UNITED STATES MARINE CORPS
MARINE CORPS FOOD SERVICE COURSES
MARINE CORPS DETACHMENT
FORT LEE, VIRGINIA 23801-1508

HAZARD ANALYSIS CRITICAL CRONTROL POINT STUDENT OUTLINE

What Will I Learn From This Class

1. **TERMINAL LEARNING OBJECTIVE.** In a Messhall / Food Service environment, state and identify the General Principles of Food Hygiene in accordance with Codex Alimentarius. (0002.01.06a)

2. **ENABLING LEARNING OBJECTIVES.**

a. In a Messhall / Food Service environment state and identify the objectives of Food Hygiene, in accordance with Codex Alimentarius. (0002.01.06a

b. In a Messhall / Food Service environment state and identify the roles of government, industry, and consumers, in accordance with Codex Alimentarius. (0002.01.06a)

c. In a Messhall / Food Service environment state, and identify the meaning of various definitions used in the presented material, in accordance with Codex Alimentarius. (0002.01.06a)

d. In a Messhall / Food Service environment state and identify the requirements in selecting the proper design, equipment layout, and structure used in a food service facility, in accordance with Codex Alimentarius. (0002.01.06a

e. In a Messhall / Food Service environment state and identify the proper storage and handling procedures for food, in accordance with Codex Alimentarius. (0002.01.06a)

f. In a Messhall / Food Service environment state, and identify the elements in an effective pest control program, in accordance with Codex Alimentarius. (0002.01.06a)

g. In a Messhall / Food Service environment state, and identify the hygiene and health risks, in accordance with Codex Alimentarius. (0002.01.06a)

3. **TERMINAL LEARNING OBJECTIVE.** In a Messhall / Food Service environment, state and identify the elements and effectiveness of a Hazard Analysis Critical Control Plan (HACCP) in accordance with "Food and Drug Administration, Department of Agriculture, National Advisory Committee on Microbiological Criteria for Foods, August 1997, and Codex Alimentarius. (0002.01.06a)

4. **ENABLING LEARNING OBJECTIVES**.

a. In a Messhall / Food Service environment state and identify the tools needed to build a food safety system in accordance with "Food and Drug Administration, Department of Agriculture, National Advisory Committee on Microbiological Criteria for Foods, August 1997, and Codex Alimentarius (0002.01.06a)

b. In a Messhall / Food Service environment, state and identify chemical, physical and food borne hazards associated with a food service operation in accordance with "Food and Drug Administration, Department of Agriculture, National Advisory Committee on Microbiological Criteria for Foods, August 1997, and Codex Alimentarius. (0002.01.06a**)**

c. In a Messhall / Food Service environment, state and identify the prerequisite programs associated with a food service operation in accordance with "Food and Drug Administration, Department of Agriculture, National Advisory Committee on Microbiological Criteria for Foods, August 1997, and Codex Alimentarius. (0002.01.06a)

d. In a Messhall / Food Service environment, state and identify the five Preliminary steps that must be completed prior to developing the HACCP plan in accordance with "Food and Drug Administration, Department of Agriculture, National Advisory

Committee on Microbiological Criteria for Foods, August 1997, and Codex Alimentarius. (0002.01.06a)

e. In a Messhall / Food Service environment, state and identify the seven basic HACCP principles in accordance with "Food and Drug Administration, Department of Agriculture, National Advisory Committee on Microbiological Criteria for Foods, August 1997, and Codex Alimentarius. (0002.01.06a)

f. In a Messhall / Food Service environment, state and identify the Decision Tree in accordance with "Food and Drug Administration, Department of Agriculture, National Advisory Committee on Microbiological Criteria for Foods, August 1997, and Codex Alimentarius. (0002.01.06a)

Let's Get Started

1. **GENERAL PRINCIPLES OF FOOD HYGIENE.** People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are at best unpleasant; at worst, they can be fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation.

a. **Food Spoilage.** Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

b. **General Principles.** These General Principles lay a firm foundation for ensuring food hygiene and should be used in conjunction with each specific code of hygienic practice, where appropriate, and the guidelines on microbiological criteria. The document follows the food chain from primary production through to final consumption, highlighting the key hygiene controls at each stage.

c. **HACCP-based approach.** It recommends a HACCP-based approach wherever possible to enhance food safety as described in Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its
Application.

2. **THE CODEX ALIMENTARIUS GENERAL PRINCIPLES OF FOOD HYGIENE.** Identifies the essential principles of food hygiene applicable throughout the food chain (including primary production through

to the final consumer), to achieve the goal of ensuring that food is safe and suitable for human consumption.

a. **Recommends.** Recommends a HACCP-based approach as a means to enhance food safety.

b. **Indicates.** Indicates how to implement those principles and provide guidance for specific codes, which may be needed for sectors of the food chain, processes or commodities to amplify the hygiene requirements specific to those areas.

c. **Governments.** Governments can consider the contents of this document and decide how best they should encourage the implementation of these general principles.

(1) Protect consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of the population, or of different groups within the population.

(2) Provide assurance that food is suitable for human consumption.

(3) Maintain confidence in internationally traded food.

(4) Provide health education programs, which effectively communicate the principles of food hygiene to industry and consumers.

d. **Industry should apply the hygienic practices set out in this document to:**

(1) Provide food, which is safe and suitable for consumption

(2) Ensure that consumers have clear and easily understood information, by way of labeling and other appropriate means, to enable them to protect their food from contamination and growth/survival of foodborne pathogens by storing, handling and preparing it correctly.

(3) Maintain confidence in internationally traded food.

(4) Consumers should recognize their role by following relevant instructions and applying appropriate food hygiene measures.

e. **Environmental Hygiene.** Potential sources of contamination from the environment should be considered. In particular, primary food production should not be carried on in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in food.

f. **Hygienic Production of Food Sources.** The potential effects of primary production activities on the safety and suitability of food should be considered at all times. In particular, this includes identifying any specific points in such activities where a high probability of contamination may exist and taking specific measures to minimize that probability. The HACCP-based approach may assist in the taking of such measures.

(1) Control contamination from air, soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production.

(2) Control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product.

(3) Protect food sources from fecal and other contamination.

g. **Handling, Storage, and Transport.**

(1) Sort food and food ingredients to segregate material which is evidently unfit for human consumption.

(2) Dispose of any rejected material in a hygienic manner.

(3) Protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport.

h. **Establishments**. In particular, establishments should normally be located away from:

(1) Environmentally polluted areas and industrial activities which pose a serious threat of contaminating food.

(2) Areas subject to flooding unless sufficient safeguards are provided.

(3) Areas prone to infestations of pests.

(4) Areas where wastes, either solid or liquid, cannot be removed effectively.

3. **EQUIPMENT, DESIGN, LAYOUT AND STRUCTURES.**

a. Permits adequate maintenance and cleaning.

b. Functions in accordance with its intended use.

c. Facilitates good hygiene practices, including monitoring.

d. The surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect in intended use.

e. Walls and partitions should have a smooth surface up to a height.

f. Floors should be constructed to allow adequate drainage and cleaning.

g. Ceilings and overhead fixtures should be constructed and finished to minimize the build up of dirt and condensation, and the shedding of particles.

h. Windows should be easy to clean, be constructed to minimize the build up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens. Where necessary, windows should be fixed.

i. Doors should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect.

j. Working surfaces that come into direct contact with food should be in sound condition, durable and easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent materials, and inert to the food, to detergents and disinfectants under normal operating conditions.

