

**Attachment 6**

**INSPECTION SYSTEM PROCEDURE GUIDE**

<b>ACTIVITY NUMBER</b>	<b>ACTIVITY</b>	<b>PAGE NO.</b>
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**Internal Code Legend:**

01#: Activity

Capital Letter: Element

Two Digit Number: Procedure

Ex. 01A01

**INSPECTION SYSTEM PROCEDURE GUIDE  
01 SANITATION STANDARD OPERATING PROCEDURES**

**01A Basic SSOP Compliance Checks**

<p><b>01A01</b></p>	<p>Written SSOP's describe procedures the establishment conducts daily to prevent direct contamination or adulteration of product.</p> <p>Pre-operational procedures are identified. Pre-operational procedures address the cleaning of food contact surfaces of facilities, equipment, and utensils.</p> <p>The frequency SSOP is specified for each procedure.</p> <p>The employee(s) responsible for implementing and maintaining the procedures are identified.</p> <p>Identified records, on a daily basis, document implementation and monitoring of SSOP's and any corrective actions taken.</p> <p>The individual with overall authority on-site, or a higher level official, signed and dated the SSOP's upon initial implementation and any modification.</p>	<p>Part 416 FSIS Dirs. 5000.1 Part 3, Par. II</p>	<p>As appropriate, review Sanitation SOP's and recordkeeping.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
01 SANITATION STANDARD OPERATING PROCEDURE**

**01B Other Sanitation**

01B01	Pre-Operational		
	The establishment--conducts pre-operational procedures before beginning operations, and monitors daily implementation procedures.	308.8 312.6 381.57 381.58 381.99	Review written pre-operational procedures in SSOP's and related records.
	Pre-operational procedures are sufficient to prevent direct contamination or adulteration of product(s).	Part 416 FSIS Dir. 5,000.1	Make determinations about compliance with regulatory requirements.
	When SSOP's--or procedures specified therein--may have failed to prevent direct product contamination or adulteration, the establishment took appropriate corrective action(s), including procedures to--ensure appropriate disposition of products that may be contaminated, restore sanitary conditions, and prevent recurrence of direct product contamination or adulteration.	Part Three, Par. III	Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s) and regulations (including identification of violative equipment, utensils, rooms, or compartments as "U.S. Rejected").
	The establishment--routinely evaluates the effectiveness of SSOP procedures, and revises procedures when necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.		
	Daily records document--implementation of pre-operational procedures, and monitoring of pre-operational procedures; corrective actions taken (if any).		
	Records are initialed and dated by employee identified in SSOP's as responsible for		

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01 SANITATION STANDARD OPERATING PROCEDURE**

**01B Other Sanitation**

<b>01B01</b>	<p>implementing and monitoring specified procedure(s).</p> <p>The establishment has implemented controls to ensure data integrity for part 416-required records maintained on computers (if any).</p> <p>Part 416-required records are--retained for at least 6 months; on-site for at least 48 hours, and available within 24 hours of request if stored off-site.</p>	<p>308.8 312.6 381.57 381.58 381.99 Part 416 FSIS Dir. 5,000.1 Part Three, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
01 SANITATION STANDARD OPERATING PROCEDURES**

**01B Other Sanitation**

<b>01B02</b>	<b>Pre-Operational</b>	308.8 312.6 381.57 381.58 381.99 Part 416 FSIS Dir. 5000.1 Part Three, Par. III	(1) Review written pre-operational procedures in SSOP's and (if available) related records.  (2) Observe conduct of pre-operational procedures in SSOP's.  (3) Observe and/or test sanitary conditions (use method in Appendix A in slaughter operations and check one or more areas/departments in other operations).  Make determination about compliance with regulatory requirements.  Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s) and regulations (including identification of violative equipment rooms or compartments as "U.S. Rejected").
	<p>The establishment--conducts pre-operational procedures before beginning operations, and monitors daily implementation procedures.</p> <p>Pre-operational procedures are sufficient to prevent direct contamination or adulteration of product(s).</p> <p>When SSOP's--or procedures specified therein--may have failed to prevent direct product contamination or adulteration, the establishment took appropriate corrective action(s), including procedures to--ensure appropriate disposition of products that may be contaminated, restore sanitary conditions, and prevent recurrence of direct product contamination or adulteration.</p> <p>Daily records document--implementation of pre-operational procedures, and monitoring of pre-operational procedures; corrective actions taken (if any).</p>		

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01 SANITATION STANDARD OPERATING PROCEDURES**

**01C Other Sanitation**

<b>01C01</b>	<b>Operational</b>	<p>308.3 308.8 312.6 318.17(j)(3) 381.57 381.61 381.99 Part 416 FSIS Dir. 5,000.1 Part Three, Par. III</p>	<p>Review written procedures in SSOP's that are conducted during establishment operations and related records.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s) and regulations (including identification of violative equipment, utensils, rooms, or compartments as "U.S. Rejected").</p>
	<p>The establishment--conducts procedures during operations at frequencies specified in SSOP's, and monitors daily implementation of procedures conducted during operations.</p> <p>Procedures conducted during operations are sufficient to or adulteration of product(s).</p> <p>When SSOP's--or procedures specified therein--may have failed to prevent direct product contamination or adulteration, the establishment took appropriate corrective action(s), including procedures to--ensure appropriate disposition of products that may be contaminated, restore sanitary conditions, and prevent recurrence of direct product contamination or adulteration.</p> <p>The establishment--routinely evaluates the effectiveness of SSOP procedures, and revises procedures when necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.</p> <p>Daily records document--implementation of operational procedures, and monitoring of operational procedures; corrective actions taken (if any).</p>		

**INSPECTION SYSTEM PROCEDURE GUIDE  
01 SANITATION STANDARD OPERATING PROCEDURES**

**01C Other Sanitation**

<b>01C01</b>	<p>Records are initialed and dated by employee identified in SSOP's as responsible for implementing and monitoring specified procedure(s).</p> <p>The establishment has implemented controls to ensure data integrity for part 416-required records maintained on computers (if any).</p> <p>Part 416-required records are--retained for at least 6 months; on-site for at least 48 hours, and available within 24 hours of request if stored off-site.</p>	<p>308.3 308.8 312.6 318.17(j)(3) 381.61 381.57 381.99 Part 416 FSIS Dir. 5,000.1 Part Three, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
01 SANITATION STANDARD OPERATING PROCEDURES**

