QUALITY ASSURANCE and OPERATING POLICY MANUAL for the BLUE CRAB INDUSTRY

Written By

George J. Flick
Thomas E. Rippen
Geoffrey M. Knobl
Cameron R. Hackney
William H. Robinson

Virginia Polytechnic Institute and State University
Virginia Sea Grant Program

Robert E. Croonenberghs
Robert J. Wittman
B. Keith Skiles

Virginia Department of Health
Division of Shellfish Sanitation

Alpha A. Diallo

Virginia Department of General Services
Division of Consolidated Laboratory Services

Stephen H. McNamara
Brian J. Donato
Mary Beth Neraas

Hyman, Phelps & McNamara, P.C.
Washington, DC.
Irvine, California

January, 1994

Virginia Sea Grant Publication VSG-93-10

CONTENTS

PLEASE TAKE NOTE: The section on HACCP is only a guide for assisting you in developing your own tailored plan. It is not meant to be used for preparing a HACCP plan for submission to a state or federal food regulatory agency.

Foreword

This manual is designed to guide blue crab processors in the efficient operation of their firms and in the sanitary production of crab meat. Preparing and implementing an operational plan that complies with state and federal food regulations is the first best step toward the production of wholesome, high quality crab meat free from disease-causing microorganisms.

Since no two processing facilities are identical, it is impossible to provide a manual to satisfy the specific requirements of all firms' operations. Some chapters of the manual deal with critical matters, however, and provide information uniform to all companies. Chapter 20, for example, contains statutory requirements of the Virginia Department of Health. The Virginia Department of Labor and Industry statutory requirements are covered in Chapters 15, 16, and 17. Chapter 22 deals with those of the Virginia Marine Resources Commission, the U.S. Food and Drug Administration's statutes are covered in Chapter 19, and statutes governing thermal processing procedures are dealt with in Chapter 7. None of the foregoing chapters should be changed for a firm's application without the assistance of a qualified individual. Chapters 18 and 21 contain legal information that should be useful to your business. All the other chapters (l-6 and 8-14) may and should be tailored to an individual firm's needs. In addition, Chapters 4, 6, 8, and 9 have been assigned a lettering system as an easy means for identifying all operating policies for a specific unit operation.

The authors realize that it may be difficult for some firms to develop a personal plan without some initial technical assistance. Please do not hesitate to contact us if you have any questions or comments concerning this manual or if you require assistance in modifying the information to meet your firm's requirements. In addition, the following agencies have indicated a willingness to make arrangements to provide personal assistance to any firm requesting it:

Virginia Polytechnic Institute and State University
Sea Grant Program
Food Science and Technology Department, Blacksburg
(703) 231-6965

Virginia Seafood Research and Extension Center, Hampton
(804) 727-4861

Virginia Department of Health, Richmond
Division of Shellfish Sanitation
(804) 786-7937

Virginia Department of General Services, Richmond
Division of Consolidated Laboratory Services
(804) 786-0592

This manual was published in a ring notebook format to facilitate the adding, modifying, or deleting of information as an individual firm's needs dictate. The authors' occasional updates will be made available to those manual owners whose names they have recorded, and those updates may be added easily to the manual.

The funds used to produce and distribute this manual were provided through a special Virginia General Assembly appropriation, without which financial assistance this project would not have been possible.

Acknowledgments

The authors thank Mr. Weston Conley, Jr., RCV Seafood Corporation; Mr. Charles Chase, Rappahannock Oyster Company, Inc.; and Mr. John Graham, Jr., Graham and Rollins Crab Company, Inc. for their assistance in preparing this manual.

Thanks are also extended to Dr. Dale Fredell, Ecolab Research Center, for his technical advice in developing the cleaning and sanitation programs.

Special thanks are extended to Ms. Diane Mahaffey and Sarah Moore for typing the manuscript and to Ms. Mary Holliman and Lynn Davis for their editorial assistance.

This work was sponsored by the Office of Sea Grant, NOAA, U.S. Department of Commerce, under Grant No. NA90AA-D-SGO45 to the Virginia Graduate Marine Science Consortium and the Virginia Sea Grant Program. The U.S. Government is authorized to produce and distribute reprints for governmental purposes, notwithstanding any copyright that may appear hereon.

Dear Manual Recipient:

The authors hope this manual is useful to you and your firm's personnel. It is obvious that no one publication can be written that applies to all blue crab processing firms. Consequently, any suggestions you have toward improving the publication would be appreciated. These could include: addition of new forms, modifications of existing test, addition of new materials (including new chapters), or improved methods of information presentation.

Please call or send your comments to the following:

1. Science and Technology Comments

George J. Flick
Geoffrey M. Knobl
Cameron R. Hackney
Food Science and Technology Department
Virginia Tech
Blacksburg, VA 2406l-0418
Phone (703) 231-6965
FAX (703) 231-9293

Robert E. Croonenberghs
Robert J. Wittman
B. Keith Skiles
Division of Shellfish Sanitation
Virginia Department of Health
Commonwealth of Virginia
1500 E. Main Street
Richmond, VA 23219
Phone (804) 786-7937
FAX (804) 786-5567

Alpha A. Diallo
Division of Consolidated Laboratory Services
Virginia Department of General Services
1 North 14th Street
Richmond, VA 23219
Phone (804) 786-0592
FAX (804) 371-0666

Legal Comments

Stephen H. McNamara, Esq.
Mary Beth Nerass, Esq.
Hyman, Phelps & McNamera, P.C.
700 Thirteenth Street, N.W.
Washington, DC 20005
Phone (202) 737-5600
FAX (202) 737-9329

Brian J. Donato, Esq.
Hyman, Phelps & McNamera, P.C.
2603 Main Street
Suite 1066
Irving, CA 92714
Phone (714) 553-7400
FAX (714) 553-7433

Any cooperation you provide in making this manual more useful to the industry will be greatly appreciated.

NOTE: Chapters 4, 6, 8, and 9 of the manual have been given corresponding alphabet designations. This uniform lettering system will enable manual users to easily identify all operating policies for a specific unit operation.

Example - For Illustrative Purposes Only

Example Blue Crab Company

1. Organizational Chart

President

President and/or owner of Example Blue Crab Company. He or she reviews the overall operational plan with the Production, Quality Assurance, and Sales Managers.

Production Manager

Reports to the President. Responsible for day-to-day operations of the facility. Responsible for directing production and for any new processes or procedures for the facility. Reviews the operational plan with President, Quality Assurance Manager, and Sales Manager. Responsible for purchasing all of the raw packaging and labeling materials.

Quality Assurance Manager

Reports to President. Responsible for carrying out the HACCP, training, and quality assurance plans, together with any changes related to the plans. Responsible for handling customer complaints and initiating recalls. Oversees the Quality Assurance Technicians and production personnel who perform all of the duties specified in the HACCP and quality assurance plans. Reviews HACCP, quality assurance, and training plans with the President, Production Manager, and Sales Manager.

Production Supervisor

Reports to the Production Manager. Oversees daily production in the facility. Works closely with the Production Manager to supervise the process of turning raw material into finished products. Decides the production schedule for the day. Responsible for overseeing all personnel in the production and refrigerated storage areas.

Sanitation Manager

Reports to the Production Manager. Oversees the daily cleanup and sanitation of the facility. Coordinates implementation and verification of HACCP, quality assurance, and training plans with Quality Assurance Manager.

Example - For Illustrative Purposes Only

Example Blue Crab Company

2. Product Descriptions

Lump
Jumbo Lump: The largest pieces of meat from the swimming leg body (backfin) chambers. Backfin: Large white pieces of crab meat from backfin cavity. The pieces are smaller than jumbo lump.

Special (Also called flake, regular, white or deluxe)
Smaller white pieces or chunks of crab meat removed from the walking leg body chambers and usually exclude backfin.

Blended Backfin
A uniform blend of backfin and special crab meat. One pound of blended backfin equals 4 ounces of backfin plus 12 ounces of special.

Claw
Includes only meat from the claw.

Mixed Meat
A mixture of lump and special meat in the same proportions as in the whole crab.

Machine-Picked Claw
Smaller than hand-picked claw with added salt.

Quik-Pik
A mixture of broken lump and special meat in the same proportions as in the whole crab separated from the shell by a mechanical process.

Minced
Crab meat separated from the shell by a mechanical process.

Fresh
Cooked crab meat.

Frozen
Cooked crab meat held in a frozen state.

Example - For Illustrative Purposes Only

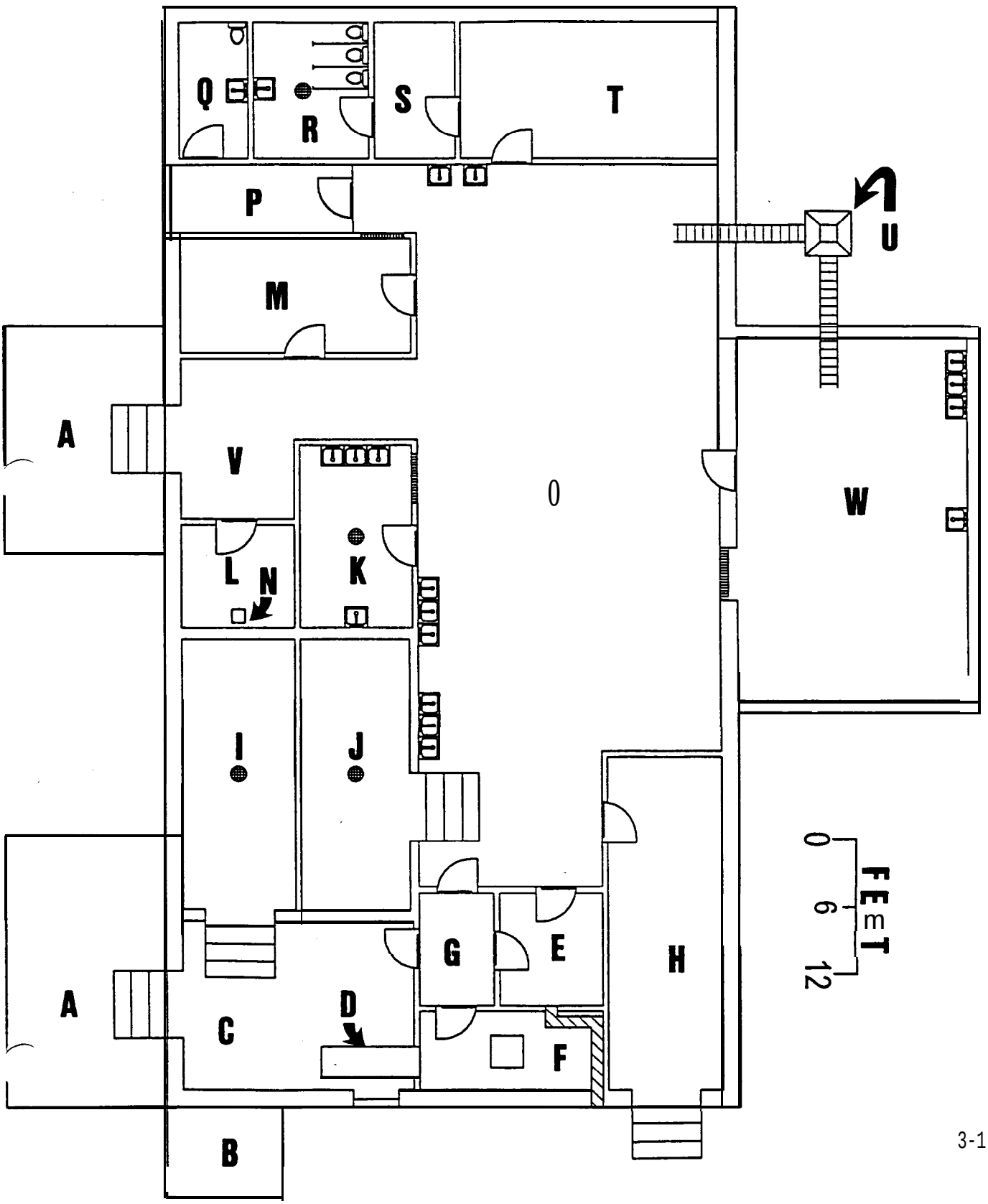
Pasteurized
Crab meat that is heated in hermetically sealed containers for a given time and at a temperature adequate to destroy all vegetative pathogenic organisms, but not to the degree of commercial sterilization. Pasteurization also decreases the number of spoilage organisms and results in a longer shelf-life at refrigerated temperatures.

Moderate Thermal (Listericidal) Processing Procedure
Crab meat that is heated in hermetically sealed containers for a given time and at a temperature sufficient to achieve six decimal reductions of Listeria monocytogenes.

All products can be obtained fresh, frozen, or pasteurized

Example - For Illustrative Purposes Only

Example Blue Crab Company
3. (Diagram-A Floor Plan for Your Firm)



A Typical Crab Processing Facility

Example - For Illustrative Purposes Only

Example Blue Crab Company

A. Loading Ramp

B. Boiler Room

C. Receiving Area

D. Crab Cooker

E. Pasteurizer

F. Air Cooling Room

G. Air Cooling and Pasteurization Room

H. Dry Storage Room

I. Raw Crab Cooler

J. Cooked Crab Cooler

K. Packing Room

L. Product Storage Area

M. Offices

N. Ice Machine

0. Crab Picking Room

P. Bathroom Hallway

Q. Men's Room

R. Women's Room

S. Cloak Room

T. Lunch Room

U. Solid Waste Conveyor and Hopper

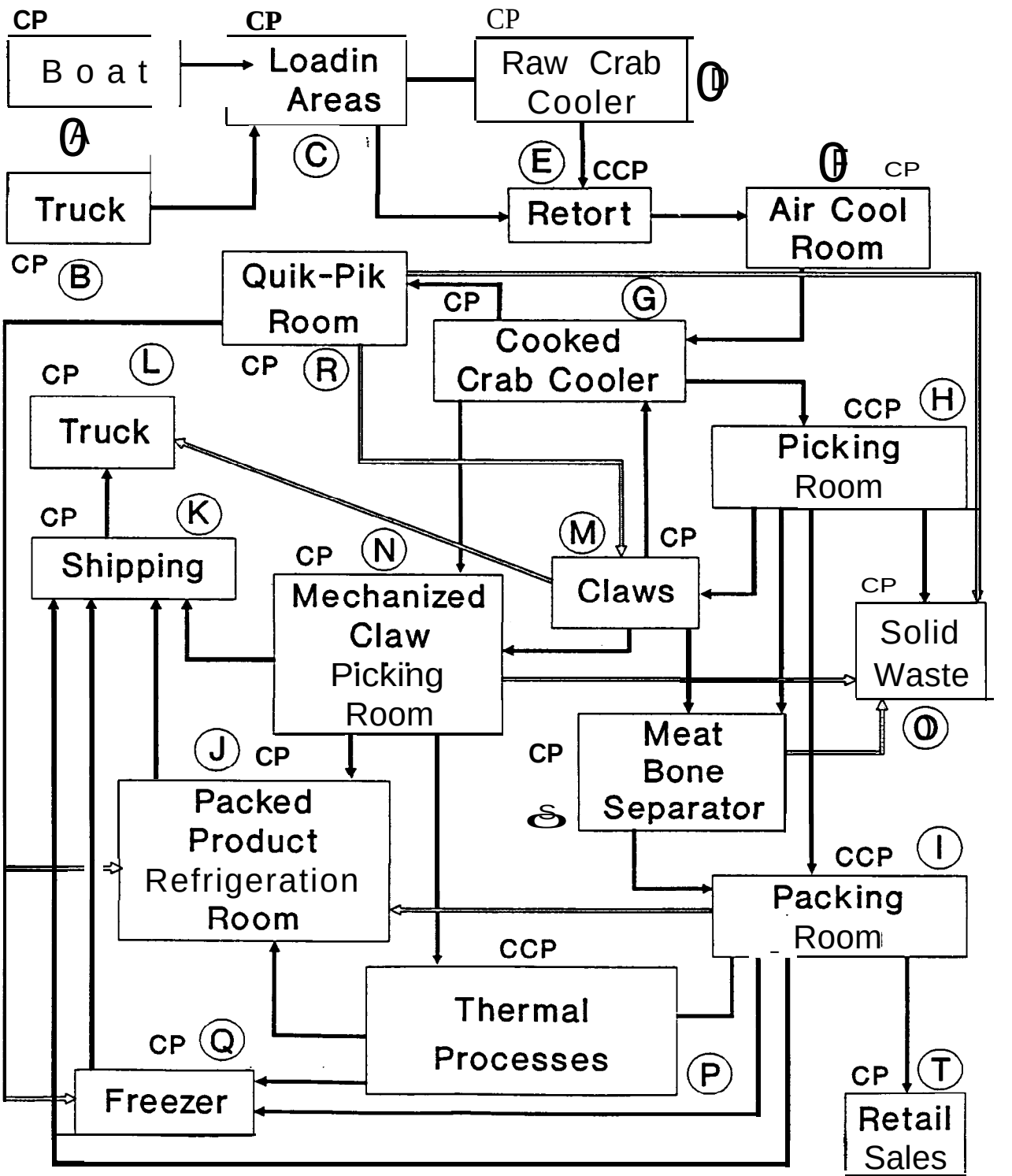
Example - For Illustrative Purposes Only

V. Shipping Area

W. Quik-Pik or Claw Machine or Meat Bone Separator Room

NOTE: Chapters 4, 6, 8, and 9 of the manual have been given corresponding alphabet designations. This uniform lettering system will enable manual users to easily identify all operating policies for a specific unit operation.

Example Blue Crab Processing Flow Chart



Example - For Illustrative Purposes Only

Example Blue Crab Company

5. Employee Education Programs

Formal employee educational programs are important to the efficient operation of a food-processing facility. Properly developed programs ensure products of high quality and wholesomeness and a safe, hazard-free working environment.

The following five educational programs should be presented each year:

- Annual employee training program
- Personal hygiene training program
- Plant sanitation and cleaning training program
- Hazard communication training program
- Work place safety training program

Additional educational programs should be developed and presented whenever a particular need is identified.

Example - For Illustrative Purposes Only

Example Blue Crab Company

Annual Training Program: Approximately 2 Hours

Each year all employees should be required to attend a meeting held just before the crab-picking season begins. Good Manufacturing Practices, sanitation practices, and employee responsibilities must be reviewed and discussed at this meeting. Attendance at this meeting should be recorded. Any employee who misses the meeting must be given an appropriate opportunity to learn what was covered at the meeting.

At the annual meeting a policy manual for the firm will be distributed to all employees. Each employee person must sign a statement pledging that they will abide by all the rules and regulations contained in the manual as well as the U.S. Food and Drug Administration (FDA) regulations setting out the general Good Manufacturing Practices. If employees do not adhere to established rules, they should be warned and then reminded of the importance of good manufacturing practices, and that repeated offenses could ultimately lead to dismissal.

Program Content

Welcome: Example Blue Crab Company representative
- Firm's goals and objectives for the coming crab season
- Employee questions and concerns
- Distribution of firm's employee manual

Sanitation: Example Blue Crab Company representative
- Plant cleaning and sanitation
- Employee hygiene - Employees will review and discuss a videotape produced by the National Fisheries Institute and Virginia Sea Grant
- Virginia Department of Health rules and regulations on crab-meat processing
- FDA Good Manufacturing Practices
- Dress code

Safety: Example Blue Crab Company representative
- Material Safety Data sheets
- Safety hazards in the work environment
- Reporting of injuries and safety hazards
- Employee evacuation in case of fire or other disaster
- Establishment of an employee safety committee

Example - For Illustrative Purposes Only

Example Blue Crab Company

Pathogens in the Crab Plant: Representative from Virginia Tech, Virginia Department of Health, Virginia Department of General Services, or other qualified individual.

- Sources of product contamination (including cross contamination)
- Employee responsibilities for pathogen control or elimination
- Microorganisms of public health significance and their control
  Listeria
  Salmonella
  Staphylococcus
  etc.

Economic Fraud: Example Blue Crab Company representative

- Fill of containers
- Proper containers/labelling
- Proper use of weigh scales

Example - For Illustrative Purposes Only

Example Blue Crab Company

Plant Sanitation and Cleaning Training Program: Approximately 2 Hours

All employees responsible for cleaning and sanitizing are required to attend a meeting at the beginning of the crab-picking season to review and discuss proper cleaning and sanitizing procedures. Attendance at this meeting should be recorded.

Program Content

Firm Sanitation Program: Example Blue Crab Company representative

- Review firm's cleaning and sanitation manual
- Employees will view one videotape on sanitation and another on Listeria in processing facilities
- Proper chemical storage, mixing, and disposal
- Proper use of cleaning equipment, brushes, and pads
- Proper sanitation of brushes and pads
- Safety equipment and its proper use
- Proper cleaning procedures
  dry cleaning
  low pressure cleaning
  sanitizing
- Evaluation of cleaning and sanitation effectiveness

Example - For Illustrative Purposes Only

Example Blue Crab Company

Hazard Communication Training Program: Approximately 1 Hour

At the beginning of the crab-picking season, all employees exposed to cleaning and sanitizing compounds are required to attend a meeting on hazard communication. Attendance should be recorded.

Program Content

Cleaning and Sanitizing Compounds Example Blue Crab Company representative

- Safe mixing procedures
- Required personal protective clothing
- Application procedures
- Disposal of excess chemicals
- First aid procedures

Example - For Illustrative Purposes Only

Example Blue Crab Company

Work Place Safety: Approximately 1.5 hours

At the beginning of the crab-picking season, all employees exposed to cleaning and sanitizing compounds or equipment are required to attend a meeting on work place safety. Attendance should be recorded.

Program Content

Processing Equipment: Example Blue Crab Company representative or other qualified individual

- Safe equipment operating procedures
- Proper equipment cleaning
- Protective equipment
- Lock out/tag out plan
- Proper and safe equipment maintenance

Cleaning Equipment - Example Blue Crab Company representative or other qualified individual

- Safe equipment operating procedures
- Proper equipment cleaning
- Proper and safe equipment maintenance
- Proper disposal of chemicals

General Safety Issues - Example Blue Crab Company representative or other qualified individual

- Proper clothing and personal safety devices
- Emergency exits
- Fire equipment and its use
- Accident reporting and first aid

Example - For Illustrative Purposes Only

Example Blue Crab Company

Thermal Process Training Program

The individual or individuals assigned responsibility for supervising pasteurization and Listericidal thermal processes will be required to attend an appropriate short course, recognized by the National Blue Crab Industry Association. The individual(s) will receive the training within one year of employment, as course availability permits.

Example - For Illustrative Purposes Only

Example Blue Crab Company

Miscellaneous Programs to be Decided on Identified Needs

Other employee education programs will be held as needed. Each additional program's topics and contents will be selected to meet new or changed requirements. Such programs may include continuing education programs offered by trade and professional organizations, health regulatory agencies, and educational institutions.

Example - For Illustrative Purposes Only

NOTE: Chapters 4, 6, 8, and 9 of the manual have been given corresponding alphabet designations. This uniform lettering system will enable manual users to easily identify all operating policies for a specific unit operation.

Example - For Illustrative Purposes Only

6. Unit Processing Operations Policies

A. Boat (Raw Product Only)
(Independent Contractor)

Harvester is responsible for product condition.

B. Truck (Raw Product Only)
(Independent Contractor)

Shipper is responsible for product condition.

C. Green Crab Unloading and Loading Areas

Product - Inspection

- Live.
- Free from fuel oil or other contaminants (Visual).
- Accurate weight.

Personnel and Equipment Movement

- Control entrance into processing and packing areas.
- Restrict use of equipment so that any which has not been properly cleaned and sanitized is not moved into processing and packing areas.
- Prohibit green crab barrels or baskets from being introduced into processing and packing areas.
- Color-code green crab area hand trucks (Green color recommended).

D. Green Crab Cooler

Product

- Discard dead crabs.
- Do not crush.
- Cook within 24 hours.
- First in, first out product rotation.

Personnel and Equipment Movement

- Control entry into processing and packaging areas.
- Restrict use of equipment so that any which has not been properly cleaned and sanitized is not moved into processing and packing areas.
- Prohibit green crab barrels or baskets from being introduced into processing and packing areas.
- Color-code green crab area hand trucks (Green color recommended).

Environment /Product

- Time/temperature
    1. A temperature range of 55°F minimum to 65°F maximum is recommended. The temperature should not exceed 65°F for more than 6 continuous hours.
    2. If the 65°F maximum temperature is exceeded for more than 6 continuous hours, the crabs should be cooked as soon as possible.

E. Retort and Cooking Area

Product

- Prevent cross contamination.
- Establish an appropriate thermal (time/temperature) process for your operation:
    1. The process should be sufficient to destroy pathogenic, vegetative, and spoilage microorganisms.
    2. If the established thermal (time/temperature) process is not attained, the crabs should be recooked according to the specified procedure.
    3. No hazards will occur if the established thermal process is exceeded.
    4. If product is improperly cooked or is cross contaminated, the product should be held under refrigeration until it is recooked or rejected.
    5. Product to be recooked should be held for no more than 48 hours.

Equipment

- Check/calibrate pressure and temperature indicators once a year, or whenever damaged.
- Check vent daily.
- Check temperature and pressure gauges daily for agreement and damage.
- Maintain crab rings or cages in proper operational and sanitary condition.
- Hoists should be shielded, or otherwise protected, to prevent contamination of crabs.

Floors

- Ensure adequate water drainage.

Personnel and Equipment Movement

- Control entry into processing and packing areas.
- Restrict use of equipment so that any which has not been previously cleaned and sanitized is not moved into processing and packing areas.
- Prohibit green crab barrels or baskets from being introduced into processing and packing areas.
- Color code green crab area hand trucks (Green color recommended).

Rings and Crab Carts

- Rings and crab carts should be stored in an area protected from contamination.

F. Air Cool Room

Environment /Product

- Move crabs into cool room immediately after cooking
- Time/temperature
    1. 4 hours maximum normally, or in extreme temperature conditions until steam is not visible.
    2. The cooling room temperature should not be lower than 28°F for more than 2 continuous hours.
    3. If the 28°F minimum temperature limit is exceeded for more than 2 continuous hours, the crabs should be immediately moved into a temperature controlled environment or processed.

Floors

- Ensure adequate water drainage.

Personnel and Equipment Movement

- Control entry into air cool room.
- Prevent use of equipment so that any which has not been previously cleaned and sanitized is not moved into air cool room.
- Prohibit green crab barrels or baskets from being introduced into air cool room
- Exclude green crab area hand trucks.
- Ensure that foot sanitizing baths are utilized and properly maintained.

G. Cooked Crab Cooler

Product

- Time/temperature (40°F recommended)
    1. The temperature should not exceed a maximum of **45**°F for greater than 8 hours and not greater than 70°F for one hour.
    2. If the product temperature limits are exceeded, the crabs should be reprocessed as soon as possible.

- A maximum holding time of 72 hours is recommended
    1. The holding time should not exceed 96 hours.
    2. If the maximum holding time of 96 hours is exceeded, the crabs will be either discarded or recooked and picked within 24 hours.

Environment

- Time/temperature (40°F recommended)
    1. The cooler temperature should not fall below the 28°F minimum for more than 2 continuous hours.
    2. If the temperature falls below 28 ° F for more than 2 continuous hours, the crabs will be either immediately processed or moved into a temperature controlled environment.
    3. If the cooler temperature exceeds 45°F for 6 continuous hours, or more than 80 °F for 1 hour, the crabs will be reprocessed as soon as possible.

Floors

. Ensure adequate water drainage.

Personnel and Equipment Movement

- Control entry into cooked crab cooler.
- Prevent use of equipment so that any which has not been previously cleaned and sanitized is not moved into cooked crab cooler.
- Prohibit green crab barrels or baskets from being introduced into cooked crab coolers.
- Exclude green crab area hand trucks.

H. Picking Room

Floor

- Ensure adequate water drainage.

Personnel and Equipment movement

- Control entry into processing and packing areas.
- Prevent use of equipment so that any which has not been previously cleaned and sanitized is not moved into processing and packing areas.
- Prohibit green crab barrels or baskets from being introduced into processing and packing areas.
- Color-code green crab area hand trucks (Green color recommended).

Personnel

- Exclude hand-to-mouth contact.
- Wash and sanitize hands before returning to work station and after any interruption.
- Clean and sanitize personal equipment (such as gloves or aprons) as well as utensils before use and as necessary during operations.
- Immediately dispose of used single-service towels.
- Knives should not be wrapped with absorbent or non-easily cleanable material.
- Seat cushions should be constructed of non-absorbent materials and be properly maintained.
- Ensure that properly maintained hand- and foot-sanitizing baths are utilized.

Product (Includes Picked Meat and Claws)

- Time (2 hours maximum recommended)
    1. Picked product should not remain in the picking room for more than 4 hours.
    2. Product remaining in the picking room for more than **4** hours will be subjected to an appropriate thermal process (see Chapter 7).

Scrap Cans

- Ensure properly identified cans are sanitized.

Scrap Conveyances

- Assure proper sanitation of hand trucks being used between scrap disposal areas and picking room.
- Color-code picking room hand trucks (Red color recommended).
- Inspect scrap containers and discard damaged or worn ones.

Example - For Illustrative Purposes Only

H. Picking Room (continued)

Claw Containers

- Inspect claw containers and discard damaged or worn ones.
- Holes in the sides of claw containers should be at least 4 inches from the bottom.
- No holes in the bottom of claw containers.

Crab Delivery

- Minimize spillage of crabs on the floor.
- Crabs that fall on the floor shall be discarded.
- Delivery equipment (shovels or buckets) should be properly maintained.
- When not in use, shovels should be stored in a sanitizer solution.
- Equipment used for transporting crabs should be sanitized after each use.

1. Packing Room

Scale

- Accuracy - Follow Division of Weights and Measures regulations established by the Virginia Department of Agriculture and Consumer Services.

Floor

- Ensure adequate water drainage.

Fresh Product

- Time/Temperature
    1. 2 hours maximum to reach 40°F or less.
    2. If the temperature does not reach 40° F or less within 2 hours, the product will be subjected to an appropriate thermal process (see Chapter 7).
- Examine for extraneous material.
- Ensure that all containers are properly labeled.

Personnel and Equipment Movement

- Control entry into processing and packing areas.
- Restrict use of equipment so that any which has not been previously cleaned and sanitized is not moved into packing areas.
- Prohibit green crab barrels or baskets from being introduced into processing and packing areas.
- Color-code packing room hand trucks (Blue color recommended).

Containers, Cans. CUPS. and Bags

- Ensure seal or seam integrity (develop a container evaluation program to include processors and factory seals or can seams).
- Ensure that all cans and containers are properly labeled and sanitized.

Equipment

- Can-seaming machine should be inspected for proper operation.
- Bag-sealing machine should be inspected for proper operation.

Personnel

- Eliminate hand-to-mouth contact.
- Wash and sanitize hands before returning to work stations after any interruption.
- Clean and sanitize personal equipment (such as gloves or aprons) as well as utensils before use and as necessary during operations.
- Ensure properly maintained hand- and foot-sanitizing baths are utilized.

Example - For Illustrative Purposes Only

J. Fresh and Pasteurized Packed Product Refrigeration Room

Floor

- Ensure adequate water drainage.

Ice

- Color code shovel (White color recommended).
- When ice is required, it should be purchased from a state-approved vendor.

Product

- Time/temperature (recommended 32° - 34° F, maximum tolerable 40° F)
    1. The temperature should not exceed 40° F for more than 4 continuous hours and not more than 60°F for more than 1 hour.
    2. If the temperature exceeds the 40°F for more than 4 continuous hours, or more than 60°F for more than 1 hour, the product will be subjected to an appropriate thermal process (see Chapter 7) or discarded.

Environment

- Time/temperature (recommended 32° F-34° F, maximum tolerable 40° F)
    1. The temperature should not exceed 40° F for more than 12 continuous hours if the product is iced. If the product is not iced, the temperature should not exceed 40° F for more than 6 continuous hours or 70° F for more than 1 hour.
    2. If the temperature of iced product exceeds 40°F for more than 12 continuous hours, or if uniced product exceeds 40 ° F for more than 6 continuous hours or 70° F for more than 1 hour, the product will be subjected to an appropriate thermal process (see Chapter 7) or discarded.
    3. The temperature should not go below 28°F for more than 2 continuous hours.
    4. If the temperature goes below 28°F for more than 2 continuous hours, the product will be immediately moved into a temperature controlled environment or sold as a previously frozen product.
- First in, first out product rotation.

Product

- All fresh products will be packed in wet ice prior to storage.
- The fresh products will be maintained in wet ice during storage time.

Equipment

- Hand trucks should have the same color code as the packing room trucks (Blue color recommended).

Example - For Illustrative Purposes Only

J. Fresh and Pasteurized Packed Product Refrigeration Room (continued)

Personnel and Equipment Movement

- Control entry into processing and packing areas.
- Restrict use of equipment so that any which has not been previously cleaned and sanitized is not moved into processing and packing areas.
- Prohibit green crab barrels or baskets from being introduced into processing and packing areas.

•

K. Shipping

Product

- All products will be packed in wet ice for shipment.
- Microbiology (Maximum recommended levels).

1. Aerobic Plate Count - 100,000/gram
2. Fecal Coliforms - 230/100 grams
3. Escherichia coli - 3.6/gram
4. Listeria monocvtogenes - 0/gram
5. Salmonella spp. - 0/gram

Personnel and Equipment Movement

- Packed product should not be shipped from green-crab receiving areas.

Floors

- Ensure adequate water drainage.

L. Truck

Product

- Meat temperature should be maintained between 28° F and 36 °F.
- Fresh product should be shipped and maintained in wet ice.
- Pasteurized product should be either packed in wet ice and/or shipped in a refrigerated truck.

Vehicle

- Temperature of the vehicle during shipment should not exceed a maximum of 36° F.

M. **Claws**

Product

- Time/temperature
    1. The temperature should not exceed a maximum of 45 °F for more than 6 continuous hours after processing (removal from the crab body).
    2. If, after processing, the 45° F maximum temperature is exceeded for more than 8 continuous hours, the product should be subjected to an appropriate thermal process (see Chapter 7) or discarded.
- First in, first out production rotation.
- Time
    1. All claws should be processed within 72 hours after removal from the crab body.
    2. Claws not processed within 96 hours after removal from the crab body will be discarded.

Transportation

- Claws being sent by other company's facilities should be transported in sanitized, covered containers.
- Claws should be moved using the hand trucks used for cooked crabs (Red color recommended).
- Restrict use of equipment so that any which has not been previously cleaned and sanitized is not moved into processing and packing areas.

Claw Containers

- Inspect claw containers and discard any that are damaged or worn.
- Holes in the side of claw containers should be at least 4 inches from the bottom, and there should be no holes in the bottom.

Example - For Illustrative Purposes Only

N. Mechanical Claw Picking Room

Floors
- Ensure adequate water drainage.

Personnel and Equipment Movement
- Control entry into processing and packing areas.
- Restrict use of equipment so that any which has not been previously cleaned and sanitized is not moved into processing and packing areas.
- Prohibit green crab barrels or baskets from being introduced into processing and packing areas.

Personnel
- Exclude hand to mouth contact.
- Wash and sanitize hands before returning to work stations after any interruption.
- Clean and sanitize personal equipment (such as gloves or aprons) as well as utensils before use and as necessary during operations.
- Ensure properly maintained hand- and foot-sanitizing baths are utilized.

Equipment
- Hand trucks should be the same as those used in the picking room and color coded (Red color recommended).

Brine
- A 65-100° salinity brine is recommended.
- The brine solution should be replaced after 6 hours.
- The brine temperature should not exceed 80°F. A process deviation will occur if the maximum temperature is exceeded for more than 30 continuous minutes.

Product- Fresh
- Time/temperature
    1. 3 hours maximum to 40° F or less.
    2. If 40°F is not reached in 4 hours, the product will be subjected to an appropriate thermal process (see Chapter 7) or discarded.
- Examine for extraneous material.
- Ensure that all containers are properly labeled.

Product- Pasteurized
- See pasteurization concerns (Chapter 7).

Example - For Illustrative Purposes Only

N. Mechanical Claw Picking Room (continued)

Scale

- Accuracy
    1. Follow Weights and Measures regulations established by the Virginia Department of Agriculture and Consumer Services.

Example - For Illustrative Purposes Only

0. Solid Waste

Personnel and Equipment Movement

- Control entry into processing and packing areas.
- Restrict use of equipment so that any which has not been previously cleaned and sanitized is not moved into processing and packing areas.
- Prohibit scrap-crab barrels or baskets from being introduced into processing and packing areas.

Solid Waste Areas

- Solid waste containers should be placed on a well-drained impervious pad, such as concrete.
- Solid waste areas should be graded to drain, and maintained to ensure adequate drainage.

Develop appropriate control program for pests:

- Control pests as allowed by law (such as type, concentrations, and application of pesticides; placement of traps):

  Rodents
  Insects
  Birds

- Domestic animals should not be allowed on premises.

Example - For Illustrative Purposes Only

P. Pasteurization/Thermal Processes

Pasteurization

- Follow Pasteurization Guidelines (see Chapter 7).
- Prevent cross contamination.
- Establish process based on a confirmed time/temperature process for your facility.

Thermal Processes (see Chapter 7)

Product

- Temperature (see Chapter 7).
- Prevent cross contamination.

Water Quality

- Change water when necessary.
- Maintain appropriate chlorine concentration (see Chapter 7).

Storage

- (see Chapter 7).

Floors

- Ensure adequate water drainage.

Equipment

- Hand trucks used to transport pasteurized product should be same as those used in the packed-product refrigeration room (Blue color recommended).
- Product, thermal process
    1. Prevent cross contamination.
    2. Establish an appropriate thermal (time/temperature) process for your operation.
- If product is improperly processed, the product should be held under refrigeration until it is recooked or rejected.
- Product to be recooked should not be held for more than 48 hours.
- Check/calibrate pressure and temperature indicator devices once a year or whenever damaged.

Establish an Appropriate Pasteurization/Phermal Process

- The process should be sufficient to destroy pathogenic vegetative and spoilage microorganisms.
- If the established thermal (time/temperature) process is not attained, the crabs will be recooked according to the specified procedure.
- No hazards will occur if the established thermal process is exceeded.

Example - For Illustrative Purposes Only

P. Pasteurization/Thermal Processes (continued)

- Make a daily check of temperature-indicating thermometers and recorders for agreement and/or damage.
- Check to assure that pasteurization rings are maintained in sanitary condition.

Q. Freezer

Environment

- Minimize ice accumulation

Equipment

- Hand trucks used to transport product should be the same as those used in the packed-product refrigeration room (Blue color recommended).

Product

- Time/temperature
    1. The temperature should not exceed a range 20°F to 35°F for more than 8 continuous hours.
    2. If the 20°F temperature is exceeded for more than 8 continuous hours, the product will be sold as a previously frozen product, provided that the temperature did not exceed 40°F for more than 8 hours.
    3. If the temperature of 40° F is exceeded for more than 8 hours the product will be discarded.
    4. First in, first out rotation rule (customer dependent).

Example - For Illustrative Purposes Only

R. Quik-Pik Room

Floors
- Ensure adequate water drainage.

Personnel and Equipment Movement
- Control entry into processing and packing areas.
- Restrict use of equipment so that any which has not been previously cleaned and sanitized is not moved into processing and packing areas.
- Prohibit green crab barrels or baskets from being introduced into processing and packing areas.

Personnel
- Wash hands after any contact with mouth.
- Wash and sanitize hands before returning to work station after any interruption.
- Clean and sanitize personal equipment (such as gloves or aprons) as well as utensils before use and as necessary during operations.
- Immediately dispose of used single-service towels.
- Assure seat cushions constructed of non-absorbent material are properly maintained.
- Properly maintained hand- and foot-sanitizing baths should be utilized.

Equipment
- Hand trucks should be the same as those used in the picking room and color coded (Red color recommended).

Product
- Time/temperature
    1. 2 hours maximum to reach 40° F or less.
    2. If the temperature does not reach 40°F within 2 hours, the product will be subjected to an appropriate thermal process or discarded.
- Examine for extraneous material.
- Ensure all containers are properly labeled.

Scale
- Accuracy - Follow Weights and Measures regulations established by the Virginia Department of Agriculture and Consumer Services.

R. Quik-Pik Room (continued)

Crab Delivery

- Minimize spillage of crabs on the floor.
- Crabs that fall on floor shall be discarded.
- Delivery equipment (such as shovels or buckets) should be properly maintained.
- When not in use, shovels should be stored in a sanitizing solution.
- Equipment used for crab delivery should be sanitized after each use.

Scrap Conveyances

- Restrict movement of unsanitized hand trucks between scrap disposal areas and picking room.
- Color-code picking room hand trucks (Red color recommended).
- Inspect scrap containers and discard damaged or worn ones.

Claw Containers

- Inspect claw containers and discard damaged or worn ones.
- Holes in sides of claw containers should be at least 4 inches from the bottom, and there should be no holes in the bottom.

Example - For Illustrative Purposes Only

S. Meat Bone Separator Room

Floors

- Ensure adequate water drainage.

Personnel and Equipment Movement

- Control entry into processing and packing area.
- Restrict use of equipment so that any which has not been previously cleaned and sanitized is not moved into processing and packing areas.
- Prohibit green crab barrels or baskets from being introduced into processing and packing areas.

Personnel

- Wash hands after any contact with mouth.
- Wash and sanitize hands before returning to work station after any interruption.
- Clean and sanitize personal equipment (such as gloves or aprons) as well as utensils before use and as necessary during operation.
- Ensure properly maintained hand- and foot-sanitizing baths are utilized.

Product

- Time/temperature
    1. 2 hours maximum to reach 40° F or less.
    2. If the temperature does not reach 40°F within 2 hours, the product will be subjected to an appropriate thermal process (see Chapter 7) or discarded.
- Examine for extraneous material.
- Ensure that all containers are properly labeled.

Scale

- Accuracy - Follow Weights and Measures regulations established by Virginia Department of Agriculture and Consumer Services.

Raw material

- Crab parts should be processed or refrigerated within 2 hours after removal.
- Crab parts will be rejected if they are not processed or refrigerated within 4 hours after removal.
- 2 hours maximum to reach 40° F or less.
- Crab parts will be rejected if they do not achieve 40° F or less within 4 hours.

Equipment

- Hand trucks used to transport pasteurized product should be the same as those used in the packed-product refrigeration room (Blue color recommended).

S. Meat Bone Separation Room (continued)

Raw Product Conveyances

- Prevent spillage of crab parts on the floor.
- Crab parts that fall on floor shall be discarded.
- Delivery equipment (such as shovels or buckets) should be properly maintained.
- Containers will be washed and sanitized after each use.

Example - For Illustrative Purposes Only

T. Retail Sales

1. Observe local and state regulations concerning retail food stores.

U. Utensils and personal equipment surfaces

1. Establish proper sanitation procedures.
2. Gloves should not have cotton cuffs.
3. When entering or re-entering work areas, rinse and sanitize gloves and aprons.

V. Hand dip stations

1. Establish proper locations and sanitizer concentrations.
2. Maintain proper sanitizer concentrations.

W. Picking bowls - food contact

1. Establish proper sanitation procedures.

X. Brushes and pads - non-food contact

1. Establish proper sanitation procedures.
2. Control movement of brushes and pad between various plant operations. Develop color code . Suggested codes: green = raw product, red = cooked product area [picking room], blue=packing area.
3. During operations store in 200 ppm quat totally immersed when possible.

Y. Shovels

1. Establish proper sanitation, use, and storage procedures.
2. Maintain proper sanitizer concentrations.
3. Recommend stainless steel for cooked crab delivery, white color for ice, red color for scrap, and green for green crabs.

Z. Hand trucks and dollies

1. Prevent movement between green and cooked crab areas and between shipping and receiving areas .Recommend color coding, green = green crab, red=cooked crab and picking rooms, blue =packing and refrigerated rooms.
2. Establish proper sanitation procedures.

Example - For Illustrative Purposes Only

AA. Walls, doors, and strip curtains

1. Establish proper cleaning and sanitizing procedures.
2. Strip curtains should not touch cooked crabs, claws, or finished product.

AB. Ceilings and air vents

1. Establish proper sanitation procedures.

AC. Lights

1. Establish proper sanitation procedures.

AD. Ice bin and shovel

1. Ice
   a. Microbiology (Should meet potable water standards).
2. Shovel
   a. Establish proper storage and color code (White color recommended).

AE. Foot baths

1. Maintain proper sanitizer concentrations.

AF. Drains

1. Establish proper sanitation procedures.

AG. Crab Carts

(see Section E).

AH. Water (well)

1. Microbiological action levels (Must meet state and federal drinking water standards).

AI. Storage of barrels/conveyances

1. Barrels used for green crabs should not be stored adjacent to barrels used for cooked crabs/parts unless adequately partitioned.

Example - For Illustrative Purposes Only

7. Special Thermal Processing Operations

PASTEURIZATION AND EXTENSION OF PRODUCT SHELF-LIFE

PROCEDURES FOR HERMETICALLY-SEALED CONTAINERS STORED UNDER REFRIGERATION

1. **Cooking**

A. As soon after delivery of live blue crabs as possible, the crabs should be cooked in accordance with Commonwealth of Virginia regulations.

B. When crabs are not cooked on the same calendar day they are received at the processing plant, they should be refrigerated in a raw crab cooler at 40-50°F until they can be cooked.

2. **Cooling**

A. After removal from the retort, cooked crabs should be air-cooled to room temperature without being disturbed. Any cooked crabs not picked approximately 8 hours after. cooling should be refrigerated at 45°F or less.

B. It is essential that the cooked crabs be protected from contamination. Cooked and raw crabs must not be stored in the same cooler. It is recommended that whole crabs be stored in the same container in which they were cooked.

3. **Picking and Packing**

A. The picking and packing operations should be performed so as to avoid contamination. Within two hours after picking, the crab meat should be delivered to the packing area, the cans sealed and then placed in either refrigerated storage or into the pasteurization process.

4. **Pasteurization**

A. Refrigerated crab meat shall be pasteurized within approximately 36 hours of the time it was picked.

Example - For Illustrative Purposes Only

B. The minimum pasteurization specification for hermetically-packaged refrigerated crab meat is the attainment of a process lethality of a minimum F = 31 minutes **(185** ° F reference temperature, z = 16°F) at the geometric center of a container approved by the Commonwealth of Virginia. Because pasteurizing may cause blueing in Gulf and South Atlantic crabs, nothing in this section shall be construed as barring any other pasteurization process that has been found equally effective. (See Section 4, E for further details on variables such as container size.

C. All pasteurizing equipment shall be standardized to assure that the above pasteurization treatment is attained.

D. The plant operator shall keep on file the standardization report, and the pasteurization procedure shall be performed in accordance with it.

E. Temperature-time requirements must be established for each water bath and for other conditions, such as the temperature of the meat, the size of the container, and other variables. Alteration of the equipment or in the stacking of containers shall require that the pasteurization procedure be restandardized. The introduction of new containers or equipment will require the development of process controls in terms of equal process lethalities.

F. In the event of a power or equipment failure that interrupts the normal pasteurization schedule, it is recommended that all cans be removed from the pasteurization vessel and refrigerated. Once all such cans have equilibrated to the refrigeration temperature, they can be pasteurized according to a schedule established for a corresponding product internal temperature (I.T.).

G. Cans are stacked into pasteurization baskets side by side in layers. Each layer is separated by a perforated (3/8 inch holes on l/2 inch centers) 28-inch diameter plastic divider.

5. Seam Sealing

A. When containers require a metal end seam, inspection of can seams shall be made:

- at the start of the seaming process;
- after, at least, every four hours of machine operation;
- and following a machine malfunction.

The inspection program requires that:

- one or more sealed containers should be torn down using accepted can-seam evaluation procedures, as currently performed by the quality assurance manager.
- Appropriate measurements should be recorded and compared to the container manufacturer's seam specifications.
- If seams are found to be out of specification, appropriate adjustments should be made to the seamer and noted on the seam evaluation form.
- Any containers closed subsequent to the last acceptable seam report should be opened, packed into new cans, and re-seamed prior to pasteurization.

B. At least one employee shall be trained in can-seam inspection and in the adjustment of can-seaming equipment. One person from management shall be responsible for reviewing can-seaming records within 48 hours of the record creation.

C. Can-seaming records shall be maintained for all can-seam inspections.

6. **Cooling, Refrigeration, and Storage**

A. The containers of meat must be chilled by circulated cooling water to 5°F within approximately 180 minutes to allow refrigerated storage after processing. The cooling water should be break-point chlorinated or treated with an appropriate concentration of another approved sanitizer. Use of this procedure does not preclude the use of any other cooling procedures that achieve the same rate of cooling.

B. Cooling water should be drained and replaced with sanitized potable water daily or after approximately 4 batches have been processed.

C. Upon completion of the cooling process, the meat shall be placed in refrigeration and cooled to a temperature of 36° F within approximately 18 hours.

D. Pasteurized crab meat, whether in or out of shipping cartons, should be maintained continuously at or below 36° F until shipped. Occasional ambient increases to 40-45° F are not deemed to be a process deviation if storage temperature returns to below 36°F within 24 hours.

E. Product containers should conspicuously feature appropriate refrigeration instructions.

Example - For Illustrative Purposes Only

7. Labeling

A. All labels used shall clearly identify the contents of the container as pasteurized crab meat, and conform to other state and federal requirements.

B. Each container shall be permanently and legibly identified with a code.

C. The following words or their equivalent shall be prominently displayed on the container label:

** Important **
Must be Kept Refrigerated

8. <u>Pasteurization Controls</u>

A. A time-temperature recording thermometer and temperature controller (combined or separate) and an indicating thermometer shall be provided for all pasteurization equipment. Indicating thermometers are mounted on the tanks but read low, which is normal in submerged systems. A qualified technician shall check the accuracy of both thermometers initially and at least once each operating season. The recording thermometer chart should be at least a 12-hours chart of at least 10 inches in diameter, but this section does not preclude the use of other recording devices if acceptable to the responsible authority.

B. The recording thermometer shall be installed so that it can be protected from vibration and from damage by loading operations or plant traffic. The thermometer mechanism shall be so located as to be protected from moisture under ordinary operating conditions. The thermometer case shall only be opened during the pasteurizing cycle for temperature checks, or for emergency adjustments or repairs, a record of which shall be made.

C. The recording thermometer shall have a range of at least l20-220°F. It should be accurate within plus or minus 1°F between 160°F and 200°F. The chart should be scaled at a maximum of 2°F intervals in the range of 160° F and 20° F.

D. The indicating thermometer should have an accuracy and readability of plus or minus 1°F between 160° F and 200° F.

E. The recording thermometer shall be equipped with an electronic, mechanical, or pneumatic clock. The recorded elapsed time as indicated by the chart rotation shall not exceed the true elapsed time shown by an accurate watch. A qualified technician shall check the accuracy of the clock as installed and once each operating season.

F. When pasteurizing, the pasteurization unit shall be operated with a recording thermometer chart in place, the pen in contact with the chart, and an inked record being made of the operating time-temperature cycle. A new chart shall be used for each day's operations, and the code number or date of each batch affixed to the chart for each pasteurizing cycle.

G. A permanent file of the used thermometer charts shall be maintained by the operator and kept available for a period of two years.

The following information should be recorded on the chart after the pasteurization cycle has been completed:

1. Date of processing.
2. Quantity of each batch processed (pounds of meat or number and size of containers).
3. Processor's code of each pack.
4. If the operator processes meat for someone else, then the processor's certification number must be recorded.
5. Mechanical or power failure, or opening of the recording thermometer case for adjustment or repair during a pasteurizing cycle.
6. After the optimum temperature has been reached and during the holding time, the reading of the indicating thermometer and the time of reading.
7. Written signature of the operator.

H. An automatic proportional-flow steam-control valve is required if steam is used as a source of heat. In addition, base covers, partitions, and baskets should be perforated for water circulation. The water bath shall be provided with effective agitation to maintain a uniform temperature.

I. The recording thermometer may be replaced with an appropriate computer-based data logger or process controller datalogger, which provides a permanent copy of the thermal process.

9. **Microbiological Standards**

A. Products shall conform to such microbiological standards as may from time to time be established by appropriate authorities.

Example - For Illustrative Purposes Only

10. Record Keeping

A. The corporation shall maintain records of results of examinations and/or copies of suppliers' guarantees or certificates that verify compliance with Food and Drug Administration regulations, guidelines, or action levels on raw materials, food-packing materials, and finished foods.

B. The corporation shall maintain processing and production records of the pasteurization process to permit public health evaluation of the product.

C. Records required by paragraphs "A" and "B" of this section shall be retained for a period of time exceeding the shelf life of the pasteurized crab meat, or 2 years from the date of pasteurization, whichever is shorter.

11. Training and Certification of Pasteurization Technicians

A. The corporation must have at least one responsible employee trained as a pasteurization technician.

B. In order to be certified as a pasteurization technician, an individual must have attended a pasteurization training program approved by the National Blue Crab Industry Association or the Virginia Department of Health.

Example - For Illustrative Purposes Only

MODERATE THERMAL (LISTERICIDAL) PROCESSING PROCEDURES

FOR PRODUCTION OF FROZEN CRAB MEAT IN BAGS

1. Filling/Sealing

In the plant's packing room, coded cook-in bags are placed one at a time on a scale and hand filled with five pounds (plus or minus one percent) of fresh crab meat. The filled bags are wiped free of water and crab meat in the seaming area with single-service, disposable paper towels. The filled bags are laid individually in a chamber-style vacuum-sealing machine, and the meat is distributed uniformly by manually shaping the bag and its contents externally; then the bags are vacuum sealed.