4. **FOOD CONTROL AND MONITORING EQUIPMENT.** These requirements are intended to ensure that:

a. Harmful or undesirable microorganisms or their toxins are eliminated or reduced to safe levels or their survival and growth are effectively controlled.

b. Where appropriate, critical limits established in HACCP-based plans can be monitored.

c. Temperatures and other conditions necessary to food safety and suitability can be rapidly achieved and maintained.

5. **CONTAINERS FOR WASTE AND INEDIBLE SUBSTANCES.** Containers for waste, by-products and inedible or dangerous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material. Containers used to hold dangerous substances should be identified and, where appropriate, be lockable to prevent malicious or accidental contamination of food.

6. **FACILITIES.**

a. An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control, should be available whenever necessary to ensure the safety and suitability of food.

b. Potable water should be as specified in the latest edition of WHO Guidelines for Drinking Water Quality, or water of a higher standard. Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), shall have a separate system. Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems.

c. Adequate drainage and waste disposal systems and facilities should be provided. They should be designed and constructed so that the risk of contaminating food or the potable water supply is avoided.

d. Adequate facilities, suitably designated, should be provided for cleaning food, utensils and equipment. Such facilities should have an adequate supply of hot and cold potable water where appropriate.

e. Adequate means of hygienically washing and drying hands, including washbasins and a supply of hot and cold (or suitably temperature controlled) water.

f. Lavatories of appropriate hygienic design.

g. Adequate changing facilities for personnel.

7. **STORAGE.**

a. Minimize air-borne contamination of food, for example, from aerosols and condensation droplets.

b. Control ambient temperatures.

c. Control odors, which might affect the suitability of food.

d. Control humidity, where necessary, to ensure the safety and suitability of food.

e. Adequate natural or artificial lighting should be provided to enable the undertaking to operate in a hygienic manner. Where necessary, lighting should not be such that the resulting color is misleading. The intensity should be adequate to the nature of the operation. Lighting fixtures should, where appropriate, be protected to ensure that food is not contaminated by breakages.

f. Permit adequate maintenance and cleaning.

f. Avoid pest access and harborage.

g. Enable food to be effectively protected from contamination during storage.

h. Where necessary, provide an environment, which minimizes the deterioration of food (e.g. by temperature and humidity control).

8. **CONTROL OF FOOD HAZARDS.**

a. **Identify steps.** Identify any steps in their operations, which are critical to the safety of food.

b. Implement effective control procedures at those steps.

c. Monitor control procedures to ensure their continuing effectiveness.

d. Review control procedures periodically, and whenever the operations change.

e. **Temperature control systems.** Temperature control systems should take into account the nature of the food, e.g. its water activity, pH, and likely initial level and types of microorganisms.

(1) The intended shelf life of the product.

(2) The method of packaging and processing.

(3) How the product is intended to be used, e.g. further cooking/processing or ready-to-eat.

f. **Specific process steps.** Specific process steps, which contribute, to food hygiene may include, chilling, thermal processing, irradiation, drying, chemical preservation, vacuum or modified atmospheric packaging.

9. **MICROBIOLOGICAL CROSS-CONTAMINATION.**

a. **Pathogens.** Pathogens can be transferred from one food to another, either by direct contact or by food handlers, contact surfaces or the air. Raw, unprocessed food should be effectively separated, either physically or by time, from ready-to-eat foods, with effective intermediate cleaning and where appropriate disinfect.

b. **Access.** Access to processing areas may need to be restricted or controlled. Where risks are particularly high, access to processing areas should be only via a changing facility. Personnel may need to be required to put on clean protective clothing including footwear and wash their hands before entering.

c. **Surfaces.** Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food, particularly meat and poultry, has been handled or processed.

10. **PHYSICAL AND CHEMICAL CONTAMINATION.** Systems should be in place to prevent contamination of foods by foreign bodies such as glass or metal shards from machinery, dust, harmful fumes and unwanted chemicals. In manufacturing and processing, suitable detection or screening devices should be used where necessary.

11. **IN CONTACT WITH FOOD.**

a. **Potable Water**. Only potable water, should be used in food handling and processing, with the following exceptions:

(1) For steam production, fire control and other similar purposes not connected with food.

(2) In certain food processes, e.g. chilling, and in food handling areas, provided this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean seawater).

b. **Documentation and Records.** Where necessary, appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf life of the product. Documentation can enhance the credibility and effectiveness of the food safety control system.

c. **Recall Procedures.**

(1) Managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid recall of any implicated lot of the finished food from the market. Where a product has been withdrawn because of an immediate health hazard, other products which are produced under similar conditions, and which may present a similar hazard to public health, should be evaluated for safety and may need to be withdrawn. The need for public warnings should be considered.

(2) Recalled products should be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety.

d. **Pest Control Systems.**

(1) Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are

likely to gain access should be kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of factories and food processing plants.

(2) The availability of food and water encourages pest harborage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls. Areas both inside and outside food premises should be kept clean. Where appropriate, refuse should be stored in covered, pest-proof containers.

(3) Pest infestations should be dealt with immediately and without adversely affecting food safety or suitability. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food.

e. **Health Status.**

(1) People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, should not be allowed to enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management.

(2) Medical examination of a food handler should be carried out if clinically or epidemiologically indicated.

f. **Illness and Injuries.** Conditions which should be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered, include:

(1) Jaundice

(2) Diarrhea

(3) Vomiting

(4) Fever

(5) Sore throat with fever

(6) Visibly infected skin lesions (boils, cuts, etc.)

(7) Discharges from the ear eye or nose

g. **Lot, Product Identification and Information.**

(1) Lot identification is essential in product recall and also helps effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. Codex General Standard for the Labeling of Prepackaged Foods (CODEX STAN 1-1985) applies.

(2) All food products should be accompanied by or bear adequate information to enable the next person in the food chain to handle, display, store and prepare and use the product safely and correctly.

(3) Prepackaged foods should be labeled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely. Codex General Standard for the Labeling of Prepackaged Foods (CODEX STAN 1-1985) applies.

12. **CONSUMER EDUCATION.**

a. **Health Education Programs.** Health education programs should cover general food hygiene. Such programs should enable consumers to understand the importance of any product information and to follow any instructions accompanying products, and make informed choices. In particular consumers should be informed of the relationship between time/temperature control and foodborne illness.

b. **Food Hygiene.** Food hygiene training is fundamentally important. All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers should have the necessary knowledge and skills to enable them to handle food hygienically. Those who handle strong cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques.

c. **Periodic Assessments**. Periodic assessments of the effectiveness of training and instruction programs should be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively.

d. **Managers and Supervisors.** Managers and supervisors of food processes should have the necessary knowledge of food

hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.

e. **Training programs.** Training programs should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.