**01C Other Sanitation**

<b>01C02</b>	<b>Operational</b>		
	<p>The establishment--conducts procedures during operations at frequencies specified in the SSOP's, and monitors daily implementation of procedures conducted during operations.</p> <p>Procedures conducted during operations are sufficient to prevent direct contamination or adulteration of product(s).</p> <p>When SSOP's--or procedures specified therein--failed to prevent direct product contamination or adulteration, the establishment took appropriate corrective action(s), including procedures to--ensure appropriate disposition of products that may be contaminated, restore sanitary conditions, and prevent recurrence of direct product contamination or adulteration.</p> <p>Daily records document--implementation procedures, conducted during operations and monitoring of procedures conducted during operations; corrective actions taken (if any).</p>	<p>308.3 308.8 312.6 318.17(j)(3) 381.61 381.99 Part 416 FSIS Dir. 5,000.1 Part Three, Par. III</p>	<p>(1) Review written procedures in SSOP's that are conducted during establishment operations and (if available) related records.</p> <p>(2) Observe conduct of procedures in SSOP's and corrective action(s) during establishment operations.</p> <p>(3) Observe and/or test sanitary conditions (check one or more areas/departments).</p> <p>Make determinations about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s) and regulations (including identification of violative equipment, utensils, rooms, or compartments as "U.S. Rejected").</p>

**INSPECTION SYSTEM PROCEDURE GUIDE  
01 SANITATION STANDARD OPERATING PROCEDURES**

**01C Other Sanitation**

<b>01C02</b>	Daily records are maintained which document the implementation and monitoring of operational activities, as well as initiation of corrective actions. The records are authenticated by the date and initials of responsible establishment employee.	308.3 308.8 312.6 318.17(j)(3) 381.61 381.99 Part 416 FSIS Dir. 11,100.3
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**INSPECTION SYSTEM PROCEDURE GUIDE  
02 LINE SLAUGHTER**

**02**  
Reserved

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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT**

**03A01 HACCP Basic Compliance Checks**

<b>03A01</b>	<p>The establishment has conducted a hazard analysis. The hazard analysis includes food safety hazards reasonably likely to occur, a flow chart, and identifies intended use or consumers of the finished product(s).</p> <p>If one or more food safety hazards are reasonably likely to occur, establishment has a written HACCP plan for each product (process).</p> <p>The establishment has conducted validation activities, and records include multiple results that verify monitoring of CCP's and conformance with critical limits, and after each deviation from a critical limit (if any), subsequent results support adequacy of corrective action(s) in achieving control.</p> <p>The establishment reassesses the hazard analysis--if, after hazard analysis revealed no food safety hazards reasonably likely to occur, there was a change that could reasonably affect whether a food safety hazard exists.</p> <p>Before producing a new product for distribution, the establishment has conducted hazard analysis and has an applicable HACCP plan. If in distribution for more than 90 days, HACCP plan has been validated.</p> <p>If the HACCP plan covers more than one product, all products are within one of nine specified</p>	<p>Part 417 § 304.3(c) or § 318.22(c)</p> <p>Directive 5000.1 Part 3, Par. II</p>	<p>When regulations first apply and as appropriate thereafter, review hazard analysis, HACCP plan(s), and recordkeeping.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT**

**03A01 HACCP Basic Compliance Checks**

<b>03A01</b>	<p>processing categories.</p> <p>The HACCP plan(s): lists food safety hazard(s) identified in hazard analysis (exception: thermally processed/ commercially sterile products produced in accordance with part 318, subpart G, or part 381, subpart X); lists CCP's for each food safety hazard; lists critical limits to be met at each CCP; lists procedures to be used to monitor each CCP <u>and</u> frequency with which performed; identifies corrective actions to be followed in response to a deviation from a critical limit at a critical control point; lists verification procedures <u>and</u> frequency with which performed.</p> <p>The recordkeeping system documents monitoring of CCP's and includes records with actual values and observations.</p> <p>The responsible establishment official signed and dated the HACCP plan upon initial acceptance, and at least annually thereafter. If the HACCP plan modified, responsible establishment official signed and dated.</p>	<p>Part 417 § 304.3(c) or § 381.22(c)</p> <p>Directive 5000.1 Part 3, Par. II</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03B Raw Product--Ground**

<b>03B01</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan.</p> <p>Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment perform a review to determine acceptability of affected product, and when necessary, action to ensure</p>	<p>Part 417          § 304.3(c) or          § 381.22(c)          § 310.25(b) or          § 381.94(b)</p> <p>Directive          5000.1          Part 3, Par. III</p>	<p>Review a random sample of HACCP plan features in operation (monitoring and verification (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits), and/or</p> <p>Review and correlate records with random observation of establishment activities.</p> <p>Take measurements when appropriate.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03B Raw Product--Ground**

<b>03B01</b>	<p>adulterated product is not distributed.</p> <p>The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment revealed that a HACCP plan no longer meets § 417.2(c) requirements the establishment modified the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements.</p> <p>Establishment records document the decisionmaking associated with the selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier.</p> <p>Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>The establishment has implemented controls to ensure data integrity for plan records</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03B Raw Product--Ground**

<b>03B01</b>	maintained on computers (if any).  417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are available within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)  Directive 5000.1 Part 3, Par. III
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03B RawProduct--Ground**

<b>03B02</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p>	<p>Verify HACCP plan implementation to determine the establishment is following the HACCP plan.</p>
	<p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p>	<p>Directive  5000.1  Part 3, Par. III</p>	<p>Establishment personnel perform tasks specified in plan, take corrective actions, and review production records as documented in its records.</p>
	<p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed.</p>		<p>The HACCP plan in operation prevents the distribution of adulterated product.</p> <p>(1) Observe monitoring and verification activities and review results for a given shipment of product.</p> <p>(2) Review records for a given shipment of product.</p>
	<p>The establishment reassessed the</p>		<p>Make determinations about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action</p>

