Chapter 9

PROCESS PREVENTIVE CONTROLS FOR HUMAN FOOD

Parameters and values (including Critical Limits), Monitoring, Corrective Action

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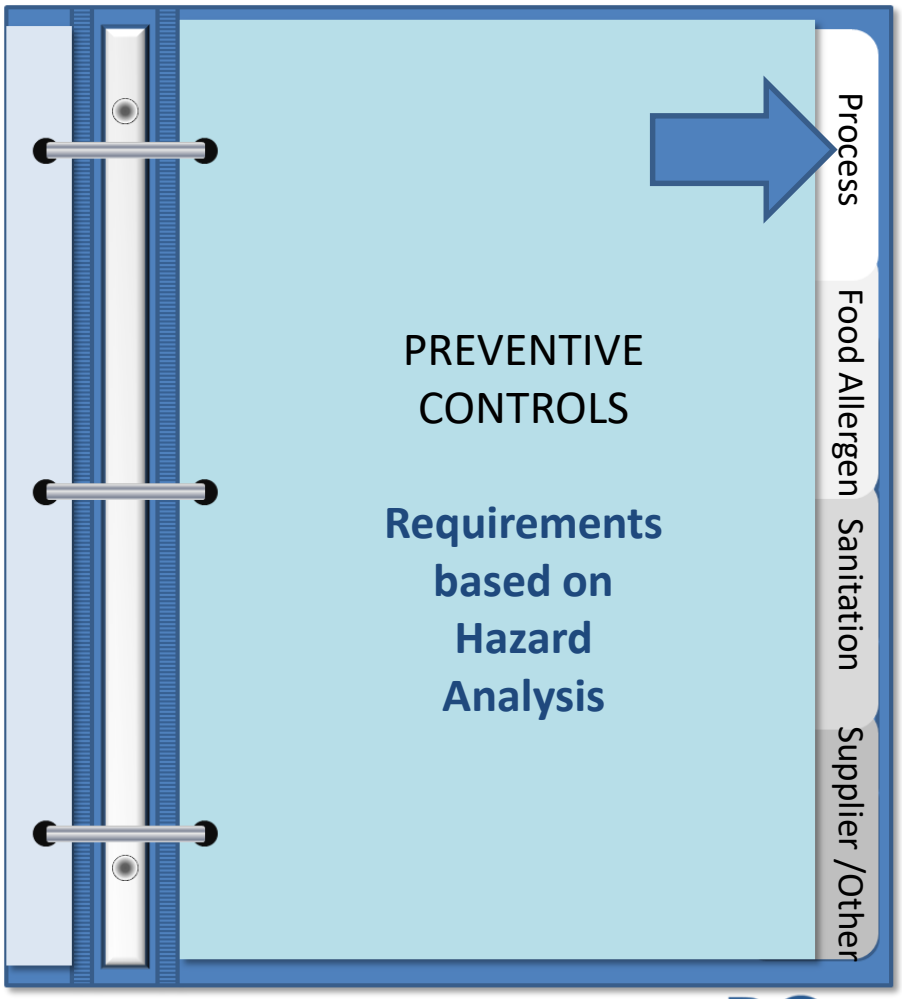
Process Preventive Controls Objectives

In this module you will learn:

- Food safety principles for <u>process</u> preventive controls including:
  - Parameters and values associated with the control (e.g., critical limits)
  - Monitoring procedures for process preventive controls, including Critical Control Points (CCPs)
  - Corrective actions for process control deviations



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Blank Process Control Form

PRODUCT: PAGE 1 of X
PLANT NAME: ISSUE DATE mm/dd/yy
ADDRESS: SUPERSEDES mm/dd/yy

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

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E.G. Food Company Example

Hazard Analysis Form

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit		PAGE X of Z
PLANT NAME: E.G. Food Company	ISSUE DATE	mm/dd/yy
ADDRESS: 360 Culinary Circle, Mytown, USA	SUPERSEDES	mm/dd/yy

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Do any potential food safety hazards require preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
Cook [eggs, milk, salt, pan release oil]	B **Survival of vegetative pathogens such as *Salmonella***	X		Thorough cooking is required to kill vegetative pathogens	Process Control – Cooking to achieve a lethal temperature	**X**	