13. **TOOLS NEEDED TO BUILD A FOOD SAFTEY SYSTEM**.

a. HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. For successful implementation of a HACCP plan, management must be strongly committed to the HACCP concept. A firm commitment to HACCP by top management provides company employees with a sense of the importance of producing safe food.

b. HACCP is designed for use in all segments of the food industry from growing, harvesting, processing, manufacturing, distributing, and merchandising to preparing food for consumption. Prerequisite programs such as current Good Manufacturing Practices (cGMPs), Standard Operating Procedures, Personal Hygiene, Pest Control, Food Specifications, Maintenance, Waste Management and Training Programs are an essential foundation for the development and implementation of successful HACCP plans. Food safety systems based on the HACCP principles have been successfully applied in food processing plants, retail food stores, and food service operations. Government agencies, trade associations and the food industry around the world have universally accepted the seven principles of HACCP.

c. The following guidelines will facilitate the development and implementation of effective HACCP plans. These guidelines should be applied as appropriate to each segment of the food industry under consideration.

d. Customers expect that the food we serve them is safe, and will not cause them illness or injury. Our goal is to provide you with the recourses that will enable you t serve a safe product.

INTERIM TRANSITION: Thus far, we've discussed the tools needed to build a food safety system. Do you have any questions? Let's review your student's workbook and answer any questions that you may have concerning some of the check on learning questions and the crossword puzzle.

14. CHEMICAL, PHYSICAL AND FOODBORE HAZARDS.

a. Chemical Hazards are found in man-made subsistence such as cleaning agents, sanitizers, solvents, pesticides or lubricants. The also can be produced by foodborne intoxication

(1) Ciguatoxin is chemical produced by algae common to coral reefs. Toxins build up via natures' food chain whereby smaller fish are consumed by larger fish.

(2) Scrombroid Toxin build-up is attributed to fish that have been improperly refrigerated or held at temperatures above 41°F for a period of four or more hours.

b. Physical hazards are common type of hazard and can be controlled by employees simply removing objects. While these hazards may be least lethal they are quite common and are often the leading cause of foodborne litigation. Physical hazards are tangible; therefore it is often easier for a court to make a decision based on tangible piece of evidence as opposed to bacteria that are difficult to determine. Packaging accounts for many physical hazards; therefore we must inspect our food products deliveries very carefully.

b. Two major challenges

(1) High Risk Foods

(a) Beef
(b) Poultry
(c) Seafood
(d) Pork
(e) Dairy

(2) High Risk Individuals

(a) Children
(b) Infants
(c) Elderly
(d) Immunocompromised individuals

c. Biological contamination is caused when microorganisms come into contact with food. The majority of food borne illness occurs with biological contamination. Most biological hazards are attributed to improper personal hygiene and cross contamination.

(1) Viruses. Found on living hosts, such as employees & customers. Controlled by personal hygiene.

(2) Parasites. Microorganisms that enter our body. Controlled by cooking internal temperature.

(a) Anisakis. Is the worm commonly found in fish and some marine mammals.

(b) Trichinosis. Is the parasitical disease found in pork products or game animals?

(3) Bacteria. Most common, ancient form of life that have been very successful.

c. **Foodborne Infection**. Living bacteria on food cause food borne infection. We control food borne infection by temperature, such as the storage, cooking and cooling.

d. **Foodborne Intoxication**. Food Borne intoxication occurs when the food or bacteria on the food produce a poison or toxin in the food. Any food that has intoxication must be discarded.

e. Norwalk Virus is often found in contaminated water or through shellfish. Purchase food from approved vendors and cook thoroughly.

f. Listeria is an infection of the intestinal tract also found in contaminated water and facilities with bad sanitation. Processed meats, dairy products and vegetables are also contaminated. Proper sanitation and avoiding cross contamination is necessary for control.

g. Its common name is E. Coli 0157:H7 and can be found in cattle and contaminated water. Undercooking ground beef, non-pasteurized dairy products and fruit and vegetables washed in contaminated water are frequent sources.

h. Salmonella is often found in the feces of animals.

It is linked to poultry, eggs and meat products, and many high protein foods. To control salmonella we must cook food properly, use pasteurized products, and avoid cross contamination.

i. Staphylococcus aureus is common bacteria found in the nose, mouth, and skin. At all times many of us have staph present on those areas. Proper hand washing and controlling employee eating, drinking and smoking are good control methods.

15. **PREREQUISITE PROGRAMS.**

a. The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite programs. Each segment of the food industry must provide the conditions necessary to protect food while it is under their control. This has traditionally been accomplished through the application of cGMPs. These conditions and practices are now considered to be prerequisite to the development and implementation of effective HACCP plans. Prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food. Many of the conditions and practices are specified in federal, state and local regulations and guidelines (e.g., cGMPs and Food Code). The Codex Alimentarius General Principles of Food Hygiene describe the basic conditions and practices expected for foods intended for international trade. In addition to the requirements specified in regulations, industry often adopts policies and procedures that are specific to their operations. Many of these are proprietary. While prerequisite programs may impact upon the safety of a food, they also are concerned with ensuring that foods are wholesome and suitable for consumption HACCP plans are narrower in scope, being limited to ensuring food is safe to consume.

b. The existence and effectiveness of prerequisite programs should be assessed during the design and implementation of each HACCP plan. All prerequisite programs should be documented and regularly audited. Prerequisite programs are established and managed separately from the HACCP plan. Certain aspects, however, of a prerequisite program may be incorporated into a HACCP plan. For example, many establishments have preventive maintenance procedures for processing equipment to avoid unexpected equipment failure and loss of production. During the development of a HACCP plan, the HACCP team may decide that the routine maintenance and calibration of an oven should be included in the plan as an activity of verification. This would further ensure that all the food in the oven is

cooked to the minimum internal temperature that is necessary for food safety.

c. The success of a HACCP system depends on educating and training management and employees in the importance of their role in producing safe foods. This should also include information the control of food borne hazards related to all stages of the food chain. It is important to recognize that employees must first understand what HACCP is and then learn the skills necessary to make it function properly. Specific training activities should include working instructions and procedures that outline the tasks of employees monitoring each CCP.

(d) Management must provide adequate time for thorough education and training. Personnel must be given the materials and equipment necessary to perform these tasks. Effective training is an important prerequisite to successful implementation of a HACCP plan.

(e) Common prerequisite programs may include, but are not limited to:

(1) Facilities. The establishment should be located, constructed and maintained according to sanitary design principles. There should be linear product flow and traffic control to minimize cross-contamination from raw to cooked materials.

(2) Supplier Control. Each facility should assure that its suppliers have in place effective GMP and food safety programs. These may be the subject of continuing supplier guarantee and supplier HACCP system verification.

(3) Specifications. There should be written specifications for all ingredients, products, and packaging materials.

(4) Production Equipment. All equipment should be constructed and installed according to sanitary design principles.

(5) Preventive maintenance and calibration schedules should be established and documented.

(6) Cleaning and Sanitation. All procedures for cleaning and sanitation of the equipment and the facility should

be written and followed. A master sanitation schedule should be in place.

(7) Personal Hygiene. All employees and other persons who enter the manufacturing plant should follow the requirements for personal hygiene.

(8) Training. All employees should receive documented training in personal hygiene, GMP, cleaning and sanitation procedures, personal safety, and their role in the HACCP program.

(9) Chemical Control. Documented procedures must be in place to assure the segregation and proper use of non-food chemicals in the plant. These include cleaning chemicals, fumigants, and pesticides or baits used in or around the plant.

(10) Receiving, Storage and Shipping. All raw materials and products should be stored under sanitary conditions and the proper environmental conditions such as temperature and humidity to assure their safety and wholesomeness.

(11) Trace-ability and Recall. All raw materials and products should be lot-coded and a recall system in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary.