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03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03B Raw Product--Ground**

<b>03B02</b>	<p>plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan. If plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed plan reassessment or modification meets the training requirements.</p> <p>Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>	<p>consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03C Raw Not Ground**

<b>03C01</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan.</p> <p>Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits).</p> <p>Review and correlate records with random observation of establishment activities.</p> <p>Take measurements when appropriate.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03C Raw Not Ground**

<b>03C01</b>	<p>adulterated product is not distributed.</p> <p>The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with the selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier.</p> <p>Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>The establishment has implemented controls to ensure data integrity for plan records maintained on computers.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03C Raw Not Ground**

<b>03C01</b>	417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)  Directive 5000.1 Part 3, Par. III
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03C Raw Not Ground**

<b>03C02</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed.</p> <p>The establishment reassessed the</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>	<p>Verify HACCP plan implementation to determine the establishment is following the HACCP plan.</p> <p>Establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records. The HACCP plan in operation prevents the distribution of adulterated product?</p> <p>(1) Observe monitoring and verification activities and review, results for a given shipment of product.</p> <p>(2) Review records for a given shipment of product.</p>
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**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03C Raw Not Ground**

<b>03C02</b>	<p>HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements.</p> <p>The establishment has implemented controls to ensure data integrity for plan records maintained on computers.</p> <p>Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03D Thermally Processed/Commercially Sterile**

<b>03D01</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan.</p> <p>Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits).</p> <p>Review and correlate records with random observation of establishment activities.</p> <p>Take measurements when appropriate.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03D Thermally Processed/Commercially Sterile**

<b>03D01</b>	<p>adulterated product is not distributed.</p> <p>The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements.</p> <p>Establishment records document the decisionmaking associated with the selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter product a shipment of product, product code, product name or other identifier.</p> <p>Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>The establishment has implemented controls to ensure data integrity for plan records</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03D Thermally Processed/Commercially Sterile**

<b>03D01</b>	maintained on computers.  417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)  Directive 5000.1 Part 3, Par. III
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03D Thermally Processed/Commercially Sterile**

<b>03D02</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed.</p> <p>The establishment reassessed the</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Verify HACCP plan implementation to determine the establishment is following the HACCP plan establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product?</p> <p>(1) Observe monitoring and verification activities and review, results for a given shipment of product.</p> <p>(2) Review records for a given shipment of product.</p> <p>Make determinations about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03D Thermally Processed/Commercially Sterile**

<b>03D02</b>	<p>HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements.</p> <p>Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03E Not Heat Treated-Shelf Stable**

<b>03E01</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan.</p> <p>Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits).</p> <p>Review and correlate records with random observation of establishment activities.</p> <p>Take measurements when appropriate.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03E Not Heat Treated-Shelf Stable**

<b>03E01</b>	<p>adulterated product is not distributed.</p> <p>The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements.</p> <p>Establishment records document the decisionmaking associated with selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter production a shipment of product, product code, product name or other identifier.</p> <p>Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03E Not Heat Treated-Shelf Stable**

<b>03E01</b>	The establishment has implemented controls to ensure data integrity for plan records maintained on computers.  417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)  Directive 5000.1 Part 3, Par. III
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03E Not Heat Treated-Shelf Stable**

<b>03E02</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed.</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Verify HACCP plan implementation to determine the establishment is following the HACCP plan establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product.</p> <p>(1) Observe monitoring and verification activities and review, results for a given shipment of product.</p> <p>(2) Review records for a given shipment of product.</p> <p>Make determinations about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03E Not Heat Treated-Shelf Stable**

<b>03E02</b>	<p>The establishment reassessed the HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements.</p> <p>Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03F Heat Treated-Shelf Stable**

<b>03F01</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan.</p> <p>Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits).</p> <p>Review and correlate records with random observation of establishment activities.</p> <p>Take measurements when appropriate.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03F Heat Treated-Shelf Stable**

<b>03F01</b>	<p>adulterated product is not distributed.</p> <p>The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements.</p> <p>Establishment records document the decisionmaking associated with selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter production a shipment of product, product code, product name or other identifier.</p> <p>Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03F Heat Treated-Shelf Stable**

<b>03F01</b>	The establishment has implemented controls to ensure data integrity for plan records maintained on computers.  417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)  Directive 5000.1 Part 3, Par. III
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03F Heat Treated-Shelf Stable**

<b>03F02</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed.</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Verify HACCP plan implementation to determine the establishment is following the HACCP plan establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product.</p> <p>(1) Observe monitoring and verification activities and review, results for a given shipment of product.</p> <p>(2) Review records for a given shipment of product.</p> <p>Make determinations about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03F Heat Treated-Shelf Stable**

<b>03F02</b>	<p>The establishment reassessed the HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements.</p> <p>Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03G Fully Cooked-Not Shelf Stable**

<b>03G01</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan.</p> <p>Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits).</p> <p>Review and correlate records with random observation of establishment activities.</p> <p>Take measurements when appropriate.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03G Fully Cooked-Not Shelf Stable**

<b>03G01</b>	<p>adulterated product is not distributed.</p> <p>The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter production a shipment of product, product code, product name or other identifier.</p> <p>Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>The establishment has implemented controls to ensure data integrity for plan records maintained on computers.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03G Fully Cooked-Not Shelf Stable**

<b>03G01</b>	417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)  Directive 5000.1 Part 3, Par. III
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03G Fully Cooked-Not Shelf Stable**

<b>03G02</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed.</p> <p>The establishment reassessed the</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Verify HACCP plan implementation to determine the establishment is following the HACCP plan establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product.</p> <p>(1) Observe monitoring and verification activities and review, results for a given shipment of product.</p> <p>(2) Review records for a given shipment of product.</p> <p>Make determinations about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03G Fully Cooked-Not Shelf Stable**

<b>03G02</b>	<p>HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements.</p> <p>Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03H Heat Treated But Not Fully Cooked-Not Shelf Stable**

