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9 CFR ' 417; Food Safety and Inspection Service (FSIS).	21 CFR ' 123; Food and Drug Administration (FDA).	Adopted August 14, 1997, by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) as a revision of their 1992 adopted HACCP System document. From the Journal of Food Protection, Volume 61, Number 9, 1998, pages 1246-1259, and as noted in the article, this article may reproduced without permission. Tables, figures, appendixes, references, and some introductory text portions are not included in this comparison document.	Adopted June 1997; Codex Alimentarius Commission and the FAO/WHO Food Standards Programme, annex to CAC/RCP 1-1969, Rev. 3.
	********** NOTE: Order of information is realigned to match, where possible, 9 CFR § 417. **********	********** NOTE: Order of information is realigned to match, where possible, 9 CFR § 417. **********	********** NOTE: Order of information is realigned to match, where possible, 9 CFR § 417. **********
' 417.2 Hazard Analysis and HACCP Plan:	**' 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) Plan:**	**HACCP principles:** HACCP is a systematic approach to the identification, evaluation, and control of food safety hazards based on the following seven principles.	**Principles of the HACCP system:** The HACCP system consists of the following seven principles.
(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive	(a) Hazard analysis. Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by	**(Realigned from page 1249 as one of the seven principles of HACCP). 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	(**Realigned 6). List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards (SEE PRINCIPLE 1):** The HACCP team should list all of the hazards that may be reasonably expected

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measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.	that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.	purpose of the hazard analysis is to develop a list of hazards that 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 an 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. 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. The hazard analysis and identification of associated control measures accomplish three	to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption. The HACCP team should next conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food. In conducting the hazard analysis, wherever possible the following should be included: the likely occurrence of hazards and severity of their adverse health effects; the qualitative and/or quantitative evaluation of the presence of hazards; survival or multiplication of microorganisms of concern; production or persistence in foods of toxins, chemicals or physical agents; and, conditions leading to the above. The HACCP team must then consider what control measures, if any, exist which can be applied for each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

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		objectives: Hazards that are to be controlled in the HACCP plan 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 CCPs in Principle 2. The process of conducting a hazard analysis involves two stages. The first, hazard identification, can be regarded as a brainstorming 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. Appendix C (not included in this comparison document) lists examples of questions that may be helpful to consider when identifying potential hazards. Hazard identification focuses on developing a list of	

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		potential hazards associated with each process step under direct control of the food operation. A knowledge of any adverse health-related events historically associated with the product will be of value in this exercise. 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 on 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,	

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		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 may 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. Hazards identified in one operation or facility may not be significant in another operation producing the same or a similar product. For example, because of differences in equipment or maintenance programs, the probability of	

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		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. Appendix D (not included in this comparison document) gives three examples of using a logic sequence in conducting a hazard analysis. Although these examples relate to biological hazards, chemical and physical hazards are equally important to consider. Appendix D (not included in this comparison document) is for illustration purposes to further explain the stages of hazard analysis for identifying hazards. Hazard identification and evaluation as outlined in Appendix D (not included in this comparison document) may eventually be assisted by biological risk assessments as they become available. Although the process and output of a risk assessment is significantly different from a hazard analysis, the identification of hazards of concern and the hazard evaluation may be facilitated by information from risk assessments.	

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		Thus, as risk assessments addressing specific hazards or control factors become available, the HACCP team should take these into consideration. On 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). For example, if a HACCP team were to conduct a hazard analysis for the production of frozen cooked beef patties (Appendices B and D, not included in this comparison document), enteric pathogens (e.g., Salmonella and verotoxin-producing Escherichia coli) in the raw meat would be identified as hazards. Cooking is a control measure that can be used to eliminate these hazards. Table 1 (not included in this comparison document) is an excerpt from a hazard analysis summary table for this product. The hazard	

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		analysis summary could be presented in several different ways. One format is a table such as Table 1 (not included in this comparison document). 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.	
(2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared,		**(Realigned from page 1249 as one of the five preliminary tasks). Develop a flow diagram that 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 that are directly under the control of the establishment. In addition, the flow diagram can include steps in the food chain that 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 (see Appendix B, not included in this comparison document). Also, a simple schematic of the facility is often useful in understanding and evaluating product and process flow.	**(Realigned 4). Construct flow diagram:** The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