(12) Pest Control. Effective pest control programs should be in place.

(13) Other examples of prerequisite programs might include quality assurance procedures; standard operating procedures for sanitation, processes, product formulations and recipes; glass control; procedures for receiving, storage and shipping; labeling; and employee food and ingredient handling practices.

16. **FIVE PRELIMINARY STEPS**.

a. **Assemble the HACCP Team**. The first task in developing a HACCP plan is to assemble a HACCP team consisting of individuals who have specific knowledge and expertise appropriate to the product and process. It is the team's responsibility to develop the HACCP plan. The team should be multi disciplinary and include individuals from areas such as engineering, production, sanitation, quality assurance, and food microbiology. The team should also include local personnel who are involved in the

operation as they are more familiar with the variability and limitations of the operation. In addition, this fosters a sense of ownership among those who must implement the plan. The HACCP team may need assistance from outside experts who are knowledgeable in the potential biological, chemical and/or physical hazards associated with the product and the process. However, a plan, which is developed totally by outside sources, may be erroneous, incomplete, and lacking in support at the local level. Due to the technical nature of the information required for hazard analysis, it is recommended that experts who are knowledgeable in the food process should either participate in or verify the completeness of the hazard analysis and the HACCP plan. Such individuals should have the knowledge and experience to correctly:

(1) Conduct a hazard analysis.

(2) Identify potential hazards.

(3) Identify hazards, which must be controlled.

(4) Recommend controls, critical limits, and procedures for monitoring and verification.

(5) Recommend appropriate corrective actions when a deviation occurs.

(6) Recommend research related to the HACCP plan if important information is not known;

(7) Validate the HACCP plan.

b. **Describe the Food and its Distribution**. The HACCP team first describes the food. This consists of a general description of the food, ingredients, and processing methods. The method of distribution should be described along with information on whether the food is to be distributed frozen, refrigerated, or at ambient temperature.

c. **Describe the Intended Use and Consumers of the Food**. Describe the normal expected use of the food. The intended consumers may be the general public or a particular segment of the population (e.g., infants, Immunocompromised individuals, the elderly, etc.).

d. **Develop a Flow Diagram**. The flow diagram describes the process. The purpose of a flow diagram is to provide a clear,

simple outline of the steps involved in the process. The scope of the flow diagram must cover all the steps in the process, which are directly under the control of the establishment. In addition, the flow diagram can include steps in the food chain, which are before and after the processing that occurs in the establishment. The flow diagram need not be as complex as engineering drawings. A block type flow diagram is sufficiently descriptive. Also, a simple schematic of the facility is often useful in understanding and evaluating product and process flow.

e. **Verify the Flow Diagram**. The HACCP team should perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram. Modifications should be made to the flow diagram as necessary and documented.

19. **SEVEN BASIC HACCP PRINCIPLES.** HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards based on the following seven principles:

a. **Conduct a Hazard Analysis**. (**Principle 1)** After addressing the preliminary tasks discussed above, the HACCP team conducts a hazard analysis and identifies appropriate control measures. The purpose of the hazard analysis is to develop a list of hazards, which are of such significance that they are reasonably likely to cause injury or illness if not effectively controlled. Hazards that are not reasonably likely to occur would not require further consideration within a HACCP plan. It is important to consider in the hazard analysis the ingredients and raw materials, each step in the process, product storage and distribution, and final preparation and use by the consumer. When conducting a hazard analysis, safety concerns must be differentiated from quality concerns. A hazard is defined as a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control. Thus, the word hazard as used in this document is limited to safety.

(1) A thorough hazard analysis is the key to preparing an effective HACCP plan. If the hazard analysis is not done correctly and the hazards warranting control within the HACCP system are not identified, the plan will not be effective regardless of how well it is followed.

(2) The hazard analysis and identification of associated control measures accomplish three objectives: Those hazards and associated control measures are identified. The analysis may identify needed modifications to a process or product so that product safety is further assured or improved.

The analysis provides a basis for determining CCP's in Principle 2.

(3) The process of conducting a hazard analysis involves two stages. The first, hazard identification, can be regarded as a brain storming session. During this stage, the HACCP team reviews the ingredients used in the product, the activities conducted at each step in the process and the equipment used, the final product and its method of storage and distribution, and the intended use and consumers of the product. Based on this review, the team develops a list of potential biological, chemical or physical hazards, which may be introduced, increased, or controlled at each step in the production process. Hazard identification focuses on developing a list of potential hazards associated with each process step under direct control of the food operation. Knowledge of any adverse health-related events historically associated with the product will be of value in this exercise.

(4) After the list of potential hazards is assembled, stage two, the hazard evaluation, is conducted. In stage two of the hazard analysis, the HACCP team decides which potential hazards must be addressed in the HACCP plan. During this stage, each potential hazard is evaluated based on the severity of the potential hazard and its likely occurrence. Severity is the seriousness of the consequences of exposure to the hazard. Considerations of severity (e.g., impact of sequelae, and magnitude and duration of illness or injury) can be helpful in understanding the public health impact of the hazard. Consideration of the likely occurrence is usually based upon a combination of experience, epidemiological data, and information in the technical literature. When conducting the hazard evaluation, it is helpful to consider the likelihood of exposure and severity of the potential consequences if the hazard is not properly controlled. In addition, consideration should be given to the effects of short term as well as long-term exposure to the potential hazard. Such considerations do not include common dietary choices, which lie outside of HACCP. During the evaluation of each potential hazard, the food, its method of preparation, transportation, storage and persons likely to consume the product should be considered to determine how each of these factors might influence the likely occurrence and severity of the hazard being controlled. The team must consider the influence of likely procedures for food preparation and storage and whether the intended consumers are susceptible to a potential hazard. However, there may be differences of opinion, even among experts, as to the likely occurrence and severity of

a hazard. The HACCP team may have to rely upon the opinion of experts who assist in the development of the HACCP plan.

(5) Hazards identified in one operation or facility may not be significant in another operation producing the same or a similar product. For example, due to differences in equipment and/or an effective maintenance program, the probability of metal contamination may be significant in one facility but not in another. A summary of the HACCP team deliberations and the rationale developed during the hazard analysis should be kept for future reference. This information will be useful during future reviews and updates of the hazard analysis and the HACCP plan.

(6) Upon completion of the hazard analysis, the hazards associated with each step in the production of the food should be listed along with any measure(s) that are used to control the hazard(s). The term control measure is used because not all hazards can be prevented, but virtually all can be controlled. More than one control measure may be required for a specific hazard. On the other hand, more than one hazard may be addressed by a specific control measure (e.g. pasteurization of milk).

(7) For example, if a HACCP team were to conduct a hazard analysis for the production of frozen cooked beef patties, enteric pathogens (e.g., *Salmonella* and verotoxin-producing *Escherichia coli*) in the raw meat would be identified as hazards. Cooking is a control measure, which can be used to eliminate these hazards. The following is an excerpt from a hazard analysis summary table for this product.

Step	**Potential Hazard(s)**	**Justification**	**Hazard to be addressed in plan? Y/N**	**Control Measure(s)**
5. Cooking	Enteric pathogens: e.g., *Salmonella*, verotoxigenic-*E. Coli*	Enteric pathogens have been associated with outbreaks of foodborne illness from under cooked	Y	Cooking

		ground beef		

(8) The hazard analysis summary could be presented in several different ways. One format is a table such as the one given above. Another could be a narrative summary of the HACCP team's hazard analysis considerations and a summary table listing only the hazards and associated control measures.