<p><b>03H01</b></p>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan.</p> <p>Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits).</p> <p>Review and correlate records with random observation of establishment activities.</p> <p>Take measurements when appropriate.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03H Heat Treated But Not Fully Cooked-Not Shelf Stable**

<b>03H01</b>	<p>adulterated product is not distributed.</p> <p>The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter production a shipment of product, product code, product name or other identifier.</p> <p>Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>The establishment has implemented controls to ensure data integrity for plan records maintained on computers.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03H Heat Treated But Not Fully Cooked-Not Shelf Stable**

<b>03H01</b>	417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)  Directive 5000.1 Part 3, Par. III
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**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03H Heat Treated But Not Fully Cooked-Not Shelf Stable**

<p><b>03H02</b></p>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed.</p> <p>The establishment reassessed the</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Verify HACCP plan implementation to determine the establishment is following the HACCP plan establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product.</p> <p>(1) Observe monitoring and verification activities and review, results for a given shipment of product.</p> <p>(2) Review records for a given shipment of product.</p> <p>Make determinations about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03H Heat Treated But Not Fully Cooked-Not Shelf Stable**

<b>03H02</b>	<p>HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements.</p> <p>Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03I Product with Secondary Inhibitors-Not Shelf Stable**

03I01	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan.</p> <p>Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Review a random sample of HACCP plan features in operation (monitoring (observation or review records for calibration of process-monitoring equipment) including activities and actions in response to deviations from critical limits).</p> <p>Review and correlate records with random observation of establishment activities.</p> <p>Take measurements when appropriate.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03I Product With Secondary Inhibitors-Not Shelf Stable**

<b>03I01</b>	<p>adulterated product is not distributed.</p> <p>The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements. Establishment records document the decisionmaking associated with selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; document slaughter production a shipment of product, product code, product name or other identifier.</p> <p>Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>The establishment has implemented controls to ensure data integrity for plan records maintained on computers.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03I Product With Secondary Inhibitors-Not Shelf Stable**

<b>03I01</b>	417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)  Directive 5000.1 Part 3, Par. III
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03I Product with Secondary Inhibitors-Not Shelf Stable**

<p><b>03I02</b></p>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed.</p> <p>The establishment reassessed the</p>	<p>Part 417          § 304.3(c) or          § 381.22(c)          § 310.25(b) or          § 381.94(b)</p> <p>Directive          5000.1          Part 3, Par. III</p>	<p>Verify HACCP plan implementation to determine the establishment is following the HACCP plan establishment personnel perform tasks specified in plan, taken corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product.</p> <p>(1) Observe monitoring and verification activities and review, results for a given shipment of product.</p> <p>(2) Review records for a given shipment of product.</p> <p>Make determinations about compliance with regulatory requirements.</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03I Product with Secondary Inhibitors-Not Shelf Stable**

<b>03I02</b>	<p>HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements.</p> <p>Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03J Slaughter**

<p><b>03J01</b></p>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit the establishment followed the procedure(s) in the HACCP plan.</p> <p>Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment--performs a review to determine acceptability of affected product, and when necessary, action to ensure</p>	<p>Part 417          § 304.3(c) or          § 381.22(c)          § 310.25(b) or          § 381.94(b)</p> <p>Directives          5000.1          6150.1          Part 3, Par. III</p>	<p>Review a random sample of HACCP plan features in operation such as: (1) monitoring at CCPs (2) corrective actions taken in response deviations from critical limits, (3) verification</p> <p>Review and correlate records with random observation of establishment activities including the verification that requirements for zero fecal tolerance are met.</p> <p>Take measurements when appropriate.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03J Slaughter**

<b>03J01</b>	<p>adulterated product is not distributed.</p> <p>The establishment reassesses the HACCP plan if a deviation not covered by a corrective action occurs, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on second consecutive series of FSIS tests; if there was a change that could affect the hazard analysis or alter a HACCP plan; if HACCP plan reassessment reveals that a HACCP plan no longer meets § 417.2(c) requirements the establishment modifies the HACCP plan. The individual who performs HACCP plan reassessment or modification meets the training requirements.</p> <p>Establishment records document the decisionmaking associated with selection and development of CCP's and critical limits, and support the monitoring and verification procedures and frequency; records document slaughter production a shipment of product, product code, product name or other identifier.</p> <p>Each record entry is made at time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03J Slaughter**

<b>03J01</b>	maintained on computers. 417.5(a)(3) required HACCP records are retained for at least 1 year for slaughter activities and refrigerated product and 2 years for frozen, preserved, or shelf-stable product; on-site for at least 6 months, and are made available to inspection program personnel within 24 hours of request if stored off-site.	Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)  Directive 5000.1 Part 3, Par. III
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**INSPECTION SYSTEM PROCEDURE GUIDE**  
**03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03J Slaughter**

<b>03J02</b>	<p>The establishment is monitoring CCP's to ensure compliance with critical limits. Records documenting monitoring include actual values.</p> <p>The establishment is performing verification activities. Records documenting verification activities include calibration of process-monitoring instruments, and actions taken in response to a deviation from a critical limit.</p> <p>If establishment has substituted an alternative sampling frequency for <u>E. coli</u>, the alternative is an integral part of HACCP verification procedures.</p> <p>The HACCP plan assigns responsibility for taking corrective action. In response to a deviation from a critical limit, establishment followed procedure(s) in plan. Records document corrective action taken to identify and eliminate cause of deviation, bring CCP under control, establish measures to prevent recurrence, and prevent distribution of adulterated product. In response to a deviation not covered with a specific corrective action, records document procedures used to segregate and hold affected product, at least until the establishment performed a review to determine acceptability of affected product, and when necessary, took action to ensure adulterated product is not distributed.</p> <p>The establishment reassessed the</p>	<p>Part 417  § 304.3(c) or  § 381.22(c)  § 310.25(b) or  § 381.94(b)</p> <p>Directive  5000.1  Part 3, Par. III</p>	<p>Verify HACCP plan implementation to determine the establishment is following the HACCP plan, establishment personnel perform tasks specified in plan, take corrective actions, and review production records as documented in its records and that the HACCP plan in operation prevents the distribution of adulterated product.</p> <p>(1) Observe monitoring and verification activities and review, results for a given lot of product.</p> <p>(2) Review records for a given lot of product.</p> <p>Make determinations about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
03 HAZARD ANALYSIS CRITICAL CONTROL POINT OTHER REQUIREMENTS**