Process Control Form

PRODUCT: Omelet – Plain, Cheese and Cheese Biscuit		PAGE Y of Z
PLANT NAME: E.G. Food Company	ISSUE DATE	mm/dd/yy
ADDRESS: 360 Culinary Circle, Mytown, USA	SUPERSEDES	mm/dd/yy

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Survival of vegetative pathogens such as *Salmonella*								

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Critical Limits – A Food Safety Principle

- Key discussion points
  - Definition of critical limit
  - How to determine critical limits for a CCP
  - The relationship between critical limits and operating limits
  - Use of the Process Control Form

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Critical Limit Definition

- The maximum or minimum value, or combination of values, to which any biological, chemical or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.
  - Derived from 21 CFR 117.135(c)(1)(ii)

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Sources of Information on Critical Limits

Information Source	Examples
FDA	Hazard Guides; guidelines, tolerances and action levels; Food Code; Pasteurized Milk Ordinance (PMO); Acidified Foods regulations
Other regulatory guidelines	State and local regulations, tolerances and action levels; USDA regulations, tolerances and action levels
Experts (internal and external)	Process authorities, university food scientists/ microbiologists, consultants, equipment manufacturers, sanitarians, trade associations
Scientific studies	In-house experiments, 3rd party challenge studies (universities or contract labs)
Scientific literature	Peer reviewed journals, food science texts, microbiology texts, Food Safety Preventive Controls Alliance information

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Critical Limit Considerations

- If a critical limit is not met, a hazard is not necessarily controlled and the safety of the product is in question
- Critical limits must be achievable
- Often a variety of options exist for controlling a particular hazard
- The selection of the best control option and critical limit is often driven by practicality and experience

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Critical Limit Examples

Product	Hazard	Critical Control Point	Critical Limit Example*
Battered product	*Staphylococcus aureus* growth and toxin formation	Batter application	Hydrated batter does not exceed 50°F (10°C) for more than 12 hr OR 70°F (21°C) for more than 3 hr, cumulative
Chopped product	Metal inclusion	Metal detector	No detectable metal fragments in finished product OR Knife blades are intact after each run
High a_W ready-to-eat foods	Pathogen growth	Cooler storage	Cooler temperature ≤41°F (5°C)

* Specific critical limits are product dependent

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Critical Limits Examples w/ Several Parameters*

Product	Hazard	Critical Control Point	Critical Limit Example
Ready-to-eat cooked and refrigerated product	*Listeria monocytogenes* survival	Cooking	≥160°F (71°C) internal product temperature for ≥1.5 min
Dried product	Pathogen growth	Drying oven	Drying schedule – Oven temperature ≥200°F (93.3°C) Time ≥120 minutes Air flow rate ≥2 ft^3/min Product thickness ≤0.5 inches (to achieve a_w ≤0.85)
Acidified product	*Clostridium botulinum* in pickled foods	Acidification	Batch schedule – Product weight < 100 lb Soak time ≥8 hr Acetic acid concentration ≥3.5%, volume ≥50 gal (to achieve maximum pH of 4.6)

* Other critical limits may be needed for other pathogens in the same product

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Example Critical Limit – Batch Process

Product:	Frozen omelet
Hazard:	Vegetative pathogens such as *Salmonella*
CCP:	Cooking
Critical limit:	Minimum product temperature of ≥158°F (70°C)*
Applicability:	Individual cook, batch process

*Based on 2013 Food Code instantaneous temperature for cooking products containing raw eggs

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Example Critical Limit – Continuous Process

Product:	Frozen omelet
Hazard:	Vegetative pathogens such as *Salmonella*
CCP:	Cooking
Critical limits:	• Oven temperature X °F (Y°C) • Belt speed X feet/minute • Batter volume in standard pan size
Applicability:	Belt fed oven

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E.G. Food Company Example

PRODUCT: Omelet - Plain
PLANT NAME: E.G. Food Company
ADDRESS: 360 Culinary Circle, Mytown, USA