Sealing Operations

A. Heat seal bonding should be sufficiently strong so that the bond will be destroyed when the film sides are forcibly spread apart; the bond should not release cleanly along the contact zone when the sides are so treated. This test should be performed on two empty bags when the sealing machine is set up at the start of operation (each time the sealer machine is turned on) and at least once every four hours of operation. At least one test bag should be filled with a small quantity of water, then sealed and hand squeezed for signs of leakage before start of operations. In addition to start-up testing, all filled bags should be visually inspected for signs of vacuum loss prior to pasteurization. If the product warms after sealing, some package loosening is to be expected. The vacuum level should be evident when the film is lifted off the product surface. Suspect bags should be opened and the meat repackaged as described above or further tested by being submerged in water (break-point chlorinated) and hand squeezed. The release of bubbles indicates leakage and the need to repackage the crab meat as before.

B. Prior to placing bags in the pasteurization basket, a minimum of ten percent of filled bags should be inspected to assure that package thickness is uniform to within 3/4 inch differential in any two locations in each bag evaluated. These bags should be selected from those that appear to have the greatest thickness variation.

2. Thermal Process (Includes Cooling)

The filled bags should be carefully laid into the pasteurization basket. Bags in each layer may touch each other but should not overlap by more than approximately two inches. (A process schedule should account for a shrink bag material that properly draws up during heating, reducing length by width dimensions). Up to approximately 280 pounds of crab meat is placed in each basket.

Each layer is separated by a rigid, stainless steel, perforated (1.25 inch holes on 3.75 inch centers) spacer designed so as to maintain 3 l/2 inch spacing. These assure waterbath circulation over and under each bag layer. All basket and spacer surfaces should be maintained to eliminate sharp edges or burrs.

The basket is submerged in a single-basket batch pasteurizer at the plant, with the timed portion of the process beginning when the waterbath returns to 187°-190° F, and is uniformly agitated by compressed air injection. A process of heating for a minimum of 120 minutes is based on initial meat temperatures (I.T.) of 32 ° F to less than 59 ° F. Freshly picked crab meat (I.T. $\geq$ 59 °F) should be heated for a minimum of 90 minutes at 187 ° -190° F. When crab meat is to be moderately thermal-processed from previously frozen crab meat, it should be handled as described in Section 3.

Continuous chart recorder/controllers at the plant record times and waterbath temperatures to document the heating portion of each bath. These devices should be serviced and calibrated to assure clock and temperature accuracy and temperature control within the prescribed range. This service should be conducted at least annually by a competent technician. Indicating thermometers are mounted on the tanks but read below the actual temperature, which is normal in submerged systems. A practice of routine comparison of temperature readings from a hand-held digital thermometer against the chart tracing is a valid and acceptable check for accuracy. The digital thermometer should be periodically calibrated against agitated ice slush and rapidly boiling water.

After heating, the basket is transferred to vigorously agitated ice slurry for approximately 90 minutes prior to racking and placement of the bags in a freezer. As before, bags should be handled carefully. Cooling water should be potable and break-point chlorinated. A heavy ice slurry should be maintained throughout the cooling period.

A. Confirm product I.T. loading at time of leading pasteurization basket within 15 minutes of placing in the pasteurizer. This confirmation can be performed nondestructively by stacking two bags and laying between them a thermocouple or other calibrated temperature-measuring device.

B. Indicate the following information on recorder charts or on attached record:
   1. Times when baskets are submerged and removed from the hot waterbath pasteurizer-(can be marked directly on the chart tracing if not obvious from the tracing).
   2. Number (or pounds) and type of package.
   3. Date of processing.
   4. Lot code.
   5. The reading of the digital thermometer after the recorder/controller set-point temperature is reached and during the holding period.
   6. Signature of operator.

C. When the bags are lifted from the basket for placing on the freezer racks, all should be visually inspected for evidence of leaks (e.g. water in bags) and, where indicated, firmly squeezed to confirm integrity. The release of air or water indicates a defect (a critical limit).

D. Records of this process should be checked by a second qualified individual within 48 hours, initialed and dated to indicate such, and maintained for two years from the date of processing.

E. Critical limits and corrective actions involve the following:

1. A thermal process deviation occurs if the hot waterbath temperature drops below 187 °F for more than five minutes after the waterbath has attained set-point temperature and stabilized. If this condition should occur for five to ten minutes, the controller set-point can be raised to 190 ° F and an additional 30 minutes added to the process (120 to 150 minutes total) depending on the I.T. If this condition should occur for longer than ten minutes, a full 90 or 120 minutes/l87 ° F process must be repeated, depending on the I.T.
2. Bag integrity failure requires that the crab meat from the defective bag(s) be repackaged and fully reprocessed in another lot.
3. Any corrective action should be performed by qualified personnel.

3. **Handling Frozen Crab Meat to be Moderately Thermal Processed and Refrozen**

A. Frozen crab meat should be thawed at a maximum ambient temperature of 45 ° F for approximately 48 to 96 hours under refrigeration. Only the quantities of crab meat that can be processed within approximately 96 hours from the time that thawing is initiated should be placed on clean racks and moved from the freezer to refrigerated storage.

As a general matter this crab meat should remain at ambient room temperatures for no more than two hours. Operations that require exposure to ambient room temperatures include, for example,

a. when crab meat is placed on the packing table during the filling operation,
b. during sealing,
c. while pasteurization baskets are being filled with bags, and
d. while the baskets await submersion in the pasteurizers.

B. Filling/Cooling (the procedures outlined in Section 1 of this protocol should be followed, with the following changes):

Packaged frozen-thawed crab meat should be opened on the packing table and the crab meat transferred to cook-in bags if the original packaging is unsuitable for thermal processing.

C. Thermal process and cooling (the procedures outlined in Section 2 of this protocol should be followed with the following changes:

The process of heating for a minimum of 120 minutes at 187 ° -189° F is based on initial meat temperatures (LT.) of 32°F or warmer.

4. **Verification**

Confirm product I.T. at time of loading pasteurization basket within 15 minutes of placing in the pasteurizer (every batch). This can be performed nondestructively by stacking two bags and laying between them a thermocouple or other calibrated temperature measuring device. Maintain a record of I.T.'s such that they can be matched with corresponding processing records. These should be reviewed by management within 48 hours, initialed and dated to indicate such, and maintained for two years from the date of processing.

Example - For Illustrative Purposes Only

HACCP PLAN

NOTE: Chapters 4,6,8, and 9 of the manual have been given corresponding alphabet designations. This uniform lettering system will enable users to easily identify all operating policies for a specific unit operation.

Example - For Illustrative Purposes Only

8. Hazard Analysis Critical Control Point Plan (HACCP)

Company Name	**Unit Operation**
Example Blue Crab Company	Harvesting

CONTROL POINT:	CRITICAL: **Yes or No**
A. Boat Dock	No

HAZARD OR DEFECT:

1. Dead or decomposed crabs
2. Contaminated crabs
3. Improperly sized crabs

CRITICAL LIMIT

1. No detectable levels of contamination or decomposition that renders the product unwholesome or unsafe.

PREVENTIVE MEASURES:

1. Check crabs upon delivery at dock to monitor and identify dead, decomposed, or contaminated crabs and foreign materials.
2. Train personnel to identify acceptable products.

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Visual and sensory (odor) examination

CORRECTIVE ACTIONS:

1. Reject unsatisfactory crabs.
2. Other contaminants may be removed by hand or washing.

RECORDS:

1. Live Crab Receiving Form

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Inspect all incoming shipments	Loading dock supervisor

Company Name	Unit Operation
Example Blue Crab Company	Harvesting and transportation

CONTROL POINT:	CRITICAL Yes or No
B. Truck Dock	No

HAZARD OR DEFECT:

1. Dead or decomposed crabs
2. Contaminated crabs
3. Incorrectly and illegal sized crabs

CRITICAL LIMIT:

1. No detectable levels of contamination or decomposition that render the product unwholesome or unsafe.

PREVENTIVE MEASURES:

1. Check crabs upon delivery at dock to monitor and identify dead, decomposed, or contaminated crabs and foreign materials.
2. Train personnel to identify acceptable products.

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Visual and sensory (odor) examination

CORRECTIVE ACTIONS:

1. Reject unsatisfactory crabs.
2. Remove other contaminants by hand or by washing.

RECORDS:

1. Live Crab Receiving Form

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Inspect all incoming shipments	Loading dock supervisor

Company Name

Example Blue Crab Company

Unit Operation

Product Receipt

CONTROL POINT:

C. Loading Area

CRITICAL Yes or No

No

HAZARD OR DEFECT:

1. Extraneous material (such as sand, seaweed) remaining on crabs
2. Dead or decomposed crabs not detected at boat or truck
3. Contaminated water

CRITICAL LIMIT:

1. Relatively free of extraneous material and dead, decomposed, and illegal size crabs.
2. Use of potable or other approved water source.

PREVENTIVE MEASURES:

1. Remove dead, decomposed, and illegal size crabs.
2. Remove extraneous material.
3. Use approved water and periodically evaluate water supply.
4. Train personnel to remove extraneous material, and dead, decomposed, and illegal size crabs.

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Visual and sensory (odor) examination

CORRECTIVE ACTIONS:

1. Rewash and recheck crabs for dead, decomposed, and illegal size crabs

RECORDS:

None

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Inspect all incoming products	Loading dock supervisor

Company Name

Example Blue Crab Company

Unit Operation

Live product storage

CONTROL POINT:

D. Green Crab Cooler

CRITICAL Yes or No

No

HAZARD OR DEFECT:

1. Improper temperature
2. Decomposition
3. Improper storage or handling

CRITICAL LIMIT

1. Temperature range from 55°F to 65 °F
2. Crab containers should be stored in such a manner as to prevent crushing of crabs or containers.

PREVENTIVE MEASURES:

1. Control storage temperature.
2. First in, first out product rotation.
3. Cook crabs within 24 hours after receipt.
4. Establish proper storage for live crabs.
5. Train workers to check temperature.

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Check temperatures and temperature log.
2. Observe length of time in storage.

CORRECTIVE ACTIONS:

1. If held at 65 ° F or above for six hours, cook as soon as possible.
2. Identify alternative storage for refrigeration failure.
3. Discard dead or crushed crabs.

RECORDS:

1. Temperature Log of Freezers and Cooling Units Form (Green crab cooler)

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review Temperature Log of Freezers and Cooling Units Form	Loading dock supervisor

Company Name	Unit Operation
Example Blue Crab Company	Raw product cooking

CONTROL POINT:	CRITICAL Yes or No
E. Retort Area	Yes

HAZARD OR DEFECT:

1. Improper cook
2. Inadequate steam quality
3. Cross contamination
4. Inadequate process schedule

CRITICAL LIMIT:

1. Product will not be cooked less than the established time and temperature limits.
2. Steam should not contain contaminants.
3. No cross contamination of cooked product with:
   a. raw products
   b. utensils used for handling raw products
   c. employees with raw product responsibilities.

PREVENTIVE MEASURES:

1. Establish written specifications for cooking time and temperature.
2. Establish written specifications for proper water treatment and broiler maintenance.
3. Train employees responsible for cooking in proper cooking procedures and handling of cooked product.

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Monitor cook times and temperatures.
2. Visual observation and checks of Steam Cooking Form and Crabs Recooked Form.
3. Monitor water treatment and boiler maintenance.
4. Avoid boiler overloading.

CORRECTIVE ACTIONS:

1. Recook crabs if cooked less than specified time and temperature; cooking of recooked product will begin at time zero and the entire cook cycle will be repeated.
2. Reject unacceptable product.
3. Products cooked in steam or treated with non-approved compounds will be held under refrigeration and the appropriate regulatory authorities contacted for a determination of appropriate disposition.
4. Cooked product cross-contaminated with raw product, raw product utensils, or employees handling raw product will be destroyed or held in refrigeration (not to exceed 48 hours) until recooked.

RECORDS:

1. Retort Thermometer Calibration Form
2. Steam Cooking Form
3. Crabs Recooked Form

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review records	Loading dock supervisor

Company Name

Example Blue Crab Company

Unit Operation

Ambient temperature cooling of cooked product

CONTROL POINT:

F. Air Cool Room

CRITICAL Yes or No

No

HAZARD OR DEFECT:

1. Potential microbial growth
2. Decomposition

CRITICAL LIMIT:

1. Crabs should be held in air cool room for no more than 4 hours. In extreme temperature conditions crabs should be held until steam is not visible.
2. Crabs should be held no more than 2 hours if the cooling room temperature is 28°F or less.

PREVENTIVE MEASURES:

1. Move crabs into cold rooms to ensure proper temperature control.
2. Exclude insects from air cool room.
3. First in, first out product rotation.

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Check air cool room temperature.
2. Check time of product in air cool room.

CORRECTIVE ACTIONS:

1. Remove crabs to temperature-controlled environment.
2. If crabs remain in air cool room for more than 4 hours, evaluate crabs for either recooking or rejection.

RECORDS:

1. Air Cooling Room Storage Form

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review Air Cooking Room Storage Form	Loading dock supervisor

Company Name	Unit Operation
Example Blue Crab Company	Cooked product refrigerated storage

CONTROL POINT:	CRITICAL Yes or No
G. Cooked Crab Cooler	No

HAZARD OR DEFECT:

1. Decomposition
2. Improper temperature
3. Cross contamination

CRITICAL LIMIT:

1. Environment
   a. Ambient temperature (45 ° F recommended)
      1) The temperature should not exceed a maximum of 45° F for more than 12 continuous hours.
      2) The cooler temperature should not go below 28° F minimum for more than 2 continuous hours.
2. Crabs should not be held for more than 72 hours.

PREVENTIVE MEASURES:

1. Train employees in

   a. Proper temperature control
   b. Proper storage
   c. Proper protection from contamination
   d. Proper sanitation procedures
   e. Proper calibration of thermometer

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Check temperature in cooked crab cooler.

CORRECTİVE ACTIONS:

1. Environment
   a. Ambient temperature (45 ° F recommended).
      I) If 45 ° F is exceeded for more than 12 continuous hours, the crabs will be processed as soon as possible.
      2) If temperature goes below 28°F for more than 2 continuous hours, the crabs will be either immediately processed or moved into a temperature-controlled environment.
   b. A maximum holding time of 72 hours is recommended.
      1) If the maximum holding time of 96 hours is exceeded, the crabs will be either discarded or recooked and picked within 24 hours.
   c. Recook or reject cross-contaminated product.

RECORDS:

1. Cooked Crab Storage Form
2. Temperature Log of Freezers and Cooling Units Form

VERIFICATION-PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review records	Loading dock supervisor

Company Name

Example Blue Crab Company

Unit Operation

Picking crabs manually

CONTROL POINT:

H. Picking Room

CRITICAL Yes or No

Yes

HAZARD OR DEFECT:

1. Bacterial contamination (product and equipment)
2. Excess shell or extraneous material
3. Time/temperature abuse
4. Equipment sanitation

CRITICAL LIMIT:

1. Picked product should not remain in the picking room for more than 4 hours
2. 170 ppm minimum quat in sanitizing solution

PREVENTIVE MEASURES:

1. Ensure proper personal hygiene.
2. Emphasize sanitation and hygiene training.
3. Establish maximum limits for presence of shell and foreign material in product.
4. Establish procedures for proper cleaning and sanitizing of equipment during and after operation.
5. Ensure proper food handling practice.
6. Monitoring of hand dips and foot baths.
7. Limit time cooked crabs are out of refrigerator.

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Frequent inspection of personnel, equipment, and products.
2. Audit of sanitation records (check lists, hand dips, foot baths).
3. Ensure proper weigh-ups.
4. Periodic biological (microbial) monitoring of product and environment.
5. Check concentrations of sanitizing solutions.

CORRECTIVE ACTIONS:

1. Product remaining in the picking room for more than 4 hours will be subjected to an appropriate thermal process.
2. Replace sanitizing solutions having concentrations below established concentration level.
3. Discard contaminated meat.
4. Increase meat weigh-up frequency and decrease time crab meat remains without refrigeration.

RECORDS:

1. Sanitizer Dip Checks Form - Picking Room
2. Sanitizer Hand Dip Checks Form - Picking Room
3. Sanitation Check Sheet
4. Production Sanitation Check Sheet

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Resnonsible
1. Review records	Picking room supervisor
2. Review product quality control results	

Company Name

Example Blue Crab Company

Unit Operation

Product Packaging

CONTROL POINT:

I. Packing Room

CRITICAL Yes or No

Yes

HAZARD OR DEFECT:

1. Incorrect weight
2. Microbial contamination (product and equipment)
3. Excessive shell or extraneous material
4. Improper container (bag, cup, can) seals
5. Improper labeling
6. Improper or inadequate equipment sanitation
7. Time/temperature abuse

CRITICAL LIMIT:

1. 2 hours maximum for packed product to reach 40° F or less
2. Correct weight ± 1.0%
3. 170 ppm minimum quat in sanitizer solution
4. Container seam specifications adequately met
5. Product exceeding state and federal microbial action levels or tolerances

PREVENTIVE MEASURES:

1. Scale calibration.
2. Proper sealing machine adjustments and calibrations.
3. Proper product labeling.
4. Proper personal hygiene.
5. Proper monitoring of hand dips and foot baths.
6. Establish maximum tolerances for shell and extraneous material.
7. Establish procedures for proper cleaning and sanitation of equipment during and after operation.
8. Train employees on sanitation and hygiene practices.
9. Limit time crab meat is above 40°F, pack into wet ice as soon as possible.

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Frequently inspect personnel, equipment, and products.
2. Audit sanitation records (check list, hand dips, and foot baths).
3. Ensure proper amount of product is in container.
4. Check scales and calibration.
5. Check concentrations of sanitizing solutions.
6. Periodically monitor (biological/microbial) both product and environment.
7. Ensure proper product temperature
8. Ensure proper label

CORRECTIVE ACTIONS:

1. If the temperature does not reach 4O°F or less within 2 hours, the product will be subjected to an appropriate thermal process (see Chapter 7).
2. Discard contaminated meat.
3. Repack containers for correct weight.
4. Replace sanitizing solutions having concentrations below established concentration level.
5. Decrease time crab meat remains without refrigeration.
6. Increase sanitation of equipment, utensils, and hands.

RECORDS:

1. Packed Product Thermometer Calibration Form
2. Pasteurized Can Seam Visual Inspection Form
3. Double Seam Evaluation Form
4. Bag Sealing Integrity Test Form
5. Bag Sealing Integrity Test Form Performed Before Pasteurization or Listericidal Process
6. Bag Integrity Visual Evaluation Form
7. Production Sanitation Check Sheet
8. Product Weight Check Form
9. Repacked Re-processed 1 lb. Can Integrity Failure Form
10. Repacked Re-processed 5 lb Bag Integrity Failure Form
11. Sanitizer Dip Checks Form - Packing Room
12. Sanitizer Hand Dip Checks Form - Packing Room
13. Scale Calibration Form

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review records	Packing room supervisor

Example - For Illustrative Purposes Only

HACCP PLAN

Company Name	**Unit Operation**
Example Blue Crab Company	Processed product refrigerated storage

CONTROL POINT:	**CRITICAL Yes or No**
J. Packed Product Refrigeration Room	No

HAZARD OR DEFECT:

1. Decomposition
2. Improper temperature

CRITICAL LIMIT:

Product

1. Time/Temperature (recommended optimum 32-34°F, not to exceed 40°F)
   a. The temperature should not exceed 40° F for more than 12 continuous hours.
   b. The temperature should not go below 28°F for more than 2 continuous hours.

PREVENTIVE MEASURES:

1. First in, first out product rotation.
2. Control storage temperature.
3. Train workers to check temperature.

MONITORING PROCEDURES:

1. Review Temperature Log of Freezers and Cooling Units Form
2. Check length of time in storage
3. Temperature alarm
4. Visually examine of ice on crab meat containers
5. Recording thermometer

CORRECTIVE ACTIONS:

Product

1. If the temperature exceeds 40° F for more than 4 continuous hours or 60° F for 1 hour, the product will be subjected to an appropriate thermal process (see Chapter 7) or discarded.
2. Discard decomposed meat.
3. Re-ice crab meat in containers.

Environment

1. If the temperature exceeds 40° F for more than 6 continuous hours or 70° F for more than 1 hour, the product will be subjected to an appropriate thermal process (see Chapter 7) or discarded.
2. If the temperature goes below 28° F for more than 2 continuous hours, the product will be immediately moved into a temperature controlled environment.
3. If the product is iced and the temperature exceeds 40° F for more than 12 continuous hours or if the product is uniced and the temperature exceeds 40° F for more than 6 continuous hours or 70° F for more than 1 hour, the product will be subjected to an appropriate thermal process (see Chapter 7) or discarded.

RECORDS:

1. Temperature Log of Freezers and Cooling Units Form

Example - For Illustrative Purposes Only

HACCP PLAN

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review Temperature Log of Freezers and Cooling Units Form	Packing room supervisor

Company Name

Example Blue Crab Company

Unit Operation

Product shipping

CONTROL POINT:

K. Shipping

CRITICAL Yes or No

No

HAZARD OR DEFECT:

1. Improper temperature

CRITICAL LIMIT:

1. All fresh product will be maintained in wet ice for shipment.
2. Cross contamination (ice)

PREVENTIVE MEASURES:

1. Maintain shipping container integrity.
2. Maintain ice in containers.
3. Use ice manufactured with approved water supply.
4. Minimize time product remains on dock.

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Visually examine of shipping containers
2. Ensure ice manufacturer used approved water supply.

CORRECTIVE ACTIONS:

1. Re-ice crab meat in containers.

RECORDS:

1. Product Evaluation Form

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review Product Evaluation Form	Packing room supervisor

Company Name	Unit Operation
Example Blue Crab Company	Delivery vehicle

CONTROL POINT:	CRITICAL Yes or No
L. Truck	No

HAZARD OR DEFECT:

1. Improper temperature
2. Loss in shipping container integrity

CRITICAL LIMIT:

1. Meat temperature should be maintained between 28° F and 36 F° during shipment.

PREVENTIVE MEASURES:

1. Ship and maintain fresh product in wet ice.
2. Pack pasteurized product in wet ice and/or shipped in a refrigerated truck.
3. Maintain sanitation of transportation unit.

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Visual observation of ice in crab meat containers
2. Temperature checks of non-iced product

CORRECTIVE ACTIONS:

1. Re-ice crab meat in container
2. Ice un-iced product to achieve proper temperature

RECORDS:

None

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review customer complaint file	Packing room supervisor

Company Name

Example Blue Crab Company

Unit Operation

Claw removal and storage

CONTROL POINT:

M. Claws

CRITICAL Yes or No

No

HAZARD OR DEFECT:

1. Time/temperature abuse
2. Decomposition
3. Microbial contamination
4. Excessive storage time

CRITICAL LIMIT:

Product

1. The temperature should not exceed 45° F for 6 continuous hours or 70°F for 1 hour after processing (removal from the crab body).
2. All claws should be processed within 72 hours after removal from the crab body.

Environment

1. The temperature should not exceed 45° F for 8 continuous hours or 80° F for 1 hour after processing (removal from the crab body).

PREVENTIVE MEASURES:

1. Maintain proper personal hygiene.
2. Emphasize sanitation and hygienic training.
3. Establish procedures for proper cleaning and sanitizing of equipment during and after operation.
4. Maintain proper temperature during storage.
5. Store for proper period of time only.
6. First in, first out product rotation.

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Frequent inspection of personnel, equipment, and product.
2. Check length of time in storage.
3. Review Temperature Log of Freezers and Cooling Units Form.

CORRECTIVE ACTIONS:

Product

1. If 45 °F is exceeded for more than 4 continuous hours or 70° F for 1 hour after processing, the product will be subjected to an appropriate thermal process (Chapter 7).
2. Claws not processed within 96 hours after removal from the crab body will be discarded.

Environment

1. If the temperature exceeds 45° F for more than 8 continuous hours or 80° F for 1 hour, the product shall be reprocessed.

RECORDS:

None

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Periodic microbiological sampling	Picking room

Company Name	Unit Operation
Example Blue Crab Company	Mechanical claw picking

CONTROL POINT:	CRITICAL: Yes or No
N. Mechanical Claw Picking Room	Yes --

HAZARD OR DEFECT:

1. Improper brine concentration
2. Improper brine temperature
3. Excessive shell or extraneous material
4. Microbial contamination (product and equipment)
5. Improper labeling
6. Incorrect weight
7. Excessive water content
8. Improper container (bag, cup, can) seals

CRITICAL LIMIT:

1. The brine solution should not be used for more than 6 hours without replacement.
2. The brine temperature should not exceed 80° F.
3. Two hours maximum for product to reach 40° F or less.
4. Correct weight ± 1.0%.
5. 170 ppm minimum quat in sanitizer solution.
6. Container seam specifications should not be exceeded.
7. Product exceeding state and federal microbial action levels or tolerances.

PREVENTIVE MEASURES:

1. Limit time crab meat is above 40° F; pack into wet ice as soon as possible.
2. Establish maximum tolerances for shell and extraneous material.
3. Label product properly.
4. Calibrate scale.
5. Maintain proper personal hygiene.
6. Establish procedures for proper cleaning and sanitation of equipment during and after operation.
7. Monitor hand dips and foot baths.
8. Train employees in sanitation hygiene.
9. Minimize time between product packing and refrigeration and/or icing.
10. Establish maximum tolerance of water pick-up.

Example - For Illustrative Purposes Only

HACCP PLAN

MONITORING PROCEDURES:

1. Frequently inspect personnel, equipment, and product.
2. Audit sanitation records (check list, hand dips, and foot baths).
3. Check salt concentration with salinometer and review Brine Concentration Log.
4. Periodically check product and environment for biological (microbial) contamination.
5. Check scales and calibration.
6. Ensure proper product temperature.
7. Ensure proper label.
8. Ensure proper amount of product is in container.
9. Check concentrations of sanitizing solutions.

CORRECTIVE ACTIONS:

1. If the temperature does not reach 40° F or less within 2 hours, the product will be subjected to an appropriate thermal process (see Chapter 7).
2. Discard contaminated meat.
3. Repack containers for correct weight.
4. Replace sanitizing solution having concentrations below established concentration level.
5. Increase sanitation of equipment, utensils, and hands.
6. Decrease time crab meat and claws remain without refrigeration.

RECORDS:

1. Packed Product Thermometer Calibration Form
2. Bag Sealing Integrity Test Form
3. Bag Sealing Integrity Test Form Performed Before Pasteurization or Listericidal Process
4. Bag Integrity Visual Evaluation Form
5. Scale Calibration Form
6. Sanitizer Dip Checks Form - Claw Room
7. Sanitizer Hand Dip Checks Form - Claw Room
8. Production Sanitation Check Sheet
9. Sanitation Check Sheet
10. Product Weight Check Form
11. Harris Claw Machine Brine Concentration Form

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review records	Mechanical picking room supervisor

Example - For Illustrative Purposes Only

HACCP PLAN

Company Name	**Unit Operation**
Example Blue Crab Company	Waste disposal areas

CONTROL POINT	**CRITICAL Yes or No**
0. Solid Waste Areas	No

HAZARD OR DEFECT:

1. Microbial contamination of personnel and equipment
2. Pests
   a. rodents
   b. insects
   c. birds
   d. domestic animals

CRITICAL LIMIT:

1. Ensure adequate water drainage.

PREVENTIVE MEASURES:

1. Control birds to the extent allowed by law.
2. Use insecticides and rodenticides properly.
3. Use sanitizers properly.
4. Eliminate domestic (cats and dogs) animals from premises.
5. Establish sanitary procedures for employees and equipment which visit solid-waste disposal areas.
6. Train employees for proper handling of insecticides and rodenticides.
7. Establish comprehensive pest control program.

MONITORING PROCEDURES:

1. Visual checks of waste disposal areas.
2. Proper supervision of pest control program.

CORRECTIVE ACTIONS:

1. Solid waste areas should be graded to drain and maintained to ensure adequate drainage.
2. Employ contract pest control firm or waste disposal firm if necessary to maintain proper sanitation of area.

RECORDS:

1. Retain receipts from contract pest control firm.
2. Retain copy of "Pesticide Applicator Certificate" of firm personnel applying controlled substances.

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review records	Picking room supervisor

Example - For Illustrative Purposes Only

HACCP PLAN

Company Name	**Unit Operation**
Example Blue Crab Company	Pasteurization/ Listericidal processes

CONTROL POINT:	**CRITICAL: Yes or No**
P. Pasteurization/Thermal Processes	Yes

HAZARD OR DEFECT:

1. Microbial contamination of containers due to leaks.
2. Inadequate process schedule established (heating and cooling).
3. Improper chlorination of cooling water.
4. Inadequate process performed (heating and cooling).

CRITICAL LIMIT:

1. Pasteurization F_{16}^{185} = 31 minimum process schedule.
2. Listericidal Process
   a. initial meat temperature 32-59° F, process 120 minutes at water bath temperature of 187- 190 ° F.
   b. initial meat temperature >5O° F, process 90 minutes at water bath temperature of 187-190 °F.

PREVENTIVE MEASURES:

1. Initiate can and/or bag seam inspection program.
2. Control time/temperature process.
3. Require operator to attend approved pasteurization course.

MONITORING PROCEDURES:

1. Review
   Pasteurization Thermometer Calibration Form
   Pasteurization or Listericidal Process Form
   Pasteurization Cooling Process Form
   Pasteurized Can Seam Visual Inspection Form
   Double Seam Evaluation Form
   Bag Sealing Integrity Test Form
   Bag Sealing Integrity Test Form Performed Before Pasteurization or Listericidal Process
   Bag Integrity Visual Evaluation Form
   Repacked-Reprocessed 1 lb. Can Integrity Failure Form
   Repacked-Reprocessed 5 lb. Bag Integrity Failure Form
2. Visual observation of water quality in cooking tank
3. Periodic biological (microbial) monitoring of product

CORRECTIVE ACTIONS:

1. Reprocess crab meat if improper thermal process applied.
2. Repack and reprocess product having defective seams.
3. Increase chlorine concentration in cooling tank.

RECORDS:

1. Review
   Pasteurization Thermometer Calibration Form
   Pasteurization or Listericidal Process Form
   Pasteurization Cooling Process Form
   Pasteurized Can Seam Visual Inspection Form
   Double Seam Evaluation Form
   Bag Sealing Integrity Test Form
   Bag Sealing Integrity Test Form Performed Before Pasteurization or Listericidal Process
   Bag Integrity Visual Evaluation Form
   Repacked-Reprocessed 1 lb. Can Integrity Failure Form
   Repacked-Reprocessed 5 lb. Bag Integrity Failure Form

VERIFICATION PROCEDURE/PRODUCT(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review all forms	Thermal process supervisor
2. Review product quality reports from state and federal health regulatory agencies	

Example - For Illustrative Purposes Only

HACCP PLAN

Company Name	**Unit Operation**
Example Blue Crab Company	Processed Product frozen storage

CONTROL POINT:	**CRITICAL: Yes or No**
Q. Freezer	No

HAZARD OR DEFECT:

1. Improper temperature maintenance
2. Product deterioration (oxidation, rancidity, and freezer burn)
3. Product decomposition

CRITICAL LIMIT:

Environment

1. The temperature should not exceed 20° F for more than 8 continuous hours.

PREVENTIVE MEASURES:

1. First in, first out product rotation.
2. Maintain adequate freezer capacity.
3. Institute adequate product code dating system.
4. Pack crab meat properly in containers and placement of containers in freezer.
5. Train workers to check temperature.
6. Control freezer temperature.

MONITORING PROCEDURES:

1. Checks of temperature
2. Review Temperature Log of Freezers and Cooling Units Form
3. Temperature alarms
4. Recording thermometer

CORRECTIVE ACTIONS:

1. If the temperature goes below 20° F for more than 9 continuous hours, the product will be sold as a previously frozen product provided that the temperature did not exceed 40°F for more than 8 hours.
2. If a temperature of 40° F is exceeded for more than 8 hours, product will be discarded.
3. Discard decomposed, spoiled, or freezer-burned product.
4. Sell thawed product as a fresh previously frozen product.

RECORDS:

1. Temperature Log of Freezers and Cooling Units Form

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review Temperature Log of Freezers and Cooling Units Form	Packing room supervisor

Example - For Illustrative Purposes Only

HACCP PLAN

Company Name	**Unit Operation**
Example Blue Crab Company	Quik-Pik Processing

CONTROL POINT:	**CRITICAL: Yes or No**
R. Quik-Pik Room	Yes

HAZARD OR DEFECT:

1. Improper temperature
2. Excessive shell or extraneous material
3. Microbial contamination (product and equipment)
4. Improper labeling
5. Incorrect weight
6. Improper container (bag, cup, can) seals
7. Improper or inadequate equipment sanitation
8. Time/temperature abuse

CRITICAL LIMIT:

1. 2 hours maximum for packed product to reach 40°F or less.
2. Correct weight ± 1.0%.
3. 170 ppm minimum quat in sanitizer solution.

PREVENTIVE MEASURES:

1. Limit time crab meat is above 40° F, pack into wet ice as soon as possible.
2. Establish maximum tolerances for shell and extraneous material.
3. Label product properly.
4. Calibrate scales.
5. Maintain proper personal hygiene.

PREVENTIVE MEASURES: (Continued)

6. Establish procedures for proper cleaning and sanitation of equipment during and after operation.
7. Monitoring hand dips and foot baths.
8. Train employees in sanitation and hygiene.
9. Minimize time between product packing and refrigeration and/or icing.

MONITORING PROCEDURES:

1. Frequent inspections of personnel, equipment, and procedures.
2. Audit of sanitation records (check list, hand dips, and foot baths).
3. Periodic biological (microbial) monitoring of product and environment.
4. Check scales and calibration.
5. Ensure proper product temperature.
6. Ensure proper label.
7. Ensure proper amount of product is in container.
8. Check concentrations of sanitizing solutions.

CORRECTIVE ACTIONS:

1. If the temperature does not reach 40 °F or less within 2 hours, the product will be subjected to an appropriate thermal process (see Chapter 7).
2. Repack containers for current weight.
3. Replace sanitizing solutions having concentrations below established concentration level.
4. Increase sanitation of equipment, utensils, and hands.
5. Decrease time crab meat remains without refrigeration.
6. Discard contaminated meat.

RECORDS:

1. Packed Product Thermometer Calibration Form
2. Bag Sealing Integrity Test Form
3. Bag Sealing Integrity Test Form Performed Before Pasteurization or Listericidal Process
4. Bag Integrity Visual Evaluation Form
5. Scale Calibration Form

Example - For Illustrative Purposes Only

HACCP PLAN

RECORDS (Continued):

6. Sanitizer Dip Checks Form - Quik-Pik Room
7. Sanitizer Hand Dip Checks Form - Quik-Pik Room
8. Production Sanitation Check Sheet
9. Sanitation Check Sheet
10. Product Weight Check Form

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review records	Quik-Pik room supervisor

Company Name	**Unit Operation**
Example Blue Crab Company	Meat Bone Separator

CONTROL POINT:	**CRITICAL Yes or No**
S. Meat Bone Separator	Yes

HAZARD OR DEFECT:

1. Improper temperature
2. Excessive shell or extraneous material
3. Microbial contamination (product and equipment)
4. Improper labeling
5. Incorrect weight
6. Improper container (bag, cup, can) seals
7. Improper or inadequate equipment sanitation
8. Time/temperature abuse

CRITICAL LIMIT:

Product

1. 2 hours maximum for packed product to reach 40° F or less.
2. Correct weight ± 1.0%.

Raw material

1. Crab parts should be processed or refrigerated within 2 hours after removal.
2. 2 hours maximum to reach 40° F or less.

PREVENTIVE MEASURES:

Processed Product

1. Limit time crab meat is above 40° F, pack into wet ice as soon as possible.
2. Establish maximum tolerances for shell and extraneous material.
3. Label properly.
4. Calibrate scales.
5. Maintain proper personal hygiene.
6. Establish procedures for proper cleaning and sanitation of equipment during and after operation.
7. Monitor hand dips and foot baths.

Example - For Illustrative Purposes Only

HACCP PLAN

PREVENTIVE MEASURES (Continued)

8. Train employees in sanitation and hygiene.
9. Minimize time between product packing and refrigeration and/or icing.

Raw Material

1. Reject crab parts if they are not processed or refrigerated within 4 hours after removal.
2. Label product properly.
3. Calibrate scales.
4. Maintain proper personal hygiene.
5. Establish procedures for proper cleaning and sanitation of equipment during and after operation.
6. Monitor hand dips and foot baths.
7. Train employees in sanitation and hygiene.
8. Minimize time between product packing and refrigeration and/or icing.
9. Establish maximum tolerances for shell and extraneous material.

MONITORING PROCEDURES:

1. Frequent inspections of personnel, equipment, and product.
2. Audit of sanitation records (check list, hand dips, and foot baths).
3. Periodic biological (microbial) monitoring of product and environment.
4. Scale check and calibration
5. Ensure proper product temperature
6. Ensure proper label
7. Ensure proper amount of product is in container
8. Check concentration of sanitizing solutions

CORRECTIVE ACTIONS:

1. Product
   a. If the temperature does not reach 40° F or less within 2 hours, the product will be subjected to an appropriate thermal process (see Chapter 7).
2. Raw Material
   a. Crab parts will be rejected if they are not processed or refrigerated within 4 hours after removal.
   b. Crab parts will be rejected if they do not achieve 40°F or less within 4 hours.
3. Discard contaminated meat.
4. Replace sanitizing solutions having concentrations below established concentration level.

CORRECTIVE ACTIONS (Continued)

5. Increase sanitation of equipment, utensils, and hands.
6. Decrease time crab meat and raw material remain without refrigeration.
7. Repack containers for correct weight.

RECORDS:

1. Packed Product Thermometer Calibration Form
2. Bag Sealing Integrity Test Form
3. Bag Sealing Integrity Test Form Performed Before Pasteurization or Listericidal Process
4. Bag Integrity Visual Evaluation Form
5. Scale Calibration Form
6. Sanitizer Dip Checks Form - Meat Bone Separator Room
7. Sanitizer Hand Dip Checks Form - Meat Bone Separator Room
8. Production Sanitation Check Sheet
9. Sanitation Check Sheet
10. Product Weight Check Form

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Procedure	Person(s) Responsible
1. Review records	Meat bone separator room supervisor

NOTE: Chapters 4,6,8, and 9 of the manual have been given corresponding alphabet designations. This uniform lettering system will enable manual users to easily identify all operating policies for a specific unit operation.

Example - For Illustrative Purposes Only

9. Cleaning and Sanitation Programs

NOTICE

The proper selection of cleaners and sanitizers, their concentrations, and the method of application depends on several factors including:

- Nature of the soil.
- Degree of cleaning and sanitation to be achieved.
- Type of cleaning and sanitizing equipment used.
- Type of surface being cleaned - food contact or non-food contact.

An important criterion is the specific kind of material used to fabricate equipment and to construct the facility. Improper cleaners and sanitizers can cause permanent damage to equipment and plant structures. Firms should obtain professional advice from a reputable dealer before purchasing any chemicals.

A firm should develop a plan to ensure proper disposal of all chemicals left over at the end of a cleaning and/or sanitation operation.

A firm should implement a hazard communication program for personnel applying cleaners and sanitizers. Limited and/or long-term skin contact or improper use of sanitizers can result in employee injury.

Note: Rinse all non-stainless steel equipment with fresh water 1/2 hour after sanitizing.

Example - For Illustrative Purposes Only

A. Boat (Raw Product Only)
Independent Contractor

Harvester is Responsible for Maintaining Proper Sanitary Conditions.

Example - For Illustrative Purposes Only

B. Truck (Raw Product Only)
Independent Contractor

Shipper is Responsible for Maintaining Sanitary Conditions.

C. Green Crab Unloading and Loading Areas (Daily)

1. Restrict the movement of personnel entering processing and packing areas directly from loading areas.
2. Dry clean
3. Sanitize under low pressure with 400 ppm quat after each cooking period and at end of operation.
4. Time the flow of green crabs into the cooking area to keep them from coming in contact with the flow of cooked crabs out of the area.

D. Raw Crab Cooler (Daily, Weekly, Monthly, and Annually)

Refrigerator (Daily)

1. Restrict the movement of personnel to processing and packing areas directly from the raw crab cooler.
2. Dry clean.

Refrigerator (Weekly)

1. Dry clean.
2. Clean with a general purpose cleaner using low pressure spray unit.
3. Rinse.
4. Low pressure sanitation using 400 ppm quat.

Evaporator (Annually)

1. Disconnect electricity to the evaporator and lock-out equipment.
2. Manually clean the coils with a brush. Use a general purpose cleaner if necessary.
3. Cover electric control devices and motor if not waterproof.
4. Sanitize under low pressure with 400 ppm quat.
5. Remove protective coverings from electric control devices and motor.
6. Connect electricity to the evaporator.

Drip Pan (Monthly)

- Pour 400 ppm quat into pan.
  DO NOT USE FOAM.

E. Retort Area (Daily)

Area

- Control personnel entering processing and packing areas directly from the cooking area.
- Dry clean.
- Sanitize under low pressure with 400 ppm quat.

Retort

- Remove debris from retort chamber.

Rings and Crab Carts

(See Part AG of this Section - page 9-27)

Foot Bath

- Maintain foot baths with 400 ppm quat to be used by employees entering picking room.

F. Air Cool Room (Daily and Weekly)

Daily Schedule

- Dry clean.
- Sanitize under low pressure with 400 ppm quat.

Weekly Schedule

1. Rinse if required.
2. Clean with a general purpose cleaner using a low pressure spray unit.
3. Rinse.
4. Sanitize under low pressure with 400 ppm quat.

G. Cooked Crab Cooler (Daily, Weekly, Monthly, and Annually)

Refrigerator (Daily)

- Restrict movement of personnel to cooked crab cooler directly from the raw crab area
- Dry clean.

Refrigerator (Weekly).

- Dry clean.
- Clean with a general purpose cleaner using a low pressure spray unit.
- Rinse.
- Sanitize under low pressure using 400 ppm quat.

Evanorator (Annually)

1. Disconnect electricity to the evaporator and lock-out equipment.
2. Manually clean the coils with a brush; use a general purpose cleaner if necessary.
3. Cover electric control devices and motor if not waterproof.
4. Sanitize under low pressure with 400 ppm quat.
5. Remove protective coverings from electric control devices and motor.
6. Connect electricity to the evaporator.

Drip Pan (Monthly)

- Pour 400 ppm quat into pan.
  DO NOT USE FOAM.

Example - For Illustrative Purposes Only

H. Picking Room (Daily and Weekly)

Floor, Splash Zone of Walls, Foot Stools, Paper Towel Holders, Sinks, Tables, Scrap Convevor (Daily)

- Dry clean.
- Low pressure (water temperature less than 140°F) rinse.
- Foam clean with chlorinated alkaline foaming detergent. Allow to penetrate soils (5 minutes).
- Use brush or pad to remove adhering soil (Dedicated and color-coded brush or pad).
- Rinse.
- Sanitize under low pressure with 400 ppm quat.

Note: Clean scrap chute from top to bottom, to prevent recontamination of cleaned surfaces.

Tables During Operations (Daily)

- Sanitize under low pressure with 200 ppm quat at beginning and end of workday.
- Sanitize periodically whenever possible during workday with 200 ppm quat.
- Remove excess sanitizer with a sanitized squeegee or single service disposable towel.

Floor During Operation (Daily)

- Sanitize under low pressure with 400 ppm quat at beginning of work day.

Chairs (Daily)

- Dry clean.
- Low pressure (water temperature less than 140°F) rinse.
- Foam clean with chlorinated alkaline foaming detergent; allow to penetrate soils (5 minutes).
- Use brush or pad to remove adhering soil (Dedicated and color-coded brush or pad).
- Rinse.
- Sanitize under low pressure with 400 ppm quat.

Claw Barrels and Crab Delivery Barrels (After Each Use)

- Dry clean.
- Low pressure (water temperature less than 140° F) rinse.
- Foam clean with chlorinated alkaline foaming detergent.
- Rinse.
- Sanitize under low pressure with 400 ppm quat.

-OR-

- Dry clean.
- Boil in Sodium Hydroxide solution.
- Rinse.

Example - For Illustrative Purposes Only

H. Picking Room (Daily and Weekly) (Continued)

Scrap Barrel (After Each Use)

- Low pressure (water temperature less than 140°F) rinse.
- Sanitize with 400 ppm quat.

Scrap Barrel (Daily)

- Dry Clean.
- Low pressure (water temperature less than 140° F) rinse.
- Foam clean with chlorinated alkaline foaming detergent.
- Rinse.
- Low pressure sanitation with 400 ppm quat.

-OR-

- Dry clean.
- Boil in Sodium Hydroxide solution.
- Rinse.

Packed Product Cans and Cups

- Sanitize with 200 ppm quat.

Foot Baths

- Maintain foot baths with 400 ppm quat to be used by employees entering picking area.

Example - For Illustrative Purposes Only

I. Packing Room (Periodically, Daily, and Weekly)

Packing Table and Scale (Periodically - When Empty, Optimally After Each Weigh Up)

- Empty the table as often as practical.
- Rinse with 200 ppm quat.
- Remove excess water after sanitizing with a single service disposable towel.

Packing Table. Scale. Weigh Window. Sinks. Paper Towel Holders (Daily)

- Dry clean.
- Rinse under low pressure (water temperature less than 140° F).
- Foam clean with chlorinated alkaline foaming detergent. Allow to penetrate soils (5 minutes).
- Use brush or pad to remove adhering soil (Dedicated and color-coded brush or pad).
- Rinse.
- Sanitize under low pressure with 200 ppm quat.
- Sanitize sinks under low pressure with 400 ppm quat.

Film Sealing Machines (Daily, When In Use)

- Wipe clean with a single service disposable towel.
- Sanitize with 200 ppm quat at end of day and before use.

Canning Machine (Daily, When In Use)

- Wipe clean with a single service disposable towel.
- Sanitize under low pressure with 400 ppm quat.

Cans. Cups, Bags

- Sanitize with 200 ppm quat.

Floors. Splash Zone of Walls. Paper Towel Holders. Sinks. Tables (Daily)

- Dry clean.
- Rinse under low Pressure (water temperature less than 140°F).
- Foam clean with chlorinated alkaline foaming detergent. Allow to penetrate soils (5 minutes).
- Use brush or pad to remove adhering soil. (Dedicated and color-coded brush or pad).
- Rinse.
- Sanitize under low pressure with 400 ppm quat.

Foot Baths

- Maintain foot baths with 400 ppm quat to be used by employees entering packing room.

J. Fresh and Packed Product Refrigeration Room (Weekly, Monthly, and Annually)

Weekly
- Inspect area and check product.

Monthly
- Dry clean, if necessary.
- Rinse (if required).
- Sanitize under low pressure with 400 ppm quat.

Annually Or As Required
- Dry clean.
- Rinse (if required).
- Clean with a general purpose cleaner using a low pressure spray unit.
- Rinse.
- Sanitize under low pressure with 400 ppm quat.

Evaporator (Annually)
1. Disconnect electricity to the evaporator and lock-out equipment.
2. Manually clean the coils with a brush; use a general purpose cleaner if necessary.
3. Cover electric control devices and motor if not water proof.
4. Sanitize under low pressure with 400 ppm quat.
5. Remove protective coverings from electric control devices and motor.
6. Connect electricity to the evaporator.

Drip Pan (Monthly)
- Pour 400 ppm quat into pan.
  DO NOT USE FOAM.

K. Shipping (Daily)

1. Restrict movement of personnel to picking and packing areas directly from the shipping area.
2. Dry clean.
3. Sanitize under low pressure with 400 ppm quat.

L. Truck (Daily Or As Necessary When In Use)

1. Dry clean.
2. Rinse (if required).
3. Clean with a general purpose cleaner using a low pressure spray unit.
4. Rinse.
5. Sanitize under low pressure with 400 ppm quat.

Example - For Illustrative Purposes Only

M. Claws

See Picking Room and Mechanical Claw Picking Room, Pages 9-10, 9-11; 9-17, 9-18.

N. Mechanical Claw Picking Room (Daily or When In Use)

Processing Eauioment
- Dry clean.
- Rinse (if required).
- Clean with a general purpose cleaner using a low pressure spray unit.
- Rinse.
- Sanitize under low pressure with 400 ppm quat.

Inspection Belt (At All Production Breaks)
- Rinse

Floor (During Operation)
- Sanitize under low pressure with 400 ppm quat at beginning of workday.

Table (During Operation)
- Rinse.
- Low pressure sanitize with 200 ppm quat at beginning of workday and at mid-shift.

Floor, Tables, Splash Zone of Walls, Sinks, Scrap Conveyor (Daily)
- Dry clean.
- Rinse under low pressure (water temperature less than 140° F).
- Foam clean with chlorinated alkaline foaming detergent. Allow to penetrate soils (5 minutes).
- Use brush or pad to remove adhering soil (Dedicated and color-coated brush or pad).
- Rinse.
- Low pressure sanitize with 400 ppm quat.

Note: Clean scrap chute from top to bottom to prevent recontamination of cleaned surfaces.

Foot Baths
- Maintain foot baths with 400 ppm quat to be used by employees entering picking area.

Scrap Barrel (After Each Use)
- Rinse under low pressure (water temperature less than 140°F).
- Sanitize with 400 ppm quat.

Scrap Barrel (Daily)
- Dry clean.
- Rinse under low pressure (water temperature less than 140° F).
- Foam clean with chlorinated alkaline foaming detergent.
- Rinse.
- Low pressure sanitation with 400 ppm quat.

-OR-

- Dry clean.
- Boil in Sodium Hydroxide solution.

- Rinse.

N. Mechanical Claw Picking Room (Daily or When In Use) (Continued)

Claw Containers (After Each Use)

- Dry clean.
- Rinse under low pressure (water temperature less than 140° F).
- Foam clean with chlorinated alkaline foaming detergent.
- Rinse.
- Low pressure sanitize with 400 ppm quat.

-OR-

- Dry clean.
- Boil in Sodium Hydroxide solution.
- Rinse.

0. Solid Waste Areas (Daily and Weekly)

Foot Baths

- Use foot baths with 400 ppm quat prior to entering processing areas.

Scrap Chute (Daily)

- Dry clean.
- Rinse under low pressure (water temperature less than 140° F).
- Foam clean with chlorinated alkaline foam detergent. Allow to penetrate soils (5 minutes).
- Use brush or pad to remove adhering soil (Dedicated and color-coded brush or pad).
- Rinse.
- Low pressure sanitize with 400 ppm quat.

Note: Clean chute from top to bottom to prevent recontamination of cleaned surfaces.

Waste Area Container Pads (Weekly)

- Dry clean.
- Low pressure (water temperature less than 140° F) rinse.
- Foam clean with chlorinated alkaline foam detergent. Allow to penetrate soils (5 minutes).
- Rinse.
- Low pressure sanitize with 400 ppm quat.

Waste Area Container Pad (Daily)

- Dry clean.
- Rinse under low pressure (water temperature less than 140° F).
- Low pressure sanitize with 400 ppm quat.

P. Pasteurization/Thermal Process (Daily or Annually)

Daily

- Remove debris from heating and cooling vats.

Annually Or As Needed

- Dry clean.
- Foam clean with chlorinated alkaline foaming detergent. Allow to penetrate soils (5 minutes).
- Use brush or pad to remove adhering soil (Dedicated and color-coded brush or pad).
- Rinse.
- Low pressure sanitize with 400 ppm quat.

Periodically

- Dry clean.
- Rinse (if necessary).
- Use a brightener to remove mineral scales.
- Rinse.

Q. Freezer (Weekly and Annually)

Freezer (Weekly)
- Inspect area and check product.

Freezer (Annually Or As Required)
- Dry clean.
- Rinse if required.
- Clean with a general purpose cleaner using a low pressure spray unit.
- Rinse.
- Low pressure sanitize with 400 ppm quat.

Evaporator (Annually Or As Required)
1. Disconnect electricity to the evaporator and lock-out equipment.
2. Manually clean the coils with a brush. Use a general purpose cleaner if necessary.
3. Cover electric control devices and motor if not waterproof.
4. Low pressure sanitize with 400 ppm quat.
5. Remove protective coverings from electric control devices and motor.
6. Connect electricity to the evaporator.

Drip Pan (Annually Or As Required)
- Pour 400 ppm quat into pan.
  DO NOT USE FOAM.

R. Quik-Pik Room

Equipment
- Dry clean.
- Rinse (if required).
- Clean with a general purpose cleaner using a low-pressure spray unit.
- Rinse.
- Low pressure sanitize with 400 ppm quat.

Inspection Belt (At All Production Breaks)
- Rinse.

Floor (During Operation)
- Low pressure sanitize with 400 ppm quat at beginning of workday.

Table (During Operation)
- Rinse.
- Low pressure sanitize with 200 ppm quat at beginning of workday and at mid-shift.

Floor, Tables, Splash Zone of Walls, Sinks, Scrap Conveyor (Daily)
- Dry clean.
- Rinse under low pressure (water temperature less than 140°F).
- Foam clean with chlorinated alkaline foaming detergent. Allow to penetrate soils (5 minutes).
- Use brush or pad to remove adhering soil (Dedicated and color-coated brush or pad).
- Rinse.
- Low pressure sanitize with 400 ppm quat.