**03J Slaughter**

<b>03J02</b>	<p>HACCP plan if a deviation not covered by a corrective action occurred, or another unforeseen hazard arose; if a raw meat product or raw poultry product tested positive for <u>Salmonella</u> at a rate exceeding performance standard on the second consecutive series of FSIS tests; or if there was a change that could affect the hazard analysis or alter a HACCP plan; if plan reassessment revealed a HACCP plan no longer meets § 417.2(c) requirements, the establishment modified the HACCP plan. Individual who performed HACCP plan reassessment or modification meet the training requirements.</p> <p>Each record entry is made at the time specific event occurs, and includes date and time recorded, and is signed or initialed by the employee who made entry.</p> <p>Prior to shipping a product for distribution, the establishment conducts a review of associated records including a determination that all critical limits were met, and when appropriate, a determination that the establishment took corrective action(s), including proper disposition of product.</p>	<p>Part 417 § 304.3(c) or § 381.22(c) § 310.25(b) or § 381.94(b)</p> <p>Directive 5000.1 Part 3, Par. III</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
04 ECONOMIC/WHOLESOMENESS**

**04A % Yield/Shrink**

<b>04A01</b>	X% yield/shrink in all applicable products meets the criteria set forth in the regulations. Actions are taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes actions to ensure that misbranded/ mislabeled product(s) do not enter into commerce.	Part 319 FSIS Dir. 7310.6 7640.1	Using establishment records and labels, calculate and/or observe product preparation for % yield and/or shrink.  To verify compliance, calculate the percentage of cook shrink and/or chill shrink by using the following formula:  $\frac{\text{Weight in} - \text{Weight out}}{\text{Weight in}} \times 100$  Make determination about compliance with regulatory requirements.  Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).
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**INSPECTION SYSTEM PROCEDURE GUIDE  
04 ECONOMIC/WHOLESOMENESS**

**04A X% Solution**

<p><b>04A02</b></p>	<p>Percent added solution in all applicable products meet the criteria set forth in the regulations. Actions are taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure that misbranded/ mislabeled product(s) do not enter into commerce.</p>	<p>319.100- 319.103 381.169 FSIS Dir. 7140.2 7140.3 7640.1 FLD Labeling Policy Book Policy Memos 41B, 42 57A, 59, 66B</p>	<p>Using establishment records and labels, calculate and/or observe product preparation for X% solution.</p> <p>To verify accurate label declaration of the percent added solution, use the following formula:</p> $\frac{\text{Finished wt.} - \text{Green wt.}}{\text{Finished weight}} \times 100$ <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
04 ECONOMIC/WHOLESOMENESS**

**04A MSS/MSP/PDBFT/PDPFT/PDCB/PDCP/AMRS**

<b>04A03</b>	<p>The establishment meets the criteria set forth in the regulations to ensure that mechanically separated species, mechanically separated poultry, partially defatted beef fatty tissue, partially defatted poultry fatty tissue, partially defatted chopped beef, partially defatted chopped poultry, and meat produced by advanced recovery systems complies with regulatory requirements. Corrective actions are taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure that product contamination does not occur and misbranded/mislabeled product(s) do not enter commerce.</p>	<p>318.24 319.5 319.6 319.15 (e) 319.29 381.47 (e) FSIS Dir. 7160.1 7160.2 7640.1</p>	<p>Using a combination of establishment records (if applicable) and observation of preparation for the applicable meat and poultry products compare to product standard.</p> <p>To verify compliance, when applicable:</p> <ul style="list-style-type: none"> <li>- Check product identification, condition, temperature, holding time/storage.</li> <li>- examine bones(for example two intact portions of neck bones or two rib bones) before and after the meat recovery systems, to observe condition and conformation.</li> </ul> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
04 ECONOMIC/WHOLESOMENESS**

**04A Batter/Breading**

**04A04**

Batter and/or breading on applicable products meets the criteria set forth in the regulations. Actions are taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes actions to ensure that misbranded/mislabeled products do not enter into commerce.

319.880  
381.166  
FLD Policy  
Memo 89  
Procedure/  
FSIS Dir.  
7640.1

Use establishment records to calculate and/or observe application and final % of batter/breading.

To verify compliance, perform batter and breading pick-up tests on one or more subgroups (according to the plant's QC programs) or batches of the product. Use the following formula:

$$\frac{\text{Breaded Wt.} - \text{Green Wt.}}{\text{Breaded weight}} \times 100$$

Make determination about compliance with regulatory requirements.

Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

**INSPECTION SYSTEM PROCEDURE GUIDE  
04 ECONOMIC/WHOLESOMENESS**

**04B Labeling**

<b>04B01</b>	<p style="text-align: center;"><b>Product Standards</b></p> <p>A product standard of identity meets the criteria set forth in the regulations. Action is taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure misbranded/mislabeled product(s) does not enter commerce.</p>	Part 319 Part 381, Subpart P FSIS Dir. 7124.1 7640.1 FLD Policy Book	<p>Use establishment records and/or observe product formulation and labeling.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
04 ECONOMIC/WHOLESOMENESS**

**04B Labeling**

<b>04B02</b>	<p><b>CN/Grade Labeling/Declared Count/Vignette</b></p> <p>CN and grade labeled products meet the criteria set forth in the regulations. Declared count and/or vignette on label is accurate. Action is taken when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure that misbranded/mislabeled product(s) do not enter into commerce.</p>	<p>317.8 381.116 FSIS Dir. 6810.1 FSIS Dir. 7010.1 FSIS Dir. 7239.4 7640.1 Rev 1 FLD Labeling Policy Book</p>	<p>Review establishment labels and observe product packaging for declared count vignette, CN, and grade labeled products.</p> <p>Select finished product labels as directed to verify that the label accurately reflects the finished product. Send copies of the labels and requested information to FLD per the FLD sampling audit program.</p> <p>Inspection personnel also can check a sample of production to verify conformance with a QC program.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
04 ECONOMIC/WHOLESOMENESS**

