HACCP Model for Raw, Non-Intact Turkey

The United States Department of Agriculture (USDA) published the Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) Systems Final Rule in July 1996 mandating all USDA inspected meat and poultry establishments implement a HACCP system. Hazard Analysis Critical Control Point (HACCP) is a systematic and scientific method of process control for the production of safe food products. The HACCP regulations (9 CFR Part 417) require establishments to develop and implement a system of controls designed to improve the safety of their products. The HACCP models' focus is on product safety, not product quality characteristics.

With the rule, FSIS made available a guidebook for the preparation of HACCP plans and a generic model for each food processing category defined in regulation (9 CFR 417.2(b)(1)). The guidebook and the generic models have been revised since their initial publication to be consistent with current science and policy. FSIS recommends you use the updated Guidebook for the Preparation of HACCP Plans when developing an establishment-specific HACCP plan.

Generic models serve as useful examples of how to meet the regulatory requirements. Each model represents a food processing category. Each processing category may contain numerous products. Therefore, each single model represents a category of products and, as such, the models do not demonstrate unique products or novel processes. The generic models are not intended to be used "as is". Establishments are to tailor the model(s) to fit the establishment's operation.

This Raw, Non-Intact model uses a ground turkey product to demonstrate hazard analysis and HACCP plan principles. The model may serve as a starting point for any ground poultry product. The model's critical control points (CCPs) do not necessarily apply to all operations or products. Products or operations may require fewer or more CCPs depending on the operation. The flow diagram demonstrates a general production process and should be modified to reflect the processes used at the establishment. The food safety critical limits selected must come from scientific documents or other reliable sources. This model includes references for guidance on the selection of critical limits.

The records produced while documenting a HACCP plan, including all documentation used to support the hazard analysis are HACCP records (CFR 417.5(a)). The selection of processing categories and HACCP models are preliminary steps to completing a hazard analysis. The documents produced during the selection process are HACCP records. Ensure you maintain the documents produced while developing a HACCP plan.

For further assistance with developing HACCP plans see the Guidebook for the Preparation of HACCP Plans and the guidance materials available on the FSIS HACCP webpage.[1]

[1] This information is best suited for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP model is for demonstration purposes only. The model does not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products.

EXAMPLE PRODUCT DESCRIPTION[2]

Process Type and Product Name: Raw, Non-Intact Turkey

Product Name	Fresh or Frozen Ground Turkey (Raw, Non-Intact)
Important product characteristics (A_w, pH, Preservatives, etc.)	None
How it is to be used	For further processing at this facility or another establishment or intended for cooking for or by end consumer[3]
Packaging (durability and storage conditions)	Tray packs (Case ready)
Shelf life and at what temperature[4]	7 Days at <40ºF; 180 days at < 0ºF
Where it will be sold (Specify intended consumers, especially at-risk populations)[5]	Sold direct to another establishment or to household consumers through retail outlets or distributed to hotels, restaurants, and institutions (HRI).
Labeling instructions	Product name, keep refrigerated or frozen, safe handling instructions, nutrition facts, establishment number, and cooking instructions
Special distribution control	Keep refrigerated or frozen

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[2] Prior to developing the HACCP plan please read the FSIS Guidebook for the Preparation of HACCP Plans for detailed descriptions of the worksheets and hazard analysis. The FSIS Guidebook for the Preparation of HACCP Plans and the generic HACCP models are intended for small and very small establishments seeking assistance in understanding the requirements in Title 9 Code of Federal Regulations (9 CFR) Part 417. The HACCP models are for demonstration purposes only. The models do not represent requirements that must be met. Establishments are required to develop HACCP plans specific to their facilities, production practices, and products.
[3] The intended use or consumer of the product must be identified in accordance with 9 CFR 417.2(a)(2). Identifying the product's intended use in the product description is one way to meet the regulatory requirements specific to 417.2(a)(2).
[4] Each establishment's products may have their own defined product shelf life.
[5] At-risk populations include young children, the elderly, and immunocompromised persons.