Note: Clean scrap chute from top to bottom to prevent recontamination of cleaned surfaces.

Foot Baths
- Use and maintain foot baths with 400 ppm quat prior to entering picking areas.

Scrap Barrel (Daily)
- Dry clean.
- Rinse under low pressure (water temperature less than 140° F).
- Foam clean with chlorinated alkaline foaming detergent.
- Rinse.
- Low pressure sanitize with 400 ppm quat.

-OR-

- Dry clean.
- Boil in Sodium Hydroxide solution.
- Rinse.

R. Quik-Pik Room (Continued)

Claw Container (after each use)

- Dry clean.
- Rinse under low pressure (water temperature less than 140° F).
- Foam clean with chlorinated alkaline foaming detergent.
- Rinse.
- Low pressure sanitize with 400 ppm quat.

-OR-

- Dry clean.
- Boil in Sodium Hydroxide solution.
- Rinse.

S. Meat-Bone Separator

Equipment
- Dry clean.
- Rinse under low pressure (water temperature less than 140°F).
- Foam clean with chlorinated alkaline foaming detergent. Allow to penetrate soils (5 minutes).
- Rinse.
- Low pressure sanitize with 200 ppm quat.

Floor (During Operation
- Low pressure sanitize with 400 ppm quat at beginning of workday.

Table (During Operation)
- Rinse.
- Low pressure sanitize with 200 ppm quat at beginning of workday and at mid-shift.

Floor. Splash Zone of Walls. Sinks. Tables (Daily)
- Dry clean.
- Rinse under low pressure (water temperature less than 140 ° F).
- Foam clean with chlorinated alkaline foaming detergent. Allow to penetrate soils (5 minutes).
- Use brush or pad to remove adhering soil (Dedicated and color-coated brush or pad).
- Rinse.
- Low pressure sanitize with 400 ppm quat.

Note: Clean scrap chute from top to bottom to prevent recontamination of cleaned surfaces.

Foot Baths
- Use and maintain foot baths with 400 ppm quat prior to entering processing areas.

Scrap Barrel (After Each Use)
- Rinse under low pressure (water temperature less than 140°F).
- Sanitize with 400 ppm quat.

Scrap Barrel (Daily)
- Dry clean.
- Rinse under low pressure (water temperature less than 140° F).
- Foam clean with chlorinated alkaline foaming detergent.
- Rinse.
- Low pressure sanitize with 400 ppm quat.

-OR-

- Dry clean.
- Boil in Sodium Hydroxide solution.
- Rinse.

T. Retail Sales

- Observe local and state regulations concerning retail foods stores.

U. Utensils (Knives), and Appropriate Personal Equipment (Gloves and Aprons) (Daily Or As Needed)

Personal Equipment
- Rinse using a single-service, disposable towel if required.
- Sanitize with 200 ppm quat.

Utensils (as knives)
- Rinse.
- Clean with general purpose cleaner.
- Sanitize with 200 ppm quat.
- Allow to drain or dry with a single-service, disposable towel.

V. Hand Dip Stations

- Use 200 ppm quat.
- Change when concentration is less than 170 ppm as measured with a test strip (Q 10 strip), or replace on an hourly basis or other scheduled basis.

W. Picking Bowls

Daily
1. Rinse.
2. Clean with general purpose cleaner.
3. Sanitize with 200 ppm quat.
4. Allow to drain for at least 1 minute.
5. Store properly.

After Each Use
1. Rinse.
2. Sanitize with 200 ppm quat.

X. Brushes and Pads Used Within Production Facility (Daily)

1. Use dedicated and color-coded brushes when possible.
2. Sanitize with 200 ppm quat (Totally immersed when possible).
3. Allow to air dry.
4. Store properly.
5. During operations store in 200 ppm quat (Totally immersed when possible).

Y. Shovels, Except Ice Shovel (After Each Use)

- Rinse.

Y. Shovels, Except Ice Shovel (After Each Use) (Continued)

- Immerse shovels in 200 ppm quat when not in use.

Z. Hand Trucks and Dollies (Daily)

Sanitize Whenever Entering A Processing Area From The Green Crab Or Outside Area

- Rinse (if necessary).
- Sanitize with 400 ppm quat.

Color-Code Hand Trucks and Dollies

Suggested Colors

Green - Raw crab areas
Red - Picking or processing areas
Blue - Packing and finished product areas

AA. Wails, Doors, Strip Curtains (Daily and Weekly)

Daily (Below Soil Level)

- Rinse under low pressure (water temperature less than 140 °F)
- Foam clean with chlorinated alkaline foaming detergent. Allow to penetrate soils (5 minutes).
- Rinse.
- Low pressure sanitize with 400 ppm quat.

Weekly or When Necessary (Above Soil Level)

- Rinse under low pressure (water temperature less than 140° F).
- Foam clean with chlorinated alkaline foaming detergent. Allow to penetrate soils (5 minutes).
- Rinse.
- Low pressure sanitize with 400 ppm quat.

AB. Ceilings and Air Vents (Yearly or When Necessary)

- Manually clean.
- Foam clean with a general-purpose cleaner if possible.
- Rinse.
- Low pressure sanitize with 400 ppm quat.

AC. Lights (Yearly or When Necessary)

- Manually clean the lights.
- Use caution to prevent electric shock. Disconnect the electricity if necessary.
- Remove light lens and clean with a general purpose cleaner.
- Rinse.
- Rinse with 400 ppm quat.

AD. Ice Bin and Shovel

Ice Bin (Yearly or When Necessary)
- Manually clean.
- Foam clean with a general purpose cleaner if possible.
- Rinse with 200 ppm quat.
- Low pressure sanitize with 200 ppm quat.

Shovel (Daily)
- Rinse.
- Low pressure sanitize with 200 ppm quat.

AE. Foot Baths

- Use 400 ppm quat.
- Change when the concentration is less than 170 ppm as measured with a test strip (Q 10 strip) or change on a scheduled basis. Schedule will change according to the volume of crabs processed.

AF. Drains

- Use a quat or chlorine ring where possible.
- When it is not possible to use a ring, pour a 400 ppm quat solution into each drain on a weekly basis.

AG. Crab Rings and Carts

Daily
- Dry clean.
- Rinse under low pressure (less than 140°F).
- Low pressure sanitize with 400 ppm quat.
- Store under protective cover.

Yearly or When Necessary
- Dry clean.
- Rinse under low pressure (less than 140°F).
- Foam clean with chlorinated alkaline foaming detergent.
- Rinse.
- Low pressure sanitize with 400 ppm quat.

- O R -

- Dry clean.
- Boil in Sodium Hydroxide solution.
- Rinse.

AH. Water (Well)

Adhere to Virginia Department of Health Regulations.

Example - For Illustrative Purposes Only

10. Cleaning and Sanitation Verification Protocol

1. PRODUCT TESTING

Product testing consists of evaluating or verifying the following components:

- Process Integrity
- Post-Processing Quality
- Final Product Quality

Effectiveness in eliminating Listeria monocytogenes.
One pound of fresh crab meat will be examined each operating month to determine if Listeria monocytogenes is present. If that organism is found, product placed in distribution will be recalled, the plant thoroughly cleaned and sanitized, the cleaning and sanitizing program reviewed, and a review conducted of employee practices. An employee training program related to the event will be conducted.

Effective Product Quality and Safety Management.
In addition to performing a Listeria monocytogenes analysis, other microbiological analyses will be conducted on the crab meat. These include:

- Total Aerobic Plate Count (mesophilic)
- Fecal Coliform Count

The tests will be performed monthly at the beginning and end of the crab season and semi-monthly during the active crab season. Any counts in excess of established tolerances will result in a review of cleaning and sanitizing programs as well as of employee hygiene.

2. ENVIRONMENTAL TESTING

Environmental testing will be divided into two categories: food and non-food contact surfaces.

Food Contact Surfaces - A Listeria monocytogenes analysis will be performed at least twice a year from the following food contact surfaces:

- 2 picking table
- 1 packing table
- 1 picking pan
- 1 claw barrel

A positive sample will result in an immediate review of the cleaning and sanitizing program and employee hygiene and increased testing for Listeria monocytogenes in the final product.

Example - For Illustrative Purposes Only

Total Aerobic Plate Count Sample.

Total plate count samples will be performed a minimum of once a week using one or more of the following methods: Petrifilm, DuCheck plates, swab, Rodac Plates, or other convenient method. The following surfaces will be analyzed:

- 2 picking tables
- 1 packing table
- 2 picking pans
- 1 claw barrel

Excessive counts on the film or plates (more than 50 per square inch) will indicate the need for improved employee training and/or cleaning and sanitizing procedures.

Non-Food Contact Surfaces

1. A Listeria monocytogenes analysis will be performed a minimum of twice during the crab season on the following non-food contact surfaces:

   - 1 floor, picking room
   - 1 floor, packing room
   - 1 strip curtain
   - 1 underside table
   - 1 underside sink
   - 1 scrap barrel
   - 1 wall picking or packing room

   Occasionally some of these samples will test positive for Listeria monocytogenes. If so, a review should be made to determine whether any contamination is within an acceptable level. If found to be unacceptable, the cleaning and sanitation program will be reviewed as well as general operating procedures. Testing will also be increased as necessary until satisfactory samples are obtained.

2. Total Aerobic Plate Count Samples

   Total aerobic plate count samples will be performed weekly using one or more of the following methods: Petrifilm, DuCheck Plates, swab, or Rodac Plates. The following surfaces will be analyzed:

Example - For Illustrative Purposes Only

- 1 floor, picking room
- 1 floor, packing room
- 1 strip curtain
- 1 underside table
- 1 underside sink
- 1 scrap barrel
- 1 wall picking room
- 1 wall packing room
- 1 wall cooked crab cooler room

Excessive growth on the film or plates (more than 50 per square inch) will indicate the need for improved training or cleaning and sanitizing procedures, or both.

The testing frequency will be increased as appropriate until the problem is identified and corrected.

TESTING AND VERIFICATION SCHEDULE

(Frequency of Testing)

	MARCH	APRIL	MAY	JUNE	JULY	AUGUST	SEPT	OCT	NOV
1. PRODUCT TESTING									
A. Listeria monocytogenes	1	1	1	1	1	1	1	1	1
B. Total Aerobic Plate Count	1	1	1	2	2	2	2	1	1
C. Fecal Coliform Count	1	1	1	2	2	2	2	1	1
2. Environmental Testing									
A. Food Contact Surfaces									
i. Listeria monocytogenes	1			1	1	1	1	1	
ii. Total Aerobic Plate Count	4	4	4	4	4	4	4	4	4
B. Non-Food Contact Surfaces									
i. Listeria monocytogenes	1			1	1	1	1		
ii. Total Aerobic Plate Count	4	4	4	4	4	4	4	4	4

VIRGINIA DEPARTMENT OF HEALTH
DIVISION OF SHELLFISH SANITATION
CRUSTACEA PLANT INSPECTION FORM

Plant Name: | Plant Certification Number: | Date:

Articles: 1 - Picking and Packing of Crustacea Meat, 2 - Pasteurization of Crabmeat, 3 - Mechanically Processed Crustacea Meat 4 - Steamed Crustaces Operations, 5 - Custom Crustacea Operations, 6 - Repacking Crustaces Meat

		MANUAL REFERENCE	*
PLANT & GROUNDS	1. Plant not subject to flooding	1,2,3,4,5,6	C
	2. Processing operations separated by partitions, space or time	1,3,6,	K
	3. Storage/lunch facilities for employees, used	1,3,5,6	O
	4. Plant premises constructed, clean, refuse containers, stored equipment, litter, drainage	1,3,5,6	O
PLANT INTERIOR	5. Floors: impervious, adequate/proper drainage, maintained, clean	1,3,5,6	O
	6. Walls, ceilings, attached equip.: constructed, smooth, lt. colored, clean, good repair	1,3,5,6	O
VECTORS	7. Insects, rodents, vermin and other animals excluded, controlled	1,3,5,6	K
UTILITIES	8. Lighting adequate, fixtures shielded	1,3,5,6	O
	9. Heating, cooling and ventilation adequate	1,3,5,6	O
WATER	10. Water supply: safe source, protected from contamination	1,2,3,5,6	C
	11. Adequate quantity, temperature and pressure of water	1,2,3,5,6	O
PLUMBING	12. Plumbing: meets code, adequate, functional, and maintained	1,2,3,5,6	K
	13. Protection against backflow, backsiphonage, cross connections	1,2,3,5,6	C
	14. Toilets: construction, location, repair, clean, adequate number, self-closing doors, paper	1,3,6	K
	15. Handwashing: number, location, repair, clean, soap, sanitizing solution, sanitary towels, waste receptacles, handwashing signs posted	1,3,5,6	K
SEWAGE	16. Sewage disposal system: properly installed, maintained, meets code, adequate	1,2,5,6	C
CHEMICALS	17. Poisonous/toxic materials: properly used, stored, separated, labeled	1,3,5,6	K
EQUIPMENT & UTENSILS	18. Food contact surfaces: properly constructed and located, identified, clean, maintained, protected from contamination	1,3,4,5,6	K
	19. Non food contact surfaces: properly constructed and located, maintained, clean	1,2,3,4,5,6	O
	20. Pressure cookers properly vented, temperature and pressure gauges provided and calibrated, vent drain or exhaust properly terminated	1,5	K
	21. Refrigeration units adequate, temperature measuring devices	1,2,3,5,6	C
CLEANING & SANITIZING	22. Facilities: properly constructed and used, detergents, brushes, three compartment sinks, test kits, approved sanitizers provided	1,3,5,6	O
	23. Food and non-food contact surfaces cleaned and/or sanitized, within time limits, effective	1,3,4,5,6	K
CRUSTACEA HANDLING & STORAGE	24. Uncooked crustacea: properly stored, refrigerated within time limits	1,5	C
	25. Crustacea properly cooked	1,5	K
	26. Cooked crustacea properly air cooled, refrigerated within time limits	1,2,4,5,6	K
	27. Cooked crustacea properly stored, handled, protected	1,5	K
	28. Processed crustacea delivered to packing room within 3 hours	1,5	K
	29. Cooked crustacea meat protected from contamination	1,2,3,4,5,6	K
	30. Dip cans not used	1,3,5	K
	31. Single service containers: clean, sanitized, stored properly, room and equipment requirements met	1,2,3,5,6	O
	32. Single service containers: approved, properly labeled	1,2,3,5,6	O
	33. Packing into containers with authorized certificate number	1,2,3,5,6	C
	34. Packed fresh product stored, shipped between 32°- 40°F	1,3,5,6	K
	35. Packed frozen product stored, shipped at 0° or less	1,3,5,6	K
	36. Chits or checks not used, overages not returned	1,5	K
	37. Packed product protected from contamination	1,2,3,5,6	K
	38. Ice: adequate, approved source, sanitary, properly protected	1,2,3,5,6	O
PERSONNEL	39. Hands washed/sanitized, good hygienic practices	1,2,3,4,5,6	K
	40. Clean outer garments. Gloves, finger cots, and other coverings impermeable, sanitized as necessary and properly stored, hair restraints	1,2,4,5,6	O
	41. Personnel with infections restricted	1,4,5,6	K
	42. Unauthorized persons prohibited	1,3,5,6	O
WASTE	43. Crab scrap waste: proper disposal, promptly removed, located	1,5	O
	44. Water disposal: meets code, adequate, installed	1,2,3,4,5,6	O
SUPERVISION	45. Supervision: responsible person designated, effective	1,2,3,4,5,6	K
RECORDS	46. Records: complete and maintained	1,2,3,4,5,6	K
MECHANIZED OPERATION	47. Crustacea bodies or claws protected from contamination, proper processing procedure	3	K
	48. Containers for mechanically picked crustacea adequate size, number, identification of containers	3	K
	49. Crustacea claws or bodies refrigerated to 40°F within time limits, processed within 48 hours	3	K
PASTEURIZED CRUSTACEA	50. Crustacea meat pasteurized in accordance with process controls within 10 hours, chilled to 38°F or less within 2 hours, maintained at 36°F or below, construction and operation of pasteurization equipment	2	C
REPACKING	51. Single, approved source	2	C
	52. Single repacking operation: duration of less than 30 min., product temperature not to exceed 50°F	2	K
	53. Emptied containers not reused	2	K

CODES: (C) Critical Item = 4 pts (K) Key Item = 2 pts (O) Other = 0.5 pt
Any critical item violation results in automatic failure

SCORE

Example - For Illustrative Purposes Only

11. Forms

1. Live Crab Receiving Form
2. Product Temperature Thermometer Calibration Form
3. Retort Thermometer Calibration Form
4. Pasteurization Thermometer Calibration Form
5. Steam Cooking Form
6. Crabs Recooked Form
7. Air Cooling Room Storage Form
8. Cooked Crab Storage Form
9. Pasteurized Can Seam Visual Inspection Form
10. Pasteurization Cooling Process Form
11. Bag Sealing Integrity Test Form
12. Bag Sealing Integrity Test Form
    Performed Before Pasteurization or Listericidal Process
13. Bag Integrity Visual Evaluation Form
14. Sodium Hydroxide Tank pH Form
15. Double-Seam Evaluation Form
16. Pasteurization or Listericidal Process Form
17. Temperature Log of Freezers and Cooling Units Form
18. Scale Calibration Form
19. Sanitizer Dip Checks Form - Picking Room
20. Sanitizer Hand Dip Checks Form - Picking Room
21. Sanitizer Dip Checks Form - Packing Room
22. Sanitizer Hand Dip Checks Form - Packing Room
23. Sanitizer Dip Checks Form - Claw Room
24. Sanitizer Hand Dip Checks Form - Claw Room
25. Sanitizer Dip Checks Form - Meat Bone Separator Room
26. Sanitizer Hand Dip Checks Form - Meat Bone Separator Room
27. Sanitizer Dip Checks Form - Scrap Room
28. Sanitizer Hand Dip Checks Form - Scrap Room
29. Sanitizer Dip Checks Form - "Quik-Pik" Room
30. Sanitizer Hand Dip Checks Form - "Quik-Pik" Room
31. Sanitizer Checks Form - Foot Baths
32. Production Sanitation Check Sheet
33. Sanitation Check Sheet
34. Product Weight Check Form
35. Sensory Product Evaluation Form
36. Repacked-Reprocessed 1 lb Can Integrity Failure Form
37. Repacked-Reprocessed 5 lb Bag Integrity Failure Form
38. Pest Control
39. Harris Claw Machine Brine Concentration Form
40. Consumer Complaint Form

Example - For Illustrative Purposes Only

41. HACCP Plan
42. Packed Product Thermometer Calibration Form
43. General Seafood Safety Check List
44. Crab Plant Sanitation Check List
45. FDA Inspection Form
46. Notice of Unusual Occurrence and Corrective Action
47. Crustacea Plant Inspection Form

Example - For Illustrative Purposes Only

1. LIVE CRAB RECEIVING FORM

Date	Seller	Weight	Accept/Reject	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

2. PRODUCT TEMPERATURE THERMOMETER CALIBRATION FORM

(Check Weekly to Plus or Minus 0.5° F)

Date	Time	Reading-Boiling Water	Reading-Ice Water	Reject/Accept	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

3. RETORT THERMOMETER CALIBRATION FORM

(Check Annually)

Date	Time	Reading-Boiling Water	Reading-Ice Water	Reject/Accept	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

4. PASTEURIZATION THERMOMETER CALIBRATION FORM

(Check Annually)

Date	Time	Reading-Boiling Water	Reading-Ice Water	Reject/Accept	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

5. STEAM COOKING FORM

Date	Batch #	Cooker Number	Time				Exhaust Check	Operator Initials
			Steam On	Start Cook	End Cook	End Vent		

Minimum Cook: 8 Minutes at 250 °F
15 PSI

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

6. CRABS RECOOKED FORM

Date	Batch #	Cooker Number	Time				Exhaust Check	Oper. Initials
			Steam On	Start Cook	End Cook	End Vent		

Minimum Cook: 8 Minutes at 250 °F
15 PSI

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

7. AIR COOLING ROOM STORAGE FORM

Date	Temp	Time In	Time Out	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

8. COOKED CRAB STORAGE FORM

Time In		Time Out		Basket I.D. #	Operator Initials
Date	Time	Date	Time		

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

9. PASTEURIZED CAN SEAM VISUAL INSPECTION FORM

Date	Code	Time	Accept Yes/No	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

10. PASTEURIZATION COOLING PROCESS FORM

Date	Time	Code	Tank #	Cooling Water Temperature	Cl ppm	Aeration Yes/No	Meat Temp After Cool

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

11. BAG SEALING INTEGRITY TEST FORM

(When Sealer is Turned on and Every Four Hours of Operation)

Date	Time	Code	Empty Bag Pull Apart Yes/No	Water Bag Pull Apart Yes/No	Product Bag Pull Apart Yes/No	Operator Initials

Evaluate a minimum of
three containers at a time.

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

12. BAG SEALING INTEGRITY TEST FORM

PERFORMED BEFORE PASTEURIZATION OR LISTERICIDAL PROCESS

(Bag Submerged in Water - Break Point Chlorinated;-

Date	Time	Code Date	Product	Bubbles Absent/ Present	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

13. BAG INTEGRITY VISUAL EVALUATION FORM

(Each Batch)

Date	Time	Code	Product	Prior to Pasteur.	After Cooling	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

14. SODIUM HYDROXIDE TANK pH FORM

Date	pH	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

15. DOUBLESEAM EVALUATION FORM

(Before operation, after a jam, and every four hours of operation)

Inspector _____ Code _____

Date _____ Can Description _____

End Evaluation

Can Company _____

Crab Company _____

Thickness 0.058-0.062"										
Length Max 0.125"										
Coverhook 0.072-0.88"										
Bodyhook 0.072-0.088"										
Overlap > 0.045"										
Tightness Ideal 90-95% Acc 80- 100%										
Countersink 0.120-o. 135"										
Pressure Ridge Distinct and Continuous										
Visual Acc/Unacc										

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

16. PASTEURIZATION OR LISTERICIDAL PROCESS FORM

Date	Time	Code	Tank #	Initial Temp	Recorder Temp	Thermom Temp	Aeration Yes/No	Oper. Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

17. TEMPERATURE LOG OF FREEZERS AND COOLING UNITS FORM

Date	Time	Green Crab	Cooked Crab	Packed Product	Freezer	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

18. SCALE CALIBRATION FORM

(Check Daily Using 1.00 Lb and 5.00 Lb Weights; +/- 1.0%)

Date	Time	Picker Weigh-In	Lump Scale	Special Scale	Claw Scale	Quik-Pik Scale	Meat Bone Separator Scale	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

19. SANITIZER DIP CHECKS FORM - PICKING ROOM

(Check Every Two Hours)

Date	Time	Cup Dip[A]	Pan/Knife Dip[A]	Floor Shovel/Broom[B]	Crab Shovel[B]	Operator Initials

A. 200 ppm Quat
B. 400 ppm Quat

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

20. SANITIZER HAND DIP CHECKS FORM - PICKING ROOM

(Check Every Two Hours)

Date	Time	Hand Dip #1	Hand Dip #2	Hand Dip #3	Hand Dip #4	Hand Dip #5	Operator Initials

200 ppm quat
Reject if less than 170 ppm

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

21. SANITIZER DIP CHECKS FORM - PACKING ROOM

(Check Every Two Hours)

Date	Time	Cup/Bag	Stainless Steel Tray	Utensils	Operator Initials

200 ppm quat
Reject if less than 170 ppm

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

22. SANITIZER HAND DIP CHECKS FORM - PACKING ROOM

(Check Every Two Hours)

Date	Time	Hand Dip #1	Hand Dip #2	Hand Dip #3	Hand Dip #4	Hand Dip #5	Operator Initials

200 ppm quat
Reject if less than 170 ppm

--

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

23. SANITIZER DIP CHECKS FORM - CLAW ROOM

(Check Every Four Hours)

Date	Time	Cup/Bag	Stainless Steel Tray	Operator Initials

200 ppm quat
Reject if less than 170 ppm

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

24. SANITIZER HAND DIP CHECKS FORM - CLAW ROOM

(Check Every Two Hours)

Date	Time	Hand Dip #1	Hand Dip #2	Hand Dip #3	Hand Dip #4	Hand Dip #5	Operator Initials

200 ppm quat
Reject if less the 170 ppm

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

25. SANITIZER DIP CHECKS FORM - MEAT BONE SEPARATOR ROOM

(Check Every Four Hours)

Date	Time	Cup/Bag	Utensils	Meat Tray	Operator Initials

200 ppm quat
Reject if less than 170 ppm

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

26. SANITIZER HAND DIP CHECKS FORM, MEAT-BONE SEPARATOR ROOM

(Check Every Two Hours)

Date	Time	Hand Dip #1	Hand Dip #2	Hand Dip #3	Hand Dip #4	Hand Dip #5	Operator Initials

200 ppm quat
Reject if less than 170 ppm

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

27. SANITIZER DIP CHECKS FORM - SCRAP ROOM

(Check Every Four Hours)

Date	Time	Scrap Barrel	Broom/ Shovel	Scrub Brush	Dip Tub	Operator Initials

400 ppm quat

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

28. SANITIZER HAND DIP CHECKS FORM - SCRAP ROOM

(Check Every Two Hours)

Date	Time	Hand Dip #1	Hand Dip #2	Hand Dip #3	Hand Dip #4	Hand Dip #5	Operator Initials

200 ppm quat
Reject if less than 170 ppm

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

29. SANITIZER DIP CHECKS FORM - "QUIK-PIK" ROOM

(Check Every Four Hours)

Date	Time	Cup/Bag	Stainless Steel Tray	Operator Initials

200 ppm quat
Reject if less than 170 ppm

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

30. SANITIZER HAND DIP CHECKS FORM - "QUIK-PIK" ROOM

(Check Every Four Hours)

Date	Time	Hand Dip #1	Hand Dip #2	Hand Dip #3	Hand Dip #4	Hand Dip #5	Operator Initials

200 ppm quat
Reject if less than 170 ppm

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

31. SANITIZER CHECKS FORM - FOOT BATHS

Date	Time	Foot Bath #1	Foot Bath -#2	Foot Bath #3	Foot Bath #4	Operator Initials

400 ppm quat

Location of Foot Bath
Bath #l Entrance to Picking Room
Bath #2 Entrance to Packing Room
Bath #3 Entrance to Claw Room
Bath #4 Entrance to Quik-Pik Room

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

32. PRODUCTION SANITATION CHECK SHEET

Employee Practices: adequate hair covering; no jewelry; no nail polish; no items in front shirt pockets; no food or beverages in processing area; hand washing at least every two hours and thoroughly. Yes No
Action to correct: _____

Outside grounds free of litter, manicured, free of dust. Yes No
Items to be maintained: _____

Dry Storage Area clean and orderly. Yes No
Action to correct: _____

Ice machine clean, functioning, adequate supply. Yes No
Action to correct: _____

END OF DAY SANITATION CHECKLIST

Equipment: Tables, Floors, Knives, Plastic Tubs, Baskets, etc. cleaned and sanitized. Yes No
Items to be recleaned: _____
All perishable food items returned to refrigerator. Yes No
Items left out: _____
Disposition: _____

Refrigerator orderly, clean, and functioning. Yes No
Action to correct: _____

Chemicals stored properly. Yes No
Action to correct: _____

Pests, insects under control. Yes No
Action to correct: _____

Rest rooms cleaned, supplied with soap, toilet tissue, and paper towels.No
Action to correct: _____

Inspected by: _____ Date: _____ Time: _____
Reviewed by: _____ Date: _____

Example - For Illustrative Purposes Only

33. SANITATION CHECK SHEET

EMPLOYEES	YES	NO
Adequate Hair Covering		
Jewelry		
Nail Polish		
Food or Beverage in Processing/Packing Areas		
Properly Wash and Sanitize Hands		
Improper Hand Contact		
Chemicals Properly Stored		
Required Corrective Action:		
EQUIPMENT	YES	NO
Tables, Floors, Walls, Knives, Pans, and Barrels Cleaned and Sanitized		
Brushes, Brooms, Squeegee and Pads Cleaned and Sanitized		
Cleaning Equipment and Chemicals Properly Stored		
Required Corrective Action:		
FACILITY	**YES**	**NO**
Green Crab Cooler Properly Cleaned and Sanitized		
Crab Cook Area Properly Cleaned and Sanitized		
Cooked Crab Cooler Properly Cleaned and Sanitized		
Packing Room Cleaned and Sanitized		
Picking Room Cleaned and Sanitized		
Packed Product Cooler Properly Cleaned and Sanitized		
Ice Machine Clean, Functioning, and Adequate		
Dry Storage Area Clean and Orderly		
Outside Grounds Free of Litter, Manicured and Free of Dust		
Required Corrective Action:		

Inspected By: _____ Reviewed by: _____

Date: _____ Date: _____

Example - For Illustrative Purposes Only

34. PRODUCT WEIGHT CHECK FORM

(Maximum 1% Deviation)

Date	Product	Weight	Accept Yes/No	Product	Weight	Accept Yes/No	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

35. SENSORY PRODUCT EVALUATION FORM

Date	Time	Product	Code	Meets Product Spec.		Foreign Material Accept/Rej	Shell Acc/Rej	Temperature	Acceptable	Operator Initials
				Yes	No					

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

36. REPACKED-REPROCESSED 1 LB CAN INTEGRITY FAILURE FORM

Date	Code	Product	Reason	Date Repacked/ Reprocessed	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

37. REPACKED-REPROCESSED 5 LB BAG INTEGRITY FAILURE FORM

Date	Code	Product	Reason	Date Repacked-Reprocessed	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

38. PEST CONTROL FORM

Date	Area	Problem	Action Taken	Chemicals Used	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

39. HARRIS CLAW MACHINE BRINE CONCENTRATION FORM

Date	Time	Salinity Degree	Brine Temperature	Operator Initials

Reviewed by: _____

Date: _____

Example - For Illustrative Purposes Only

40. CONSUMER COMPLAINT FORM

Date _____ Time _____

Individual Receiving Complaint _____

Individual Investigating Complaint _____

Consumer's Name _____

Address _____

_____

_____

State _____

City _____ Zip _____

Phone Area code ( ) _____

Fax Area code ( ) _____

Complaint _____

_____

_____

_____

_____

_____

_____

_____

_____

Example - For Illustrative Purposes Only

CONSUMER COMPLAINT FORM (Continued)

Identification of Product

Product Code _____

Container Type and Size _____

Product Code _____

Are Other Containers Available? Yes _____ No _____

Was a Doctor or Hospital Involved? Yes _____ No _____

Name _____

Address _____

_____

Phone Area Code ( ) _____

Corrective Action Taken _____ Yes _____ No

Nature of Corrective Action: _____

_____

_____

_____

Example - For Illustrative Purposes Only

41. HACCP PLAN

Company Name **Unit Operation**

CONTROL POINT: **CRITICAL: Yes or No**

HAZARD OR DEFECT:

CRITICAL LIMIT:

PREVENTATIVE MEASURES:

Example - For Illustrative Purposes Only

HACCP PLAN (Continued)

MONITORING PROCEDURES:

CORRECTIVE ACTIONS:

RECORDS:

VERIFICATION PROCEDURE/PERSON(S) RESPONSIBLE:

Example - For Illustrative Purposes Only

42. PACKED PRODUCT THERMOMETER CALIBRATION FORM

(Check Annually)

Date	Time	Reading-Boiling Water	Reading-Ice Water	Reject/Accept	Operator Initials

Reviewed by:_____

Date: _____

Example - For Illustrative Purposes Only

43. GENERAL SEAFOOD SAFETY CHECKLIST

FIRE/PROPERTY LOSS	YES	NO
Portable fire extinguishers provided and currently serviced?		
lf no fire hydrants are available, has a fire department connection been installed on a private well/pump in coordination with the local fire department?		
Good housekeeping maintained in all buildings?		
Are combustible materials kept a safe distance from heaters (minimum 5')?		
Weeds and dry grass cleared away at least 25' from building?		
Flammable liquids well controlled: - Storage tanks at least 25' from buildings? - Emergency electrical shutoff for fuel pumps marked? - U.L. Listed or FM approved flammable liquids safety cans used?		
Regular maintenance provided on compressors?		
Welding areas well maintained with no combustible materials in work area?		
Smoke detectors provided and tested periodically?		
Sprinkler systems inspected and tested periodically?		
EMPLOYEE SAFETY	**YES**	**NO**
Do you have a written Safety Policy?		
Do you have an Injury Prevention Program which includes: 1. Identified person or persons responsible for implementing the program? 2. An inspection program or system to identify worksite hazards on an ongoing basis? 3. Established methods and procedures for correcting unsafe or unhealthy conditions in a timely manner?		

EMPLOYEE SAFETY (Continued)	YES	NO
4. Safety training for employees? 5. Method to communicate with employees about Safety and Health 6. Enforcement and disciplinary system to insure that employees comply with set Safety & Health policies?		
Machinery/equipment regularly inspected for guards, proper electrical connections; regular maintenance provided?		
GENERAL LIABILITY	**YES**	**NO**
Visitors - escorted by responsible personnel?		
Walkways, parking areas, etc. in good condition?		
Have all vendors and contractors provided Certificates of Insurance with limits equal to or greater than your own?		
Materials Safety Data Sheets (MSDS) used and kept on file for each chemical?		
Chemicals stored in well ventilated/secured building - not part of main buildings, maintenance, or repair shops?		
If you have any underground tanks on property, are they being tested for leaks?		
Do you dispose of waste products, including water and processing waste, in compliance with regulations?		
Vehicles/equipment operated by experienced employees?		
PRODUCT LIABILITY	**YES**	**NO**
Sanitation checklist being completed on a frequent basis?		
Do you have a Hazard Analysis and Critical Control Point (HACCP) Program?		
Is there a written Quality Control program?		
Do you have a procedure for pest control?		
Is there a written recall program?		
Do you have a well-maintained refrigeration system for product storage and product shipping?		

FLEET	Yes	No
Does your Fleet Safety Program include: - Written rules and regulations for all drivers? - Annual MVR checks? - Disciplinary Action for poor MVR's and rule violations? - Regular vehicle inspections performed by qualified mechanic? - Maintenance, repair and inspection records kept on file and up to date? - Vehicles secured at night, keys removed? - Do drivers have Commercial Drivers Licenses?		

Example - For Illustrative Purposes Only

44. CRAB PLANT SANITATION CHECKLIST

PREMISES	YES	NO
Free of improperly stored equipment, litter, waste, refuse and uncut weeds or grass		
Excessive dusty roads, yards or parking lots		
Inadequately drained areas		
Proper care exercised to effect exclusion of pests, dirt and other filth originating from sources not under the establishment's control		
RAW MATERIALS	**YES**	**NO**
Design, materials or construction of walls, floors or ceilings prevent their maintenance in a sanitary manner		
Ceilings over areas with unpackaged crab free of peeling paint or condensates		
Exterior openings, where practicable, equipped with screens or other effective means to prevent the entrance of insects, rodents and other animals		
Insect and rodent control effective in those areas where screening of exterior openings is impractical		
Air curtains, if used, in compliance with National Sanitation Standard No. 37		
Screen doors outward opening or self-closing		
Processing area opens directly into living quarters, garage or heavy maintenance shop		
Plant arrangement permits inadvertent transfer of inedible byproducts to edible product surfaces or picking and packaging materials		

Example - For Illustrative Purposes Only

CRAB PLANT SANITATION CHECKLIST (Continued)

LIGHTING	YES	NO
Sufficient lighting		
Lights, etc., in processing areas are safety type or equipped with protective shields		
VENTILATION	**YES**	**NO**
Accumulation of condensates in processing or storage areas		
Presence of mold in processing or storage areas		
Presence of objectionable odors		
Excludes contaminants from processing areas		
WATER SUPPLY	**YES**	**NO**
Adequate supply of both hot and cold water		
Easily accessible		
Protected against contamination and pollution and no cross-connection exists between safe water and unsafe water supply or sewage disposal system		
Potability certificates current and available; water supply found to be potable		
Seawater used only as specified		
Seawater outlets used only as specified		
DISPOSAL OF WASTES	YES	NO
Liquid wastes disposed only in a sanitary manner		
Dry wastes collected in suitable containers conveniently located throughout the plant		

Example - For Illustrative Purposes Only

CRAB PLANT SANITATION CHECKLIST (Continued)

DISPOSAL OF WASTES (Continued)	YES	NO
Product waste collected in suitable containers and are covered when not in use		
All waste collected and disposed of at frequent intervals and in a sanitary manner		
LAVATORY ACCOMMODATIONS	**YES**	**NO**
Sufficient number of toilets provided		
Tissue paper		
All doors to toilet rooms self-closing, tight fitting and do not open directly into a processing area. Maintained in a sanitary condition and kept in good repair at all times		
Sign directing employees to wash hands		
Hot water present		
Soap and sanitizers present		
Hand-drying facilities present		
Waste receptacles		
Toilet rooms separately vented to the outside		
CONSTRUCTION AND REPAIR OF EQUIPMENT, CONTAINERS AND UTENSILS	YES	NO
Product contact surfaces of all equipment, containers and utensils constructed from suitable, smooth, impervious, nontoxic corrosion-resistant material		
Scales, picking tables, packing tables, benches and similar equipment, where it is practicable, made of non-corrosive material		

Example - For Illustrative Purposes Only

CRAB PLANT SANITATION CHECKLIST (Continued)

CONSTRUCTION AND REPAIR OF EQUIPMENT, CONTAINERS AND UTENSILS (Continued)	**YES**	**NO**
Design of equipment, containers and utensils is such that it provides protection from contaminants and can be readily cleaned and effectively sanitized		
Constructed or located so that all product contact surfaces are accessible for cleaning, maintenance and inspection		
Equipment, containers or utensils in good repair		
CLEANING AND SANITIZING TREATMENT	**YES**	NO
Product contact surfaces or equipment, containers and utensils thoroughly cleaned and sanitized after use		
Cleaning methods prevent contamination or adulteration		
Chemicals used in cleaning and sanitizing treatment are properly labeled or stored		
Approved chemicals used for cleaning and sanitizing		
Rooms and areas used for receiving, processing and storing of raw materials and finished product maintained in a clean sanitary manner		
METHODS	**YES**	**NO**
Methods prevent contamination of product		
Methods prevent deterioration of product		

Example - For Illustrative Purposes Only

CRAB PLANT SANITATION CHECKLIST (Continued)

SANITATION CONTROLS	YES	NO
Use of in-plant sanitation program		
Sanitation control of raw materials is sufficient to protect the product		
Sanitation control of finished product is sufficient to protect the product		
Test and examination results are on file and made available to the inspector		
CONTROL OF INSECTS, BIRDS AND ANIMALS	**YES**	**NO**
Birds and animals are excluded from the plant		
Insect and rodent control measures are effective		
Insecticides or rodenticides are safe for use as prescribed by EPA or USDA		
Employed by approved methods or handled and stored in a safe manner		
COOLING AND REFRIGERATION FACILITIES	**YES**	**NO**
Facilities adequately cool and maintain the raw materials and finished product in a chilled state		
Facilities maintain products in a frozen state		
Design of equipment prevents contamination or adulteration of product		
Thermometer present in refrigerated room		
Freezers and cold storage compartments are fitted with proper control devices to ensure materials are held at proper temperature		

Example - For Illustrative Purposes Only

CRAB PLANT SANITATION CHECKLIST (Continued)

STORAGE FACILITIES	**YES**	**NO**
Storing methods minimize deterioration		
Storage facilities are clean, sanitary, and in good repair		
Shelves, cabinets or dunnage used where necessary to prevent contamination and deterioration		
VEHICLES AND TRANSPORTATION FACILITIES	**YES**	**NO**
Constructed or operated to protect contents from contamination and deterioration		
Properly maintained and clean		
Capable of maintaining 40°F or less for chilled product		
Capable of maintaining 0 ° F or less for frozen product		
PERSONNEL	**YES**	**NO**
Disease Control 1. Are personnel with disease, working in plant in any capacity in which there is a reasonable possibility of food ingredients becoming contaminated by such person or of disease being transmitted by such person to other individuals? 2. Plant management requires employees to report illness or injury to supervisors		
Cleanliness 1. Specified personnel wearing clean outer garments, maintaining a high degree of personal cleanliness and conforming to hygienic practices while on duty, to the extent necessary to prevent contamination of food products		

Example - For Illustrative Purposes Only

CRAB PLANT SANITATION CHECKLIST (Continued)

PERSONNEL (Continued)	YES	NO
Cleanliness (Continued) 2. Specified personnel wash their hands thoroughly to prevent contamination by undesirable microorganisms before starting, after each absence from the work station and at any other time when the hands may have become soiled or contaminated		
3. Specified personnel remove all insecure jewelry and when food is being manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized		
4. Specified personnel use gloves of an impermeable material, except where inappropriate or incompatible with work involved in food handling, maintaining them in an intact, clean and sanitary condition		
5. Specified personnel wear hair nets, caps, masks or other effective hair restraints		
6. Specified personnel store clothing or other personal belongings, eat food, drink beverages, chew gum, expectorate or use tobacco in any form in area where food or food ingredients are exposed or in areas used for washing equipment or utensils		
7. Specified personnel take other necessary precautions to prevent contamination of foods with microorganisms or foreign substances		

Example - For Illustrative Purposes Only

CRAB PLANT SANITATION CHECKLIST (Continued)

PERSONNEL (Continued)	YES	NO
Education and Training 1. Personnel responsible for identifying sanitation failures or food contamination have a background in education or experience or combination thereof, to provide a level of competency necessary for production of clean wholesome food 2. Food handlers and supervisors receive appropriate training in proper food-handling techniques and food protection principles and are cognizant of the danger of poor personal hygiene, unsanitary practices, and other vectors of contamination		
Supervision Responsibility for assuring compliance by all personnel with all requirements of this document and clearly assigned competent supervisory personnel.		

Example - For Illustrative Purposes Only

45. FDA INSPECTION FORM

Date _____ Time In _____

Inspector's Name (Print) _____

Badge or I.D. Number _____

District Office _____

Immediate Supervisor's Name _____

Inspected Plant with Other Inspectors:

_____

_____

_____

Met with Our Personnel: _____

_____

_____

Inspected Our Plant With _____
(Employee's Name)

Comments During Inspection Trip _____

_____

_____

_____

_____

Example - For Illustrative Purposes Only

FDA INSPECTION FORM (Continued)

Samples Taken (describe) _____

_____

_____

Lot or Codes _____

_____

Other Identification _____

Did you obtain the receipt for samples taken? _____

Comments After Inspection _____

_____

_____

_____

_____

Time Out _____

Signed (Employee) _____

Title _____

Example - For Illustrative Purposes Only

46. NOTICE OF UNUSUAL OCCURRENCE AND CORRECTIVE ACTION

(Not covered by other forms)

Date _____ Time _____

Operation or processing step _____

_____

_____

_____

Description of the problem _____

_____

_____

Corrective Action _____

_____

_____

Name _____ Date: _____

Reviewed by: _____

Date: _____

12. Pest Control and Management

Controlling insect and rodent pests is an important part of maintaining the sanitation and quality control standards necessary in seafood processing. Each establishment has its own particular quality control standards and a program to achieve them. An effective pest control program involves the participation of management and pest control personnel. The Plant Manager or Quality Control Manager must work closely with the pest control personnel.

The majority of seafood processing operations assign the most capable and dependable employees to handle pest control. However, their training and experience in pest control may be limited. The objective of this training-resource manual is to provide pest control personnel with the detailed and specific information necessary to design and conduct an effective pest control program. The topics covered include:

Management and pest control personnel
Pest control and objectives
Pesticide storage and mixing
Spraying techniques
Pest identification
Rodent control
Equipment

A. Management and Control Personnel

A good pest management or pest control program in seafood processing operations is not based on pesticides, equipment, or frequency of application. Rather, it should be based on a coordinated effort between the processing plant management and the pest control personnel. Both groups must understand the other's role and priorities.

The pest control personnel usually can accomplish little without full involvement and cooperation of management in an overall sanitation effort. Both must understand that controlling pests requires a complete sanitation program, accounting for all facets of the operation from raw material to shipping and distribution.

Management and pest control personnel should survey the facility and discuss the operating and cleaning schedules, physical conditions inside and outside the facility, employee and operating practices, and storage of pest control chemicals and equipment. Both should become aware of the other's limitations. For example, if the facility is not on a thorough cleaning schedule, which helps to control insects and rodents within equipment and around the building, the pest control personnel will have great difficulty eliminating or managing these pests. If the processor receives rodent or insect-infested materials or doesn't properly store materials, the pest control personnel will not be able to control infestations of ingredients. Rodent trapping programs and crack and crevice treatments can't be properly

carried out if storage and processing areas are not organized to allow for perimeter access. Before a pest control program can be developed and carried out, both management and pest control personnel must understand each other's responsibilities and role in pest control.

2. Pest Control and Management Objectives

Control of pests associated with seafood processing operations must be based on both chemical and non-chemical control methods. Controlling cockroaches and other pests with chemicals alone is becoming increasingly more difficult. In most insect and rodent populations there is some degree of resistance to the commonly used pesticides. Continued dependence on chemicals for the control of pests will increase insecticide and rodenticide resistance in the pest population -- and may result in an uncontrollable increase in the pests. Future pest control programs must integrate chemical and nonchemical (sanitation, traps, preventive measures) methods into an ongoing program, under the direction of trained and properly equipped personnel, and with the objective of pest management.

Guidelines for designing a pest management program for seafood processing operations are as follows:

Program Orientation

Orient the program to the entire pest population, rather than to localized infestations. Individual pests - rats, cockroaches - should be interpreted as members of a large group or population that may occupy an entire building.

Design

Design a program for the entire processing operation, rather than for specific rooms or parts of the operation. Most insect and rodent pests are not limited to infesting one part of a building, but probably move throughout the building. Pest control in only one part may simply force the pests to an untreated portion, and reduce the effectiveness of the control effort.

Objectives

The objective of the program is to manage those pests that are present year round, and are present in large numbers. The objective is to decrease the level of abundance of these pests rather than eliminate or eradicate them.

For some pests and in some situations, elimination may be possible or even necessary. For example, rodents are serious health hazards to food processing operations, and it is necessary to eliminate them from all areas of the operation. Elimination of rodents and some other pests may be possible, perhaps after the pest population is reduced through pest management practices. However, it is more realistic to think in terms of a continuous or on-going pest management program, designed to keep pest populations low, than to work toward pest elimination and program conclusion. It is virtually impossible to eliminate or eradicate most pests from an environment favorable for them. Pest control programs must be on-going and continuously improved.

The concept of pest management involves dealing with pest populations that are interacting

with the total environment. Pest management requires the integration of sanitation, prevention, exclusion, mechanical control methods, and chemical pesticides into a program with the goal of significantly reducing (and possibly eliminating) a pest population.

C. Pesticides

1. Insecticides

Understanding both the way insecticides kill insects and the dangers of overexposure to humans is an important aspect of pest management programs.

a) Exposure - At the present time, the most widely used organic insecticides are the organophosphates, carbamates, and pyrethroids. These and other pesticide chemicals may enter the body in a wet or dry state through the skin (dermal absorption), through breathing (respiratory absorption), and through the mouth (oral absorption). Dermal absorption is the most common route of exposure.

   Insecticides are absorbed at different rates on various areas of the body. Protective clothing should be worn to prevent skin absorption. Special care should be given to protect the scalp, ear canal, and forehead. The abdominal area and waistline should be protected to prevent chemical access to the scrotum area.

   Data have shown that most accidents occur during the mixing and loading operations. It is extremely important to wear protective clothing when concentrated chemicals are being handled, as well as during application.

b) How Insecticides Work - The normal life of an insect depends on a vast number of complex chemical reactions (metabolic processes). Alteration of any of the metabolic processes will affect the insect. Some alterations result in sudden death,. while others are less drastic. Different kinds of insecticides may alter metabolic processes in one or more ways; that is, they may have one or more modes of action. As an example, the organophosphate and carbamate insecticides, once inside the body, interfere primarily with the nervous system by inhibiting or depressing the enzyme cholinesterase. All living things with cholinesterase in the nervous system-such as insects, birds, animals, and humans-may be poisoned by these chemicals. However, in order to understand how these insecticides affect the nervous system, and thereby the symptoms and treatments of poisonings, it is necessary to see how the nervous system works.

   The nervous system-which includes the brain-is the most complex system in the body. It consists of millions of cells which make up a message or communication system throughout the body The messages (or stimuli) travel along this network in the form of an electric impulse. Think of it as a spark!

   The nerve cells are “connected” at the synapse. The ends of the connecting nerve cells intertwine, but do not actually touch each other. Stimuli "spark" across the synapse in a chemical known as acetylcholine. After the stimulus is across the

synapse, the acetylcholine is broken down by cholinesterase. Then the cholinesterase breaks down and the synapse is back to "normal."

When a finger is stuck with a pin, the stimulus begins at the skin. The stimulus or spark travels down thousands of nerve fibers and across the synapses. Some of the stimuli go to the muscles to make you jerk back, while others go to the brain where they are interpreted as the feeling of pain. This example is extremely simplified, but it serves to illustrate the basic components and workings of the nervous system.

Organophosphate and carbamate insecticides each inhibit a type of cholinesterase, causing an accumulation of acetylcholine so that all stimuli or "sparks" continue to arc across the synapses, stimulating continuous muscle contractions or tremors. Thus, the nervous system is "poisoned."

2. Rodenticides

Rodenticides are pesticides used to control rodents such as rats, mice, and squirrels. They are normally employed in solid baits, in liquid forms, as dusts, or as volatile chemicals used as fumigants. The most effective rodenticides are those with a high toxicity and palatability, and with one or more safety features. Rodenticides used in solid baits or liquid forms can be divided into two groups based on the mode of action:

a) the acute rodenticides
b) the chronic rodenticides.

The acute rodenticides are those in which a lethal quantity of poison is ingested in a single dose with the food or drink of a rodent. They cause death by heart paralysis, by gastrointestinal and liver damage, or by attacking the central nervous system. The target animal must consume a lethal dose before the onset of poisoning symptoms. A sub-lethal dose may produce side effects that will make the rodent "bait shy." Pre-baiting is recommended before applying acute rodenticides so the animal will be conditioned to the bait. The non-poisonous bait is first presented to the rodents until they freely feed regularly and then it is replaced by bait containing the poison.

Chronic rodenticides bring about death of an animal only after the poisoned bait or liquid has been consumed on a number of occasions. Because the poison is consumed over a period of time, a low dosage is lethal. For example, a brown rat can survive a single 50 mg/kg dose, but succumbs to 5 consecutive doses of 1 mg/kg taken on successive days. The symptoms of the poison are so delayed that the animal never learns to associate discomfort with the bait consumption, and continues to feed until a lethal dose has been ingested. The main components possessing chronic poisoning action are the anti-coagulants, which interrupt the synthesis of blood-clotting factors so the poisoned animals die from internal bleeding. Chronic rodenticides are relatively nontoxic to domestic animals and man; however, there is no such thing as a "safe" rodenticide.

However toxic a chemical poison may be, it will not be lethal unless a rodent, of its own volition, consumes a lethal dose. Additives are sometimes included in the bait to improve performance. Attractants such as flavoring or oils are sometime added to bait to make it more appealing by enhancing the taste or masking disagreeable odors. Anticoagulants may be made more lethal by adding potentiating agents that accentuate the action of the anticoagulants. Preservatives and binders are used in baits to keep them from deteriorating over time. To guard against accidental consumption of the poisoned bait by nontarget animals, safety additives may be incorporated. Since rodents are unable to vomit, it is often the practice to incorporate an emetic agent in the bait. The emetic agent will induce vomiting and provide a safety factor for non-target animals.

Secondary poisoning to animals which feed on dead or dying rodents should be anticipated. The danger may be reduced by removing rodent carcasses whenever possible.

Acute or chronic poisons may be used in dust formulations. A poisoned dust is placed in the holes and burrows of rodents where it adheres to their feet and fur and is transferred to the mouth during normal cleaning and grooming activities. This method requires a high concentration of poison since the animal can be expected to consume only small amounts. The advantage of contact dusts is that rodents do not suspect the source of illness.

In situations where rodents do not respond to poisoned baits or dusts, a fumigation technique can be used. Rodents breathe the volatile substances and gases which cause death.

3. Avicides

Avicides are pesticides used to control birds in pest situations. Some common avicides include compound DRC 1339 and Avitrol. Most avicides are acute poisons which act on the central nervous system. The reaction time required to kill a bird varies with the type of poison. Strychnine used as an avicide will kill birds shortly after the bait is consumed while the avicide containing the compound DRC 1339 does not kill the birds for several hours, generally after they go to roost. This difference in mode of action is important in reducing the effects of secondary poisoning to animals that consume dead birds. Birds dying at the roost sites can be easily picked up and disposed of.

No avicide has been found that is specific for a given bird; thus, there is always a danger that non-target birds will be affected. A poison such as strychnine is lethal to all animals while DRC 1339 is more lethal to starlings and blackbirds, but will also kill smaller birds. Avitrol is an avicide used to control blackbirds. A bird ingesting avitrol reacts with distress symptoms and calls which frighten away the remainder of its flock from the feeding area with a minimum of mortality. The advantage of Avitrol is that only a few birds need to ingest the bait; thus a relatively small amount of bait needs to be put out.