**04B Labeling**

	<b>Net Weight</b>		
<p><b>04B03</b></p>	<p>Stated net weight/drained weight on package/container meet regulatory requirements. Scales are calibrated and tare weights established. Action is taken by the establishment when either the establishment or FSIS determines that the requirements have not been met. This includes action to ensure that misbranded/mislabeled product(s) do not enter into commerce.</p>	<p>317.2 (h)(i) 317.18 through 317.22 381.121 (a) thru (e) FSIS Dir. 7240.1 7640.1 Field Manual for In-Plant Meat and Poultry Net Weight Compliance Testing.</p>	<p>Review establishment records and conduct net weight/drained weight, scale calibration, or tare weight checks.</p> <p>To verify scale calibration and tare weight, check scales with available weight and then randomly select the specific number of empty containers, weigh, and calculate the average weight. For QC inspection, follow QC program requirements.</p> <p>To verify net weight/drained weight calculations and statements, inspection personnel can check scales with available weights and then perform net weight/drained weight inspection procedures. For QC inspection follow QC program requirements.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>

**INSPECTION SYSTEM PROCEDURE GUIDE  
04 ECONOMIC/WHOLESOMENESS**

**04B Labeling**

**04B04**

**General Labeling**

All product is accurately and completely labeled and all ingredients, etc. properly identified in accordance with the criteria set forth in the regulations. Action is taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure that misbranded/mislabeled product(s) do not enter into commerce.

Part 316  
Part 317  
318.7  
Part 319  
381.147  
FSIS Dir.  
6810.2  
7131.1  
7220.1  
7640.1  
Labeling Policy  
Book  
FLD Policy  
Memos 16A,  
27, 29, 30A,  
41B, 51, 93,  
102, 103

Review records and/or observe labels, containers, and meat/nonmeat ingredients.

Select finished product labels as directed to verify that the label accurately reflects the finished product. Send copies of the labels and requested information to FLD per the FLD sampling audit program.

Make determination about compliance with regulatory requirements.

Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

**INSPECTION SYSTEM PROCEDURE GUIDE  
04 ECONOMIC/WHOLESOMENESS**

**04C Finished Product Standards/AQL/Boneless Meat Defect Criteria/Pork Skins/Moisture**

<b>04C01</b>	<p>The establishment meets the criteria set forth in the regulations to ensure that all standards other than those with food safety consequences meet regulatory requirements for all applicable products. Food safety requirements are covered in HACCP. Action is taken by the establishment when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure that misbranded/ mislabeled product(s) do not enter into commerce.</p>	<p>310.3 318.2 318.5 318.6 381.66 381.76 381.145 FSIS Dir. 6120.1</p> <p>MPI Bulletins 75-56 78-111 79-42 80-4 FLD Labeling Policy Book</p>	<p>Use establishment records and/or observe plant performance of activities.</p> <p>To verify compliance:</p> <ul style="list-style-type: none"> <li>- perform pre-chill FPS testing twice per line per shift.</li> <li>-perform post-chill FPS twice per shift</li> <li>- perform giblet AQL testing twice per day</li> <li>-perform carcass AQL test(s)</li> <li>-Perform a lot based boneless meat reinspection or verify operation of plant's QC program by observing reinspection techniques and classification of defects by plant personnel. Observe plant's disposition of a lot of product when a rejection limit is reached. Confirm that all product on hand is reworked and reinspected as identified in plant's program.</li> <li>-perform reinspection on pork skins for popping or verify plants QC program.</li> </ul>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
04 ECONOMIC/WHOLESOMENESS**

**04C Finished Product Standards/AQL/Boneless Meat Defect Criteria/Pork  
Skins/Moisture**

<b>04C01</b>	310.3	-Review plant
	318.2	records/observe plant
	318.5	activities to verify
	318.6	compliance with regulatory
	381.66	requirements relating to
	381.76	moisture adsorption.
	381.145	Make determination about
	FSIS Dir.	compliance with regulatory
	6120.1	requirements.
	MPI Bulletins	Document failure(s) to
	75-56	comply with regulatory
	78-111	requirements on NR and
	79-42	(when appropriate) take
	80-4	other action consistent with
	FLD Labeling	applicable directive(s).
	Policy Book	

**INSPECTION SYSTEM PROCEDURE GUIDE  
05 SAMPLING**

**05A Microbiological Sampling**

<b>05A01</b>	<p><b><u>E. coli</u> Testing and Criteria</b></p> <p>The establishment has written procedures for collecting samples <u>E. coli</u> testing.</p> <p>Procedures: identify employee(s) designated to collect samples; address-- location(s) of sampling, how randomness is achieved, and handling of samples to ensure sample integrity.</p> <p>Establishment collects samples for <u>E. coli</u> testing.</p> <p>Establishment records analytical results on process control chart or table.</p>	<p>310.25(a) or 381.94(a) (Subpart. (1), (2)(I), and (4))</p> <p>FSIS Directive 5000.1 Part 4, Par. II</p>	<p>As appropriate, review procedures and recordkeeping.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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<b>05A02</b>	<p>The establishment collects samples from the type of livestock or poultry it slaughters in greater numbers; selects carcasses randomly; selects carcasses samples at required location in process, and by procedure specified in the regulations.</p>	<p>§ 310.25(a) or § 381.94(a)</p> <p>Directive 5000.1 Part 4, Par. III</p>	<p>Observe sample collection and review procedures and records.</p> <p>Make determinations about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>

**INSPECTION SYSTEM PROCEDURE GUIDE  
05 SAMPLING**

**05A Microbiological Sampling**

<p><b>05A03</b></p>	<p style="text-align: center;"><b>Salmonella</b></p> <p>Applicable product(s), cattle, swine, chicken or turkey; or raw ground product including fresh sausage, may not test positive for Salmonella at a rate that exceeds the applicable national pathogen reduction performance standard.</p>	<p>310.25(b) 318.9 381.94(b) FSIS Directive 5000.1 10,210.1</p>	<p>Collect, process, and mail the sample as directed to determine compliance with the regulatory standard.</p> <p>Based on information provided by the laboratories, make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
SAMPLING**

