredient with the appropriate inert carrier (usually flour, lime, gypsum, sulfur, sand, clay, or talc) and grinding it to the appropriate particle size. Usually, an active ingredient is diluted to a concentration ranging anywhere from 0.1 to 20 percent. Other compounds that may be added

to the mixture include stabilizers or dyes. After grinding, the mixture is often blended with fine clay and vegetable dye to add color. Powders usually contain anywhere from 15 to 75 percent active ingredient and 1 to 2 percent surfactants. The remainder of the formulation consists of inert ingredients. After blending with a carrier, wetting agent, and dispersing agent, the mixture is ground to desired particle size and packaged for distribution.

Granules - Formulation of granules is similar to the mixing operation of dusts and powders. An active ingredient, usually anywhere from 0.1 to 20 percent, is adsorbed onto a sized granular carrier, such as clay, sand, vermiculite, diatomaceous earth, ground corn cobs, or bentonite. Usually, the granular carrier is within a 30 to 60 mesh particle size and is impregnated with a solution of active ingredient. If the active ingredient is a liquid, it is sprayed directly onto the granules. Solid active ingredients are melted or dissolved in a solvent for dispersal onto the granules. Pesticide granule products are generally intended for direct aerial and ground application.

Emulsifiable Concentrates - Emulsifiable concentrates are the liquid equivalent of wettable powders. In these products, the concentration of active ingredient usually ranges from 15 to 80 percent. Surfactants constitute about 5 percent of the product with the remainder being organic solvent, such as xylene.

Aerosols and Fumigants - An aerosol pesticide product is characterized by its packaging and by the suspension of fine solids or liquid particles that result when its applied. Such products are usually under pressure in cans or bottles and are applied directly from the containers by spray. Aerosols generally consist of 2 percent or less of the active ingredient and the remainder of the formulation consisting of a solvent, a propellant (nitrogen, carbon dioxide), and a wide range of additives. Aerosols are used in homes so they generally contain odor suppressants, disinfectants, antimildews, repellents, or synergists, which promote pesticide action. Fumigants are generally self-propelled and the active ingredient concentration is usually 90 percent or more. The propellant constitutes the remaining 10 percent (or less) of the formulation. Propellants used are similar to those used in aerosols.

Custom blender

Custom blending is a service that enables users to tailor their pesticide purchases to cover specific needs. Custom blending is the mixing (for example) of two or more pesticides, pesticide(s) and fertilizer(s), or pesticide(s) and animal feed(s) in various quantities, thus making available unique products for certain applications.

Distributor

Distributors distribute, sell, offer for sale, hold for distribution, ship, hold for shipment, deliver for shipment, release for shipment, or receive pesticide products. Distributors can also be wholesalers. They often purchase pesticide products in bulk and distribute them to dealers or retailers.

Warehouser

A warehouser is a person that stores pesticide products, generally for producers or distributors. Some distributors (such as chain-stores) may have their own warehouse that store pesticide products in addition to other products.

Dealer/retailer

Dealers and retailers sell pesticide products to the end user. Dealers generally sell pesticide products to agricultural end users and industrial and institutional end users. Retailers generally sell to households.

Many agricultural dealers perform a variety of services. Most commonly, custom blenders or bulk repackagers provide the service of custom application of pesticides, fertilizers, and blends.

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CHAPTER 2

PREPARING FOR AN INSPECTION

To accomplish the objectives of a pesticide product inspection, pre-inspection planning should begin well in advance of an inspector's visit to an establishment. Prior to the inspection, the inspector should:

- Be knowledgeable of applicable regulations,
- Understand the current policies and procedures for conducting pesticide product compliance inspections,
- Be knowledgeable of the basic facts pertaining to the establishment to be inspected, including the type of business conducted, the physical layout of the premises, and the establishment's record of compliance with environmental laws,
- Be knowledgeable of the records and samples (i.e., evidence) necessary to support findings of potential violations,
- Be well-versed in the safety equipment and procedures to be used to provide protection from potential hazards at the establishment and from sampling pesticides,
- Confirm, if possible, whether a warrant may be needed to conduct the inspection; if necessary, obtain the warrant, and
- Assure that a laboratory is available and has the capability to analyze anticipated samples in a timely manner.

Pre-inspection activities include preparing an inspection scheme; reviewing available records; and gathering the documents, forms, and equipment needed for the inspection.

2.1 Inspection Schemes

The goal of a pesticide inspection is to identify establishments that have committed violations and to provide a deterrent against future violations. To accomplish these purposes, it is

important to focus resources on significant, enforceable, and nationally important cases that can serve as examples.

The following factors should be considered when scheduling an inspection:

- Location of the establishment. Two or three establishments in the same geographic area may be inspected at the same time, thus saving resources.
- Seasonal nature of operations at the establishment. The inspection must occur during those months in which the facility is operational.
- Size of the establishment, number of employees, and probable length of time of the inspection. If three days are available for an inspection, the inspector should not select an establishment that will take four days to inspect.
- Special circumstances. An establishment that is not operating normally because of a strike, for example, should not be selected for inspection at that time.

2.2 Reviewing Records

A thorough review of records held by the regulating agency pertaining to the establishment to be inspected should be conducted as part of the pre-inspection planning. Such a review is critical as it provides establishment-specific information that makes the inspector's job easier. For example, the inspector will be able to determine in advance of the inspection whether the establishment has ever violated any provisions of the applicable regulations, so that they could then inspect to ensure that compliance has been achieved and that there is no recurrence of the violation.

Information obtained from record reviews can be helpful to the inspector in developing a written inspection plan and in gathering the necessary inspection documents and equipment. In addition, establishment representatives are likely to be more responsive to an inspector who already has a thorough understanding of the facility operations.

Objectives of Records Review

The objectives of the records review include the following:

- Become familiar with the size, operations, physical layout of the establishment
- Learn about the compliance history of the establishment
- Obtain information from an investigation request
- Discover inadequacies and inconsistencies in the information on the establishment so that they can be clarified during the inspection

- Clarify technical and legal issues before conducting the inspection
- Develop a written inspection plan that focuses on the issues pertinent to the particular establishment to be inspected.