D. Pests Associated with Seafood Processing

A variety of insects and other animals are attracted to seafood materials, processing equipment, and plants. Some of these animals can be serious pests in seafood processing

plants; others are only occasionally associated with these operations. The most common pests include insects (cockroaches, flies, flour beetles), rodents (rats, mice), and some birds.

Control of pests associated with seafood processing requires a thorough knowledge of their biology, habits, and seasonal occurrence. Chemical or non-chemical methods can be more effective when the applicator knows the target pest.

E. Insects

Insects are the most common and probably the most difficult pests to control in seafood processing operations. Control strategies depend on the life history and habits of the individual pest, and on the chemicals registered for use against that pest. Some insects, such as house flies, fruit flies, and crickets are seasonal pests; they usually breed outside the processing plant, and are most common in late summer (August, September). Cockroaches and flour beetles are year-round pests, but may be more numerous at certain times of the year.

Information on the biology, habits and certain aspects of control of common and occasional insect pests is presented below.

1. Cockroaches

The most common and most important pests of food-processing plants are cockroaches. Most common because they occur around the world-in every plant, in every food industry; most important because they can carry and spread numerous disease organisms. Cockroaches are known to carry four strains of poliomyelitis, more than 40 different pathogenic bacteria, and the eggs of several pathogenic worms. It has been estimated that a single cockroach can carry a total of 13,470 bacteria.

Female cockroaches do not lay eggs one at a time; instead they produce small egg cases that contain from 6 to 40 eggs. This egg case is deposited in a hiding place with adequate food and water. Young cockroaches begin feeding soon after they hatch from the egg case. They feed on the same materials as the adults, and look like adults except for size and absence of wings. After shedding their skin several times to grow larger, they become winged adults. Adult cockroaches live for a few months to over a year, depending on the species. They mate several times, and the females generally produce one egg case per month.

The mouthparts of cockroaches are the biting-and-chewing type. These insects can feed on a variety of foods, but they prefer starchy and sugary material. They will sip milk, nibble at cheese, meats, pastry, flour, meal, grease, chocolate, and other foods. They can feed just as freely on book binding, shoe lining, dead insects, other cockroaches, and human waste. They usually feed at night when they are not likely to be disturbed by human activities.

a) German Cockroach - This is the most common and widespread cockroach in food processing plants-around the world. It is a small insect, about 3/4" long, and is yellowish brown with two dark-brown stripes behind the head. Both male and female have well-developed wings.

The female carries the egg case protruding from the tip of the abdomen until hatching time. The egg cases are hidden in areas with abundant food, water, and hiding places. The adult female may live for about 9 months and produce about 140 young.

In seafood processing plants, German cockroaches will infest the main food preparation (ground level) and storage areas, as well as offices, clothing lockers, and restrooms. They are not usually found in storage areas below ground level.

b) American Cockroach - This is the largest cockroach in the United States; adults may reach at length of 2 inches. Adult cockroaches are brown, and the young are pale brown.

The female American cockroach hides her egg cases as soon as they are produced. The adult female may live for 12 to 18 months and produce as many as 33 egg cases.

American cockroaches usually inhabit basements, storage rooms, garbage areas, and sewers. These places are slightly cooler than the habitats of the German cockroach, and the cracks and crevices to hide in are larger.

In seafood processing plants the American cockroach usually infests large storage areas (below ground level), loading docks, and basements. This cockroach is frequently associated with door trash bins and storage areas. Adults may move into the building from these areas at night.

c) Oriental Cockroach - This pest is about 1” long, dark brown to black; the wings are very short in the male and absent in the female. The young are pale brown.

The female hides the egg case soon after it is formed. Each female can produce one egg case per month for the 5-6 months of her life.

The preferred habitat of the oriental cockroach is similar to that of the American cockroach. They usually inhabit areas below ground level, such as basements, storage areas, sewers. In seafood processing plants they are common in below-ground storage areas.

d) Cockroach Control - Cockroaches are a year-round pest in all food processing plants. Therefore, control of these pests has to be a year-round project, and it has to be in the form of sanitation and the use of chemicals.

The first step and most important aspect of control is sanitation. Recognizing that cockroaches require food, water, and a hiding place, and then moving against these areas with an ongoing sanitation program, is the foundation of cockroach control. Chemical control has to follow sanitation; it cannot be used alone or in place of it.

2. Flies

The most common of the seasonal pests of seafood processing plants are flies. A variety of flies are associated with these plants, but the most common are the house fly and the fruit fly.

a) House Fly - This insect is found all over the world. It is a pest to all segments of society, from households to industry. Like cockroaches, house flies can spread pathogenic organisms to humans and their food. It has been estimated that a single fly can carry 3,680,OOO bacteria. The pathogenic organisms are collected on the feet and mouthparts when the fly visits garbage, and some of the organisms are taken into the gut. The organisms are deposited when the fly crawls on human food or are deposited in the fly's excrement.

The house fly passes through three stages on its way to becoming an adult. From 75 to 150 eggs are deposited at one time, and there are several such layings at intervals of 3 or 4 days. Under warm summer temperatures, the egg requires 8-12 hours to hatch. The maggot that hatches from the egg begins feeding and gnawing. The maggot stage lasts about 5 days. When full-grown, the maggot changes to the pupa stage. This is a resting stage, and lasts about 4 days. The adult fly comes out of the small seed-like pupa stage - and the cycle starts all over.

The maggot stage in the fly's life does most of the feedings; the adult simply takes in a little fluid for quick energy. The adults may be attracted to rotting garbage by the smell and also by a desire to lay eggs. They are attracted to window screens and picnics for the same reason - the smell of food. The danger comes when flies move from garbage or manure to human food.

House flies are more abundant in the late summer and fall because the population has been building during the warm summer months. The adults enter buildings in search of food and shelter from the cool nights. Once inside they seldom leave.

House Fly Control - Since house flies are probably breeding away from the plant site, and flying to the site, there is little hope of controlling the size of the fly population outside the plant. Control must be aimed at 1) preventing entrance to the plant and 2) reducing the number inside the plant.

Most food processing plants use air screens and appropriate doors. These are excellent mechanical controls for flies, if they are strong enough. The stronger the better.

Control inside the plant can be achieved with electric grids. These work by attracting the adult flies to a special blue light and killing them with an electrical shock. These traps should be run day and night, and the catch basin should be cleaned out every day.

b) Fruit Flies - These tiny flies are also seasonal pests. They are abundant in the late summer and fall. The adults are small (about l/10" long), with light brown bodies and red eyes. The adults are attracted to fruit, especially rotting fruit. Since they are not attracted to sewage or animal waste, the amount of pathogenic bacteria they carry is probably limited.

The life cycle and feeding habits of fruit flies are similar to those of house flies. In the late summer there is an abundance of rotting plants and fruit, thus allowing the fruit fly population to increase rapidly. The adult flies live about a month.

Fruit Fly Control - Complete control of these pests-as for most insect pests-is nearly impossible. Air curtains and electric traps may be somewhat effective. Removal of all attractive material (rotting fruit, fermenting foods) around the building will help.

3. Flour Moths

The flour moths are among the most common insect pests of grain products. They are called flour moths because they prefer milled cereal products such as flour and meal; they seldom attack sound kernels of grain.

Flour moths and other insect pests of grain products are present throughout the flour manufacturing and distribution scheme. These pests can be found at the mill, in warehouses, in delivery trucks, and at their final destination. Therefore, these insects are likely to be a constant problem and will need constant attention.

Female moths lay eggs singly or in small groups, not in egg cases like cockroaches. Caterpillars hatch from the eggs and feed on the foodstuff. The caterpillars grow and shed their skin several times before they are fully grown. The caterpillar spins a silken cocoon and transforms into a pupa, from which the adult develops and later emerges. Males and females live for a short time; the females die soon after the eggs are laid.

The infestation and damage to the flour is done by the caterpillar stage. Adult moths do not feed; they return to the flour only to lay eggs.

Indian Meal Moth

This medium-sized moth has a wing expanse of about three-fourths inch. The adult moth is easily distinguished from other grain pests by the color bands on the large, front wings. The outer two-thirds of the wings are reddish brown; the region behind the head is gray.

Female moths can lay from 100 to 300 eggs, singly or in groups, on food material. The eggs hatch in about three days. The caterpillars feed upon grain products, dried fruits, nuts, and a wide variety of foodstuffs.

When full grown, the Indian meal moth caterpillar is about half an inch long and is grayish white, sometimes varying to greenish and pinkish colors. The caterpillar spins a web as it becomes fully grown and leaves a silken thread behind wherever it crawls. This webbing is often dense enough to attract attention when sacks of flour or meal have become heavily infested.

During warm weather, the Indian meal moth may pass through the egg, larval, and pupal stages in 6-8 weeks.

Mediterranean Flour Moth

This small moth has a wingspread of about 1 inch. Its large front wings are gray with wavy black markings.

The female moth lays small white eggs in accumulations of flour and meal, on which the hatched catapillars feed. The full-grown caterpillar spins a silken cocoon, in which it transforms into a reddish-brown pupa.

During warm weather, the Mediterranean flour moth requires 8-9 weeks to pass through the egg, larval, and pupal stages.

4. Flour Beetles

Such a great number of beetles infest stores of flour that listing them all or providing life history data is not practical. Three of the most common species are presented here; the other species have similar habits and life histories.

Flour beetles are often present throughout the manufacturing and distribution process. Like flour moths they can be a pest at the mill and in the food-processing operation, and require constant attention.

Female beetles lay eggs singly in the flour. The larva or "'grub" that hatches from the egg will feed on the foodstuff. The grub stage may last 14-16 months. The full-grown grub builds a cocoon out of scraps of the food material and transforms to a pupa. Male and female beetles often live for several months to a year.

The infestation and damage to the flour is done by the adult and grub stages. Adults and grubs have chewing mouthparts.

Sawtoothed Grain Beetle - This small, brown beetle is probably the most common flour pest. It is slender, about one-tenth inch long, with six sawtooth projects on each side of the thorax.

Adult beetles usually live 6-10 months, but some may live as long as 3 years. The female lays 43-285 eggs loosely in the flour and meal. The eggs hatch in about 4 days and the grub begins feeding. The adult and grub stages feed on all food of plant origin, especially grain products such as flours, meals, nut meats, candies, and dried fruits.

Red Flour Beetle and Confused Flour Beetle - These small, shiny, reddish-brown beetles are about one-seventh inch long. They are distributed over the world and are very abundant in the United States. They are general feeders on grain products, and are the most abundant and injurious insect pests of flour mills in the United States.

The average life of the adults is about 1 year. The female lays an average of 450 eggs loosely in flour or food material in which the adults live. The eggs hatch in 5-12 days and small worm-like grubs emerge. The grub stage feeds on flour or other food material made from grain.

When fully grown, the larvae transform into pupae; they do not construct a cocoon. Shortly afterwards they transform to adults. In summer, the period from egg to adult is about 6 weeks. The life cycle is prolonged by cold weather, as is true of all grain pests.

Cigarette Beetle

As its name implies, the cigarette beetle is primarily a pest of dried tobacco either in the stored, bundled form or in cigars and cigarettes. But they can feed on a variety of stored products including cereal products, ginger, raisins, dates, pepper, and dried fish.

The adult beetles are oval, about one-tenth of an inch long, and are covered with small hairs which give them a silky, yellowish-brown color. The female produces about 100 eggs, which are deposited on or near the adult beetles. The larvae are creamy white except for the yellow head and brown mouthparts. They become fully grown in about 40 days. The entire life cycle can be completed in 45-50 days, and there may be 3-6 generations a year.

5. Casual Invaders

There are several other insects and arthropods that occasionally invade food-processing operations. They represent no threat or potential infestation, but may cause concern.

a) Silverfish

These insects are often found in food processing operations, but are not a serious or potentially harmful pest. These insects prefer vegetable matter with a high carbohydrate and protein content. However, indoors they will feed on flour, starch, paper, glue, sugar, molds, and dried fish. They can go for up to 1 year without food, so sanitation alone will not eliminate an infestation, although it may prevent new ones from starting.

b) Ground Beetles

These blackish-brown beetles are common in late summer and fall. The adults are good fliers, and will come to lights at night. The larval stages live outdoors.

c) Sowbugs

These small relatives of the crawfish are usually found in dark, moist environments. They feed on vegetation, and will not infest buildings unless there is a moisture problem.

d) Centipedes

These fast-moving, predacious animals are usually not seen in numbers. They feed on insects and spiders inside and outside buildings. Control is rarely recommended for these animals.

e) Ants

Only a few ants build their nests inside buildings. Most have their nests outside in the soil and invade buildings looking for food. Control must be directed at the point of entry, outside the building.

f) Crickets

These insects are most common in late summer and fall, when the population is composed of adults. They are good fliers, are attracted to lights at night, and will seek a warm location on cool fall nights.

g) Spiders

Spiders are usually pests in the spring and fall. They are abundant in the spring when males and females are mating, and in the fall when some seek shelter from the cool weather. It may be very difficult to eliminate this problem, but there is some relief in knowing that spiders are beneficial animals-feeding on insects and other spiders.

The black widow and brown recluse spider are the only poisonous species in the eastern United States.

6. Rodents

a) Mice

Mice can cause a great deal of damage to processing plant materials. Because of their habit of nibbling, they contaminate much of the material not actually destroyed. A knowledge of mouse habits is important in developing effective control programs. Each male mouse stakes out a territory around his nest. He may not travel more than ten feet from his nest if food is close. For this reason, baits should be placed 10-20 feet apart. Mice are not suspicious of new foods and eagerly sample them. Mice also investigate any new object in their territory, so that changing bait or trap placements will improve control.

b) Rats

Rats are serious pests because they contaminate and destroy food products, carry diseases and external parasites, and often bite people. A knowledge of rat behavior is essential to successful control.

Rats which have become conditioned to eating a particular food approach new food cautiously. If it tastes bad or makes them sick, they won't eat it again (bait shyness). When baiting, more effective control can be obtained by using a bait that is fresh and identical to the food the rats are using. If different food is used, it may be necessary to pre-bait a few nights before adding a toxicant to the bait. Rats also require free water to drink. If water sources can be eliminated, liquid baits are effective. Rats, especially males, establish "territories" and fight to preserve this area from strange males. Reducing or eliminating of food sources and harborage increases this competition, and the rat population decreases. Rats also prefer to run next to walls or other surfaces; therefore, traps and baits should be placed in these runways.

The first part of any good rat control program consists of determining just where the rats are living, feeding, and traveling, and the extent of the infestation. Once this has been done, it is essential to eliminate their shelter areas and their food and water supplies. These sanitation measures are the backbone of successful control. However, in many instances, it may be best to poison or trap before upsetting the environment so that the rats do not scatter. It is also necessary to close off all entrances and exits rats can use to come and go from buildings. This is called rat-proofing, and must be done in many instances to obtain adequate control.

7. Pest Birds

There are many species of birds in the United Sates, but only three are normally considered pests around food manufacturing plants. All three cause problems in cities. All three survive well in close association with man. They are objectionable primarily because their droppings can be a serious food contaminant. They may also spread disease. Their droppings deface buildings, and their nests plug gutters and cause roofs to leak. Their noise and odor are offensive to many people. They sometimes also carry mites which can bite people.

a) English Sparrows (House Sparrow)

These birds are grayish, 3-4 inches long. The male has a prominent black throat, and a small black conical beak. The voice is a non-musical chirp. The egg is creamy white.

The nest is made of loosely-woven grasses, paper, and string. Sparrows prefer openings or hollows for nesting and will use any sort of nesting box, cavity, or opening in buildings.

They produce several broods each year using the same nesting areas over and over.

b) Pigeons

These birds are 6-10 inches long and vary in colors. They have a fan-shaped tail during take-off and landing, and the head bobs when walking. Their voice is a long, soft coo-oo-o. The eggs are white. They prefer to live and roost on roofs and high ledges.

The nest on ledges is not woven, but made with twigs and often soiled with excrement.

c) Starlings

The body and wings are gold-flecked, iridescent blue-black. They have large speckled bills that are yellow or olive.

In flight, they can be recognized by their short square tails and their short triangular wings. The eggs are bluish green.

Control - Shooting may be hazardous in some locations and may not be allowed by some local ordinances. It is a very effective means of killing scattered individuals or small flocks. It is best carried out by no more than a few individuals with low-powered guns who understand what they are doing. Where permissible, shooting with a 22-calibre gun, using # 12 birdshot, is effective.

Chemical control with avicides or other pesticides in certain situations may be the only means of effective control. Pesticides may not be used in a manner inconsistent with the label. Decisions as to the need, type of toxicant used, and manner in which it is used should be made by professionals. Information on current registered uses of specific compounds is available from the manufacturer or retailer. Sources of up-to-date pesticide recommendations include: industry representatives: the Cooperative Extension Service; local health, environmental, and agricultural departments; and technical experts in universities and state and federal agencies.

Poisons may be prohibited or may be too risky to use because of the dangers to humans, pets, or desirable birds. Poison sprays on roosts may be effective but dangerous; label directions must be followed precisely.

Toxicant baits, when eaten by pigeons, starlings, or sparrows, produce distress reactions in some birds, which frighten the rest of the flock away from the area.

Prebaiting is necessary when chemical baits are used, just as when trapping is to be done. --

Chemical baits are most effective when used against small flocks and when conditions can be carefully controlled.

Associated Problems - Dry, dusty droppings may contain fungus spores that can cause human diseases. Workers cleaning such areas, or involved in hand-capture of birds, should wear approved respirators. A worker should not smoke, eat, or drink anything until after his dusty clothes are removed and he has washed thoroughly.

Ectoparasites such as mites, made homeless when pigeons are removed, may migrate into areas where humans work and live. This problem can be prevented by spraying or dusting nesting or roosting areas as part of the control operations. Any good acaricide can be used if the label directions are followed.

8. Rodents and Their Control

Domestic rodents constitute a major food industry pest problem. There are three major domestic rodents in the United States, the house mouse, Mus musculus; the Norway (brown or sewer) rat, Rattus norvegicus and the roof (black or ship) rat, Rattus rattus. Rats eat almost everything people or livestock use as food. They contaminate much more than they eat, with the result that contaminated food products must be destroyed. Damaged packages must be repaired or replaced. Before you can control rodents, it is important you identify the correct species and know its behavior patterns.

9. Rodent Control Procedures

Complete control of rats and mice is essential to every food and feed processing plant and storage facility and must be accomplished to satisfy legal requirements, prevent losses, and meet individual company operating standards. While the degree of emphasis on any single phase of rodent control varies with the building structure, location, and species of rodent involved, an effective control program must start by building rodents out.

Exclude rodents from plants and warehouses by having every possible opening in outer walls, at floor/wall junctions, and at all exterior doors tight enough to prevent rodent entry, and by installing guards across runways to prevent entry at loading doors. There should be no openings larger than l/4 inch.

Good housekeeping and proper storage practices discourage rodents by eliminating their food and harborage. It is important to maintain a clearance of 18 inches between pallets of merchandise and the wall. This clearance allows room behind the stock for proper cleaning and pest control. A stock rotation system, utilizing the first in - first out method, is a necessity in all sound warehousing programs.

After every practical measure to build rodents out, and to eliminate their food and harborage has been taken, these preventive controls can be supplemented with baiting and trapping. In most cases, only those rodenticides falling within the anticoagulant group can be used in specific areas of food-processing facilities. These are available in several forms, such as granular, cereal-based bait, paraffinized bait pellets, and bait blocks. Paraffinized bait pellets and bait blocks should be limited to granular or cereal-based materials.

Unless there is a possibility of rat entry into a plant, liquid baits will be ineffective, since rodents require little water and they can live for many months on a grain diet, obtaining sufficient moisture from their food. The toxic ingredient in all of these baits is one of several anticoagulants, so named because they inhibit the normal coagulation of blood. The use of colored dyes for rodent baits helps prevent accidental human consumption through mistaken identity. Those cereal baits dyed with alkali-fast green appear to have the greatest rodent acceptance.

Proper placement of bait stations is very important. It is necessary to place bait stations around the exterior boundaries of food plants because the purpose in exterior perimeter baiting is to attract and eliminate rodents before they can invade the building. On the outside, bait stations should be positioned approximately every 50-100 feet around the perimeter of the building, which has been cleared of all vegetative matter and trash. Also the perimeter of the property line should be included in the baiting program. Again, the bait stations should be positioned approximately every 50-100 feet around the perimeter.

Bait stations being used around the exterior of the building should be large enough to accommodate more than one rat at a time. Each station should have at least two openings approximately 2 l/2 inches in diameter. The bait stations for exterior use may be constructed of metal or wood, so as to protect the bait from the weather and from disturbance by nontarget animals and children.

If bait stations are used inside plants, they need to be limited to non-food storage areas.

Two inexpensive materials for bait stations, which can be used in non-food storage areas, are water-resistant cardboard and formed plastic. Bait stations should be placed against walls and the adjacent areas kept clean.

When handling any baits, do not smoke, eat, drink, or put your hands near your mouth. After handling baits, wash your hands, using soap and water. As a safety factor, it is suggested that only ready-mixed baits be used.

All rodenticides received and used must be properly labeled. Labels contain directions of safe use, caution statement, and first aid and medical instructions. It is important that you read the label, understand label instructions, and follow label instructions during use. All bait stations and bait handling containers must also be properly labeled.

Store unused rodenticides in a locked area with access restricted to authorized personnel. The locations of all bait stations should be noted so that inspections can be made rapidly and the bait that has been consumed can be quickly replaced. At each inspection, smooth the surface of the granular baits so that new signs of feeding will show readily. Also, examine bait blocks for signs of rodent gnawing. Replace moldy, wet, caked, or insect-infested baits with fresh ones.

Records should be maintained indicating where baits have been disturbed, dead rodents found, droppings or tracks observed, or rodents have been caught in traps.

Some rats prefer burrows for nesting and harboraging. Burrows are found in earthbanks, in grassy areas, around weeds, under trash, around concrete slabs and railroad tracks, and in similar secluded places.

Reliance entirely upon bait stations for rodent control will not produce the desired results. It is necessary to kill rodents quickly upon entry into a building and, therefore, trapping must be used. The most popular, least expensive, and probably the most effective trap is the wooden 4-way snap trap. An enlarged trigger can be fitted into the wooden trap by inserting a piece of cardboard on the tripping device. This provides a treadle, covering nearly half the trap, which is easily sprung by a rodent traveling from any angle. Different size traps are used to catch mice and rats. To be effective, traps must be placed along walls or other runways with the trigger end abutted to the passage. An ample number of traps should be placed in each area requiring preventive control.

Be sure that the trap is properly set and in place.

Overhead beams, trusses, and ceiling wall junctions should not be overlooked as potential runways. Traps should be set across any obvious runways in overhead areas. On vertical structures, traps can be glued or otherwise fastened across runways.

When a rodent is suspected of being in a particular area, whether inside or out, lightly smooth a dusty material, such as talcum powder, around the suspected area. If rodents are present, you can observe their tracks in the dust. Then cover all possible avenues of escape with traps. Traps can be placed either unbaited or baited. When baiting traps, a variety of baits can be used, such as gum drops, peanut butter, bacon, or a piece of hot dog or cheese. The proper method of applying bait to traps is to pace a small amount on the trigger. Too much bait could prevent the trigger from activating properly, plus it looks messy.

Where a variety of food is plentiful, it is often just as effective to use traps without bait on them. The key is to place the trap properly so it is tripped by the rodent as it travels the wall/floor. All traps should be checked at least 3 times a week to be sure they are properly set and that dead rodents have been removed.

In order to indicate locations where traps are to be placed, a marking can be painted about the trap.

The automatic Ketch-All trap is especially good in wet areas and where other mouse traps are frequently tripped accidentally. A Ketch-All is a spring-powered box-type trap capable of catching up to l0 or more mice in one setting. These traps must be properly positioned against the wall. The easiest method of disposing of mice caught in a Ketch-All trap is to dunk the entire trap into a bucket of water to drown the mice. The mice can then be disposed in a covered waste container.

Remember the three fundamentals for effective rodent control:

a) build them out.
b) good housekeeping and proper storage.
c) trapping and baiting.

10. Mouse and Rat Facts

Preventing rodents from entering buildings requires some knowledge of their biology and behavior. The following list of facts will help provide basic information on rats and mice.

A mouse can squeeze through a l/4" wide crack under or beside a door. A rat needs l/2" wide crack to get in.

Mice live successfully outside or inside buildings-They can live in trash, grass, even in a small hole in the soil. Mice do not construct long, wandering burrow systems as rats do.

A mouse needs only a 3" x 1" hole for a home. A stable, protected place available for only a few days will induce a mouse to build a nest. Rats require a larger, more protected place, stable for several days before nest building.

Mice are very inquisitive. The average mouse takes only 10 minutes to investigate a new feeder. Rats will wait about 30 hours to explore a new food source.

A house mouse will eat at 2 or 3 locations, and just nose around 20 others in a 2-hour period (9:00 p.m. - 11:00 p.m.) in one night. The next night it will completely change the feeding locations, but still nose around those visited the first night. Rats will eat at the same location night after night.

A mouse may not seek out water in a dry location, but it will drink if water is available.

Mice are “stay-at-homes” compared to rats. Home territory is about 15 ft. to 30 ft. from an established nest. A rat has a home territory of 150 ft., but may travel l/2 mile from its nest site.

Mice can travel in some rail car and truck shipments, particularly in wrapped pallets. Rats have rarely been received in shipments of merchandise.

Characteristics of Domestic Rodents

	Norway Rat	Roof Rat	House Mouse
Weight	10 - 17 oz.	8 - 12 oz.	l/2 - 3/4 oz.
Total Length, nose to tip of tail	12 3/4 - 18 in.	13 3/4 - 17 3/4 in.	6 - 7 1/2 in.
Head and Body	Blunt muzzle Heavy, thick body 7 - 10 in.	Pointed muzzle Slender Body 6 l/2 - 8 in.	Small 2 l/2 - 3 l/2 in.
Tail	Shorter than head plus body	Longer than head plus body	Equal to or a little longer than body plus head
	Carried with less movement, comparatively, than roof rat. Lighter colored on underside	Uniform coloring top and bottom at all ages and for all subspecies.	
	6 - 8 l/2 in.	7 l/2 - 10 in.	3 - 4 in.
Ears	Small, close-set Appear prominent	Half buried in fur, Large for size of animal	Large, prominent, stand out from head
Fur	Coarse, generally red-brown to gray-brown	Black to slate gray; tawny above, gray-white below; or tawny above, white to lemon belly	Silky, dusky gray or gray

The four incisor teeth of rats and mice are as hard as steel. These animals can chew through asphalt, most plastics, plaster, sheet aluminum, wood, etc.

Building materials which will resist the “cutting” attack of rats and mice are: concrete block, brick or tile, 26 gauge or thicker galvanized sheet steel, l/4" glass, l/4" mesh, 19-gauge steel wire mesh or hardware cloth, l/4" 26 gauge perforated metal.

11. Physical Control

There are four goals for an effective physical control program for rodents:

a) stable nesting sites inside and outside the building must be eliminated;

b) all access holes must be closed;

c) traps, glue boards, bait stations, and all other safe control measures must be used inside and out to control rodents; and

d) a reliable inspection program must be established to prevent rodents from being introduced in delivered merchandise.

A good physical control program would include the following control measures:

a) Fill all potential nesting holes inside the building.

b) Eliminate all entry or nesting holes on the exterior of the building walls by closing holes down to an l/8" gap under doors; filling holes around pipes, electrical service through walls, vents, and cover drains.

c) Remove weeds and grass around outside of building.

d) Clean up spilled food as soon as possible.

e) Use multi-catch mouse traps inside and outside every entrance leading into the building. They catch mice and small rats outside more easily than inside.

f Use trigger mouse traps where a severe problem exists and manpower is available for twice daily inspection.

g) The careful and correct use of ultrasonic devices can be very helpful.

12. Equipment

Pest control personnel cannot carry out an effective program without quality equipment and chemicals. The most important pieces of equipment include:

a) stainless steel, compressed air sprayer
b) mechanical or thermal fogging device (ULV/ULD)
c) bulb duster,
d) flashlight.

Two especially useful items of equipment are air screens (or air curtains) and insect electrocuting units.

The proper use and maintenance of pest control equipment is an important part of any program.

1. Compressed Air Sprayer

The one-gallon sprayer is the most important tool for insect control. A stainless-steel sprayer with a multiple-spray nozzle can apply insecticides safely and accurately to insect harborage. Routine maintenance to keep this piece of equipment in proper working order will insure the safe and accurate placement of chemicals in a seafood plant.

2. Fogging Devices

Mechanical fogging devices are relatively simple to operate and require little maintenance. The aerosol particles are produced by spinning discs and rotors. In some of the units these discs and rotors need periodic adjustment to keep the size of the droplets small. If they are out of adjustment, the droplet size in the fog will be large and the fog will not travel into cracks and crevices to reach insects.

Examine the pesticide tank for residues, and clean tank regularly to prevent clogging. Check the hose to the pesticide tank for dirt, and clean regularly.

3. Bulb Duster

Small bulb dusters can be effective tools for applying insecticide powder into small cracks and crevices. When used properly, these small (4 to 8 oz.) hand-operated dusters can apply a thin layer of dust to insect harborage. Clumps of powder or thick layers of dust should be avoided. A small pebble or bearing in the bulb will aid in breaking up clumps of powder, and will agitate the contents of the duster, thus making it easier to apply a fine layer of dust.

4. Insect Electrocuting Units

Most insects are attracted to light. Flies in a dark room will move toward a window. Moths and other insects will fly to lights at night, and even some cockroaches will fly to lights. Insects are attracted to both visible light and ultraviolet (black) light (light just beyond the violet end of the visible spectrum). Some flies and moths are strongly attracted to ultraviolet light, and this attraction can be used against them in a control device - an electrocuting unit.

Electrocuting units are designed for either indoor or outdoor use. They are usually of aluminized frame construction, with chrome-plated electrical grids and guards, and removable insect-catch traps. Units are available in a variety of sizes and shapes, and are designed to hang from the ceiling, attach to a wall, or stand free. The attractant lamps are usually 40 or 80 watt.

How the units work-Insects attracted to ultraviolet (black) light are lured to the electrocuting unit through the strong attraction of the 40 or 80 watt bulb. In flying toward the light, the insects contact the electric grid in front of the bulb. When contact is made, night and day-flying insects-such as house flies, fruit flies, moths-are electrocuted by the grid charged with high voltage (about 4000V) and low current (9 milliamps). This charge is harmless to humans should the units be accidentally touched.

Range

The attractant range of electrocuting units is difficult to measure. Each insect species has a different eye structure with a different range of visual activity, ranging from 2 feet to 90 feet. Effective results with an electrocuting unit depend on the visual range of the insect, and the power factor of the attractant bulb. A 40 to 80 watt bulb-will usually perform 3 to 10 times more effectively than a 15 to 40 watt bulb.

Placement

Correct placement is a key factor in the degree of control achieved with electrocuting units. The units should be placed so as to attract and/or intercept the target pests. Moths and other night-flying insects are best controlled with ceiling-mounted units, while house flies are more likely to be intercepted from floor level up to a four to five foot height. Because sunlight or other strong light sources, as well as air currents, affect insect behavior. and flight patterns, units should be placed out of drafts and away from strong light.

5. Air Screens

Air screens (or air curtains) are the most effective method of keeping flies and other flying insects out of food preparation areas. Air screens create an invisible barrier of high ve!ocity air to stop insects from infiltrating food facilities and other clean work areas. To assure maximum efficiency in repelling insects, select a model that fits the door size and can provide adequate air velocity at ground level as well

as at the nozzle. Flies may be prevented from entering a doorway at the doorknob level, but walk easily through the door at ground level. To be effective, air screens must be installed on the outside of the doorway, be aimed properly to repel insects, and have adequate velocity at the top and bottom of the doorway. Conventional fans mounted above doors do not provide effective air screens.

13. Calculations and Mixing

Directions for mixing pesticides are always given on the pesticide label. Always read the directions before mixing; do not rely on old labels or directions-labels and mixing directions are frequently updated. When mixing a pesticide to spray, it is most important to add the correct amount of chemical to the water. Too little may result in a poor control job, while too much chemical may result in illegal residues, exposure to non-target animals, or unnecessary expense. Read the label and follow the directions to achieve effective control and safe use.

Sometimes it is necessary to prepare large quantities of a pesticide, and the calculations may not be explained on the label. The calculations necessary for large quantities are relatively simple; some examples are presented below.

a) Calculations

Sometimes you will find directions on how to make a finished spray of a specific percentage, for instance a 1% spray for cockroaches. The pesticide may be formulated as a 57% emulsifiable concentrate (EC). To make a 1% finished spray you would add 1 part of pesticide to 56 parts of water. For example, for 1 fluid ounce you would add 56 fluid ounces (1 3/4 quarts) of water.

When mixing percentages you should remember that 1 gallon of water weighs about 8.3 pounds. Thus, to make a 1% mix of pesticide in 100 gallons of water you must add 8.3 pounds of active ingredient (actual pesticide) of pesticide to 100 gallons of water.

Formula for wettable powder percentage mixing: to figure the amount of wettable powder (WP) to add to get a given percentage of active ingredient in the tank:

$$\frac{\text{(gallons of spray wanted)} \times \text{(\% pesticide wanted)} \times 8.3 \text{ (lbs/gal)}}{\text{(\% active ingredient in pesticide used)}}$$

Formula for emulsifiable concentrate percentage mixing: to figure the amount of emulsifiable concentrate (EC) to add to get a given percentage of active ingredient (actual pesticide) in the tank:

$$\frac{\text{(gallons of spray wanted) x (\% of pesticide wanted) x 8.3 lbs/gal}}{\text{(pounds of active ingredient per gallon of concentrate) x 100}}$$

Useful Facts to Remember:

- 1 gallon of water weighs about 8.3 pounds
- 1 pound = 16 ounces = 453.6 grams
- 1 pint = 16 fluid ounces = 473 milliliters
- 1 quart = 32 fluid ounces = 946 milliliters

b) Mixing

Most modem pesticides are designed to be mixed with water, then applied to control specific pests. Mixing wettable powders and emulsifiable concentrates requires careful attention to some simple rules:

- fill spray can or container to l/2 with water,
- add the measured amount of pesticide,
- add the remainder of water to the full mark.

14. Pesticide Application Methods

Before undertaking insect control with an insecticide near food processing, it is essential to recognize that EPA has established some definitions to assist in the regulation and control of insecticides in food-handling establishments. The definitions they use are as follows:

a) Food is defined by Section 201 (f) of the Federal Food, Drug and Cosmetic Act to mean (1) articles used for food or drink of man and animals, (2) chewing gum, and (3) articles used for components of any such article.

b) A Food Handling Establishment is an area or place other than a private residence in which food is held, processed, prepared, and/or served.

1) Non-Food Areas of food-handling establishments include garbage rooms, lavatories, floor drains (to sewers), entrances and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets, and storage areas (after food has been packed, canned, or bottled).

2) Food Areas of food-handling establishments include areas of receiving, serving, storage (dry, cold, frozen, raw), packaging (canning, bottling, wrapping, boxing), preparing (cleaning, slicing, cooking, grinding), edible waste storage, and closed processing systems.

c) Non-Residual Insecticides are those products applied to obtain insecticidal effects only during the time of treatment, and applied either as space treatments or contact treatments.

1) Space Treatment is the dispersal of insecticides into the air by foggers, misters, and aerosol devices for control of flying insects and exposed crawling insects.

2) Contact Treatment is the application of a wet spray for immediate effect.

d) Residual Insecticides are those products applied to obtain insecticidal effects lasting several hours or longer and are applied as general, spot, or crack and crevice treatment.

1) General Treatment is application to broad expanses of surface such as walls, floors, ceilings, or as outside treatment.

2) Spot Treatment is application to limited areas on which insects are likely to occur, but which will not be in contact with workers. These areas may be floors, walls, and bases or the outside of equipment. For this purpose, a "spot" will not exceed 2 square feet.

3) Crack and Crevice Treatment is application of small amounts of insecticides into cracks and crevices in which insects hide or through which they may enter the building. Such openings commonly occur in expansion joints, between different elements of construction, and between equipment and floors. These openings lead to voids such as hollow walls, equipment legs and bases, conduits, motor housing, and electrical junctions or switch boxes.

15. Application for Methods for Specific Pests

Cockroaches

These pests are associated with almost all aspects of seafood processing, and are present throughout the year. Cockroach control must be an ongoing program, and includes sanitation along with accurate placement of chemical insecticides.

Cockroaches require food, water, and a hiding place to successfully infest an area. Sanitation can eliminate some of the food and water, and therefore help to control cockroaches. Chemical insecticides applied to cockroach hiding places can be very effective in controlling cockroach infestations. Chemicals applied along baseboards, or as a general spray or fog are not effective in controlling cockroaches. Indeed, these "general applications" may promote infestations that are resistant to insecticides and difficult to kill. Chemicals should be placed where cockroaches hide (cracks and crevices, in equipment, behind sinks, etc.) so that they will be forced to come in contact with the insecticide that can kill them.

Chemicals applied to open spaces, exposed to air, light, and heat, can lose their potency in a short period of time. Cockroaches contacting these chemicals may not die because the residue is not potent enough. However, chemicals applied to cracks and crevices, where cockroaches hide, will remain potent longer, and contact more individual cockroaches.

The best application method for cockroach control is to use a compressed air sprayer with the nozzle set on pin stream or a nozzle equipped with a special plastic crack-and-crevice tip. Use the pin stream or the special tip to direct the chemical into suspected cockroach hiding places. Dust formulations can be effective if applied to dry areas where there is little or no air movement.

Some of the typical places to treat for cockroaches include:

a) compressor area of refrigerators and freezers
b) drip pan of a "frost free" refrigerator
c) electrical boxes
d) floor drains
e) above drop ceilings
f) boxes stored near food or water, especially near refrigerators
g) employee locker room and lunch areas
h) soft drink machines
i) dishwashing machines

Periodically changing the chemical used for cockroach control is not recommended, unless the effectiveness of the chemical is decreasing. Cockroaches can become resistant to some chemicals when used over a long period of time (and used improperly). Changing chemicals every six months or year may result in resistance to several insecticides, and leave nothing that provides control. Continue to use one chemical; switch to another only when it fails to give control.

Flies

Several species of flies can be pests of seafood processing operations, including house flies, fruit flies, and cluster flies. These pests are a seasonal problem; the warm summer and fall weather provide excellent breeding conditions for the larvae. Rarely do house flies and fruit flies breed inside food processing operations. The adults present inside have come in through doors and windows. Fly control must include sanitation outside buildings, and the exclusion of adult flies. Chemical control of flies is limited to fogging or space sprays. Mechanical and electrical devices are effective.

There have been several improvements on the traditional "fly paper" strips for fly control. Devices that attract adult flies to a sticky surface are effective and have been approved for food-handling areas.

The placement of electrocuting devices can influence how effectively they control indoor flies. Consider these facts about house flies and black light (=looks blue) electrocuting units:

a) 3-day-old male house flies are most attracted to black lights.
b) 5- to 6-day-old male house flies are not attracted to black lights.
c) The older (in days) and the hungrier male and female flies, the more they are attracted to blacklights that are about 1 foot off the floor.

When positioning black-light electrocuting units, consider placing at least one unit 1 to 2 feet off the floor, and other units 6-8 feet off the floor. This arrangement should provide maximum coverage.

There are some chemical methods of controlling flies inside and outside seafood processing plants. Granular baits (commonly called "fly grits") can be scattered around garbage and refuse areas. Adult flies are attracted to these baits and are killed. Some of these baits are effective even in damp or wet conditions, and some are not effective in wet areas. Chemical control inside buildings is usually limited to aerosol sprays, fogging, or ULV/ULD (Ultra Low Volume/Ultra Low Delivery) treatment. Each of these methods disperses chemicals into the air to kill various flying insects, including flies. The chemicals most commonly used include pyrethrins and resmethrin. In general, these chemicals provide quick knockdown and kill, but provide no residual control. Fogging and ULV/ULD treatment methods must be used only when production is stopped. All exposed surfaces must be cleaned before being again exposed to food or preparation materials.

Flour beetles, mealworms, silverfish. There are a variety of pests that must be treated on a need basis. Treatment with insecticides should follow a thorough inspection and clean up program. Flour beetles and mealworms do not move far from the site of infestation. The use of a heavy-duty vacuum cleaner can be very effective in controlling these pests. Direct the hose into cracks and crevices to pick up loose flour and other food particles. A strong vacuum will pick up infested food and insects.

Chemical control of these insects requires the use of a residual insecticide in cracks and crevices, and spot application. Apply the insecticide in an area where the insects are most often seen. Repeat application on a 10- to 15-day schedule.

16. Commonly Used Insecticides and Rodenticides

a) Insecticides

A variety of insecticides are registered for use in and around food processing operations. They differ in residual activity and in where (crack and crevice, food storage, food preparation areas) they can be applied.

BAYGON (propoxur) - A carbamate insecticide characterized by fast knockdown, long residual and flushing effect. Particularly effective against insects such as cockroaches and flies where rapid knockdown and residual properties are important.

BAYTEX (fenthion) - An organophosphate insecticide characterized by long residual activity. For general use as a residual insecticide in crack and crevice application indoors and general treatment outdoors for a wide variety of pests.

BORIC ACID - A common household or medicine cabinet item that can be used as an insecticide, primarily for the control of cockroaches. Applied as a dry, light dust, boric acid has residual activity. It can be used as a crack and crevice treatment, but must be kept dry to be effective.

CYGON (dimethoate) - An organophosphate insecticide used as a residual spray for controlling houseflies and other insects. For treating the outside of buildings.

DIAZINON (diazinon) - An organophosphate insecticide used extensively in controlling a variety of insects, particularly cockroaches. It is characterized by a long residual effect and broad-spectrum control of insects indoors and outdoors. Available in dust, emulsifiable concentrate, and encapsulated formulations.

DURSBAN (chlorpyrifos) - An organophosphate insecticide effective in controlling a variety of insects. Particularly effective against insects such as cockroaches where residual activity is necessary. Can be used in crack and crevice treatment of food areas and general treatment outdoors.

DDVP (dichlorvos) - An organophosphate insecticide. A contact and stomach poison, it acts also as a fumigant. Can be applied as a crack and crevice, and as a general spray, to both food and non-food areas. Effective against a wide range of insects. Available formulations include: emulsifiable concentrations, wettable powder, oil-base concentrations, aerosols, resin strips, and baits.

DRIONE - A combination of amorphous silica gel and pyrethrins synergized with-peperonyl butoxide. This insecticide dust can be applied as a crack and crevice treatment to food and non-food areas. It is effective against a wide variety of pests.

FICAM (bendiocarb) - A carbamate insecticide. A contact insecticide, it has no fumigant action at normal working temperatures, and is characterized as a non-repellent/non-flushing, odorless, and non-staining insecticide. Effective against a wide range of insects, it can be applied as a crack and crevice and general spray to both food and non-food areas. Available formulations include a wettable powder and a dust.

KNOX OUT (diazinon) - An organophosphate insecticide in which diazinon is enclosed in tiny capsules (or beads) of thin plastic material to control release of the chemical and extend the residual life. It is effective against a wide range of insects.

KILLMASTER (chlorpyrifos) - An organophosphate insecticide in which chlorpyrifos is held in an organic solvent or binder and released a little at a time at the top surface of the coating. Applications can be made as a paint-on, spot, or crack-and-crevice treatment.

MALATHION (malathion) - An organophosphate insecticide, characterized by its broad spectrum control and its low toxicity to mammals. Cythion (a brand name for malathion) is a low-odor product manufactured by a patented process, and is recommended for indoor use. Malathion can be applied as a crack-and-crevice and general spray to food areas and non-food areas.

ORTHENE (acephate) - An organophosphate insecticide. Spot treatments can be applied to food and non-food areas, but not while food is being prepared. Effective against resistant strains of German cockroaches.

PYRENONE - This combination of pyrethrins and piperonyl butoxide is used in ratios ranging from 5:1 to 2O:l by weight, as pressurized sprays, solutions, wettable powders. It is effective against a variety of insects.

PYRETHRINS - A botanical insecticide, the flowers of a chrysanthemum plant are the source of the active principle of this insecticide. Pyrethrins are characterized by a flushing-action and rapid knockdown of a wide range of insects. However, there is little residual activity. Pyrethrins have a low order of toxicity to mammals, and can be applied as a spray to both food areas and non-food areas.

PYRETHORIDS - Pyrethroids are synthetic pyrethrin-like compounds produced to duplicate the activity of natural pyrethrins.

RESMETHRIN - A synthetic pyrethroid insecticide, characterized by flushing activity and a moderate residual life. It can be applied to non-food areas and outside areas.

SAFROTIN (propetemphos) - An organophosphate insecticide, effective against cockroaches, ants, silverfish, and other insect pests. It may be used only in non-food areas of food-handling establishments.

SEVIN (carbaryl) - A carbamate insecticide, characterized by short residual activity. This insecticide can be applied only to non-food areas and outside areas.

b) Rodenticides

Rodenticides differ widely in their chemical nature. They also differ widely in the hazard they present under practical conditions.

WARFARIN - An anticoagulant that is effective in controlling rats and mice. It is odorless and tasteless and effective in very low dosages. Action is not rapid; usually about a week is required before a reduction in the rodent population is effected. Warfarin has found ready acceptance where rodents do not tend to become bait shy after once tasting the material. They continue to consume it until its anti-clotting properties have produced death through internal bleeding.

FUMARIN - An anticoagulant that is effective in controlling rats and mice. It is recommended as a multiple-dose rat poison. Three to five consecutive feedings, daily or not over two days apart, cause death by internal bleeding.

RED SQUILL - A rodenticide made from plant material. It is specific for rats and non-toxic to other warm-blooded animals when used in recommended dosages. The specific toxicity to rats is due to their inability to vomit; the product induces vomiting in other animals. Red Squill is mixed in baits.

DIPHACIN. PIVAL - Anticoagulants- that have the same anticoagulant properties as Warfarin, and have replaced Warfarin where rodent avoidance behavior (bait shyness) has made it ineffective. Sold as baits, they must be ingested for several consecutive days before they become effective.

TALON - An anticoagulant that is effective against a variety of pest rodents. It is effective against rodents which are resistant to conventional anticoagulants. Only a single feeding is necessary for rodent death to occur.

13. Product Recall Plan

From time to time a seafood processor may need to remove one of its products from the market. The vast majority of recalls are voluntary. Whether the problem is minor or life-threatening, good advance planning is the key to resolving it thoroughly and quickly. This section of the operations manual is intended to help a company create a product recall plan or help it evaluate and improve a recall plan that is already in existence.

Definitions

For precise legal definitions, consult an attorney on FDA guidelines. Generally speaking, terms are interpreted as follows:

Correction

A correction means a firm is modifying, adjusting, relabeling, destroying, or inspecting a product, without removing it to another location, so firm will not be in violation.

Recall

A recall means a firm, on its own initiative or at the request of a government agency, is removing or correcting some aspect of a marketed product which would be found to be in violation and against which action would otherwise be taken. Recall does not include a market withdrawal or a stock recovery.

Market withdrawal

A market withdrawal means a firm is removing or correcting a distributed product where either there is no FDA violation or a minor violation against which FDA would not act. This includes such purposes as normal stock rotation and, in the absence of manufacturing or distribution problems, response to actual or alleged tampering with individual units.

Stock recovery

A stock recovery means a firm is removing or correcting a product that is unmarketed and/or has not left the firm's control.

Recall classification

A recall classification is the FDA number designating the severity of the health hazard presented by the recalled product.

> Class I indicates a strong chance the product will cause bad health consequences or death.
> Class II indicates the product will probably cause temporary or medically reversible bad health consequences, but serious consequences are remote.
> Class III indicates the product is not likely to cause adverse health consequences.

Depth of recall

Depth of recall are levels used to indicate how far into the distribution chain the recall will extend, depending on the seriousness of the hazard and how far the product has been distributed.

- Consumer or User Level may vary with the product and includes any intermediate wholesale or retail level; may include the individual consumer.
- Retail Level is the recall level immediately before the consumer level-for example, grocery stores-and includes any intermediate levels.
- Wholesale Level includes all distribution levels between the manufacturer and the retailer.

Objectives

A recall has three basic objectives:

1. Locate the recalled product already in the marketplace.
2. Remove the product form the marketplace.
3. Provide accurate, up-to-date information throughout the recall.

Failure to conduct a recall when products are, or could be considered to be, illegal, unsafe, or a threat to public health can have serious consequences, including product liability lawsuits and civil or even criminal penalties. Lawsuits against a company, its officer and/or its employees seriously degrades a product's image and damages a company's reputation. The more serious the problem, the more swift and effective the recall must be.

FDA Considerations

A good recall plan must include an understanding of the United States Food and Drug Administration ("FDA") requirements. Keep in mind that FDA has the responsibility for insuring that food products which present a real or potential threat to public health are removed from the marketplace and reconditioned or destroyed. FDA is always concerned that recalls of such products are done quickly and completely. While the firm is morally and legally responsible for its product, it is FDA's privilege and duty to evaluate whether that responsibility is being met. Although it does not have statutory authority to compel a recall, FDA can request one and can back up its request with the real threat of enforcement action. Once FDA is involved in monitoring a recall, you can be certain that, to some extent, FDA will call the shots and will not accept a poorly done, last-minute plan of action. For this reason, a recall plan should be drafted thoroughly and in advance, with the help of an attorney, and legal advice should be sought before considering any recall. The FDA's guidelines, policies, and procedures for recalls are contained in Title 21 of the Code of Federal Regulations Part 7, more specifically 21 C.F.R. 7.40-7.59. Details on FDA enforcement actions related to this question can be found in Chapter 18, Section C of this manual.

State Regulations

State regulations vary concerning product recalls. Some states have recall powers while other states have limited authority. Each processor should be aware of their state's regulations and include a copy in this section.

Investigating Product Problems

Recalls are initiated as a result of customer or consumer complaints. It is essential that every legitimate consumer and/or customer complaint be investigated thoroughly and documented. Sometimes a product problem is identified in-house, that is, before the product leaves the processor; it should be investigated and documented in the same way. Any investigation should be as objective as possible, and every effort must be made to assess a complaint fairly and not cover over a problem. The company must keep an accurate record of what was reported, when, and by whom, as well as how the company acted in response. If a product problem is determined to be one that could threaten public health, recall action must be taken right away, with consideration given to involving FDA in the process.

General Recall Procedures

An example of how a product recall plan is implemented is included at the end of this chapter. Important steps to initiating a recall include the following:

- Have a well-thought-out, written recall plan in place that can be activated immediately; speed will be critical if management determines recall to be necessary.
- Have a well-trained recall team in place, from management down, prepared to organize, analyze, document, and disseminate critical information about a product problem.
- Management should actively and promptly seek detailed information on the nature and level of the product problem.
- Management, depending on the nature and extent of a product problem, should make and document a decision for either immediate recall, market withdrawal, stock recovery, or the need for additional information.
- Once a decision has been made to institute a recall, the recall must be initiated immediately, and those involved must be given appropriate written notice.
- If management believes the product problem endangers public health, a further decision must be made about informing FDA or other relevant governmental authorities.
- If a determination is made to notify FDA, follow FDA procedures and requests regarding the recall; be prepared to present a recall plan for FDA's review and, if well done, agreement.
- The recall team must be fully informed of their responsibilities, which will depend on the depth of the recall, determined by the nature of the product problem and, in some instances, by its FDA classification or state requirements.
- Determine the distribution of the product and identify the code numbers to be recalled.
- Decide as soon as possible what will be done with the recalled product, whether it is to be destroyed, reconditioned as food for human beings, as food for animals, or for another use. Destruction plans can require contact with Environmental Protection Agency personnel at the state or federal level, depending on the nature of the product problem.
- Issue warning to the public when, as, and if necessary.

- Prepare weekly status reports documenting the recall and use them to prepare status reports for FDA or for the appropriate state agency.
- Monitor the recall closely and assess whether it is being carried out quickly and effectively, take remedial steps as necessary, and document all effectiveness checks and remedies.
- Stay in contact with customers and consumers, as necessary.
- Stay in contact with FDA and/or state agencies, as necessary.
- Decide in advance what constitutes completed recall; notify all involved.

Product Recalls

All products will be labeled with a production code. This is an example of the code: 0901911. The first two digits represent the month, the second two the day, the third two the year and the final digit the production line. The example above would be a production day of September 01, 1991 from line one. Each product will have a corresponding code to represent that date of production and the production line.

All customer complaints are directed through the sales representative who handles that account. The sales representative fills out a complaint memo and gives it to the Quality Assurance Manager.

The Quality Assurance Manager decides if a product recall should be initiated, whether it be from a customer complaint or an internal finding. Once the Quality Assurance Manager decides to initiate a recall, he will first identify the product and production dates that need to be recalled. Next all of the sales representatives are notified of the recall. The sales representatives then notify the customers who are under their responsibility. Each sales representative will then notify the Quality Assurance Manager as to which customers have the affected product and how much of the product they have. All recalled products will be delivered back to Example Blue Crab Company.

A. Federal Recall

If the recall is of a serious nature, i.e. illness, death or injury, the Quality Assurance Manager will notify the media and the local FDA district office of the recall. Recalled products will be destroyed by the Example Blue Crab Company or reconditioned as deemed appropriate by FDA.