**05B Economic Sampling**

<b>05B01</b>	<b>Scheduled Sampling</b>	318.9	Randomly select sample. Process sample and mail to designated laboratory.
	Randomly select as applicable:	318.19	
	Cooked sausage 30% fat maximum (total 40% fat+added water)	Part 319 Part 381 Subpart P	
	Cooked sausage 10% added water	381.146 FSIS Dirs.	
	Italian sausage (fat)	7110.2	
	Fresh pork/beef/breakfast sausage (fat)	7130.3 7140.2	
	Smoked pork sausage (fat)	7330.1	
	Ground beef/hamburger/ground pork	7640.1 10,210.1	
	Moisture-protein ratio controlled product		
	Dry cured product		
	pH controlled product		
	Corned beef hash		
	Lard		
	PFF controlled product (QC verification only)		
	Fat percentage label claim product (child nutrition label claim)		
	Oleomargarine		

**INSPECTION SYSTEM PROCEDURE GUIDE  
SAMPLING**

**05B Economic Sampling**

<b>05B02</b>	<p style="text-align: center;"><b>Directed Sampling</b></p> <p>Collect, process, and mail samples upon request from computer-generated instruction (PFF, bacon, species, potted meat, listeria etc.) or upon instructions from circuit supervisor, district office, or Washington headquarters</p>	381.146 FSIS Dir. 10,210.1 10,520.1	Collect, process, and mail samples upon request from computer-generated instruction (PFF, bacon, species, potted meat, listeria, etc.) or upon instructions from circuit supervisor, district office, or Washington headquarters.
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**INSPECTION SYSTEM PROCEDURE GUIDE  
05 SAMPLING**

**05C Residue**

<b>05C01</b>	Samples of poultry and livestock for residue determination, in-plant residue testing (SOS, STOP, CAST, FAST), and diagnostic sampling shall be taken.	310.21 381.9 381.80 381.146 FSIS Dirs. 7355.1 10,210.1 10,220.1	Collect random samples as requested for monitoring and surveillance samples, or submit diagnostic samples as necessary. Inspector generated samples are to be collected as directed or required. Prepare sample and mail to designated laboratory. Perform in-plant residue testing on livestock as required.
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**INSPECTION SYSTEM PROCEDURE GUIDE  
06 OTHER REQUIREMENTS**

**06A Export**

<b>06A01</b>	<p>A completed application or other request will be furnished to the inspection point with all pertinent information. The product for inspection must meet all foreign requirements, be of current production and in good condition, facilities must be acceptable, plant personnel must be adequately trained to present and stamp product, product presented for sampling must be in acceptable condition whether fresh or frozen, and slaughter dates must be provided upon request. Certificates are completed under FSIS security and copies appropriately distributed by exporter.</p>	<p>322.2 381.105-108 381.111 FSIS Dir. 9000 Series</p>	<p>Review the application or other requests to verify that all pertinent information is included.</p> <p>Check paperwork, certification, marking, and product to ensure that foreign country product specifications are met and product is within allowable production dates.</p> <p>Observe plant personnel assigned to assist in export inspection to determine if adequately trained.</p> <p>Check a lot of product to determine if product is accessible for random selection.</p> <p>Select containers for inspection, adequate marking and labeling.</p> <p>Review foreign countries' requirements for slaughter dates, if required, observe slaughter dates and certification furnished by the applicant.</p> <p>Proofread all documents. Initial minor alterations. Void unusable certificates. Cancel unused space. Sign</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
06 OTHER REQUIREMENTS**

**06A Export**

<b>06A01</b>	322.2 381.105-108 381.111 FSIS Dir. 9000 Series	original and supplemental certificates.  Make determination about compliance with regulatory requirements.  Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).
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**INSPECTION SYSTEM PROCEDURE GUIDE  
06 OTHER REQUIREMENTS**

**06B01 Custom Exempt/Retail**

<b>06B01</b>	<p>The establishment is conducting custom-exempt/retail-exempt operations in accordance with all applicable regulatory requirements including time/space separation and adequate procedures to assure that product does not bear the mark of inspection. Actions are taken by the establishment when either FSIS or the establishment determines that the standards have not been met. This includes actions to ensure misbranded/mislabeled product(s) do not enter commerce.</p>	<p>303.1 316.16 317.16 320.1 381.10 381.14 381.15 381.175 FSIS Dir. 5930.1</p>	<p>Review applicable records and/or observe plant conditions.</p> <p>To verify compliance, observe area where retail/custom activities are conducted to determine proper separation of facilities and products; review records to verify that hours worked agree with plant's identified schedule.</p> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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**INSPECTION SYSTEM PROCEDURE GUIDE  
06 OTHER REQUIREMENTS**

**06D Facilities and Equipment**

<b>06D01</b>	<b>Facilities and Equipment</b>		
	Plant facilities (including lighting, ventilation, and plumbing) and equipment meet regulatory requirements and therefore do not pose a public health hazard or result in product contamination. Welfare areas and lockers are clean. Outside premises are clean and orderly. Actions are taken by the establishment when either the establishment or FSIS determines that the requirements have not been met. This includes action to ensure that product contamination does not occur and misbranded/mislabeled product(s) do not enter commerce.	307.2 310.1 381.36 381.76 381 Subpart H FSIS Dirs. 5000.1 5220.1 Rev. 1 7640.1 11,000.2 11,000.4 11,220.2 11,240.5 11,520.4	To verify compliance, review applicable records and/or observe random areas of the establishment facility or equipment, including condition, use, and maintenance.  Make determination about compliance with regulatory requirements.  Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).