Types of Information to be Reviewed

The types of information and data to be reviewed include:

- General establishment information. Such information includes:
 - Maps and/or aerial photographs showing the location of the establishment and its relationship to the surrounding area
 - Names, titles, and telephone numbers of the owner, operator, or agent in charge of the establishment
 - Organizational structure
 - Special entry requirements pertaining to the establishment (if any)
 - Safety equipment and health and safety training requirements
 - Water, air, and waste treatment and pollution control equipment
 - Descriptions of the establishment's record keeping and filing systems
 - Physical layout of establishment
 - Size of establishment.

This types of information is especially useful in planning the details of the inspection, as well as in preparing the necessary documents and equipment. Information on personnel and organizational structure, for example, can help determine who should be part of the opening conference and who should be interviewed during the inspection.

- Previous inspection and enforcement information. Through a review of previous inspection records, the following information should be obtained:
 - Compliance history, including reports, follow up studies, findings, and remedial action
 - Specific details on past or present noncompliance
 - Previous enforcement actions
 - Pending enforcement actions and compliance schedules.

2.3 Preparing a Written Inspection Plan

After the information has been obtained and reviewed, the next step is to develop an organized inspection plan. The purpose of the written inspection plan is to serve as a blueprint to guide the inspector in conducting the inspection. The time invested in producing a quality inspection plan should, in the long run, save time for the inspector and the establishment representative once the inspector arrives at the inspection site. The inspection plan can also be used to brief the establishment representatives during the opening conference. However, a copy of this plan

should not be given to establishment representatives because the inspector may want to deviate from it during the inspection.

Written inspection plans may vary in length and subject matter, but generally include the following components:

- Establishment background and reason for present inspection. This section provides a brief history of factors relevant to the establishment (e.g., previous inspection dates and types of inspections; previous compliance problems and their resolution) and identifies the reason for the present inspection (e.g., “for cause,” neutrally-selected inspection).
- Scope. The inspection plan should clearly state the scope of the inspection. The scope of the inspection is a function of the purpose of the inspection. For example, if an inspection is undertaken in response to a suspected violation, then the scope would include the records, operations and areas of the establishment that need to be inspected to determine compliance with applicable regulations suspected of being violated.
- Inspection activities. The most appropriate inspection activity and evidence collecting technique(s) for the inspection should be listed in the plan. These activities could include the following:
 - Observations. List of the activities, operations, areas, and equipment to be observed (e.g., areas where pesticides or devices are held for distribution or sale or areas where pesticide wastes are stored).
 - Record reviews. List of the records to be reviewed and the required contents of the such records.
 - Interviews. List of the titles, and names if known, of key personnel with whom the inspector intends to meet at opening conference and throughout the remainder of the inspection process, including the closing conference.
 - Sample Collection. A sampling plan should be developed according to agency procedures. Sampling inspections also require detailed quality assurance activities and logistical planning.
- Safety (or Contingency) Procedures. This section might include a description of the safety procedures for the type of inspection activity being conducted. Safety procedures for a pesticide inspection should include identification of the expected hazards and types of exposures to be encountered and necessary safety equipment. For example, if pesticide samples must be taken, then the plan should include potential hazards posed by each of the substances, and the recommended sampling and safety procedures.
- Personnel Resource Requirements. This section of the plan should identify what personnel will be needed to conduct the inspection and who will be the lead inspector.
- Schedule of Activities. This section of the plan should identify the time

requirements and order for the inspection activities. In addition, milestones should be identified (i.e., what must get done vs. what is optional).

Inspection Equipment

Whenever possible, equipment necessary for the inspection should be prepared in advance of the inspection. The following equipment should be available, as necessary, for any pesticide product inspection:

Equipment Checklist for Sampling and Taking Photographs

- ___ Camera, film, flash, and batteries
- ___ Plastic bags and tape
- ___ Sharpie pen
- ___ Sample bottles (plus necessary preservatives, etc.)
- ___ 55-gallon bung hole opener
- ___ Paper towels/hand cleaner
- ___ Coveralls/protective suit
- ___ Rubber gloves, apron, and boots
- ___ Respirator
- ___ Stainless steel trowel
- ___ Boston round bottles
- ___ Plastic tubing
- ___ Grain trier or golf tube

Safety Equipment Checklist (should be available to the inspector)

- ___ First aid kit
- ___ Hard hat
- ___ Protective footwear
- ___ Safety glasses
- ___ Fire extinguisher
- ___ Airtight containers for storing highly toxic and corrosive samples
- ___ Supply of clean water for washing in the case of an accident
- ___ Emergency eye wash kit

Safety Procedures and Equipment

Each inspector should be knowledgeable of all safety requirements and practices. Safety equipment should be maintained in good condition and proper working order and should be used in accordance with established requirements and instructions. Because of the toxicity of pesticides, there are numerous safety guidelines that must be followed. For example, the inspector should always open and sample pesticide containers in areas where spills can be cleaned up easily and properly. Inspectors should always wash their hands after sampling. The safety procedures for handling or sampling pesticides and those for accessing emergency

treatment (in the event of an accident involving pesticides) should be available as a reference for the inspector during inspection and should be included in the inspection plan.

In addition, the inspector should be certain to take the following documents and materials on an inspection:

- Product labels. The inspector should always bring to the inspection site copies of the most recently approved product labels for those pesticides (both general and restricted use) that are likely to be encountered at the inspection site.
- Copies of applicable regulations. Having copies of these documents available allows the inspector to immediately address inquiries from the regulated community pertaining to statutory and regulatory requirements.

CHAPTER 3

SAMPLING

3.1 Sample Collection

The purpose of inspecting a pesticide producer or marketplace establishment is to determine whether the establishment complies with the applicable regulations and to encourage compliance. Samples collected during the inspection, in addition to documentation (e.g., records), become the evidence on which compliance is determined. If the information collected during the inspection indicates a violation, it may be used as the basis for an enforcement action. For this reason, samples collected during an inspection must be of known quality and collected following sound technical procedures to ensure their reliability for use as evidence.

Pesticide product samples include formulated materials from companies that manufacture, formulate or otherwise process pesticides (i.e., producers) and from commercial entities that sell wholesale or retail pesticides (i.e., dealers). Sometimes pesticide product samples are collected at the user level or at a port of entry.