(b) **Determine Critical Control Points (CCP's) (Principle 2)** A critical control point is defined as a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. The potential hazards that are reasonably likely to cause illness or injury in the absence of their control must be addressed in determining CCP's.

(1) Complete and accurate identification of CCP's is fundamental to controlling food safety hazards. The information developed during the hazard analysis is essential for the HACCP team in identifying which steps in the process are CCP's. One strategy to facilitate the identification of each CCP is the use of a CCP decision tree. Although application of the CCP decision tree can be useful in determining if a particular step is a CCP for a previously identified hazard, it is merely a tool and not a mandatory element of HACCP. A CCP decision tree is not a substitute for expert knowledge.

(2) Critical control points are located at any step where hazards can be prevented, eliminated, or reduced to acceptable levels. Examples of CCP's may include: thermal processing, chilling, testing ingredients for chemical residues, product formulation control, and testing product for metal contaminants. CCP's must be carefully developed and documented. In addition, they must be used only for purposes of product safety. For example, a specified heat process, at a given time and temperature designed to destroy a specific microbiological pathogen, could be a CCP. Likewise, refrigeration of a precooked food to prevent hazardous microorganisms from multiplying, or the adjustment of a food to a pH necessary to prevent toxin formation could also be CCP's. Different facilities preparing similar food items can differ in the hazards identified and the steps, which are CCP's. This can be due to differences in each facility's layout, equipment, selection of ingredients, processes employed, etc.

c. Establish Critical Limits (Principle 3) A critical limit is a maximum and/or minimum value to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard. A critical limit is used to distinguish between safe and unsafe operating conditions at a CCP. Critical limits should not be confused with operational limits, which are established for reasons other than food safety.

(1) Each CCP will have one or more control measures to assure that the identified hazards are prevented, eliminated or reduced to acceptable levels. Each control measure has one or more associated critical limits. Critical limits may be based upon factors such as: temperature, time, physical dimensions, humidity, moisture level, water activity (a_w), pH, titratable acidity, salt concentration, available chlorine, viscosity, preservatives, or sensory information such as aroma and visual appearance. Critical limits must be scientifically based. For each CCP, there is at least one criterion for food safety that is to be met. An example of a criterion is a specific lethality of a cooking process such as a 5D reduction in *Salmonella*. The critical limits and criteria for food safety may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental results, and experts.

(2) An example is the cooking of beef patties. The process should be designed to ensure the production of a safe product. The hazard analysis for cooked meat patties identified enteric pathogens (e.g., verotoxigenic *E. coli* such as *E. coli* O157:H7, and salmonellae) as significant biological hazards. Furthermore, cooking is the step in the process at which control can be applied to reduce the enteric pathogens to an acceptable level. To ensure that an acceptable level is consistently achieved, accurate information is needed on the probable number of the pathogens in the raw patties, their heat resistance, the factors that influence the heating of the patties, and the area of the patty which heats the slowest. Collectively, this information forms the scientific basis for the critical limits that are established. Some of the factors that may affect the thermal destruction of enteric pathogens are listed in the following table. In this example, the HACCP team concluded that a thermal process equivalent to 155° F for 16 seconds would be necessary to assure the safety of this product. To ensure that this time and temperature are attained, the HACCP team for one facility determined that it would be necessary to establish critical limits for the oven temperature and humidity, belt

speed (time in oven), patty thickness and composition (e.g., all beef, beef and other ingredients). Control of these factors enables the facility to produce a wide variety of cooked patties, all of which will be processed to a minimum internal temperature of 155° F for 16 seconds. In another facility, the HACCP team may conclude that the best approach is to use the internal patty temperature of 155° F and hold for 16 seconds as critical limits. In this second facility the internal temperature and hold time of the patties are monitored at a frequency to ensure that the critical limits are constantly met as they exit the oven. The example given below applies to the first facility.

Process Step	CCP	Critical Limits
5. Cooking	YES	Oven temperature: ___° F Time; rate of heating and cooling (belt speed in ft/min): ____ft/min Patty thickness: ____in. Patty composition: e.g. all beef Oven humidity: ____% RH

d. <u>Establish Monitoring Procedures</u> (Principle 4)

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification. Monitoring serves three main purposes. First, monitoring is essential to food safety management in that it facilitates tracking of the operation. If monitoring indicates that there is a trend towards loss of control, then action can be taken to bring the process back into control before a deviation from a critical limit occurs. Second, monitoring is used to determine when there is loss of control and a deviation occurs at a CCP, i.e., exceeding or not meeting a critical limit. When a deviation occurs, an appropriate corrective action must be taken. Third, it provides written documentation for use in verification.

(1) An unsafe food may result if a process is not properly controlled and a deviation occurs. Because of the potentially serious consequences of a critical limit deviation, monitoring procedures must be effective. Ideally, monitoring should be continuous, which is possible with many types of physical and chemical methods. For example, the temperature and

time for the scheduled thermal process of low-acid canned foods is recorded continuously on temperature recording charts. If the temperature falls below the scheduled temperature or the time is insufficient, as recorded on the chart, the product from the retort is retained and the disposition determined as in Principle 5. Likewise, pH measurement may be performed continually in fluids or by testing each batch before processing. There are many ways to monitor critical limits on a continuous or batch basis and record the data on charts. Continuous monitoring is always preferred when feasible. Monitoring equipment must be carefully calibrated for accuracy.

(2) Assignment of the responsibility for monitoring is an important consideration for each CCP. Specific assignments will depend on the number of CCP's and control measures and the complexity of monitoring. Personnel who monitor CCP's are often associated with production (e.g., line supervisors, selected line workers and maintenance personnel) and, as required, quality control personnel. Those individuals must be trained in the monitoring technique for which they are responsible, fully understand the purpose and importance of monitoring, be unbiased in monitoring and reporting, and accurately report the results of monitoring. In addition, employees should be trained in procedures to follow when there is a trend towards loss of control so that adjustments can be made in a timely manner to assure that the process remains under control. The person responsible for monitoring must also immediately report a process or product that does not meet critical limits.

(3) All records and documents associated with CCP monitoring should be dated and signed or initialed by the person doing the monitoring. When it is not possible to monitor a CCP on a continuous basis, it is necessary to establish a monitoring frequency and procedure that will be reliable enough to indicate that the CCP is under control. Statistically designed data collection or sampling systems lend themselves to this purpose.

(4) Most monitoring procedures need to be rapid because they relate to on-line, "real-time" processes and there will not be time for lengthy analytical testing. Examples of monitoring activities include: visual observations and measurement of temperature, time, pH, and moisture level.

(5) Microbiological tests are seldom effective for monitoring due to their time-consuming nature and problems with assuring detection of contaminants. Physical and chemical measurements are often preferred because they are rapid and

usually more effective for assuring control of microbiological hazards. For example, the safety of pasteurized milk is based upon measurements of time and temperature of heating rather than testing the heated milk to assure the absence of surviving pathogens.

(6) With certain foods, processes, ingredients, or imports, there may be no alternative to microbiological testing. However, it is important to recognize that a sampling protocol that is adequate to reliably detect low levels of pathogens is seldom possible because of the large number of samples needed. This sampling limitation could result in a false sense of security by those who use an inadequate sampling protocol. In addition, there are technical limitations in many laboratory procedures for detecting and quantitating pathogens and/or their toxins.