PAGE 1 of X
ISSUE DATE mm/dd/yy
SUPERSEDES mm/dd/yy

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Vegetative pathogens such as *Salmonella*	Omelet temperature is ≥158°F (70°C) instantaneous before transfer to assembly table							

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Monitoring – A Food Safety Principle

- Key discussion points:
  - Definition of monitoring
  - Purpose of monitoring
  - Design of a monitoring system
  - Methods and equipment for monitoring critical limits

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Monitor Definition

- “To conduct a planned sequence of observations or measurements to assess whether control measures are operating as intended.”
  - 21 CFR 117.3 Definitions

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Purpose of Monitoring Process Controls

- To track the operation of the process and enable the identification of trends toward a critical limit that may trigger process adjustments
- To identify when there is a loss of control or when a “deviation” from a critical limit occurs
- To provide written documentation that can be used to verify that the process is under control

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Elements of Monitoring

1. What to monitor
2. How to monitor
3. Frequency to monitor
4. Who will monitor

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What Might Be Monitored?

Depends on process, examples include:

- Temperature
- Time
- Volume / weight
- Line speed
- Flow rate
- Bed depth
- Acid addition
- pH
- Water activity
- Chemical concentration
- Appearance
- Process performance
- Many others

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How is Monitoring Conducted?

Depends on the nature of the control. Examples include:

- Calibrated thermometer
- Calibrated pH meter
- Calibrated chart recorder
- In-line analyzer
- “Real time” laboratory analysis
- Visual checks

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Continuous Monitoring Considerations

- Continuous monitoring is preferred
- Continuous monitoring examples
  - Temperature recording chart
  - Metal detector
  - Dud detector
  - In-line pH probe
  - Bar code scanner
  - Vision system for foreign material

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Non-continuous Monitoring Considerations

- Used when continuous systems are not feasible
- Frequency of non-continuous monitoring
  - How much does the process normally vary?
  - How close are normal values to the critical limit?
  - How much product is at risk if the critical limit is not met?
- Non-continuous monitoring examples
  - Temperature checks at specified intervals
  - Batch process water activity checks
  - Antimicrobial chemical levels in produce wash water

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Exception Records

- Exception records are generated only when a limit is not met; e.g.,
  - Cooler records when temperature goes above a set limit
  - X-ray that responds only to foreign material
- Often an alarm alerts the operator of a problem
- Exception record systems must be validated

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Who Will Monitor?

- Trained, designated employee
- Not necessarily quality assurance
- Best if it is a different person than the one who verifies records

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Qualifications for Monitoring Individuals

- Trained in monitoring techniques through on-the-job training or similar approaches
- Fully understand the importance of monitoring
- Accurately report each monitoring activity
- Understand actions to take when deviation occurs
  - Immediate corrective actions related to the process
  - Timely report deviation for other actions

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E.G. Food Company Example

PRODUCT: Omelet - Plain — PAGE 1 of X

PLANT NAME: E.G. Food Company — ISSUE DATE mm/dd/yy

ADDRESS: 360 Culinary Circle, Mytown, USA — SUPERSEDES mm/dd/yy

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Cook	Vegetative pathogens such as *Salmonella*	Omelet temperature is ≥158°F (70°C) instantaneous before transfer to assembly table	Omelet temperature is ≥158°F (70°C)	Infrared surface thermometer	Each cook station, 4 times per shift, about every 2-3 hours	QA technician, or designee			

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PRODUCT Omelet - Frozen		PAGE 27 of 34
PLANT NAME: E.G. Food Company	ISSUE DATE	09/20/2015
ADDRESS: 360 Culinary Circle, Mytown, USA	SUPERSEDES	08/06/2015

Cook Log

Hazard: Vegetative pathogens such as *Salmonella*

Parameters, values or critical limits: Omelet temperature is ≥158°F (70°C) instantaneous before transfer to assembly table.

Who, How, Frequency: QA technician or designee, checks an omelet temperature each cook station 4 times/shift (every 2-3 hr) using an infrared surface thermometer.