The overall sample collection and analysis process includes:

- Sample collection planning
- Sample collection (including documentation)
- Sample identification
- Transfer to the laboratory
- Analysis of the sample(s)
- Reporting of analytical results
- Evaluation of analytical results
- Case preparation, enforcement action, and final disposition

Thus, although sample collection is only one step in the overall enforcement process, it is a key element in that all subsequent activity is contingent on its adequacy. Effective communication with the laboratory is a critical component in the process.

Official samples, as well as records and other information obtained during sampling, must always be collected and treated as though the material will be used as evidence in an enforcement action. This involves ensuring that each sample is properly collected, prepared, and documented. The primary factors to consider when collecting a pesticide product sample are:

- Communicating effectively with the receiving laboratory
- Ensuring that an adequate amount and representative portion of a batch of the product is collected for analysis
- Assuring that no cross-contamination occurs during sampling of large containers and that proper containers and caps are utilized
- Assuring that all official samples are properly identified, preferably with a unique numbering or other identification system
- Recording the inspector's observations of the sampled batch, such as photographs, copies of records, data, correspondence, and/or results of interviews
- Obtaining any labeling and literature that pertain to the sampled product or batch
- Obtaining signed statements or sworn affidavits from persons who may potentially serve as witnesses

Official samples are collected at a producer establishment based on the producer's assertions that the material being sampled is representative of what is actually being sold and that the product is stored in areas where finished goods are being held for shipment (e.g., loading docks, warehouses). Marketplace samples are considered to have been "released for shipment."

The focus of the ensuing discussion is on the collection of physical pesticide samples as part of inspections conducted at producer establishments and marketplace facilities; however, most of the described procedures and documentation requirements also apply to formulation (and tank-mix) samples collected as part of use investigations.

Sample Collection Planning

The key to the collection of pesticide product samples that will: (1) be suitable for analysis, (2) be adequate to support case development, (3) be admissible as sound evidence, and (4) withstand critical cross-examination efforts, is to conduct such sampling with sound planning and as part of an overall effective quality assurance program. This sample collection planning effort will normally constitute an element of the overall preinspection plan.

In most cases involving routine compliance inspections, whether conducted at producers or dealers, the planning will simply involve implementation of appropriate standard operating procedures (SOPs). For more complex compliance inspections and those investigations involving suspect violations or other problems, an individual detailed sampling plan may be necessary. For example, the sampling plan in the latter case could involve multiple types of samples, special safety considerations, consultation or participation by other experts, and/or comprehensive preliminary involvement by the laboratory.

Regardless of whether the inspection/investigation is routine in nature or is more complex, the following factors should be considered by the inspector prior to taking any pesticide samples - it being recognized that some factors may be self-evident or nonapplicable in many situations:

- Background Information: Knowledge of pesticide products that are likely to be available as determined from previous inspections, data bases, Internet searches, and trade complaints.
- Statutes/Regulations: An understanding of applicable statutes and regulations is necessary.
- Personnel: The sampling situation may require more than one person (e.g., large number of samples from large containers), or require someone with more experience or expertise than yourself.
- Equipment: There may be special considerations that might warrant the use of nonroutine sampling tools, containers, or specialized safety equipment (e.g., bulk storage tanks).
- Cost: Some required samples are quite expensive, particularly the newer specialized compounds. Arrangements may be necessary to provide payment.
- Chain-of-Custody: Make arrangements to assure chain-of-custody for all samples, both physical control and documentation, particularly if samples are going to be shipped or transported to the laboratory by a third party.
- Analytical: The following questions should be considered: Has the laboratory been consulted regarding the collection and analysis of the proposed samples, particularly in the case of a new or complex situation, or when new formulations are encountered? Factors such as container composition, sample size, preservation, the need for additional information such as suspect contaminants, may warrant consultation with the laboratory. It must be ascertained whether or not the laboratory 1) has the necessary expertise and/or instrumentation, and 2) the analysis can be completed by a prescribed deadline. Consult with the laboratory concerning quality control measures and shipping information.

Quantity of Sample to be Collected

The amount of each product to be collected depends largely on the amount of material required for the anticipated laboratory analysis and to assure representativeness, including the quantity required for quality control purposes (i.e., splits, repeat examinations, and replicates). Considering these sampling needs, the sample size is to be kept to a minimum to reduce the burden of disposal of the unused sample portion and to mitigate potential human and/or environmental exposure.

Small-size Sample Units (Retail)

Small-size sample units are those that contain 1 gallon or less of liquid or 20 pounds or less of

solids. These units are characterized by market-ready packages typically intended for retail distribution. Samples of these pesticide products will consist of an entire container (or group of containers) that is purchased from the producer, dealer, or user. Samples are preferably taken from original, previously unopened shipping cases.

Large-size Sample Units

Large size sample units, or bulk samples, are those that contain more than 1 gallon of liquid or more than 20 pounds of solids. These are also units that are typically supplied to marketplace establishments for direct commercial use. When sampling these large-size units, it is recommended that smaller samples be removed from these larger containers in the field. This will reduce costs for larger amounts, make handling during sampling and subsequent analysis easier, and reduce the amount of material to be disposed of following testing.

Some situations warrant departures from these guidelines, such as granular or pelletized lawn care products. For these types of formulations, the entire retail unit should always be collected and submitted to the laboratory. Experience has shown that these granular products are almost always nonuniform in nature and it is much easier for the laboratory to obtain an adequate portion for analysis than for the inspector to try and obtain a small representative sample in the field.

Equipment and Techniques for Sampling from Containers

When sampling from large containers in the field, care should be given to the selection of sampling equipment and sample container composition. Physical samples should not be placed in direct contact with incompatible materials. Organic materials, such as plasticizers, may leach from rubber and some plastics into the pesticide sample. Similarly, some pesticides can leach through plastic containers. To minimize these problems, glass or stainless steel construction materials are recommended; however, plastic tubing, scoops, etc. may be used for sampling where the pesticide material is in direct contact for only a short time. A chemical substance should never be placed directly into a plastic bag or plastic bottle for storage or transport.

Some formulations, such as aqueous-based antimicrobial products are often packaged in plastic; these original containers are suitable for storage and shipment as long as there is no sign of deterioration. If deterioration or other leakage is noted the sample should be transferred to a glass container to assure adequate containment during shipment to the laboratory.