(e) **Establish Corrective Actions (Principle 5)** The HACCP system for food safety management is designed to identify health hazards and to establish strategies to prevent, eliminate, or reduce their occurrence. However, ideal circumstances do not always prevail and deviations from established processes may occur. An important purpose of corrective actions is to prevent foods, which may be hazardous from reaching consumers. Where there is a deviation from established critical limits, corrective actions are necessary. Therefore, corrective actions should include the following elements: (a) determine and correct the cause of non-compliance; (b) determine the disposition of non-compliant product and (c) record the corrective actions that have been taken. Specific corrective actions should be developed in advance for each CCP and included in the HACCP plan. As a minimum, the HACCP plan should specify what is done when a deviation occurs, who is responsible for implementing the corrective actions, and that a record will be developed and maintained of the actions taken. Individuals who have a thorough understanding of the process, product and HACCP plan should be assigned the responsibility for oversight of corrective actions. As appropriate, experts may be consulted to review the information available and to assist in determining disposition of non-compliant product.

f. **Establish Verification Procedures (Principle 6)** Verification is defined as those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan. The NAS (1985) pointed out that the major infusion of science in a HACCP system centers on proper identification of the hazards, critical

control points, critical limits, and instituting proper verification procedures. These processes should take place during the development and implementation of the HACCP plans and maintenance of the HACCP system.

(1) One aspect of verification is evaluating whether the facility's HACCP system is functioning according to the HACCP plan. An effective HACCP system requires little end product testing, since sufficient validated safeguards are built in early in the process. Therefore, rather than relying on end-product testing, firms should rely on frequent reviews of their HACCP plan, verification that the HACCP plan is being correctly followed, and review of CCP monitoring and corrective action records.

(2) Another important aspect of verification is the initial validation of the HACCP plan to determine that the plan is scientifically and technically sound, that all hazards have been identified and that if the HACCP plan is properly implemented these hazards will be effectively controlled. Information needed to validate the HACCP plan often include (1) expert advice and scientific studies and (2) in-plant observations, measurements, and evaluations. For example, validation of the cooking process for beef patties should include the scientific justification of the heating times and temperatures needed to obtain an appropriate destruction of pathogenic microorganisms (i.e., enteric pathogens) and studies to confirm that the conditions of cooking will deliver the required time and temperature to each beef patty.

(3) Subsequent validations are performed and documented by a HACCP team or an independent expert as needed. For example, validations are conducted when there is an unexplained system failure; a significant product, process or packaging change occurs; or new hazards are recognized.

(4) In addition, a periodic comprehensive verification of the HACCP system should be conducted by an unbiased, independent authority. Such authorities can be internal or external to the food operation. This should include a technical evaluation of the hazard analysis and each element of the HACCP plan as well as on-site review of all flow diagrams and appropriate records from operation of the plan. A comprehensive verification is independent of other verification procedures and must be performed to ensure that the HACCP plan is resulting in the control of the hazards. If the results of

the comprehensive verification identify deficiencies, the HACCP team modifies the HACCP plan as necessary.

(5) Verification activities are carried out by individuals within a company, third party experts, and regulatory agencies. It is important that individuals doing verification have appropriate technical expertise to perform this function. Examples of verification activities of a Company Established HACCP Verification Schedule

Activity	Frequency	Responsibility	Reviewer
Verification Activities Scheduling	Yearly or Upon HACCP System Change	HACCP Coordinator	Plant Manager
Initial Validation of HACCP Plan	Prior to and During Initial Implementation of Plan	Independent Expert(s)[(a)]	HACCP Team
Subsequent validation of HACCP Plan	When Critical Limits Changed, Significant Changes in Process, Equipment Changed, After System Failure, etc.	Independent Expert(s)[(a)]	HACCP Team
Verification of CCP Monitoring as Described in the Plan (e.g., monitoring of patty cooking temperature)	According to HACCP Plan (e.g., once per shift)	According to HACCP Plan (e.g., Line Supervisor)	According to HACCP Plan (e.g., Quality Control)
Review of Monitoring, Corrective Action Records to Show Compliance with the Plan	Monthly	Quality Assurance	HACCP Team

Comprehensive HACCP System Verification	Yearly	Independent Expert(s)[a]	Plant Manager
[a] Done by others than the team writing and implementing the plan. May require additional technical expertise as well as laboratory and plant test studies.			

g. <u>Establish Record-Keeping and Documentation Procedures</u> (Principle 7) Generally, the records maintained for the HACCP System should include the following:

(1) A summary of the hazard analysis, including the rationale for determining hazards and control measures.

(2) The HACCP Plan

(3) Listing of the HACCP team and assigned responsibilities.

(4) Description of the food, its distribution, intended use, and consumer.

(5) Verified flow diagram.

(6) HACCP Plan Summary Table that includes information for:

(a) Steps in the process that are CCP’s

(b) The hazard(s) of concern.

(c) Critical limits

(D) Monitoring*

(E) Corrective actions*

(F) Verification procedures and schedule*

(G) Record-keeping procedures*

(7) * A brief summary of position responsible for performing the activity and the procedures and frequency should be provided.

6. **THE DECISION TREE**.

(a) A decision tree is tools a used to determine which control points are CCP’s. Although the cook step is typically the CCP, in many instances all points prior to cook step must be carefully evaluated with the decision tree process to determine if they are CCP’s. (A common mistake is to specify control points as CCP’s.)

(b) Important considerations when using the decision tree.

(1) The decision tree is used after the hazard analysis.