B. State Recall

There may be occasions in which a recall is initiated by the Virginia Department of Health, Division of Shellfish Sanitation. If this occurs, there is some specific information that will be required by the Division. The name, type, size, form, shipping or unit package, and a brief description of the product are needed in addition to the code numbers from the lot, the recalling firm, the reasons for recall, the volume of product in commerce, the distribution pattern, the firm's recall strategy, and the contact official at the firm. The Division will work closely with the firm to assure that the recall occurs smoothly and that the problem which precipitated the recall is abated. The plan for final disposition of the recalled product will be worked out with the Division. The Division's objective in any recall is to abate a potential health hazard as soon as possible with minimal inconvenience to the public and the producer.

Note: See page 13-3 for a discussion on product recalls

Example - For Illustrative Purposes Only

14. Consumer Complaint File Procedure

AI1 consumer complaints are directed through the sales representative that handles the account where the complaint originated. The sales representative fills out a complaint memo and gives it to the Quality Assurance Manager. The Quality Assurance Manager fills out a Customer Complaint Form and investigates the cause of the complaint. Action is taken to correct the cause of the complaint if it is a legitimate complaint. If any action is taken because of a complaint, it is recorded on the Customer Complaint Form.

All of the Customer Complaint Forms and memos from the sales representatives are kept on file in the Quality Assurance Manager's office.

VIRGINIA OCCUPATIONAL SAFETY AND HEALTH

VOSH PROGRAM DIRECTIVE: 02-211A ISSUED: June 15, 1991

SUBJECT: Control of Hazardous Energy Sources (Lockout/Tagout) Standard

A. Purpose.

This directive establishes and amends procedures for uniform enforcement of the Lockout/Tagout Standard, § 1910.147 of Subpart J.

B. Scope.

This directive applies to all VOSH personnel and specifically to Occupational Safety Enforcement (General Industry) and Voluntary Compliance personnel.

C. Reference.

45 Federal Register 41012 (June 17, 1980).
53 Federal Register 15495 (April 29, 1988).
54 Federal Register 36644 (September 1, 1989).
55 Federal Register 38667 (September 20, 1990).
OSHA Instruction STD 1.73 (September 11, 1990).

D. Cancellation.

VOSH Program Directive 02-211.

E. Action.

The Assistant Commissioner, Directors and Supervisors shall assure that employers understand the provisions of this Directive and comply with the policies and procedures contained in it.

F. Effective Date.

The effective date is July 1, 1991.

G. Expiration Date.

Not Applicable.

H. Background.

Please refer to VOSH Program Directive 12-237C.

I. Summary

This standard is federal identical and includes federal technical corrections. It supplements existing lockout related provisions contained throughout the general industry standards by providing comprehensive and uniform procedures. The standard requires that lockout be used for machines and equipment which are capable of being locked out unless the employer can demonstrate that use of a tagout device is as effective as use of a lockout device in disabling a machine and in protecting employees from the releases of potentially hazardous energy during the performance of maintenance and servicing activities.

J. Standard with Citation and Compliance Guidelines.

CAVEAT: This standard is NOT applicable to the safeguarding of workers from the normal production operations related to operating various production and process equipment in the General Industry environment, not is it applicable to the hazards of contacting electrically live parts (exposure to electric current). Such hazards continue to be regulated at VOSH Standard 1910, Subparts 0 and S, respectively.

CAVEAT: This standard does NOT replace existing specific VOSH lockout/tagout provisions, such as those noted in Appendix B. Where applicable, it supplements the requirements of such standards by establishing a lockout/tagout procedure, the training of employees in energy control programs and periodic inspections of the programs.

TABLE OF CONTENTS

NOTE: **Chapter numbers here do not always correspond with the chapter designations in the text.**

§ 1910.147 - COMROLOF HAZARDOUS ENERGY SOURCES (lockout/tagout).

(a) Scope, application and purpose-

(1) *Scope.*

(i) This standard covers the servicing and maintenance of machines and equipment in which the unexpected energization or start up of the machines or equipment, or release of stored energy could cause injury to employees. This standard establishes minimum performance requirements for the control of such hazardous energy.

The term "unexpected **energization"** means **the** unanticipated or unforeseen movement of **a** component or **a** system.

(ii) This standard does not cover the following:

(A) Construction, agriculture and maritime employment;

(B) Installations under the exclusive control of electric utilities for the purpose of power generation, transmission and distribution, including related equipment for communication or metering; and

Non-utility employers in workplaces that are engaged in the activities of power generation, transmission and distribution are covered by this standard.

(C) Exposure to electrical hazards from work on, near, or with conductors or equipment in electric utiliiation installations, which is covered by Subpart S of this part; and

(D) Oil and gas well drilling and servicing.

(2) *Application.*

(i) This standard applies to the control of energy during servicing and/or maintenance of machines and equipment.

As defined in section (b) below.

(ii) Normal production operations are not covered by this standard (See Subpart 0 of this Part). Servicing and/or maintenance which takes place during normal production operations is covered by this standard only if;

As defined in section (b) below.

(A) An employee is required to remove or bypass a guard or other safety device; or

(B) An employee is required to place any part of his or her body into an area on a machine or piece of equipment where work is actually performed upon the material being processed (point of operation) or where an associated danger zone exists during a machine operating cycle.

The term "associated danger zone" means areas other than the point of operation where an employee could be exposed to injury.

Note: Exception to paragraph (a)(2) (ii): Minor tool changes and adjustments, and other minor servicing activities, which take place during normal production operations, are not covered by this standard if they are routine, repetitive, and integral to the use of the equipment for production, provided that the work is performed using alternative measures which provide effective protection (See Subpart 0 of this Part).

(iii) This standard does not apply to the following.

(A) Work on cord and plug connected electric equipment for which exposure to the hazards of unexpected energization or start up of the equipment is controlled by the unplugging of the equipment from the energy source and by the plug being under the exclusive control of the employee performing the servicing or maintenance.

(B) Hot tap operations involving transmission and distribution systems for substances such as gas, steam, water or

petroleum products when they are performed on pressurized pipelines, protided that the employer demonstrates that (1) continuity of services is essential; (2) shutdown of the system is impractical; and (3) documented procedures are followed, and special equipment is used which will provide proven effective protection for employees.

VOSH agrees with federal OSHA's intent that this operation should be allowed in certain limited conditions where continuity of service is essential and system shutdown is impractical such shutdown may not be practical because shutting down the system may be more hazardous than allowing the continued operation of the system. Conducting such operations simply to expedite work is prohibited.

(3) *Purpose.*

(i) This section requires employers to establish a program and utilize procedures for affixing appropriate lockout devices or tagout devices to energy isolating devices, and to otherwise disable machines or equipment to prevent unexpected energization; start-up or release of stored energy in order to prevent 'injury to employees.

(ii) When other standards in this part require the use of lockout or tagout, they shall be used and supplemented by the procedural and training requirements of this section.

(b) Definitions applicable to this section.

Affected employee. **An employee whose job requires him/her to operate or use a machine or equipment on which servicing or maintenance is being performed under lockout or tagout, or whose job requires him/her to work in an area in which such servicing or maintenance is being performed.**

Authorized employee. A person who locks out or tags out machines or equipment in order to perform servicing or maintenance on that machine or equipment. An affected employee becomes an authorized employee when

Implicit in this definition is that the authorized employee has been designated to perform such duties by the employer.

that employee's duties include performing servicing or maintenance covered under this section.

The "authorized employee" not only attaches the lock or tag but must also perform the servicing or maintenance to the affected machines or equipment (except as outlined for group servicing).

Capable of being locked out. **An energy isolating device is capable of being locked out if it has a hasp or other means of attachment to which, or through which, a lock can be affixed, or it has a locking mechanism built into it. Other energy isolating devices are capable of being locked out, if lockout can be achieved without the need to dismantle, rebuild, or replace the energy isolating device or permanently alter its energy control capability.**

Energized. **Connected to an energy source or containing residual or stored energy.**

Energy isolating device. **A mechanical device that physically prevents the transmission or release of energy, including but not limited to the following: A manually operated electrical circuit breaker; a disconnect switch; a manually operated switch by which the conductors of a circuit can be disconnected from all ungrounded supply conductors and, in addition, no pole can be operated independently; a line valve; a block: and any similar device used to block or isolate energy. Push buttons, selector switches, and other control circuit type devices are not energy isolating devices.**

Energy source. **Any source of electrical, mechanical, hydraulic, pneumatic, chemical, thermal, or other energy.**

This standard also applies to piping systems, and specifically at paragraph (d) (S), requires that accumulators shall be discharged and that pressurized lines shall be blocked and bled.

Hot tap. **A procedure used in the repair, maintenance and services activities which involves welding on a piece of equipment (pipelines, vessels or tanks) under pressure, in order to install connections or appurtenances. It is commonly**

used to replace or add sections of pipeline without the interruption of service for air, gas, water, steam, and petrochemical distribution systems.

Lockout. **The placement of a lockout device on an energy isolating device, in accordance with an established procedure, ensuring that the energy isolating device and the equipment being controlled cannot be operated until the lockout device is removed.**

Lockout device. **A device that utilizes a positive means such as a lock, either key or combination type, to hold an energy isolating device in the safe position and prevent the energizing of a machine or equipment. Included are blank flanges and bolted slip blinds.**

Normal production operations. **The utilization of a machine or equipment to perform its intended production function.**

Servicing and/or maintenance. **Workplace activities such as constructing, installing, setting up, adjusting, inspecting, modifying and maintaining and/or servicing machines or equipment. These activities include lubrication, cleaning or unjamming of machines or equipment and making adjustments or tool changes, where the employee may be exposed to the unexpected energization or start-up of the equipment or release of hazardous energy.**

Setting up. **Any work performed to prepare a machine or equipment to perform its normal production operation.**

Tagout. **The placement of a tagout device on an energy isolating device, in accordance with an established procedure, to indicate that the energy isolating device and the equipment being con-**

Lockout or tagout is not required by this standard if the employer can demonstrate that the alternative means enables the servicing employee to clean, unjam or otherwise service the machine without being exposed to unexpected energization or activation of equipment or release of stored *energy.*

trolled may not be operated until the tagout device is removed.

Tagout device. **A prominent warning device, such as a tag and a means of attachment, which can be securely fastened to an energy isolating device in accordance with an established procedure, to indicate that the energy isolating device and the equipment being controlled may not be operated until the tagout device is removed.**

(c) *General-(1) Energy control program. The* employer shall establish a program consisting of energy control procedures, employee training and periodic inspections to ensure that before any employee performs any servicing or maintenance on a machine or equipment where the unexpected energizing start up or release of stored energy could occur and cause injury, the machine or equipment shall be isolated from the energy source, and rendered inoperative.

Such program and procedures must be in writing as outlined in paragraph (c)(4). Refer to Appendix A for an example of typical procedures Use of this Appendix is not mandatory

This section will normally be cited as "serious" if an employer fails to have an energy control program except as provided by the note under (C)(4)(i).

(2) Lockout/tagout (i) If an energy isolating device is not capable of being locked out, the employer's energy control program under paragraph (c)(l) of this section shall utilize a tagout system.

This section will normally be cited as "serious" if an employer fails to tagout where lockout cannot be accomplish&

(ii) If an energy isolating device is capable of being locked out, the employer's energy control program under paragraph (c)(1) of this section shall utilize lockout, unless the employer can demonstrate that the utilization of a tagout system will provide full employee protection as set forth in paragraph (c)(3) of this section.

VOSH agrees with federal OSHA that lockout is a surer means of ensuring deenergization of equipment than tagout, and that it should be the preferrd method. If equipment is capable of being locked out, and an employer chooses to implement a tagout procedure, it must be demonstrated to provide equivalent safety to a lockout for such equipment.

This section will normally be cited as "serious" if an employer utilizes a tagout device in lieu of lockout and full employee protection is not provided.

(iii) After January 2, 1990, whenever replacement, or major repair, renovation or modification of a machine or equipment is performed, and whenever new machines or equipment are installed, energy

This section will normally be cited as "othcr-than-serious" whenever an employer has failed to modify such machines or equipment to accept a lockout device.

isolating devices for such machine or equipment shall be designed to accept a lockout device.

(3) Full employee protection.

(i) When a tagout device is used on an energy isolating device which is capable of being locked out, the tagout device shall be attached at the same location that the lockout device would have been attached, and the employer shall demonstrate that the tagout program will provide a level of safety equivalent to that obtained by using a lockout program.

This section will normally be cited as "serious" if an employer fails to install a tagout device at the same location that a lockout device would be installed.

This section will normally be cited as "serious" if an employer fails to demonstrate that the tagout procedure is equally effective.

(ii) In demonstrating that a level of safety is achieved in the tagout program which is equivalent to the level of safety obtained by using a lockout program, the employer shall demonstrate full compliance with all tagout-related provisions of this standard together with such additional elements as are necessary to provide the equivalent safety available from the use of a lockout device. Additional means to be considered as part of the demonstration of full employee protection shall include the implementation of additional safety measures such as the removal of an isolating circuit element, blocking of a controlling switch, opening of an extra disconnecting device, or the removal of a valve handle to reduce the likelihood of inadvertent energization.

This section will normally be cited as "serious" if an employer fails to demonstrate full compliance with tagout procedures.

(4) Energy control procedure. (i) Procedures shall be developed, documented and utilized for the control of potentially hazardous energy when employees are engaged in the activities covered by this section.

This section will normally be cited as "serious" if an employer fails to develop, document and utilize energy control procedures (see note for exception). Refer to Appendix c for procedure content checklist.

Note: Exception: The employer need not document the required procedure for a particular machine or equipment, when all of the following elements exist: (1) The machine or equipment has no potential

This note provides that similar machines and/or equipment (those using the same type and magnitude of energy) which have the same or similar types of controls can be covered with a single procedure.

for stored or residual energy or reaccumulation of stored energy after shut down which could endanger employees: (2) the machine or equipment has a single energy source which can be readily identified and isolated; (3) the isolation and locking out of that energy source will completely deenergize and deactivate the machine or equipment; (4) the machine or equipment is isolated from that energy source and locked out during servicing or maintenance; (5) a single lockout device will achieve a locked-out condition; (6) the lockout device is under the exclusive control of the authorized employee performing the servicing or maintenance; (7) the servicing or maintenance does not create hazards for other employees; and (8) the employer, in utilizing this exception, has had no accidents involving the unexpected activation or reenergization of the machine or equipment during servicing or maintenance.

See Appendix D for checkoff sheet of these elements.

(ii) The procedure shall clearly and specifically outline the scope, purpose, authorization, rules, and techniques to be utilized for the control of hazardous energy, and the means to enforce compliance including, but not limited to, the following:

This section will normally be cited as "other-than-serious" if an employer's procedures fail to clearly and specifically outline the scope, purpose, authorization, rules and techniques utilized. Where tagout programs are used by the employer, the enforcement officer shall verify that the employer has implemented an effective means of enforcing the program which could involve disciplinary action.

(A) A specific statement of the intended use of the procedure;

(B) Specific procedural steps for shutting down, isolating, blocking and securing machines or equipment to control hazardous energy;

(C) Specific procedural steps for the placement, removal and transfer of lockout devices or tagout devices and the responsibility for them; and

(D) Specific requirements for testing a machine or equipment to determine and

STANDARD	CITATION AND COMPLIANCE GUIDANCE
verify the effectiveness of lockout devices, tagout devices, and other energy control measures.	
(5) Protective materials and hardware. (i) Locks, tags, chains, wedges, key blocks, adapter pins, self-locking fasteners, or other hardware shall be provided by the employer for isolating, securing or blocking of machines or equipment from energy sources.	This section will normally be cited as "serious" if an **employer** fails **to** provide protective materials and hardware.
(ii) Lockout devices and tagout devices shall be singularly identified; shall be the only devices(s) used for controlling energy; shall not be used for other purposes; and shall meet the following requirements;	**A** facility-wide utilization of one of following is an acceptable lockout device: a. A standardized lock adopted by the employer and used for no other purpose. b. Any lock uniformly identified or marked by the employer and used for no other purpose. This section will normally be cited as "other-than-serious" if an employer fails to implement an acceptable lockout and tagout device identification or uses such devices for other purposes. This section will normally be cited as "serious" if something other than such a lockout or tagout device to be **used.**
(A) Durable. **(1) Lockout and tagout devices shall be capable of withstanding the environment to which they are exposed for the maximum period of time that exposure is expected.**	This section willl normally be cited as "other-than-serious" for nondurable devices
(2) Tagout devices shall be constructed and printed so that exposure to weather conditions or wet and damp locations will not cause the tag to deteriorate or the message on the tag to become illegible.	This section will normally be cited as "other-than-serious" for a deteriorated device that is still legible. A "serious" violation shall be issued if such device is illegible.
(3) Tags shall not deteriorate when used in corrosive environments such as areas where acid and alkali chemicals are handled and stored.	This section will normally be cited as "other-than_serious" for a deteriorated device that is still legible A "serious" violation shall be issued if such device is illegible.
(B) standardized. Lockout and tagout devices shall be standardized within the facility in at least one of the following criteria: Color, shape, or size	This section will normally be cited as "other-than-serious" if lockout and tagout devices are not standardized

and additionally, in the case of tagout devices, print and format shall be standardized.

(C) Substantial-(1) Lockout devices. **Lockout devices shall be substantial enough to prevent removal without the use of excessive force or unusual techniques, such as with the use of bolt cutters or other metal cutting tools.**

This section will normally be cited as "serious" if such lockout devices could be removed by hand.

(2) *Tagout devices.* Tagout devices, including and [sic] their means of attachment, shall be substantial enough to prevent inadvertent or accidental removal. Tagout device attachment means shall be of a non-reusable type, attachable by hand, self-locking, and non-releasable with a minimum unlocking strength of no less than 50 pounds and having the general design and basic characteristics of being at least equivalent to a one-piece, all-environment-tolerant nylon cable tie.

This section will normally be cited as "serious" if such tagout devices could be removed by hand.

***(D) Identifiable* Lockout devices and tagout devices shall indicate the identity of the employee applying the device(s).**

This section will normally be cited as "other-than-serious" if the device does not indicate employee applying the device(s).

(iii) Tagout devices shall warn against hazardous conditions if the machine or equipment is energized and shall include a legend such as the following: Do Not Start, Do Not Open, Do Not Close, Do Not Energize, Do Not Operate.

This section will normally be cited as "serious" if tagout devices do not include warning legends against hazardous conditions.

(6) Periodic inspection. **(i) The employer shall conduct a periodic inspection of the energy control procedure at least annually to ensure that the procedure and the requirements of this standard are being followed.**

This section will normally be cited as "serious" if periodic inspections are not conducted.

STANDARD	CITATION AND COMPLIANCE GUIDANCE
(A) The periodic inspection shall be perfomed [sic] by an authorized employee other than the one(s) utilizing the energy control procedure being inspected.	This section will normally be cited as "serious" if periodic inspections are not conducted by an authorized employee as stated.
(B) The periodic inspection shall be conducted to correct any deviations or inadequacies identified.	This section will normally be cited as "other-than-serious".
(C) Where lockout is used for energy control, the periodic inspection shall include a review, between the inspector and each authorized employee, of that employee's responsibilities under the energy control procedure being inspected.	This section will normally be cited as "other-than-serious."
(D) where tagout is used for energy control, the periodic inspection shall include a review, between the inspector and each authorized and affected employee, of that employee's responsibilities under the energy control procedure being inspected, and the elements set forth in paragraph (c)(7)(ii) of this section.	This section will normally be cited as "serious" where the inspection does not include such a review.
(ii) The employer shall certify that the periodic inspections have been performed. The certification shall identify the machine or equipment on which the energy control procedure was being utilized, the date of the inspection, the employees included in the inspection, and the person performing the inspection.	This section will normally be cited as "other-than-serious" where **the** employer fails to make such certification.
(7) Training and communication. **(i) *The* employer shall provide training to ensure that the purpose and function of the energy control program are understood by employees and that the knowledge and skills required for the safe application, usage, and removal of energy controls are acquired by employees. The training shall include the following:**	This section will normally be cited as "serious" if an employer fails to provide any training. For the purposes of this standard, there are three types of employees: (1) "authorized" "affected" and Tither". Different levels of training are required for each type. The differing training requirements are based upon their respective roles in the control of energy and the knowledge which they must **possess to safely accomplish their tasks as related to lockout/tagout procedures.**

STANDARD	CITATION AND COMPLIANCE GUIDANCE
(A) Each authorized employee shall receive training in the recognition of applicable hazardous energy sources, the type and magnitude of the energy available in the workplace, and the methods and means necessary for energy isolation and control.	This section will normally be cited as "serious" if an employer fails to provide a training program which covers, at a minimum the following tbrce areas: the energy control program elements of energy control procedure relevant to employee duties, and the requirements of the standard_
(B) Each affected employee shall be instructed in the purpose and use of the energy control procedure.	This section will normally be cited as "serious" if an employer fails to provide instruction.
(C) All other employees whose work operations are or may be in an area where energy control procedures may be utilized, shall be instructed about the procedure, and about the prohibition relating to attempts to restart or reenergize machines or equipment which are locked out or tagged out.	The term"other employees" means non-affected or non-authorized employees The training requirements for these otber employees arc minimal, essentially what is required is only that these employees know wbat the energy control program does and that they are not to touch any locks, tags or equipment covered by the program. This section will normally be cited as "other-than-serious".
(ii) When tagout systems are used, employees shall also be trained in the following limitations of tags:	This section establishes a requirement for additional training for all employees in plants or facilities where tagout is the preferred method of energy control. This section shall normally be cited when an employer has not complied with subsections A through F below. This section will normally be cited as "serious."
(A) Tags are essentially warning devices affixed to energy isolating devices, and do not provide the physical restraint on those devices that is provided by a lock.	
(B) When a tag is attached to an energy isolating means, it is not to be removed without authorization of the authorized person responsible for it, and it is never to be bypassed, ignored, or otherwise defeated.	
(C) Tags must be legible and understandable by all authorized employees, affected employees, and all other employees whose work operations are or may be in the area, in order to be effective.	

(D) Tags and their means of attachment must be made of materials which will withstand the environmental conditions encountered in the workplace.

(E) Tags may evoke a false sense of security, and their meaning needs to be understood as part of the overall energy control program.

(F) Tags must be securely attached to energy isolating devices so that they cannot be inadvertently or accidentally detached during use.

(iii) Employee retraining.

(A) Retraining shall be provided for all authorized and affected employees whenever there is a change in their job assignments, a change in machines, equipment or processes that present a new hazard, or when there is a change in the energy control procedures.

This section will normally be cited as "serious"

(B) Additional retraining shall also be conducted whenever a periodic inspection under paragraph (c)(6) of this section reveals, or whenever the employer has reason to believe, that there are deviations from or inadequacies in the employee's knowledge or use of the energy control procedures.

This section will normally be cited as "other-than-serious" Employee retraining may be required as the result of periodic inspection of procedures and practices whenever an employer has reason to believe inadequacies exist or changes in equipment or processes occur, e.g. a "near miss".

(C) The retraining shall reestablish employee proficiency and introduce new or revised control methods and procedures, as necessary.

This section will normally be cited as "other-than-serious"

(ii) The employer shall certify that employee training has been accomplished and is being kept up to date. The certification shall contain each employee's name and dates of training.

Lack of, or deficiency in documentation or certification of such employee training under this section will normally be cited as "other-than-serious".

(8) Energy isolation. **Lockout or tagout shall be performed only by the authorized employees who are performing the servicing or maintenance.**

This section will normally be cited as "other-than-serious" Refer to definition of authorized employee in section (B).

(9) Notification of employees **Affected employees shall be notified by the employer or authorized employee of the application and removal of lockout devices or tagout devices. Notification shall be given before the controls are applied, and after they are removed from the machine or equipment.**

This section will normally he cited as "serious" Lack of notification to affected employees may expose them to the risk of unexpected energization.

(d) Application of control. **The established procedures for the application of energy control (the lockout or tagout procedures) shall cover the following elements and actions and shall be done in the following sequence:**

This section will normally be cited as "serious" if all elements and actions listed in items 1-6 below are not contained in the established procedure.

This section will normally be cited as "other-than-serious" if all elements and actions listed in items 1-6 below have been accompolished but not in the proper sequence.

(1) Preparation for shutdown **Before an authorized or affected employee turns off a machine or equipment, the authorized employee shall have knowledge of the type and magnitude of the energy, the hazards of the energy to be controlled, and the method or means to control the energy.**

Failure to comply with this section will normally be cited under section (c)(7)(i)(A).

(2) Machine or equipment shutdown. The **machine or equipment shall be turned off or shut down using the procedures established for the machine or equipment An orderly shutdown must be utilized to avoid any additional or increased hazard(s) to employees as a result of the equipment stoppage.**

Failure to comply with this section will normally be cited under section (c)(4)(i).

(3) Machine or equipment isolation. **All energy isolating devices that are needed to control the energy to the machine or equipment shall be physically located and operated in such a manner as to isolate the machine or equipment from the energy source(s).**

Failure to comply with this section will normally be cited as "serious". The term "physically located" as used in this section means to go and find all existing locations of the energy isolating devices.This section does not affect the location of the energy isolating devices or require their relocation.

(4) *Lockout or tagout device appli-Cation. (i)* Lockout or tagout devices shall be affixed to each energy isolating device by authorized employees.

Failure to comply with this section will normally be cited under section (c)(8).

(ii) Lockout devices, where used, shall be affixed in a manner to [sic] that will hold the energy isolating devices in a "safe" or "off" position.

(iii) Tagout devices, where used, shall be affixed in such a manner as will clearly indicate that the operation or movement of energy isolating devices from the "safe" or "off' position is prohibited.

(A) Where tagout devices are used with energy isolating devices designed with the capability of being locked, the tag attachment shall be fastened at the same point at which the lock would have been attached.

This section ■ will normally be cited under (c)(3)(i).

(B) Where a tag cannot be affixed directly to the energy isolating device, the tag shall be located as close as safely possible to the device, in a position that will be immediately obvious to anyone attempting to operate the device.

(5) Stored energy. **(i) Following the application of lockout or tagout devices to energy isolating devices, all potentially hazardous stored or residual energy shall be relieved, disconnected, restrained, and otherwise rendered safe.**

This section will normally be cited as "serious".

(ii) If there is a possibility of reaccumulation of stored energy to a hazardous level, verification of isolation shall be continued until the servicing or maintenance is completed, of until the possibility of such accumulation no longer exists.

STANDARD	CITATION AND COMPLIANCE GUIDANCE
(6) Verification of isolation. **Prior to starting work on machines or equipment that have been locked out or tagged out, the authorized employee shall verify that isolation and deenergization of the machine or equipment have been accomplished.**	This section will normally be cited as "serious".
(e) Release from lockout or tagout. Before lockout or tagout devices are removed and energy is restored to the machine or equipment, procedures shall be followed and actions taken by the authorized employee(s) to ensure the following:	This section will normally be cited as "serious' if subsequent items 1 through 3 of the standard are not accomplished.
(1) The machine or equipment. **The work area shall be inspected to ensure that nonessential items have been removed and to ensure that machine or equipment components are operationally intact.**	This section will normally be cited as "serious"
(2) *Employees.* (i) The work area shall be checked to ensure that all employees have been safely positioned or removed.	This section will nomally be cited as "serious"
(ii) Before lockout or tagout devices are removed and before machines or equipment are energized, affected employees shall be notified that the lockout or tagout devices have been removed.	Such failure to notify would normally be cited under section (c)(9).
(iii) After lockout or tagout devices have been removed and before a machine or equipment is started, affected employees shall be notified that the lockout or tagout device(s) have been removed.	
(3) *Lockout or tagout devices removal.* Each lockout or tagout device shall be removed from each energy isolating device by the employee who applied the device.	Unauthorized lockout or tagout device removal will normally be cited as "serious". Exceptions to paragraph (e)(3) must be documented in the employers written program. VOSH agrees with federal OSHA's intent that:

"Under the exception to paragraph (e)(3), the employer may direct the removal of a lockout or tagout

Exception to paragraph **(e)(3): When the authorized employee who applied the lockout or tagout device is not available to remove it. that device may be removed under the direction of the employer, provided that specific procedures and training for such removal have been developed, documented and incorporated into the employer's energy control program. The employer shall demonstrate that the specific procedure provides equivalent safety to the removal of the device by the authorized employee who applied it. The specific procedure shall include at least the following elements:**

(i) Verification by the employer that the authorized employee who applied the device is not at the facility;.

(ii) Making all reasonable efforts to contact the authorized employee to inform him/her that his/her lockout or tagout device has been removed; and

(iii) Ensuring that the authorized employee has this knowledge before he/she resumes work at that facility.

(f) Additional requirements. **(1) Testing or positioning of machines, equipment or components thereof. In situations in which lockout or tagout devices must be temporarily removed from the energy isolating device and the machine or equipment energized to test or position the machine, equipment or component thereof, the following sequence of actions shall be followed:**

device by another employee only if the **energy** control program incorporates specific procedures and training for that purpose and only where the employer can demonstrate that the alternative procedure will provide equivalent safety to having the employee remove his/her own device. [This is] necessary to ensure that the employee who is protected by the device is not exposed to energy hazards either at the time of its removal or afterwards" - 54 Fed. Reg. 36680.

This section will normally be cited as "serious". VOSH agrees with federal OSHA's intent that:

"Paragraph (f)(l) requires that the employer develop and utilize a procedure that establishes a sequence of actions to be taken in situations where energy isolating devices are locked out or tagged out and there is a need for testing or positioning of the machine or equipment or components thereof. These actions are required in order to maitain the integrity of any lockout or tagout proctection for the servicing employees . It is also necessary in order to provide optimum safety coverage for employees when they have to go from a deenergized condition to an energized one and then return the system to lockout or tagout control. It is during these transition periods that employee exposure to hazards is high, and a sequence of steps to accomplish these tasks safely is needed..

Paragraph (f)(l) prescribes a logical sequence of steps to be followed in situations where energy isolating devices are locked out or tagged out, and when there is a need to test or position the machine, equipment or

components thereof. The steps offer necessary protection to employees when they are involved in this activity. The procedure is clear cut and should require little or no explanation other than the contents of the standard itself.

It should be pointed out that...the removal of the lockout or tagout devices and the reenergization of the machine and equipment --[is allowed]... **ONLY** [emphasis added] during the limited time necessary for the testing or positioning of the machine, equipment or component thereof. This paragraph does not allow the employer or employee to disregard the requirement for locking out or tagging out during the other portions of the servicing or maintenance operations. This exception is only a temporary measure to be used only to accomplish a particular task for which energization is essential." - *54* Fed. Reg. 36680.

(i) Clear the machine or equipment of tools and materials in accordance with paragraph (e)(1) of this section;

(ii) Remove employees from the machine or equipment area in accordance with paragraph (e)(2) of this section;

(iii) Remove the lockout or tagout devices as specified in paragraph (e)(3) of this section;

(iv) Energize and proceed with testing or positioning;

(v) Deenergize all systems and reapply energy control measures in accordance with paragraph (d) of this section to continue the servicing and/or maintenance.

(2) Outside personnel (contractors, etc.). **(i) Whenever outside servicing personnel are to be engaged in activities covered by the scope and application of this standard, the on-site employer and the outside employer shall inform each other of their respective lockout or tagout procedures.**

This section will normally be cited as "other-than-serious". VOSH agrees with federal OSHA that:

"These requirements are necessary when outside personnel work on machines or equipment because their activities have the same or greater potential for exposing employees to servicing hazards as would exist of the employer's own employees were performing the work...This standard is intended to ensure that both the employer and the outside service personnel are aware that their interaction can be a possible source of injury to employees and that the close coordination of these activities is needed in order to reduce the likelihood of such injury." - *54* Fed Reg. 36680.

STANDARD	CITATION AND COMPLIANCE GUIDANCE
(ii) The on-site employer shall ensure that his/her employees understand and comply with the restrictions and prohibitions of the outside employer's energy control program.	This section will normally be cited as serious.
(3) *Group lockout or tagout* (i) When servicing and/or maintenance is performed by a crew, craft, department or other group, they shall utilize a procedure which affords the employees a level of protection equivalent to that provided by the implementation of a personal lockout or tagout device.	**This section will normally be cited as serious.**
(ii) Group lockout or tagout devices shall be used in accordance with the procedures required by paragraph (c)(4) of this section including, but not necessarily limited to, the following specific requirements:	
(A) Primary responsibility is vested in an authorized employee for a set number of employees working under the protection of a group lockout or tagout device (such as an operations lock);	The term "authorized employee" as used for group lockout or tagout means the authorized employee in charge of the group servicing operation.
(B) Provision for the authorized employee to ascertain the exposure status of individual group members with regard to the lockout or tagout of the machine or equipment and	VOSH agrees with federal OSHA that determining the exposure status of individual group members and taking appropriate measures to control or limit that exposure includes, but is not limited to the following: 1. "Verification of shutdown and isolation of the equipment or process before allowing a crew member to place a personal lockout or tagout device on an energy isolating device, or on a lockout box, board, or cabinet," and 2 "Ensuring that all employees in the crew have completed their assignments, removed their lockout and/or tagout devices from the energy isolating device, the box lid or other device used, and are in the clear before turning the equipment or process over to tbe operating personnel or simply turning the machine or equipment on." - 54 Fed Reg. 36682
(C) When more than one crew, craft, department, etc. is involved, assignment of overall job-associated lockout or tagout control responsibility to an authorized employee designated to coordinate affected work forces and ensure continuity of protection; and	VOSH agrees with federal OSHA that determining the exposure status of an individual group and taking appropriate measures to control or limit that exposure includes, **but** is not limited to: "...[p]roviding the necessary coordinating procedures for ensuring the safe transfer of lockout or tagout control devices between other groups and work shifts." -54 Fed. Reg. 36682.

(D) Each authorized employee shall affix a personal lockout or tagout device to the group lockout device, group lockbox, or comparable mechanism when he or she begins work, and shall remove those devices when he or she stops working on the machine or equipment being serviced or maintained.

Failure of employees to affix their own devices to indicate that they are exposed to the hazards of the servicing operations will normally be cited as "serious". Such employees, by clearing the equipment and removing their own devices, indicate that they are no longer exposed to the hazards of the servicing operation Failure to remove their own devices will normally be cited as "other-than-serious."

(4) *Shift or personnel changes.* Specific procedures shall be utilized during shift or personnel changes to ensure the continuity of lockout or tagout protection, including provision for the orderly transfer of lockout or tagout device protection between off-going and oncoming employees, to minimize exposure to hazards from the unexpected energization or start-up of the machine or equipment, or release of stored energy.

This section willl normally be cited as "serious" VOSH agrees with federal OSHA tbat one feasible and acceptable way to achieve compliance with this section would be: "In situations where the off-going employee removes his/her lockout or tagout device before the on-coming employee arrives, the procedure could allow for the off-going employee to apply a tagout device at the time he/she removes his/her device, indicating that the lock had been removed but that the machine or equipment had not been reenergized `The on-coming employcc would verify that the system was still deenergizcd, and would remove the interim tag and substitute his/her lockout device. This would insure that the continuous protection is maintained from one shift to another." -54 Fed. Reg. 36683.

Carol Amato
Commissioner

Attachments:

Appendix A: Typical Minimal Lockout or Tagout System Procedures

Appendix B: Other Lockout /Tagout Standards

Appendix C: Checklist for Energy Control Procedure

Appendix D: Checklist of Exception to Energy Control Procedure

Appendix E: Checklist for Tagout System

Appendix F: Checklist for Tagout System Training

Appendix G: Training/Retraining Checklist

Appendix H: Checklist for Group Lockout or Tagout

Appendix I: Checklist for Removal of Lockout or Tagout Devices

Distribution:

Commissioner of Labor and Industry
Assistant Commissioner for Enforcement
Assistant Commissioner for Training and Public Services
Directors and Supervisors
Director of Program Evaluation and Technical Support
Director of Enforcement Policy
Safety and Health Staff
OSHA Regional Administrator, Region III

APPENDIX A - TYPICAL MINIMAL LOCKOUT OR TAGOUT SYSTEM PROCEDURES

General

The following simple lockout procedure is provided to assist employers in developing their procedures so they meet the requirements of this standard. When the energy isolating devices are not lockable, tagout may be used, provided the employer complies with the provisions of the standard which require additional training and more rigorous periodic inspections. When tagout is used and the energy isolating devices are lockable, the employer must provide full employee protection (see paragraph (c)(3)) and additional training and more rigorous periodic inspections are required. For more complex systems, more comprehensive procedures may need to be developed, documented and utilized

Lockout Procedure

Lockout procedure for

(Name of Company for single procedure or identification of equipment if multiple procedures are used)

Purpose

This procedure establishes the minimum requirements for the lockout of energy isolating devices whenever maintenance or servicing is done on machines or equipment. It shall be used to ensure that the machine or equipment is stopped, isolated from all potentially hazardous energy sources and locked out before employees perform any servicing or maintenance where the unexpected energization or start-up of the machine or equipment or release of stored energy could cause injury.

Compliance With This Program

AlI employees are required to comply with the restrictions and limitations imposed upon them during the use of lockout. The authorized employees are required to perform the lockout in accordance with this procedure. All employees, upon observing a machine or piece of equipment which is locked out to perform servicing or maintenance shall not attempt to start, energize or use that machine or equipment.

Type of compliance enforcement to be taken for violation of the above.

Sequence of Lockout

(1) Notify all affected employees that servicing or maintenance is required on a machine or equipment and that the machine or equipment must be shut down and locked out to perform the servicing or maintenance.

Name(s)/Job Title(s) of affected employees and how to notify.

(2) The authorized employee shall refer to the company procedure to identify the type and magnitude of the energy that the machine or equipment utilizes, shall know the methods to control the energy. Type(s) and magnitude(s) of energy, its hazards and the methods to control the energy.

(3) If the machine or equipment is operating, shut it down by the normal stopping procedure (depress stop button, open switch, close valve, etc.).

Type(s) and location(s) of machine or equipment operating controls.

(4) De-activate the energy isolating device(s) that the machine or equipment is isolated from the energy source(s).

Type(s) and location(s) of energy isolating devices.

(5) Lock out the energy isolating device(s) with assigned individual lock(s).

(6) Stored or residual energy (such as that in capacitors, springs, elevated machine members, rotating flywheels, hydraulic systems, and air, gas, steam, or water pressure, etc.) must be dissipated or restrained by methods such as grounding, repositioning, blocking, bleeding down, etc.

Type(s) of stored energy - methods to dissipate or restrain.

(7) Ensure that the equipment is disconnected from the energy source(s) by first checking that no personnel are exposed, then verify the isolation of the equipment by operating the push button or other normal operating control(s) or by testing to make certain the equipment will not operate.

Caution: Return operating control(s) to neutral or "off" position after verifying the isolation of the equipment.

Method of verifying the isolation of the equipment

(8) The machine or equipment is now locked out.

Restoring Equipment to Service When the servicing or maintenance is completed and the machine or equipment is ready to return to normal operating condition, the following steps shall be taken.

(1) Check the machine or equipment and the immediate area around the machine or equipment to ensure that nonessential items have been removed and that the machine or equipment components are operationally intact

(2) Check the work area to ensure that all employees have been safely positioned or removed from the area

(3) Verify that the control are in neutral.

(4) Remove the lockout devices and re-energize the machine or equipment

Note: The removal of some forms of blocking may require re-energization of the machine before safe removal.

(5) Notify affected employees that the servicing or maintenance is completed and the machine or equipment is ready for use.

APPENDIX B

Other Lockout/Tagout Standards

The following listing indicates a number of VOSH/OSHA standards which currently impose lockout/tagout related requirements. The list does not necessarily include all lockout/tagout VOSH/OSHA 1910 standards.

Confined Space - General Industrv and Construction

1910.146

Powered Industrial Trucks

1920.178(q)(4)

Overhead and Gantry Cranes

1910.179(g)(5) (i), (ii), (iii)

1910.179(l)(2) (i) (c), (d)

Derricks

1910.181 (f) (2) (i)(c), (d)

Woodworking Machinerv

1910.213(a)(10)

1910.213(b)(5)

Mechanical Power Presses

1910.217(b) (8) (i)

1910.217(d)(9) (iv)

Forging Machines

1910.218(a)(3) (iii), (iv)

1920.218(d) (2)

1910.218(e) (1) (ii), (iii)

1910.218(f)(l)(i), (ii), (iii)

1910.228(f) (2) (i), (ii)

1910.218(h) (2), (5)

1910.218(i)(l), (2)

1910.218(j) (1)

Welding, Cutting and Brazing

1910.252(c) (l)(i)

Pulp, Paper and Paperboard Mills

1910,261(b)(4)

1910.261 (f) *(6)(i)*

1910.261(g)(l5)(i)

1910.261(g)(19)(iii)

1910.261(j)(4) (iii)

1910.261(j) (5) (iii)

1910.261(k) *(2)* ***(ii)***

Textiles

19l0.262(c)(1)

1910.262(n)(2)

1910.262(p)(1)

1910.262(q) (2)

Bakery Equipment

l910.263(1)(3)(iii)(b)

1910.263(1)(8)(iii)

Sawmills

1910.265(c)(13)

1910.265(c)(26)(v)

Confined Space - Telecommunications

1910.268(t)

Grain Handling

1910.272(e) ***(1)(ii)***

1910.272(g) ***(1)(ii)***

1910.272(l) ***(4)***

Electrical

1910.399

APPENDIX C

Checklist for

Energy Control Procedure

1. ___ Employer has developed a procedure for the control of potentially hazardous energy when employees are engaged in servicing and maintenance of equipment/machinery.
   Detail _____

2. ___ The procedure is documented.

3. ___ The procedure is utilized.

4. ___ The energy control procedures contain the following in the control of hazardous energy:

   a. ___ clearly and specifically outlined scope and purpose

   b. ___ authorization

   c. ___ rules

   d. ___ techniques

   e. ___ means to affect compliance such as:

      i. ___ specific statement of intended use of procedure
      Detail: _____

      ii. ___ specific procedural steps- for shutting down, isolating, blocking and securing machines or equipment to control hazardous energy
      Detail: _____

C-l

___ iii___ specific procedural steps for placement, removal and transfer of lockout devices or tagout devices and the responsibility for them
Detail _____

iv.___ specific requirements for testing a machine or equipment to determine and verify the effectiveness of lockout devices, tagout devices, and other energy control measures.
Detail _____

APPENDIX D

Checklist for

Exception to Energy Control Procedure

The employer need not document the required procedure for a particular machine or equipment, when all of the following elements exist:

(1) _____ *the machine or eguipment has no potential for stored or residual energy or reaccumulation of stored energy after shut down which endanger employees;*

(2) _____ *the machine or equipment has a single energy source which can be readily identified and isolated;*

(3) _____ *the isolation and locking out of that energy source will completely de-energize and deactivate the machine or equipment;*

(4) _____ *the machine or equipment is isolated from that energy source and locked out during servicing or maintenance;*

(5) _____ *a single lockout device will achieve a locked-out condition;*

(6) _____ *the lockout device is under the exclusive control of the authorized employee performing the servicing or maintenance;*

(7) _____ *the servicing or maintenance does not create hazards for other employees; and*

(8) _____ *the employer, in utilizing this exception, has had no accidents involving unexpected activation or re-energization of the machine or equipment during servicing or maintenance.*

APPENDIX E

Checklist for Tagout System

This checklist should be used whena tagout system is utilized.

1 ____ A tagout device has been placed on the energy isolating device.

2. ____ There is a means of attaching a warning device to indicate that the energy isolating device and the equipment being controlled may not be operated until the tagout device is removed.

3. ____ The tagout device and its means of attachment are substantial enough to prevent inadvertent or, accidental removal.

4. ____ A tagout device is affixed in a manner that will hold the energy isolating devices in a "safe" or "off" position.

5. ____ The tagout device attachment is fastened at the same point at which a lock would have been attached.

6. ____ The attachment is self-locking.

7. ____ The tagout device is attachable by hand.

8. ____ The attachment is releasable with minimum unlocking strength of no less than 50 pounds.

9. ____ The attachment is at least equivalent to a one-piece, all-environment-tolerant nylon cable tie.

10. ____ Tagout devices are standardized in color, shape, or size.

APPENDIX F

Checklist for Tagout System Training

1. ____ *Employer has developed, documented, and implemented a training program which covers use of tags.*
Detail: _____
_____
_____
_____
_____

2. ____ *Employer's safety program for use of tag-out systems includes, but is not limited to, additional safety measures such as the following:*

   a. ____ *Removal of isolating circuit element.*

   b. ____ *Blocking of control switch.*

   c. ____ *Opening of extra disconnecting device.*

   d. ____ *Removal of valve handle(s) (where applicable) to reduce likelihood of inadvertent energization.*

3. ____ *Tagout device warns against a hazardous condition if machine or equipment is energized.*

4. ____ *Tagout device includes a legend such as:*

   ___ *DO NOT START* ____ *DO NOT OPEN*

   ___ *DO NOT CLOSE* ____ *DO NOT ENERGIZE*

   ___ *DO NOT OPERATE*

APPENDIX G

Training Checklist

1. ____ *Employer has provided employees with energy control program training. If yes, answer all below.*

2. ____ *The training includes instruction for each authorized employee in the recognition of applicable hazardous energy sources.*

3. ____ *The training includes instruction for each affected or other employee in the purpose and use of the energy control procedure.*

4. ____ *The training includes the types and magnitudes of the energy available in the workplace.*

5. ____ *The training provides the methods and means necessary for energy isolation and control.*
Detail: _____

Retraining Checklist

1. ____ *Retraining provided for all authorized and affected employees whenever there is a change in their job assignment.*

2. ____ *Retraining provided for all authorized and affected employees whenever there is a change in machines, equipment, or processes presenting new hazards.*

3. ____ *A change in the energy control procedures.*

4. ____ *Additional retraining has been conducted whenever employer has had reason to believe that there have been inadequacies in employee's knowledge or deviations from the use of energy control procedures.*
Detail: _____

5. ____ *Employer has certified that employee training has been accomplished and kept up-to-date.*
Detail: _____

APPENDIX H

Checklist for Group Lockout or Tagout

1. ____ *Authorized employee has verified shutdown and isolation of equipment or process before allowing group members to lockout or tagout.*
Detail: _____

2. ____ *Authorized employee has verified that all employees in the* crew *completed their assignments and removed their lockout and/or tagout devices from energy isolating device?*
Detail: _____

3. ____ *When more than one crew, craft, department, etc. is involved, assignment of overall job-associated lockout or tagout responsibility has been given to an authorized employee to cordinate affected work forces and ensure continuity of protection.*
Detail: _____

APPENDIX I

Checklist for

Removal of Lockout or Tagout Devices

1. ____ Specific procedures and training for such removal have been developed, documented and incorporated into employer's energy control program.

2. ____ The lockout or tagout device has been removed from energy lsolating device by employee who applied the device.

   a. ____ Is there employer verification when authorized employee who applied the device is not at the facility.
   Detail: _____

   b. ____ Reasonable efforts have been made to contact authorized employee that his/her lockout device has been removed.
   Detail: _____

   c. ____ Authorized employee was made aware of efforts to inform him/her of removal of lockout device before authorized employee resumed work.
   Detail: _____

I-1

16. WRITTEN HAZARD COMMUNICATION PROGRAM

Comments and Discussion:

All private employers and all public sector organizations are responsible for developing, implementing and maintaining a written hazard communication program for their workplaces by May 23, 1988. (For the manufacturing SIC codes 20-39 and all public sector organizations the effective date was May 25, 1986.)

Employers are to describe details of their hazard communication programs in a written plan. The written hazard communication plan, which is a documentation of how the employer is meeting the requirements of the Hazard Communication Standard, will be a vehicle for promoting safety in the workplace by providing information to employees about health and safety providing information to employees about health and safety hazards. This written program must include provisions related to:

-- Labels and other forms of warning,

-- Material Safety Data Sheets, and

-- Employee Information and Training.

Kev Provisions:

1. A written hazard communication plan must include:

   a. A list of all hazardous chemicals (products) in the workplace. The chemical names used on this list should correspond with those on the material safety data sheets.

   b. A description of how the criteria of the Standard are satisfied pertaining to:

      (1) Labeling and other forms of warning
      (2) Material safety data sheets
      (3) Employee training.

   c. Descriptions of the methods the employer will use to inform employees:

      (1) Of the hazards of non-routine tasks (i.e. cleaning a chemical vat)

      (2) Of the hazards associated with chemicals contained in unlabeled pipes in their work area.

d. Employers who produce, use or store hazardous chemicals at a workplace in such a way that employees of the other employer(s) may be exposed must describe the methods the employer will use:

(1) To provide information for each hazardous chemical the other employer(s)' employees may be exposed to while working. (May provide copy of MSDS or make available at a central location in the workplace.)

2. The written hazard communication plan is to be available to employees, their designated representatives, Virginia Occupational Safety and Health (VOSH), and the National Institute of Occupational Safety and Health (NIOSH).

3. Any existing written hazard communication plan which complies with the requirements that have been outlined above is acceptable.

Other Recommendations for a Written Plan:

1. Give specific information including the names of individuals responsible for various aspects of the program. Include an appendix listing titles with corresponding names and responsibilities.

a. Example: Labels and Other Forms of Warning

1) Give title of person(s) responsible for ensuring in-plant labeling

2) Give title of person(s) responsible for ensuring labels are on shipped containers

3) Describe the procedure to follow if containers received are not labeled properly

4) Describe the labeling system(s) used (Put an example in an appendix)

5) Describe written alternatives to in-plant labeling, if used

6) Give procedure to review and update label information when necessary.

b. Example: Material Safety Data Sheets

1) Give title of person(s) responsible for obtaining and maintaining data sheets

2) Describe how sheets are to be maintained (e.g. notebooks in the work area(s))

3) Explain how employees will have access to MSDSs

4) Give procedure to follow when MSDS is not received at time of first shipment

5) Give procedure to follow when MSDS received is incomplete

6) Give procedure for review and updating of sheets

7) Describe alternatives to actual data sheets used.

c. Example: Training

1) Give title of person(s) responsible for conducting training

2) Describe the format of the program used (audiovisuals, classroom instruction, etc.)

3) Describe the subject content of the program

4) Give procedure for initial training and retraining employees when a new hazard is introduced in the workplace

5) Describe documentation of training (i.e. employee sign).

2. Review and update the plan on a periodic basis. Include a review date and signature blank for responsible person in the written plan.

EXAMPLE OF A

WRITTEN HAZARD COMMUNICATION PROGRAM

I. Introduction

The OSHA Hazard Communication Standard was promulgated to ensure that all chemicals would be evaluated and that information regarding the hazards would be communicated to employers and employees. The goal of the standard is to reduce the number of chemically related occupational illnesses and injuries.

In order to comply with the Hazard Communication Standard, this written program has been established for (name of company). All divisions and sections of the company are included within this program. Copies of this written program will be available (for review by any employee) in the following locations:

_____

_____

_____

Basic components of the program include:

- Hazardous Chemical Inventory List
- Material Safety Data Sheets
- Labels and Other Forms of Warning
- Employee Information and Training
- Nonroutine Tasks
- Unlabeled Pipes
- On-Site Contractors
- Program Review

II. Hazardous Chemical Inventory List

A list of all known hazardous chemicals (products) used at (name of company) is contained in Appendix A of this written program.

A list of hazardous chemicals used by each department is kept with material safety data sheets in the respective departments.

III. Hazard Determination

Example A

All hazardous chemicals in this facility are purchased materials; there are no manufactured or intermediate hazardous chemicals. Therefore, (name of company) shall rely on the hazard determination made by the chemical manufacturer as indicated on the MSDS.

Example B

Hazardous chemicals in this facility are either purchased materials, by-products of the manufacturing or work process, or a chemical end product manufactured at this facility.

For purchased hazardous chemicals (Name of Compav) will rely on the hazard determination made by the chemical manufacturer as indicated on the MSDS.

For a chemical by-products and/or end product for which a generic MSD cannoSbe purchased (Name of Company) will evaluate the chemical using the procedure described in Appendix B.

IV. Material Safety Data Sheets (MSDS)

When chemicals are ordered, the (title of person ordering) shall specify on the purchase order that chemicals are not to be shipped without corresponding material safety data sheets.

When MSDSs arrive, they will be reviewed for completeness by (title of person). Should any MSDS be incomplete, a letter will be sent immediately to the manufacturer requesting the additional information.

A complete file of MSDSs for all hazardous chemicals to which employees of this company may be exposed will be kept in labeled binders in (location) and (location).

MSDSs for hazardous chemicals used by departments will be kept in labeled binders in office of the respective departments. MSDSs will be available for employees during each work shift. Should MSDSs be unavailable, please contact (title & number) immediately.

MSDSs will be reviewed annually by (title). Should there be any MSDS that has not been updated within the past year, a new MSDS will be requested.

After three documented requests for an MSDS have been unsuccessful, the problem will be reported to the nearest Virginia Occupational Safety and Health (VOSH) office

V. Labels and Other Forms of Warning

The Hazard Communication Standard requires that hazardous chemicals be labeled by manufacturers. The label must contain the following:

Chemical identify
Appropriate hazard warnings
Name and address of the chemical manufacturer, importer, or other responsible Party

When chemicals are ordered by (title) the purchase order will indicate the need for the above stated information to be included on the labels or (name of company) will refuse acceptance of the shipment.

Upon delivery of chemicals, (title) will ensure that chemicals are labeled properly. Any chemicals without proper labeling will not be accepted.

When chemicals are transferred from the manufacture's containers to secondary containers, the supervisor of each section will ensure that the containers are labeled with the identity of the chemicals and appropriate hazard warnings.

See Appendix C for an example of in-plant labeling.