Large-size Solid Units

When planning the inspection for sampling of solid unit material, equipment such as a grain trier, or a disposable plastic tube or scoop should be included in the equipment list. Additional sampling tools should be taken on the inspection to avoid having to decontaminate sampling equipment in the field. Samples should be taken from the predominant batch or lot. To avoid contamination, a new or cleaned sampling tool should be used for each sample taken. Glass containers should be used to store and ship samples. Lid liners should preferably be made of

Teflon ®; (*®Teflon is a registered trademark and appears hereafter without ®.*) however, polyethylene has also proven suitable for most formulations; aluminum foil or latex liners should not be used. Following sampling, nondisposable grain samplers should be cleaned with soap and water and solvent (e.g., acetone) and dried prior to reuse. Plastic tubes and scoops are to be disposed of following the method identified on the product label for empty containers or other authorized procedure.

Equipment needed to collect samples of dry materials includes the following:

- Protective gloves and eye wear
- A grain sampler. This item can be found in several forms:
 - Metal two-part grain thief available from major scientific supply companies
 - Disposable plastic golf ball tubes available from sporting goods stores
 - 4-foot x ½-inch I.D. PVC tubing available from hardware or home and garden store
- Wide-mouth glass jars (2-ounce or 4-ounce, depending on the sample size needed) with Teflon-lined lids
- Data sheets, identification tags, 4 mil plastic bags (various sizes), official seals, and chain-of-custody forms (if necessary)

A recommended procedure for collecting dry samples from bags is as follows:

1. If possible, turn the bag of pesticide product over several times, both horizontally and vertically, and then lay the bag on its side on piece of protective paper or other disposable covering.
2. Through the opened seam or a tear in one of the top corners of the bag, insert the closed grain sampler (with the outer sleeve opening facing up) or plastic tube in a diagonal direction into the bag.
3. If a grain thief is employed, push the closed grain sampler to the opposite corner of the bag, then open and close the grain sampler to collect the sample. The intent is to collect a representative sample of the material from different portions of the bag. If a plastic sampling tube is used simply push it to the opposite corner of the bag.
4. Withdraw the sampling device containing the sample, being careful to avoid spilling and puffing the contents into the air. The plastic sampling tube can be tilted slightly downward (covering the open end of the tube with the thumb) while withdrawing the tube so as to fully retain the sampled material.
5. Transfer the material from the sampler by tilting the tube into a glass jar; label, officially seal, complete chain-of-custody form, and prepare for shipment to the laboratory.
6. If more sample is needed, take a similar sample from the other top corner of the bag.

7. Samples from the same unit may be composited; samples from different units of the same batch are to be placed in separate containers; however, the same sampling tube may be used without decontaminating. Samples from different batches of the same product require use of new or decontaminated sampling equipment.

These procedures for collecting samples of solid material from bags can be modified as needed to collect solids from other types of containers. By carefully following a sampling protocol, cross-contamination during sampling can be minimized. If plastic tubes are used to collect samples, it is recommended that they be destroyed after each use by cutting them up and disposing of the pieces in an authorized manner.

Large-size Liquid Units

Samples should be collected in the field from producer establishment and marketplace liquid pesticide products in containers in excess of 1 gallon in size. Liquid units should be sampled using a siphon device with unused disposable type plastic tubing, or a new or decontaminated reusable glass thief for each batch or lot to be sampled. If the label directions indicate that the product to be sampled should be mixed before use, the unit should be agitated prior to sampling. Glass containers should be used to store and ship all samples. Teflon lid liners are preferred; however, polyethylene may also be used in most cases. Rubber, aluminum foil, or paper-lined lids must not be used. Plastic tubes should be disposed of by the method identified on the product label for disposal of empty containers or other authorized procedure.

Equipment needed to collect sub-samples from liquid units include the following:

- A new or decontaminated glass thief or siphon device with disposable tygon tubing
- 40-mL volatile organic analysis (VOA) vial or 1-pint glass bottle with Teflon-lined lid
- Identification labels, plastic bags, and official seals
- Labeled shipping container(s) with appropriate packing material and other office supplies, shipping forms, official seals, and chain-of-custody forms.

The following is a recommended procedure for collecting samples from larger units in the field:

1. Thoroughly agitate the material to be sampled, if required, by shaking or rolling the unit before sampling.
2. Insert siphon hose or glass tube (thief) through the access port in the bulk container being sampled.
3. Collect a composite sample from three depths: near the bottom, the middle, and the top of the liquid level. If a glass thief is employed, a representative sample may be obtained by

slowly lowering the thief to the bottom of the container, allowing liquid to fill the glass tubing as it is submerged.

4. Cover the top of the thief tightly with the thumb and carefully transfer the sample into the glass sample container. If sediment, layering, or phase separation is observed, collect a duplicate sample using the same thief or tubing; decontamination is usually not necessary.
5. Label, officially seal, and package the sample container for shipment.
6. Properly dispose of the hose and other disposable sampling equipment. Clean other contaminated sampling equipment with soap and water, rinsing with water and acetone, and allowing to dry before using to collect additional samples.

Tanks

Techniques for collecting liquid samples from tanks, such as those utilized in bulk repackaging operations, have not been well established or standardized. At a minimum, the inspector should discuss with laboratory personnel and their supervisor the proposed method for sampling bulk repackaging tanks or other larger (greater than 55 gallons) storage units. In such cases it may be desirable to consult with hazardous waste inspectional staff to assure the collection of a representative sample in a safe manner. If the unit does not look secure, sampling should not be attempted without supervisory approval. The inspector should also be aware that a sample collected from a release valve or discharge spigot may not be representative of the contents of the entire tank.

3.2 Safety Practices

While Section II of this manual provides more detailed health and safety information, this segment will address the basic issues associated with pesticide product inspections.

It is the responsibility of each inspector to protect themselves and others during pesticide handling and sampling activities associated with an inspection. The inspector can best achieve this by staying current with all required health and safety training. To minimize risks during sampling, appropriate protective clothing and safety equipment must be used. Protective gear must be adequate to prevent accidental exposure to pesticides through the eyes, nose, mouth, and skin. At a minimum, the inspector should follow the safety precautions specified on the label of the product being sampled. The inspector should be aware of the establishment's safety requirements and basic emergency treatment. While on-site, it is advisable that the inspector be familiar with the location of medical assistance in the event of an emergency.