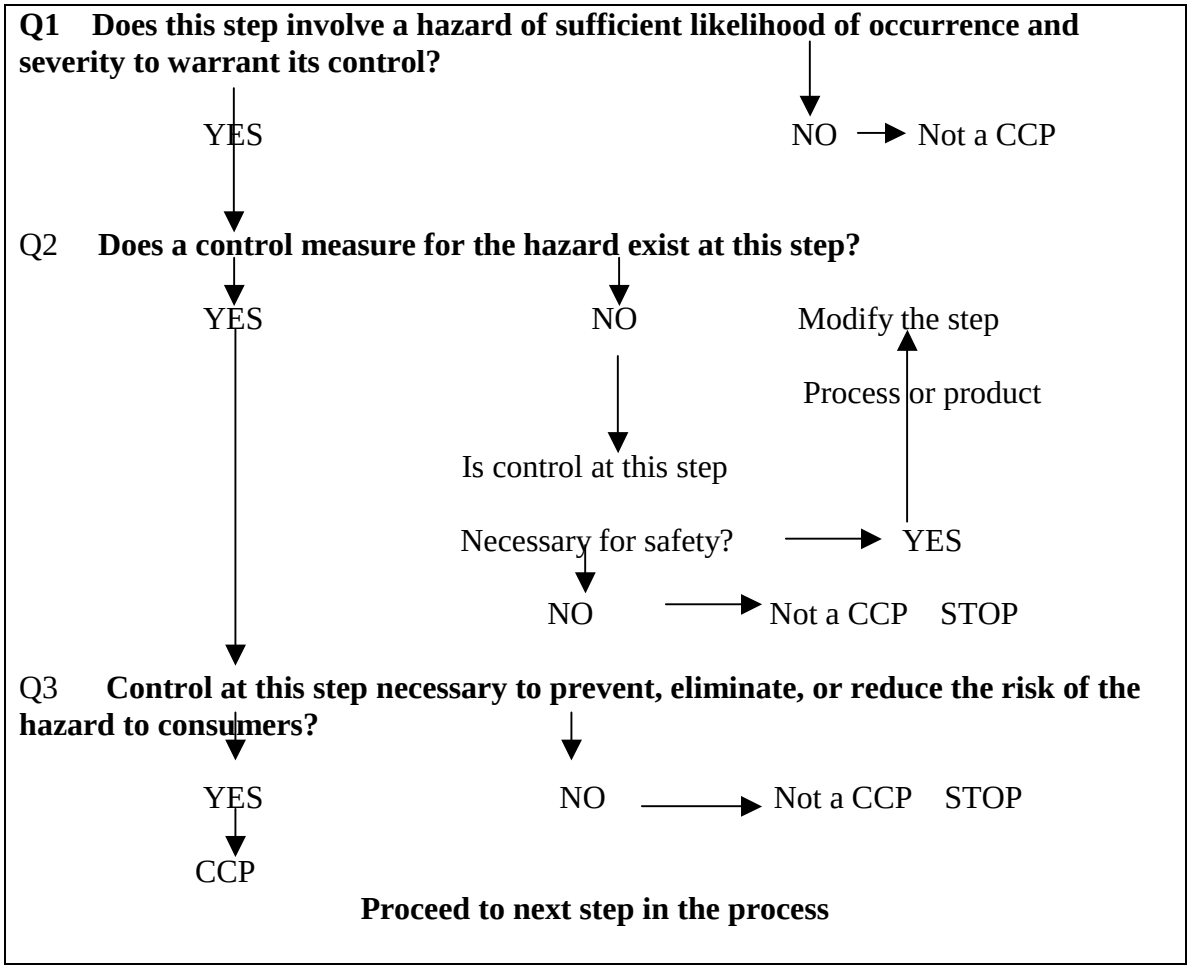
(2) The decision tree then is used at the steps where a hazard that must be addressed in the HACCP plan had been identified.

(3) A subsequent step in the process may be more effective for controlling a hazard and may be the preferred CCP.

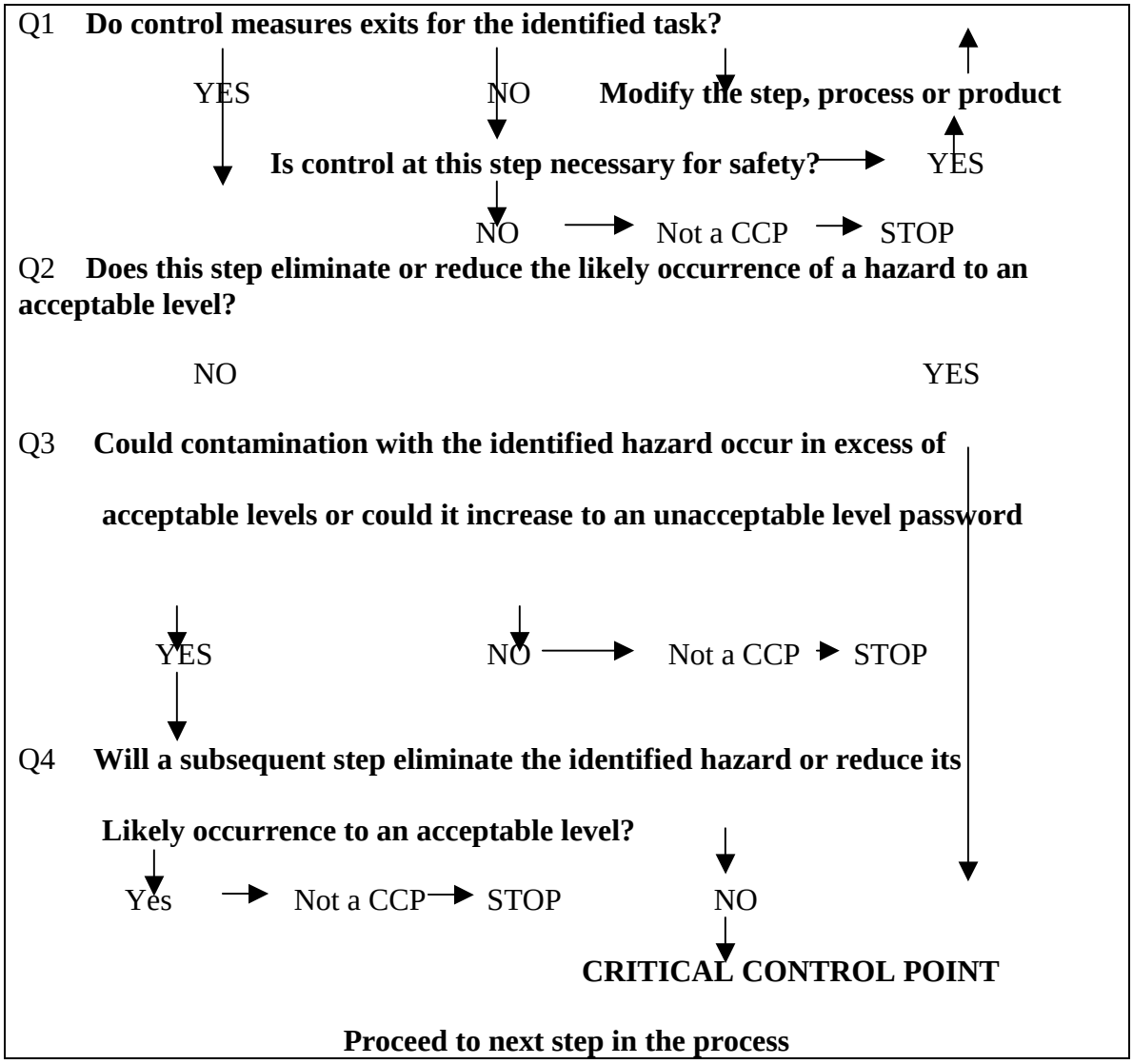
(4) More that one step is a process may be involved in controlling a hazard.

(5) More than one hazard may be controlled by a specific control measure.

EXAMPLE 1.