EXAMPLE LIST OF PRODUCT INGREDIENTS AND INCOMING MATERIAL[6]

Process Type and Product Name: Raw, Non-Intact Turkey

Meat and Meat by-products	Turkey trim (dark and light meat, skin on and skin off) from outside source purchase and in-house slaughter operations
Non-meat food ingredients	None
Antimicrobial interventions and processing aids[7]	Antimicrobial Acid[8]
Packaging materials	Tray packaging, retail plastic packaging and roll-stock plastic, self-adhesive labels
Restricted ingredients and allergens	None
Other	None

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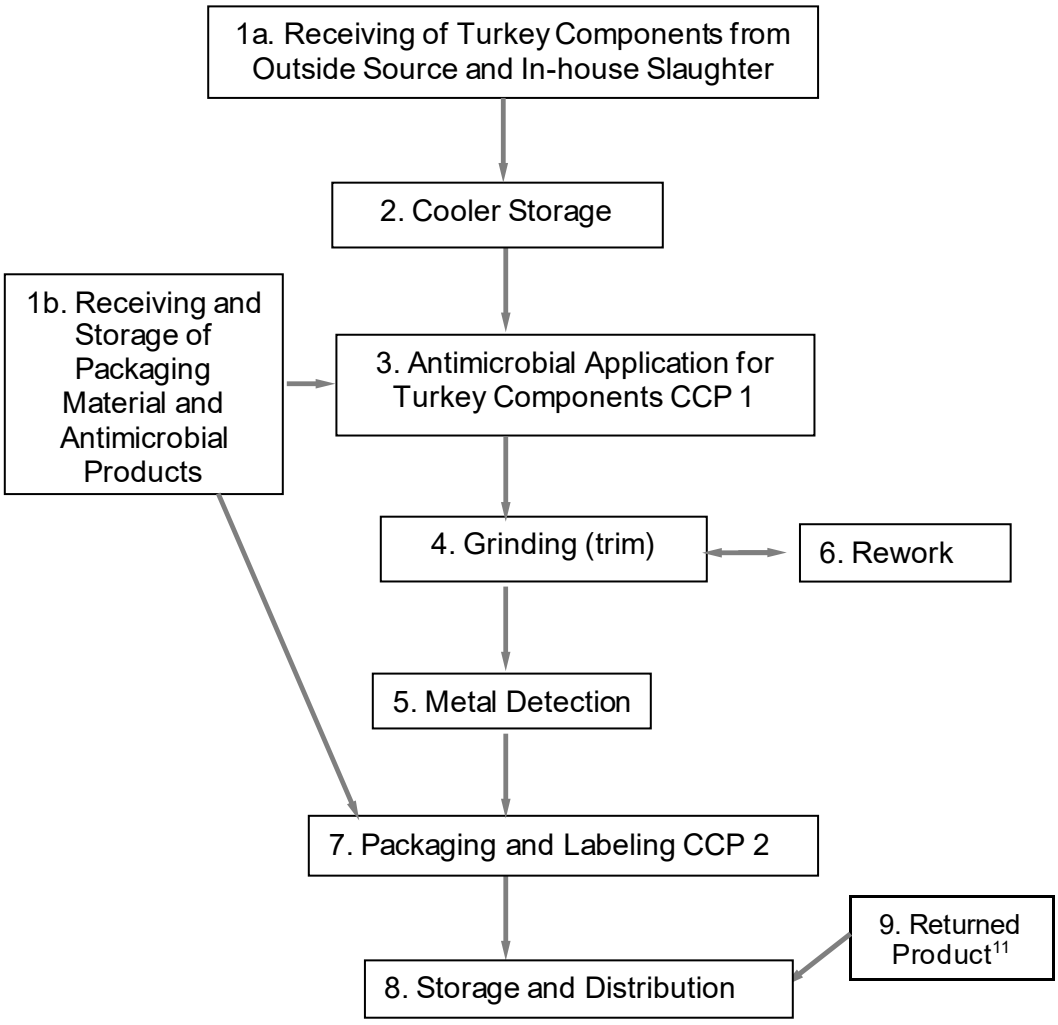
[6] List all meat, non-meat ingredients, restricted ingredients (for example, nitrites), processing aids, and packaging material used in production of this product. This is important to help identify any special ingredients or processes to address in the HACCP plan. See the FSIS Compliance Guideline Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling for detailed information on allergens. To review restrictions on the use of nitrite and sodium ascorbate or sodium erythorbate, see 9 CFR 424.22(b).