The entire labeling procedure will be reviewed annually by (title) and changed as necessary.

VI. Employee Information and Training

Prior to starting work, new employees of (name of company) will attend a health and safety orientation program. (title) is responsible for organizing and conducting initial training. Training will consist of (number) sessions of (number) minutes each.

The format for the training program will be _____

The following topics will be covered:
An overview of the requirements of the Hazard Communication Standard
The labeling system and how to use it
How to review MSDS s and where they are kept
Chemicals present in work operations
Physical and health effects of hazardous chemicals
Methods and observation techniques used to determine the presence or release of hazardous chemicals in the area
Personal protective equipment and work practices to lessen or prevent exposure to chemicals

Steps the company has taken to lessen or prevent exposure to chemicals
Safety/emergency procedures to follow if exposure occurs
Location and availability of the written program.

Following each training session, the employee is required to sign and date the training record verifying attendance. See Appendix D for a sample training record.

Before any new employee can begin work which requires the use of or potential exposure to hazardous chemicals, training as indicated above must be completed.

Additional training will be provided with the introduction of each new hazard. Records of this additional training will be maintained.

VII. Non-Routine Tasks

Hazardous non-routine tasks at (name) have been identified as follows:

Task	Hazardous Chemicals

Prior to any employee beginning a hazardous non-routine task, he/she must report to _____ to determine the hazards involved and the protective equipment required.

VIII. Unlabeled Pipes

Work activities are often performed in areas where chemicals are transferred through pipes. These pipes are not required to be labeled; however, the employee needs to be aware of potential hazards. Prior to starting work in areas having unlabeled pipes, the employee shall contact (title to determine:

The identity of the chemical in the pipes
Potential hazards
Safety precautions

IX. Multi-Employer Workplaces

Often one (1) or more contractors work on site at (Name of Company) or employees of (Name of Company) work at a site with employees of other employers. When employees of other employers are exposed to chemicals used or stored by (Name of Company), then the other employers will be provided with:

A copy of the MSDS.

Information on any precautionary measures that need to be taken to protect employees.

The chemical labeling system used.

(Name of Position of Employee) is responsible for providing other employers with a MSDS or ensuring that the MSDS is available at (Location).

(Name) is responsible for providing other employers with information on precautionary measures that need to be taken to protect employees. This information will be provided (verbally, in writing, or other methods).

(Name or Position of Emplovee) is responsible for informing other employers of the labeling system used. this information will be provided (verbally, in writing, or other methods). (If a number of pictograph system is used, then the legend explaining the numbers and pictograph should be given to the employers or posted in the work area). (Appendix E contains a listing of titles with corresponding names and responsibilities as designated in this program).

X. Program Review

This Written Hazard Communication Program for (name ofcompany) will be reviewed by (title) annually and updated as necessary. Appendix F contains the review and signature form.

APPENDIX A

Hazardous Chemical Inventory List

Hazardous Chemicals	Work Processes
Chemical Name (common name)	

APPENDIX B

Procedures for Evaluating Chemical By-Products/End Products

APPENDIX C

Example of In-House Labeling

APPENDIX D

Training Record

Date	Topic	Employee Signature

APPENDIX E

Titles with Corresponding Names and Responsibilities

Title	Name	Responsibiblity

APPENDIX F

The Written Hazard Communication Program for (name of company) has been reviewed and updated.

DATE	SIGNATURE	TITLE
_____	_____	_____

SECTION (f)

LABELS AND OTHER FORMS OF WARNING

Comments and Discussion:

Since labels and other forms of warning will be the primary initial source of warning for employees, the requirements of this section of the Standard are very important to the effectiveness of the overall hazard communication program.

Key Provisions:

1. Chemical manufacturers, importers, and distributors must ensure that every container of hazardous chemicals leaving the workplace bears a label specifying:

   a. The identity of the hazardous chemical

   b. Appropriate hazard warnings

   c. The name and address of the chemical manufacturer, importer or other responsible party.

2. Labels affixed to containers by the manufacturer, importer or distributor must not conflict with the requirements of the Hazardous Materials Transportation Act.

3. Substances with specific OSHA standards must be labeled by the manufacturer, importer, or distributor in a way which includes the specific labeling requirements of that standard. For example, the VOSH inorganic Arsenic Standard, 1910.1018(p), provides that containers which contain inorganic arsenic must have a label which bears the following legend:

   DANGER
   CONTAINS INORGANIC ARSENIC
   CANCER HAZARD
   HARMFUL IF INHALED OR SWALLOWED
   USE ONLY WITH ADEQUATE VENTILATION

4. Employers must ensure that each container in the workplace is labeled or otherwise marked. The information must include:

   a. The identity of the hazardous chemical(s) contained

   b. "Appropriate" hazard warnings for employee protection.

5. Signs, placards, process sheets, batch tickets, operating procedures may be used for stationary process containers rather than individually labeling each piece of equipment.

These alternatives must contain the same information as labels and must always be readily accessible to employees.

6. Exemptions to in-house individual container labeling include:

   a. Pipes and piping systems

   b. Portable containers, the contents of which are to be used during the workshift by employee who transferred the material into the container.

7. Employers must not remove labels from incoming containers unless they are immediately marked with the required information.

8. All forms of warnings must be in English. Other languages, in addition to English, may be used where needed.

9. Various coding systems incorporating colors, symbols, and/or numbers may be used in labeling secondary containers in the workplace to describe hazardous properties of a chemical and appropriate protective equipment. If a coding system is used in-house, employees must be trained about the specifics of the coding system.

10. The label affixed to the container by the manufacturer should include any known target organ effects in the hazard warning.

11. Existing labels and other forms of warnings may be utilized if they meet the requirements of this Standard.

SECTION (g)

MATERIAL SAFETY DATA SHEETS

Comments and Discussion:

Material Safety Data Sheets (MSDS) will be the back-bone of the hazard communication program, as they contain extensive detailed information related to hazardous chemicals. The MSDS will be maintained and available as a backup to the information provided on the labels and other forms of warning. In medical emergency situations and other emergencies, the MSDS will be the most important item due to the nature of the information.

Key Provisions:

1. Chemical manufacturers and importers must obtain or develop a MSDS on each hazardous chemical they produce or import.

2. Employers must maintain a MSDS for each hazardous chemical they use.

MSDS REQUIREMENTS

1. The MSDS must be in English and must include:

   a. The identity used on the label

      - Single substance: chemical and common names

      - Mixtures tested as a whole: chemical and common name(s) of all ingredients which contribute to known hazards, and common name(s) of the mixture itself

      - Mixtures untested as whole: chemical and common names of all ingredients which are health hazards and which are in concentrations of 1% or greater; carcinogens in concentration of 0.1% or more.

   b. Physical and chemical characteristics of the hazardous chemicals

   c. Physical hazards (potential for fire, explosion, etc.)

   d. Known acute and chronic health effects and related health information

   e. Primary routes of entry into the body

   f. Information on exposure limits

   g. Whether hazardous chemical is considered a carcinogen by OSHA, the

International Agency for Research on Cancer or the National Toxicology Program

h. Precautions for safe handling

i. Generally acceptable control measures (engineering controls, work practices, personal protective equipment)

j. Emergency and first aid procedures

k. Date of MSDS preparation or last change

l. Name, address and phone number of party responsible for preparing/distributing the MSDS (see example of complete MSDSs on p. 60).

2. No blank spaces are permitted; if information is not found or not applicable, spaces should be marked accordingly.

3. One MSDS may be used for similar mixtures with essentially the same hazards and contents

4. The chemical manufacturer, importer or employer must ensure that the MSDS accurately reflects scientific evidence. New information must be added to the MSDS within three months.

5. The MSDS is to be provided to purchasers with their first shipment. Unless otherwise specified, the MSDS may be forwarded by mail, computer link-up, etc. An updated MSDS must be transmitted with the next shipment.

6. Distributors must provide MSDSs to purchasers.

7. Copies of MSDSs must be readily accessible during each work shift to employees when they are in their work area(s)."

8. An MSDS may be kept in any format as long as the requirements are met. Acceptable formats include: manuals, files and computer terminals if the information is readily accessible.

9. MSDSs are to be made available to designated representatives, Virginia Occupational Safety and Health and the Director, National Institute for Occupational Safety and Health.

Additional Responsibilities

Employers must seek MSDSs if they are not forwarded automatically with each first shipment. (See Appendix E, p. 99 for sample request letter.) Should employers learn that a chemical manufacturer does not have the appropriate MSDSs he should contact the VOSH office in the area for follow-up. Documentation of attempts to obtain MSDSs (copies of letters, notes regarding phone requests) should be maintained. Although chemical manufacturers are responsible for the accuracy of the information contained on the MSDS, employers must ensure that there are not obvious omissions of data (See Appendix E, p. 101 for a sample letter requesting more information on a deficient MSDS.)

NOTE: In view of the above requirements for MSDSs, it may be prudent for larger employers to develop a system of MSDS storage that is broken down by department or work process rather than on a company-wide basis.

17. A BRIEF GUIDE TO RECORDKEEPING REQUIREMENTS FOR OCCUPATIONAL INJURIES AND ILLNESSES

Regional Offices of the Bureau of Labor Statistics

Region I
Kennedy Federal Building
Suite 1603
Boston, MA 02203
Phone: (617) 565-2327

Region II
Room 808
201 Varick Street
New York, NY 10014
Phone: (212) 337-2400

Region III
3535 Market Street
P.O. Box 13309
Philadelphia, PA 19101
Phone: (215) 596-1154

Region IV
1371 Peachtree Street, N.E.
Atlanta, GA 30367
Phone: (404) 347-4416

Region V
9th Floor
Federal Office Building
230 S. Dearborn Street
Chicago, IL 60604
Phone: (312) 353-1880

Region VI
Federal Building
525 Griffin Street, Room 221
Dallas, TX 75202
Phone: (214) 767-6970

Regions VII and VIII
911 Walnut Street
Kansas City, MO 64106
Phone: (816) 426-2481

Regions IX and X
71 Stevenson Street
P.O. Box 3766
San Francisco, CA 94119
Phone: (415) 744-6600

Preface

The information in this pamphlet explains the requirements of the Occupational Safety and Health Act of 1970 and Title 29 of the ***Code of Federal Regulations,*** Part 1904 (29 CFR Part 1904) for recording and reporting occupational injuries and illnesses. The Occupational Safety and Health Act of 1970 and 29 CFR Part 1904 require employers to prepare and maintain records of occupational injuries and illnesses. The act made the Secretary of Labor responsible for the collection, compilation, and analysis of statistics of work-related injuries and illnesses. The Bureau of Labor Statistics (BLS) administers this recordkeeping and reporting system. In most States, a State agency cooperates with BLS in administering these programs.

Records of injuries and illnesses are necessary for carrying out the purposes of the act. They provide a basis for a statistical program which produces injury and illness data which are used by OSHA in measuring and directing the agency's efforts. The records are also helpful to employers and employees in identifying many of the factors which cause injuries or illnesses in the workplace. In addition, OSHA records are designed to assist safety and health compliance officers in making OSHA inspections.

This pamphlet summarizes the OSHA recordkeeping requirements of 29 CFR Part 1904, and provides basic instructions and guidelines to assist employers in fulfilling their recordkeeping and reporting obligations. Many specific standards and regulations of the Occupational Safety and Health Administration (OSHA) have additional requirements for the maintenance and retention of records of medical surveillance, exposure monitoring, inspections, accidents and other activities and incidents relevant to occupational safety and health, and for the reporting of certain information to employees and to OSHA. These additional requirements are not covered in this pamphlet. For information on these requirements, employers should refer directly to the OSHA standards or regulations or contact their OSHA Area Office.

Further information on the requirements outlined in this pamphlet is available in the free detailed report, ***Recordkeeping Guidelines for Occupational Injuries and Illnesses,*** which may be obtained by using the order form on page 18. Assistance can also be obtained by contacting the participating State agency or the BLS regional office for your area. The **BLS** regional offices are listed on the inside front cover. State agencies are listed at the end of this publication.

The following government agencies are involved in OSHA recordkeeping:

A. ***The Occupational Safety and Health Administration. U.S. Deportment of Labor.*** The Occupational Safety and Health Administration is responsible for developing, implementing, and enforcing safety and health standards and regulations. OSHA works with employers and employees to foster effective safety and health programs which reduce workplace hazards.

B. ***Bureau of Labor Statistics, U.S. Department of Labor.*** The Bureau of Labor Statistics is responsible for administering and maintaining the OSHA recordkeeping system, and for collecting, compiling, and analyzing work injury and illness statistics.

C. ***State Agencies Many States*** cooperate with **BLS** in administering the OSHA recordkeeping and reporting programs. Some States have their own safety and health laws which may impose additional obligations. Employers should consult their State safety and health laws concerning these requirements.

These guidelines were prepared in the BLS office of Occupational Safety and Health Statistics, by Stephen Newell, under the general direction of William M. Eisenberg, Associate commissioner.

OMB DISCLOSURE STATEMENT

We estimate that the use of this supplementary instruction booklet will take an average of 6 minutes per reference, which is included in the estimate of time for completing and reviewing either a line entry on an OSHA Form No. 200 and/or an entire OSHA Form No. 101. If you have any comments regarding this estimate or any other aspect of this recordkeeping system, send them to the Bureau of Labor Statistics, Division of Management Systems (1220-0029), Washington, D.C. 20212 and to the Offjce of Management and Budget, Paperwork Reduction Project (1220-0029), Washington, DC. 20503.

Contents

Chapter I. Employers Subject to the Recordkeeping Requirements of the Occupational Safety and Health Act of 1970

The recordkeeping requirements of the Occupational Safety and Health Act of 1970 apply to private sector employers in all States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Trust Territories of the Pacific Islands.

A. Employers who must keep OSHA records

Employers with 11 or more employees (at any one time in the previous calendar year) in the following industries must keep OSHA records. The industries are identified by name and by the appropriate Standard Industrial Classitication (SIC) code:

- Agriculture, forestry, and fishing (SIC's 01-02 and 07-09)
- Oil and gas extraction (SIC 13 and 1477)
- Construction (SIC's 15-17)
- Manufacturing (SIC's 20-39)
- Transportation and public utilities (SIC's 41-42 and 44-49)
- Wholesale trade (SIC's 50-51)
- Building materials and garden supplies (SIC 52)
- General merchandise and food stores (SIC's 53 and 54)
- Hotels and other lodging places (SIC 70)
- Repair services (SIC's 75 and 76)
- Amusement and recreation services (SIC 79), and
- Health services (SIC 80).

If employers in any of the industries listed above have more than one establishment with combined employment of 11 or more employees, records must be kept for each individual establishment.

B. Employers who infrequently must keep OSHA records

Employers in the industries listed below are normally exempt from OSHA recordkeeping. However, each year a small rotating sample of these employers is required to keep records and participate in a mandatory statistical survey of occupational injuries and illnesses. Their participation is necessary to produce national estimates of occupational injuries and illnesses for ***all*** employers (both exempt and nonexempt) in the private sector. If an employer who is regularly exempt is selected to maintain records and participate in the Annual Survey of Occupational Injuries and Illnesses,. he or she will be notified in advance and supplied with the necessary forms and instructions. Employers who normally do not have to keep OSHA records include:

1. All employers with no more than 10 full- or part-time employees ***at any one time*** in the previous calendar year.

2. Employers in the following retail trade, finance, insurance and real estate, and services industries (identified by SIC codes):

- Automotive dealers and gasoline service stations (SIC 55)
- Apparel and accessory stores (SIC 56)
- Furniture, home furnishings, and equipment stores (SIC 57)
- Eating and drinking places (SIC 58)
- Miscellaneous retail (SIC 59)
- Banking (SIC 60)
- Credit agencies other than hanks (SIC 61)
- Security, commodity brokers, and services (SIC 62)
- Insurance (SIC 63)
- Insurance agents, brokers, and services (SIC 64)
- Real estate (SIC 65)
- Combined real estate insurance, etc. (SIC 66)
- Holding and other investment offices (SIC 67)
- Personal services (SIC 72)
- Business services (SIC 73)
- Motion pictures (SIC 78)
- Legal services (SIC 81)
- Educational services (SIC 82)
- Social services (SIC 83)
- Museums, botanical, zoological gardens (SIC 84)
- Membership organizations (SIC 86)
- Private households (SIC 88), and
- Miscellaneous services (SIC 89).

Even though recordkeeping requirements are reduced for employers in these industries, they, like nonexempt employers must comply with OSHA standards, display the OSHA poster, and report to OSHA within 48 hours any accident which results in one or more fatalities or the hospitalization of five of more employees. Also, some State safety and health laws may require regularly exempt employers to keep injury and illness records, and some States have more stringent catastrophic reporting requirements.

C. Employers and individuals who never keep OSHA records

Tbe following employers and individuals do not have to keep OSHA injury and illness records:

- ***Self-employed individuals;***
- ***Partners with no employees;***
- *Employers* ***of domestics in*** **the employers' private residence for the purposes of housekeeping or child care, or both, and**
- ***Employers engaged in religious activities concerning the*** **conduct of religious services or rites. Employees engaged in such activities include clergy, choir members, organists and other musicians, ushers, and the like. However, records of injuries and illnesses occurring to employees while performing secular activities must be kept. Recordkeeping is also required for employees of private hospitals and certain commercial establishments owned or operated by religious organizations.**

State and local government agencies are usually exempt from OSHA recordkeeping. However, in certain States, agencies of State and local governments are required to keep injury and illness records in accordance with State regulations.

D. Employers subject to other Federal safety and health regulations

Employers subject to injury and illness recordkeeping requirements of other Federal safety and health regulations are not exempt from OSHA recordkeeping. However, records used to comply with other Federal recordkeeping obligations may also be used to satisfy the OSHA recordkeeping requirements. The forms used must be equivalent to the log and summary (OSHA **No. 200**) and the supplementary record (OSHA **No. 101).**

Chapter II. OSHA Recordkeeping Forms

Only two forms are used for OSHA recordkeeping. One form, the OSHA NO. 200, serves as both the Log of Occupational Injuries and Illnesses, on which the occurrence and extent of cases are recorded during the year; and as the Summary of Occupational Injuries and Illnesses, which is used to summarize the log at the end of the year to satisfy employer posting obligations. The other form, the Supplementary Record of Occupational Injuries and Illnesses, OSHA No. 101, provides additional information on each of the cases that have been recorded on the log.

A. The Log and Summaryof Occupational Injuries -and Illnesses, OSHA No. 200

The log is used for recording and classifying occupational injuries and illnesses, and for noting the extent of each case. The log shows when the occupational injury or illness occurred, to whom, the regular job of the injured or ill person at the time of the injury or illness exposure, the department in which the person was employed, the kind of injury or illness, how much time was lost, whether the case resulted in a fatality, etc. The log consists of three parts: A descriptive section which identifies the employee and briefly describes the injury or illness; a section covering the extent of the injuries recorded, and a section on the type and extent of illnesses.

Usually, the OSHA No. 200 form is used by employers as their record of occupational injuries and illnesses. However, a private form equivalent to the log, such as a computer printout, may be used if it contains the same detail as the OSHA No. 200 and is as readable and comprehensible as the OSHA No. 200 to a person not familiar with the equivalent form. It is important that the columns of the equivalent form have the same identifying number as the corresponding columns of the OSHA No. 200 because the instructions for completing the survey of occupational injuries and illnesses refer to log columns by number. It is advisable that employers have private equivalents of the log form reviewed by BLS to insure compliance with the regulations.

The portion of the OSHA No. 200 to the right of the dotted vertical line is used to summarize injuries and illnesses in an establishment for the calendar year. Every nonexempt employer who is required to keep OSHA records must prepare an annual summary for each establishment based on the information contained in the log for each establishment. The summary is prepared by totaling the column entries on the log (or its equivalent) and signing and dating the certification portion of the form at the bottom of the page.

B. **The Supplementary Record of Occupational Injuries and Illnesses OSHA No. 101**

For every injury or illness entered on the log, it is necessary to record additional information on the supplementary record, OSHA No. 101. The supplementary record describes how the accident or illness exposure occurred, lists the objects or substances involved, and indicates the nature of the injury or illness and the part(s) of the body affected.

The OSHA No. 101 is not the only form that can be used to satisfy this requirement. To eliminate duplicate recording, workers' compensation, insurance, or other reports may be used as supplementary records if they contain all of the items on the OSHA No. 101. If they do not, the missing items must be added to the substitute or included on a separate attachment.

Completed supplementary records must be present in the establishment within 6 workdays after the employer has received information that an injury or illness has occurred.

Chapter III. Location, Retention, and Maintenance of Records

Ordinarily, injury and illness records must be kept by employers for each of their establishments. This chapter describes what is considered to be an establishment for recordkeeping purposes, where the records must be located, how long they must be kept, and how they should be updated.

A. Establishments

If an employer has more than one establishment, a separate set of records must be maintained for *each* one. The recordkeeping regulations define an establishment as "a single physical location where business is conducted or where services or industrial operations are performed." Examples include a factory, mill, store, hotel, restaurant, movie theater, farm, ranch, sales office, warehouse, or central administrative office.

The regulations specify that distinctly separate activities performed at the same physical location (for example, contract construction activities operated from the same physical location as a lumber yard) shall each be treated as a separate establishment for recordkeeping purposes. Production of dissimilar products; different kinds of operational procedures; different facilities; and separate management, personnel, payroll, or support staff are all indicative of separate activities and separate establishments.

B. Location of records

Injury and illness records (the log, OSHA No. 200, and the supplementary record, OSHA No. 101) must be kept for every physical location where operations are performed. Under the regulations, the location of these records depends upon whether or not the employees are associated with a fixed establishment. The distinction between fixed and nonfixed establishments generally rests on the nature and duration of the operation and not on the type of structure in which the business is located. A nonfixed establishment usually operates at a single location for a relatively short period of time. A fixed establishment remains at a given location on a long-term or permanent basis. Generally, any operation at a given Site for more than 1 year is considered a fixed establishment. Also, fixed establishments are generally places where clerical, administrative, or other business records are kept.

1. ***Employees associated with fixed establishments*** Records for these employees should be located as follows:

a. Records for employees working at fixed locations, such as factories. stores, restaurants, warehouses, etc., should be kept at the work location.
b. Records for employees who report to a fixed location but work elsewhere should be kept at the place where the employees report each day. These employees are generally engaged in activities such as agriculture., construction, transportation, etc.
c. Records for employees whose payroll or personnel records are maintained at a fixed location, but who do not report or work at a single establishment, should be maintained at the base from which they are paid or the base of their firm's personnel operations. This category includes generally unsupervised employees such as traveling salespeople, technicians, or engineers.

2. ***Employees not associated with fixed establishments.*** Some employees are subject to common supervision, but do not report or work at a fixed establishment on a regular basis. These employees are engaged in physically dispersed activities that occur in construction, installation, repair, or service operations. Records for these employees should be located as follows:

a. Records may be kept at the field office or mobile base of operations.
b. Records may also be kept at an established central location. If the records are maintained centrally: (1) The address and telephone number of the place where records are kept must be available at the worksite; and (2) there must be someone available at the central location during normal business hours to provide information from the records.

C. Location exception for the log (OSHA No. 200)

Although the supplementary record and the annual summary must be located as outlined in the previous section, it is possible to prepare and ***maintain the log*** at an alternate location or by means of data processing equipment, or both. Two requirements must be met: (1) Sufficient information must be available at the alternate location to complete the log within 6 workdays after receipt of information that a recordable case has occurred; and (2) a copy of the log updated to within 45 calendar days must be present at all times in the establishment. This loeation exception applies only to the

log, and not to the other OSHA records. Also, it does not affect the employer's posting obligations.

D. Retention of OSHA records

The log and summary, OSHA No. 200, and the supplementary record, OSHA No. 101, must be retained in each establishment for 5 calendar years following the end of the year to which they relate. If an establishment changes ownership, the new employer must preserve the records for the remainder of the 5-year period. However, the new employer is not responsible for updating the records of the former owner.

E. Maintenance of the log (OSHA No. 200)

In addition to keeping the log on a calendar year basis, employers are required to update this form to include newly discovered cases and to reflect changes which occur in recorded cases after the end of the calendar year. Maintenance or updating of the log is different from the retention of records discussed in the previous section. Although all OSHA injury and illness records must be retained, only the log must be updated by the employer. If, during the 5-year retention period, there is a change in the extent or outcome of an injury or illness which affects an entry on a previous year's log, then the first entry should be lined out and a corrected entry made on that log. Also, new entries should be made for previously unrecorded cases that are discovered or for cases that initially weren't recorded but were found to be recordable after the end of the year in which the case occurred. The entire entry should be lined out for recorded cases that are later found nonrecordable. Log totals should also be modified to reflect these changes.

Chapter IV. Deciding Whether a Case Should Be Recorded and How To Classify It

This chapter presents guidelines for determining whether a case must be recorded under the OSHA recordkeeping requirements. These requirements should not be confused with recordkeeping requirements of various workers' compensation systems, internal industrial safety and health monitoring systems, the ANSI z. 16 standards for recording and measuring work injury and illness experience, and private insurance company rating systems. Reporting a case on the OSHA records should not affect recordkeeping determinations under these or other systems. Also-

Recording an injury or illness under the OSHA system does not necessarily imply that management was at fault, that the worker was at fault, that a violation of an OSHA standard has occurred, or that the injury or illness is compensable under workers' compensation or other systems

A. Employees vs. other workers on site

Employers must maintain injury and illness records for their own employees at each of their establishments, but they are ***not*** responsible for maintaining records for employees of other firms or for independent contractors, even though these individuals may be working temporarily in their establishment or on one of their jobsites at the time an injury or illness exposure occurs. Therefore, before deciding whether a case is recordable an employment relationship needs to be determined.

Employee status generally exists for recordkeeping purposes when the employer supervises not only the output, product, or result to be accomplished by the person's work, but also the details, means, methods, and processes by which the work is accomplished. This means the employer who supervises the worker's day-today activities is responsible for recording his injuries and illnesses. Independent contractors are not considered employees; they are primarily subject to supervision by the using firm only in regard to the result to be accomplished or end product to be delivered. Independent contractors keep their own injury and illness records.

Other factors which may be considered in determining employee status are: (1) Whom the worker considers to be his or her employer; (2) who pays the worker's wages; (3) who withholds the worker's Social Security taxes; (4) who hired the worker; and (5) who has the authority to terminate the worker's employment.

B. Method used for case analysis

The decisionmaking process consists of five steps:

1. Determine whether a case occurred, that is, whether there was a death, illness, or an injury;
2. Establish that the case was work related; that it resulted from an event or exposure in the work environment;
3. Decide whether the case is an injury or an illness; and
4. If the case is an illness, record it and check the appropriate illness category on the log; or
5. If the case is an injury, decide if it is recordable based on a finding of medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job.

Chart 1 presents this methodology in graphic form.

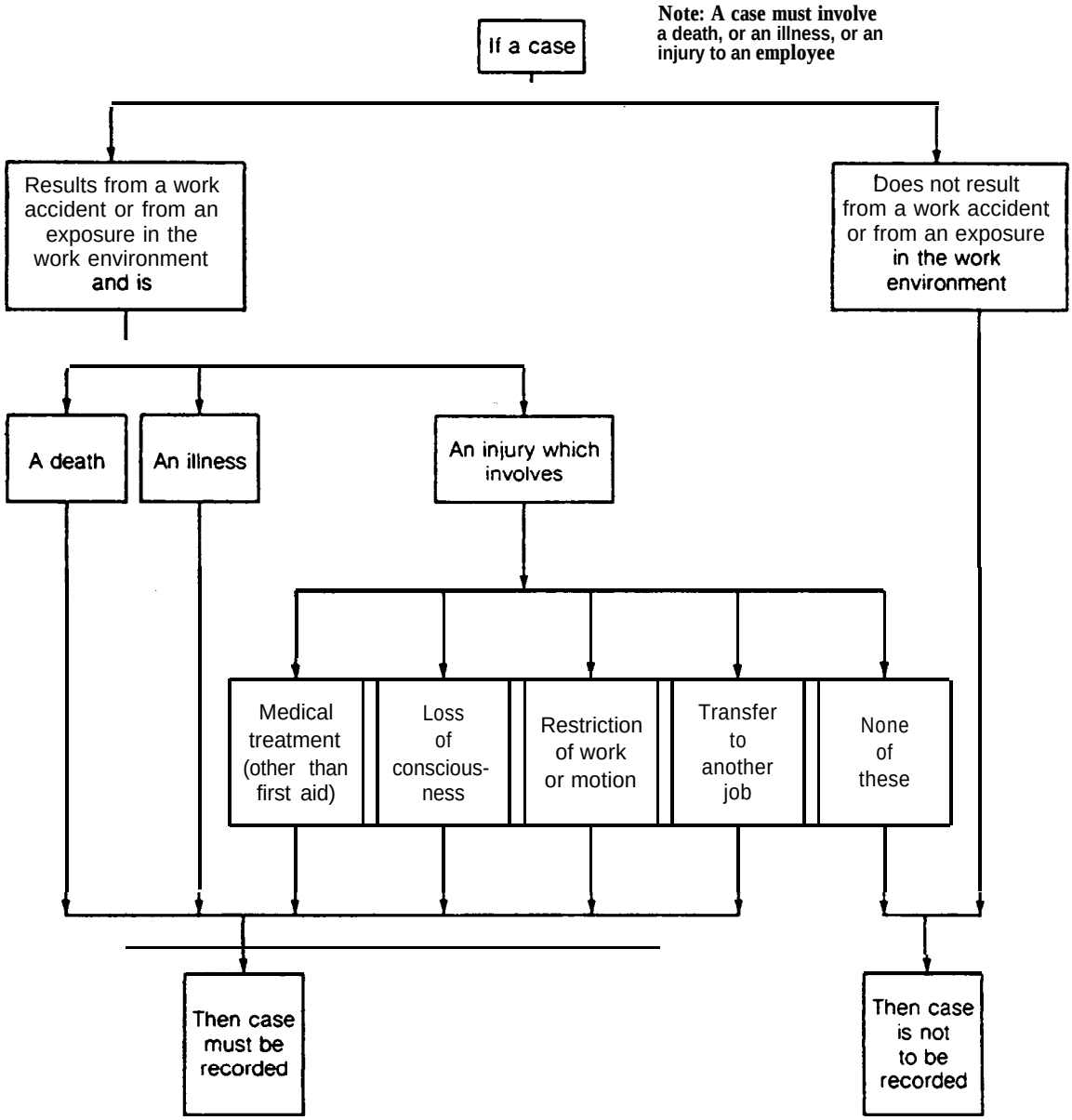
C. **Determining whether a case occurred**

The first step in the decisionmaking process is the determination of whether or not an injury or illness has occurred. Employers have nothing to record unless an employee has experienced a work-related injury or illness. In most instances, recognition of these injuries and illnesses is a fairly simple matter. However, some situations have troubled employers over the years. Two of these are:

1. ***Hospitalization for observation.*** If an employee goes to or is sent to a hospital for a brief period of time for observation, it is not recordable, provided no medical treatment was given, or no illness was recognized. The determining factor is not that the employee went to the hospital, but whether the incident is recordable as a work-related illness or as an injury requiring medical treatment or involving loss of consciousness, restriction of work or motion, or transfer to another job.

2. ***Differentiating a new case from the recurrence of a previous injury or illness*** Employers are required to make new entries on their OSHA forms for each new recordable injury or illness. However, new entries should

Chart 1. Guide to recordability of cases under the Occupational Safety and Health Act



not be made for the recurrence of symptoms from previous cases, and it is sometimes diflicult to decide whether or not a situation is a new case or a recurreuce. The following guidelines address this problem:

a **Injuries The aggravation of a previous injury almost always results from some new incident involving the employee (such as a slip, trip, fall, sharp twist, etc.). Consequently, when work related, these new incidents should be recorded as new cases.**

b. ***Illnesses.*** **Generally, each occupational illness should be recorded with a separate entry on the OSHA No. 200. However, certain illnesses, such as silicosis, may have prolonged effects which recur over time. The recurrence of these symptoms should not be recorded as new cases on the OSHA forms, The recurrence of symptoms of previous illnesses may require adjustment of entries on the log for previously recorded illnesses to reflect possible changes in the extent or outcome of the particular case.**

Some occupational illnesses, such as certain dermatitis or respiratory conditions, may recur as the result of new exposures to sensitizing agents, and should be recorded as new cases.

D. Establishing work relationship

The Occupational Safety and Health Act of 1970

requires employers to record only those injuries and illnesses that are work related. ***Work relationship is established under the OSHA recordkeeping system when the injury or illness results from an event or exposure in the work environment. The work environment is primarily composed of: (1) The employer's premises, and (2) other locations where employees are engaged in work-related activities or are present as a condition of their employment.*** When an employee is off the employer's premises, work relationship must be established; when on the premises, this relationship is presumed. The employer's premises encompass the total establishment, including not only the primary work facility, but also such areas as company storage facilities. In addition to physical locations, equipment or materials used in the course of an employee's work are also considered part of the employee's work environment.

1. ***Injuries and illnesses resulting from events or exposures on the employer's premises*** Injuries and illnesses that result from an event or exposure on the employer's premises are generally considered work related. The employer's premises consist of the total establishment. They include the primary work facilities and other areas which are considered part of the employer's general work area.

The presumption of work relationship for activities on the employer's premises is rebuttable. Situations where the presumption would not apply include: (1) When a worker is on the employer's premises as a member of the general public and not as an employee, and (2) when employees have symptoms that merely surface on the employer's premises, but are the result of a nonwork-related event or exposure off the premises.

The following subjects warrant special mention:

a. **Company restrooms, hallways, and cafeterias are all considered to be *part* of the employer's premises and constitute part of the work environment. Therefore, injuries occurring in these places are generally considered work related.**

b. **For OSHA recordkeeping purposes, the definition of work premises *excludes all* employer controlled ball fields, tennis courts, golf courses, parks, swimming pools, gyms, and other similar recreational facilities which are often apart from the workplace and used by employees on a voluntary basis for their own benefit, primarily during off-work hours. Therefore, injuries to employees in these recreational facilities are not recordable unless the employee was engaged in some work-related activity, or was required by the employer to participate.**

c. **Company parking facilities are generally not considered part of the employer's premises for OSHA recordkeeping purposes. Therefore, injuries to employees on these parking lots are not presumed to be work related, and are not recordable unless the employee was engaged in some work-related activity.**

2. ***Injuries and illnesses resulting from events or exposures off the employer's premises*** When an employee is off the employer's premises and suffers an injury or an illness exposure, work relationship must be established; it is not presumed. Injuries and illness exposures off premises are considered work related if the employee is engaged in a work activity or if they occur in the work environment. The work environment in these instances includes locations where employees are engaged in job tasks or work-related activities, or places where employees are present due to the nature of their job or as a condition of their employment.

Employees who travel on company business shall be considered to be engaged in work-related activities all the time they spend in the interest of the company, including, but not limited to, travel to and from customer contacts, and entertaining or being entertained for the purpose of transacting, discussing, or promoting business, etc. However, an injury/illness would not be recordable if it occurred during normal living activities (eating, sleeping, recreation); or if the employee deviates from a reasonably direct route of travel (side trip for vacation or other personal reasons). He would again be in the course of employment when he returned to the normal route of travel.

When a traveling employee checks into a hotel or motel, he establishes a "home away from home." Thereafter, his activities are evaluated in the same manner as for nontraveling employees. For example, if an employee on travel status is to report each day to a fixed worksite, then injuries sustained when traveling to this worksite would be considered off the job. The rationale is that an employee's normal commute from home to office would not be considered work related. However, there are situations where employees in travel status report to, or rotate among several different worksites after they establish their "home away from home" (such as a salesperson traveling to and from different customer contacts). In these situations, the injuries sustained when traveling to and from the sales locations would be considered job related.

Traveling sales personnel may establish only one base of operations (home or company office). A sales person with his home as an office is considered at work when he is in that office and when he leaves his premises in the interest of the company.

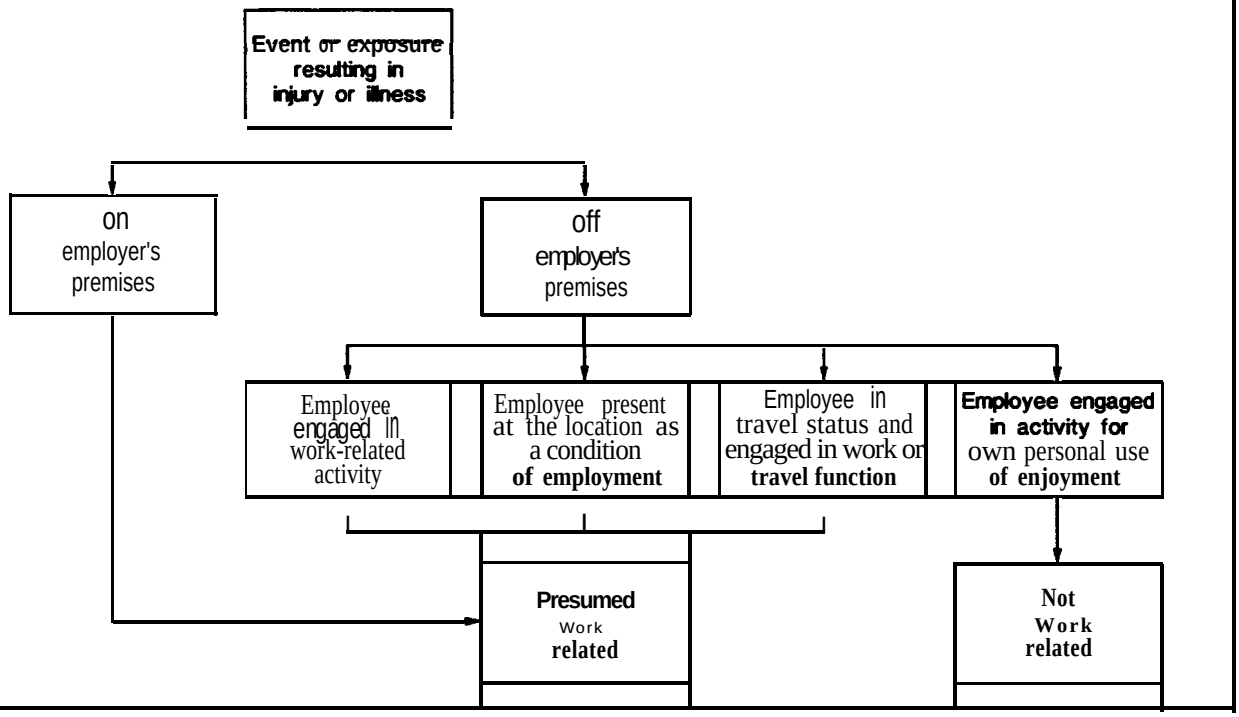
Chart 2 provides a guide for establishing the work relationship of cases.

E. Distinguishing between injuries and illnesses

Under the OSH Act, all work-related illnesses must be recorded, while injuries are recordable only when they require medical treatment (other than first aid), or involve loss of consciousness, restriction of work or motion, or transfer to another job. The distinction between injuries and illnesses, therefore, has significant recordkeeping implications.

Whether a case involves an injury or illness is determined by the nature of the original event or exposure

Chart 2. Guidelines for establishing work relationship



which caused the case, not by the resulting condition of the affected employee. Injuries are caused by instantaneous events in the work environment. Cases resulting from anything other than instantaneous events are considered illnesses. This concept of illnesses includes acute illnesses which result from exposures of relatively short duration.

Some conditions may be classified as either an injury or an illness (but not both), depending upon the nature of the event that produced the condition. For example, a loss of hearing resulting from an explosion (an instantaneous event) is classified as an injury; the same condition arising from exposure to industrial noise over a period of time would be classified as an occupational illness.

F. Recording occupational illnesses

Employers are required to record the occurrence of all occupational illnesses, which are defined in the instructions of the log and summary as:

> Any abnormal condition or disorder, other than one resulting from an occupational injury, cansed by exposure to environmental factors associated with employment. It includes acute and chronic illnesses o r diseases which may be caused by inhalation, absorption, ingestion, or direct contact.

The instructions also refer to recording illnesses which were "diagnosed or recognized." Illness exposures ultimately result in conditions of a chemical, physical, biological, or psychological nature.

Occupational illnesses must be diagnosed to be recordable. However, they do not necessarily have to be diagnosed by a physician or other medical personnel. Diagnosis may be by a physician, registered nurse, or a person who by training or experience is capable to make such a determination. Employers, employees, and others may be able to detect some illnesses such as skin diseases or disorders without the benefit of specialized medical training. However, a case more difficult to diagnose, such as silicosis, would require evaluation by properly trained medical personnel.

In addition to recording the occurrence of occupational illnesses, employers are required to record each illness case in 1 of the 7 categories on the front of the log. The back of the log form contains a listing of types of illnesses or disorders and gives examples for each illness category. These are only examples, however, and should not be considered as a complete list of types of illnesses under each category.

Recording and classifying occupational illnesses may be difficult for employers, especially the chronic and long term latent illnesses. Many illnesses are not easily detected; and once detected, it is often difIicult to determine whether an illness is work related. Also, employees may not report illnesses because the symptoms may not be readily apparent, or because they do not think their illness is serious or work related.

The following material is provided to assist in detecting occupational illnesses and in establishing their work relationship:

*1. **Detection and diagnosis of occupational illnesses***

An occupational illness is defined in the instructions on

the log as any work-related abnormal condition or disorder (other than an occupational injury). Detection of these abnormal conditions or disorders, the first step in recording illnesses, is often difficult. When an occupational illness is suspected, employers may want to consider the following:

a. A medical examination of the employee's physiological systems. For example:

- Head and neck
- Eyes, ears, nose, and throat
- Endocrine
- Genitourinary
- Musculoskeletal
- Neurological
- Respiratory
- Cardiovascular, and
- Gastrointestinal;

b. Observation and evaluation of behavior related to emotional status, such as deterioration in job performance which cannot be explained;
c. Specific examination for health effects of suspected or possible disease agents by competent medical personnel;
d. Comparison of date of onset of symptoms with occupational history;
e. Evaluation of results of any past biological or medical monitoring (blood, urine, other sample analysis) and previous physical examinations;
f. Evaluation of laboratory tests: Routine (complete blood count, blood chemistry profile, urinalysis) and specific tests for suspected disease agents (e.g., blood and urine teats for specific agents, chest or other X-rays, liver function tests, pulmonary function tests); and
g. Reviewing the literature, such as Material Safety Data Sheets and other reference documents, to ascertain whether the levels to which the workers were exposed could have produced the ill effects.

2. ***Determining whether the illness is occupationally related.*** The instructions on the back of the log define occupational illnesses as those "caused by environmental factors associated with employment." In some cases, such as contact dermatitis, the relationship between an illness and work-related exposure is easy to recognize. In other cases, where the occupational cause is not direct and apparent, it may be difficult to determine accurately whether an employee's illness is occupational in nature. In these situations, it may help employers to ask the following questions:

a. Has an illness condition clearly been established?
b. Does it appear that the illness resulted from, or was aggravated by, suspected agents or other conditions in the work environment?
c. Are these suspected agents present (or have they been present) in the work environment?
d. Was the ill employee exposed to these agents in the work environment?
e. Was the exposure to a sufficient degree and/or duration to result in the illness condition?
f. Was the illness attributable solely to a nonoccupational exposure?

G. Deciding if work-related injuries are recordable

Although the OSH Act requires that all work-related deaths and illnesses be recorded, the recording of nonfatal injuries is limited to certain specific types of cases: Those which require medical treatment or involve loss of consciousness; restriction of work or motion; or transfer to another job. Minor injuries requiring only first aid treatment are ***not*** recordable.

1. ***Medical treatment.*** It is important to understand the distinction between medical treatment and first aid treatment since many work-related injuries are recordable only because medical treatment was given.

The regulations and the instructions on the back of the log and summary, OSHA No. 200, define medical treatment as any treatment, other than first aid treatment, administered to injured employees. Essentially, medical treatment involves the provision of medical or surgical care for injuries that are not minor through the application of procedures or systematic therapeutic measures.

The act also specifically states that work-related injuries which involve only first aid treatment should not be recorded. First aid is commonly thought to mean emergency treatment of injuries before regular medical care is available. However, first aid treatment has a different meaning for OSHA recordkeeping purposes. The regulations define first aid treatment as:

> . . any one-time treatment, and any followup visit for the purpose of observation, of minor scratches, cuts, burns, splinters, and so forth, which do not ordinarily require medical care. Such one-time treatment, and followup visit for the purpose of observation, is considered first aid even though provided by a physician or registered professional personnel.

The distinction between medical treatment and first aid depends not only on the treatment provided, but also on the severity of the injury being treated. First aid is: (1) Limited to one-time treatment and subsequent observation; ***and*** (2) involves treatment of only minor injuries, ***not*** emergency treatment of serious injuries. Injuries are ***not*** minor if:

a. They must be treated only by a physician or licensed medical personnel;
b. They impair bodily function (i.e., normal use of senses, limbs, etc.);
c. They result in damage to the physical structure of a nonsuperlicial nature (e.g., fractures); or
d. They involve complications requiring followup medical treatment.

Physicians or registered medical professionals, working under the standing orders of a physician, routinely treat minor injuries. Such treatment-may constitute first aid. Also, some visits to a doctor do not involve treatment at all. For example, a visit to a doctor for an examination or other diagnostic procedure to determine

whether the employee has an injury does not constitute medical treatment. Conversely, medical treatment can be provided to employees by lay persons; i.e., someone other than a physician or registered medical personnel.

The following classifications list certain procedures as either medical treatment or first aid treatment.

Medical Treatment:

The following are generally considered medical treatment. Work-related injuries for which this type of treatment was provided or should have been provided are almost always recordable:

- Treatment of **INFECTION**
- Application of ANTISEPTICS during second or subsequent visit to medical personnel
- Treatment of SECOND OR THIRD DEGREE BURN(S)
- Application of SUTURES (stitches)
- Application of BUTTERFLY ADHESIVE DRESSING(S) or STERI STRIP(S) in lieu of sutures
- Removal of FOREIGN BODIES EMBEDDED IN EYE
- Removal of FOREIGN BODIES FROM WOUND; **if** procedure is **COMPLICATED** because of depth of embedment, size, or location
- Use of **PRESCRIPTION MEDICATIONS** (except a single dose administered on first visit for minor injury or discomfort)
- Use of hot or cold **SOAKING THERAPY during second or subsequent visit to** medical personnel
- Application of hot or cold **COMPRESS(ES) during second or** subsequent visit to medical personnel
- **CUTTING AWAY DEAD SKIN** (surgical debridement)
- Application of **HEAT THERAPY during second or subsequent visit** to medical personnel
- Use of WHIRLPOOL BATH THERAPY **during second or subsequent visit** to medical personnel
- POSITIVE X-RAY DIAGNOSIS (fractures, broken bones, etc.)
- **ADMISSION TO A HOSPITAL** or equivalent medical facility **FOR TREATMENT.**

First Aid Treatment:

The following are generally considered first aid treatment (e.g., one-time treatment and subsequent observation of minor injuries) and should not be recorded if the work-related injury does not involve loss of consciousness, restriction of work or motion, or transfer to another job:

- Application of **ANTISEPTICS** during first visit to medical personnel
- Treatment of **FIRST DEGREE BURN(S)**
- Application of **BANDAGE(s)** during any visit to medical personnel
- Use of **ELASTIC BANDAGE(S) during first visit** to medical personnel
- Removal of **FOREIGN BODIES NOT EMBEDDED IN EYE** if only irrigation is required
- Removal of **FOREIGN BODIES FROM WOUND;** if procedure is **UNCOMPLICATED,** and is, for example, by **TWEEZERS** or other simple technique
- Use of **NONPRESCRIPTION MEDICATIONS AND** administration of **single dose of PRESCRIPTION MEDICATION** on first visit for minor injury or discomfort
- **SOAKING THERAPY** on initial visit to medical personnel or removal of bandages by **SOAKING**
- Application of hot or cold **COMPRESS(ES)** during first visit to medical personnel
- Application of **OINTMENTS** to abrasions to prevent drying or cracking
- Application of **HEAT THERAPY** during first visit to medical personnel
- Use of **WHIRLPOOL BATH THERAPY during first visit** to medical personnel
- **NEGATIVE X-RAY DIAGNOSIS**
- **OBSERVATION** of injury during visit to medical personnel.

The following procedure, by itself, is not considered medical treatment:

- Administration of **TETANUS SHOT(S)** or **BOOSTER(S).** However, these shots are often given in conjunction with more serious injuries; consequently, injuries requiring these shots may be recordable for other reasons.

2. ***Loss of consciousness*** **If an employee loses consciousness as the result of a work-related injury, the case must be recorded no matter what type of treatment was provided. The rationale behind this recording requirement is that loss of consciousness is generally associated with the more serious injuries.**

3. *Restriction of work or motion* **Restricted work activity occurs when the employee, because of the impact of a job-related injury, is physically or mentally unable to perform all or any part of his or her normal assignment during all or any part of the workday or shift. The emphasis is on the employee's ability to perform normal job duties. Restriction of work or motion may result in either a lost worktime injury or a nonlost-worktime injury, depending upon whether the restriction extended beyond the day of injury.**

4. *Transfer to another job.* **Injuries requiring transfer of the employee to another job are also considered serious enough to be recordable regardless of the type of treatment provided. Transfers are seldom the sole criterion for recordability because injury cases are almost always recordable on other grounds, primarily medical treatment or restriction of work or motion.**

Chapter V. Categories for Evaluating the Extent of Recordable Cases

Once the employer decides that a recordable injury or illness has occurred, the case must be evaluated to determine its extent or outcome. There are three categories of recordable cases: Fatalities, lost workday cases, and cases without lost workdays. Every recordable case must be placed in only one of these categories.

A. Fatalities

All work-related fatalities must be recorded, regardless of the time between the injury and the death, or the length of the illness.

B. Lost workday cases

Lost workday cases occur when the injured or ill employee experiences either days away from work, days of restricted work activity, or both. In these situations, the injured or ill employee is affected to such an extent that: (1) Days must be taken off from the job for medical treatment or recuperation; or (2) the employee is unable to perform his or her normal job duties over a normal work shift, even though the employee may be able to continue working.

1. Lost workday cases involving days away from work are cases resulting in days the employee would have worked but could not because of the job-related injury or illness. The focus of these cases is on the employee's inability, because of injury or illness, to be present in the work environment during his or her normal work shift.
2. Lost workday cases involving days of restricted work activity are those cases where, because of injury or illness, (1) the employee was assigned to another job on a temporary basis, or (2) the employee worked at a permanent job less than full time, or (3) the employee worked at his or her permanently assigned job but could not perform all the duties normally connected with it. Restricted work activity occurs when the employee, because of the job-related injury or illness, is physically or mentally unable to perform all or any part of his or her normal job duties over all or any part of his or her normal workday or shift. The emphasis is on the employee's inability to perform normal job duties over a normal work shift.

Injuries and illnesses are not considered lost workday cases unless they affect the employee beyond the day of injury or onset of illness. When counting the number of days away from work or days of restricted work activity, do not include the initial day of injury or onset of illness, or any days on which the employee would not have worked even though able to work (holidays, vacations, etc.).

C. Cases not resulting in death or lost workdays

These cases consist of the relatively less serious injuries and illnesses which satisfy the criteria for recordability but which do not result in death or require the affected employee to have days away from work or days of restricted work activity beyond the date of injury or onset of illness.

Chapter VI. Employer Obligations for Reporting Occupational Injuries and Illnesses

This chapter focuses on the requirements of Section 8(c)(2) of the Occupational Safety and Health Act of 1970 and Title 29, Part 1904, of the Code of Federal Regulations for employers to make reports of occupational injuries and illnesses. It does not include the reporting requirements of other standards or regulations of the Occupational Safety and Health Administration (OSHA) or of any other State or Federal agency.

A. The Annual Survey of Occupational Injuries and Illnesses

The survey is conducted on a sample basis, and firms required to submit reports of their injury and illness experience are contacted by BLS or a participating State agency. A firm not contacted by its State agency or BLS need not file a report of its injury and illness experience. Employers should note, however, that even if they are not selected to participate in the annual survey for a given year, they must still comply with the recordkeeping requirements listed in the preceding chapters as well as with the requirements for reporting fatalities and multiple hospitalization cases provided in the next section of this chapter.

Participants in the annual survey consist of two categories of employers: (1) Employers who maintain OSHA records on a regular basis, and (2) a small, rotating sample of employers who are regularly exempt from OSHA recordkeeping. The survey procedure is different for these two groups of employers.

1. *Participation of firms regularly maintaining OSHA records.* When employers regularly maintaining OSHA records are selected to participate in the Annual Survey of Occupational Injuries and Illnesses, they are mailed the survey questionnaire in February of the year following the reference calendar year of the survey. (A firm selected to participate in the 1985 survey would have been contacted in February of 1986.) The survey form, the Occupational Injuries and Illnesses Survey Questionnaire, OSHA No.200-S, requests information about the establishment(s) included in the report and the injuries and illnesses experienced during the previous year. Information for the injury and illness portion of the report form usually can be copied directly from the totals on the log and summary, OSHA NO. 200, which the employer should have completed and posted in the establishment by the time the questionnaire arrives. The survey form also requests summary information about the type of business activity and number of employees and hours worked at the reporting unit during the reference year.