Corrective Action: Hold product back to the last good check and evaluate – rework, discard, or release. Determine root cause – retrain or correct as appropriate

Date:

Time	Cook Station	Cook name	Temperature (°F)	QA Tech (initials)

Corrective Actions and Corrections

- Key discussion points
  - The definition of corrective action and corrections
  - Procedures for corrective actions
  - Record-keeping requirements for corrective actions

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Definitions

Corrective action

- Procedures that must be taken if preventive controls are not properly implemented.
  - from 21 CFR 117.150(a)(1)

Correction

- An action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).
  - 21 CFR 117.3

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Corrective Actions

- Must be taken when process preventive controls are not properly implemented, resulting in a deviation
  - E.g., there is a deviation from a critical limit
- Unsafe product may have been produced
- Appropriate to the nature of the hazard and preventive control

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Corrective Action Procedures

- Written procedures must describe steps to taken to:
  1. Identify and correct a problem with implementation
  2. Reduce likelihood of occurrence
  3. Evaluate affected food for safety
  4. Prevent affected food from entering commerce if you cannot ensure the food is not adulterated

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Corrective Action Examples

Process Examples

- Immediate adjustment of process
- Employees stop line when deviation occurs
- Apply alternate process
- Repair equipment
- Retrain employees
- Evaluate operation

Product Examples

- Hold product
- Evaluate product
- Determine product disposition
  - Release, rework or destroy product

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Unanticipated Problems Include:

- Preventive control not properly implemented and a corrective action procedure has not been established
- One or more preventive controls are ineffective
- Review of records finds:
  - the records incomplete,
  - the activities did not follow the Food Safety Plan, or
  - corrective action decisions were not appropriate

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Unanticipated Problems

- Required corrective action includes:
  1. Standard corrective action procedures
     - Identify and correct an implementation problem
     - Reduce the likelihood of occurrence
     - Evaluate all implicated product for safety
     - Prevent adulterated or misbranded product from entering commerce
  2. Reanalyze the Food Safety Plan
     - See Chapter 13 Verification and Validation Procedures

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Corrective Actions Required Records

1. Actions taken to identify and correct the problem,
2. Actions taken, when necessary, to reduce the likelihood that the problem will recur
3. Safety evaluation for all affected food
4. Records demonstrate that food that is potentially injurious to health did not enter commerce

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E.G. Food Company Example

Corrective Action Form PLANT NAME: E.G. Food Company ADDRESS: 360 Culinary Circle, Mytown, USA	PAGE 1 of X
Date of Record:	Code or Lot Number:
Date and Time of Problem:	
Description of Problem and Root Cause:	
Actions Taken to Restore Order to the Process:	
Person Taking Action (name and signature) :	
Amount of Product Involved in Problem:	
Evaluation of Product Involved with Problem:	
Final Disposition of Product:	
Reviewed by (Name and Signature):	Date:

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Operating Limit Definition

- Criteria that are more stringent than critical limits and that are used by an operator to reduce the risk of a deviation.
  - National Seafood HACCP Alliance. 2011

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Operating Limit Uses

- Operating limits may be established:
  - For quality reasons
  - To avoid deviating from a critical limit
  - To account for process variability