[7] FSIS and the Food and Drug Administration (FDA) have a memorandum of understanding (MOU) that establishes the working relationship followed when responding to notifications for the use of food additives (including ingredients) intended for use in the production of FSIS regulated products. FSIS determines the suitability of the use of food ingredients used in the production of meat, poultry, and egg products. FSIS consults, as necessary, with FDA on the requirements under the Federal Food, Drug & Cosmetic Act and its implementing regulations. See FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products for the list of suitable ingredients.

[8] Antimicrobial interventions even if considered processing aids must be addressed in the HACCP system. See the FSIS Compliance Guideline HACCP Systems Validation April 2015 (page 5).

EXAMPLE PROCESS FLOW DIAGRAM[9]

Process Type and Product Name: Raw, Non-Intact Turkey[10]



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[9] This is an example flow diagram. Establishments' flow diagrams for the same product may be different. Establishments determine which steps are included in their process. The steps must represent all relevant hazards in the hazard analysis.
[10] If receiving both in-house and outside (purchased) trim, product flow and lots should be separated for traceability reasons. When in-house and purchased trim is combined, maintain a record of the finished product source material(s).
[11] The Returned Product step (9) is shown connected to step 8 Storage and Distribution. Returned product may re-enter the production system at different process steps depending on condition or problem. Returned product may be relabeled, re-ground, discarded, tempered, etc.

EXAMPLE HAZARD ANALYSIS[12]

Raw, Non-Intact Turkey

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Ingredient / Process Step	**Potential Hazards (introduced or controlled) at this Step[13]**	**Is the Potential Food Safety Hazard Reasonably Likely to Occur (RLTO)? (Yes or No)[14]**	**Justification / Basis for Decision in Column 3[15]**	**If yes in Column 3 (hazard RLTO), What Control Measures Can Be Applied to Prevent, Eliminate, or Reduce the Hazard to Acceptable Levels[16]**	**Is this Step a Critical Control Point (CCP)?[17]**
1a. Receiving of Turkey Components from Outside Source and In-house Slaughter	B: Outgrowth of Pathogens: *Salmonella, Campylobacter*	No	Turkey components received from establishments with validated HACCP systems or from the establishment's slaughter process include antimicrobial applications and other measures to reduce biological hazards to acceptable levels. Written Turkey Receiving Standard Operating Procedure (SOP) to establish product specifications at receiving to prevent the introduction of hazards at the receiving step. Letter of Guarantee (LOG) is on file for each supplier of turkey		

[12] See the FSIS Guideline for Controlling *Campylobacter* in Raw Poultry, and the FSIS Guideline For Controlling *Salmonella* in Raw Poultry for best practices and a list of scientific and technical references.

[13] Hazards are grouped into three categories: Biological (B), Chemical (C), and Physical (P). Biological hazards are living organisms. Chemical hazards may be naturally occurring in foods, used or added during the processing of foods, or administered to live animals. Physical hazards are a component of a food that is unexpected, such as plastic, glass, metal, or bone in a boneless product. See the Guidebook for the Preparation of HACCP Plans for more information about hazards identification.

[14] Place the justification for your decision in column 4. Control measures for hazards not reasonably likely to occur are entered in column 4. Control measures for hazards reasonably likely to occur are entered in column 5. If a hazard is reasonably likely to occur, then a CCP must be addressed at this step or a later step. See FSIS Meat and Poultry Hazards and Controls Guide for a list of frequently used controls.