2. *Participation of normally exempt small employers and employers in low-hazard industries* A few regularly exempt employers (those with fewer than 11 employees in the previous calendar year and those in designated low-hazard industries) are also required to participate in the annual survey. Their participation is necessary for the production of injury and illness statistics that are comparable in coverage to the statistics published in years prior to the exemptions. These employers are notified prior to the reference calendar year of the survey that they must maintain injury and illness records for the coming year. (A firm selected to participate in the 1985 survey would have been contacted in December 1984.) At the time of notification, they are supplied with the necessary forms and instructions. During the reference calendar year, prenotified employers make entries on the log, OSHA No. 200, but are not required to complete a Supplementary Record of Occupational Injuries and Illnesses, OSHA No. 101, or post the summary of the OSHA No. 200 the following February (regularly participating employers do both).

B. Reporting fatalities and multiple hospitalizations

All employers are required to report accidents resulting in one or more fatalities or the hospitalization of five or more employees. (Some States have more stringent catastrophic reporting requirements.)

The report is made to the nearest office of the Area Director of the Occupational Safety and Health Administration, U.S. Department of Labor, unless the State in which the accident occurred is administering an approved State plan under Section 18(b) of the OSH Act. Those 18(b) States designate a State agency to which the report must be made.

The report must contain three pieces of information: (1) Circumstances surrounding the accident(s), (2) the number of fatalities, and (3) the extent of any injuries. If necessary, the OSHA Area Director may require additional information on the accident.

The report should be made within 48 hours after the occurrence of the accident or within 48 hours after the occurrence of the fatality, regardless of the time lapse between the occurrence of the accident and the death of the employee.

Chapter VII. Access to OSHA Records and Penalties for Failure To Comply With Recordkeeping Obligations

The preceding chapters describe recordkeeping and reporting requirements. This chapter covers subjects related to insuring the integrity of the OSH recordkeeping process-access to OSHA records and penalties for recordkeeping violations.

A. Access to OSHA records

All OSHA records, which are being kept by employers for the 5-year retention period, should be available for inspection and copying by authorized Federal and State government officials. Employees, former employees, and their representatives are provided access to only the log, OSHA No. 200.

Government officials with access to the OSHA records include: Representatives of the Department of Labor, including OSHA safety and health compliance officers and BLS representatives; representatives of the Department of Health and Human Services while carrying out that department's research responsibilities; and representatives of States accorded jurisdiction for inspections or statistical compilations. "Representatives" may include Department of Labor officials inspecting a workplace or gathering information, officials of the Department of Health and Human Services, or contractors working for the agencies mentioned above, depending on the provisions of the contract under which they work.

Employee access to the log is limited to the records of the establishment in which the employee currently works or formerly worked. All current logs and those being maintained for the 5-year retention period must be made available for inspection and copying by employees, former employees, and their representatives. An employee representative can be a member of a union representing the employee, or any person designated by the employee or former employee. Access to the log is to be provided in a reasonable manner and at a reasonable time. Redress for failure to comply with the access provisions of the regulations can be obtained through a complaint to OSHA.

B. Penalties for failure to comply with recordkeeping obligations

Employers committing recordkeeping and/or reporting violations are subject to the same sanctions as employers violating other OSHA requirements such as safety and health standards and regulations.

Glossary of Terms

Annual summary. Consists of a copy of the occupational injury and illness totals for the year from the OSHA No. 200, and the following information: The calendar year covered; company name; establishment address; certification signature, title, and date.

Annual survey. Each year, BLS conducts an annual survey of occupational injuries and illnesses to produce national statistics. The OSHA injury and illness records maintained by employers in their establishments serve as the basis for this survey.

Bureau of Labor Statistics (BLS). The Bureau of Labor Statistics is the agency responsible for administering and maintaining the OSHA recordkeeping system, and for collecting, compiling, and analyzing work injury and illness statistics.

Certification. The person who supervises the preparation of the Log and Summary of Occupational Injuries and Illnesses, OSHA No. 200, certifies that it is true and complete by signing the last page of, or by appending a statement to that effect to, the annual summary.

Cooperative program. A program jointly conducted by the States and the Federal Government to collect occupational injury and illness statistics

Employee. One who is employed in the business of his or her employer affecting commerce.

Employee representative. Anyone designated by the employee for the purpose of gaining access to the employer's log of occupational injuries and illnesses.

Employer. Any person engaged in a business affecting commerce who has employees.

Establishment. A single physical location where business is conducted or where services or industrial operations are performed; the place where the employees report for work, operate from, or from which they are paid.

Exposure. The reasonable likelihood that a worker is or was subject to some effect, influence, or safety hazard; or in contact with a hazardous chemical or physical agent at a sufficient concentration and duration to produce an illness.

Federal Register. The official source of information and notification on OSHA'S proposed rulemaking, standards, regulations, and other official matters, including amendments, corrections, insertions, or deletions.

First aid. Any one-time treatment and subsequent observation of minor scratches, cuts, bums, splinters, and so forth, which do not ordinarily require medical care. Such treatment and observation are considered first aid even though provided by a physician or registered professional personnel.

First report of injury. A workers' compensation form which may qualify as a substitute for the supplementary record, OSHA No. 101.

Incidence rate. The number of injuries, illnesses, or lost workdays related to a common exposure base of 100 full-time workers. The common exposure base enables one to make accurate interindustry comparisons, trend analysis over time, or comparisons among firms regardless of size. This rate is calculated as:

$$N/EH \times 200{,}000$$

where:

- N = number of injuries and/or illnesses or lost workdays
- EH = total hours worked by all employees during calendar year
- 200,000 = base for 100 full-time equivalent workers (working 40 hours per week, 50 weeks per year).

Log and Summary (OSHA NO.200). The OSHA recordkeeping form used to list injuries and illnesses and to note the extent of each case.

Lost workday cases. Cases which involve days away from work or days of restricted work activity, or both.

Lost workdays. The number of workdays (consecutive or not), beyond the day of injury or onset of illness, the

employee was away from work or limited to restricted work activity because of an occupational injury or illness.

(1) Lost workdays--away from work **The number of workdays (consecutive or not) on which the employee would have worked but could not because of occupational injury or illness.**

(2) Lost workdays - restricted work activity. The number of workdays (consecutive or not) on which, because of injury or illness: **(1)** The employee was assigned to another job on a temporary basis, or *(2)* the employee worked at a permanent job less than full time; or (3) the employee- worked at a permanently assigned job but could not perform all duties normally connected with it.

The number of days away from work or days of restricted work activity does not include the day of injury or onset of illness or any days on which the employee would not have worked even though able to work.

Low-hazard industries. Selected industries in retail trade; finance, insurance, and real estate; and services which are regularly exempt from OSHA recordkeeping. To be included in this exemption, an industry must fall within an SIC not targeted for general schedule inspections and must have an average lost workday case injury rate for a designated 3-year measurement period at or below 75 percent of the U.S. private sector average rate.

Medical treatment. Includes treatment of injuries administered by physicians, registered professional personnel, or lay persons (i.e., nonmedical personnel). Medical treatment does not include first aid treatment (one-time treatment and subsequent observation of minor scratches, cuts, burns, splinters, and so forth, which do not ordinarily require medical care) even though provided by a physician or registered professional personnel.

Occupational illness. Any abnormal condition or disorder, other than one resulting from an occupational injury, caused by exposure to environmental factors associated with employment. It includes acute and chronic illnesses or diseases which may be caused by inhalation, absorption, ingestion, or direct contact. The following categories should be used by employers to classify recordable occupational illnesses on the log in the columns indicated:

Column 7a. ***Occupational skin diseases or disorders.***
Examples: Contact dermatitis, eczema, or rash caused by primary irritants and sensitizers or poisonous plants; oil acne; chrome ulcers; chemical burns or inflammations; etc.

Column 7b. ***Dust diseases of the lungs (pneumoconioses).***
Examples: Silicosis, asbestosis, and other asbestos-related diseases, coal worker's pneumoconiosis, byssinosis, siderosis, and other pneumoconioses.

Column 7c. ***Respiratory conditions due to toxic agents***
Examples: Pneumonitis, pharyngitis, rhinitis or acute congestion due to chemicals, dusts, gases, or fumes; farmer's lung, etc.

Column* 7d.** ***Poisoning (systemic effects of toxic materials).
Examples: Poisoning by lead, mercury, cadmium, arsenic, or other metals; poisoning by carbon monoxide, hydrogen sulfide, or other gases; poisoning by benzol, carbon tetrachloride, or other organic solvents; poisoning by insecticide sprays such as parathion, lead arsenate; poisoning by other chemicals such as formaldehyde, plastics, and resins; etc.

Column 7e. ***Disorders due to physical agents (other than toxic materials),***
Examples: Heatstroke, **sunstroke, heat exhaustion, and other effects of environmental heat; freezing, frostbite, and effects of exposure to low temperatures; caisson disease; effects of ionizing radiation (isotopes, X-Rays, radium); effects of nonionizing radiation (welding flash, ultra-violet rays, microwaves, sunburn); etc.**

Column 7f. ***Disorders associated with repeated trauma***
Examples: Noise-induced hearing loss; synovitis, tenosynovitis, and bursitis; Raynaud's phenomena; and other conditions due to repeated motion, vibration, or pressure.

Column 7g. ***All other occupational illnesses***
Examples: Anthrax, brucellosis, infectious hepatitis, malignant and benign tumors, food poisoning, histoplasmosis, coccidioidomycosis. etc.

Occupational injury. Any injury such as a cut, fracture, sprain, amputation, etc., which results from a work accident or from a single instantaneous exposure in the work environment.

Note: Conditions resulting from animal bites, such as insect or snake bites, and from one-time exposure to chemicals are considered to be injuries.

Occupational injuries and illnesses, extent and outcome. All recordable occupational injuries or illnesses result in either:

(1) Fatalities, regardless of the time between the injury, or the length of illness, and death;
(2) Lost workday cases, other than fatalities, that result in lost workdays; or
(3) Nonfatal cases without lost workdays.

Occupational Safety and Health Administration (OSHA). OSHA is responsible for developing, implementing, and enforcing safety and health standards and regulations. OSHA works with employers and employees to foster effective safety and health programs which reduce workplace hazards.

Posting. The annual summary of occupational injuries and illnesses must be posted at each establishment by February 1 and remain in place until March 1 to provide employees with the record of their establishment's injury and illness experience for the previous calendar year.

Premises, employer's. Consist of the employer's total establishment; they include the primary work facility and

other areas in the employer's domain such as company storage facilities, cafeterias, and restrooms.

Recordable cases. All work-related deaths and illnesses, and those work-related injuries which result in: Loss of consciousness, restriction of work or motion, transfer to another job, or require medical treatment beyond first aid.

Recordkeeping system. Refers to the nationwide system for recording and reporting occupational injuries and illnesses mandated by the Occupational Safety and Health Act of 1970 and implemented by Title 29, Code of Federal Regulations, Part 1904. This system is the only source of national statistics on job-related injuries and illnesses for the private sector.

Regularly exempt employers. Employers regularly exempt from OSHA recordkeeping include: (A) All employers with no more than 10 full- or part-time employees at any one time in the previous calendar year; and (B) all employers in retail trade; finance, insurance, and real estate; and services industries; i.e., SIC's 52-89 (except building materials and garden supplies, SIC 52; general merchandise and food stores, SIC's 53 and 54; hotels and other lodging places, SIC 70; repair services, SIC's 75 and 76; amusement and recreation services, SIC 79; and health services, SIC 80). (Note: Some State safety and health laws may require these employers to keep OSHA records.)

Report form. Refers to survey form OSHA No. 200-S which is completed and returned by the surveyed reporting unit.

Restriction of work or motion. Occurs when the employee, because of the result of a job-related injury or illness, is physically or mentally unable to perform all or any part of his or her normal assignment during all or any part of the workday or, shift.

Single dose (prescription medication). The measured quantity of a therapeutic agent to be taken at one time:

Small employers. Employers with no more than 10 full- and/or part-time employees among all the establishments of their firm at any one time during the previous calendar year.

Standard Industrial Classification (SIC). A classification system developed by the Office of Management and Budget, Executive Office of the President, for use in the classification of establishments by type of activity in which engaged. Each establishment is assigned an industry code for its major activity which is determined by the product manufactured or service rendered. Establishments may be classified in 2-, 3-, or 4-digit industries according to the degree of information available.

State (when mentioned alone). Refers to a State of the United States, the District of Columbia, and U.S. territories and jurisdictions.

State agency. State agency administering the OSHA recordkeeping and reporting system. Many States cooperate directly with BLS in administering the **OSHA** recordkeeping and reporting programs. Some States have their own safety and health laws which may impose additional obligations.

Supplementary Record (**OSHA No.** 101). The form (or equivalent) on which additional information is recorded for each injury and illness entered on the log.

Title 29 of the Code of Federal Regulations, Parts 1900-1999. The parts of the Code of Federal Regulations which contain OSHA regulations.

Volunteers. Workers who are not considered to be employees under the act when they serve of their own free will without compensation.

Work environment. Consists of the employer's premises and other locations where employees are engaged in work-related activities or are present as a condition of their employment. The work environment includes not only physical locations, but also the equipment or materials used by the employee during the course of his or her work.

Workers' compensation systems. State systems that provide medical benefits and/or indemnity compensation to victims of work-related injuries and illnesses.

ORDER FORM

Type or print

Please complete this **form** and mail it to **the** appropriate BLS regional office or participating State agency.

From:

Name _____

Firm _____

Street Address _____

City, State, Zip Code _____

Please send me the following items at no charge: Quantity

A Brief Guide to Recordkeeping Requirements for Occupational Injuries and Illnesses (18pp.)..... ____

Recordkeeping Guidelines for Occupational Injuries and Illnesses (84 pp.) ..... ____

OSHA No. 200 Forms (Log and Summary of Occupational Injuries and Illnesses) ..... ____

OSHA No. 101 Forms (Supplementary Record of Occupational Injuries and Illnesses) .. ____

ADDRESS LABEL

Name _____

Firm _____

Street Address _____

City, State, Zip **Code** _____

Participating State Agencies

Agencies preceded by an asterisk (*) have a State safety and health plan under section 18(b) of the act in operation and may be contacted directly for information regarding State regulations.

Alabama Department of Labor
651 Administrative Bldg.
Montgomery, AL 36130
Phone: 205-261-3460

*Alaska Department of Labor
Research and Analysis Section
P.O. Box 25501. Juneau, AR 99802
Phone: 9074654520

Government of American Samoa
Department of Manpower Resources
Division of Labor
Pago Pago, AS 96799
Phone: 633-5849

*Industrial Commission of Arizona
Division of Administration/Management
Research and Statistics Section
P.O. Box 19070, Phoenix, AZ 85005
Phone: 602-255-3739

Workers' Compensation Commissiin OSH
Arkansas Department of Labor
OSH Research and Statistics, Suite 219
1515 W. 7th St., Little Rock, AR 72201
Phone: 501-371-2770

*California Department of Industrial Relations, Labor Statistics and Research Division
P.O. Box 6880, San Francisco, CA 94101
Phone: 415-557-1466

Colorado Department of Labor and Employment, Division of Labor
1313 Sherman St., Rm. 323
Denver, CO 80203
Phone: 303-866-3748

*Connecticut Department of Labor
200 Folly Brook Blvd.
Wethersfield. CT 06109
Phone: 203-566-4380

Delaware Department of Labor
Division of Industrial Affairs
820 N. French St., 6th FL
Wilmington. DE 19801
Phone: 302-571-2888

Florida Deparment of Labor and Employment Security
Division of Worker's Compensation
2551 Executive Center
Circle West, Rm. 204
Tallahassee, FL 32301-5014
Phone: 904-488-3044

Guam Department of Labor
Bureau of Labor Statistics
Occupational Safety and Health Statistics
P.O. Box 23548, Guam Main Facility
Guam, M.I. 96921
Phone: 477-9241

*State of Hawaii
Department of Labor and Industrial Relatious. Research and Statistics Office - OSHA
P.O. Box 3680, Honolulu, HI 96811
Phone: 808-548-7638

*Indiana Department of Labor
Research and Statistics Division
State Office Bldg.-Rm. 1013
100 N. Senate Ave.
Indianapolis, IN 46204
Phone: 317-232-2681

● Iowa Division of Labor Services
307 East 7th St., Des Moines, LA 50319
Phone: 515-281-3606

Kansas Department of Health and Environment
Division of Policy and Planning
Research and Analysis
Topeka, KS 66620
Phone: 913-862-9360 Ext. 280

*Kentucky Labor Cabinet
Occupational Safety and Health Program
U.S. 127 South Bldg., Frankfort, KY 40601
Phone: 502-564-3100

Louisiana Department of Labor
Office of Employment Security-OSH
P.O. Box 94094
Baton Rouge, LA 70804
Phone: 504-342-3126

Maine Department of Labor
Bureau of Labor Standards
Division of Research and Statistics
State Office Bldg., Augusta, ME 04330
Phone: 207-289-4311

*Maryland Department of Licensing and Regulation
Division of Labor and Industry
501 St. Paul Pl. Baltimore, MD 21202
Phone: 301-333-4202

Massachusetts Department of Labor and Industries
Division of Industrial Safety
100 Cambridge St., Baton, MA 02202
Phone: 617-727-3593

*Michigan Department of Labor
7150 Harris Dr., Secondary Complex
P.O. Box 30015, Lansing, MI 48909
Phone: 517-322-1848

*Minnesota Department of Labor and Industry IMSD
444 Lafayette Rd., 5th FL
St. Paul MN 55101
Phone: 612-296-4893

Mississippi State Department of Health
Office of Public Health Statistics
P.O. Box 1700
Jackson, MS 39215-1700
Phone: 601-354-7233

Missouri Department of Labor and Industrial Relations
Division of Workers' Compensation
P.O. Box 58. Jefferson City, MO 65102
Phone: 314-751-4231

Montana Department of Labor and Industry
Workers' Compensation Division
5 South Last Chance Gulch
Helens, MT 59601
Phone: 406-444-6515

Nebraska Workers' Compensation Court
State Capitol, 12th Fl.
Lincoln. NE 68509-4967
Phone: 402-471-3547

*Nevada Department of Industrial Relations
Division of Occupational Safety and Health
1370 South Curry St.
Carson City, NV 89710
Phone: 702-885-5240

New Jersey Department of Labor and Industry
Division of Planning and Research, CN 057
Trenton, NJ 08625
Phone: 609-292-8997

*New Mexico Health and Environment Department
Environmental Improvement Division
Occupational Health and Safety
P.O. Box 968
Sante Fe, NM 87504-0968
Phone: 505-827-2875

New York Department of Labor
Division of Research and Statistics
1 Main St., Rm 907
Brooklyn, NY 11201
Phone: 718-797-7701

*North Carolina Department of Labor
Research and Statistics Division
214 West Jones St.
Raleigh, NC 27603
Phone: 919-733-4940

Ohio Department of Industrial Relations
OSH Survey Office
P.O. Box 12355, Columbus, OH 43212
phone: 614-466-7520

Oklahoma Department of Labor
Supplemental Data Division
1315 North Broadway Pl.
Oklahoma City, OK 73105
Phone: 405-235-1447

*Oregon-Workers' Compensation Department
Research and Statistics Section
21 Labor and Industries Bldg.
Salem, OR 97310
Phone: 503-378-8254

Pennsylvania Department of Labor and Industry
Office of Employment Security
7th and Forster Sts.
Labor and Industry Bldg.
Harrisburg, PA 17121
Phone: 717-787-1918

*Puerto Rico Department of Labor and Human Resources
Bureau of Labor Statistics
505 Munoz Rivers Ave.
Hato Rey, PR 00918
Phone:809-754-5339

Rhode Island Department of Labor
220 Elmwood Ave., Providence,RI 02907
Phone: 401-457-1852

*South Carolina Department of Labor
Division of Technical Support
P.O. Box 11329. Columbii, SC 29211
Phone: 803-734-9652

*Tennessee Department of Labor
Research and Statistics
501 Union Bldg., 6th Fl.
Nashville, TN 37219
Phone: 615-741-1748

Texas Department of Health
Division of Occupational Safety
1100 West 49th St., Austin, TX 78756
Phone: 512-458-7287

● Utah Industrial Commission
OSH Statistical Section
160 East 300 South
Salt Lake City, UT 84145-0580
Phone: 801-530-6827

*Vermont Department of Labor and Industry
State Office Bldg.
Montpelier, VT 05602
Phone: 802-828-2765

*Virgin Islands Department of Labor
P-0. Box 3359
St. Thomas, VI 00801
Phone: 809-776-3700

*Virginia Department of Labor and Industry
Planning and Research
205 North 4th St.
P.O. Box 12064. Richmond, VA 23241
Phone: 804-786-2384

● State of Washington
Department of Labor and Industries
Division of Industrial Safety and Health
P.O. Box 2589
Olympia, WA 98504
Phone: 206-753-4013

West Virginia Department of Labor
OSH Project Director
Rm. 319, Bldg. 3, Capitol Complex
1800 Washington St. East
Charleston, WV 25305
Phone: 304-348-7890

Wisconsin Department of Industry, Labor and Human Relations
Workers' Compensation Division
Research Section
201 E. Washington Ave.
P.O. Box 7901
Madison WI 53707
Phone: 608-266-7850

*Wyoming Department of Labor and Statistics
Herschler Bldg., 2 East
Cheyenne, WY 82002
Phone: 307-777-6370

* U. S. GOVERNMENT PRINTING OFFICE 1990 262-285/26173

18. The FDA Inspection

Food and Drug Administration (FDA) inspections have a serious regulatory purpose. The inspector comes, usually, to determine whether the inspected company is complying with the requirements of the Federal Food, Drug, and Cosmetic Act (FDC Act) and FDA regulations. Your company must regard the inspector as a policeman gathering evidence, evidence that ultimately could be used against the company. Almost every FDA-initiated recall, civil seizure action, injunction action, and criminal prosecution has as its basis data acquired by an FDA inspector during an inspection. Therefore, it is critically important that you have a good understanding of FDA's rights and your company's rights during an inspection, and that you act accordingly to manage the inspection to protect your company as best you can.

I. INSPECTION PLAN

Every FDA-regulated company should have a standard operating procedure, a written plan, for coping with the FDA inspection. The plan should explain for affected personnel (1) FDA's rights, (2) the company's rights, and (3) company policies and practices to be followed during the FDA inspection.

This paper is intended to help you to develop such a plan for your company, or to review and refine your existing procedures if you already have an inspection plan. A useful way to approach this subject is to discuss a hypothetical FDA inspection, from start to finish.

II. RECEIVING THE INSPECTOR

Before beginning an inspection, the FDA inspector is required by the FDC Act to present (1) credentials identifying himself/herself and (2) a written notice of inspection (Form FDA-482) to the owner, operator, or agent in charge of the establishment to be inspected[1/] Your company's inspection plan should designate the person to receive and accompany the inspector. "Back-up" personnel should also be identified. These persons should be trained so that they understand thoroughly the extent of FDA's rights, your company's rights, and your company's policies with respect to the various matters likely to arise during an inspection.

III. COMPANY RECORD OF THE INSPECTION

Upon receiving the inspector, your company representative (referred to "you," hereafter for convenience) should begin immediately to compile a comprehensive record of the inspection. This record should open with the notice of inspection provided by the inspector. Examine his or her credentials. Record the full name of each inspector. If later, FDA should institute an enforcement action based upon the inspection, you would want to be certain of the identity of each FDA inspector, for depositions or other preparation of your defense.

IV. WHAT ABOUT **A WARRANT?**

The FDC Act provides that FDA inspectors are authorized . . .

> to enter, at reasonable times, any factory, warehouse, or establishment in which food . . . [is] manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food . . . in interstate commerce; and . . . to inspect..[2/]

The FDC Act makes no mention of requiring a warrant from a United States district judge or magistrate to authorize the inspection. Furthermore, the FDC Act provides that "refusal to permit entry or inspection" is a criminal offense.[3/]

However, in 1978 the United States Supreme Court, in Marshall v. Barlow's. Inc., ruled that it is unconstitutional for inspectors of the Occupational Safety and Health Administration (OSHA) to conduct an inspection without a warrant unless the inspected company consents to the inspection.[4/] In this decision, the Supreme Court stated that "warrantless searches are generally unreasonable" and that "this rule applies to commercial premises as well as homes." Nevertheless, the Supreme Court stated that warrantless inspections are permitted, as an "exception," for "pervasively regulated" businesses "long subject to close supervision and inspection." The Court identified the "liquor" and "firearms" industries as examples of the exceptional circumstances in which warrantless inspections are permitted without the consent of an inspected firm.

FDA asserts that companies subject to regulation under the FDC Act come within the exception in Marshall v. Barlow's. Inc. that permits unconsented warrantless inspections of pervasively regulated industries. However, the United States district courts have ruled "both ways" on the issue of whether an unconsented and warrantless inspection under the FDC Act is constitutional in light of the Barlow's decision.[5/] Since FDA probably can obtain an inspection warrant anyway, simply by telling a United States district judge or magistrate that the Agency has not inspected your company for a while and that it wants to see what you are doing, most companies decide to permit an inspection without attempting to insist upon a warrant.

FDA does not routinely obtain a warrant before attempting to conduct an inspection. If an FDA inspector should arrive at your company armed with a warrant, this would be a most unusual and suspicious circumstance, requiring prompt and careful attention. If the warrant should provide for photographs, for access to manufacturing records, or for other FDA activity you otherwise would refuse to permit, it is especially important to react immediately; you may find it necessary to comply with the warrant until you can reach the judge or magistrate who issued the document.

V. BEFORE THE INSPECTION BEGINS

Before the inspector begins to examine your establishment, ask why he/she is

there, and attempt to determine what he/she intends to review. It sometimes happens, for example, that the inspector is interested only in a particular subject, and that you can provide desired information without "opening the door" for him/her to wander generally through your establishment. In such a case, you may want to obtain the information for the inspector and let him/her depart as quickly as possible.

Also, before allowing an inspection to commence, you should tell the inspector of your company's policies that will control the inspection. For example, you may want to tell the inspector (1) that company policy prohibits taking cameras into the plant and that the inspector must leave any camera in his/her car or in your office, and (2) that any questions or requests for information are to be directed only to you and not to other company employees. (In Sections IX-XI below, this paper reviews several policies that you should consider adopting.)

VI. CONDUCT OF THE INSPECTION -- FDA'S LIMITED RIGHTS

Suppose the inspector states that his/her purpose is to conduct a routine surveillance inspection of your establishment: What is the extent of FDA's inspection authority?

The FDC Act provides FDA authority

> to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment. finished and unfinished materials. containers, and labeling therein.

(Emphasis added.[6/])

Note particularly what the Act does not state. It does not mention, for example, any FDA right of access to manufacturing records including master formula records, batch production records, results of analyses, or complaint files. You generally are not required to show such records to the FDA inspector. (Caveat: FDA does have authority to inspect such records in certain exceptional cases.[7/])

Technically, the law does not require even that you talk to the inspector. However, when an inspector asks reasonable questions about the types of products you manufacture, your manufacturing procedures, and the like, you probably will want to respond. After all, you may save yourself a lot of time and trouble. If the inspector should have to remain in your plant for two weeks in order to determine the nature of your operations, he/she may decide to do just that, when you could avoid such an extended FDA presence simply by answering reasonable questions.

VII. TAKING OF SAMPLES

The FDC Act provides that the inspector is authorized to collect samples.[8/] During an inspection, FDA inspectors routinely take samples of finished and unfinished

materials and of labeling, and companies generally permit the taking of reasonable samples of this type. The courts have recognized that this is an appropriate inspection function.[9/] You may insist that the inspector pay for the fair value of samples taken, but many companies do not bother to do this unless the value is substantial.

VIII. "HOLDING" A SUSPECT PRODUCT

While he/she may take samples of materials in your establishment, the FDA inspector does not have the authority to detain or embargo foods that he/she believes to be in violation of the FDC Act (except for items that are being imported into the United States). The inspector may request that you voluntarily hold a food that he/she believes to be adulterated or misbranded, but he/she cannot require that you do so (except for imports).

"Seizure" of an article in your establishment pursuant to the FDC Act requires the institution of a civil proceeding in a United States district court. In general, before an article can be "seized" under the FDC Act, the following chain of events must occur: The FDA district office recommends to FDA headquarters that a civil seizure be instituted, and if FDA headquarters agrees, the FDA chief counsel writes to the local United States attorney, requesting the initiation of a civil seizure action. Assuming the United States attorney agrees (as he/she usually does), he/she files a complaint for forfeiture in the local United States district court, and then the United States marshal serves upon the article a "warrant for arrest." Service of this warrant upon the article accomplishes seizure. Thereafter, there will be a trial before the court to determine, on the merits, whether the food is adulterated or misbranded and should be condemned as alleged by FDA (However, FDA may ask state health officials to detain goods until a federal civil seizure action is accomplished. State officials may exercise authority under state law to embargo goods pending FDA action.[10/])

IX. CONDUCT OF THE INSPECTION -- PROTECTING YOUR COMPANY'S RIGHTS AND INTERESTS

Let's now consider several policies or procedures you can adopt to control the conduct of the FDA inspection, in order to protect your company's rights and interests:

- You should accompany the FDA inspector at all times. Do not allow the inspector to proceed unattended by the company representative.

- Advise the inspector that any questions or requests for data are to be directed only to the company's designated representative.

(The FDC Act authorizes only "reasonable" inspections, and, surely, it is not reasonable to permit someone who is not an employee to roam unattended through your establishment asking questions of whomever he or she pleases. Such activity could be disruptive of production and perhaps even dangerous to someone who is not familiar with your plant.)

- Employees other than the company representative should be instructed not to speak to the inspector. They should not volunteer conversation, and if asked a question by the inspector, they should respond that it is company policy not to discuss their work with visitors and that any questions should be directed to the company representative designated to accompany the inspector.

- Keep a detailed record of all that the inspector says or does. This information may become important in the future, especially if FDA should undertake regulatory action based upon the inspection.

- Whenever the FDA inspector takes a sample of anything, you also should take a sample of the same article, to be maintained as a part of your company's record of the inspection. For example, if FDA samples a particular lot of finished product, or a particular label, you want to be certain that you have taken an identical companion sample, which will then be available for your efficient reference if FDA subsequently asks questions or undertakes regulatory action.

- Do not sign or initial "affidavits" or other documents. FDA inspectors frequently enter information that they believe to be important on a form entitled "Affidavit" and then ask a company representative to sign or initial the form, thereby acknowledging the accuracy of the statement. There is no obligation for you to sign or initial any such affidavit, and there is no good reason to do so. Any admissions in the statement could be used against you and your company in court.

Many companies have a standard policy that their employees are not authorized to sign or initial any documents for the FDA inspector. If the inspector asks for written acknowledgment with respect to a particular matter, ask the inspector to submit a written request to your company, for review and consideration by management and company counsel. In practice, this usually will be the end of the matter because FDA inspectors generally are loath to request anything in writing.

- If the FDA inspector calls your attention to a violation of law that is easily correctable, try promptly to correct the situation during the course of the inspection.

- Do not volunteer information. It may be reasonable to provide certain information in response to questions from the inspector, but there is no reason to suggest new avenues of interest that otherwise might not be investigated.

- Always be honest in everything you say to the inspector. It can be entirely appropriate to tell an inspector that he/she has no statutory right to require you to provide certain information, and to decline to provide it. It would be a very different matter, however, to give the inspector a potentially devious, or dishonest, response. The former should be understood and respected. The latter just invites trouble, and can be a criminal offense[11/]

- Finally, be polite. You may need to be firm in asserting your company policies or in protecting your rights in some other respect, but you should always remain courteous. Personal animosity cannot help you.

X. PHOTOGRAPHS

FDA asserts that it has the right to take photographs, and the inspector probably will argue with you if you tell him/her not to bring a camera into the plant. The FDA Inspection Operations Manual (IOM) includes a section instructing the inspector to insist that he/she has a right to take photographs, and to cite particular judicial decisions if a company refuses to permit photography[12/].

However, a statement appearing earlier in the Manual, which the inspector is unlikely to mention, explains why FDA really wants the photographs: The IOM tells the inspector"... [photographs] are one of the most effective and useful forms of evidence of violations."[13/]

There are two judicial decisions that the inspector will cite to you if you refuse to permit photographs: (1) United States v. Acri Wholesale Grocerv Co. actually stands for the proposition that if a company permits FDA to take photographs without objection, the photographs may be used in evidence against the company in a judicial enforcement action such as a criminal prosecutio[14/]; and (2) Dow Chemical Co. v. United States upheld the authority of Environmental Protection Agency (EPA) inspectors to take

photographs of company property from an airplane.[15] So far as we can determine, however, no reported judicial decision has ever yet punished a company solely for refusal to permit photographs during an FDA inspection.

It appears that many companies that are knowledgeable about their rights under the FDC Act do not permit photographs during an inspection. You should consider this matter together with your own legal counsel. Photographs may overemphasize a particular detail in a misleading way, or may reveal trade secret manufacturing procedures that you do not want to release outside of your control. If you are firm about it, the FDA inspector will probably put away the camera and proceed with the inspection, although he/she may report that you have "partially refused" to permit a proper inspection.

XI. ACCESS TO MANUFACTURING RECORDS

You generally are not required to provide the FDA inspector access to your manufacturing records (product recipes or formulas, batch production records, analytical data, complaint files, etc.). The FDA inspector may make repeated efforts to examine and copy such records, but (unless, as noted in Section VI above, the records concern exceptional products) he/she generally is not entitled to require you to let him see or copy any of your manufacturing records.[16]

There is, however, a "middle ground" approach you may wish to consider for responding to FDA requests for such records. If, for example, the FDA inspector states that he/she wants to see your production records to verify that you include in your products the ingredients listed on the labels, you may elect to follow a selective "look but don't copy" policy. That is, in order that he/she may verify that your company does use in its products the ingredients that it lists on the labels, you may want to let the inspector very briefly see a few pertinent records from your files, but not permit him/her to copy the information. This approach has the advantage of allowing the inspector to confirm that you follow proper procedures in a responsible manner, without releasing from your control documents that may include trade secret information.

XII. SHIPPING RECORDS

The FDC Act provides that "persons receiving foods . . . in interstate commerce or holding such articles so received," shall, upon written request, permit an FDA inspector...

> at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food . . . or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof.

(Emphasis added.[17])

Accordingly, if FDA so requests in writing, you must provide access to records

concerning interstate shipment.

However, the Act provides that evidence obtained in this manner may not be used against you or your company in a criminal prosecution (although it may be used in a civil seizure action or injunction). If the inspector does request such information, you should insist that the request be made in writing before providing the documents if you want to assure yourself and your company of the protection afforded by the statute with respect to any resulting criminal prosecution.

XIII. THE "EXIT INTERVIEW"

At the completion of the inspection, the FDA inspector usually will ask to meet with the "owner, operator, or agent in charge." At this time, the FDA inspector provides an FDA form entitled "Inspectional Observations" (Form FDA-483), listing observations the inspector believes are vio1ations.[18/]

It is prudent to discuss with the inspector this list of observations. If you do not understand an item, ask about it. If you do not agree with a particular observation, explain your position. If you have corrected an observation during the course of the inspection, tell the inspector. Ask the inspector to make any appropriate changes in the list of observations at this time. Also, if you intend to correct certain observations, explain what you intend to do. Even if the inspector does not amend the list of observations, he/she should include your comments in the report of the inspection (the Establishment Inspection Report [EIR], discussed in Section XV below). Such comments may affect the way the inspector and his/her superiors at FDA evaluate the inspection. **You want to satisfy FDA that you are taking all reasonable steps to manufacture clean, safe, and accurately labeled products.**

Also, during the exit interview, the FDA inspector will provide a "Receipt for Samples" (Form FDA-484) for all samples taken during the course of the inspection (unless he/she has already provided such documentation when the samples were taken). At this time, you should confirm that you have taken companion samples (for your own internal inspection report and future reference) of all articles sampled by the inspector.

If during an exit interview you promise the inspector to make particular corrections, be certain to do as you have promised. The next time an FDA inspector visits your plant, he/she will determine, and report, whether promised corrections have been made.

XIV. AFTER THE INSPECTION

Promptly after the inspection, appropriate company personnel should meet to discuss the inspection. Was your company in compliance with the requirements of law? If not, what corrective steps should be taken? Were the inspector's "Inspectional Observations" accurate? If you disagreed with the inspector's observations during the exit interview, did he/she make appropriate changes in the written list of observations?

If the inspector noted violations, were they of such significance that some type of follow-up regulatory action might be expected from the Agency? Who in corporate management should be advised of the inspection and its outcome?

Depending upon the nature of the "Inspectional Observations" and the exit interview, after the inspection you may want to send FDA a written response to the inspector's list of observations, thereby making certain that the FDA record includes a complete statement of your views.

XV. THE "EIR"

After departing, the FDA inspector usually prepares a detailed Establishment Inspection Report (EIR). The EIR becomes FDA's primary record of the inspector's visit to your firm, and it will be reviewed by FDA compliance officers looking for violations of law. (If product samples were taken, they may be examined in an FDA laboratory, Also, labeling taken by the inspector may be examined at FDA offices.)

You will, of course, be interested to know what the inspector has said about your establishment in the EIR, and you may obtain a copy of the EIR when FDA has closed its file on your inspection.[19/] If FDA refuses to release a copy of the EIR concerning your inspection, the Agency may still have an "open" file on the matter, i.e., the Agency may still be considering whether to institute some form of regulatory action.

One reason to request a copy of the EIR is that EIRs are subject to release under the Freedom of Information Act to any member of the public, including your competitors. Accordingly, you may want to review the EIR to determine whether FDA has inadvertently failed to purge the document of trade secret information before release. If you find FDA releasing an EIR that reveals trade secret information concerning your establishment, you should object to the Agency immediately.

XVI. FDA ANALYSES

If FDA performs analytical work on a sample of an ingredient or finished product taken during the inspection, you are entitled to a copy of the results of analysis.[20/] Note that you should be able to obtain such reports of analyses without waiting until FDA "closes the file" concerning the inspection.[21/] Thus, you may be able to obtain analytical results before you can obtain the EIR. (If FDA performs analytical work, you generally can also obtain from FDA a portion of the sample that was analyzed, so that you may perform analytical work on the same sample tested by FDA.[22/])

XVII. CONCLUSION

If FDA should conclude that an inspection has revealed significant violations of the FDC Act or of FDA regulations, the Agency may initiate regulatory action (e.g., issue a warning letter, request a recall, or recommend a civil seizure action, an injunction, or a criminal prosecution). It is precisely because of the serious enforcement actions that can arise out of an inspection that it is so important for you to understand

and to exercise your rights during an inspection, and to keep a detailed record of each inspection.

Never forget the potentially serious nature of any FDA inspection. In order to protect your company's rights and interests, you should establish standard operating procedures for your company for the management of FDA inspections, and affected company personnel should be thoroughly trained to follow the procedures. We hope this paper will help you to establish an effective inspection plan for your company.

REFERENCES

1/ Section 704(a) of the FDC Act, 21 U.S.C. § 374(a).

2/ Ibid

3/ Section 301(f) of the FDC Act, 21 U.S.C. § 331(f).

4/ Marshall v. Barlow's, Inc., 436 U.S. 307 (1978).

5/ Compare United States v. Roux Laboratories. Inc., 456 F. Supp. 973 (M.D. Fla. 1978) (ruling FDA may not conduct an inspection of a cosmetic establishment without a warrant if the company does not consent) with United States v. New England Grocers Supply Co., 488 F. Supp. 230 (D. Mass. 1980) (ruling that neither a warrant nor consent was required for an FDA inspection of a grocery warehouse).

6/ Section 704(a) of the FDC Act, 21 U.S.C. § 374(a).

7/ E.g., FDA regulations provide for inspection of certain records of manufacture concerning thermally processed low-acid foods packaged in hermetically sealed containers. 21 C.F.R. § 108.35(h).

8/ Sections 702(b), 704(c) and (d) of the FDC Act, 21 U.S.C. § § 372(b), 374(c) and(d).

9/ United States v. 75 Cases . . . Peanut Butter, 146, 146 F.2d 124 (4th Cir. 1944), cert. denied, 325 U.S. 856 (1945); UnitedStates v. El Rancho Adolphus Products, 140 F. Supp. 645 (M.D. Pa. 1956), affd, 243 F.2d 367 (3rd Cir. 1957), cert. denied, 353 U.S. 976 (1957); United States v. Roux Laboratories. Inc., supra, note 5.

10/ See, e.g., United States v. An Article of Food . ..345/50-Pound Bags, 622 F.2d 768, 769 at note 1 (5th Cir. 1980).

11/ 18 U.S.C. § 1001.

12/ FDA Inspection Operations Manual Subchapter 520, Section 523.1 "In-Plant Photographs" (TN 87-18; December 4, 1987).

13/ FDA Inspection Operations Manual Subchapter 520, Section 523 "Photographs-Photocopies" (TN-87-18; December 4, 1987).

14/ United States v. Acri Wholesale Grocery Co., 409 F. Supp. 529 (S.D. Iowa 1976).

15/ Dow Chemical Co. v. United States, 106 S.Ct. 1819 (1986).

16/ See note 7 above for an exceptional situation in which FDA regulations provide for inspections of manufacturing records. Similarly, FDA regulations provide for agency inspection of certain manufacturing records for acidified foods. 21 C.F.R. § 108.25(g).

17/ Section 703 of the FDC Act, 21 U.S.C. § 373.

18/ Section 704(b) of the FDC Act, 21 U.S.C. § 374(b), provides that "Upon completion of any such inspection . . . and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food . . . in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packaged, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

19/ 21 C.F.R. § § 20.64, 20.101.

20/ Section 704(d) of the FDC Act, 21 U.S.C. § 374(d); see also 21 C.F.R. § 20.105(c).

21/ Ibid.

22/ Section 702(b) of the FDC Act, 21 U.S.C. § 372(b); 21 C.F.R. § 2.10(c).

19. PART ll0-Federal Government Rules and Regulations for Good Manufacturing Practices

Subpart A - General Provisions

Section

Subpart B - Buildings and Facilities

Subpart C - Equipment

Subpart D - [Reserved]

Subpart E - Production and Process Controls

Subpart F - [Reserved]

Subpart G - Defect Action Levels

Authority: Secs. 402,701,704, of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

Source 51 FR 24475, June 19, 1986, unless otherwise noted.

Subpart A - General Provisions

§ 110.3 Definitions

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) are applicable to such terms when used in this part. The following definitions shall also apply:

- ***Acid foods or acidified foods*** means foods that have an equilibrium pH of 4.6 or below.
- "Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.
- ***Batter*** means a semi-fluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.
- ***Blanching,*** except for tree nuts and peanuts, means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.
- ***Critical control*** point means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.
- ***Food*** means food as defined in section 201(f) of the act and includes raw materials and ingredients.
- ***Food-contact surfaces*** are those surfaces that contact human food and those surfaces from which drainage onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food-contact surfaces" includes utensils and food-contact surfaces of equipment.
- ***Lot*** means the food produced during a period of time indicated by a specific code.
- ***Microorganisms*** means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the act. Occasionally in these regulations, FDA uses the adjective "microbial" instead of using an adjectival phrase containing the word "microorganism."
- ***Pest*** refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies and larvae.
- ***Plant*** means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.
- ***Quality control operation*** means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the act.
- ***Rework*** means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.

. ***Safe-moisture level*** is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.

- ***Sanitize*** means to adequately treat food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.
- ***Shall*** is used to state mandatory requirements.
- ***Should*** is used to state recommended or advisory procedures or identify recommended equipment.
- ***Water activity (a_w)*** is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 110.5 Current good manufacturing practice

- The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or (2) within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).
- Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

§ 110.10 Personnel.

The plant management shall take all reasonable measures and precautions to ensure the following:

- ***Disease control.*** Any person who by medical examination or supervisory observations, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel shall be instructed to report such health conditions to their supervisors.
- ***Cleanliness.*** All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to:

1. Wearing outer garments suitable to the operation in a manner that protects against the contamination of food, food-contact surfaces, or food-packaging materials.
2. Maintaining adequate personal cleanliness.
3. Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.
4. Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.
5. Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material.
6. Wearing, where appropriate, in an effective manner, hair nets, head-bands, caps, beard covers, or other effective hair restraints.
7. Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.
8. Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco.
9. Taking any other necessary precautions to protect against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

- Education and training. Personnel responsible for identifying sanitation failures or food contamination should have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food. Food handlers and supervisors should receive appropriate training in proper food handling techniques and food-protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.

- ***Supervision.*** Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

§ 110.19 Exclusions.

- The following operations are not subject to this part: Establishments engaged solely in the harvesting, storage, or distribution of one or more “raw agricultural commodities,” as defined in section 201(r) of the act, which are ordinarily cleaned, prepared, treated, or otherwise processed before being marketed to the consuming public.
- FDA, however, will issue special regulations if it is necessary to cover these excluded operations.

Subpart B - Buildings and Facilities

§ 110.20 Plant and grounds

Grounds. The grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:

1. Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests.
2. Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.
3. Adequately draining areas that may contribute to contamination of food by seepage, foot-borne filth, or providing a breeding place for pests.
4. Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraph (a) (1) through (3) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that maybe a source of food contamination.

- *Plant construction and design.* Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-manufacturing purposes. The plant and facilities shall:
  1. Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.
  2. Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination maybe reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

3. Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:

(i) Using protective coverings
(ii) Controlling areas over and around the vessels to eliminate harborages for pests
(iii) Checking on a regular basis for pests and pest information
(iv) Skimming the fermentation vessels, as necessary

4. Be constructed in such a manner that floors, walks, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts, and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.
5. Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety-type light bulbs, fixtures, sky-lights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.
6. Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging materials, and food-contact surfaces.
7. Provide, where necessary, adequate screening or other protection against pests.

§ 110.35 Sanitary operations

- General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of the act. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

- ***Substances used in cleaning and sanitizing; storage of toxic materials.***
  1. Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:

(i) Those required to maintain clean and sanitary conditions;
(ii) Those necessary for use in laboratory testing procedures;
(iii) Those necessary for plant and equipment maintenance and operation; and
(iv) Those necessary for use in the plant's operations.

2. Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products should be followed.

- Pest ***control.*** No animals or pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs in unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials.
- ***Sanitation of food-contact surfaces.*** All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.
  1. Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.
  2. In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food-contact surfaces of the equipment shall be cleaned and sanitized as necessary.
  3. Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.
  4. Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.
  5. Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.
- ***Storage and handling of cleaned portable equipment and utensils.*** Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored in a location and manner that protects food-contact surfaces from contamination.

[51 FR 24475, June 19, 1986, as amended at 54 FR 24892, June 12, 1989]

§ 110.37 Sanitary facilities and controls

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

. *Water supply.* The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.

. ***Plumbing.*** Plumbing shall be of adequate size and design and adequately installed and maintained to:
   1. Carry sufficient quantities of water to required locations throughout the plant.
   2. Properly convey sewage and liquid disposable waste from the plant.
   3. Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
   4. Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
   5. Provide that there is not back-flow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

. ***Sewage disposal.*** Sewage disposal shall be made into an adequate sewage system or disposed of through other adequate means.

. ***Toilet facilities.*** Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement may be accomplished by:
   1. Maintaining the facilities in a sanitary condition.
   2. Keeping the facilities in good repair at all times.
   3. Providing self-closing doors.
   4. Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive airflow systems).

. ***Hand-washing facilities.*** Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:
   1. Hand-washing and, where appropriate, hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
   2. Effective hand-cleaning and sanitizing preparations.
   3. Sanitary towel service or suitable drying devices.
   4. Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands.

5. Readily understandable signs directing employees handling unprotected food, unprotected food-packaging materials, food-contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.
6. Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

- ***Rubbish and offal disposal*** Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minirnize the potential for the waste becorning an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Subpart C - Equipment

§ 110.40 Equipment and utensils.

- All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.

- Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

- Equipment that is in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

- Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.

- Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.

- Instruments and controls used for measuring, regulating, or recording temperature, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained, and adequate in number for their designated uses.

- Compressed air or their gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.

Subpart D - [Reserved]

Subpart E - Production and Process Controls

§ 110.80 Processes and controls.

All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles. Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function. All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination. All food that has become contaminated to the extent that it is adulterated within the meaning of the act shall be rejected or, if permissible, treated or processed to eliminate the contamination.

- *Raw materials and other ingredients.*
  1. Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration. Raw materials shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food. Containers and carriers of raw materials should be inspected on receipt to ensure that their condition has not contributed to the contamination of deterioration of food.
  2. Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of the act. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.
  3. Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with current Food and Drug Administration regulations, guidelines, and action levels for poisonous or deleterious substances before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished 'by purchasing raw materials and other ingredients under a supplier's guarantee or certification, or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.
  4. Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with applicable Food and Drug Administration regulations, guidelines, and defect

action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification, or examination of these materials for contamination.

5. Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of the act. Material scheduled for rework shall be identified as such.
6. Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of the act.
7. Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

. ***Manufacturing operations.***

1. Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

2. All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, a_W, pH, pressure, flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical break-downs, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.
3. Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated within the meaning of the act. Compliance with this requirement may be accomplished by any effective means, including:

   (i) Maintaining refrigerated foods at 45°F (7.2°C) or below as appropriate for the particular food involved.
   (ii) Maintaining frozen foods in a frozen state.
   (iii) Maintaining hot foods at 140°F (60° C) or above.
   (iv) Heat-treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures.

4. Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH, or controlling a_W, that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of the act.

5. Work-in-process shall be handled in a manner that protects against contamination.

6. Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food. Food transported by conveyor shall be protected against contamination as necessary.

7. Equipment, containers, and utensils used to convey, hold, or store raw food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.

8. Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.

9. Food, raw materials, and other ingredients that are adulterated within the meaning of the act shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of the act before being incorporated into other food.

10. Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting, and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food-contact surfaces, and by using time and temperature controls at and between each manufacturing step.

11. Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning. Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.

12. Batters, breading, sauces, gravies, dressings, and other similar preparations shall be treated or maintained in such a manner that they are protected against contamination. Compliance with this requirement may be accomplished by any effective means, including one or more of the following:

(i) Using ingredients free of contamination.
(ii) Employing adequate heat processes where applicable.
(iii) Using adequate time and temperature controls.
(iv) Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them.
(v) Cooling to an adequate temperature during manufacturing.
(vi) Disposing of batters at appropriate intervals to protect against the growth of microorganisms.

13. Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement may be accomplished by any effective means including:

(i) Use of a quality control operation in which the critical control points are identified and controlled during manufacturing.
(ii) Adequate cleaning and sanitizing of all food-contact surfaces and food containers.
(iii) Using materials for food containers and food-packaging materials that are safe and suitable, as defined in § 130.3(d) of this chapter,
(iv) Providing physical protection from contamination, particularly airborne contamination.
(v) Using sanitary handling procedures.

14. Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the a_w of food.
(ii) Controlling the soluble solids-water ratio in finished food.
(iii) Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w, of the food does not increase to an unsafe level.

15. Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement may be accomplished by any effective means, including employment of one or more of the following practices:

(i) Monitoring the pH of raw materials, food in process, and finished food.
(ii) Controlling the amount of acid or acidified food added to low-acid food.

16. When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality, and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in this part.
17. Food-manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food-grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.

§ 110.93 Warehousing and distribution

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Subpart F [Reserved]

Subpart G - Defect Action Levels

§ 110.110 Natural or unavoidable defects in food for human use that present no health hazard

- Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration established maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.
- Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.
- Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.
- The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect levels of the final food.
- A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Industry Programs Branch (HFF-326), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C. St. SW., Washington, DC 20204.

COMMONWEALTH of VIRGINIA

ROBERT B. STROUBE, M.D., M.P.H.
STATE HEALTH COMMISSIONER

Department of Health
P. 0 BOX 2448
RICHMOND. VA 23218

NOTICE

Rules and Regulations of the Virginia State Board of Health regarding shellfish and crab meat processing and distribution are not included in this edition of this manual because they are currently under review and revision. To receive information on Virginia requirements please call (804)786-7937 or write to:

Virginia Department of Health
Division of Shellfish Sanitation
1500 East Main Street, Suite 109
Richmond, Virginia 23219

21. FEDERAL GOVERNMENT ENFORCEMENT ACTIONS

WARNING LETTERS, RECALLS, SEIZURES AND INJUNCTIONS

A. INTRODUCTION

This paper discusses the civil sanctions that the United States Food and Drug Administration (FDA) can bring against a company or product once the agency believes that a significant violation of law has occurred. These sanctions include *warning letters, recalls, civil seizure actions,* and *injunctions.*

B. WARNING LETTERS

Background

On May 23,1991, Commissioner Kessler of the FDA issued a memorandum outlining a new Warning Letter policy saying, "The FDA cannot afford to be perceived as a 'paper tiger' that inspects a firm, writes a letter, waits, then writes another letter, and so on." The Commissioner ordered the elimination of both the notice of adverse findings and the regulatory letter. In the past, these two (2) pieces of correspondence normally gave a company fair warning that they were headed into trouble and allowed for early negotiations with FDA. Now, there is only the (usually out-of-the-blue) Warning Letter to tell a company FDA believes it is in serious trouble. It is FDA's view that in the past companies "gamed" the agency by filing vacuous responses and making bogus promises in response to notices of adverse findings and regulatory letters. Commissioner Kessler believes FDA-regulated industries attempted to forestall agency enforcement by taking up time and wasting FDA assets. Not only did the memorandum of May 23, 1991, eliminate the notice of adverse findings and the regulatory letter but it also changed the character of a warning letter. Someone receiving the new Warning Letter now must understand that it is the harbinger of civil sanctions against the company and/or product.