Selecting the appropriate safety equipment for sampling depends on the type and volume of pesticide to be sampled. Collecting small-size samples from marketplace establishments will usually require only a minimum of safety procedures and equipment. When taking samples from larger-sized containers at producer, dealer, or user sites, inspectors must heed the handling precautions found on pesticide labels. Similarly, instructions for the use of safety equipment (i.e., compatibility warnings) must be followed. At a minimum, the following safety

equipment should be used during sampling:

- Hand protection - organic liquid-proof gloves, preferably of latex or synthetic rubber, long enough to protect the wrist
- Eye protection - goggles or face shield
- Protective footwear in the form of rubber soled, non-skid, metal-toed shoes and plastic disposable shoe covers, or rubber/neoprene boots
- Hard hat
- Coveralls made of closely woven fabric or Tyvek® (*®Tyvek is a registered trademark and appears hereafter without ®*) or long rubber apron
- Respiratory protective device when sampling toxic materials from large size units. Various cartridges must be used to protect against different chemical vapors and gases. The inspector should be careful to select the appropriate cartridge for the product being sampled. **Note: The use of respiratory protective devices requires appropriate training and fit-testing. Before using this type of equipment, the inspector should ensure that their training and fit-testing is current.**

Before sampling any pesticide, the precautionary statements on the label should be read to determine whether the pesticide is toxic through dermal absorption, inhalation, or ingestion. Some pesticides may be injurious through all three routes. After determining which exposure routes should be avoided for the particular pesticide to be sampled, the proper safety equipment may be selected. The inspector should always be careful when collecting samples, regardless of the declared toxicity of the pesticide. There is always the risk that the pesticide product may be mislabeled or improperly formulated.

- When collecting samples, the inspector should remain alert to hazards such as spilled or improperly stacked materials, moving equipment, poor ventilation, and bad lighting. The following general guidelines are provided for the safe handling or sampling of pesticides:
 - Read the label and, at a minimum, follow the handling instructions for mixing and loading.
 - Use care and the proper tools when opening and closing larger containers.
 - Open and sample pesticides in areas where leaks and spills can be cleaned up easily and properly.
 - If chemicals are spilled on clothing or directly onto the skin, remove the clothing immediately and wash the exposed dermal area thoroughly with plain water. Always keep a change of clothing on hand for such emergencies.
- Wash hands immediately after sampling.

- Do not use the mouth to siphon and do not put hands near the mouth and eyes during sampling operations.
- Keep a supply of clean water and waterless hand cleanser readily available.
- Know the limitations of the protective equipment being used, especially respirators.
- Have the phone numbers of local hospitals, doctors, or poison control centers available.

Duplicate Samples

Duplicate samples are collected only at the pesticide product establishment's request; however, the inspector must make the offer. These samples should be collected, identified, and sealed using the same equipment, techniques, and sampling protocols used to collect official samples. The United States Environmental Protection Agency, for example, defines duplicate samples as an equal amount of the product taken in the same manner from the same container. In the case of small-size units, such a sample is defined as the same number of units taken from the same shipping containers, bearing the same codes or batch numbers, if so coded.

While a firm may request that duplicate samples from small-size units be prepared by dividing the contents of these units into equal portions, small-size units are not to be subdivided. The reasons for this are: (1) the integrity of the sample as evidence is more difficult to maintain and defend; (2) cross-contamination is minimized; (3) the possibility of exposure during sampling is minimized; and (4) the laboratory can determine the net contents, if necessary.

3.3 Quality Assurance Procedures

Standard operating procedures (SOPs) should be followed for routine sampling and investigations. (Section III of this manual provides additional information on SOPs.) For more complex investigations, the inspector will develop a project or investigation plan that outlines the number and types of samples to be collected and special sampling procedures, if required. The inspector should consult the appropriate plans and procedures prior to conducting an inspection to ensure their inspection will meet QA objectives. In addition, it is the responsibility of the inspector to discuss with the laboratory and their supervisor the requirements necessary if samples are to be submitted to an efficacy or other special purpose laboratory.

3.4 Sample Documentation

The objective of sample documentation is to validate sample integrity and, thus, whether or not the sample can be used as evidence. The sample must be uniquely identified and chain-of-custody must be established at the point at which the sample is collected and continued through all subsequent activities. Additional necessary documentation regarding the nature and circumstances of each sample needed as evidence should be recorded in the field notebook. At a minimum, the following items should be recorded in the field notebook:

- Sample site identification and/or project number

- General location (e.g., address of facility)
- Specific location (of sampled products in facility)
- Area description and related observations
- Date and time of sampling
- Sample description
 - Container contents (specific material collected)
 - Name of pesticide(s) for which analysis is needed
 - Reason for collection
 - Quantity of sample collected (volume, number, weight)
 - Identity (sample numbers) of related samples, if any
- Sampling Method
 - Composite, grab, or prepackaged unit
 - Devices and tools used - Precleaning of equipment and decontamination between uses
- Storage and shipping
 - Primary container and lid type and any precleaning used
 - Packaging procedure
 - Preservation, if applicable
 - Method of transfer to laboratory (including date and time)
- Other documentation
 - Custody and document control records
 - Books and records information
 - Photographs
 - Statements and affidavits
 - Technical and professional remarks
 - Correspondence, phone logs, notes, etc.

For samples collected at the marketplace establishment, it is important to note the origin and date of shipment of each batch sampled. The origin and movement of each lot sampled should be documented with invoices, shipping records, and dealer's statements and other records as available.

3.5 Sample Preparation and Chain-of-Custody

Each sample should be identified in the inspector's handwriting with the date, sample number, and the inspector's initials. When more than one unit is collected, each unit should be further

identified with an additional number or letter. This identification is normally written on the label (for smaller retail-size units) or an adhesive strip placed on the vial, bottle, or jar for samples collected from larger-size containers. Separate labels and all collateral labeling (e.g., circulars, inserts, instruction sheets, etc.) should also be similarly identified. Circulars that have been removed from the sample for identification, should be reinserted into the original packages.

When identifying larger-size unit samples, the handwritten label should also provide the following information for the safety of those handling the sampled product:

- Brand name of the product
- Principal active ingredients and labeled concentrations
- Company name and address as shown on label
- Distinguishing marks or code numbers
- Label should be stamped in red ink with "POISON" and skull and crossbones if the product's label was so marked.