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		(**Realigned from page 1249 as one of the five preliminary tasks). 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.	**(Realigned 5). On-site confirmation of flow diagram:** The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate.
((a)(2) continued) and the intended use or consumers of the finished product shall be identified.		(**Realigned from page 1249 as one of the five preliminary tasks). 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.).	**(Realigned 3). Identify intended use:** The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g., institutional feeding, may have to be considered.
(3) Food safety hazards might be expected to arise from the following:	(Realigned from § 123.6(c)(1)) Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:		
(i) Natural toxins;	(i) Natural toxins		
(ii) Microbiological contamination;	(ii) Microbiological contamination;		
(iii) Chemical contamination;	(iii) Chemical contamination;		
(iv) Pesticides;	(iv) Pesticides;		

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(v) Drug residues; (vi) Zoonotic diseases;	(v) Drug residues		
(vii) Decomposition;	(vi) Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;		
(viii) Parasites;	(vii) Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;		
(ix) Unapproved use of direct or indirect food or color additives; and	(viii) Unapproved use of direct or indirect food or color additives; and		
(x) Physical hazards.	(ix) Physical hazards;		
(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the	(b) The HACCP plan. Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, as described in paragraph (a) of this section. A HACCP plan shall be specific to: (1) Each location where fish and fishery products are processed by that processor; and (2) Each kind of fish and fishery product		

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following processing categories: (i) Slaughter--all species. (ii) Raw product—ground. (iii) Raw product--not ground. (iv) Thermally processed—commercially sterile. (v) Not heat treated—shelf stable. (vi) Heat treated—shelf stable. (vii) Fully cooked—not shelf stable. (viii) Heat treated but not fully cooked—not shelf stable. (ix) Product with secondary inhibitors—not shelf stable. (2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.	processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are identical for all fish and fishery products so grouped or for all production methods so grouped.		
3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product	(Realigned) (e) Products subject to other regulations. For fish and fishery products that are subject to the requirements of part 113 or 114 of this chapter, the HACCP plan need		

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is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.	not list the food safety hazard associated with the formation of Clostridium botulinum toxin in the finished, hermetically sealed container, nor list the controls to prevent that food safety hazard. A HACCP plan for such fish and fishery products shall address any other food safety hazards that are reasonably likely to occur.		
(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:	(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:		
(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.	(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with paragraph (a) of this section, and that thus must be controlled for each fish and fishery product.		
(2) List the critical control points for each of the identified food safety hazards, including, as appropriate: (i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and (ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;	(2) List the critical control points for each of the identified food safety hazards, including as appropriate: (i) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment; and (ii) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest;	**(Realigned from page 1250 as one of the seven principles of HACCP). Determine the critical control points (CCPs) (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 CCPs. Complete	**(Realigned 7). Determine Critical Control Points (SEE PRINCIPLE 2):** There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree (e.g. Diagram 2, not included in this comparison document), which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production,

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		and accurate identification of CCPs 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 CCPs. One strategy to facilitate the identification of each CCP is the use of a CCP decision tree (Examples of decision trees are given in Appendices E and F, not included in this comparison document). 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. Critical control points are located at any step where hazards can be either prevented, eliminated, or reduced to acceptable levels. Examples of CCPs may include thermal processing, chilling, testing ingredients for chemical residues, product formulation control, and testing product for metal contaminants. CCPs 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	slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision tree is recommended. If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

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		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 CCPs. Different facilities preparing similar food items can differ in the hazards identified and the steps that are CCPs. This can be because of differences in each facility's layout, equipment, selection of ingredients, processes employed, etc.	
(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;	(3) List the critical limits that must be met at each of the critical control points;	**(Realigned from page 1251 as one of the seven principles of HACCP). 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. Each CCP will have one or	**(Realigned 8). Establish critical limits for each CCP (SEE PRINCIPLE 3):** Critical limits must be specified and validated if possible for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, Aw, available chlorine, and sensory parameters such as visual appearance and texture. Since the publication of the decision tree by Codex, its use has been implemented many times for training purposes. In many instances, while this tree has been useful to explain the logic

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		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 on 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. An example is the cooking of beef patties (Appendix B not included in this comparison document). 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	and depth of understanding needed to determine CCPs, it is not specific to all food operations, e.g. slaughter, and therefore it should be used in conjunction with professional judgement, and modified in some cases.