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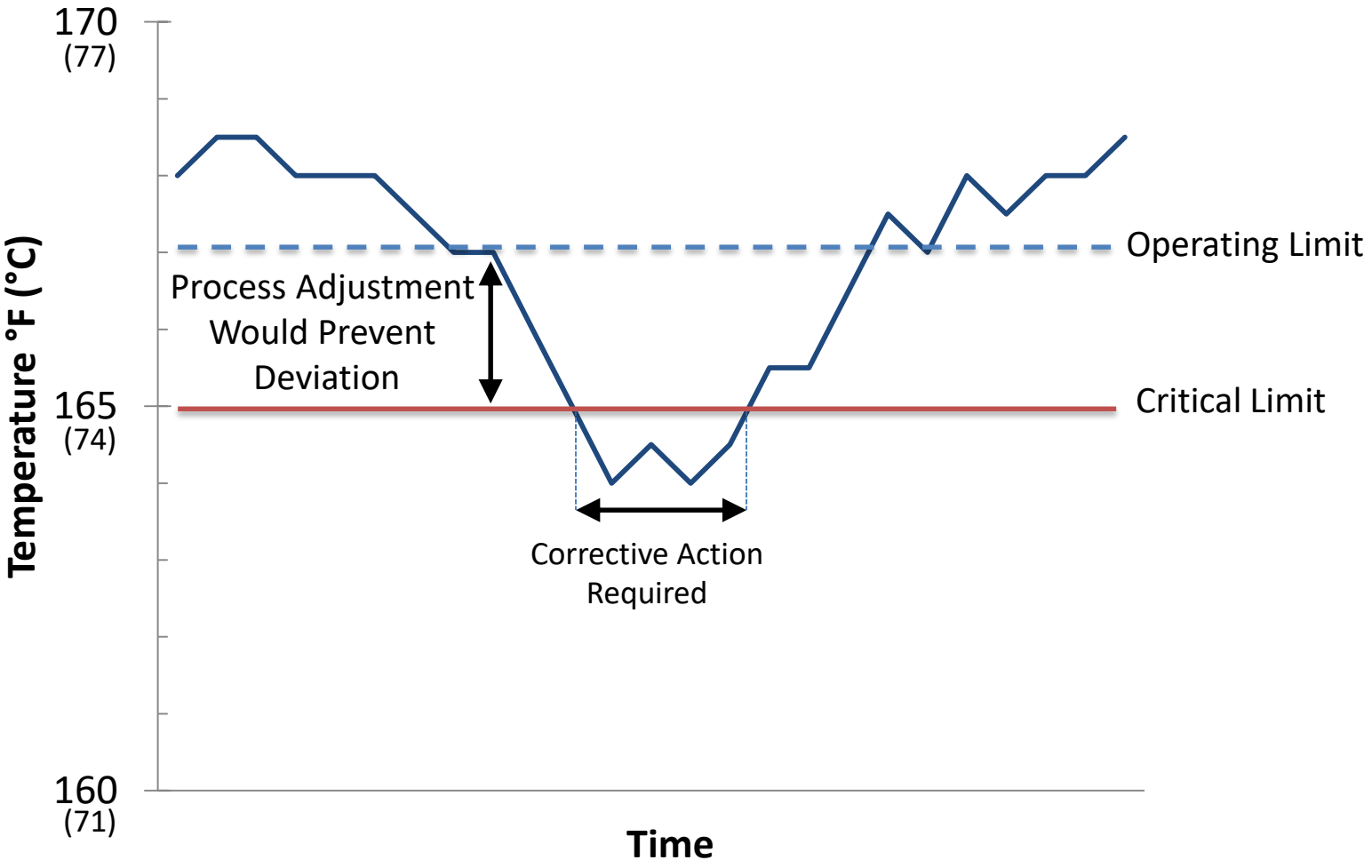
Operating Limits Versus Critical Limits



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E.G. Food Company Example

PRODUCT: Omelet - Plain									PAGE 1 of X
PLANT NAME: E.G. Food Company								ISSUE DATE	mm/dd/yy
ADDRESS: 360 Culinary Circle, Mytown, USA								SUPERSEDES	mm/dd/yy
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Process Preventive Controls Summary

- Procedures must be documented for the process-related hazards requiring a preventive control identified through the hazard analysis process.
  - These controls are usually CCPs.
  - Specific controls depend on the nature of the hazard and the nature of the preventive control.

continued

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Process Preventive Controls Summary

- For each process-related preventive control identified, the following must be recorded, as appropriate:
  - Parameters and values (e.g., valid critical limits) that must be met
  - Monitoring procedures, including what, how, frequency and who
  - Corrective actions that identify the implicated product, determine its disposition, correct the cause and determine that the preventive controls are working again
    - Corrections may be appropriate in some situations
  - Verification and records (discussed in subsequent chapters)

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EXERCISE

- Use the hazard analysis from the previous exercise.
- Was a hazard requiring a process preventive control identified in the hazard analysis?
- Complete a process preventive control form through the corrective action column for **ONE** step in the model plan process. Useful questions to guide discussion:
  - What do you do to control the step?
  - What considerations did you take into account?
- Potential resources:
  - Hazards chapters and Appendix 4 on biological hazards
- Pick a spokesperson to summarize the process to the rest of the class.

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