Warning Letters Now

Warning Letters are issued directly by FDA's district directors although some areas do require Center for Food and Applied Nutrition, FDA, concurrence (rarely withheld) prior to issuance of a letter. If a district wants or needs concurrence, they must ask for it within fifteen (15) working days from the conclusion of an inspection. The Center must respond to a district within fifteen (15) working days. The new Warning Letter does not commit the agency to take enforcement action, but alleged violators had better take note that failure to take "prompt corrective action" may very well result in an agency enforcement action or actions. According to FDA, these letters are supposed to be issued only for violations of regulatory significance, but since FDA determines what constitutes a violation of regulatory significance, the agency totally controls this issue. The Warning Letter gives a company fifteen (15) working days to respond. It is possible to obtain consent for additional time, but the willingness to do so varies district-by-district. Warning letters are on public display at the FDA's Freedom of Information Staff Office in Rockville, Maryland. They are also publicized in industry trade press and through FDA's press releases.

One of FDA's goals in going to Warning Letters was to reduce the time between inspection and issuance of the letter. This goal has been met. The average elapsed time between the completion of the inspection and the Warning Letter is now less than 9 weeks. With regulatory letters, the average turnaround time was approximately twice as long.

Unfortunately, alacrity has been achieved at the cost of conveying substantially less information. This is particularly true for Warning Letters involving alleged sanitary conditions deficiencies. Regulatory letters almost always referred to the specific problems and even gave some illustrations of the alleged deviations or deficiencies. Warning Letters offer few, if any details.

Seafood Warning Letters FY '91 and FY '92

Seafood companies (not including fish oils), received a total of 32 Warning Letters in FY '91 and 53 in FY '92. The following is the breakdown of the alleged violations for each year:

	FY'91	FY'92
Misbranded	11	9
Adulterated	16	37
Combined (Misbranded and Adulterated)	--	3
Drug Claim	5	--
Other (i.e., failure to inspect, shipping problem)		4
	32	53

What to Do

The use of Warning Letters is now viewed by FDA as an effective enforcement strategy. So how do you handle one? Several of the more important points to keep in mind are:

First, Warning Letters are potentially quite serious. They are often a prelude to litigation by FDA Therefore, companies should give their responses a very high priority. It is the manufacturer's best chance to address the allegations. The failure to respond is often interpreted by FDA as indifference by the company to its regulatory obligations.

Second, in many instances the response will necessarily include references to changes or modifications in the company's practices. This is particularly true for alleged GMP violations, since companies often advise FDA of proposed or completed changes. It is extremely important that any promises be kept. FDA will reinspect. And if the company has not kept its word, FDA is much more likely to seek severe sanctions.

Third, there is no room for sarcasm or anger in the response. Companies that receive Warning Letters often feel aggrieved, and sometimes justifiably so. An intemperate response, while personally satisfying, is likely to backfire.

Finally, think carefully about what you say or write. Your response is an important document and deserves detailed attention. Statements made in the response can come back to haunt the company. Nor does the company want to pass up the chance to defuse what may be a critical situation.

C. PRODUCT RECALLS

1. FDA Guidelines

FDA has issued detailed regulations to guide the conduct of product recalls.[1] These regulations, however, are "guidelines" that FDA suggests manufacturers and distributors follow "with respect to their *voluntary* removal or correction of marketed violative products.[2] FDA does *not* assert that these regulations have the mandatory force of law.

2. Not Entirely Voluntary

Of course, the "voluntary" procedures that FDA has described in its "guidelines" are supported in part by the threat that failure to comply could result in an FDA-initiated civil seizure action or other FDA-initiated judicial action. "...recall is an alternative to an FDA-initiated court action for removing or correcting violative, distributed products..[3]

3. Not all Violations Require Recalls

Not all violations of FDA requirements are worthy of a recall. Technical violations --e.g., failure to spell an ingredient name correctly in labeling, failure to place the net quantity of contents in the proper area of the label may cause a product officially to be deemed 'misbranded" and may require prospective correction, but such violations should not require a recall. FDA regulations provide that a "recall" does *not* include a situation that "involves a minor violation.[4] Again, the agency retains the privilege of deciding what is minor.

4. Recall Procedures

FDA's regulations prescribe detailed procedures for conducting a recall. Upon discovering that a distributed product is in violation of law, a company should conduct an evaluation of the risk to health presented by the product. If the risk is sufficiently serious to merit a recall, the responsible person should establish a recall strategy, including a detailed plan for recovery of the product down to the appropriate level in the chain of distribution. Not all recalls need to be pursued to the same level. Depending upon the seriousness of a violation, a recall to the wholesale level may be sufficient. If, however, severe health risks are presented, one may want to try to find all violative products, including even efforts to recapture items that have been sold to retail customers.[5]

5. Effective Checks

FDA generally believes that if a recall should be conducted, the responsible person should follow up to verify that persons who have been notified to return a product have in fact performed as requested. The intensity of such effectiveness checks can vary depending upon the seriousness of the health hazard presented by the product.[6]

6. Should You Notify FDA?

1. FDA regulations state that a firm that decides "to remove or correct a distributed product...because it believes the product to be violative is requested to notify immediately the appropriate Food and Drug Administration district office..."[7] A firm is not required, however, to notify FDA that it is conducting a recall.

2. Notification to FDA has significant downside aspects. For example, FDA "will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall...[8]. Industry trade newspapers and the general media routinely monitor the FDA ***Enforcement Report.*** Accordingly, a recall listing in the Report can produce adverse publicity.

3. Furthermore, advising FDA of a recall can result in considerable FDA intrusion into the recall process. FDA regulations state that a recalling firm "will be asked to provide" FDA certain information about the recall.[9] Thereafter, FDA will conduct its own "evaluation of the health hazard presented" and assign the recall a classification (i.e., "class I," "class II," or "class III"), "to indicate the relative degree of health hazard...". FDA will then "advise the firm of the assigned recall classification [and] recommend any appropriate changes in the firm's strategy for the recall...". FDA may even determine that a Public warning (including an FDA press release directed to the media) is needed.[10]

4. Experience indicates that, when advised of a recall, FDA personnel are sometimes helpful and cooperative in providing advice and guidance to a company and work well with company personnel in the conduct of the recall. However, FDA personnel can and do recommend steps that a company will view as difficult and unreasonable, and may cause the company to need to pursue a recall to a level that does not appear to the company to be necessary or appropriate. FDA can also call for more publicity than the company believes is warranted.

5. One possible plus of notifying FDA is that the agency may be less likely to take punitive action against a company over a matter where the company has, on its own, initiated an effective recall and invited FDA to monitor the activity. (There is, however, no guarantee that information volunteered to FDA in the course of discussing a company-initiated recall will not be used against the company in a subsequent FDA enforcement action.)

6. If a company has recall insurance, it may be important to advise FDA of the recall and to have the agency officially list the recall in the FDA ***Enforcement Report--***to document for the insurance company that a recall was necessary and appropriate, and that the process was not an unnecessary market withdrawal of a product that really did not require a recall.

7. Stock Recoveries and Market Withdrawals

Not all product pullbacks are recalls. If a product has not been "marketed" or "has not left the direct control of the firm," a product pullback can be deemed a "stock recovery" (no matter how serious the product defect), and not a "recall.[11] A "market withdrawal" is a removal or correction of a *distributed* product that involves a "minor violation that would not be subject to legal action by the Food and Drug Administration or which involves no violation..."[12]

8. Contingency Plan

It generally is prudent for a company to have a contingency plan in place for initiating and conducting a recall. Such a plan needs to be devised with the particular products, personnel, organization, and distribution practices of the company specifically in mind. At least, a company should designate certain personnel who can meet quickly and who have the authority to investigate the facts and to determine how to proceed when a report arises that indicates that a significantly violative product may have been distributed.

D. CIVIL SEIZURE ACTIONS

1. FDC Act

Section 304 of the Federal Food, Drug, and Cosmetic Act (FDC Act), "Seizure," provides for the seizure and condemnation of articles that are in violation of the Act's requirements, e.g., adulterated or misbranded foods, drugs, cosmetics, or devices.[13]

2. FDA Recommends Action to U.S. Attorney/DOJ

FDA does not have the authority to file a civil seizure action itself. Instead, FDA recommends to the appropriate United States attorney (part of the Department of Justice [(DOJ)] that a civil seizure action be initiated.[14] FDA and the U.S. attorney's office/DOJ usually work together cooperatively, but the U.S. attorney is ***not*** required to accept FDA's recommendations. Occasionally, a U.S. attorney's office can be persuaded that an action recommended by FDA is not appropriate and should be settled. On other occasions, a U.S. attorney's office may be busy with other matters of higher priority, in which case an FDA-recommended civil seizure action may remain pending for many months or even years.

3. Administrative Practice at FDA

1. Usually, an FDA district office will not have authority immediately to recommend a civil seizure action to the local U.S. attorney.

2. This so-called "streamlined" process of administrative review is intended to result in nationwide consistency of practice concerning cases that the agency recommends for judicial enforcement, and to be certain that individual cases have the necessary factual support and appear to meet the requirements of law before recommendation to a U.S. attorney. The process can take months, however, and

not infrequently it happens that target articles have been moved and are gone by the time a complaint for forfeiture is filed and a United States marshal arrives with a warrant for arrest of the property. (FDA sometimes persuades a company voluntarily to hold a product until a civil seizure action can be initiated. Also, the agency may request state officials to exercise their authority under state law to embargo an article, and thereby prevent its removal until FDA can complete the process of recommending a civil seizure action.)

4. Procedure in Court

To initiate a seizure, the United States attorney for the district where the article is located files with the local United States district court a complaint for forfeiture.[15] The court then authorizes a warrant for the arrest of the article, which is served on the article by a United States marshal.[16] Once arrested, the article cannot be moved without the permission of the court and posting of a court-approved bond. Anyone violating this prohibition is subject to criminal and/or civil sanctions.

The owner of the article that has been seized may then file a claim "within 10 days after process has been executed, or within such additional time as may be allowed by the court, and shall serve an answer within 20 days after the filing of the claim.[17] Thereafter, a trial on the merits will be held, with opportunity for pretrial discovery, motions for summary judgment, and other standard procedures applicable in civil proceedings. Section 304(b) of the FDC Act provides that "the procedure...shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury.[18]

5. **Default**

Most civil seizure actions that are filed at the request of FDA end in default decrees, i.e., no one comes forth to file a claim and defend the seized article, and the United States attorney eventually obtains an order from the court to have it destroyed.

6. Consent Decree Authorizing Article To Be Brought Into Compliance With Law

When a company does claim a seized article that it acknowledges to be in violation of law, it may enter into a consent decree in which it agrees to a judgment of condemnation, ruling that the article is in violation of law, but providing for release of the article, under bond, for the claimant to bring it into compliance with law (e.g., perhaps by relabeling) under the supervision of FDA. The expenses of such supervision are paid by the person obtaining release of the article under bond.[19] FDA has a standard form of consent decree which provides, among other things, for posting a ***bond*** of approximately twice the value of the article and which gives FDA personnel control over determination of whether a condemned article has successfully been brought into compliance. FDA attorneys generally argue that the terms of the decree are not negotiable, but occasionally a U.S. attorney can be persuaded to depart from the standard form.

5. INJUNCTIONS

Section 302 of the FDC Act, "Injunction Proceedings," provides that the United States district courts shall have jurisdiction to restrain violations of the FDC Act.[20] Injunctions are being recommended more frequently by FDA When granted, an injunction can have a devastating impact upon a company (for example, if it requires the company to cease operations).

The courts often have been generous in granting injunctions to the United States when evidence has been presented that a violation of the FDC Act has occurred, even in circumstances where there is no showing of irreparable injury or immediate threat of harm. "The Food, Drug, and Cosmetic Act...provides for injunctive relief. Its provisions were adopted by Congress in the public interest and it should be given a liberal interpretation. There is sufficient showing [to justify an injunction], where as here, the Government presents evidence of violations of the provisions of a statute enacted for the protection of the public. Nor is it necessary to demonstrate the precise way in which the violations of the law might result in injury to the public interest."[21]

However, a *preliminary* injunction may be denied by a court where (1) it is difficult for the court to determine, absent a hearing on the merits, whether a manufacturer is in compliance with the FDC Act, or (2) there is no showing of immediate danger or possibility of future violations.[22]

As in the case of civil seizure actions, FDA does not have the authority to initiate an injunction directly, but must recommend the action to the U.S. attorney/DOJ. Injunction actions, like civil seizure actions, are tried in the United States district courts pursuant to applicable provisions of the Federal Rules of Civil Procedure. In 1991, FDA, as part of the Commissioner's enforcement initiative, "streamlined' the process by which the agency seeks injunctive relief. FDA's new process makes it easier for the agency to get a decision from the district to the Office of General Counsel, allowing for quicker action against alleged violations.

1/ "Recalls (Including Product Corrections) -- Guidelines on Policy, Procedures, and Industry Responsibilities," 21 C.F.R. §§7.40-7.59. See also definitional regulations, 21 C.F.R. 7.1, 7.3.

2/ 21 C.F.R.11 §7.1. (Emphasis added.)

3/ 21 C.F.R. §7.40(a)

4/ 21 C.F.R. §7.3(j).

5/ See generally 21 C.F.R. §§7.41, 7.42, 7.46, 7.49.

6/ 21 C.F.R. §7.42(b)(3)

7/ 21 C.F.R. §7.46(a). (Emphasis added.)

8/ 21 C.F.R. §7.50.

9/ 21 C.F.R. §7.46.

10/ See generally 21 C.F.R. §§7.1(m), 7.41, 7.42, 7.46.

11/ 21 C.F.R. §7.3(k).

12/ 21 C.F.R. §7.3(j).

13/ 21 U.S.C. §334.

14/ 21 U.S.C. §§ 335, 336, 337.

15/ 21 U.S.C. §334.

16/ Rules C and E, Supplemental Rules for Certain Admiralty and Maritime Claims.

17/ Rule C, paragraph (6), Supplemental Rules for Certain Admiralty and Maritime Claims..

18/ 21 U.S.C. §334(b).

19/ 21 U.S.C. §334(d)(1).

20/ 21 U.S.C. §332.

21/ United States V. Nutrition Service. Inc., 227 F. Supp. 375 (W.D. Pa. 1964). Cf. United States v. Sars of Louisiana, 324 F. Supp. 307, 310 (E.D. La. 1971) (injunction denied; by time case came to trial, defendants were found to have complied with all

recommendations of FDA inspectors, and the court also found that is was "not... reasonable to expect that the defendants will commit violative acts in the future"); United States v. W.F. Morgan & Sons, 155 F. Supp. 40 (E.D. Va. 1957) (injunction denied because of disputed evidence of past violations and an inadequate showing of the probability of future violations).

22/ United States v. Chattanooga Bakery. Inc., 19381964 FDLI Jud. Rec. 975 (E.D. Tenn. 1949); United States v. Cargill, Inc., 1938-1964 FDLI Jud. Rec. 2081 (N.D.N.Y. 1963); United States v. Cowley Pharmaceutical. Inc., 1938-1964 FDLI Jud. Rec. 473 (D. Mass. 1948)

22. VIRGINIA MARINE RESOURCES COMMISSION RULES AND REGULATIONS

§ 28.2-228. License for purchase of fish, shellfish, or marine organisms from the catcher; fee.

A. Any person, purchasing from the catcher, oysters or clams caught from the public grounds of the Commonwealth or the Potomac River, or crabs, fish, or other seafood caught from the waters of the Commonwealth or the Potomac River, shall pay a license fee of (i) fifty dollars for each place of business and (ii) twenty-five dollars for each boat or motor vehicle used for buying.

B. No license shall be required for any person purchasing seafood for personal consumption, any place of business which is solely a restaurant, or any person who operates a business which is subject to local license taxes under § 58.1-8708 and who has in his possession no more than one bushel of peeler crabs to be sold as bait. (1970, c. 726, § 28.1-119.1; 1979, c. 274; 1980, c. 218; 1984, c. 816; 1988, c. 27; 1992, c. 836.)

§ 28.2-24 1. Registration of commercial fishermen required; penalty.

A. On and after January 1, 1993, holders of gear licenses, except those issued pursuant to § 28.2-402, issued January 1, 1992, through December 31, 1992, shall register as commercial fishermen as provided for in regulation.

B. Fishermen who do not hold gear licenses issued betwen January 1, 1992, and December 31, 1992, shall apply to the Commission for registration as commercial fishermen on or before December 31, 1992, as provided in regulation.

C. On and after January 1, 1993, fishermen not registered as commercial fishermen but who desire to sell their catch shall apply to the Commission for registration as commercial fishermen. The effective date of status as a commercial fisherman shall be two years from the date the application is approved by the Commission. A person whose registration as a commercial fisherman is not effective shall not sell, trade or barter his catch or give his catch to another in order that it may be sold, traded or bartered.

D. For purposes of this section and §§ 28.2-242, 28.2-243 and 28.2-244, "commercial fisherman" means any person who fishes in tidal waters using any gear and who sells, trades or barters his catch or gives his catch to another in order that it may be sold, traded or bartered.

E. The cost of registration as a commercial fisherman shall be $150 annually, due no later than the effective date of registration. All fees collected from the registration of commercial fishermen shall be deposited in the state treasury and credited to the Marine Fishing Improvement Fund as established in § 28.2-208.

F. Registrations of commercial fishermen shall not be transferable.

G. Whenever a court finds that a defendant has violated any of the provisions of this section, the court shall assess a civil penalty of $500. All civil penalties assessed pursuant to this section shall be paid into the Marine Fishing Improvement Fund as established in § 28.2-208.

H. Only commercial fishermen with valid registrations may purchase licenses pursuant to § § 28.2-301, 28.2-501 and 28.2-702. (1992, cc. 493, 503)

§ 28.2-244. Purchase of shellfish or finfish; penalty.

A person shall not purchase shellfish or finfish from any fisherman who is known by such person to have not registered as a commercial fisherman as required by § 28.2-241. Whenever a court finds that a defendant has violated the provisions of this section, the court shall assess a civil penalty of $500. All civil penalties assessed pursuant to this section shall be paid into the Marine Fishing Improvement Fund as established in § 28.2-208. (1992, cc. 493, 503.)

§ 28.2-702. (Effective January 1, 1994) Licenses to take crabs; shedding operations; amount of fee.

Any person desiring to take or catch crabs for market or profit from the waters of this Commonwealth, or waters under its jurisdiction, or any person desiring to engage in the business of buying or marketing crabs for packing or canning crabs, shall pay to any officer the following fees:

1. For each person taking or catching crabs by dip nets, $8;
2. For ordinary trotlines, $8;
3. For patent trotlines, $31;
4. For up to 100 crab pots, $29;
5. For over 100 but not more than 300 crab pots, $48;
6. For over 300 but not more than 500 crab pots, $100;
7. For over 500 crab pots, $250;
8. For each boat used for taking or catching hard crabs with dredges, $58;
9. For each crab trap or crab pound, $5;
10. For each single-rigged crab-scrape boat, $16;
11. For each double-rigged crab-scrape boat, $32;
12. For up to 20 tanks and floats for shedding crabs, $15; and
14. For taking or catching peeler crabs using peeler pots, $29. (Code 1950, § 28-170; 1954, c. 368; 1956, c. 293; 1960, c. 517; 1962, c. 406, 28-l-165; 1964, c. 393; 1966, c. 684; 1968, c. 785; 1970, c. 726; 1979, c. 274; 1983, cc. 307, 603; 1985, c. 180; 1990,

c. 154; 1992, c. 886; 1993, c. 11.)

§ 28.2-708. Limitations on sizes of crabs to be taken; inspection of catch; exemption; penalty.

A. It is unlawful for any person to catch, take or have in his possession more than ten hard crabs per United States standard bushel or thirty-five hard crabs per barrel, which measure less than 5 inches across the shell from tip to tip of the longest spikes, or to destroy them in any manner. Those undersized crabs in excess of the allowance level shall be immediately returned to the water alive. Adult female crabs, peeler crabs and soft crabs are exempt from these limitations.

B. Any officer may grade or cull any number of barrels, baskets or containers of crabs in any person's possession.

If the officer finds more than ten undersize hard crabs per United States standard bushel or thirty-five per barrel, he shall seize the entire quantity of crabs in or from each such container, and the person who possessed the crabs shall immediately return them to the water. Refusal to return the crabs to the water is a separate offense from any other violation.

Crabs which have been purchased by and are in the possession of a buyer and crabs which have been transported at least five miles from the nearest salt water are exempt from this requirement.

D. The Commission may change such size restrictions for a period not to exceed sixty days to respond to significant ecological changes.

E. A violation of this section is a Class 3 misdemeanor. (Code 1950, § 28-172; 1960, c. 517; 1962, c. 406, § 28.1-167; 1966, c. 684; 1970, cc. 610, 726; 1977, c. 35; 1978, c. 369; 1981, c. 52; 1985, c. 166; 1992, c. 836.)

§ 28.2-226. (Effective January 1, 1994) Exemptions from licensing requirements.

A. The following activities are exempt from the licensing requirements of this subtitle:

1. Taking by dip net, hand line, or two crab pots, as much as one bushel of hard crabs and two dozen peeler crabs in any one day for personal use only.

2. Taking a maximum of one bushel of oysters in any one day for personal use, when taken by hand or with ordinary tongs.

3. Taking a maximum of 250 clams in any one day for personal use, when taken by hand or with ordinary tongs.

4. Using one tank or float no greater than four feet in width and eight feet in

length for shedding crabs for personal use.

B. No license shall be required of an oyster grounds leaseholder, or other person authorized or employed by a leaseholder, to harvest oysters or clams from the leasehold. However, this exemption shall not apply to other requirements to obtain permits, including those permits for dredging or scraping on leaseholds provided in §28.2-516, or for removal and transportation of shellfish from condemned areas as required by §§28.2-810 and 28.2-811. (Code 1950, §§ 28-80,28-137,28-170,28-177; 1954, c. 368; 1956, c. 293; 1960, c. 517; 1962, c. 406, §§ 28.1-78, 28.1-120, 28.1--165, 28.1-174; 1964, c. 393; 1966, c. 684; 1968, c. 785; 1970, c. 726; 1979, c. 274; 1983, cc. 307, 603; 1985, c. 180; 1988, c. 75; 1990, c. 154; 1991, c. 285; 1992, c. 836; 1993, c. 11.)

§ 28.2-226.2. Commission to establish requirements for commercial gear licenses used for recreational purposes.

PREAMBLE

This regulation establishes licenses for the recreational and personal use of certain fishing and crabbing gear. It limits the amount of gear and the catch, and establishes gear identification requirements and harvest reporting requirements for the licensees.

§ 1. AUTHORITY, PRIOR REGULATION, EFFECTIVE DATE:

A. This regulation is promulgated pursuant to the authority contained in Sections 28.2-226.1 and 28.2-226.2 of the Code of Virginia.

B. This regulation replaces Emergency Regulation 450-01-0090 which was promulgated and made effective on April 12, 1993.

C. The effective date of this Regulation is June 1, 1993.

§ 2. PURPOSE:

The purpose of this regulation is to establish licenses for the recreational and personal use of certain fishing and crabbing gear. Limits are established on the amount of gear which may be used and the amount of catch which may be taken. Gear identification requirements and harvest reporting requirements are established to reduce the possibilities of gear conflicts and to assess the levels of harvest made by recreational users of commercial gear.

§ 3. RECREATIONAL GEAR LICENSES:

A. Any person desiring to take or catch finfish or shellfish for recreational purposes in the tidal waters of Virginia using commercial gear authorized under Section 28.2-226.1 of the Code of Virginia shall first pay the specified fee and obtain the license for the appropriate gear, as follows:

1. Recreational Gill Net, $7.50;
2. Recreational Fish Cast Net, $8.00;
3. Recreational Fish Dip Net, $6.00;
4. Recreational Crab Pot, $29.00;
5. Recreational Crab Trap, $5.00;
6. Recreational Ordinary Crab Trot Line, $8.00.

B. Any license to use fishing gear for recreational purposes shall be issued to an individual for his exclusive use and shall not be transferable.

C. No person shall be issued more than one recreational gill net license, more than one recreational crab pot license, nor more than one crab trap license.

D. No license shall be required of any person taking minnows, menhaden, or mullet with a cast net for personal use as bait which is not to be sold, traded, or bartered.

§ 4. GEAR RESTRICTIONS:

A. It shall be unlawful for any person to use any gill net greater than 300 feet in length when licensed for recreational purposes under this regulation. Any person licensed to use a recreational gill net shall stay within 100 yards of such net when it is overboard. Failure to attend such net in this fashion is a violation of this regulation.

B. It shall be unlawful for any person to use more than 5 crab pots when licenses for recreational purposes under this regulation.

C. Any law or regulation applying to the setting or fishing of commercial gill nets, cast nets, dip nets, crab pots, crab traps or crab trot lines shall also apply to these gear when set or fished for recreational purposes.

D. It shall be unlawful for any person to use any recreational gill net, fish cast net, or fish dip net to catch and possess any species of fish whose commercial fishry is regulated by an annual harvest quota.

E. It shall be unlawful for any person using a recreational gill net, fish cast net, or fish dip net to take and possess more than the recreational bag limit for any species regulated by such a limit. When fishing from any boat, using gear

§ 28.2-227. Special nonresident harvester's license; fee and oath; revocation penalty.

PREAMBLE

This regulation establishes a nonresident harvesters license fee for any nonresident desiring to take or catch marine fish, crabs, or any other seafood, except oysters, clams, or other mollusks, from the tidal waters of the Commonwealth, for which a license is required:

§ 1. AUTHORITY, EFFECTIVE DATE:

A. This regulation is promulgated pursuant to the authority contained in Section 28.2-227, Code of Virginia.

B. The effective date of this regulation is January 1, 1994.

§ 2. PURPOSE:

The purpose of this regulation is to establish the fee for the Nonresident Harvesters License.

§ 3. FEE ESTABLISHED:

The fee for the Nonresident Harvesters License shall be $350.00.

§ 4. EXCEPTIONS:

The Nonresident Harvesters License shah not be required for persons licensed to fish with saltwater recreational licenses required under Sections 28.2-302.1 - 28.2-302.9, Code of Virginia.

§ 5. PENALTY:

Penalties for violations of this regulation are prescribed in Sections 28.2-225 and 28.2-227E of the Code of Virginia.

§28.2-241 Registration of commercial fishermen required; exemption; penalty.

A. On and after January 1, 1993, holders of gear licenses, except those issued pursuant to § 28.2-402, issued January 1, 1992, through December 31, 1992, shall register as commercial fishermen as provided for in regulation.

B. Fishermen who do not hold gear licenses issued between January 1, 1992, and December 31, 1992, shall apply to the Commission for registration as commercial fishermen on or before December 31, 1992, as provided in regulation.

C. On and after January 1, 1993, fishermen not registered as commercial fishermen but who desire to sell their catch shall apply to the Commission for registration as commercial fishermen. The effective date of status as a commercial fisherman shall be two years from the date of the application is approved by the Commission. A person whose registration as a commercial fisherman is not effective shall not sell, trade or barter his catch or give his catch to another in order that it may be sold, traded or bartered.

D. For purposes of this section and § § 28.2-242, 28.2-243 and 28.2-244, "commercial fisherman" means any person who fishes in tidal waters using any gear and who sells, trades or barters his catch or gives his catch to another in order that it may be sold, traded or bartered.

E. The cost of registration as a commercial fisherman shall be $150 annually, due no later than the effective date of registration. All fees collected from the registration of commercial fishermen shall be deposited in the state treasury and credited to the Marine Fishing Improvement Fund as established in § 28.2-208.

F. Registrations of commercial fishermen shall not be transferable.

G. Whenever a court finds that a defendant has violated any of the provisions of this section, the court shall assess a civil penalty of $500. All civil penalties assessed pursuant to this section shall be paid into the Marine Fishing Improvement Fund as established in § 28.2-208.

H. Only commercial fishermen with valid registrations may purchase licenses pursuant to § § 28.2-301, 28.2-501 and 28.2-702.

I. Persons who have obtained a recreational gear license pursuant to § 28.2-226.1 or § 28.2-302.1 are exempt from the provisions of this section. (1992, cc. 493, 503; 1993, c. 219.)

§ 28.2-2442. Report of harvest required.

All harvests shall be reported by either commercial fishermen, licensed buyers, or self marketers in the manner and form prescribed by the Commission. (1992, cc. 493, 503; 1993, c. 287.)

Appendix I

A. HACCP PLAN OVERVIEW

1.1 What Does HACCP Do?

1.2 HACCP

B. HOW TO DEVELOP A HACCP PLAN

1 INTRODUCTION

2 DEVELOPMENT OF A HACCP PLAN

2.1 STEP 1 - Prepare Process Flow Charts

2.1.1 Develop the Flow Charts

2.1.2 Assess Potential Hazards at Each Step

2.2 STEP 2 - Identify Critical Control Points

2.3 STEP 3 - Set Critical Limits That Must Be Met At Each CCP

2.4 STEP 4 - Define Monitoring Procedures

2.5 STEP 5 - Define Corrective Actions

2.6 STEP 6 - Devise a Record Keeping System

2.7 STEP 7 - Establish Verification Procedures

3 REGISTRATION AND CERTIFICATION OF PLANTS

4 PRODUCT RECALL SYSTEM

HACCP PLAN OVERVIEW

The principles of HACCP as generally recognized for seafood processing operations by the National Fisheries Institute, the National Marine Fisheries Service and the U.S. Food and Drug Administration are contained in the Seafood Industry Hazard Analysis Critical Control Point (HACCP) Training Manual (NFI, 1991). Although not officially adopted to date, this manual provides a valuable discussion of the concepts and implementation of HACCP. The excerpts which follow are provided as an aid to managers and employees who are contemplating the development of HACCP programs. Contact NFI, Sea Grant institutions, or an appropriate regulatory agency regarding more complete training programs and materials.

1.1 What Does HACCP Do?

HACCP provides a more focused approach to the control of hazards in food than is achievable by traditional inspection and quality control programs. It does **not** require continuous inspection. Rather, HACCP is a combination of industry self-inspection and government monitoring. HACCP can be boiled down to the following: the program is based on the identification and control of potential hazards versus the end use of the product. The ability to identify and to control potential hazards is absolutely fundamental to the successful implementation of HACCP. Once the potential hazards are identified, HACCP allows you to focus efforts to control the hazards at specific *critical* points in the process. Furthermore, since the hazards are identified with regard to the end use of the product, more control and monitoring will be necessary for products such as cooked crabmeat, which do not require additional cooking, than for fresh fish which in all probability will be cooked.

Simply then, what do you do under HACCP as a seafood processor? You study and critique your plant procedures from the receipt of raw materials through shipment of the final product. You determine which processing steps are critical elements in controlling hazards and you assess overall sanitation. Then you write your own HACCP plan identifying the steps to be monitored and the records to be kept that will indicate compliance with your plan. This is not as difficult as it may sound; there are documents and aids already developed that will assist you. The remainder of this chapter, as well as the other chapters in this training manual, are designed to assist you in identifying the potential hazards in your specific processing plant and to assist in developing effective control and monitoring procedures.

1.2 HACCP

The HACCP procedure was developed by the National Advisory Committee for Microbiological Criteria for Foods, an independent panel of food safety experts convened by the National Academy of Sciences (NAS) at the request of federal food inspection agencies. To understand and implement an effective HACCP program, you as a seafood processor must follow the steps in Table 1.

	Table 1. Implementation of a HACCP Program
Step	Process
1.	Prepare a process flow chart. Assess the hazards associated with each operational step: growing, harvesting, using raw materials and ingredients, processing, manufacturing, distribution, marketing, preparation, and consumption of the food.
2.	Identify the critical control points (CCPs) where the identified hazards can be controlled.
3.	Set the critical limits that must be met at each CCP.
4.	Define monitoring procedures to ensure critical limits are met.
5.	Define corrective actions to be taken when the monitoring procedures identify a deviation.
6	Devise record-keeping systems that document the effectiveness of the HACCP plan.
7	Establish verification procedures to ensure that the HACCP system is working correctly. Verification measures may include biological, physical, chemical, and sensory methods. Where they are needed, establish limiting criteria.

Initially, the process may seem unnecessary and perhaps difficult, but it is absolutely essential. The reason for this perceived difficulty is that you will be asked to evaluate closely your production processes. You are familiar with these processes. Consequently, it can be difficult to step back and view them with a critical eye. It may be helpful to imagine yourself as an outsider viewing the process for the first time and asking questions, especially **"why'** and **"what if'** questions.

HOW TO DEVELOP A HACCP PLAN

1. INTRODUCTION

In this section, we are going to describe how you, as a member of the seafood industry, can develop your own HACCP plan. This plan will not only be appropriate for your own seafood processing operation, but it will also meet the requirements of the federal agency that will eventually be responsible for administering a seafood inspection program based on the HACCP system. You will see that the procedures for developing a HACCP plan are quite straight-forward, involving only seven basic steps, all of which can be accomplished by you and your staff. Before we get to these seven steps, however, let's first define some terms so that you have a clear understanding of what we are talking about.

As you know, "HACCP" stands for "Hazard Analysis Critical Control Point." What does this really mean?

Hazard

First, the term "hazard" as used here simply means a chance for, or the risk of, an unacceptable biological, chemical, physical, or economic property in a food product that could cause consumer distress or illness.

Hazard Analysis

Next, the term "hazard analysis" means the process of identifying biological, chemical, physical, or economic-fraud risks relative to a food product or manufacturing process which takes into consideration the intended end use of the food product. They key word here is end-use; it means that the conditions or situations that should be considered hazardous are those that present a risk only with respect to the ultimate use of the product. For example, the presence of certain pathogens in raw materials would not necessarily be considered hazardous if the pathogens are destroyed during processing. Such is the case with fully cooked products and those intended to be fully cooked by the consumer before being eaten. On the other hand, the presence of glass in a product would obviously be considered a hazard whether it was eventually cooked or not.

Critical Control Points

A "critical control point" is an area or item of equipment in the processing facility where specific operational steps in a manufacturing process take place, and where the loss of control of such steps would automatically result in an unacceptable safety, hygiene, or economic-fraud risk.

Food Safety

"Food safety" risks are those that could cause harm to a consumer's health or physical well-being. Safety issues are usually addressed through biological, chemical, or physical criteria, and are distinct from issues relating to food hygiene or economic fraud.

Food Hygiene

"Food hygiene" refers to those characteristics of a product or process relating to wholesomeness or facility sanitation.

Economic Fraud

"Economic fraud" refers to those illegal or misleading actions which defraud purchasers. Such actions include, among other things, species substitution, short weight, overglazing, and short fill. Also included is the excessive use of so-called approved chemicals in processing, such as the overuse of sulfites to slow down decomposition, as well as the misuse of chemicals, such as sodium tripolyphosphate, originally intended to minimize drip loss, for the express purpose of adding weight to the final product.

HACCP System

A "Hazard Analysis Critical Control Point" system is a non-traditional inspectional approach to controlling hazards in foods. It is a two-part process done on a commodity-by-commodity basis. The first part deals with defining the consumer hazards within a specific food commodity relative to the intended use of the product. The second part deals with: 1) flow charting each operational step of a food-manufacturing process and defining the hazards associated with each step; 2) assessing the relative importance of the hazards and identifying the critical control points of the manufacturing process; 3) determining the appropriate preventive measures to be employed; 4) determining the monitoring procedures, either by observation or by measurement, that are needed to ensure that hazards are being controlled; 5) establishing the critical limits that must be met at each Critical Control Point and the corrective actions to be taken to return deviations to acceptable limits; 6) developing the records necessary for monitoring that will ensure hazards are being controlled; and 7) establishing verification procedures to assure an effective HACCP plan.

The HACCP Plan

A "HACCP Plan" is a planning document and its related records which, under a HACCP-based inspection system, would be required to be on file at each processing facility. The planning document and related records are established by the facility in conjunction with the regulatory agency prior to the facility's admission to a HACCP seafood surveillance program. Such a plan includes: 1) documentation of critical control points, 2) action taken when critical deviations occur, 3) disposition of product subjected to "critical" deviations, 4) clear designation of the records to be made available for government inspections, and 5) provisions for record maintenance.

And now we are down to the original purpose at hand...the development of your HACCP plan so that you can operate successfully under the HACCP system described above.

2. DEVELOPMENT OF A HACCP PLAN

Although a fully-developed plan would likely include much general information that you already possess, such as organizational charts and responsibilities, company directives concerning product manufacture, process specifications, etc., the components that are essential to a HACCP plan can be developed by you and your staff by following the seven basic steps below:

1 - Prepare process flow charts and assess potential hazards
2 - Identify critical control points
3 - Set critical limits that must be met at each CCP
4 - Define monitoring procedures
5 - Define corrective actions
6 - Devise record keeping systems
7 - Establish verification procedures

2.1 STEP 1 - Prepare Process Flow Charts and Assess Potential Hazards

The first step in starting a HACCP program is to prepare a detailed process flow chart for your major processing operation (or charts for each distinct processing operation) from which you will analyze your operations.

2.1.1 Development of the Flow Chart

The chart should list the sequence of specific operational steps (control points) in the manufacturing process of your food product where microbiological, chemical, physical, and/or economic factors can be controlled (see sample on the following page). In addition to developing such flow charts, standard operating procedures (SOPs) should be written and followed by your firm. The SOPS relate to the operations that must be accomplished at each process step in terms of both the product processing methods and sanitation controls.

Each chart should begin with the “receiving” of fresh and/or frozen raw materials and end with the “shipping” of your product to the wholesale or retail trade.

Chapter 4 contains a general process flow chart for raw processed crab meat. It identifies specific processing steps or control points where hazards can be monitored and controlled. Of these control points, various steps are identified as “critical control points.” How to determine such critical control points is discussed in "Step 2" of this section.

2.1.2 Assess Potential Hazards At Each Step

Following development of your process flow chart(s), you are ready to begin the identification and assessment of hazards that could occur at each processing step (control point). Using your process flow chart as a guide, at each step in the processing operation, ask yourself the following question:

. What can go wrong at this step in terms of product safety, wholesomeness, and economic fraud?

The following are examples of hazards that could arise at individual processing steps for various seafood products. You may determine that one or more of these hazards could occur at any single step in the processing of your product.

Microbiological/Chemical	Physical	Economic
• Fuel oil	• Filth	• Excess moisture
• Pathogens	• Insect/rodent contamination	• Excess glaze
• Cross-contamination	• Metal fragments	• Short weights
• Contaminated dip	• Shell fragments	• Mislabeling
• Contaminated ice	• Other foreign materials	• Misgrading
• Decomposition	• Parasites	• Masking country of origin
• Time/temperature abuse	• Freezer burn	• Incorrect product in package
• Chemical contamination	• Dehydration	• Wrong proportions of additives, ingredients
• Additive abuse	• Damaged packaging	
	• Damaged product	
	• Improper sealing of package	

2.2 STEP 2 - Identify Critical Control Points

You must now determine the relative importance of the hazards involved in the processing of each of your products. It is here that the “Critical Control Point Analysis” phase of the HACCP system takes place. Evaluate each hazard in each processing step by answering the question: “Does the critical control of this hazard occur here or at another step?” That is, if there should be a failure to control this hazard at this specific step in the manufacturing operation, would it automatically result in an unacceptable safety, hygienic, or economic risk

in terms of the end use of the product? For all steps where the answer to this question is "yes," such steps should be considered "critical control points."

A simple method of deciding whether a control point is critical is to follow the Critical Control Point Decision Tree contained in Figure 1, Chapter 4.

2.3 STEP 3 - Set Critical Limits That Must be Met At Each CCP

The third step in setting up your HACCP plan is to establish the limits which must be met at each "critical control point." A critical limit is defined as one or more prescribed tolerances that must be met to ensure that the plan effectively controls a hazard or risk. There may be more than one limit for a critical control point. If any one of those limits is out of tolerance, the process will be out of control, and a potential hazard or risk can exist.

Examples of criteria frequently used for limits are temperature, time, moisture level, amounts of preservatives, additives and ingredients, net weight, and fill of container. Many types of limit information may be needed for control of a critical control point.

2.4 STEP 4 - Define Monitoring Procedures

Your next step is to determine the appropriate "monitoring procedures" to be used with the various preventive measures. Such procedures should be primarily observations or physical measurements that can be readily carried out in terms of realistic time delays and costs. Examples of such monitoring procedures include the following:

- Sampling and inspection of fresh and frozen raw materials
- Checks and documentation of temperatures of raw materials
- Checks and documentation of temperatures of product
- Checks and documentation of temperatures of coolers/freezers
- Checks of temperature and humidity in dry storage rooms
- Checks of inventory control
- Checks of amounts of additives used for each batch/lot
- Monitoring adequacy and potability of water supply
- Product sampling for bacterial analysis
- Periodic checks of net weights
- Checks of labels used
- Checks of production schedules
- Periodic checks of process control specification
- Visual inspections of product and equipment
- Checks of equipment maintenance
- Supervisory check points throughout the processing operation

2.5 STEP 5 - Define Corrective Actions and Preventive Measures to Control Hazards

The fifth step in setting up your HACCP plan is to determine, for each processing step, the appropriate corrective actions to be taken when prescribed limits are exceeded, and the preventive measures to control the potential hazards you identified earlier.

Listed below are examples of some common corrective actions and preventive measures that all seafood processors might consider in developing a plan:

- Rejecting unsatisfactory raw and finished product
- Physically separating of raw and finished product in storage
- Using approved, potable water supply
- Ensuring proper time/temperature control
- Using only approved chemicals
- Using adequate screens to keep out insects/pests
- Ensuring proper removal of extraneous materials
- Ensuring proper maintenance and sanitation of equipment
- Ensuring proper calibration if scales
- Using visual and organoleptic inspection of product
- Ensuring proper packaging/labeling of product
- Ensuring proper rotation of product in storage (FIFO)
- Using standard operating procedures for plant
- Using training programs for employees
- Ensuring good personal hygiene of employees
- Employing good housekeeping practices
- Using trucks capable of maintaining proper temperatures
- Ensuring proper loading of trucks
- Developing a product recall system
- Requiring individual accountability from supervisors

2.6 STEP 6 - Devise a Record Keeping System

In addition to the "monitoring procedures" and "corrective actions" that you have already identified for each processing step, the HACCP system requires that your plan include one additional safeguard, particularly for those processing steps you determined to be "critical control points." That safeguard is the inclusion of a suitable record-keeping system in your HACCP plan.

The key to a successful application of the HACCP inspection system is the ability of plant management, quality control personnel, and regulatory authorities to perform routine and meaningful examinations of the process controls used, the level of plant sanitation, and the product itself throughout the entire processing operation. Most of these examinations are, in turn, dependent on the examination of the records maintained by your plant in these areas. Such records provide several vital functions: 1) they document that the critical limits set for a critical control point have been met by recording the results of monitoring activities; 2) if critical limits were exceeded, they document what control action was taken and the disposition of the product; and 3) they offer product traceability from start to finish.

It is recognized that a plant, in the course of doing business, must keep records of many types and kinds of information. However, HACCP regulatory authorities will need only those records that verify monitoring results, pinpoint problems, and provide product traceability. They will have no need for any information that is legitimately of a proprietary nature!

Records can be of different types. In most cases, they need not be complex. In fact, the simpler the better, as long as they provide the necessary information. Examples of some of the primary records of these types are:

- Invoices of receipt of raw products
- Raw product origin certification records (Molluscan ISSC)
- Incoming product inspection reports
- Product purchasing and processing specifications
- Quality control and assurance reports
- Scale calibration records
- Additives use logs
- Time/temperature records
- Unit and package weight records
- Shipping records, etc.
- Logs of NUOCAs (Notices of Unusual Occurrences and Corrective Actions taken)

The NUOCAs come into existence only when deficiencies are found during the established monitoring process. They provide valuable supplementary information to your other routinely-used processing records, particularly those required for critical control points. They serve to record what you found to be wrong, unusual, or unacceptable from a potential safety, quality, or economic hazard standpoint during the course of a particular processing step...and what action(s) you or your plant personnel took to correct it. NUOCAs may be separate forms of your own design which record such basic information as:

- Date and time of occurrence
- Processing step involved
- Problem identified
- Corrective action taken
- Other comments

Or, NUOCAs may simply be your inclusion of the above information onto another type of record you may be using, such as one of those indicated above. For example, the receipt of a decomposed product by the Receiving Department and its consequent return to the shipper could be noted on your copy of the receiving invoice. That invoice would now serve as your NUOCA.

2.7 STEP7 - Establish Verification Procedures

The seventh and final step is to establish adequate verification procedures to assure that your HACCP plan is in fact being complied with and that it is effective. Both the producer and the regulatory agency have a role in verifying HACCP plan compliance. Verification confirms that all hazards were identified in the HACCP plan when it was developed. Verification activities include: establishment of appropriate verification inspection schedules; review of the HACCP plan; review of records kept for critical control points; review of process deviations and product dispositions; visual inspections of operations to observe if critical control points are under control; random sampling and analysis of products; and a written record of verification inspections which certifies compliance with the HACCP plan or deviations from the plan and the corrective actions taken.

There, we have the seven steps for the development of a HACCP plan. As we said, these steps are straightforward, rational, and reasonably easy to accomplish. There are, however, two other important aspects of a mandatory HACCP system that need to be addressed in your plan. They are: Registration and Certification of Plants and a Product Recall System.

3. REGISTRATION AND CERTIFICATION OF PLANTS

A mandatory seafood surveillance program will likely require all plants processing finished products for export or domestic trade be registered (for identification purposes only) and then certified in terms of plant process and sanitation controls. Sanitation (plant hygiene) will likely be assessed through use of an appropriate Plant Sanitation Compliance Checklist. The example on the following pages was developed for the manufacturers of raw fish products.

Such plant sanitation compliance checklists are comprehensive forms intended for intermittent use in determining the general sanitation compliance of a plant. They are not intended for use on a daily basis and, in fact, cannot be used to determine if a plant will product a safe and wholesome product during any day's run. Note that the sanitation compliance checklist incorporates minor, major, serious, and critical deficiency scores, defined as follows:

Minor defect
One not in accordance with the requirements, but is not major, serious, or critical in terms of deterioration of product quality.

Major defect
One which inhibits general sanitation; the deterioration of product quality, however, is not serious or critical.

Serious defect
One which prevents proper plant sanitation; may result in tainted, decomposed or unwholesome product, but is not considered critical.

Critical defect
One which results in unwholesome product; presents health and safety threats; is not in accordance with Good Manufacturing Practices (GMP).

You should determine the maximum number of minor, major, or serious items acceptable for your plant at any one time. However, at no time should your plant operate with a critical deficiency.

Table 2. Sample Plant Sanitation Compliance Check List

For Seafood Processing Plants

Premises	Minor	Major	Ser	Crit*	Check If OK
1. Litter, waste, or improperly stored equipment	X				
2. Excessively dusty roads, parking lots.	X				
3. Inadequate drainage	X				
4. Controls not in place to discourage pests such as flies and rodents		X			
BUILDING CONSTRUCTION 5. Design, materials or construction inhibits sanitation		X			
6. Ceilings over exposed product not free of peeling paint			X		
7. Exterior openings, where practical, not equipped with screens, etc., to prevent entrance of pests, etc.		X			
8. Air curtains, strip doors, and screen doors, if installed, must be effective		X			

Premises	Minor	Major	Ser	Crit*	Check if OK
9. Processing area opens directly (without barriers) into living quarters, garage, or heavy maintenance shop		X			
LIGHTING 10. Lighting is inadequate	X				
11. Lights in product, packaging, or ingredient storage areas not safety type and unshielded			X		
VENTILATION 12. Accumulation of condensates over exposed product, packaging material or ingredients.	0	X			
13. Mold is present in processing or storage area	X				
WATER SUPPLY 14. a. Inadequate supply of cold or hot water b. Water not accessible		X X			
15. Water subject to contamination, e.g., siphoning, cross-connection.				X	
16. Fresh water not potable				X	
17. Water not approved by appropriate authorities for food processing				X	
18. Seawater not treated as specified in HACCP plan				X	
19. Seawater not approved by appropriate authorities for food processing			X		

Premises	Minor	Major	Ser	Crit*	Check if OK
ICE 20. Not made from potable water or appropriately treated seawater				X	
21. Not made from an approved water supply				X	
22. Not manufactured, handled or used in a sanitary manner			X		
23. Transferred and re-used on other raw products	X				
DISPOSAL OF WASTES 24. Liquid waste not disposed of in a sanitary and timely manner		X			
25. Dry waste not collected in suitable containers conveniently located throughout the plant or disposed of in a sanitary and timely manner	X				
26. Product waste not collected or disposed of in a sanitary manner		X			
27. Absence of functional washing facilities, tissue, soap, hot water, hand drying facilities, or signs directing employees to wash hands.			X		
28. Insufficient number of toilets as defined by USDA requirements	X				

Premises	Minor	Major	Ser	Crit*	Check if OK
CONSTRUCTION AND REPAIR OF EQUIPMENT, CONTAINERS AND UTENSILS 29. Product contact surfaces of all equipment, containers, and utensils not constructed from suitable, impervious, non-toxic corrosion-resistant material, with the exclusion of the re-use of wooden boxes holding round or gutted fish until appropriate research is concluded			X		
30. Design, construction, or location of equipment, containers, and utensils is such that it demonstrably contributes to contamination and cannot be cleaned nor effectively sanitized, with the exclusion of the re-use of wooden boxes holding round or gutted fish until appropriate research is concluded				X	
3 1. Equipment, containers, or utensils not in good repair	X				
32. No demonstrated monitoring program to remove used or abused containers, utensils, and equipment	X				

Premises	Minor	Major	Ser	Crit*	Check if OK
CLEANING AND SANITIZING 33. Equipment, utensils and containers not cleaned and sanitized before use			X		
34. Cleaning methods do not preclude product contamination			X		
35. Rooms and areas used for receiving, processing, and storing raw materials and finished product not maintained in a clean and sanitary manner		X			
36. Absence of effective in-plant sanitation program			X		
37. Sanitation control of finished product not sufficient to protect the product from contamination			X		
38. Absence of accessible washing and/or hand-dipping stations		X			
INSECTS. BIRDS. ANIMALS 39. Birds and animals not excluded from the plant			X		
40. Insect & rodent control measures not effective			X		
CHEMICALS 41. Insecticides or rodenticides not used as prescribed by EPA or USDA		X			

Premises	Minor	Major	Ser	Crit*	Check if OK
42. Chemicals not employed by approved methods or handled and stored in an unsafe manner		X			
43. Chemicals, toxins, sanitizer, food additives not properly labeled or stored		X			
44. Unapproved chemicals and sanitizer used			X		
FROZEN. REFRIGERATED, DRY STORAGE FACILITIES 45. Shelves, cabinets, dunnage, and/or other methods not used where necessary to inhibit contamination	X				
46. Storing methods do not minimize deterioration	X				
47. Storage facilities not clean, not sanitary, or not in good repair: a. Product packaging and ingredient storage b. Other storage		X X			
48. Plant management does not have in effect measures to restrict people with known disease (i.e., cuts, boils, influenza, etc.) from contaminating the product		X			

Premises	Minor	Major	Ser	Crit*	Check if OK
49. Personnel Cleanliness - Personnel specified not maintaining a high degree of personal cleanliness and conforming to hygienic practices while on duty (e.g., lack of clean outer garments, hairnets, wearing jewelry (other than unadorned wedding bands); chewing gum, drinking coffee, using tobacco, eating at their work station; storage of personal belongings at work station)	X				
50. Personnel Practices - Personnel not taking necessary precautions to minimize contamination of foods with microorganisms or foreign substances (e.g., gloves not in sanitary and good condition; touching face, hair; picking product off the floor; not washing hands)		X			
51. Training of personnel in food hygiene is inadequate	X				
52. Appropriate supervisors (e.g., production, line, quality control, etc.) not held accountable for the cleanliness compliance of their employees		X			

4. PRODUCT RECALL SYSTEM

And finally, your HACCP plan will be required to include a suitable product recall system. Recall is an effective method of removing or correcting consumer products that are in violation of laws concerned with the safe manufacture of food products in the United States and with their distribution to either domestic or foreign markets. Recall is a voluntary action whereby manufacturers and distributors carry out their responsibility to protect the public from products that present a risk of injury or gross deception or are otherwise defective.

The current Food and Drug Administration's (FDA) enforcement policy on product recall is provided in Section 21 of the Code of Federal Regulations (CFR). It is likely that this policy would remain essentially unchanged under any future mandatory seafood surveillance program, regardless of the federal agency chosen to implement it.

In brief, a recall procedure starts with an evaluation by FDA scientists of the health hazard presented by a product being recalled or considered for recall. Next, a recall strategy is developed by FDA (and by the recalling firm for a firm-initiated recall) to suit the circumstances of the recall. A recall may be either an FDA-requested recall or a firm-initiated recall. In either case, it must address: 1) the level in the distribution chain to which the recall is to extend; 2) a public warning that the product being recalled presents a serious hazard to health; and 3) checks to verify that all appropriate consignees have received notification of the recall and have, in turn, taken appropriate action.

FDA suggests a firm take advance precautions against the disruptions of a recall. They are: 1) prepare and maintain a current written contingency plan for initiating a recall in accordance with the recommended CFR; 2) use sufficient coding of regulated products to make possible positive lot identification; and 3) maintain product distribution records to aid in locating the products that are being recalled.

FIGURE 1. CRITICAL CONTROL POINT DECISION TREE