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		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 that 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 Table 2 (not included in this comparison document). In this example, the HACCP team concluded that a thermal process equivalent to 155^{o}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	

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		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 in Table 2 (not included in this comparison document) applies to the first facility.	
(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;	(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;	**(Realigned from page 1251 as one of the seven principles of HACCP). Establish monitoring procedures (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 toward loss of	**9. Establish a monitoring system for each CCP (SEE PRINCIPLE 4):** Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results

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		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. 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	indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

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		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. Assignment of the responsibility for monitoring is an important consideration for each CCP. Specific assignments will depend on the number of CCPs and control measures and the complexity of monitoring. Personnel who monitor CCPs 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 toward 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	

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		must also immediately report a process or product that does not meet critical limits. 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. 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. Microbiological tests are seldom effective for monitoring because of 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	

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		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. 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.	
(5) Include all corrective actions that have been developed in accordance with Sec. 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and	(5) Include any corrective action plans that have been developed in accordance with Sec. 123.7(b), to be followed in response to deviations from critical limits at critical control points;	**(Realigned from page 1252 as one of the seven principles of HACCP). 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	**10. Establish corrective actions (SEE PRINCIPLE 5):** Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur. The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be

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		important purpose of corrective actions is to prevent foods that 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 noncompliance; (b) determine the disposition of noncompliant 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 of the actions taken will be developed and maintained. 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 noncompliant product.	documented in the HACCP record keeping.
(6) Provide for a recordkeeping system that documents the monitoring of	(Realigned 7). Provide for a recordkeeping system that documents the monitoring of	**(Realigned from page 1253 as one of the seven principles of HACCP). Establish**	**(Realigned 12). Establish Documentation and Record Keeping (SEE PRINCIPLE 7):**

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the critical control points. The records shall contain the actual values and observations obtained during monitoring.	the critical control points. The records shall contain the actual values and observations obtained during monitoring.	**record-keeping and documentation procedures (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 (listing of the HACCP team and assigned responsibilities; description of the food, its distribution, intended use, and consumer; verified flow diagram); HACCP Plan Summary Table that includes information for: (Steps in the process that are CCPs; the hazard(s) of concern; critical limits; monitoring*; corrective actions*; verification procedures and schedule*; record-keeping procedures*. [* A brief summary of position responsible for performing the activity and the procedures and frequency should be provided.] Table 4 (not included in this comparison document) is an example of the format for a HACCP plan summery table. 3. Support documentation such as validation records. 4. Records that are generated during the operation of the plan. Examples of HACCP records are given in Appendix H (not included in this comparison document).	Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation. Documentation examples are: Hazard analysis; CCP determination; critical limit determination. Record examples are: CCP monitoring activities; deviations and associated corrective actions; modifications to the HACCP system. An example of a HACCP worksheet is attached as Diagram 3 (not included in this comparison document).

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(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with Sec. 417.4 of this part.	(realigned) (6) List the verification procedures, and frequency thereof, that the processor will use in accordance with Sec. 123.8(a);	(**Realigned from page 1252 as one of the seven principles of HACCP). 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 National Academy of Sciences 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 plan and maintenance of the HACCP system. An example of a verification schedule is given in Table 3 (not included in the comparison document). 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, because 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	**(Realigned 11). Establish verification procedures (SEE PRINCIPLE 6):** Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include: Review of the HACCP system and its records; review of deviations and product dispositions; confirmation that CCPs are kept under control. Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan.

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		HACCP plan, verification that the HACCP plan is being correctly followed, and review of CCP monitoring and corrective action records. 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. 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;	

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		a significant product, process, or packaging change occurs; or new hazards are recognized. 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 identifies deficiencies, the HACCP team modifies the HACCP plan as necessary. 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. The role of regulatory and industry in HACCP was further described by the NACMCF. Examples of verification activities are included as Appendix G (not	

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		included in this comparison document).	