The above instructions would also apply to all small-sized samples that are wrapped and sealed for shipping in such a way as to obscure the product's label. Copies of appropriate bin labels can be taped to each container, if available, in lieu of the above information.

Samples should be sealed by placing an inverted plastic bag (4 mil thickness, recommended), tying a knot, and turning the excess amount of bag back over the knot and taping the excess bag below the knot. It is important that the sample label be legible through the plastic bag. It is preferable to have each glass unit sealed in a separate bag, or at a minimum, packaged so that there is no direct contact of glass upon glass. In addition to ensuring custody, the plastic bag provides some degree of containment in case of breakage or leakage.

A complete and accurate chain-of-custody record is a critical component of official sample documentation. The purpose of an irrefutable chain-of-custody is to trace possession and assure integrity of an official sample from the time it is collected until it is introduced as evidence in a legal proceeding. An accurate, written record of the movement of the sample should be maintained on a chain-of-custody form.

3.6 Temporary Storage and Shipment to the Laboratory

Following collection, documentation, and initiation of chain-of-custody, the officially sealed samples should be stored in a secure area prior to transfer to the laboratory. All documentation will normally accompany the sample(s) to the laboratory, preferably in a protective plastic envelope. At a minimum, the laboratory should receive the label, an investigation summary report, any chain-of-custody forms, as well as any correspondence or records related to the product's ingredients, stability, or mixing for use. Pesticide product samples can be transferred to the laboratory either by: (1) direct or personal transfer, or (2) common carrier (air

or surface). Whatever the method of transfer, the inspector and/or laboratory personnel must maintain a record of how the sample was transferred, including all shipping papers and receipts.

Regardless of which method is employed for sample transfer to the laboratory, several requirements need to be followed:

- Glass containers must never be packaged directly against each other, either within the same plastic bag or within the same shipping container.
- The sample label should always be legible through the protective plastic bag.
- Liquid samples should not be packaged with solids in the same shipping container.
- A copy of an investigative summary report or equivalent form should be included with the samples, protected in a plastic bag or sleeve.
- The laboratory director or designee should be notified by telephone that the samples are being shipped, the mode of transfer, and the expected arrival date.

3.7 Post Sampling Activities

After completing all sampling activities, the inspector should restore the premises to an orderly condition. When carton or cases have been opened, they should be backfilled and reclosed, if possible. Any spillage should be cleaned up and large containers should be closed. Hand trucks, tools, rags, and other supplies or equipment should be returned.

3.8 Shipment of Samples

Producer and marketplace establishment pesticide product samples may be transferred to the laboratory (in order of preference) by: (1) personal or hand-delivery, (2) commercial carrier (air or surface), or (3) the postal service. If pesticide samples cannot be hand-delivered to the laboratory, the services of a commercial shipping or overnight package firm (either surface or air) are preferred over use of the postal service for both timeliness and reliability. Regardless of whether a commercial shipping service or the postal service is used, specific restrictions apply to transfer of formulations considered to be hazardous materials (e.g., poisons, flammables, oxidizers, or corrosives). Also, all sample transfers (whether by hand, mail, or commercial carrier) should be documented on the appropriate chain-of-custody record.

3.9 Disposal/Decontamination of Sampling Equipment

Inspectors should be aware of all requirements regarding the proper disposal of sampling equipment. Where equipment has been damaged or contaminated to the point that it is no longer usable, such equipment should be properly cleaned, sealed, and deposited in the appropriate waste containment facility. Broken glass bottles or jars and glass thieves require

wrapping in multiple layers of newspaper prior to placing in bags. If contaminated, this broken glassware will require depositing in an approved hazardous waste storage or handling facility. If it is necessary to reuse glass or metal sampling equipment, inspectors will need to decontaminate these implements after each sample. Decontamination normally requires washing and rinsing, which creates a rinsate that should be disposed of in accordance with the applicable regulations.

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CHAPTER 4

IDENTIFYING OTHER POTENTIAL VIOLATIONS

Because environmental statutes and regulations are complex, only obvious violations may be detected by the untrained eye. In conducting a pesticide product inspection, the inspector may be able to detect such violations, both inside and outside the facility, by simply keeping their eyes open and asking simple questions. Inspectors should take note of:

- Housekeeping Practices
 - Stains or discoloration of soil, floors, or other surfaces
 - Sloppy housekeeping or poor maintenance in work or storage areas
- Storage Practices
 - Improper shelters for storage and waste areas
 - Rusted, leaking tanks (above and below ground)
 - Secondary containment devices
 - Leak detection devices
 - Location and condition of drains or drainage systems
 - Leaking or improperly sealed drums, barrels, tanks, or other containment devices
 - Unlabeled drums, barrels, tanks, or other containment devices
 - Cracked, broken, or leaking pipes, joints, or valves
 - Improperly stored materials (e.g., sludges, other wastes)
- Wastewater Discharges
 - Sheens or discoloration on receiving waters
 - Effluent that is dirty, cloudy, or contains particles
 - Ditches, pits, or lagoons with evidence of past discharges
- Air Emissions
 - Opaque smoke being emitted from any smokestack, vent, or opening. (Opaque smoke is defined as smoke, not steam, that is dark enough to obscure anything behind the plume for at least five minutes.)
 - Unusual odors or strong chemical smells

- Other Environmental Problems
 - Distressed vegetation (unhealthy, discolored, or dead), including vegetation in streams/ponds
 - Pollution control equipment that is not working or that is disconnected
 - Any renovations or demolitions conducted during that last 18 months that involved removing or disturbing asbestos-containing material
 - Remediation projects in progress
 - Old electrical components, such as transformers or capacitors
 - Any type of construction activity or disturbance near wetlands

CHAPTER 5

DOCUMENTING EVIDENCE

The purpose of documentation is to ensure that evidence collected during the course of an inspection can be used as evidence in court. Evidence needed to substantiate suspected violations (or compliance) should be collected and documented in accordance with applicable regulations. The purpose of this module is to familiarize the inspector with 1) the types of evidence typically gathered during a pesticide inspection and, 2) methods for documenting that evidence so that it may be admissible in legal proceedings.