[15] Scientific references are important in making decisions, providing justifications, and validating the HACCP system. When scientific references are used for decisions, the referenced article must be part of the HACCP records. If the scientific justification is from FSIS, then list the document name. If justification is not from FSIS, then HACCP system design must be supported by documentary evidence – that is, the theoretical principles, expert advice from processing authorities, scientific or technical data, peer-reviewed journal articles, pathogen modeling programs, or other information demonstrating that particular process control measures can adequately prevent, reduce, or eliminate specific hazards. These non-FSIS supporting documents must be kept for the life of the HACCP plan.

[16] Because the results obtained under prerequisite programs could affect decisions made in the hazard analysis, an establishment is required to maintain records associated with these programs as supporting documentation for its hazard analysis (9 CFR 417.5(a)). When an establishment determines that a potential hazard is not reasonably likely to occur because the implementation of a prerequisite program (e.g., Sanitation standard operating procedures (Sanitation SOP), written sanitary dressing procedures incorporated into prerequisite programs, purchase specifications, or antimicrobial interventions) prevents conditions that make the potential hazard likely, that prerequisite program then becomes part of the HACCP system and as a result, must be validated. This means that establishments must maintain scientific or technical support for the design of those prerequisite programs used to support decisions in the hazard analysis and must collect in-plant validation data to support that the programs are implemented as designed (see FSIS Compliance Guideline HACCP Systems Validation, page 5).

[17] To determine a CCP, see FSIS Guidebook for the Development of HACCP Plans for decision tree to evaluate the areas of control (column 5) to determine the best CCP to control, reduce, or eliminate a hazard.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
			product. Prerequisite program at product receiving to monitor incoming product temperatures and packaging or container conditions to prevent pathogen outgrowth and product contamination.		
	C: None				
	P: Foreign Material	No	Written Foreign Material SOP[18] for visual inspection of product containers at receiving.		
1b. Receiving and Storage of Packaging Material and Antimicrobial Products	B: None				
	C: Non-food grade packaging material and Antimicrobials	No	Letter of Guarantee (LOG) for packaging materials and antimicrobials. Written Chemical Receiving, Storage, and Use SOP for management of antimicrobials.		
	P: Foreign material	No	Receiving Letters of Guarantee (LOG) from suppliers for foreign material specifications. Written Foreign Material SOP for visual inspection of product containers at receiving. Written Storage SOP for packaging materials and antimicrobials.		

[18] This Foreign Material SOP (prerequisite program) should have details on how this procedure is preventing the hazard from occurring (metal prevention controls) as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Foreign Material SOP and plant data related to on-going verification activities then become part of recordkeeping and historical data.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
2. Cooler Storage	B: Pathogen outgrowth (*Salmonella, Campylobacter)*	No	Pathogen outgrowth may result if temperatures are not maintained at levels to prevent bacterial multiplication. Product is placed in storage coolers or freezers to prevent product temperatures that promote pathogen outgrowth (Tompkin, R.B. 1996).[19] Written Sanitation and Temperature Control SOP for condition of use and maintaining cooler temperatures to prevent outgrowth of microorganisms.		
	C: None				
	P: None				
3. Antimicrobial Application for Turkey Components	B: Outgrowth of Pathogens (*Salmonella, Campylobacter)*	Yes	Well documented that raw poultry may carry pathogens. Antimicrobial dips are documented to reduce pathogenic contamination to acceptable levels on meat.	Antimicrobial dips and their scientifically validated critical operational parameters are used to reduce pathogens.[20]	Yes CCP 1
	C: Inappropriate concentration of antimicrobial dips	No	Written Chemical Receiving, Storage, and Use SOP for mixing and determining concentration of chemicals to ensure the mixture is made per the manufacturer's instructions and is within the allowable limits identified in Directive 7120.1 (Food Contact Notification (FCN) number).[21]		

[19] The Significance of time-temperature to growth of foodborne pathogens during refrigeration at 40-50°F (Tompkin, R.B. 1996)

[20] If an establishment implements a process consistent with the process specifications described in the scientific support, and the scientific support contains microbiological data specifying the level of pathogen reduction achieved by the intervention strategy for the target pathogen identified in the hazard analysis, the in-plant validation data collected during the 90 day initial validation period will consist of data on quantifiable characteristics of the critical operational parameters, such as pressure, temperature, and concentration. However, if an establishment implements different critical operational parameters in the process from the scientific support, or the scientific support identified does not contain microbiological data, then the establishment should collect in-plant data demonstrating the critical operational parameters that it has implemented can all be met AND should collect in-plant microbiological validation data or identify scientific support with microbiological data that demonstrates the effectiveness of those implemented critical operational parameters (FSIS Compliance Guideline HACCP Systems Validation, page 27).