Q1 Does this step involve a hazard of sufficient likelihood of occurrence and severity to warrant its control?
YES
NO
Not a CCP
Q2 Does a control measure for the hazard exist at this step?
YES
NO
Modify the step
Process or product
Is control at this step
Necessary for safety?
YES
NO
Not a CCP
STOP
Q3 Control at this step necessary to prevent, eliminate, or reduce the risk of the hazard to consumers?
YES
NO
Not a CCP
STOP
CCP
Proceed to next step in the process

EXAMPLE 2


Q1 Do control measures exits for the identified task?
YES
NO
Modify the step, process or product
Is control at this step necessary for safety?
YES
NO
Not a CCP
STOP
Q2 Does this step eliminate or reduce the likely occurrence of a hazard to an acceptable level?
NO
YES
Q3 Could contamination with the identified hazard occur in excess of acceptable levels or could it increase to an unacceptable level password
YES
NO
Not a CCP
STOP
Q4 Will a subsequent step eliminate the identified hazard or reduce its Likely occurrence to an acceptable level?
Yes
Not a CCP
STOP
NO
CRITICAL CONTROL POINT
Proceed to next step in the process

LIST OF SUPPORTING PAPERS

A. Student workbook

B. Decision Tree

C. Logical Sequence

D. Hazard Analysis (completed form

E. Hazard Analysis (blank Form)

Assemble HACCP Team

Describe Product

Identify Intended Use

Conduct Flow Diagram

On-Site Confirmation of the Flow Diagram

Hazard Analysis, List all Potential Hazards

Determine Critical Control Points

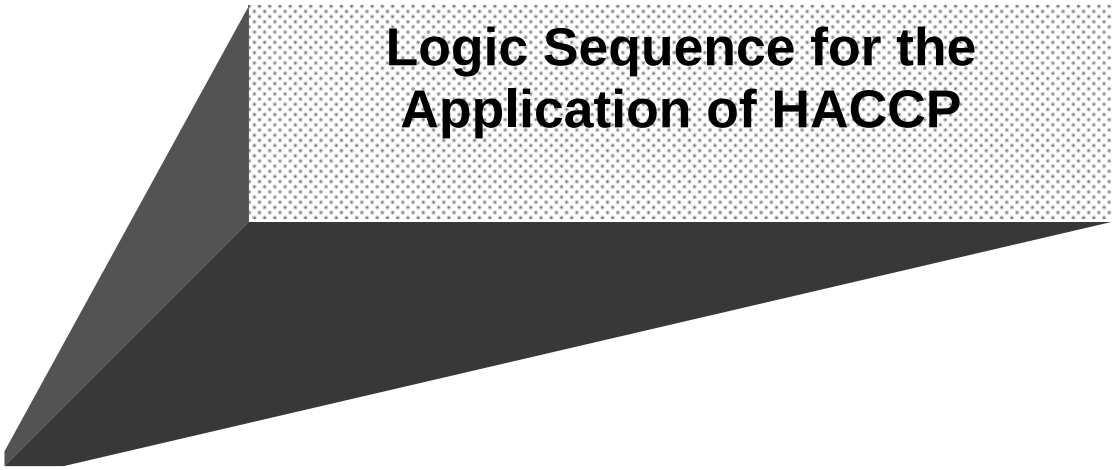
Establish Critical Limits

Monitoring System

Corrective Actions

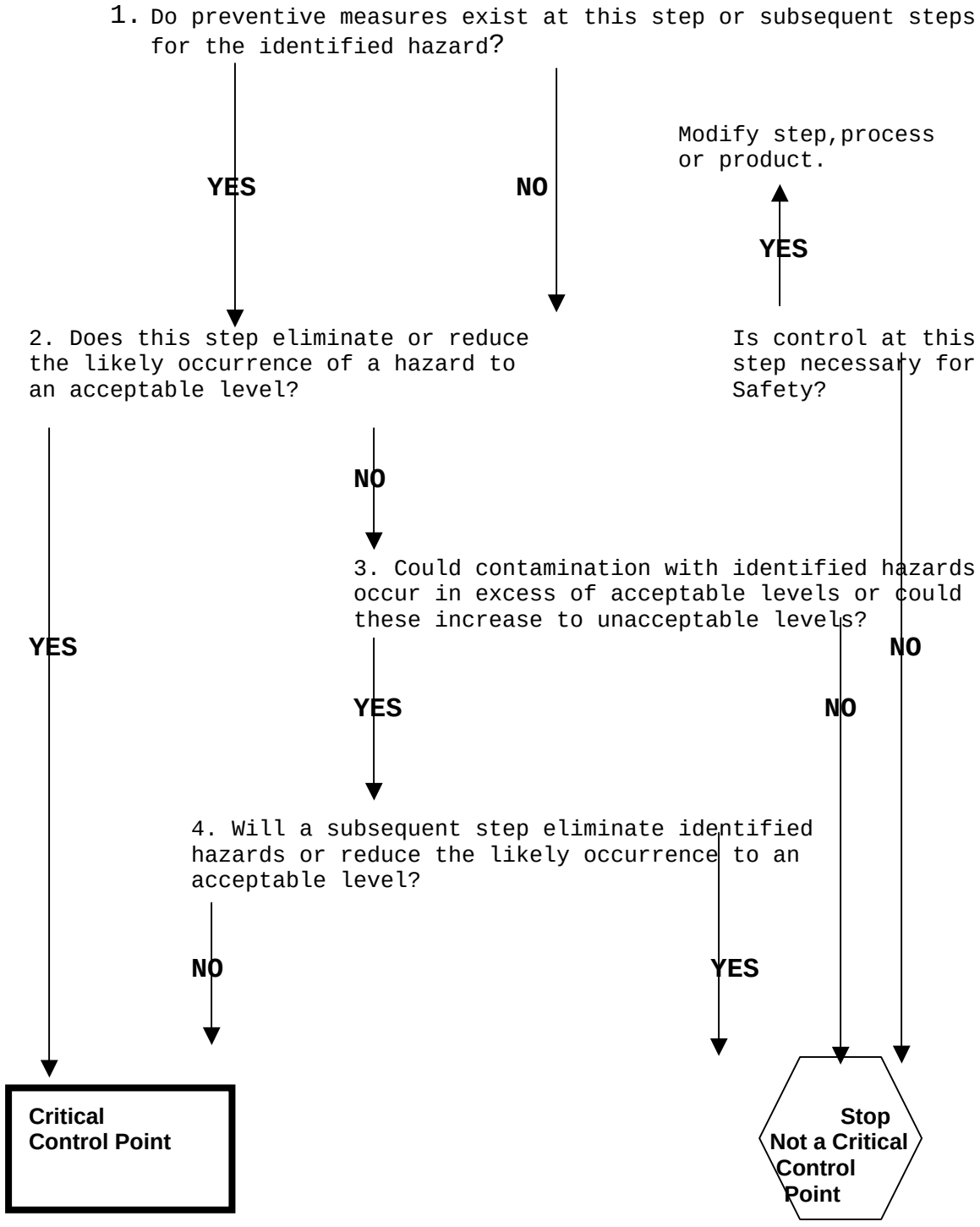
Verification Procedures

Record Keeping



Logic Sequence for the Application of HACCP

CCP DECISION TREE



A decision tree is tools a used to determine which control points are CCP's. Although the cook step is typically the CCP, in many instances all points prior to cook step must be carefully evaluated with the decision tree process to determine

if they are CCP’s. (A common mistake is to specify control points as CCP’s.

Definitions

For the purpose of this Code, the following expressions have the meaning stated:

Cleaning - the removal of soil, food residue, dirt, grease or other objectionable matter.

Contaminant - any biological or chemical agent, foreign matter, or other substances not intentionally added to food, which may compromise food safety or suitability.

Contamination - the introduction or occurrence of a contaminant in food or food environment.

Disinfection - the reduction, by means of chemical agents and/or physical methods, of the number of microorganisms in the environment, to a level that does not compromise food safety or suitability.

Establishment - any building or area in which food is handled and the surroundings under the control of the same management.

Food Hygiene - all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

Hazard - a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

HACCP - a system that identifies, evaluates, and controls hazards, which are significant for food safety.

Food handler - any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements

Food safety – is assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Food suitability – is assurance that food is acceptable for human consumption according to its intended use.

Primary production - those steps in food chain up to and including, for example, harvesting, slaughter, milking, fishing.