5.1 Types of Evidence

- Documentary evidence. A “document” having significance and effect due to its content, such as various types of records and the inspector’s field notebook
- Demonstrative evidence. Something prepared or selected to illustrate or otherwise make a relevant fact clearer and easier to understand
- Testimonial evidence. A person’s reported impressions and the opinions the person formed based on those impressions
- Real evidence (i.e., physical evidence). The evidentiary object, such as a pesticide sample

During the course of a pesticide product inspection, inspectors may make observations, conduct interviews, obtain statements, review and copy records, take physical samples, take photographs, and write notes in field notebooks. The testimony of the inspector, the samples and photographs, the notes and reports, and the sample tags and chain-of-custody forms, may all become evidence. Though not necessarily associated with a specific violation, inspectors also document information relevant to establishing the legality of the inspection. Field notes regarding entry procedures, signed items such as required forms, entry warrants, etc., serve as evidence that the inspector conducted a lawful inspection and had the authority to collect the evidence supporting the alleged violation(s). Thus, these items are critical to any subsequent

actions.

5.2 Documenting Records

Immediate and adequate identification is essential to properly tracking the records collected and identifying them in court. The following strategy, employed by US EPA inspectors, can be used to track and identify all documents collected by an inspector.

- Develop a method for initialing/dating records - By initialing and dating all records, an inspector verifies their validity. Initials and date should be in the same location on all documents (preferably on the back of the copy) and should be written at the time of collection. An inspector must be able to positively state that s/he wrote the information.
- Assign a separate sample identification number to each document using a standard coding system. The inspector should ensure that numbers used for the inspection are consistently assigned throughout the inspection.
- Enter the number into the field notebook for each document obtained during an inspection. In addition to the identification number, the following information should also be entered:
 - source of the record (i.e., type of file, individual who supplied record)
 - physical location of the record (i.e., building number, room number)
 - manner of collection (i.e., photocopy, duplicate copy)

It is important to the admissibility of records as evidence that enough information be documented to demonstrate the records authorship, location, and distribution.

5.3 Inspector's Field Notes/Notebook

The inspector's field notebook is documentary evidence and will be used in the preparation of the inspection report or to refresh the inspector's memory prior to giving testimony. The field notebook is the basis for all inspection documentation and should contain accurate and comprehensive documentation of all inspection activities.

Because the notebook can be subject to discovery and possible disclosure to opposing counsel in a trial, it is imperative that only facts be entered into it. Nowhere in the notebook should potential violations be discussed; instead, the inspector should meticulously document all of the observed conditions that led her/him to think there may be a violation. The language written in the field notebook should be objective, factual, and free of personal feelings and conclusions of law. Ideally, a bound notebook with consecutively numbered pages should be used. Also, the inspector must put their name, address, and telephone number on the inside cover of the field notebook.

The following are typical examples of the information that should be documented in the field notebook:

- General information. An inspector should make certain to record all general facility information, including names and titles of facility officials, size of the facility, description of operations, number of employees, recordkeeping practices, etc.
- Sampling procedures. An inspector should record all sample collection equipment, field analytical equipment, equipment used for physical measurements, calculations, results, and calibration data for field sampling and analytical and physical measurement. All sampling and field analysis equipment must be traceable to the specific piece of equipment used and the inspector who did the work. The inspector should also include the rationale for taking the particular sample, including sample selection and representativeness.
- Unusual conditions or problems. All such conditions and problems should be noted and described in detail.
- Interview notes. These notes should include the names and titles of individuals interviewed, their duties and responsibilities, questions asked, and their answers.
- Other incidents. If, while on site, any incidents of noteworthy concern occur, such as an electrical power failure or evidence of tampering with government vehicles or equipment, the inspector should record it in the field notebook.
- Administrative data. The inspector should document all such data, including the time the inspection started and concluded, time of sampling, etc.

It is absolutely imperative that the inspector keep detailed notes of every aspect of inspection, including interviews, visual observations, records assessments, and sample collection and handling. The recorded information should show if the establishment is in compliance with applicable regulations as well as any potential violations. Entries pertaining to sampling should correlate with particular samples, photographs, copies of records, or other documentary evidence collected. This allows the inspector to trace the exact time, place, conditions, and procedures employed for gathering each piece of evidence.

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CHAPTER 6

CLOSING CONFERENCE

Upon completion of a pesticide product inspection, an inspector should hold a closing conference with establishment representatives. The closing conference is intended as a time for the inspector to resolve final administrative matters concerning the inspection and to formally wrap up the on-site portion of the inspection. During the closing conference, it is important for the inspector to:

- Maintain the good rapport developed during the inspection
- Ensure all necessary paperwork is completed
- Obtain any additional information

- Confirm important facts

It is not required that a specific individual (e.g., the owner, operator, or agent-in-charge) attend the closing conference, just that establishment representatives are present. The individuals who participate should be those employees who are responsible for specific areas that were covered during the inspection.

Prior to the closing conference, the inspector may want to review the inspection findings in a pre-closing conference planning session. It is imperative that the inspector be aware of, and understand, any problems found during the inspection. The inspector should determine whether or not there are any unresolved issues, if any follow-up information or records must be requested from the facility, and all necessary records or data that were requested and that are needed to document any negative findings are in his/her possession. The inspector should also establish the order in which findings will be presented. Such planning will facilitate the closing conference and ensure that all necessary items will be addressed.

6.1 Summarize Inspection Findings

During the closing conference, the inspection findings should be summarized in an objective and factual manner. The inspector should explain what s/he did while on the inspection. While it is appropriate for the inspector to state that a potential violation may have occurred, it is imperative that conclusive or accusatory language is not used. By presenting the inspection findings in a concise and factual manner, the inspector can bring to the attention of the facility what violations may have been found without making judgmental statements regarding the degree of seriousness of violations noted, and the resulting level of enforcement action that may result.

6.2 Clarify Outstanding Issues

After briefly discussing the inspection findings and prior to completing the necessary documentation, the inspector may want to ask follow-up questions. Issues may have been noted in the field notebook during the inspection that need to be addressed before the inspector leaves the establishment, and the closing conference provides a forum for discussion of any such unresolved issues. If this opportunity to ask questions of establishment representatives is not taken during the closing conference, it may be necessary to make follow-up telephone calls, possibly delaying the completion of the inspection report.

6.3 Answer Establishment Questions

The closing conference is an opportunity for a two-way exchange of information. The inspector should be prepared to answer any questions and to address any concerns that establishment representatives might have and to clarify any confusing issues. However, the inspector should be careful to answer only those questions that are within their ability, knowledge, or authority. Questions posed to the inspector by facility personnel should be directed to a responsible official if the inspector has any doubt as to the correct answer.