[21] Provide reference for scientific support and validation for effective concentrations and support for critical operational parameters that reduce biological hazards. FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains the list of substances that may be used in the production of meat and poultry products. The list contains the allowable amounts and the intended use of the approved antimicrobials. The list (Directive 7120.1) can be used as supporting documentation for chemical hazard controls (safety and suitability). Directive 7120.1 cannot be used as support for the control of biological hazards because the antimicrobial concentration needed to control bacteria is different from the concentrations required for safety and suitability.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
	P: None				
4. Grinding (trim)	B: Pathogen outgrowth (*Salmonella, Campylobacter)*	Yes	Pathogen outgrowth may occur during processing procedures due to processing room temperatures, product handling and grinding equipment.	The hazard is controlled later at CCP 2 Packaging and Labeling. Written Sanitation program for grinding operation. Temperature Control During Grinding SOP to prevent pathogen outgrowth during production.	No
	C: None				
	P: Metal contamination and Bone fragments	No	Written Equipment Examination and Preventive Maintenance on Grinder SOP[22] to prevent metal contamination from equipment. Written Preventive Maintenance of Bone Separator on Grinder SOP to establish controls for bone contamination prevention.		
5. Metal Detection	B: None				
	C: None				
	P: Metal contamination	No	Written Metal Detection SOP for products. Metal Detection SOP records supporting historical data for low likelihood of occurrence due to routine maintenance of grinding equipment.[23]		

[22] This Written Equipment Examination and Preventive Maintenance on Grinder SOP (prerequisite program) should have details on how this procedure is preventing the hazard from occurring (such as metal prevention controls) as well as the on-going verification procedures. These controls should be evident within the written document upon review. The Grinder SOP and plant data related to on-going verification activities then become part of recordkeeping and historical data.

[23] Note: this "historical data" must be supported with evidence from the establishment through the establishment's history or validation data with reference to the actual SOP (which is a prerequisite program). When historical data is not available (for example, a HACCP plan for a new process or product), then system design must be supported by other documentary evidence. Documentary evidence such as the FSIS Meat and Poultry Hazards and Controls Guide, which states "appropriate screening procedure for monitoring equipment" is a frequently used control for foreign material hazards when grinding products.

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
6. Rework	B: Pathogen outgrowth (*Salmonella, Campylobacter)*	No	Written Rework Procedures SOP for establishing rework procedures, lot, and temperature control.		
	C: None				
	P: None				
7. Packaging and Labeling	B: Pathogen outgrowth (*Salmonella, Campylobacter)*	Yes	Processing could result in product temperatures above 45°F.	CCP 2 includes a measure of the product temperature as the ground turkey is packaged. Written Sanitation program for packaging operation.	Yes CCP 2
	C: None				
	P: None				
8. Storage and Distribution	B: Pathogen Outgrowth (*Salmonella, Campylobacter)*	No	Pathogen outgrowth may result if temperatures are not maintained at levels to prevent bacterial multiplication. Product is packaged and placed in storage coolers or freezers to prevent product temperatures that promote pathogen outgrowth (Tompkin, R.B. 1996). Written Refrigerated Storage Conditions and Temperatures SOP including controls and verification. Written Cooler Sanitation SOP for cleaning of storage coolers/freezers. Written Product Loading SOP for monitoring truck holding temperature at loading.		
	C: None				
	P: None		Written Product Loading SOP for monitoring the cleanliness of the product holding compartment at the time of loading.		