**INSPECTION SYSTEM PROCEDURE GUIDE  
06 OTHER REQUIREMENTS**

**06D Facilities and Equipment**

<b>06D02</b>	<b>Inspection Requirements</b>	308.3 308.8 310.3 381.50(a)-(f) 381.91 FSIS Dirs. 5000.1 5220.1, Rev. 1 7640.1 MPI Bulletin 77-34 78-40 79-68 83-14 83-16	Observe inspection and reprocessing stations condition, use, and maintenance to verify compliance.  Verify that linespeeds do not exceed the regulatory requirements.  Verify that efficient inspection can be performed on carcasses and parts.  Perform at least two presentation tests per shift as per slaughter QC program.  Make determination about compliance with regulatory requirements.  Document failure(s) to comply with regulatory requirements or NR and (when appropriate) take other action consistent with applicable directive(s).
	Inspection and Reprocessing Stations meet the criteria set forth in regulation to ensure they are adequate for the purpose and do not pose a public health hazard. Actions are taken when either the establishment or FSIS determines that the requirements have not been met. This includes action to ensure that product contamination does not occur and misbranded/mislabeled products do not enter into commerce.		

**INSPECTION SYSTEM PROCEDURE GUIDE  
06 OTHER REQUIREMENTS**

**06D Facilities and Equipment**

<b>06D03</b>	<b>Condemned and Inedible</b>	307.2 308.13 310.3 Part 314 318.12 381.53 381.55 381.152 381.193 FSIS Dir. 5000.1 7010.4	Review records and/or observe handling, marking, denaturing, salvaging and/or disposal of condemned and inedible material, and containers.  Make determination about compliance with regulatory requirements.  Document failure(s) to comply with regulatory requirements or NR and (when appropriate) take other action consistent with applicable directive(s).
	Condemned and inedible products, salvage of such products, and the facilities where they are handled meet according to regulatory requirements. Actions are taken by the establishment when either FSIS or the establishment determines that the standards have not been met. This includes action to ensure that product contamination does not occur and misbranded/mislabeled product(s) do not enter commerce.		

**INSPECTION SYSTEM PROCEDURE GUIDE  
06 OTHER REQUIREMENTS**

**06E Sewage**

**06E01**

**Sewage**

Sewage handling, treatment and equipment must meet regulatory requirements. Actions are taken by the establishment when either the establishment of FSIS determines that the requirements have not been met. This includes action to ensure that product contamination does not occur and misbranded/mislabeled products do not enter into commerce.

308.3(c)  
381.49  
381.50  
FSIS Dir.  
5000.1  
11,100.3

Review applicable records and/or observe sewage handling, treatment, or equipment.

To verify compliance, check waste facilities and the type of material being handled to see that plant refuse is removed from processing areas, and observe for unacceptable conditions or practices with regard to plant's handling and disposal of waste.

Make determination about compliance with regulatory requirements.

Document failure(s) to comply with regulatory requirements or NR and (when appropriate) take other action consistent with applicable directive(s).

**INSPECTION SYSTEM PROCEDURE GUIDE  
06 OTHER REQUIREMENTS**

**06F Water**

<b>06F01</b>	<b>Certification</b>  Current water potability certificate supplied by State or local health agency is available. Action is taken by the establishment when either the establishment or FSIS determines that the requirements have not been met. This includes action to ensure that adulterated product does not enter into commerce.	308.3 381.50(a) FSIS Dir. 5000.1	Check water potability certificate to verify compliance.  Make determination about compliance with regulatory requirements.  Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).
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**INSPECTION SYSTEM PROCEDURE GUIDE  
06 OTHER REQUIREMENTS**

**06F Water**

06F02	Requirements		
	<p>The establishment meet the regulatory the criteria set forth in the regulations. Actions are taken when either the establishment or FSIS determines that the standards have not been met. This includes action to ensure that product contamination does not occur and misbranded/mislabeled products do not enter into commerce.</p>	<p>308.3(d)(1)(4) (5) 308.8(c) 381.50(a)-(e) 381.66(c) FSIS Dirs. 5000.1 7640.1 MPI Bulletins 77-34 79-68 83-14</p>	<p>Review records and/or observe establishment water use, reuse, chlorination, backflow, and potability.</p> <p>To verify compliance, when applicable:</p> <p>-observe chlorinator or iodicators and determine if functional. Evaluate plant's records of chlorine or iodine testing.</p> <p>-check for cross-connections and identification if nonpotable water is used.</p> <p>-observe plant's water supply system for the following:</p> <ul style="list-style-type: none"> <li>• Water pressure and sufficiency</li> <li>• Hot water supply</li> <li>• Dead-end pipelines</li> </ul> <p>-observe water and steamlines to determine if requirements have been met. Review records of backflow prevention device tests.</p> <p>Make determination about compliance with regulatory requirements.</p>

**INSPECTION SYSTEM PROCEDURE GUIDE  
06 OTHER REQUIREMENTS**

**06F Water**

**06F02**

308.3(d)(1)(4) (5) 308.8(c) 381.50(a)-(e) 381.66(c) FSIS Dirs. 5000.1 7640.1 MPI Bulletins 77-34 79-68 83-14	Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).
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**INSPECTION SYSTEM PROCEDURE GUIDE  
06 OTHER REQUIREMENTS**

**06G Pest and Rodent Control**

<b>06G01</b>	<p>Pest and rodent controls meet all requirements in the regulations to ensure that pests and rodents are not present in the establishment, harborage is not provided, and pesticides and rodenticides are properly used, handled, and stored. Actions are taken by the establishment when either the establishment or FSIS determines that the regulatory requirements have not been met. This includes action to ensure that product contamination does not occur, insanitary conditions do not result, and misbranded/ mislabeled products do not enter into commerce.</p>	<p>308.3(h) 381.59 381.60(a)(b) FSIS Dir. 5000.1 7640.1</p>	<p>Review establishment documentation/ records and/or conduct observation/hands-on of pest and rodent control, harborage, pesticide storage and use.</p> <p>To verify compliance, when applicable:</p> <ul style="list-style-type: none"> <li>-observe plant's premises for evidence that the pest and rodent control program is effective.</li> <li>-observe the production area or a sample of the area to verify that the pest and rodent control program is effective.</li> <li>-observe the storage of pesticides/rodenticides.</li> </ul> <p>Make determination about compliance with regulatory requirements.</p> <p>Document failure(s) to comply with regulatory requirements on NR and (when appropriate) take other action consistent with applicable directive(s).</p>
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