CHAPTER 7

POST-INSPECTION ACTIVITIES

Completion of the on-site portion of an inspection is not the final activity in the inspection process. After the on-site inspection, the inspector still has several responsibilities, some of which must be completed within a relatively short time frame. It is the post-inspection activities that close the book on the inspector's role in the inspection process. The post-inspection activities an inspector must complete include:

- Storing and shipping samples
- Reviewing inspection documents (e.g., records, photographs, notebook entries that were collected while on site) for completeness
- Conducting follow-up activities, as necessary
- Writing the inspection report
- Maintaining and archiving the inspection documents.

The following sections of this module will discuss these post-inspection activities in more detail.

7.1 Storing and Shipping Samples

Following collection, documentation, and initiation of the chain-of-custody (all of which occur onsite), all physical samples must be stored in a secure area prior to transfer to the laboratory. The inspector is responsible for sample custody at all times from the initiation of the chain-of-custody until the custody is transferred to the laboratory. Keep to a minimum the amount of time between the date a sample is collected and the date any enforcement action is taken. With this in mind, samples should be forwarded to the laboratory as soon as possible for analysis. Upon completion of analysis by the laboratory, the results will be forwarded to the inspector.

7.2 Reviewing Inspection Documents

Once samples have been forwarded to the laboratory for analysis, the inspector should then review the material that was collected while onsite. Such a review will allow the inspector to determine if proper and sufficient information has been obtained to establish a violation (or establish that the site is in compliance). Performing this review within a few days of the inspection will allow the inspector to assess the completeness of the information while it is still fresh. If the inspector determines that information is lacking, it still allows sufficient time to initiate any follow-up activities.

7.3 Follow-Up Activities

The purpose of conducting follow-up activities is to ensure that the inspector has sufficient information (i.e., evidence) pertaining to an establishment's compliance with applicable regulations to be able to make enforcement decisions.

7.4 Report Preparation

The purpose of an inspection report is to present a complete and factual record of the inspection process from opening conference, through the inspection, to closing conference. The report should contain enough information about the facility and the inspection (as well as observations made during the inspection) to facilitate enforcement decisions pertaining to the inspected facility and to develop a case, as necessary.

The Inspection Report

The inspector should prepare the inspection report as soon as possible following the inspection. The actual amount of time required to prepare the report will depend on obtaining any additional required information in a timely fashion (e.g., sample analysis results). This timeframe should allow the inspector sufficient time to conduct necessary follow-up and to append to the report (and mention in the narrative) any data obtained during follow-up.

In preparing the report, the inspector should have the following objectives in mind:

- To include in the report all of its basic elements, ensuring that the report not only contains copies of relevant forms and documents as appendices, but that the narrative component of the report references those forms and documents
- To substantiate with as much evidence as possible each potential violation.
- To write the report in clear and concise language, using first person and past tense
- To present factual and accurate information pertaining to all steps in the inspection process from opening to closing conference and follow-up
- To make only those observations that are based on firsthand knowledge of the facility since enforcement personnel must be able to depend on the accuracy of all information
- To include only information that is relevant to the facility and its compliance with applicable regulations. (Irrelevant facts can interfere with enforcement decisions.)

The inspection report should not, under any circumstances, include the inspector's conclusions regarding compliance or noncompliance. Conclusions should be contained in a separate memorandum or other format that is clearly separate from the inspection report. The reason for this is that in an enforcement case, the entire inspection report is subject to discovery by the opposing side. If conclusions of law or opinions are in the report, it may

weaken the inspector's credibility by suggesting bias.

Elements of the Inspection Report

While inspection reports may vary in general content and format, there are certain elements that should be contained in each inspection report to ensure that necessary information is not inadvertently overlooked. The report should always contain enough information so the reader can determine:

- Specific reason for the inspection
- Participants in the inspection
- Compliance with all required notices, receipts, and other legal requirements or explanations as to why requirements were not followed
- Actions taken (and chronology)
- Reference to Standard Operating Procedures (SOPs) followed or if not an explanation as to why SOPs or other requirements were not followed
- Statements, records, physical samples, and other evidence obtained
- Observations made
- Results of sample analyses.

While conducting the follow-up, the inspector should attempt to obtain answers to questions that were not addressed during the inspection and to obtain outstanding relevant documents. The inspector should focus on obtaining information necessary to fill in gaps in material already obtained from the regulating agency's records.

The inspection report should be a concise and chronological account of observations made and activities undertaken during the inspection, from opening conference to closing conference and follow-up. The field notebook and/or an inspection checklist (if used) are useful tools for developing the narrative. These tools can help the inspector recall and include in the narrative important details concerning the inspection. The inspector should also include the reason for the inspection and any

relevant historical information such as reports and any knowledge of prior violations obtained during the pre-inspection process.

Perhaps the most important guide to the inspector for writing the inspection report is the outline that should be prepared prior to writing the narrative portion of the report. The purpose of the outline is to serve as a blueprint for the development of the inspection report. A well-developed outline will ensure that the inspector includes in the narrative all information pertinent to the inspection. The following outline may be modified based upon the particular circumstances of

a given inspection.

- Title Page
- Index
- Facility Information
 - Company name, address, and telephone number
 - Number of employees
 - Approximate sales (year)
 - Type of facility
 - Parent company name and address
 - Parent company approximate sales (year)
 - Primary areas of business
- Inspection Information
 - Type of inspection conducted
 - Date and time of inspection
 - Responsible official's name, title, and telephone number
 - Name inspector
 - Other facility participants

- Inspection findings

This section should provide a summary of the inspection findings and the factors that led to the inspector's conclusions.

- Exhibits

Exhibits to the inspection report should include all documentary evidence (i.e. affidavits, statements, drawings and maps, mechanical recordings, printed matter, and photographs) that support the observations made during the inspection (and which should be described in the report narrative, as appropriate). The inspector should be sure that any data (e.g., analytical sample results) attached to the report as an exhibit is labeled as such and is mentioned within the narrative. Also, the inspector should prepare an index of exhibits (or attachments) listing the name and the location of each exhibit. This index should precede the exhibits and serve as a reference for enforcement personnel.

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