Step	Potential Hazard	RLTO	Justification / Basis	Controls	CCP
9. Returned Product	B: Pathogen Outgrowth (*Salmonella, Campylobacter*)	No	Reinspection SOP implemented before accepting returned product. Person(s) or business returning the product must demonstrate the product was held in the appropriate temperature range and in a sanitary manner. When such assurance is not available, returned product is rejected or destroyed. Opened packages are not accepted. Accepted product enters the appropriate step of the production system based on findings of product evaluation. Notify FSIS personnel when returned product has been accepted. Pathogen outgrowth may result if product temperature was not maintained at levels to prevent multiplication. (Tompkin, R.B. 1996).		
	C: None				
	P: Foreign material	No	Reinspection SOP implemented before accepting returned product.		

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EXAMPLE HACCP PLAN

Raw, Non-Intact Turkey

Control Point (CCP)	Significant Hazard(s)	Critical Limits for Each Control Measure	Monitoring Procedures				Corrective Action	Verification	Records
			What	How	Frequency	Who			
CCP 1 Antimicrobial Application for Turkey Components[24]	Pathogens: *Salmonella, Campylobacter*[25]	The antimicrobial solution is mixed to an effective concentration of 650-750 ppm (FCN #).[26] Solution is applied to all surfaces.	Monitor the preparation and mixing of the antimicrobial solution. Assess the solution concentration at the point of application. Observe product during application of the solution. Record observations.	Mix solution per manufacturer's instructions. Use titration kit to check the solution's antimicrobial concentration. Record observations on the Antimicrobial Check Form	The preparation and mixing of the solution is observed once per shift. The concentration is checked once during each two-hour period of production. The application of the antimicrobial dip is observed once per shift.	Designee	If a deviation from the critical limit occurs, a supervisor will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence (9 CFR 417.3)	Randomly, once per week, a supervisor observes each monitoring function. Once per week, a supervisor verifies the implementation of corrective actions for each critical limit deviation. Once per shift a supervisor reviews records per (9 CFR 417.4(a)(2)(iii))	Antimicrobial Check form Pre-shipment Records Records Review Form Verification Records Corrective Action Log

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[24] FSIS Directive 7120.1, Safe and Suitable Ingredients Used in Meat, Poultry and Egg Products contains approved substances for use; however, each establishment must validate their own process for efficacy and control of biological hazards. See FSIS Compliance Guideline HACCP Systems Validation.

[25] See the FSIS Guideline for Controlling *Campylobacter* in Raw Poultry, and the FSIS Guideline For Controlling *Salmonella* in Raw Poultry for best practices and *Campylobacter* and *Salmonella* controls.

[26] Scientific or technical support is required to validate the critical limits (parameters) for antimicrobial use, are part of the hazard analysis, and need to be maintained for the life of the HACCP plan (see FSIS Compliance Guideline HACCP Systems Validation). NOTE: Critical operating parameters need to be addressed in this section as they are related to the scientific justification for use. Critical parameters include but are not limited to the following: type of sprayer, dip, volume, coverage, chemical contact time, solution temperature, etc. Define operational parameters which are specific to each establishment.

EXAMPLE HACCP PLAN

Raw, Non-Intact Turkey

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for Each Control Measure	Monitoring Procedures				Corrective Action	Verification	Records
			What	How	Frequency	Who			
CCP 2 Packaging and Labeling	Pathogen: *Salmonella, Campylobacter*	Temperature of product as it is packaged will be at 40˚F or less.	Measure ground product temperature	Use a calibrated handheld infrared thermometer to assess product temperature.	Two case ready packages each hour during grinding operations.	Designee	If a deviation from the critical limit occurs, a supervisor will: 1. Hold all product produced after the last acceptable check until appropriate disposition taken (no product injurious to health will enter commerce); 2. Determine and eliminate the cause of the deviation; 3. Bring the CCP under control; 4. Take measures to prevent recurrence (9 CFR 417.3)	Once per shift, a supervisor will observe the designee measure product temperature. Once per shift, a supervisor will review records. Once per week, a supervisor will calibrate thermometer per manufacturer's procedures.	Pre-shipment Records Review Form Product Temperature Form Thermometer Calibration Form